**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Part 425**

**[CMS–1345–P]**

**RIN 0938–AQ22**

# Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations

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

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would implement 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 these provisions, providers of services and suppliers can continue to receive traditional Medicare fee-for-service payments under Parts A and B, and be eligible for additional payments based on meeting specified quality and savings requirements.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 6, 2011.

**ADDRESSES:** In commenting, please refer to file code CMS–1345–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1345–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1345–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses: a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

*Submission of comments on paperwork requirements.* You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Dr. Terri Postma (410)786–8084.

**SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

## Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a table of contents.

I. Background
A. Introduction and Overview of Value-Based Purchasing
B. Statutory Basis for the Medicare Shared Savings Program
C. Overview and Intent of the Medicare Shared Savings Program
D. Related Affordable Care Act Provisions
1. Establishment of Center for Medicare and Medicaid Innovation (Innovation Center)
2. Independence at Home Medical Practices
3. State Option To Provide Health Homes
4. Community Health Teams
E. Related Ongoing CMS Efforts
1. Physician Group Practice Demonstration
2. Medicare Health Care Quality Demonstration
II. Provisions of the Proposed Rule
A. Organizations of the Proposed Rule
B. Eligibility and Governance
1. Eligible Entities
2. Legal Structure and Governance
a. Legal Entity
b. Governance
c. Composition of the Governing Body
3. Leadership and Management Structure
4. Accountability for Beneficiaries
5. Agreement Requirement
6. Distribution of Savings
7. Sufficient Number of Primary Care Providers and Beneficiaries
8. Required Reporting on Participating ACO Professionals
9. Processes To Promote Evidence-Based Medicine, Patient Engagement, Reporting, and Coordination of Care
a. Processes To Promote Evidence-Based Medicine
b. Processes To Promote Patient Engagement
c. Processes To Report on Quality and Cost Measures
d. Processes To Promote Coordination of Care
10. Patient Centeredness Criteria
a. Beneficiary Experience of Care Survey
b. Patient Involvement in Governance
c. Evaluation of Population Health Needs and Consideration of Diversity
d. Implementation of Individualize Care Plans and Integration of Community Resources
11. ACO Marketing Guidelines
12. Program Integrity Requirements
a. Compliance Plans
b. Compliance With Program Requirements
c. Conflicts of Interest
d. Screening of ACO Applicants
e. Prohibition on Certain Required Referrals and Cost Shifting
C. Establishing the 3-YearAgreement With the Secretary

1. Options for Start Date of the Performance Year
2. Timing and Process for Evaluating Shared Savings
3. Data Sharing
4. Sharing Aggregate Data
5. Identification of Historically Assigned Beneficiaries
6. Sharing Beneficiary Identifiable Claims Data
a. Legal Authority To Provide Beneficiary Identifiable Data to ACOs
(1) Sharing Data Related to Medicare Parts A and B
(2) Sharing Data Related to Medicare Part D
b. Beneficiary Opportunity To Opt Out of Claims Data Sharing
7. New Program Standards Established During 3-Year Agreement Period
8. Managing Significant Changes to the ACO During the Agreement Period
9. Future Participation of Previously Terminated Program Participants
D. Assignment of Medicare Fee-For-Service Beneficiaries
1. Operational Identification of an ACO
2. Definition of Primary Care Services
3. Prospective vs. Retrospective Beneficiary Assignment to Calculate Eligibility for Shared Savings
4. Majority vs. Plurality Rule for Beneficiary Assignment
5. Beneficiary Information and Notification
E. Quality and Other Reporting Requirements
1. Introduction
2. Proposed Measures To Assess the Quality of Care Furnished by an ACO
a. General
b. Considerations in Selecting Measures
1. Use of Measures
2. Scoring Methodology
c. Proposed Quality Measures for Use in Establishing Quality Performance Standards that ACOs Must Meet for Shared Savings
3. Requirements for Quality Measures Data Submission by ACOs
a. General
b. GPRO Tool
c. Certified EHR Technology
4. Quality Performance Standards
a. General
b. Option 1—Performance Scoring
(1) Measure Domains and Measures Included in the Domains
(2) Methodology for Calculating a Performance Score for Each Measure Within a Domain
(3) Methodology for Calculating a Performance Score for Each Domain
(4) The Quality Performance Standard Level
c. Option 2—Quality Threshold
(1) Minimum Quality Threshold
(2) Considerations in Establishing a Quality Threshold
5. Incorporation of Other Reporting Requirements Related to the Physician Quality Reporting System and Electronic Health Records Technology Under Section 1848 of the Act
6. Public Reporting
7. Aligning ACO Quality Measures with other Laws and Regulations
F. Shared Savings Determination
1. Background
2. Overview of Shared Savings Determination
3. Establishing an Expenditure Benchmark
a. Background
b. Option 1
c. Option 2
d. Summary
4. Adjusting the Benchmark and Average Per Capita Expenditures for Beneficiary Characteristics
5. Technical Adjustments to the Benchmark Impact of IME and DSH
6. Technical Adjustments to the Benchmark Impact of Geographic Payment Adjustments on the Calculation of the Benchmark
7. Technical Adjustments to the Benchmark Impact of Bonus Payments and Penalties on the Calculation of the Benchmark and Actual Expenditures
8. Trending Forward Prior Years' Experience To Obtain an Initial Benchmark
a. Flat Dollar vs Growth Rate as a Benchmark Trending Factor
b. National vs Local Growth Rate as a Benchmark Trending Factor
9. Updating the Benchmark During the Agreement Period
10. Minimum Savings Rate (MSR) and Sharing Rate
11. Net Sharing Rate
12. Additional Shared Savings Payments
13. Withholding Performance Payments To Offset Future Losses
14. Performance Payment Limit
G. Two-Sided Model
1. Risk-Based Payment Models
2. Two Tracks Provide Incremental Approach to Incorporating Risk
3. Elements of the Two-Sided Model
a. Beneficiary Notification and Protections
b. Eligibility Requirements
c. Quality Performance Measurement and Scoring
d. Shared Savings Methodology
(1) Minimum Savings Rate
(2) Additional Shared Savings Payments
(3) Net Sharing Rate
(4) Calculating Sharing in Losses
(5) Maximum Shared Savings and Shared Loss Caps
e. Ensuring ACO Repayment of Shared Losses
f. Future Participation of Under-performing Organizations
g. Public Reporting
h. Impact on States
4. Verification of Savings and Losses
H. Monitoring and Termination of ACOs
1. Monitoring Avoidance of At Risk Beneficiaries
2. Monitoring Compliance with Quality Performance Standards
3. Terminating an ACO Agreement
4. Reconsideration Review Process
I. Coordination With Other Agencies
1. Waivers of CMP, Anti Kickback, and Physician Self Referral Laws
2. IRS Guidance Relating to Tax Exempt Organization
3. Antitrust Policy Statement
4. Prohibition Against the Shared Savings Program Participation by ACOs With Market Power
a. Coordinating the Shared Savings Program Application With the Antitrust Agencies
b. Competition and Quality of Care
c. Competition, Price, and Access to Care
J. Overlap With Other CMS Shared Savings Initiatives
1. Duplication in Participation in Medicare Shared Savings Programs
2. Transition of the Physician Group Practice (PGP) Demonstration Sites Into the Shared Savings Program
3. Overlap With the Center for Medicare & Medicaid Innovation (Innovation Center Shared Savings Models
III. Collection of Information Requirements
IV. Response to Comments
V. Regulatory Impact Analysis
A. Introduction
B. Statement of Need
C. Anticipated Effects
1. Effects on the Medicare Program
a. Assumptions and Uncertainties
b. Detailed Stochastic Modeling Results
c. Further Considerations
2. Impact on Beneficiaries
3. Impact on Providers and Suppliers
D. Alternatives Considered
E. Accounting Statement and Table
F. Conclusion

## Acronyms

ACO Accountable Care Organizations
AHRQ Agency for Healthcare Research and Quality
BCBSMA Blue Cross Blue Shield of Massachusetts
BIPA Benefits Improvement and Protection Act
BQI Better Quality Information
CAD Coronary Artery Disease
CAHPS Consumer Assessment of Health Providers and Systems
CAHs Critical Access Hospitals
CAM Complementary and Alternative Services
CBIC Competitive Bidding Implementation Contractor
CCNC Community Care of North Carolina
CHCs Community Health Centers
CHIP Children's Health Insurance Program
CMMI Center for Medicare and Medicaid Innovation
CMP Civil Monetary Penalties
CMS Centers for Medicare and Medicaid Services
CNM Certified Nurse Midwife
CMS–HCC CMS Hierarchal Condition Category
COPD Chronic Obstructive Pulmonary Disease
CP Certified Psychologist
CSW Clinical Social Worker
CVE Chartered Value Exchange
CWF Common Working File
DHHS Department of Health and Human Services
DM Diabetes Mellitus
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
EDB Enrollment Database
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 Health Care Providers Systems and Surveys
HCC Hierarchal Condition Category
HCO Health Care Organizations
HCPCS Health Care Procedural Coding System
HHA 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 Services Administration
HVBP Hospital Value Based Purchasing
IHIE Indiana Health Information Exchange
IME Indirect Medical Education
INPC Indiana Network for Patient Care
IOM Institute of Medicine
IPPS Inpatient Prospective Payment System
IQR Inpatient Quality Reporting
IRS Internal Revenue Services
LTCHs Long-Term Acute Care Hospitals
MA Medicare Advantage
MAeHC Massachusetts eHealth Collaborative
MDCs Major Diagnostic Categories
MedPAC Medicare Payment Advisory Commission
MHCQ Medicare Health Care Quality
MMA Medicare Prescription Drug, Improvement, and Modernization Act
MPFS Medicare Physician Fee Schedule
MS–DRGs Medicare Severity-Diagnosis Related Groups
MSP Minimum Savings Percentage
MSR Minimum Savings Rate
NC–CCN North Carolina Community Care Networks
NCH National Claims History
NCQA National Committee for Quality Assurance
NP Nurse Practitioner
NPI National Provider Identifier
NQF National Quality Forum
NYCLIX The New York Clinical Information Exchange
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 Centers
RHQDAPU Reporting Hospital Quality Data for Annual Payment Update
RIA Regulatory Impact Analysis
SNFs Skilled Nursing Facilities
SOR Privacy Act Systems of Record
SSA Social Security Administration
SSN Social Security Number
TIN Tax 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. Following the enactment of Public Law 111–148, the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (enacted on March 30, 2010), amended certain provisions of Public Law 111–148. These public laws are collectively known as the Affordable Care Act. The Affordable Care Act includes a number of provisions designed to improve the quality of Medicare services, support innovation and the establishment of new payment models in the program, better align Medicare payments with provider costs, strengthen program integrity within Medicare, and put Medicare on a firmer financial footing.

With respect to quality improvement, the Affordable Care Act includes provisions to expand value-based purchasing, broaden quality reporting, improve the level of performance feedback available to suppliers, create incentives to enhance quality, improve beneficiary outcomes, and increase the value of care.

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. We have significant experience in developing, refining, and expanding health care quality performance measures through our experience with value-based demonstration efforts, noting some of these efforts later in the document, and various Medicare payment systems. For example, since 2005, we have applied the Hospital Inpatient Quality Reporting (IQR) Program under the hospital inpatient prospective payment system. Hospital IQR provides differential payments to hospitals that meet certain requirements, including publicly reporting their performance on a defined set of inpatient care performance measures. Beginning in 2007, under the physician fee schedule, we have provided for quality measure reporting through the Physician Quality Reporting System, which includes incentive payments for eligible professionals who satisfactorily report data on quality measures for covered professional services furnished to Medicare beneficiaries. In 2009, Congress passed the Health Information and Technology for Economic and Clinical Health (HITECH) Act. As part of the Electronic Health Records (EHR) Incentive Program under HITECH, we have defined measures for the meaningful use of certified electronic health records technology and have developed incentive payment programs for both Medicare and Medicaid providers. We have extended similar efforts to additional payment systems, including the hospital outpatient prospective payment system and various post-acute care systems.

In addition to improving quality, value-based purchasing initiatives seek to reduce growth in health care expenditures. It is widely recognized that the trajectory for the nation's health care spending is unsustainable. Medicare beneficiaries share in the burden of rising costs, as they pay higher premiums, and larger cost-sharing obligations and out-of-pocket expenses. The Affordable Care Act includes a series of reforms expected to significantly slow growth in the Medicare spending rate while simultaneously strengthening the care provided to Medicare beneficiaries. These reforms build upon existing value-based purchasing efforts currently underway within CMS to find ways to better coordinate care and reduce unnecessary services to lower the growth in Medicare spending while improving the quality of care received by beneficiaries.

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 volume. In implementing these value-based purchasing initiatives, we seek to meet certain common goals, as follows:

- Improving quality.

++ Value-based payment systems and public reporting should rely on a mix of standards, processes, outcomes, and patient experience measures, including measures of care transitions and changes in patient functional status. Across all programs, we seek to move as quickly as possible to the use of outcome and patient experience measures. To the extent practicable and appropriate, these outcome and patient experience measures should be adjusted

for risk or other appropriate patient, population, or provider characteristics.

++ To the extent possible, and recognizing differences in payment system readiness and statutory authorities, measures should be aligned across Medicare and Medicaid's public reporting and payment systems. We seek to evolve a focused core-set of measures appropriate to each specific provider category that reflects the level of care and the most important areas of service and measures for that provider.

++ The collection of information should minimize the burden on providers to the extent possible. As part of that effort, we will continuously seek to align our measures with the adoption of meaningful use standards for health information technology (HIT), so the collection of performance information is part of care delivery.

++ To the extent practicable, the measures used by the Shared Savings Program should be nationally endorsed by a multistakeholder organization. We should align measures with best practices among other payers and the needs of the end users of the measures.

• Lowering growth in expenditures.

++ Providers should be accountable for the cost of care, and be rewarded for reducing unnecessary expenditures and be responsible for excess expenditures.

++ In reducing excess expenditures, providers should continually improve the quality of care they deliver and must honor their commitment to do no harm to beneficiaries.

++ To the extent possible, and recognizing differences in payers' value-based purchasing initiatives, providers should apply cost reducing and quality improving redesigned care processes to their entire patient population.

As noted previously, the Affordable Care Act includes provisions to expand value-based purchasing, broaden quality reporting, improve the level of performance feedback available to suppliers, create incentives to enhance quality, improve beneficiary outcomes, and increase the value of care. Among these provisions, section 3022 of the Affordable Care Act 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 Affordable Care Act intends the Medicare Shared Saving Program to be a program "that promotes accountability for a patient population and 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." The Shared Savings Program is a key Medicare delivery system reform initiatives that will be implemented under 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 expenditures. We refer to this approach throughout the document as the three-part aim.

*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. Section 1899(a)(1) of the Act requires the Secretary to establish this program no later than January 1, 2012. Section 1899(a)(1)(A) of the Act further provides that, "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 [ACO]". Section 1899(a)(1)(B) of the Act also provides that ACOs that meet quality performance standards established by the Secretary are eligible to receive payments for "shared savings".

Section 1899(b)(1) of the Act establishes the types of groups of providers of services and suppliers, with established mechanisms for shared governance, that are eligible to participate as ACOs under the program, subject to the succeeding provisions of section 1899 of the Act, as determined appropriate by the Secretary. Specifically, sections 1899(b)(1)(A) through (E) of the Act provide, respectively, that the following groups of providers of services and suppliers are eligible to participate:

• 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(b)(2) of the Act establishes the requirements that such eligible groups must meet in order to participate in the program. Specifically, sections 1899(b)(2)(A) through (H) of the Act provide, respectively, that eligible groups of providers of services and suppliers must meet the following requirements to participate in the program as ACOs:

• The ACO shall be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service (FFS) beneficiaries assigned to it.

• The ACO shall enter into an agreement with the Secretary to participate in the program for not less than a 3-year period.

• The ACO shall 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.

• The ACO shall include primary care ACO professionals that are sufficient for the number of Medicare FFS beneficiaries assigned to the ACO. At a minimum, the ACO shall have at least 5,000 such beneficiaries assigned to it in order to be eligible to participate in the Shared Savings Program.

• The ACO shall 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.

• The ACO shall have in place a leadership and management structure that includes clinical and administrative systems.

• The ACO shall 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 such enabling technologies.

• The ACO shall 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.

Section 1899(b)(3) of the Act establishes the quality and other reporting requirements for the Shared Savings Program. For purposes of quality reporting, section 1899(b)(3)(A) of the Act provides that the Secretary shall determine appropriate measures to assess the quality of care furnished by the ACO, such as measures of clinical processes and outcomes, patient and,

where practicable, caregiver experience of care, and utilization (such as rates of hospital admissions for ambulatory care sensitive conditions). Section 1899(b)(3)(B) of the Act requires an ACO 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. This provision further states that such data may include care transitions across health care settings, including hospital discharge planning and post-hospital discharge follow-up by ACO professionals, as determined to be appropriate by the Secretary. Section 1899(b)(3)(C) of the Act requires the Secretary to establish quality performance standards to assess the quality of care furnished by ACOs. That section also requires that the Secretary shall seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care. Finally, section 1899(b)(3)(D) of the Act provides that the Secretary may, as the Secretary determines appropriate, incorporate reporting requirements and incentive payments related to the Physician Quality Reporting System 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 of the Act, and may use alternative criteria than would otherwise apply under such section for determining whether to make such payments. CMS should not take the incentive payments described in the preceding sentence into consideration when calculating any payments otherwise made under of section 1899(d) the Act.

Section 1899(b)(4) of the Act prohibits duplication in participation in other shared savings programs by participants in the Shared Savings Program. Specifically, a provider of services or supplier that participates in any of the following is not eligible to participate in an ACO under the Shared Savings Program: A model tested or expanded under section 1115A of the Act that involves shared savings under this title, any other program or demonstration project that involves such shared savings, or the Independence at Home Demonstration under section 1866E of the Act.

Section 1899(c) of the Act provides the Secretary with discretion to determine an appropriate method to assign Medicare FFS beneficiaries to an ACO participating in the Shared Savings Program. This discretion is limited, however, by the fact that under the Act, assignment must be based on beneficiaries' utilization of primary care services provided under Medicare by an ACO professional who is a physician as defined in section 1861(r)(1) of the Act.

Section 1899(d) of the Act establishes the principles and requirements for payments and treatment of savings under the Shared Savings Program. Specifically, section 1899(d)(1)(A) of the Act provides that, subject to the requirements concerning monitoring avoidance of at-risk patients, payments shall continue to be made to providers of services and suppliers participating in an ACO under the original Medicare FFS program under Parts A and B in the same manner as they would otherwise be made, except that a participating ACO is eligible to receive payment for shared savings if the following occur:

- The ACO meets quality performance standards established by the Secretary; and
- The ACO meets the requirements for realizing savings.

Section 1899(d)(1)(B) of the Act establishes the savings requirements and the method for establishing and updating the benchmark against which any savings would be determined. Specifically, section 1899(d)(1)(B)(i) of the Act establishes that, in each year of the agreement period, 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 FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark. The Secretary shall determine the appropriate percent of shared savings to account for normal variation in Medicare expenditures, based upon the number of Medicare FFS beneficiaries assigned to an ACO. Section 1899(d)(1)(B)(ii) of the Act, in turn, 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 FFS beneficiaries assigned to the ACO. This benchmark must 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 FFS program, as estimated by the Secretary. Furthermore, the benchmark must be reset at the start of each new agreement period.

Section 1899(d)(2) of the Act provides for the actual payments for shared savings under the Shared Savings Program. Specifically, if an ACO meets the quality performance standards established by the Secretary, and meets the savings requirements, a percent (as determined appropriate by the Secretary) of the difference between the estimated average per capita Medicare expenditures in the year, adjusted for beneficiary characteristics, and the benchmark for the ACO may be paid to the ACO as shared savings and the remainder of the difference shall be retained by the Medicare program. The Secretary is required to establish limits on the total amount of shared savings paid to an ACO.

Section 1899(d)(3) of the Act requires the Secretary to monitor ACOs for avoidance of at-risk patients. Specifically, if 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. Section 1899(d)(4) of the Act, in turn, provides that the Secretary may terminate an agreement with an ACO if it does not meet the quality performance standards established by the Secretary. Section 1899(e) of the Act provides that chapter 35 of title 44 of the U.S. Code, which includes such provisions as the Paperwork Reduction Act (PRA), shall not apply to the Shared Savings Program. Section 1899(f) of the Act further provides the Secretary with the authority to waive such requirements of sections 1128A and 1128B of the Act and title XVIII of the Act as may be necessary to carry out the Shared Savings Program. Section 1899(g) of the Act establishes limitations on judicial and administrative review of the Shared Savings Program. This section provides that there shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following:

- The specification of criteria under 1899(a)(1)(B) of the Act.
- The assessment of the quality of care furnished by an ACO and the establishment of performance standards under 1899(b)(3) of the Act.
- The assignment of Medicare FFS beneficiaries to an ACO under 1899(c) of the Act.
- The determination of whether an ACO is eligible for shared savings under 1899(d)(2) of the Act and the amount of such shared savings, including the determination of the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries

assigned to the ACO and the average benchmark for the ACO under 1899(d)(1)(B) of the Act.

• The percent of shared savings specified by the Secretary under 1899(d)(2) of the Act and any limit on the total amount of shared savings established by the Secretary under such subsection.

• The termination of an ACO under 1899(d)(4) of the Act for failure to meet the quality performance standards.

Section 1899(h) of the Act defines some basic terminology that applies to the Shared Savings Program. Specifically, section 1899(h)(1) of the Act defines the term "ACO professional" as a physician (as defined in section 1861(r)(1) of the Act) or a practitioner described in section 1842(b)(18)(C)(i) of the Act (that is, a physician assistant, nurse practitioner or clinical nurse specialist (as defined in section 1861(aa)(5) of the Act)). Section 1899(h)(2) of the Act defines the term "hospital" as a hospital (as defined in section 1886(d)(1)(B) of the Act." (A "subsection (d) hospital" is a hospital located in one of the fifty States or the District of Columbia, excluding hospitals and hospital units that are not paid under the inpatient prospective payment system under section 1886(d)(1)(B) of the Act, such as psychiatric, rehabilitation, long term care, children's, and cancer hospitals.) Section 1899(h)(3) of the Act defines the term "Medicare fee-for-service beneficiary" as an individual who is enrolled in the original Medicare FFS program under Medicare Parts A and B and is not enrolled in a Medicare Advantage (MA) plan under Medicare Part C, an eligible organization under section 1876 of the Act, or a Program of All-Inclusive Care for the Elderly (PACE) under section 1894 of the Act.

Section 1899(i) of the Act provides that the Secretary may use either a partial capitation model or other payment model, rather than the payment model described in section 1899(d) of the Act, for making payments under the Shared Savings Program. Sections 1899(i)(2)(B) and 1899(i)(3)(B) of the Act require that any such model maintain budget neutrality. Specifically, these sections require that any such model adopted by the Secretary, "does not result in spending more for such ACO for such beneficiaries than would otherwise be expended for such ACO for such beneficiaries for such year if the model were not implemented, as estimated by the Secretary."

Finally, section 1899(k) of the Act provides for an extension to the Physician Group Practice (PGP) demonstration: "During the period beginning on the date of the enactment of this section and ending on the date the program is established, the Secretary may enter into an agreement with an ACO under the demonstration under section 1866A, subject to rebasing and other modifications deemed appropriate by the Secretary."

*C. Overview and Intent 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. In order to meet the intent of the Shared Savings Program as established by the Affordable Care Act, we will focus on achieving, as our highest-level goal, the three-part aim, which consists of the following:

• Better care for individuals—as described by all six dimensions of quality in the Institute of Medicine report: Safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity;

• Better health for populations with respect to educating beneficiaries about the upstream causes of ill health—like poor nutrition, physical inactivity, substance abuse, economic disparities—as well as the importance of preventive services such as annual physicals and flu shots; and

• Lower growth in expenditures by eliminating waste and inefficiencies while not withholding any needed care that helps beneficiaries.

Under the Shared Savings Program, ACOs will only share in savings if they first generate shareable savings and then meet the quality standards. In the spirit of the three-part aim and the vision of always keeping the beneficiary in the forefront of all decisions, we believe that an ACO should embrace the following goals:

• An ACO will put the beneficiary and family at the center of all its activities. It will honor individual preferences, values, backgrounds, resources, and skills, and it will thoroughly engage people in shared decision-making about diagnostic and therapeutic options.

• An ACO will ensure coordination of care for beneficiaries regardless of its time or place. In an ACO, people will find that they no longer carry the burden of ensuring that everyone caring for them has the information they need. Beneficiaries will see that organizational teamwork improves their health care.

• An ACO will attend carefully to care transitions, especially as beneficiaries journey from one part of the care system to another.

• An ACO will manage resources carefully and respectfully. It will ensure continual waste reduction, and that every step in care adds value to the beneficiary. An ACO will be able to make investments where investments count, and move resources to meet beneficiaries' needs. Because of its capabilities with respect to prevention and anticipation, especially for chronically ill people, an ACO will be able to continually reduce its dependence on inpatient care. Instead, its patients will more likely be able to be home, where they often want to be, and, during a hospital admission, they receive assurance that their discharges will be well coordinated, and that they will not return due to avoidable complications.

• An ACO will be proactive by reaching out to patients with reminders and advice that can help them stay healthy and let them know when it is time for a checkup or a test.

• An ACO will collect, evaluate, and use data on health care processes and outcomes sufficiently to measure what it achieves for beneficiaries and communities over time and use such data to improve care delivery and patient outcomes.

• An ACO will be innovative in the service of the three-part aim of better care for individuals, better health for populations, and lower growth in expenditures. It will draw upon the best, most advanced models of care, using modern technologies, including telehealth and electronic health records, and other tools to continually reinvent care in the modern age. It will monitor and compare its performance to other ACOs, identify and examine new processes for care improvement, and adopt those approaches that are demonstrated to be effective.

• An ACO will continually invest in the development and pride of its own workforce, including affiliated clinicians. It will maintain and execute plans for helping build skill, knowledge, and teamwork.

As proposed in this notice of proposed rulemaking (NPRM), the Shared Savings Program encourages providers of services and suppliers to form ACOs that seek to achieve a three-part aim of better care for individuals, better health for populations, and lower growth in expenditures. The proposed

rule establishes the requirements for ACOs to take responsibility for improving the quality of care they deliver to a group of Medicare FFS beneficiaries, while lowering the growth in costs, in return for a share of the resulting savings. In addition to establishing a shared savings model for rewarding quality and financial performance, the program also holds ACOs accountable for excess expenditures by establishing, as an option, a two-sided risk model which requires repayment of losses to us. This represents a new approach for the Medicare FFS program, under which providers have traditionally had little or no financial incentive to coordinate the care for their patients or to be accountable for the total costs and quality of the care provided.

Since there is little comparative experience with implementing a Shared Savings Program and alternative payment models at the national level, we sought input on the impact of this proposed program from a wide range of external experts, including credentialed actuaries, clinical managers, and academic researchers on the potential impact of the program through, for example, the White House meeting, multiple listening sessions, Special Open Door Forum on ACOs, Workshop Regarding ACOs with CMS, OIG, and the Antitrust Agencies, and a Request For Information. Incorporating their input, we estimate that up to 5 million Medicare beneficiaries will receive care from providers participating in ACOs, many of which are located in higher cost areas, and that the program can have a significant impact on lowering Medicare expenditure growth. Furthermore, projections on the initial impact of the program by the Congressional Budget Office also suggest the Shared Savings Program could result in significant savings to the Medicare program.

We also believe that the Shared Savings Program should provide an entry point for all willing organizations who wish to move in a direction of providing value-driven healthcare. Consequently, in accordance with the authority granted to the Secretary under section 1899(i) of the Act, we are proposing for comment creating and implementing both a shared savings model (one-sided model) and a shared savings/losses model (two-sided model). Under this proposal, balanced maximum sharing rates under the two options to provide greater reward for ACOs accepting risk while maintaining an incentive to encourage ACOs not immediately ready to accept risk to participate in the one-sided model. This approach provides an entry point for organizations with less experience managing care and accepting financial risk, such as physician-driven organizations or smaller ACOs, to gain experience with population management in the FFS setting before transitioning to more risk.

We believe that ACOs electing to initially enter the one-sided model automatically transition to a two-sided risk model during the final year of their initial agreement. We also believe that a two-sided model that builds off a one-sided model could be offered as an option at the beginning of the program. We would immediately reward ACOs electing to enter the two-sided model with higher sharing rates available under that model. This approach provides an opportunity for more experienced ACOs that are ready to accept risk to enter a sharing arrangement that provides greater reward for greater responsibility. For more detail on the two-sided risk model refer to section II.G. of this proposed rule.

In addition to the opportunity to implement alternative payment models such as partial capitation under 1899(i) of the Act, the Center for Medicare and Medicaid Innovation (Innovation Center), created by the Affordable Care Act also has authority to test innovative payment models. As we gain experience with the shared savings model and alternative payment models, we will continue to refine and improve the program over time to make it increasingly effective in achieving our three-part aim of better care for individuals, better health for populations, and lower growth in expenditures. Finally, 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 to ensure a coordinated and aligned inter- and intra-agency effort in the implementation of the program. The result of this effort is the release of several notices with which potential participants are strongly encouraged to become familiar. Detailed descriptions of these notices appear in section II.I of this proposed rule, and include: (1) A joint CMS and DHHS OIG Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center; (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; and (3) a proposed Antitrust Policy Statement issued by the FTC and DOJ (collectively, the Antitrust Agencies).

*D. Related Affordable Care Act Provisions*

The Affordable Care Act intends to improve quality and make health care more affordable through the Shared Savings Program as well as through other provisions. There are four programs authorized by the Affordable Care Act discussed later in the document which may affect Shared Savings Program policy or help to guide future Shared Savings Program policy, or may intersect with the Shared Savings Program in other ways.

1. Establishment of Center for Medicare and Medicaid Innovation (Innovation Center)

Section 1115A of the Act, as added by section 3021 of the Affordable Care Act, required the establishment of the new Innovation Center not later than January 1, 2011 to test innovative payment and service delivery models to reduce program expenditures under Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) while preserving or enhancing the quality of care furnished to beneficiaries under these programs. In selecting such models for testing, the statute requires the Secretary to give preference to models that also improve the coordination, quality, and efficiency of health care services furnished under Medicare, Medicaid, and CHIP.

Section 1115A authorizes the Secretary to expand the duration and scope of a model being tested through rulemaking (including implementation on a nationwide basis) to the extent the Secretary—

- Determines expected expansion to reduce spending under the applicable title without reducing the quality of care or improve the quality of patient care without increasing spending;
- Obtains a certification from our Chief Actuary that such expansion would reduce (or would not result in any increase in) net program spending under applicable titles; and
- Determines that such expansion would not deny or limit the coverage or provision of benefits under Medicare, Medicaid, or CHIP.

Through the Innovation Center, we plan to explore alternative payment models for the Shared Savings Program. As we test and refine these models, gain operational experience, and put the necessary infrastructure in place to support program wide implementation, including critical monitoring and

patient protection infrastructure, we plan to make these options available under the Shared Savings Program in future rulemaking. Our intent is to move participants of the demonstration models that have a demonstrated track record of realizing shared savings and high quality performance into the Shared Savings Program in future agreement periods.

2. Independence at Home Medical Practices

Section 1866E of the Act, as added by section 3024 of the Affordable Care Act authorizes the Secretary to conduct a demonstration program to test a payment incentive and service delivery model that utilizes Independence at Home Medical Practices, which are comprised of physician and nurse practitioner directed home-based primary care teams, to provide services designed to reduce expenditures and improve health outcomes for certain Medicare beneficiaries.

Subject to performance on quality measures established for the demonstration, participating practices may be eligible to receive an incentive payment in the form of shared savings. In determining whether savings were generated, the Secretary shall establish an estimated annual spending target, for the amount the Secretary estimates would have been spent in absence of the demonstration, for items and services covered under Parts A and B furnished to applicable beneficiaries for each qualifying Independence at Home medical practice. A practice is eligible to receive an incentive payment if actual expenditures for the year for the applicable beneficiaries it enrolls are less than the estimated spending target established for the year. An incentive payment for each year shall be equal to a portion of the amount by which actual expenditures for applicable beneficiaries under Parts A and B for the year are estimated to be less than 5 percent less than the estimated spending target for the year.

3. State Option To Provide Health Homes

Section 1945 of the Act, as added by section 2703 of the Affordable Care Act authorizes a State option under Medicaid to provide a health home for individuals with chronic conditions. The definition of the term "health home" is defined as a designated provider (including a provider that operates in coordination with a team of health care professionals) or a health team selected by an eligible individual with chronic conditions to provide health home services. Health home services are defined as comprehensive and timely high-quality services, including comprehensive care management; care coordination and health promotion; comprehensive transitional care, including appropriate follow-up, from inpatient to other settings; patient and family support (including authorized representatives); referral to community and social support services, if relevant; and use of health information technology to link services, as feasible and appropriate.

Under section 1945 of the Act, States pay the designated provider, team of health care professionals operating with such a provider, or health team for the provision of health home services to each eligible individual with chronic conditions that selects them as their health home. A State specifies in their State plan amendment the methodology it will use to determine payment for health home services. The methodology may be tiered to reflect, with respect to each eligible individual with chronic conditions, the severity or number of such individual's chronic conditions or the specific capabilities of the provider, team of health care professionals, or health team. A time-limited higher Federal Medicaid matching payment is available for health home services.

4. Community Health Teams

Section 3502 of the Affordable Care Act requires the Secretary to establish a program to provide grants to or enter into contracts with eligible entities to establish community based interdisciplinary, inter-professional teams (referred to in the statute as "health teams") to support primary care practices, including obstetrics and gynecology practices, within the hospital service areas served by the eligible entities. These grants or contracts shall be used to establish health teams to provide support services to primary care providers and provide capitated payments to primary care providers as determined by the Secretary. For purposes of this section, primary care is the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of the family and community.

A health team established under a grant or contract must establish contractual agreements with primary care providers to provide support services. The team must support patient-centered medical homes, defined as a mode of care that includes—(1) Personal physicians; (2) whole person orientation; (3) coordinated and integrated care; (4) safe and high-quality care through evidence-informed medicine, appropriate use of health information technology, and continuous quality improvements; (5) expanded access to care; and (6) payment that recognizes added value from additional components of patient centered care.

Health teams must also collaborate with local primary care providers and existing State and community-based resources to coordinate—(1) disease prevention; (2) chronic disease management; (3) transitioning between health care providers and settings; and (4) case management for patients, including children, with priority given to those amenable to prevention and with chronic diseases or conditions identified by the Secretary. In collaboration with local health care providers, a health team must develop and implement interdisciplinary, interprofessional care plans that integrate clinical and community preventive and health promotion services for patients, including children, with a priority given to those amenable to prevention and with chronic diseases or conditions identified by the Secretary.

*E. Related Ongoing CMS Efforts*

1. Physician Group Practice Demonstration

We have previous experience developing and implementing shared savings models through demonstrations. First, under section 412 of the Medicare, Medicaid, and CHIP Benefits Improvement and Protection Act of 2000 (BIPA), we implemented the Physician Group Practice (PGP) Demonstration in April of 2005—our first attempt at establishing a Shared Savings ACO model. The PGP Demonstration offered a unique payment model by which PGP providers received their normal Parts A and B FFS payments for services rendered and offered an additional performance payment for demonstrating "value." The performance payments were tied directly to achieving targets for process and outcome quality measures as well as cost savings. The PGP Demonstration showed that physician-driven organizations are willing to engage in efforts to improve the overall quality and cost efficiency of care for the patient population they serve. Under the demonstration, the PGPs were accountable for a patient population to whom they provided the plurality of office-based evaluation and

management care. The assignment of patients to the PGP at the end of each performance year and data has shown that assigned patients had on average four or five visits at the PGP during the year. This provided the opportunity for the organizations to better coordinate services and improve the quality and efficiency of care provided to Medicare FFS patients. Medicare patients retained their entitlement to see any Medicare provider they chose and were not enrolled or required to only see PGP physicians under the demonstration.

Based on their experience with the PGP demonstration, participants identified several factors as critical to improving quality and the opportunity to share savings:

- An integrated organization with an environment that supports expending resources on multiple programs and initiatives to improve quality and reduce unnecessary services.
- Dedicated physician leadership with a proven ability to motivate physicians to participate in the development and implementation of quality improvement and other clinical programs and initiatives.
- Health information technology that facilitates the aggregation and analysis of data, allows patient-level feedback, and provides alerts and reminders at the point of care.
- Experience with non-Medicare payer initiatives, particularly through a managed care affiliate, to improve quality and reduce expenditure growth.

Under the demonstration, at the end of the third performance year, all 10 of the PGPs continued to improve the quality of care for patients with chronic illness or who required preventive care by achieving benchmark or target performance on at least 28 out of 32 quality markers for patients with diabetes, coronary artery disease, congestive heart failure, hypertension, and for cancer screening. Two of the PGPs achieved benchmark quality performance on all 32 quality measures. Over the course of the first three years, 6 of the 10 groups shared in approximately $46 million in savings.

2. Medicare Health Care Quality Demonstration

We have begun testing models under the Medicare Health Care Quality (MHCQ) Demonstration, created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 1866C(b) of the Act, as added by section 646 of the MMA, required the Secretary to establish a 5-year demonstration program under which the Secretary was required to approve demonstration projects that examine health delivery factors that encourage the delivery of improved quality in patient care. Section 3021(c) of the Affordable Care Act amended section 1866C of the Act to allow the Secretary to expand, through rulemaking, the duration and scope of a demonstration the Secretary is conducting under that section to the extent determined appropriate by the Secretary if the demonstration meets certain criteria. The MHCQ Demonstration Projects design examine the extent to which major, multi-faceted changes to traditional Medicare's health delivery and financing systems lead to improvements in the quality of care provided to Medicare beneficiaries, without increasing total program expenditures. We approved one such program, the Indiana Health Information Exchange (IHIE).

Beginning July 1, 2009, we began the first MHQC project, the IHIE's implementation of a regional, multi-payer, pay-for-performance and quality reporting program, based (by-and-large) on a common set of quality measures. The expectation is such that the IHIE's interventions provide important empirical evidence on the effectiveness of pay-for-performance, health IT, and multipayer initiatives in improving the quality and efficiency of care provided to Medicare beneficiaries.

IHIE aggregates our claims and administrative data in the demonstration with other data processed in conjunction with its regional health information exchange (HIE). Data used from the various sources generate patient-level and provider level quality reports, alerts, and reminders for participating providers. By incorporating our data into IHIE's HIE and producing these quality reports, IHIE can provide participating physicians with a more complete picture of the care that is or is not being provided to their Medicare patients and give physicians the information they need to positively impact the quality and cost of care being provided.

During the demonstration, we review cost and quality data for Medicare FFS beneficiaries that have at least one office or other outpatient evaluation and management (E&M) visit with an IHIE participating physician. It is expected that an estimated 100,000 Medicare beneficiaries residing in the Indianapolis metropolitan area will meet this criterion in each year of the demonstration.

Quality of care is measured at the population-level (that is, performance measurement will focus on whether or not the site has achieved improvements in quality when looking at the entire group of treated patients) using a set of Medicare specific quality measures. Improvements in the quality of care provided to Medicare beneficiaries are determined on the extent to which IHIE participating physicians are able to reduce the gap between the maximum attainable level for a quality measure and the baseline performance for the quality measure. We used approximately 14 ambulatory care quality measures in the first year, growing to approximately 30 in the fifth year.

Quality-contingent shared savings are available with our calculating savings in the intervention population by comparing actual costs to expected costs for treated beneficiaries. Expected costs for the intervention group are projected using adjusted utilization trends from a comparison group. In general, calculated Medicare savings are the difference between the expected costs and actual costs for beneficiaries in the intervention group. At least 50 percent of shared savings that are available to be paid for payment to the site are contingent on quality of care results for the year. Only after quality of care performance results for a year are determined can the final amount of shared savings to be paid to the site be determined.

## II. Provisions of the Proposed Rule

### *A. Organization of the Proposed Rule*

The remainder of this document is organized as follows: In section II.A. of this proposed rule, we propose an operational definition of an ACO for purposes of the shared savings program. In section II.B. of this proposed rule, we put forth proposed eligibility requirements for an ACO to participate in this program. In section II.C. of this proposed rule, we propose requirements for an ACO to commit to a 3-year participation agreement under this program and present a proposal for data sharing with ACOs. In section II.D. of this proposed rule, we discuss our proposed methodology for assigning beneficiaries to an ACO. In section II.E. of this proposed rule, we present our proposals regarding quality measures and the methodology for measuring ACO performance under this program. In section II.F. of this proposed rule, we discuss our proposed shared savings payment methodology, including the establishment of an expenditure benchmark, performance target, minimum savings percentage, sharing rate, performance cap. In section II.G. of this proposed rule, we discuss our proposal for introducing risk into the

shared savings program, the two-sided model and differences from the one-sided model. In section II.H. of this proposed rule, we discuss our proposal for monitoring ACO performance and we propose grounds and procedures for terminating agreements. In section II.I. of this proposed rule, we discuss our efforts to coordinate the development of this proposed rule with other Federal agencies to ensure a coordinated and aligned inter- and intra-agency effort in the implementation of the program. In section II.J. of this proposed rule, we discuss overlap in Medicare programs and how this might affect Shared Savings Program participants. Finally, in section V. of this proposed rule, we present our Regulatory Impact Analysis, which sets forth an analysis of the impact of these proposals on affected entities and beneficiaries.

For purposes of this proposed rule, we propose definitions for the following terms:

- *Accountable care organization* (ACO) means a legal entity that is recognized and authorized under applicable State law, as identified by a Taxpayer Identification Number (TIN), and comprised of an eligible group (as discussed in section II.B. of this proposed rule) of ACO participants that work together to manage and coordinate care for Medicare FFS beneficiaries and have established a mechanism for shared governance that provides all ACO participants with an appropriate proportionate control over the ACO's decision making process,
- *ACO participant* means a Medicare-enrolled provider of services and/or a supplier (as discussed in section II.B. of this proposed rule, as identified by a TIN).
- *ACO provider/supplier* means a provider of services and/or a supplier (as discussed in section II.B. of this proposed rule) that bills for items and services it furnishes to Medicare beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare rules and regulations.

*B. Eligibility and Governance*

1. Eligible Entities

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) and critical access hospitals (CAHs), among others, are not specifically designated as eligible participants in the Shared Savings Program under section 1899(b)(1) of the Act. We note, however, that the statutorily defined groups of providers and suppliers that are eligible to participate in the Shared Savings Program as ACOs, would also have to meet the eligibility criteria discussed in detail later in this proposed rule in order to qualify for participation in the program. 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 have considered whether it would be advisable, at least in the initial stage of the Shared Savings Program, to—(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.

Some have argued that ACOs would be most effective if they include certain entities as ACO participants. For example, the Medicare Payment Advisory Commission (MedPAC) has noted that provider groups with hospitals in their systems may be most effective in generating savings. The MedPAC notes that hospitals working with physician teams can prevent further hospitalizations after discharge and provide ongoing services to keep the patient as healthy as possible. Also, the savings generated by ACOs, in many cases, are expected to result from reduced inpatient admissions. As a result, provider groups with hospitals may have a greater incentive to coordinate care to ensure that a portion of the revenue lost from decreased admissions is made up through shared savings. (To view the MedPAC discussion referenced previously go to: *http://www.medpac.gov/documents/jun09_entirereport.pdf.*)

Another option for limiting eligibility would be to restrict eligibility to only those ACO professionals providing primary care services. Primary care professionals may have the best opportunity to reduce unnecessary costs by ensuring care coordination for beneficiaries with multiple chronic conditions. By coordinating with specialists to whom the beneficiary has been referred, primary care providers can reduce unnecessary repetition of laboratory testing or imaging. By ensuring timely access to the outpatient services, primary care providers can also reduce the number of avoidable admissions. Limiting eligibility for the Shared Savings Program to primary care providers, therefore, may be desirable to emphasize the important role played by these professionals and ensure a primary care focus for the program. Adopting either of these approaches would require a narrower eligibility definition than is permitted (although not required) under the statute.

However, the benefits of limiting eligibility need to be balanced against the prospect that such limitations could compromise potential innovations and forfeit the opportunity to assess new models that could potentially transform health care in ways that improve quality and beneficiary satisfaction while better controlling costs. More importantly, defining eligibility narrowly also has the potential to impede development of

ACOs that include other provider and supplier types, especially those that provide services in rural and other underserved areas. For example, while section 1899(b)(1) of the Act does not mention certain entities such as critical access hospital (CAHs), federally qualified health centers (FQHCs), or rural health clinics (RHCs) in its listing of entities eligible to form an ACO under the Shared Savings Program 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 in rural and other underserved areas and for low-income beneficiaries, including those dually eligible for Medicare and Medicaid. Permitting participation by these groups of providers and suppliers has the potential to improve coordination and quality of care for a greater number of beneficiaries in more communities, while better controlling costs in more varied settings and across a broader array of providers and suppliers.

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 expansion of eligibility would allow additional Medicare enrolled providers and suppliers to form an ACO to participate in addition to the four groups specified in section 1899(b)(1)(A)–(D) of the Act. Specifically, 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 the four groups specified in section 1899(b)(1)(A)–(D) of the Act in order to meet statutory criteria. We have 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, the specific payment methodologies, claims billing systems, and data reporting requirements that apply to these entities pose 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.D of this proposed rule, consistent with section 1899(c) of the Act, which provides that beneficiaries shall be assigned to an ACO based on their utilization of primary care services furnished by an ACO professional who is a physician, our proposed methodology for assignment of beneficiaries is to assign beneficiaries to an ACO on the basis of receiving a plurality of their primary care services as described in section II.D. of this proposed rule from a physician, as defined in section 1861(r)(1) of the Act, with a specialty designation of general practice, family practice, internal medicine and geriatric medicine. 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.

At this time, FQHC claims for services furnished prior to January 1, 2011 do not include HCPCS codes that identify the specific service provided. Thus, although the claims do contain information concerning the attending physician and the rendering health professional (for example, physician, physician assistant, nurse practitioner), who actually provided the service, they do not currently provide for associating the rendering provider with the specific services furnished to the beneficiary.

RHCs predominantly provide primary care services to their populations. Most RHC services are provided by non-physician practitioners such as PAs and NPs. RHCs submit claims for each encounter with a beneficiary and receive payment based on an interim all-inclusive rate for the RHC. As in the case of FQHCs, RHC claims distinguish general classes of services (for example, clinic visit, home visit by RHC practitioner, 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. These claims do not include HCPCS codes that identify the specific service provided. The claims also contain limited information concerning the individual practitioner, or even the type of health professional (for example, physician, PA, NP), who provided the service.

For FQHCs and RHCs, therefore, we currently lack the requisite data elements (service code, physician, physician specialty, and specific attribution of services to the rendering health care professionals) in the claims and payment systems to enable us to determine (1) beneficiary assignment during the performance year under section 1899(c) of the Act, which requires that assignment to an ACO be based on utilization of primary care services furnished by a physician; and (2) expenditures during the 3-year benchmark. In the case of FQHCs, we recently finalized regulations requiring the collection of HCPCS codes for services beginning in 2011, in preparation for the development of the FQHC PPS. However, there is no statutory requirement for collecting from FQHCs the other data elements, such as the direct link between provider and service, which would be required for beneficiary assignment under the Shared Savings Program. Moreover, there is neither the statutory requirement for collection of HCPCS codes from RHCs nor any plan to expand this data collection effort to RHCs. In both the case of FQHCs and RHCs, reporting the information necessary to participate in the Shared Savings Program would be a significant change in operations that we are reluctant to impose through regulation without either a statutory requirement or clear support for such a regulatory change from the FQHC and RHC community at large that they would be willing to have all RHC/FQHCs provide this information uniformly, solely to enable independent formation of an ACO for purposes of participation in the Shared Savings Program by the subset of those FQHC/RHCs that choose to do so.

Therefore, in the absence of the data elements required for assignment of beneficiaries, it is not possible for FQHCs and RHCs to participate in the Shared Savings Program by forming their own ACOs. It is, however, possible for them to join as an ACO participant in an ACO containing one or more of the statutory organizations eligible to form an ACO (as specified in section 1899(b)(1)(A)–(D) of the Act) and upon which assignment can be made consistent with the statute and the assignment methodology proposed in section II.D. of this proposed rule. However, we note that even in this case, for the reasons stated previously, we would not have the data necessary to consider FQHC or RHC patients in the assignment process. Thus, assignment of beneficiaries to ACOs in which FQHCs and RHCs are participating would have to be based solely on data from the other eligible ACO participants upon whom assignment can be based. As the Shared Savings Program develops, we will continue to assess the possibilities for collecting the requisite data from FQHCs and RHCs, and in light of any such developments we will consider

whether it is 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.

The situation is somewhat more complicated with regard to CAHs. Section 1834(g) of the Act provides for two payment methods for outpatient CAH services.

Under the method specified in section 1834(g)(1) of the Act (referred to as the standard method), facility services are paid at 101 percent of reasonable costs to the CAH through the Medicare fiscal intermediary or the Medicare Part A/B MAC, while payments for physician and other professional services are made separately to the physician or other practitioner under the MPFS through Medicare carriers. Accordingly, CAHs that bill under the standard method would not submit claims with information on individual practitioners, or the type of health professional (for example, physician, PA, NP), that provided a specific service.

Under the method specified in section 1834(g)(2) of the Act (referred to as method II), a CAH submits bills for both the facility and the professional services to its Medicare fiscal intermediary or its Medicare Part A/B MAC. If a CAH chooses this method for outpatient services, the physician or other practitioner must reassign his or her right to bill the Medicare program for those services to the CAH. Under method II, the CAH receives—(1) 101 percent of the reasonable cost payment for its facility costs; and (2) 115 percent of the amount otherwise paid under the MPFS for professional services under Medicare.

Thus, current Medicare payment and billing policies could generally support the formation of an ACO by a CAH billing under method II.

In summary, in this proposed rule, we considered three options for defining the range of potentially eligible providers and suppliers that would be eligible to form an ACO. One option that we considered would be to limit eligibility initially to the groups specifically identified in the statute. Under this option, only the four groups specified in section 1899(b)(1)(A)–(D) of the Act would be eligible to form an ACO and participate in the program.

A second option would be to narrowly define which groups of providers of services and suppliers are eligible to form an ACO and participate in the Shared Savings Program. The approach noted by MedPAC is one example of this option. This option would require the participation of a hospital in the ACO so that only partnerships or joint venture arrangements between hospitals and ACO professionals or hospitals employing ACO professionals (groups specified in 1899(b)(1)(C)–(D) of the Act) would be eligible to participate in the program. Another example of this option would be limiting participation to only those entities comprised of primary care professionals so that only ACO professionals in group practice arrangements or networks of individual practices of ACO professionals (groups specified in 1899(b)(1)(A)–(B) of the Act) would be eligible to form an ACO and participate in the program. This approach would be grounded in the premise that ACOs should be primary care-focused and that primary care professionals are in the best position to both reduce the fragmentation of services and improve the overall quality of care delivered to Medicare beneficiaries.

Under the third option, the four groups specified in section 1899(b)(1)(A)–(D) of the Act would be eligible to form an ACO and participate in the program, but in addition, we would employ the discretion provided to the Secretary under section 1899(b)(1)(E) of the Act to allow other Medicare enrolled entities, such as CAHs billing under method II to form an ACO. Additionally, employing Secretarial discretion to expand the definition of eligible providers or suppliers would allow other Medicare enrolled entities such as FQHCs and RHCs, to become ACO participants, if the ACO that is formed is able to meet the other qualifications to participate in the program.

After evaluating the three options for defining the range of potentially eligible providers and suppliers, we have decided to propose the third option. Under this proposal, the four groups specifically identified in section 1899(b)(1)(A)–(D) of the Act, and CAHs billing under method II, would have the opportunity to form ACOs independently. In addition, the four statutorily indentified groups, as well as CAHs billing under method II, could establish an ACO with broader collaborations by including additional Medicare enrolled entities such as FQHCs and RHCs and other Medicare-enrolled providers and suppliers as defined in the Act as ACO participants. While this proposal potentially increases the administrative complexity of implementing the program and could also require stronger measures to oversee the varied kinds of ACO arrangements that might evolve, we believe this approach best serves the goals of the program by allowing greater opportunities for broadly transforming the health care delivery system and increasing access to high quality and lower cost care under the Shared Savings Program for Medicare beneficiaries regardless of where they live. Specifically, this option allows for a wide variety of ACO configurations that incorporate a broad range of health care providers and suppliers, including safety net providers, post-acute care facilities, FQHCs, RHCs, and CAHs, which we believe will enable ACOs to offer more comprehensive care and better serve the needs of rural communities. The proposal also offers greater opportunity for innovation by ACOs in determining the most effective organizational structure to meet the needs of their respective populations.

In addition to requesting comment on this proposal generally, we are soliciting comment on the following: (1) The kinds of providers and suppliers that should or should not be included as potential ACO participants; (2) the potential benefits or concerns regarding including or not including certain provider or supplier types; (3) the administrative measures that would be needed to effectively implement and monitor particular partnerships; (4) other ways in which we could employ the discretion provided to the Secretary to allow the independent participation of providers and suppliers not specifically mentioned in the statute, for example, through an ACO formed by a group of FQHCs and RHCs; and (5) any operational issues associated with our proposal. We will 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 determine that it is feasible and consistent with the requirements of the program for more entities to participate as ACOs. 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 are also proposing 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 believe that this proposal to encourage participation by RHCs and FQHCs in ACOs is appropriate in light of the special role that these entities play in the health care delivery system, especially in providing care to otherwise underserved and vulnerable populations. We discuss how this proposal affects the determination

of shared savings under the program in section II.F. of this proposed rule.

2. 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 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

The ACO's legal entity may be structured in a variety of ways, including as a corporation, partnership, limited liability company, foundation, or other entity permitted by State law. As discussed previously in section II. B. of this proposed rule, and consistent with section 1899(b)(1)(A)–(D) of the Act, certain specified groups of providers of services and suppliers who have a mechanism of shared governance may be eligible to participate as ACOs in the Shared Savings Program. In addition to the groups specifically identified in the statute, we are proposing to use the Secretary's discretion under section 1899(b)(1)(E) of the Act to expand the list of eligible groups of providers and suppliers that may participate in the Shared Savings rogram. Specifically, we are proposing that ACOs may incorporate other groups of Medicare enrolled providers and suppliers, many of whom would not be able to form ACOs and participate in the program independently. As described previously, each of the Medicare-enrolled providers and suppliers that join together to form an ACO is identified by their Medicare-enrolled TIN and is referred to herein as an ACO participant. Regardless of whether an ACO participant is able to meet the eligibility criteria for participation in the Shared Savings Program independently or must join with others in order to meet criteria, we propose that the ACO must demonstrate a mechanism of shared governance that provides all ACO participants with an appropriate proportionate control over the ACO's decision making process.

In response to the request for information (RFI) that appeared in the November 17, 2010 **Federal Register** (75 FR 70165), we received comments regarding the need for us to remain flexible when defining the required legal structure to allow for a variety of structural options. For example, commenters noted that we should permit existing organizations to participate in the Shared Savings Program instead of requiring the formation of a new legal entity in order to avoid additional costs and duplication of organizational competencies. Commenters also recommended that the legal structure requirements should not disadvantage solo and small groups of physicians with fewer resources relative to larger hospital and physician groups by requiring the use of specific structures that may result in increased costs, implementation delays, and cumbersome operational requirements for these smaller entities. Moreover, our intent is to encourage participation by not-for-profit, community-based organizations.

When considering options for the legal structure of ACOs, we sought to balance the need for an organization to be recognized by the State with the need for flexibility to permit the participants to select the appropriate organizational structure for their ACO. We also considered the importance of minimizing costs related to organizing as a specific 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 believe 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 in order to best achieve the objectives of the Shared Savings Program and that it must have a TIN. Therefore, we are proposing to require an ACO to 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; (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 note that by proposing that the ACO be required to have a TIN, we are not proposing to require that the ACO itself be enrolled in the Medicare program, in contrast to this requirement for each ACO participant.

Also, by proposing that each ACO must be constituted as a legal entity appropriately recognized and authorized under applicable State law, we are not proposing to require that existing legal entities appropriately recognized under State law must form a separate new entity for the purpose of participating in the Shared Savings Program. If the existing legal entity meets the eligibility requirements to be an ACO, as described in this proposed rule, it may operate as an ACO, as long as it is recognized under applicable State law and is capable of receiving and distributing shared savings, repaying shared losses, and performing the other ACO functions identified in the statute and regulations, including the requirement for shared governance for ACO participants.

For example, a hospital employing ACO professionals, which is one of the entities identified in section 1899(b)(1) of the Act, may be eligible to participate in the Shared Savings Program as an ACO with its current legal structure, as recognized under applicable State law, and would not be required to develop a separate new entity. We recognize, however, that the absence of a separate legal entity to operate the ACO may make it more difficult for us to audit and otherwise assess ACO performance. We solicit comment on whether we should require all ACOs participating in the Shared Savings Program to be formed as a distinct legal entity appropriately recognized and authorized to conduct its business under applicable State law or whether an existing legal entity could be permitted to participate in the Shared Savings Program as an ACO, including entities that have similar arrangements with other payors. However, we propose that if an existing entity, such as a hospital employing ACO professionals would like to include as ACO participants other providers of services and suppliers who are not already part of its existing legal structure, a separate entity would have to be established in order to provide all ACO participants a mechanism for shared governance and decision making.

We propose that each ACO would 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. An ACO must provide in its application evidence 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 solicit comment on our proposal for the required legal structure and seek input on other suitable legal structure requirements that we should consider adding in the final rule or through subsequent rulemaking. Moreover, our intent is to encourage not-for-profit, community-based organizations to participate in the Shared Savings Program. We request comment on whether requirements for the creation of a separate entity would create disincentives for the formation of ACOs and whether there is an alternative requirement that could be used to achieve the aims of shared governance and decision making and the ability to receive and distribute payments for shared savings.

b. Governance

Although 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 further requires that an "ACO shall have in place a leadership and management structure that includes clinical and administrative systems," the statute does not specify the elements that this shared governance mechanism or the accompanying leadership and management structures must possess. We believe 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 envision a mechanism that is transparent, accountable to the affected beneficiary community, and also accountable and responsive to the ACO participants and the ACO providers/suppliers they represent. Further, we would anticipate that the leadership and management structures would provide for adequate authority to enable the ACO to execute its core functions of enhancing the quality, efficiency, and patient-centeredness of the health care services furnished to assigned beneficiaries.

Commonly used mechanisms for establishing shared governance are a board of directors, board of managers, or other similar governing bodies that provide a mechanism for representation and control in shared decision-making for all ACO participants. Accordingly, we are proposing that an ACO must establish and maintain a governing body with adequate authority to execute the statutory functions of an ACO, as defined by the shared governance criterion described in more detail later in this proposed rule. 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 evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care," as required under section 1899(b)(1)(G) of the Act. As discussed in more detail later in the document, this governing body would be comprised of the ACO participants or their designated representatives, include Medicare beneficiaries served by the ACO, and possess broad responsibility for the ACO's administrative, fiduciary, and clinical operations. While the representatives on the governing body could be serving in a similar or complementary manner for an ACO participant within the ACO, 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 comprised of a self-contained financially and clinically integrated entity that has a pre-existing board of directors or other governing body, such as a hospital that employs ACO professionals, we are also proposing that the ACO would not need to form a separate governing body, as long as that governing body is able to meet all other criteria required for ACO governing bodies. In this case, the integrated 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. Although we wish to provide potential ACOs with some flexibility on corporate governance and ACO formation, we are concerned that allowing existing entities to be ACOs would complicate our monitoring and auditing of the ACO. We solicit comment on this issue.

Moreover, our intent is to encourage not-for-profit, community-based organizations to participate in the Shared Savings Program. We request comment on whether 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 is an alternative requirement that could be used to achieve the aims of shared governance and decision making.

c. Composition of the Governing Body

For purposes of the Shared Savings Program, the ACO is, by definition, comprised of groups of Medicare-enrolled providers and suppliers (ACO participants) that agree to work together to manage and coordinate care for beneficiaries, and have established a mechanism for shared governance—as opposed to an outside entity directing their day-to-day operations. Therefore, we believe that the ACO should be operated and directed by Medicare-enrolled entities that directly provide health care services to beneficiaries. Stakeholders have indicated to us that in the private sector, entrepreneurial management companies and health plans have expressed interest in forming or participating in ACOs. Often, small groups of providers 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 propose that in order 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. This proposal ensures that ACOs remain provider-driven, but also leaves room for both non-providers and small provider groups to participate in the program.

We are requesting comment on this proposal for whether more or less than 75 percent control of the governing body being held by the ACO participants is an appropriate percentage. We are also requesting comment on whether the appropriate representative should be held by persons employed by and representing Medicare-enrolled TINs.

As discussed in more detail later in the document, we believe a process for integrating community resources is an essential part of patient centeredness.

We are proposing that ACOs be required to describe how they will partner with community stakeholders as part of their application. ACOs that have a community stakeholder organization serving on their governing body would be deemed to have satisfied that application criterion.

Additionally, as discussed in more detail later in the document, we are proposing a requirement that ACOs provide for beneficiary involvement in

their governing processes. Specifically, we are proposing that ACOs will be required to demonstrate a partnership with Medicare FFS beneficiaries by having beneficiary representation in the ACO governing body.

3. 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." We believe this 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. Based on their experience with the PGP demonstration, participants identified several factors as critical to improving quality and the opportunity to share savings:

- An integrated organization with an environment that supports expending resources on multiple programs and initiatives to improve quality and reduce unnecessary services.
- Dedicated physician leadership with a proven ability to motivate physicians to participate in the development and implementation of quality improvement and other clinical programs and initiatives.
- Health information technology that facilitates the aggregation and analysis of data, allows patient-level feedback, and provides alerts and reminders at the point of care.
- Experience with non-Medicare payer initiatives, particularly through a managed care affiliate, to improve quality and reduce expenditure growth.

In addition, another important factor that must be considered is whether the leadership and management structure of the ACO should include appropriate safeguards to ensure the ACO's integration and likelihood of achieving quality improvements and cost efficiencies. The Antitrust Agencies have developed criteria to assess whether collaborations of otherwise competing health care providers should be condemned as per se illegal under antitrust law or subject to a more thorough evaluation under the "Rule of Reason," which would examine likely procompetitive or anticompetitive effects.[1] To avoid per se condemnation as "shams" that facilitate price fixing or other per se illegal activities, collaborations of competing health care providers must show that they are integrated ventures that are likely to, or do, enable their participants jointly to achieve cost efficiencies and quality improvements in providing services. The efficiency-enhancing integration "must likely generate procompetitive benefits that enhance the participants' ability or incentives to compete, and thus offset any anticompetitive tendencies of the arrangement."[2]

Accordingly, the antitrust perspective focuses on how collaboration, including coordinated care, can lower costs and improve quality, just as the intent of the Shared Savings Program under section 1899 of the Act is to promote accountability for Medicare beneficiaries, improve the coordination of FFS items and services, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery. For antitrust purposes, collaborations of competing health care providers may use either financial or clinical integration, or both, as means to achieve cost efficiencies and quality improvements.[3] To demonstrate financial integration, participants in collaboration must share substantial financial risk, so they have the incentive to cooperate in controlling costs and improving quality by managing the provision of services.[4] To demonstrate clinical integration, participants must 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.[5] The Federal Antitrust Agencies have concluded that successfully achieving clinical integration requires the establishment and operation of active and ongoing processes and mechanisms to facilitate, encourage, and assure the necessary cooperative interaction.[6]

We believe that these criteria also 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 also note that these criteria are very similar to the factors identified previously by participants in the PGP demonstration as critical to improving quality and controlling the cost of health care. Similarly, antitrust analyses have examined whether participants in such a collaboration are committed to the collective development and implementation of evidence-based protocols and benchmarks, to individual and group accountability for adherence to those protocols and benchmarks, to the development of technology to facilitate providers' compliance, to the measurement of compliance with those protocols, and to improved performance with respect to benchmarks, among other things.[7]

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. As discussed in more detail in section II. I. of this proposed rule, competition between ACOs is expected to have significant benefits for Medicare beneficiaries, by improving the quality of care they receive, protecting their access to a variety of providers, and helping to sustain the Medicare program by controlling costs. Furthermore, 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 requirements will help to ensure that an ACO organization participating in the Shared Savings Program will not subsequently face an antitrust challenge that its conduct is per se illegal, which could prevent the ACO from fulfilling the 3-year term of its agreement under the Shared Savings Program.

Accordingly, we believe an ACO, the ACO participants, and ACO providers/suppliers should demonstrate an organizational commitment to the Shared Savings Program and the terms of the 3-year agreement, both as a group and individually, as well as the leadership and management capabilities

[1] *Arizona* v. *Maricopa County Medical Society,* 457 U.S. 332 (1982).

[2] Letter from Jeffrey Brennan, Assistant Director, Bureau of Competition, Federal Trade Commission to John J. Miles, Ober, Kaler, Grimes & Shriver (February 19, 2002), available at *http://www.ftc.gov/bc/adops/medsouth.shtm.*

[3] Department of Justice and Federal Trade Commission, Statements of Antitrust Enforcement Policy in Health Care, Statement 8 (1996), available at *http://www.ftc.gov/reports/hlth3s.pdf.*

[4] Id.

[5] See, for example, Letter from Markus Meier to John J. Miles, Ober, Kaler, Grimes & Shriver 7 (June 18, 2007), available at *http://www.ftc.gov/bc/adops/070618mewdsouth.pdf.*

[6] Id.

[7] *See, for example,* Letter from Markus H. Meier, Assistant Director, Bureau of Competition, Federal Trade Commission to Christi J. Braun, Ober, Kaler, Grimes & Shriver 8 (April 13, 2009), *available at http://www.ftc.gov/os/closings/staff/090413tristateaoletter.pdf;* Letter from Markus H. Meier, Assistant Director, Bureau of Competition, Federal Trade Commission to Christi J. Braun & John J. Miles, Ober, Kaler, Grimes & Shriver 7 (Sept. 17, 2007), *available at http://www.ftc.gov/bc/adops/gripa.pdf;* Letter from Jeffrey Brennan, Assistant Director, Bureau of Competition, Federal Trade Commission to John J. Miles, Ober, Kaler, Grimes & Shriver (Feb. 19, 2002), *available at http://www.ftc.gov/bc/adops/medsouth.shtm.*

necessary to achieve the three-part aim by managing and coordinating the care of assigned Medicare beneficiaries. We note that the statute permits ACO participants that form an ACO to use a variety of collaborative organizational structures, including collaborations short of merger, to evidence the required organizational commitment and leadership and management capabilities.

Thus, consistent with the requirement 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 are proposing that ACOs 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 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 in that State.
- ACO participants and ACO providers/suppliers would have a meaningful commitment to the ACO's clinical integration program to ensure its likely success. Meaningful commitment may include, for example, a meaningful financial investment in the ACO, or a meaningful 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 participant to make the clinical integration program succeed.
- The ACO would have a physician-directed quality assurance and process improvement committee that would oversee an ongoing quality assurance and improvement program. The quality assurance program would establish internal performance standards for quality of care and services, cost effectiveness, and process and outcome improvements, and hold ACO providers/suppliers accountable for meeting the performance standards. The program would also have processes and procedures in place to identify and correct poor compliance with such standards and to promote continuous quality improvement.
- 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, lower growth in expenditures. The guidelines and care delivery processes would cover diagnoses with significant potential for the ACO to achieve quality and cost improvements, taking into account the circumstances of the individual beneficiary, and could be accomplished, for example, through an integrated electronic health record with clinical decision support. ACO participants and ACO providers/suppliers would have to agree to comply with these guidelines and processes and to be subject to performance evaluations and potential remedial actions.
- 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 care via, for example, shared clinical decision support, feedback from patient experience of care surveys or other internal or external quality and utilization assessments.

As discussed later in the document, and in section II. C. of this proposed rule, it is our expectation that ACO participants and ACO providers/suppliers participating in the ACO would make a commitment to participate in the ACO for not less than 3 years. However, we recognize it will be necessary for the ACO to include a remedial process for ACO participants that fail to comply with the ACO's internal procedures and performance standards, including the possibility of expulsion of significant outliers. We caution that expulsion cannot be used as a mechanism to avoid at-risk beneficiaries.

In order to determine an ACO's compliance with these requirements, as part of the application process, we are proposing 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, the shared savings that 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, such as the internal performance standards and the processes for monitoring and evaluating performance;
- 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; and
- 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.

In an effort to allow flexibility and innovation, we are proposing that ACOs with innovative leadership and management structures have the opportunity 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 may 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. For example, if an ACO does not have a physician-directed quality assurance and process improvement committee, the ACO would need to describe how it plans to oversee an ongoing quality assurance and improvement program as described previously. Additionally, we seek 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 request comment on the proposed leadership and management structure and whether the compliance burden associated with these requirements will discourage participation, hinder innovative organizational structures, or whether there are other or alternative leadership and management requirements that would enable these organizations in meeting the three-part aim.

4. 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 are proposing 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. The certification would be included as part of the ACO's application and 3-year participation agreement.

5. 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 are proposing to limit participation agreements to a 3-year period. We are seeking comments on this proposal and whether a longer agreement period should be considered initially.

If the ACO is approved for participation, we propose that an authorized representative—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 the ACO participants agree to the requirements set forth in the 3-year agreement between the ACO and us—sign a 3-year participation agreement and submit the signed agreement to us. This participation agreement would include an acknowledgment that the ACO agrees to comply with all of the requirements for participation in the Shared Savings Program and that all contracts or arrangements between or among the ACO, ACO participants, ACO providers/suppliers, and other entities furnishing services related to ACO activities must require compliance with the ACO's obligations under the 3-year agreement. The participation agreement would be signed by an authorized representative of the ACO after it has been approved for participation. The ACO would be responsible for providing a copy of the agreement to its ACO participants and ACO providers/suppliers. We are soliciting comment on this proposal, including any additional measures or alternative means that we should consider to fulfill this requirement.

We also recognize that, while having signed a 3-year participation agreement with us in good faith and with the intention to participate in the program for the full 3-year agreement period, there may be instances where an ACO might need to discontinue its participation in the Shared Savings Program prior to the end of the agreement period. As described in section II. H. Monitoring and Termination of ACOs of this proposed rule, we propose to require an ACO to give us 60 days advance written notice of its intention to terminate its agreement to participate in the Shared Savings Program and the effective date of its termination. As described in more detail in section II. F of this proposed rule, we propose the ACO will be subject to a 25 percent withhold of shared savings in order to offset any future losses under the two-sided model. We propose that if an ACO completes its 3-year agreement successfully, we will refund in full any portion of shared savings withheld during the course of the 3-year agreement period that is not needed to offset losses. We further propose that in the event an ACO's 3-year agreement is terminated before the completion of the 3 years, we will retain any portion of shared savings withheld.

Finally, it is our intention that all ACOs, ACO participants, and ACO providers/suppliers with direct or indirect obligations under the Shared Savings Program 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, as discussed in section II. F. or otherwise extend to all parties with obligations to which the particular certification applies.

We are considering the best way to achieve this end and solicit public comments on this issue.

6. Distribution of Savings

As discussed previously, an ACO must be a legal entity appropriately recognized and authorized to conduct its business under State law, and would be identified by a TIN. We propose to make any shared savings payments directly to the ACO as identified by its TIN. The TIN associated with the ACO's legal entity may, or may not, be enrolled in the Medicare program, unlike the ACO participant TINs that are Medicare-enrolled groups of providers of services and suppliers. Therefore, because the statute contemplates payment directly to the ACO, we are proposing to pay the ACO TIN directly. We acknowledge that this proposal could 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 the payment withhold described in more detail in section II. F, Shared Savings Determination, as well as the other safeguards for assuring ACO repayment of shared losses described in section II.G.of this proposed rule. We solicit comments on our proposal to make shared savings payments directly to the ACO, as identified by its TIN. In addition, we are soliciting comment on our proposal to make shared savings payments to a non-Medicare-enrolled entity.

While 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, the statute does not establish any requirements for the manner in which shared savings payments are distributed. We have considered whether it would be appropriate, under the broad discretion granted to the Secretary in implementing the Shared Savings Program, to propose criteria for the distribution of shared savings by the ACO. Although we do not believe we have the authority to specify how shared savings must be distributed (so long as the distribution is consistent with all applicable legal requirements), 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. More specifically, ACOs would have to indicate how potential shared savings would be used to promote accountability for their Medicare population and the coordination of their care as well as how they might be invested in infrastructure

and redesigned care processes for high quality and efficient health care service delivery. Therefore, we propose 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, and how any shared savings will be used to align with the aims of better care for individuals, better health for populations, and lower growth in expenditures. We believe the proposed requirement would achieve the most appropriate balance among objectives for encouraging participation, innovation, and achievement of program while still focusing on the aims of better care for individuals, better health for populations, and lower growth in expenditures. Additionally, it is the intention of this requirement for ACOs to include this description in the application, to both guard against improper financial incentives as well as ensure appropriate beneficiary protections.

7. 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 fee-for-service 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. C. of this proposed rule, we discuss our proposal to assign beneficiaries to an ACO on the basis of primary care services rendered by physicians with primary care specializations in general practice, internal medicine, family practice, and geriatric medicine. We are proposing that this algorithm will also be used to assign beneficiaries during the baseline years in order to establish a historical per capita cost benchmark against which the ACO would be evaluated during each year of the agreement period. We believe it is reasonable to assume that if by using this algorithm the ACO demonstrates a sufficient number of beneficiaries to fulfill this eligibility requirement for purposes of establishing a benchmark, then the ACO also contains a sufficient number of primary care professionals to provide care to these beneficiaries. It is also reasonable to assume the ACO would continue to approximate this number in each year of the agreement period. Thus, we are proposing 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 three-year benchmarking period using the ACO participant TINs exceeds the 5,000 threshold for each year. We are soliciting comment on this proposal as well as any additional guidance that could be considered for meeting these requirements.

While an ACO could meet the requirements in section 1899(b)(2)(D) of the Act when it applies to participate in the Shared Savings Program, the number of assigned beneficiaries could fall below the 5,000 level due to either significant events, such as when an ACO professional or group of professionals cease to participate in the ACO, or in those instances where the actual number of beneficiaries is close to 5,000 as a result of normal fluctuations in patient populations. The requirements under section 1899(b)(2)(D) of the Act are important with respect both to the sufficiency of the ACO to provide primary care services to its assigned beneficiary population and statistical stability for purposes of calculating per capita expenditures and assessing quality performance. Simply stated, and as described in detail in section II.D. of this proposed rule, as the number of assigned beneficiaries increases, the minimum savings rate (MSR) gets smaller. Conversely, as the number of assigned beneficiaries decreases, the MSR expands thus making it significantly more difficult for an ACO to obtain shared savings. So, retaining 5,000 assigned beneficiaries is important from both the perspective of the capacity of the ACO to provide primary care services to its assigned beneficiary population as well as the ability of the ACO to realize shared savings by exceeding the MSR.

Thus, we considered what action, if any, should be taken in the event the number of beneficiaries falls below 5,000. 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 dropped below 5,000. We considered terminating the ACO for falling below 5,000 beneficiaries immediately or after giving the ACO an opportunity to implement a corrective action plan. We have concerns that immediately terminating an ACO or denying it an opportunity to share in savings because its population fell slightly may discourage participation among smaller ACOs. We believe this would be inconsistent with the goals of allowing greater opportunities for broadly transforming the health care delivery system and increasing access to high quality and lower cost care under the Shared Savings Program for Medicare beneficiaries regardless of where they live. Another option would be to take no action if the ACO falls below 5,000 assigned beneficiaries. Taking no action in these instances would be inconsistent with the statutory requirement that an ACO have 5,000 assigned beneficiaries in order to be eligible to participate in the Shared Savings Program and would reduce incentives for smaller provider organizations to affiliate with other providers and suppliers to be successful under the Shared Savings Program. A third option might be to adjust, or scale, the shared savings in those instances where the number of assigned beneficiaries falls below the floor of 5,000 over the course of a performance year. If shared savings are realized, and all other requirements of participation are met, an ACO that falls below the 5,000 assigned beneficiary floor could realize shared savings but at a reduced rate of savings that would parallel the number of beneficiaries assigned to the ACO. Thus, the amount of the incentive payment would be scaled to the number of beneficiaries in the ACO during the performance year. However, since the MSR adjusts with the number of assigned beneficiaries, there is a built-in incentive for ACOs to increase their beneficiary population.

We believe a reasonable compromise would balance the statutory requirements, program incentives, and recognition of expected variation in an ACO's assigned population. Thus, we are proposing that if an ACO's assigned population falls below 5,000 during the course of the agreement period, we would issue a warning and place the ACO on a corrective action plan. The ACO would remain eligible for shared savings for the performance year for which the warning was issued. We further propose that if the ACO fails to meet the eligibility criterion of having more than 5,000 beneficiaries by the completion of the next performance year, the ACO's participation agreement will be terminated and the ACO will not be eligible to share in savings for that year. Thus, for example, if during the first performance year, an ACO's assigned population fell below 5,000, we would issue a warning, notifying the ACO of the variation in their assigned population. The ACO would be placed on a corrective action plan which could include, for example, a plan to add more

primary care providers to the ACO. The ACO would remain eligible to share in savings for the first performance year. However, if the ACO's assigned population had not returned to at least 5,000 by the end of the second performance year, then that ACO's agreement will be terminated and the ACO would not be eligible to share in savings for the second performance year. We also propose to reserve 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 request 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.

8. 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 FFS beneficiaries to an ACO, the implementation of quality and other reporting requirements * * *, and the determination of payments for shared savings * * *." As discussed in sections II.B. and II.D. of this proposed rule, we are proposing to define an ACO operationally as a legal entity that is comprised of a group of ACO participants which are in turn defined to mean Medicare-enrolled providers or suppliers, as identified by their TINs. However, TIN level data alone may not be entirely sufficient for a number of purposes in the Shared Savings Program such as implementing our methodology for beneficiary assignment and calculating the quality performance score. Accordingly, to satisfy the requirements under section 1899(b)(2)(E) of the Act, we are proposing that entities applying to participate in the Shared Savings Program must provide not only the TINs of the ACO and the ACO participants, but also a list of national provider identifiers (NPIs) associated with the ACO providers/suppliers, which separately identifies the physicians that provide primary care.

We are also proposing to require an ACO to 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.

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

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. Several of these standards deal with how patient care is provided by the ACO, with a focus on processes and methods to: (1) Promote higher quality of care; (2) better coordinate care; and (3) meet the needs and concerns of patients and their families, including effectively engaging patients and their families in medical decision-making. 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 such enabling technologies."

With regard to each of the specific requirements under section 1899(b)(2)(G) of the Act, we have two options. One option is simply to propose to require documentation of an ACO's plans 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 such enabling technologies." Under this option, we would not establish any more specific criteria for these requirements. However, we would expect that the required documentation present convincing evidence of concrete and effective plans to satisfy these requirements, by providing specific processes and criteria that the ACO intends to use for promoting, improving, and assessing evidence-based medicine, beneficiary engagement, reporting of quality and cost measures, and coordination of care. Such processes would have to include provisions for internal assessment of cost and quality of care within the ACO, and employ these assessments in continuous improvement of the ACO's care practices.

The other option is to identify specific criteria that we would propose to require ACOs to meet with regard to each of these requirements. For example, with regard to the requirement to promote evidence-based medicine, we could provide a detailed description of evidence-based guidelines for various conditions and diseases for which we would hold ACOs accountable, including specific instructions for how an ACO would demonstrate it is following these guidelines and monitoring compliance among its ACO participants and ACO providers/suppliers. We could also specify a number of conditions for which the ACO would maintain an evidence-based medicine preventive health guidelines program. Similarly, we could identify and require the use of specific decision support tools, patient activation measures, or other patient support tools in order for an ACO to satisfy the requirement for beneficiary engagement.

However, we have concerns that a prescriptive approach would be premature and potentially impede innovation and the goals of this program. Thus, for the requirements under section 1899(b)(2)(G) of the Act, we are proposing that in order to be eligible to participate in the Shared Savings Program, the ACO 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. We are proposing this option in order to allow ACOs the flexibility to choose the tools for meeting these requirements that are most appropriate for their practitioners and patient populations. Over time, 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 are also specifically soliciting 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. Later in the document, we discuss the concepts of evidence-based medicine, patient engagement, internal quality and cost reporting, and coordination of care, and describe how Shared Savings Program applicants can establish compliance with the requirements of section 1899(b)(2)(G) of the Act.

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 * * *." Evidence-based medicine can be generally defined as the application of the best available evidence gained from the scientific method to clinical decision-making. It seeks to assess the strength of evidence of the risks and benefits of treatments (including lack of treatment) and diagnostic tests, and

applies this evidence to the processes of medical decision-making and treatment. In practice, such an approach should involve the establishment and implementation of evidence-based guidelines, based on the best available evidence concerning the effectiveness of medical treatments, at the organizational or institutional level. A genuine evidence-based approach would also involve regularly assessing and updating such guidelines to promote continuous improvement in the quality of care in light of new evidence concerning the effectiveness of medical treatments. We propose that as part of the application, the ACO would describe the evidence-based guidelines it intends to establish, implement, and periodically update.

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." The term "patient engagement" is the active participation of patients and their families in the process of making medical decisions. Patient engagement in decision-making requires consideration not only of the best scientific evidence concerning medical treatment, but also the opportunity for patients and families to assess prospective treatment approaches in the light of their own values and convictions. 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 what might be termed "health literacy" in patients and their families. Health literacy is the possession of basic knowledge about maintaining good health, avoiding preventable medical conditions, managing existing conditions, as well as knowledge about how the care system works (for example, the roles of primary care physicians and specialist physicians, the nature and operation of both public and private health insurance, etc.).

We propose that as part of the application, the ACO would describe the patient engagement processes it intends to establish, implement, and periodically update.

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." 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 would expect ACOs to be able to monitor both costs and quality internally and make appropriate modifications based upon their collection of such information.

We propose 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.

d. Processes To Promote Coordination of Care

Finally, 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." 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. Compliance with this requirement may involve a range of strategies which may include the following examples:

- A capability to use predictive modeling to anticipate likely care needs.
- Utilization of case managers in primary care offices.
- Having a specific transition of care program that includes clear guidance and instructions for patients, their families, and their caregivers.
- Remote monitoring.
- Telehealth.
- The establishment and use of health information technology, including electronic health records and an electronic health information exchange to enable the provision of a beneficiary's summary of care record during transitions of care both within and outside of the ACO.

The provisions of any free services (telehealth, case managers, etc.) between parties in a position to generate Federal health care program referrals could trigger evaluation under the relevant fraud and abuse laws. Stakeholders interested in this issue may also wish to comment on the joint OIG/CMS notice referenced in section II.I of this proposed rule.

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 develop policies to place any restrictions that are not legally required on the exchange of medical records with providers who are not part of the ACO. We are proposing 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.

10. Patient-Centeredness Criteria

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." A patient-centered, or person-centered, orientation could be defined as care that incorporates the values (to the extent the informed, individual patient desires it) of transparency, individualization, recognition, respect, dignity, and choice in all matters, without exception, related to one's person, circumstances, and relationships in health care. Patient-centered care should extend not only to the patient but to the family and caregivers of the patient. Patient-centeredness is one of the Institute of Medicine's (IOM's) aims for improvement in health care. In IOM's report "Crossing the Quality Chasm: A New Health System for the 21st Century," providing patient-centered care is defined as "providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions." (to view IOM's report discussed previously, visit *http://iom.edu/Reports/2001/Crossing-the-Quality-Chasm-A-New-Health-System-for-the-21st-Century.aspx*) The National Partnership for Women and Families suggests the following principles for patient-centered care: (1) Care is comprehensive, coordinated, personalized, and planned; (2) patients' experience of care is routinely assessed and improved; (3) patients and their caregivers are full partners in their care; (4) transitions between settings of care are smooth, safe, effective, and efficient; (5) patients can get care when and where they need it; (6) care is integrated with the community resources patients need to maintain health and wellbeing; and (7) continuous quality improvement and elimination of disparities are top

priorities. (To view the Statement of Debra L. Ness, President, Nat'l Partnership for Women & Families, Senate Finance Committee, Roundtable on Delivery System Reform April 21, 2009 visit *http://www.nationalpartnership.org/site/DocServer/090421_SenateFinanceRoundtableStatement_Ness.pdf?docID=4881*)

The statutory requirement for "patient-centeredness criteria" clearly implies that one goal of the Shared Savings Program is for ACOs to 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. Drawing from the perspectives discussed previously, we believe the following list of proposed patient-centeredness principles should inform the care provided by an ACO participating in the Shared Savings Program:

- Care should be individualized based on the person's unique needs, preferences, values, and priorities.
- Beneficiaries should have access to their own medical records and to clinical knowledge so that they may make informed choices about their care.
- Beneficiaries (and their caregivers and/or family members where applicable) should be encouraged to be partners in care and make choices regarding the care they receive, based on both the medical record and clinical knowledge (that is, evidence-based medicine) provided by their ACO and the beneficiary's individual values.
- Beneficiary and caregiver and/or family experience of care should be routinely assessed and the ACO should seek to improve it where opportunities for improvement are identified.
- Care should be integrated with the community resources beneficiaries require to maintain well-being.
- Transitions in care among providers in the ACO, as well as other providers outside the ACO from whom the beneficiaries may also seek care, should be supported consistent with the patient-centeredness goals of coordinating care and having information follow patients by, for example, developing processes for the electronic exchange of information.

In the light of these principles, we believe the following processes and actions listed later in the document would be necessary to ensure the patient-centered orientation required by section 1899. We propose 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 how the ACO will use the results to improve care over time. As discussed in more detail later in the document, and as proposed in section II.E. of this proposed rule, scoring on this survey would help the ACO meet the quality performance standard.
- Patient involvement in ACO governance. As discussed in more detail later in the document, 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 their patient populations, and a plan to address the needs of their population. As discussed in more detail later in this document, the ACO would be required to describe this process as part of the application and describe how it would consider diversity in its patient population and 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. This proposal and application requirements are discussed in more detail later in this document.
- A mechanism in place for the coordination of care (for example, via use of enabling technologies or care coordinators). The ACO would be required to describe its mechanism for coordinating care for Medicare beneficiaries. 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 EHR Incentive program. The ACO would be required to describe their process or their plan to develop a process to electronically exchange summary of care information during care transitions. Additionally, in section II.E. of this proposed rule, we propose to include care transitions measures as part of the assessment of ACO quality.
- 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. The ACO would be required to describe its process, as discussed in section II.E. of this proposed rule, for communicating clinical knowledge/evidence-based medicine and describe how the ACO providers/suppliers will engage the beneficiary in shared decision-making.
- Written standards in place for beneficiary access and communication and a process in place for beneficiaries to access their medical record. As part of its application, the ACO would be required to submit its written standards for beneficiary access and communication. Additionally, the ACO would be required to describe its process for beneficiaries to access their medical record.
- 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. As described previously, the documents submitted to meet leadership and management criteria related to quality assurance and clinical integration program would satisfy this patient-centeredness criterion.

We believe that this list provides a comprehensive set of criteria for realizing and demonstrating patient-centeredness in the operation of an ACO. Accordingly, we are proposing to require that ACOs demonstrate patient-centeredness as required by the statute by addressing all 8 areas outlined previously. We also considered confining the list of mandatory criteria to only those items specifically mentioned in section 1899(b)(2)(H) of the Act that is, to "the use of patient and caregiver assessments" and "the use of individualized care plans." However, the statute clearly identifies these two items only as examples of patient-centeredness, and specifies that an ACO must be required to demonstrate that it meets patient-centeredness criteria "specified by the Secretary." Thus, we believe the Secretary is required to define and has discretion to specify criteria in addition to the two criteria that are specifically mentioned in the statute.

We note there is substantial overlap and alignment between these patient centeredness criteria as defined by the Secretary in accordance with section 1899(b)(2)(H) of the Act and the processes ACOs are required to define and documents they are required to submit as discussed previously to fulfill eligibility as outlined in section 1899(b)(2)(G) of the Act and 1899(b)(2)(F) of the Act. Therefore, many of the ways an ACO defines certain processes required by statute may also serve to demonstrate it meets patient centeredness criteria as defined by the Secretary, thus reducing the

burden for the ACO in meeting eligibility requirements.

We are soliciting comment on whether there are redundancies in the list of the 8 criteria or other considerations that might justify narrowing the list. We are also interested in whether the patient centeredness criteria as defined by the Secretary are sufficient to ensure that ACOs participating in the Shared Savings Program meet the eligibility requirement to demonstrate patient centeredness or whether there are additional patient centeredness criteria that should be added to our proposed list in order to meet the goals of improving the quality of health care delivery and improving patient satisfaction with their care. Additionally, we seek comment on whether these criteria are burdensome and whether they might create disincentives to participate or make it difficult for small entities to participate in the program.

Later in the document, we discuss 4 of the 8 criteria in detail and solicit comment regarding (a) Implementation of the beneficiary experience of care survey; (b) beneficiary involvement in governance; (c) identification of population health needs and consideration of diversity; and (d) implementation of individualized care plans and integration of community resources.

a. Beneficiary Experience of Care Survey

As discussed previously, we propose 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. 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 propose to require ACOs to collect and report on measures of beneficiaries' experience of care and we expect ACOs to submit their plan on how they will promote, assess, and continually improve in weak areas identified by the survey.

Many surveys are being used in both the private and public sectors, including the Medicare Health Outcomes Survey used by Medicare Advantage (MA) plans, Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey tools, and Health Resources Services Administration's (HRSA's) Health Center Patient Satisfaction Survey. We are proposing that ACOs be required to use a specified survey that assesses beneficiary experience of care and functional status. As proposed in section II.E. of this proposed rule, scoring on the patient experience of care survey would become part of the assessment of the ACOs quality performance. Specifically, we are proposing that ACOs be required to use the Clinician and Group CAHPS survey. We also propose to require adoption of an appropriate functional status survey module that may be incorporated into the CAHPS survey. The CAHPS Survey is a nationally recognized survey, developed by the Agency for Healthcare Research and Quality (AHRQ), which is widely used across the health care spectrum. The survey is designed to standardized patient questionnaires that can be used to compare results across sponsors and over time, which identifies the issues that are salient to consumers and influence their decisions. Since the ACO must contain primary care ACO professionals but otherwise has flexibility to incorporate other types of ACO participants, we believe the Clinician and Group CAHPS Survey is an appropriate tool to assess beneficiary experience of care and functional status in the ACO. Using this standard and well established survey instrument, we can more easily compare outcomes and beneficiary satisfaction across ACOs, as well as in certain modules in common between ACOs and Medicare FFS and MA plans. It would also help to ensure that survey measures are adequate to meet the program's purposes and that measures employed in the instrument are valid and reliable. However, we recognize that requiring the use of a specific survey instrument would increase the administrative burden of the Shared Savings Program on ACOs who are not currently using the specified instrument. Accordingly, we are soliciting comment on whether other existing survey tools would be more appropriate for ACO quality assessment.

We also considered proposing to allow ACOs to continue using the survey tools with which they are already familiar or of their own choosing at least in the initial stages of the program. Allowing ACOs to employ survey tools of their own choosing would provide maximum flexibility for ACOs, and would be least disruptive to existing ACO initiatives to survey beneficiary experience. However, allowing ACOs to employ survey tools of their own choosing would severely impede our ability to compare beneficiary experience across ACOs. Moreover, in some instances, the instruments selected by ACOs may use measures that are insufficient to meet the program's purposes, or measures which are not valid and reliable. In other instances, it might be that ACOs using more comprehensive survey tools would be unfairly penalized from the perspective of the performance standards in comparison to ACOs using less extensive surveys.

b. Patient Involvement in Governance

Another of the proposed patient-centered criteria discussed previously is the requirement that ACOs provide for patient involvement in their governing processes. We are proposing that, in order to satisfy this criterion, ACOs will 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. We believe the best way to demonstrate a patient-centered program is for Medicare beneficiaries to have a voice in the decision making process. Although, there may be concerns or differences in the ability of some ACOs to include a beneficiary on the governing board, given State laws, we are seeking comment on the inclusion of a Medicare beneficiary serviced by the ACO on the governing body. In order to safeguard against any conflicts of interest, 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.

We recognize that a requirement for representation by a Medicare beneficiary serviced by the ACO, on an ACO's governing body will not necessarily guarantee outcomes that are in line with the goals of the Shared Savings Program in general or patient-centered criteria in particular. Medicare beneficiary representation on an ACO's governing body may even be relatively ineffectual if Medicare beneficiaries hold relatively few seats on the governing body. Furthermore, such a requirement may pose difficulties for ACOs that already have a governing body and bylaws that do not require or may even prohibit Medicare beneficiary presence, and this requirement may therefore reduce the number of ACOs that participate in the Shared Savings Program, at least in its initial stages. However, we believe it is important to the patient-centered orientation of the Shared Savings Program to provide for beneficiaries to have a voice in ACO governance.

We considered proposing that, instead of requiring direct Medicare beneficiary representation on ACO governing bodies, ACOs could demonstrate a partnership with Medicare FFS

beneficiaries by having a Medicare beneficiary advisory committee or panel. Such a proposal would also serve to indicate the importance of beneficiary engagement in the ACO's activities to improve the quality and efficiency of health care services. It would also provide ACOs with the opportunity to form committees or panels that represent the voices of all of their patient types, including Medicare FFS beneficiaries. In addition, a unified advisory committee voice may, under some circumstances at least, be more effective than, a single beneficiary representative in the ACO governing body in advancing the goal of beneficiary participation in ACO governance. Furthermore, it would avoid requiring existing ACO governing bodies that do not currently have or whose bylaws do not permit Medicare beneficiary representation to revise their bylaws or to forego participation in the Shared Savings Program. However, a pure advisory committee or panel may be an inadequate conduit for Medicare beneficiary participation in ACO governance compared to their presence on the actual decision-making body of the ACO. Presence on the governing body would provide beneficiaries with an active role in the decision-making process and thus give beneficiaries more influence over the ACO's activities. In contrast, as an advisory committee or panel member, the beneficiary's voice provides guidance on the Shared Savings Program ACO's decision-making without the benefit of more active control over ACO activities.

Therefore, we are proposing that ACOs be required to demonstrate a partnership with Medicare FFS beneficiaries and meet patient centeredness criteria by including a Medicare beneficiary serviced by the ACO on the ACO governing body. We are soliciting comment on whether the requirement for beneficiary participation should include a minimum standard for such beneficiary participation on ACO governing bodies (for example, a minimum number of beneficiaries, or a minimum proportion of control over an ACO's governing body.). In addition, we are soliciting comment on the possible role of a Medicare beneficiary advisory panel or committee in promoting the goal of engaging patients in ACO governance. In particular, we seek comment on whether—(1) a Medicare beneficiary advisory panel or committee would be sufficient in and of itself in providing for appropriate patient participation in ACO governance; and (2) establishing Medicare beneficiary advisory panels or committees should be required in addition to requiring patient representation on ACO governing bodies.

We request comment on the proposal to engage in partnership with Medicare beneficiaries. We are specifically interested in whether this requirement will create disincentives for participation among smaller entities.

c. Evaluation of Population Health Needs and Consideration of Diversity

A third proposed patient-centered criterion on which we are seeking comments is the requirement that an ACO has a 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 populations. Several institutions and associations such as National Committee for Quality Assurance (NCQA) and AHRQ have made recommendations regarding evaluation of population health and diversity. For example, NCQA has developed multicultural health care standards and guidelines which include requirements for collecting of patient information that help the organization understand the composition of the population, providing culturally and linguistically appropriate services, and detecting health care disparities. Other institutions and associations have developed similar guidelines which emphasize promoting cultural sensitivity and addressing disparities through provider/management education and the translation of surveys and health promoting literature distributed by the provider into languages relevant to the provider's population. 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.

Accordingly, we propose that, in order to satisfy this patient-centered criterion, ACOs would be required to describe in their application their process for evaluating the health needs of their Medicare population, including consideration of diversity, and a plan to address the needs of their Medicare population.

d. Implementation of Individualized Care Plans and Integration of Community Resources

Finally, we are proposing that ACOs must have systems in place to identify high-risk individuals and processes to develop individualized care plans for targeted patient populations. The plan must 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 the beneficiary consents, the care plan should be shared with the caregiver, family, and others involved in the beneficiary's care. We propose that an ACO would be required to 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 are requesting comments on our proposal that ACOs be required to demonstrate use of individualized care plans for targeted beneficiary populations in order to be eligible for the Shared Savings Program. In order to satisfy this requirement fully, we propose that the development of such individualized care plans must grow from adherence of a related patient-centeredness criterion, that is, their development should be a result of shared decision-making which fully engages beneficiaries and their families, taking into account their values and preferences in developing a unique plan of care for each individual.

The individualized care plans should include identification of community and other resources to support the beneficiary in following the plan. To this end, we believe that a process for integrating community resources into the ACO is an important part of patient centeredness. A wide variety of organizations, although not necessarily ACO participants, may be considered a community resource, including: Employers, commercial health plans, local businesses, State/local government agencies, local quality improvement organizations or collaboratives (such as health information exchanges). Collaboration with these types of community resources can be an important part of enabling ACOs to take account of the entirety of Medicare beneficiary population's needs relative to their environment. Community stakeholder engagement in an ACO could be explicitly incorporated via community representation on the governing body, by having a community representative on an advisory board, or by other innovative mechanisms.

Individualized plans of care are not only an integral part of providing quality health care to both high-risk patients or patients with multiple chronic conditions, but are equally important in proactively maintaining the health for any beneficiary. For purposes of the application to participate in the Shared Savings Program, we propose 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 propose that ACOs be required to 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 request comment on these proposals. We are specifically interested in whether these requirements will create disincentives for participation among smaller entities.

11. ACO Marketing Guidelines

We believe there is a potential for beneficiaries to be misled about Medicare services available from an ACO or about the providers and suppliers from whom they can receive those services. 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, or ACO providers/suppliers to engage in behavior that may confuse or mislead beneficiaries about the Shared Savings Program or their Medicare rights. For example, although it is expected that ACO providers/suppliers participating in an ACO will refer patients to other ACO providers/suppliers in the ACO, we are concerned that beneficiaries may be misled into thinking the ACO is similar to a managed care organization, and that they may only receive services or only certain services from the other participating ACO providers/suppliers.

Although section 1899 of the Act is silent with regard to marketing activities and other forms of beneficiary communications by ACOs, section 1899(b)(2)(H) of the Act requires an ACO to demonstrate "that it meets patient-centeredness criteria." We believe that in order to be truly patient-centered, an ACO must not only provide care coordination that is tailored to the needs of the individual beneficiary, but also avoid engaging in activities that may prevent its assigned beneficiaries from taking advantage of the full range of benefits to which they are entitled under the Medicare FFS program, including the right to choose between healthcare providers and care settings. As a result, issuing beneficiary communications or engaging in marketing activities that may be confusing or misleading would not be patient-centered because these activities restrict the ability of beneficiaries and/or their caregivers to be informed about their health care choices and thus limit the opportunity for beneficiaries to be properly involved in the management of their own care.

Accordingly, we think it would be 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 by ACOs to ensure that such communications and marketing by ACOs are used only for appropriate purposes, such as notification that a beneficiary's healthcare provider is participating in the ACO, issuance of any CMS required notices, notification of provider or ACO terminations. This policy will protect Medicare beneficiaries by minimizing the potential that they will be misled or confused by ACO marketing. Additionally, the policy is consistent with marketing provisions used in other Medicare programs such as MA.

We are proposing that all ACO marketing materials, communications, and activities related to the ACO and its participation in the Shared Savings Program, such as mailings, telephone calls or community events, that are used to educate, solicit, notify, or contact Medicare beneficiaries or providers/suppliers regarding the ACO and its participation in the Shared Savings Program, be approved by us before use to protect beneficiaries and to ensure that they are not confusing or misleading. This requirement would also apply to any materials or activities used by ACO participants or ACO providers/suppliers on behalf of the ACO to communicate about the ACO's participation in the Shared Savings Program in any manner to Medicare beneficiaries. In addition, we would want to ensure that materials distributed to beneficiaries do not misrepresent Shared Savings Program policies or suggest that we endorse the ACO, its ACO participants, or its ACO providers/suppliers.

We are further proposing that before any changes can be made to any approved materials, the revised materials must be approved by us before use. Finally, because the failure to comply with these requirements would demonstrate that the ACO does not meet the patient-centeredness criteria and therefore may no longer be eligible to participate in the program, we propose that an ACO that fails to adhere to these requirements may be placed under a corrective action plan or terminated, at our discretion.

For purposes of the Shared Savings Program, we are proposing to define ACO marketing materials, communications, and activities as including, but not limited to, general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, mailings, or other activities, conducted by or on behalf of the ACO, or by ACO participants, or ACO providers/suppliers participating in the ACO, or by other individuals on behalf of the ACO or its participating providers and suppliers. If these materials or activities are used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers regarding the ACO and its participation in the Shared Savings Program, they must be approved by us.

We do not believe that the following materials and activities would be subject to our approval: Beneficiary communications that are informational materials, that are customized or limited to a subset of beneficiaries; and materials that do not include information about the ACO or providers in the ACO; materials that cover beneficiary-specific billing and claims issues or other specific individual health related issues; and educational information on specific medical conditions, (for example, flu shot reminders), or referrals, for example, as discussed in section II. C. of this proposed rule, exceptions to the definition of "marketing" under the HIPAA Privacy Rule.

12. Program Integrity Requirements

Section 1899(a)(1)(A) of the Act authorizes the Secretary to specify criteria that ACO participants must meet in order to work together to manage and coordinate care for Medicare FFS beneficiaries through an ACO. Using this authority, we propose 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.

a. Compliance Plans

We are proposing that an ACO must have a compliance plan that addresses how the ACO will comply with applicable legal requirements. 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. We are proposing that the ACO demonstrate that it has a compliance plan that includes at least the following elements, which are common in the compliance industry: 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 or ACO providers/suppliers to report suspected problems related to the ACO; compliance training of the ACO's employees and contractors; and a requirement to report suspected violations of law to an appropriate law enforcement agency. Nothing in this rule would prevent an ACO from using or building on an existing compliance program, if it has one (or if its ACO participants have programs that can be incorporated). To achieve an effective compliance program, an ACO may also want to consider coordinating its compliance efforts with existing compliance efforts of its ACO providers/suppliers. It is not our intention that an ACO would need to engage in duplicative efforts to meet the compliance program requirement. The goal is for ACOs to have effective compliance mechanisms.

b. Compliance With Program Requirements

We propose that, notwithstanding any relationships that the ACO may have with other entities related to ACO activities, the ACO maintains ultimate responsibility for compliance with all terms and conditions of its agreement with us. We propose 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 require compliance with the obligations under the 3-year agreement, including the document retention and access requirements discussed in section II.H of this proposed rule. We solicit comments on our proposal.

We must ensure the accuracy, completeness, and truthfulness of information submitted to us to determine an organization's eligibility to participate in the Shared Savings Program as an ACO, its compliance with program requirements, its eligibility for shared savings payments, and the amount of any payments owed to or by the ACO. To that end, we propose that an authorized representative of the ACO—specifically, an executive who has the ability to legally bind the ACO—must certify the accuracy, completeness, and truthfulness of information contained in its Shared Savings Program application, 3-year agreement, and submissions of quality data and other information. The certification must be made at the time the application, agreement, and information is submitted.

We further propose that, as a condition of receiving a shared savings payment, an authorized representative with authority to legally bind the ACO must make a written request to us for payment of the shared savings in a document that certifies the ACO's compliance with program requirements as well as the accuracy, completeness, and truthfulness of any information submitted by the ACO the ACO participants, or the ACO providers/suppliers to us, including any quality data or other information or data relied upon by us in determining the ACO's eligibility for, and the amount of, a shared savings payment or the amount owed by the ACO to us. We further propose that, if such data are generated by ACO participants or another individual or entity, or a contractor, or subcontractor of the ACO or the ACO participants, such ACO participant, individual, entity, contractor, or subcontractor 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.

c. Conflicts of Interest

We are proposing that the ACO governing body have a conflicts of interest policy that applies to members of the governing body. The purpose of this proposal is to ensure that members of the governing body act in the best interests of the ACO and Medicare beneficiaries We propose that 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 would also address remedial action for members of the governing body that fail to comply with the policy. We solicit comments on this proposal, including the scope and content of such a policy.

d. Screening of ACO Applicants

The Medicare program includes substantial screens of enrolling providers and suppliers, including, for example, newly enrolling ACO participants. ACOs will not be subject to those existing screens because they are not enrolling in Medicare. Consistent with our efforts throughout the Medicare program to strengthen provider enrollment standards and encourage compliance with program requirements, we are considering screening 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. 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 solicit comments on the nature and extent of such screening and the screening results that would justify rejection of an application or increased scrutiny.

e. Prohibition on Certain Required Referrals and Cost-Shifting

In section II.D. of this proposed rule, we propose to assign beneficiaries to an ACO after the conclusion of a performance period, but we also indicate that we are considering assigning beneficiaries to an ACO on a prospective basis at the beginning of a performance period. We are concerned that ACOs or ACO participants may offer or be offered inducements to overutilize 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 under the Shared Savings Program. The risk of such abuse might be heightened if the final rule provides for prospective assignment of beneficiaries. To address the risk of inappropriate cost-shifting within Medicare and other Federal health care programs, we are considering prohibiting ACOs and their ACO participants from conditioning participation in the ACO on referrals of Federal health care program business

that the ACO or its ACO participants know or should know is being provided to beneficiaries who are not assigned to the ACO.

*C. Establishing the 3-Year Agreement With the Secretary*

1. Options for Start Date of the Performance Year

Section 1899 (b)(2)(B) of the Act, as added by section 3022 of the Affordable Care 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 * * * " 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 agreements. In this section of this proposed rule, we will discuss our proposals for establishing an application period and for setting the start date for the 3-year agreements with ACOs.

We considered several options for establishing start dates, with the corresponding 3-year agreement periods: Annual start dates; semiannual start dates; rolling start dates; and delayed start dates. In our consideration of these options, we attempted to balance the need for maximum flexibility for program applicants with the advantages of establishing a streamlined administrative approach. Adopting an annual application period and start date would create cohorts of ACO applicants, which would be simultaneously evaluated for eligibility to participate in the program. Agreements with ACOs of the same cohort would take effect on the same date each year. This would allow for more streamlined processes around agreement renewal and performance analysis, evaluation and monitoring.

However, under section 1899(a)(1) of the Act, the Secretary must establish the Shared Savings Program by not later than January 1, 2012. 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 could allow ACOs to apply on a "rolling" basis in which applications are accepted and evaluated any time of year and the ACO's agreement period would begin after a determination that the eligibility requirements had been met. In this way, applicants could apply throughout the course of the year as they become ready and we could review and approve applications and begin performance periods on a rolling basis.

After exploring the various alternatives, it has become clear that the greatest barrier to any option other than an annual uniform start date relates to appropriate beneficiary assignment, particularly for markets where there may be multiple ACOs. First, 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.D. of this proposed rule, we propose that beneficiaries will 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. 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. In addition, adopting multiple start dates within a year would require multiple cycles for application review and approval, calculation of baselines and targets, data sharing, quality reporting, and financial reconciliation, which would impose a significant administrative challenge.

After evaluating the various options for start date, we are proposing 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 propose that the performance years be based on the calendar year to be consistent with most CMS payment and quality incentive program cycles. In other words, we propose: (1) To adopt the general requirement that ACO applications must be submitted by a deadline established by us; (2) we will review the applications and approve applications from eligible organizations prior to the end of the calendar year; (3) the requisite 3-year agreement period will begin on the January 1 following approval of an application; and (4) the ACO's performance periods under the agreement will begin on January 1 of each respective year during the agreement period.

However, we are concerned that, in light of the short time frame for implementing the Shared Savings Program in the first year of the program, a January 1 start date might not provide the flexibility necessary to allow all interested ACOs to complete their application packages. Accordingly, we solicit comment on any alternatives to a January 1 start date that would allow the greatest number of qualified organizations to apply to participate in the first year of the program. One specific example of an alternative to a single start date of January 1 for the first year of the Shared Savings Program might be to add an additional start date of July 1 and to allow the agreement period for ACOs with a July 1 start date to be increased to 3.5 years. Under this example, the first performance year of the agreement period would be defined as 18 months in order that all of the agreement periods would synchronize with ACOs entering the program on January 1 of the following year. We envision that if adopted, this alternative would only be available in the first year of the program and for all subsequent years all applications would have to be reviewed and accepted prior to the beginning of the applicable calendar year and all agreements would be for 3 years.

2. Timing and Process for Evaluating Shared Savings

Section 1899(d)(1) of the Act, as added by section 3022 of the Affordable Care 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 have therefore been 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. For this reason, all Medicare service and expenditure data have what can be defined as a claims run-out period. The claims run-out period is the time between when a Medicare-covered service has been furnished to a beneficiary and when the final payment is actually issued for the respective service.

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 claim 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 would have to work with our Office of the Actuary to determine if the calculation of a completion percentage is warranted. 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 ensure accurate and complete claims data are used 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 are considering, and seek 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 with us for ACOs found to be holding claims back, or attributing claims submitted after the run-out period to the following performance period.

We propose using a 6-month claims run-out to calculate the benchmark and per capita expenditures for the performance year. A 6-month claims run-out will allow us to more accurately determine the per capita expenditures associated with each respective ACO. Although the use of a 6-month claims run out will delay the computation of shared savings payments and the provision of feedback to participating ACOs, the trade-off for a more accurate calculation of per capita costs is warranted. More accurately defining the per capita expenditures will allow us to share the appropriate amount of savings or alternatively, if no shared savings are realized, it will allow the ACO to focus on potential areas for improvement. However, we seek comment on whether there are additional considerations that might make a 3-month claims run-out more appropriate.

3. Data Sharing

Under section 1899(b)(2)(A) of the Act, as added by section 3022 of the Affordable Care 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." 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, we generally expect that participating ACOs are able to, or are working toward, independently identifying and producing 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, we also recognize that while an ACO typically should have, or is moving toward having, complete information for the services it provides to or coordinates on behalf of its FFS beneficiary population, it may not have complete information on a FFS beneficiary who, for example, has chosen to receive services, medications or supplies from providers of services and suppliers outside its organization. We believe that providing ACOs with an opportunity to request CMS claims data, as described later in this proposed rule, on their potentially assigned beneficiary population would allow them to understand the totality of care provided to beneficiaries assigned to them by identifying the services and supplies that fee-for-service beneficiaries receive during the performance year both within and outside of the ACO. We believe that access to this data would promote coordinated care and a better understanding of the population served by the ACO with resulting positive impacts on both the quality and efficiency of ease of delivered. ACOs represent a positive step toward transforming the current health care system and we want to ensure that participating organizations have access to information that will assist them in achieving both improvements in the quality of care and a better understanding of the population served by the ACO while simultaneously lowering the growth in health care costs.

We could provide data to ACOs in different forms with a focus on different levels of information, for example, aggregated population level data or beneficiary identifiable data. These data could be combined with data collected within the ACO. For example, our data could be combined with provider level data compiled within the ACO. Combining aggregate and beneficiary identifiable data as well as provider level and other internally generated data would provide ACOs with a more complete picture about the care their assigned beneficiaries receive both within and outside the ACO, their ACO participants and ACO providers/suppliers' patterns of care, and could be used to assess their performance relative to their previous years' performance. With this information, in accordance with established privacy and security protections, ACOs would be 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 identify which categories of beneficiaries would benefit most from care coordination and other patient-centered approaches. For a more complete discussion of the requirements

associated with the sharing of internally generated data, please see section II.B. of this proposed rule

4. Sharing Aggregate Data

Because we believe that ACOs have the potential to significantly improve the quality of care provided to Medicare beneficiaries while improving the efficiency and cost-effectiveness of that care, we believe that, where feasible, we should provide information to help ACOs improve the quality of care, improve the health of their beneficiary population, and create efficiencies within their systems. One possible approach is to provide aggregated data on beneficiary use of health care services. An ACO should be able to use aggregated data reports on its assigned or potentially assigned beneficiary population to monitor, understand, and manage its utilization and expenditure patterns as well as to develop, target, and implement quality improvement programs and initiatives. For example, if data shows that an ACO's beneficiary population had a high rate of hospital readmissions, the ACO could consider the need for actions to improve discharge coordination among its attending physicians, hospitals, and post-acute care providers or to improve access to primary care clinics. Similarly, an analysis of aggregated Part D data that shows beneficiaries were not filling their prescriptions could lead to interventions applicable to all beneficiaries designed to assess and develop strategies to overcome difficulties in filling prescriptions. Likewise, aggregated data could show a relatively high incidence within the ACO's beneficiary population of certain types of procedures relative to national benchmarks, potentially prompting an ACO to further explore and examine the appropriateness of its ACO participants' and ACO providers/suppliers' practice patterns by using provider-level data.

In the PGP demonstration, we provided several types of aggregate data to the participating group practices. We generated an annual profile report that provided the following information:

- Financial performance including number of patients seen, number of patients assigned, per capita expenditures, risk score, benchmark, total assigned beneficiary expenditures, minimum savings amount, shareable savings, and annual performance payment.
- Quality performance scores, including numerator, denominator, and rate for each measure along with the target benchmark for each measure.
- Aggregated metrics on the assigned beneficiary population, including a breakdown of the population into high risk score beneficiaries, beneficiaries with 1 or more hospitalizations, and chronic disease subpopulations such as patients with congestive heart failure, coronary artery disease, hypertension, chronic obstructive pulmonary disease, and diabetes.
- The number of patients overall and in each subpopulation with emergency department visits, hospital discharges, physician visits and their corresponding rate for the assigned population.

The feedback received on the PGP demonstration suggested that making these data available was helpful to the participating practices; they noted the benefits of having aggregate data that were more easily digestible compared to "data dumps" comprised of claims-based data.

In general, by making similar types of aggregate, data available to ACOs participating in the Shared Savings Program, we believe ACOs would have a more complete picture of the services rendered to their assigned FFS beneficiaries, which would allow the pursuit of a variety of strategies to streamline and consolidate care provision in a way that enhances quality and slows the growth in Medicare expenditures for their assigned beneficiary population. Thus, providing aggregated Medicare data reports to ACOs in the beginning of the program may be especially helpful to ACOs as they identify priority areas of care upon which to focus. Accordingly, similar to the PGP demonstration, we propose to provide aggregate data reports which would include, when available, aggregated metrics on the assigned beneficiary population, and beneficiary utilization data at the start of the agreement period based on historical data used to calculate the benchmark. We further propose to include these data in conjunction with the yearly financial and quality performance reports. Additionally, we propose to provide quarterly aggregate data reports to ACOs based upon the most recent 12 months of data from potentially assigned beneficiaries. We request comments on these proposals as well as the kinds of aggregate data and frequency of data reports that would be most helpful to the ACO's efforts in coordinating care, improving health, and producing efficiencies.

5. Identification of Historically Assigned Beneficiaries

Based upon feedback from the PGP demonstration, the RFI comments on the Shared Savings Program, and Shared Savings Program Open Door Forums, we propose to make certain limited beneficiary identifiable data available at the beginning of the first performance year. In addition to sharing aggregated data reports based on the ACO's historically assigned beneficiary population, we believe the ACO would benefit from understanding which of their fee-for-service beneficiaries were used to generate the aggregated data reports. Accordingly, we propose to disclose the name, date of birth (DOB), sex and Health Insurance Claim Number (HIC) of the historically assigned beneficiary population. We believe that knowing these identifiers would be useful to the ACO in two ways: First, the ACO providers could use the information to identify the beneficiaries, review their records, and identify care processes that may need to change. For example, the ACO might look at whether an inability to get a timely clinic appointment resulted in an avoidable emergency room visit for a particular patient. Second, experience with the PGP demonstration has suggested that a high percentage of historically assigned patients will continue to receive care from the ACO participants and ACO providers/suppliers. Knowing individuals who have been assigned in the past would help the ACO participants to identify individuals who may benefit from improved care coordination strategies going forward.

Providing a list of historically assigned patients to the ACO may also raise concerns. In section II.D. of this proposed rule, we have proposed to assign beneficiaries to the ACO retrospectively. One reason for this is that we believe that the ACO should be evaluated on the quality and cost of care furnished to those beneficiaries who actually chose to receive care from ACO participants during the course of each performance year. Another reason for retrospective assignment is to encourage the ACO to redesign its care processes for all Medicare FFS beneficiaries, not just for the subset of beneficiaries upon whom the ACO is being evaluated. We recognize that providing a list of historically assigned beneficiaries may provide an opportunity for the ACO to identify and avoid at-risk beneficiaries that appear on the list so that the costs of these beneficiaries do not appear in the calculation of the ACO's actual expenditures during a performance year. We are addressing this concern through the proposal described in section II.H. of this proposed rule, that takes steps to ensure ACOs do not avoid at-risk beneficiaries.

Furthermore, we recognize that there are a number of issues and sensitivities surrounding the disclosure of

individually-identifiable (patient-specific) health information, and note that a number of laws place constraints on the sharing of individually identifiable health information. For example, section 1106 of the Act generally bars the disclosure of information collected under the Act without consent unless a law (statute or regulation) permits for the disclosure. In this instance, the HIPAA Privacy Rule permits that legal authority and provides for this proposed disclosure of individually identifiable health information by us.

Under the HIPAA Privacy Rule, covered entities (defined as health care plans, providers that conduct covered transactions, and health care clearinghouses) are barred from using or disclosing individually identifiable health information (called "protected health information" or PHI) in a manner that is not explicitly permitted or required under the HIPAA Privacy Rule. When another entity conducts a function or activity involving the use or disclosure of individually identifiable health information on behalf of a covered entity, that entity is a business associate of the covered entity. (45 CFR 160.103). Under the HIPAA Privacy Rule, a covered entity may disclose PHI to business associates if it obtains "satisfactory assurances that the business associate will appropriately safeguard the information" (45 CFR 164.502(e)). These satisfactory assurances generally take the form of contractual obligations to protect the data as the covered entity is required to do under the HIPAA Privacy Rule. Any use or disclosure of PHI that a covered entity can make under the HIPAA Privacy Rule can also be performed on its behalf by a business associate if the use or disclosure is authorized in the contract between the covered entity and the business associate.

The Medicare FFS program, a "health plan" function of the Department, is subject to the HIPAA Privacy Rule limitations on the disclosure of PHI. The ACO participants and ACO providers/suppliers are also covered entities, provided they are health care providers as defined by 45 CFR 160.103 and they or their agents electronically engage in one or more HIPAA standard transactions, such as for claims, eligibility or enrollment transactions. Similarly, an ACO may itself be a HIPAA covered entity if it is a health care provider that conducts such transactions. Alternatively, based on their work on behalf of ACO participants and ACO providers/suppliers in conducting quality assessment and improvement activities, the ACOs will qualify as the business associates of their covered entity ACO participants and ACO providers/suppliers.

In light of these relationships, the proposed disclosure of the four identifiers would be permitted by the HIPAA Privacy Rule under the provisions that permit disclosures of PHI for "health care operations" purposes. Under those provisions, a covered entity is permitted to disclose PHI to another covered entity for the recipient's health care operations purposes if both covered entities have or had a relationship with the subject of the PHI to be disclosed (which is true here), the PHI pertains to that relationship (which is also true here) and the recipient will use the PHI for a "health care operations" function that falls within the first two paragraphs of the definition of "health care operations" in the HIPAA Privacy Rule. (45 CFR 164.506(c)(4)). The first paragraph of the definition of health care operations includes "population-based activities relating to improving health or reducing health costs, protocol development, case management and care coordination" (45 CFR 164.501). We believe that this provision is extensive enough to cover the uses we would expect an ACO to make of the identifying data elements for the historically assigned patients. In coming to this conclusion, we recognize that an individual's authorization is generally required before using or disclosing PHI for marketing purposes, 45 CFR 164.508, but we also note that both those ACOs acting as a covered entity (as opposed to business associates) and those ACOs acting on behalf of covered entity ACO participants and ACO providers/suppliers as business associates will be able to use the four data elements to communicate with individuals on the list to describe available services and for case management and care coordination purposes under the exceptions to the definition of "marketing" under the HIPAA Privacy Rule, 45 CFR 164.501.

Furthermore, when using or disclosing PHI, or when requesting this information from another covered entity, covered entities must make "reasonable efforts to limit" the information that is used, disclosed or requested the "minimum necessary" to accomplish the intended purpose of the use, disclosure or request, 45 CFR 164.502(b). We believe that the provision of the four proposed data elements would constitute the minimum data necessary to accomplish the Shared Savings Program goals of the ACO.

The Privacy Act of 1974 also places limits on agency data disclosures. The Privacy Act is a Federal withholding statute. It applies when the Federal government maintains a system of records by which information about individuals is retrieved by use of the individual's personal identifiers (names, Social Security numbers, or any other codes or identifiers that are assigned to the individual). The Privacy Act generally prohibits disclosure of information from a system of records to any third party without the prior written consent of the individual to whom the records apply, 5 U.S.C. 552a(b). "Routine uses" are an exception to this general principle. A routine use is a disclosure outside of the agency that is compatible with the purpose for which the data was collected. Routine uses are established by means of a publication in the **Federal Register** about the applicable system of records describing to whom the disclosure will be made and the purpose for the disclosure. We believe that the proposed data disclosures are consistent with the purpose for which the data discussed in this rule was collected, and thus, should not run afoul of the Privacy Act, provided we ensure that an appropriate Privacy Act system of records "routine use" is in place prior to making any disclosures.

Therefore, at the beginning of the agreement period, at the request of the ACO, we are proposing to provide the ACO with a list of beneficiary names, date of birth, sex, and HICN derived from the assignment algorithm used to generate the 3-year benchmark. As discussed in section II.B. of this proposed rule, these are beneficiaries who received the plurality of primary care services from primary care physicians who are ACO participants. We seek comment on this proposal and on whether and how this information would be beneficial to the goals of improved care coordination and improving care delivery for the ACO's assigned beneficiary population.

6. Sharing Beneficiary-Identifiable Claims Data

While the availability of aggregate beneficiary information and the identification of the beneficiaries used to determine the benchmark should 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. For example, knowing which beneficiaries have frequent emergency department visits could help the ACO develop systems to ensure these beneficiaries have timely access to office-based care.

The PGP demonstration provided beneficiary identifiable claims data to the participating sites but the beneficiary identifiable claims data that was provided was the previous year's historical data on those beneficiaries that might be assigned to the site. The feedback we received from the PGP demonstration was that the historical beneficiary identifiable claims data was useful in some instances but that current year beneficiary claims data would be preferred and result in a more proactive approach to coordinating care. Through comments on the November 17, 2010 RFI, open door forums, and other venues, stakeholders have expressed the importance of timely data on their patient population. They submit that they will need detailed data for their patients so they can establish baseline levels of utilization and patient morbidity, identify key beneficiaries and subpopulations for proactive care coordination efforts, and track their progress against defined performance measures. These data are especially important for ACOs made up of small and individual practices that may not have fully developed information technology systems. Additionally, stakeholders have expressed a desire to receive updated beneficiary identifiable claims data on either a monthly or quarterly basis.

For these reasons we believe sharing beneficiary identifiable claims data with ACOs will assist them in improving care for individuals, improving health of their population, and reducing the growth in expenditures for their assigned beneficiary population. However, there are clear legal and practical limitations on how useful these CMS claims data may be to an ACO. For example, providers have said that they would like to know when their patients are admitted to the hospital in "real time". We are not able to provide this type of data since we generally only become aware of a hospital admission at the time of discharge when the hospital bills us for the service. So, there will always be a claims lag that will make our data less useful for "real time" responses. Unlike claims data, real time information may be more readily available through development and use of an interoperable electronic health record or participation in local/regional health information exchanges, or through more effective coordination with admitting and discharging personnel in hospitals that the ACO's patients utilize, something that is consistent with the overall purpose and intent of the Shared Savings Program (see Section II.B. of this proposed rule). Moreover, unlike MA plans, under the Shared Savings Program, freedom of choice for FFS beneficiaries is retained, which means that a full analysis of the beneficiary population cared for by the ACO during the course of the performance year can only be performed retrospectively.

It should also be noted that 42 U.S.C. 290dd–2 and implementing regulations at 42 CFR part 2 restrict the disclosure of patient records by Federally conducted or assisted substance abuse programs, except as expressly authorized. The law states that "records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall * * * be confidential." Such data may be disclosed only with the prior written consent of the patient, or as otherwise provided in the statute and regulations. Consistent with this requirement, claims containing this specifically protected information would not be included in any beneficiary identifiable claims data shared with ACOs.

As discussed later in the document in more detail, we are proposing to give the ACO the opportunity to request certain beneficiary identifiable claims data on a monthly basis, in compliance with applicable laws, in the form of a standardized data set about the beneficiaries currently being served by the ACO participants and ACO providers/suppliers. We propose to limit the beneficiaries covered by such data sets to those who have received a service from a primary care physician participating in the ACO during the performance year, and who have not opted out of having us share their claims data with the ACO. In order to obtain beneficiary information that is subject to 42 CFR 290dd, the individual must have provided his or her prior written consent. Furthermore, we also propose to limit the content of this data set to the minimum data necessary for the ACO to effectively coordinate care of its patient population.

As noted previously, there are limitations on the content and timeliness of data that we can share with an ACO. If an ACO chooses to request beneficiary identifiable claims data as part of the application process, we propose that 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. If an ACO does not choose to request these data at the time of its application, it will be required to submit a formal request for data during the agreement period that includes a description of how it intends to use the requested data for the purposes noted previously. We solicit comment on these proposals.

Additionally, when an ACO is accepted to participate in the Shared Savings Program, we propose to require ACOs to enter into a Data Use Agreement (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 propose 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 propose 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 termination from the Shared Savings Program or additional sanctions and penalties available under the law. For example, under the Privacy Act, any "person who knowingly and willfully requests or obtains any record concerning an individual from an agency under false pretenses shall be guilty of a misdemeanor and fined not more than $5,000" 5 U.S.C. 552a(i)(3). In those instances where an ACO does not choose to request the data at the time of their application, the ACO will be required to submit a formal request for data during the agreement period. We propose that the ACO would be required to certify compliance with the DUA in the same manner in which prospective ACOs did in the original application process. We solicit comment on these proposals.

a. Legal Authority To Disclose Beneficiary-Identifiable Claims Data to ACOs

As noted previously, section 1106 of the Act generally bars the disclosure of information absent patient authorization

that is collected under the Act unless a law (statute or regulation) provides for disclosure. Once again, we believe that the HIPAA Privacy Rule permits disclosure for purposes of sharing Medicare Part A and B claims data with ACOs participating in the Shared Savings Program. Similarly, we believe the regulations governing the sharing of Part D data would permit us to share information regarding prescription drug claims with ACOs. We also believe that the proposed disclosures of claims data under Parts A, B, and D are consistent with the purposes for which the data were collected, and thus, for the reasons discussed previously would be permitted under the Privacy Act if we ensure that an appropriate Privacy Act System of Records "routine use" is in place prior to making any disclosures.

(1) Sharing Data Related to Medicare Parts A and B

As discussed in section II.B. of this proposed rule, the ACOs are tasked with working with ACO participants and ACO providers/suppliers to evaluate their performance, conduct quality assessment and improvement activities, and conduct population-based activities relating to improved health for their assigned beneficiary population. When done by or on behalf of a covered entity, these are covered functions and activities that would qualify as "health care operations" under the first and second paragraphs of the definition of health care operations at 45 CFR 164.501. These activities are done by the ACOs either on their own behalf as covered entities, or on behalf of their covered entity ACO participants and ACO providers/suppliers, in which case the ACOs would be the business associate of its ACO participants and ACO providers/suppliers.

The proposed disclosure of Part A and B claims data would be permitted by the HIPAA Privacy Rule provisions governing disclosures for "health care operations." As discussed previously in the context of our proposed disclosure of the four data elements about the historically assigned beneficiary population, a covered entity is permitted to disclose PHI to another covered entity for the recipient's health care operations if both covered entities have or had a relationship with the subject of the records to be disclosed (which is true here), the records pertain to that relationship (which is also true here) and the recipient plans to use the records for a "health care operations" function that falls within the first two paragraphs of the definition of "health care operations" in the HIPAA Privacy Rule. 45 CFR 164.506(c)(4). The first two paragraphs of the definition of health care operations include a covered entity or its business associate evaluating a provider's or supplier's performance, conducting quality assessment and improvement activities, and conducting population-based activities relating to improved health. 45 CFR 164.501. We believe that these provisions are extensive enough to cover the uses we would expect an ACO to make of the Parts A and B claims data set that we are proposing to make available to them. Thus, we believe that there is authority for us to disclose to an ACO, as the business associate of the covered entity, the minimum Medicare Parts A and B data necessary to allow ACOs to conduct the health care operation activities outlined previously.

Accordingly, barring a beneficiary requesting to opt-out of having his or her information shared as described later in the document, and subject to applicable confidentiality laws, we are proposing to make Part A and Part B data about patients who have had a visit with a primary care physicians participation in the ACO during the performance year available upon request to participating ACOs this data would be used for the purposes of aiding the ACO as it evaluates the performance of ACO participants and ACO providers/suppliers, conducts quality assessment and improvement activities, and conducting population-based activities relating to improved health. In doing so, we will only disclose the minimum data necessary to accomplish these purposes in accordance with the requirements of the HIPAA Privacy Rule. We believe that 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 from and thru dates of service; the provider or supplier ID; and the claim payment type.

As discussed previously, we will not disclose any patient information related to alcohol and substance abuse that is subject to 42 CFR 290dd without the patient's written consent.

Similar to the process by which ACOs can receive the four beneficiary identifiable data points, under this proposal, in order to receive data, ACOs would be required to attest in either their initial application or in their subsequent formal request for data if they failed to request data in the application stage, that; (1) They are a covered entity or a business associate of covered entity ACO participants and ACO suppliers/providers under the Shared Savings Program; (2) their business associate agreement with these ACO participants and ACO providers/suppliers authorizes them to seek PHI on behalf of the ACO participants and ACO providers/suppliers for one of the health care operations purposes laid out previously; (3) their request reflects the minimum data necessary to do that health care operations work; and (4) that their use of these requested data would be limited to the Shared Savings Program activities related to one or more of the health care operations purposes laid out previously or (1) They are a HIPAA covered entity; (2) they are requesting the claims data about their own patients for one of the health care operations purposes laid out previously; (3) their request reflects the minimum data necessary to do that health care operations work; and (4) that their use of these requested data would be limited to the Shared Savings Program activities related to one or more of the health care operations purposes laid out previously.

(2) Sharing Data Related to Medicare Part D

Beneficiary identifiable Medicare prescription drug information could also be beneficial to ACOs for improving the care coordination of their patient population. Having a complete picture, for example, of the beneficiary's medication regimen can assist in avoiding duplication or adverse interactions among medications.

We issued a final rule in May of 2008 authorizing the Secretary to recollect Part D claims data that were originally collected for Part D payment purposes for research, analysis, reporting, and public health functions (73 FR 30664). In that final rule, we noted our intent to use the data for a wide variety of purposes including "supporting care coordination and disease management programs," and "supporting quality improvement and performance measurement activities." (42 CFR 423.505(f)(3)(v), (vi)). We also expressed our view that "it is in the interest of public health to share the information collected…with entities outside of CMS for legitimate research, or in cases of other governmental agencies, for purposes consistent with their mission." (73 FR 30666). Accordingly, the regulations specified when data would be shared with outside entities, such as other government agencies, and external entities, including researchers.

The Part D data rule did not expressly address the question of whether Part D data could be shared with external entities, such as ACOs, for purposes other than research. However, in the rule, we noted that sharing Part D claims data, in addition to Parts A and B data, could have salutary effects on

the evaluation and functioning of the Medicare programs as well as improving the clinical care furnished to beneficiaries. Furthermore, the rule explicitly contemplated the use of Part D data to support care coordination and disease management programs, as well as quality improvement and performance measurement activities, which are central to the Shared Savings Program and its success.

We believe that ACOs participating in the Shared Savings Program would use information on prescription drug use in order to improve the quality of care furnished to their assigned beneficiaries and to enhance care coordination for these beneficiaries. As a result, although the Part D data rule did not expressly address the question of whether Part D data could be shared with external entities for purposes other than research, we believe that the release of Part D claims data to ACOs for the purpose of supporting care coordination, quality improvement, and performance measurement activities, would be consistent with the purposes outlined in the Part D data rule. The Part D data will be released in accordance with the requirements outlined in the regulations at 42 CFR 423.505(m)(1). As a result, certain data elements may be unavailable or available only in an aggregated format.

Accordingly, consistent with the regulations governing the release of Part D data, we propose to provide ACOs with the minimum Part D data necessary to permit the 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 propose that the minimum data elements necessary to perform these functions 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.

a. Beneficiary Opportunity To Opt-Out of Claims Data Sharing

Although we have the legal authority within the limits described previously to share Medicare claims data with ACOs without the consent of the patients, and while we believe that these data will provide a valuable tool to assist ACOs 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, we nevertheless believe that beneficiaries should be notified of, and have meaningful control over who, has access to their personal health information for purposes of the Shared Savings Program. Thus, we are proposing to require that, as part of its broader activities to notify patients at the point of care that their provider or supplier is participating in an ACO, as discussed in Section II. D., the ACO must also inform beneficiaries of its ability to request claims data about them if they do not object. We believe that this notification will give the beneficiaries meaningful choice as to whether this information may be shared. The only exceptions to this advanced notice would be the initial four data points (the beneficiary's name, date of birth, sex, and HICN) that we will provide to ACOs for individuals in the 3-year data set used to determine the ACO's benchmark.

We believe that to be meaningful, the opportunity to make a choice as to whether their information may be shared would: (1) Allow the individual advance notice and time to make a decision; (2) be accompanied by adequate information about the benefits and risks of making their data available for the proposed uses; (3) not compel consent; and (4) not use the choice to permit their information to be shared for discriminatory purposes.

We considered two alternative mechanisms for implementing meaningful beneficiary choice: having beneficiaries affirmatively choose to permit us to share their protected health information through the signing of a consent or authorization ("opt-in"); and sharing protected health information with the ACO unless beneficiaries indicate that they choose not to have this information shared ("opt-out").

A requirement of patient choice about whether to participate in a system of information exchange, whether opt-in or opt-out should provide an excellent opportunity for providers to engage patients in true patient-centered care, creating a strong incentive for an ACO and its ACO participants and ACO providers/suppliers to forge a positive relationship with each beneficiary. Consumers have consistently expressed strong support for the implementation and exchange of electronic health information, believing that these technologies have the potential to improve care coordination, reduce paperwork, and reduce the number of unnecessary and repeated tests and procedures.[8] Successful electronic health information exchange systems have engaged consumers, physicians and other stakeholders at an early stage to ensure that choice is integrated into the architecture of the systems.[9]

Many organizations engaging in health information exchange have selected opt-in models for patient consent. For example, the Massachusetts eHealth Collaborative (MAeHC) achieved an average of 90 percent participation in three pilot communities using an opt-in system. The New York Clinical Information Exchange (NYCLIX) has also realized high patient participation rates by using an opt-in method of patient choice.[10] An opt-in method has several advantages. Consumers have consistently expressed a desire that their consent should be sought before their health information may be shared.[11] Obtaining affirmative written permission would also provide documentation of the beneficiary's choice.

However, many organizations find that an opt-in approach significantly reduces both provider and beneficiary participation for administrative reasons, and not because patients are making an active choice not to participate.[12] Where

[8] See Schneider, S. et al. "Consumer Engagement in Developing Electronic Health Information System." Prepared for: *Agency for Healthcare Research and Quality,* July 2009, at 16. Available at: *http://www.healthit.ahrq.gov/portal/server.pt/gateway/PTARGS_0_1248_888520_0_0_18/09%E2%80%900081%E2%80%90EF.pdf%00%00* at 16; Markle Foundation. *Survey Finds Americans Want Electronic Personal Health Information to Improve Own Health Care,* November 2006, at 1. Available at: *http://www.markle.org/downloadable_assets/research_doc_120706.pdf.*

[9] See Goldstein, M.M. and A.L. Rein. *Consumer Consent Options for Electronic Health Information Exchange: Policy Considerations and Analysis,*" March, 2010. Available at: *http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11673_911197_0_0_18/ChoiceModelFinal032610.pdf.*

[10] J. Shapiro, J. Bartley, G. Kuperman, Health Information Exchange Consent Policy Influences: Emergency Department Patient Data Accessibility. ACEP 2010. See also N. Daurio, et al. Implementation of an Enterprise-wide Electronic Health Record: A Nurse-Physician Partnership, in K. Saranto *et al.,* eds, Connecting Health and Humans (IOS Press 2009).

[11] Schneider, at 36–37. Public Attitudes Toward Medical Privacy. (2000). Conducted by The Gallup Organization on behalf of the Institute for Health Freedom. Available at: *http://forhealthfreedom.org/Gallupsurvey/IHF–Gallup.html.*

[12] See Micky Tripathi, David Delano, Barbara Lund and Lynda Rudolph. "Engaging Patients for Health Information Exchange." Health Affairs. Volume 28, Number 2. March/April 2009; Missouri Office of Health Information Technology. *Opt-in Versus Opt-out: Consent Models for Health Information Exchange through Missouri's Statewide Health Information Exchange Network.* Jefferson City: Missouri. Department of Social Services (2010). Available online at *http://www.dss.mo.gov/*

Continued

opt-in rates are very high, significant paperwork burdens arise as providers must track consents for the majority of their patient population. Reducing such burdens is one of the major reasons that other organizations engaged in health information exchange have adopted an opt-out approach. [12] [13] An opt-out approach is used successfully in most systems of electronic exchange of information [13] because it is significantly less burdensome on consumers and providers while still providing an opportunity for caregivers to engage with patients to promote trust and permitting patients to exercise control over their data. We are concerned about the effect of an opt-in approach on beneficiary participation and the additional administrative burdens on physician practices. Therefore, we propose affording beneficiaries the ability to opt-out of sharing their protected health information with the ACO. We believe this opportunity coupled with notification of how protected health information will be shared and used affords beneficiaries meaningful choice. An example of the opt-out approach would be 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 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, we propose that the beneficiary would be given a form stating that they have been informed of their physician's participation in the ACO and explaining how to opt-out of having their personal data shared. The form could include a phone number and/or e-mail address for beneficiaries to call and request that their data not be shared. As discussed in section II. D., the Shared Savings Program lays the foundation for a beneficiary-centered delivery system that should create a new relationship between beneficiaries and care providers based, in large part, on patient engagement in the new care system. 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.

We therefore propose to develop a communications plan, discussed in more detail in section II. D of this proposed rule, that will offer insight into both the Shared Savings Program in general and the beneficiaries' right to opt-out of the data sharing portion of the ACO Shared Savings Program.

As noted previously, ACOs will 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 opt-out of claims data sharing.

A beneficiary that chooses to opt-out is only opting out of the data sharing portion of the program. The decision to opt-out in no way effects use of the beneficiaries' data or assignment to the ACO for purposes of determining such calculations as ACO benchmarks, per capita costs, quality performance, or performance year per capita expenditures. Our data contractor will maintain a running list of all HICNs that have chosen to opt-out of data sharing. We will monitor whether ACOs continue to request data on beneficiaries who have opted out of having their data shared and will take appropriate actions against any ACO that is found to violate this requirement.

We request comments on our proposals related to the provision of both aggregate and beneficiary identifiable data to ACOs. We are particularly interested in comments on the kinds and frequency of data that would be useful to ACOs, potential privacy and security issues, and the implications for sharing protected health information with ACOs, and the use of a beneficiary opt-out, as opposed to an opt-in, to obtain beneficiary consent to the sharing of their information.

7. New Program Standards Established During 3-Year Agreement Period

The Shared Savings Program is a new program designed to encourage providers to redesign care processes in order to achieve the outcomes of better care for individuals, better health for populations, and lower growth in expenditures for Medicare FFS beneficiaries. We anticipate 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 will make changes and improvements to the Shared Savings Program. For example, we expect to integrate lessons learned from Innovation Center initiatives to shape and change the Shared Savings Program over time. Because we expect that these changes may occur more frequently than the length of the 3-year agreement periods, the question arises as to whether those ACOs that have already committed to a 3-year agreement to participate in the Shared Savings Program should be subject to those changes. 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.

In the Shared Savings Program, regulatory changes could affect a variety of different components of the program, including quality measures, reporting requirements, monitoring requirements, program integrity, and eligibility requirements. If the agreements are subject to all changes in the applicable regulations, it is possible that some ACOs that were eligible for participation in the program at the start of their respective 3-year agreement might become ineligible based upon modifications to the regulations. Creating an environment in which the continued eligibility of existing program participants is uncertain could be detrimental to the success of 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 up to 3 different sets of requirements, based upon the year in which the ACO entered the program. Additionally, requiring ACOs to adhere to certain regulatory changes related to quality measures, routine program integrity changes, 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 do not believe that requiring ACOs to adhere to

*hie/leadership/pdf2010/optin_vs_optout_overview.pdf.*

[12] See Goldstein, M.M. and A.L. Rein. *Consumer Consent Options for Electronic Health Information Exchange: Policy Considerations and Analysis,*" March, 2010, at 35. Available at: *http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11673_911197_0_0_18/ChoiceModelFinal032610.pdf.*

[13] See Goldstein, M.M. and A.L. Rein. *Consumer Consent Options for Electronic Health Information Exchange: Policy Considerations and Analysis,*" March, 2010, at 35. Available at: *http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11673_911197_0_0_18/ChoiceModelFinal032610.pdf.*

regulatory modifications related to quality measures, routine program integrity changes, processes for quality management and patient engagement, and patient centeredness criteria is likely to affect either the ACOs' underlying organizational structure or their continued eligibility to participate in the Shared Savings Program—although it may necessitate changes in how ACOs design and deliver care to meet these program requirements, as compared to descriptions of these processes in their initial applications.

We propose that ACOs be subject to future changes in regulation with the exception of the following program areas:

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

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 propose that in those instances where regulatory modifications effectuate changes in the processes associated with an ACO pertaining to design, delivery, and quality of care that the ACO will be required to submit to us for review and approval, as a supplement to their original application, an explanation of how they will address key changes in processes resulting from these modifications. If an ACO fails to effectuate the changes needed to adhere to the regulatory modifications, we propose 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 fails 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. of this proposed rule. We propose that ACO participants shall continue to be subject to all requirements applicable to FFS Medicare, such as routine CMS business operations updates and changes in FFS coverage decisions, as they may be amended from time to time. In other words, nothing in the Shared Savings Program shall be construed to affect the payment, coverage, program integrity, and other requirements that apply to providers and suppliers under FFS Medicare.

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

Aside from changes that an ACO may experience as a result of regulatory changes, the ACO itself may also experience significant changes within the course of its 3-year agreement period due to such events as: The following:

- Deviations from approved application for reasons such as the drop out of an ACO participant upon which assignment is based; changes in overall governing board composition (in terms of interests represented) 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 criteria) as outlined in the application criteria for acceptance into the program; or changes in planned distribution of shared savings.
- A material change, as defined in detail in section II. H. of ACOs of this proposed rule, in the ACOs provider composition, including the addition of ACO providers/suppliers such that the ACO requires a mandatory antitrust review or re-review as discussed in section II. I. Coordination with Other Agencies., and other circumstances under which an ACO or an ACO participant is unable to complete its 3-year commitment.
- Government-required ACO reorganization, or exclusion of ACO participants or ACO providers/suppliers, or conduct restriction due to: OIG excluding 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. Since an ACO is admitted to the program based on its application, adding ACO participants during the course of the 3-year agreement may deviate from its approved application and jeopardize the ACO's eligibility since the ACO would differ from its approved application and could be subject to further antitrust review. Changes such as this may result in termination of the 3-year agreement and forfeiture of the 25 percent withhold of shared savings earned by the original ACO participants. We therefore propose that the ACO may not add ACO participants during the course of the 3-year agreement. In order to maintain flexibility, however, we propose that the ACO may remove ACO participants (TINs) or add/subtract ACO providers/suppliers (NPIs). We request comment on this proposal that ACOs may not add ACO participants and how this proposal might impact small or rural ACOs. We propose that the ACO be required to notify us in order to have its new structure approved whenever significant changes, such as those referenced previously, occur to its structure. We have identified five outcomes that may result from our review:

- 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 3-year agreement, including an antitrust review, if warranted.
- 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 agreement year as discussed in section II. B. of this proposed rule.
- CMS and the ACO may mutually decide to terminate the agreement.

We propose that when an ACO reorganizes its structure by excluding ACO participants or by adding or excluding ACO providers/suppliers, deviates from its approved application, changes information contained in its approved application, or experiences other changes which may make it unable to complete its 3-year agreement, it must notify us within 30 days of the event for reevaluation of its eligibility to continue to participate in the Shared Savings Program. We would respond in one of the five ways specified previously. We request comment on this proposal.

9. Future Participation of Previously Terminated Program Participants

As described in section II.H. of the proposed rule, there are a number of circumstances under which we may terminate our agreement with an ACO, including avoidance of at-risk beneficiaries and failure to meet the quality performance standards. In contrast, there are also many reasons why an ACO participant TIN, used for assignment, or individual ACO providers/suppliers may drop out of an ACO; such as government exclusion, relocation, retirement, a voluntary decision to terminate participation, or bankruptcy.

Permanently barring former program participants from subsequent participation in the Shared Savings Program due to a voluntary or forced termination from an ACO appears unduly harsh given the dynamic nature of organizational membership. Alternatively, we do want to ensure our policy on subsequent participation in the Shared Savings Program does not provide a second chance for under-performing organizations or to providers or suppliers who have been terminated for failing to meet program integrity requirements.

We propose the ACO disclose to CMS whether the ACO, its ACO participants, or its ACO providers/suppliers 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 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 3-year agreement period. We propose that such ACOs may not begin another 3-year agreement period until the original agreement period has lapsed. Additionally, because we believe that subsequent participation in the Shared Savings Program should not provide a second chance for under-performing organizations, we propose that an ACO may not reapply to participate in the Shared Savings Program if it previously experienced a net loss during its first 3-year agreement period. We seek comment on these proposals and whether requirements for denying participation to ACOs that previously under-perform would create disincentives for the formation of ACOs. We are specifically interested in whether this requirement will create disincentives for participation among smaller entities.

*D. Assignment of Medicare Fee-for-Service Beneficiaries*

Section 1899(c) of the Act, as added by section 3022 of the Affordable Care 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) of the Affordable Care 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." In addition, subsection 1899(h)(1)(B) defines an ACO professional to include practitioners described in section 1842(b)(18)(C)(i) of the Act, such as PAs and NPs.

Thus, although the statute defines the term "ACO professional" to include both physicians and non-physician practitioners, such as advance practice nurses, physician assistants, and nurse practitioners, for purposes of beneficiary assignment to an ACO, the statute requires that we consider only beneficiaries' utilization of primary care services provided by ACO professionals who are physicians. The method of assigning beneficiaries therefore must take into account the beneficiaries' utilization of primary care services rendered by physicians. 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" in section 1899(b)(1)(A) of the Act). However, assignment of beneficiaries to ACOs is to be determined only on the basis of primary care services provided by ACO professionals who are physicians.

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 proposed 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), the ACO will then be held accountable "for the quality, cost, and overall care of the Medicare FFS 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 as 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 notification regarding their potential assignment to an ACO are further discussed at the end of this section.

1. Operational Identification of an ACO

The first step in developing a method for assigning beneficiaries is to establish a clear operational method of identifying an ACO that correctly associates its health care professionals and providers with the ACO. It is designed to be consistent with the statutory definition of an ACO as well as the eligibility and other requirements for an organization to participate in the Shared Savings Program as an ACO. As discussed in section II.B. of this proposed rule, 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 fee-for-service 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.

From a technical, operational perspective, there are two data sources that could be used to identify the specific providers of services and suppliers participating in these kinds of arrangements as ACOs—specifically, their—(1) National Provider Identifier (NPI); and (2) TIN. Under the Medicare program, individual practitioners are defined by their NPI, but generally file and receive payment for Medicare claims based on their TIN. The TIN may be an employer identification number (EIN) or social security number (SSN). Some individual physicians and other ACO professionals, for example, do not have EINs, and enroll in the Medicare program through their SSNs. Physicians and other ACO professionals who are members of a group practice and bill for their services through the group may not have individual EINs but may use a group EIN for billing Medicare rather than their individual SSNs. While all physicians and practitioners have TINs (either EINs or SSNs), not all physicians and practitioners have Medicare enrolled TINs. For example, physicians and other ACO professionals who are members of a group practice often bill for their services through the group and may not have individual Medicare enrolled TINs. Groups of physicians and practitioners, however, necessarily have TINs which they employ for billing Medicare, because a TIN must be used for billing purposes. It should be noted that, under the Shared Savings Program, the standard restrictions on disclosure of information apply. (For a discussion regarding the public disclosure of information under the Shared Savings Program, see the discussion in section II.E. of this proposed rule.)

Under the PGP demonstration, beneficiaries were assigned and group quality performance was measured by identifying practices operationally as a collection of Medicare enrolled TINs. Through this demonstration we found that TINs provide the most direct link between the beneficiary and the practice providing primary care services. Further, TINs are more stable than NPIs and more likely to provide complete longitudinal data required for benchmarking and beneficiary assignment, and to promote the stability necessary for the ACO to commit to redesigning care processes and complete the required 3-year agreement period. The reason NPIs tend to be less stable is because individual physicians and practitioners often change from one practice to another, potentially rendering data continuity and beneficiary assignment problematic when only NPIs are available. In the PGP demonstration, the individual NPIs associated with the TIN were identified from claims data and provider enrollment information, providing for more effective monitoring of performance within the ACO. Finally, reporting at the TIN level appeared to reduce the reporting burden for practices participating in the PGP demonstration.

Therefore, we are proposing to identify an ACO operationally as a collection of Medicare enrolled TINs. More specifically, an ACO will be identified operationally as a set of one or more TINs 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, a single group practice that participates in the Shared Savings Program would be identified by its TIN. A network of independent practices that forms an ACO would be identified by the set of TINs of the practices constituting the ACO. We are proposing to require that organizations applying to be an ACO provide their ACO participant TINs. Each TIN can be systematically linked to an individual physician specialty code by us. Therefore, under this approach, beneficiaries would be assigned to an ACO through a TIN based on the primary care services they received from physicians billing under that TIN.

We also propose 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 (defined as physicians with a designation of internal medicine, geriatric medicine, family practice, and general practice, as discussed in this rule) by whom beneficiary assignment is established.

ACO participant TINs upon which beneficiary assignment is not dependent (for example, acute care hospitals, surgical and medical specialties, RHCs, and FQHCs) would be required to agree to participate in the ACO for the term of the 3-year agreement, but would not be restricted to participation in a single ACO. As stated in section II.G. of this proposed rule, competition in the marketplace promotes quality of care for Medicare beneficiaries, protects access to a variety of providers, and helps sustain the Medicare program by controlling cost pressures. All of these benefits to Medicare patients would be reduced or eliminated if we allow the creation of ACOs with significant market power. This is especially important in certain areas of the country that might not have many specialists. In addition, exclusivity of ACO participant TINs upon which beneficiary assignment is not dependent might also contribute to the prospects that ACOs could develop excessive market power, especially in areas with shortages of physicians. In turn, greater market power could provide opportunities for these organizations to engage in activities that raise issues of fraud and abuse, such as those related to self-referrals. For these reasons, physicians upon whom assignment is dependent would be committed for a 3-year period and be exclusive to one ACO. Conversely, to ensure that physicians and other entities upon which assignment is not dependent (that is, hospitals, FQHC, RHCs, specialists) can participate in more than one ACO, and thereby facilitate the creation of competing ACOs, these providers and suppliers would be committed to the 3-year agreement but would not be exclusive and would have the flexibility to join another ACO.

Based on our experience, we recognize that the TIN level data alone will not be entirely sufficient for a number of purposes in the Shared Savings Program. In particular, NPI data will be useful to assess the quality of care furnished by an ACO. For example, NPI information will be necessary to determine what percent of physicians

and other practitioners in the ACO are registered in the HITECH program (discussed in section II.E. of this proposed rule). NPI data will also be helpful in our monitoring of ACO activities (which we discuss in section II.H. of this proposed rule). Therefore, we are also proposing 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. As we discuss in more detail later in the document, for purposes of the Shared Savings Program, we are proposing to define primary care physicians as those physicians that practice in the areas of internal medicine, general practice, family practice, and geriatric medicine. We welcome comments on our proposal to require reporting of TINs along with information about the NPIs associated with the ACO.

In summary, we believe that our proposal to define the ACO operationally as a group of Medicare-enrolled TINs, while also collecting information about the NPIs associated with those TINs, allows us to link the beneficiary, type of service provided, and the type of physician providing the services for purposes of beneficiary assignment to the ACO as required by statute. This approach also offers the most complete longitudinal data required for benchmarking and beneficiary assignment, most effectively limits administrative burden for participating providers and suppliers, and makes it possible for us to take advantage of infrastructure and methodologies already developed for group-level reporting and evaluation. Moreover, this option affords us the most flexibility and statistical stability for monitoring and evaluating quality and outcomes for the population of patients assigned to the ACO.

2. 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 in the next section. In this section of this proposed rule, we discuss how to identify the appropriate primary care services on which to base the assignment and our proposal for defining primary care services for this purpose.

In order to ensure the statistical reliability of the required performance measurements and benchmarks, ACOs must have a sufficient number of assigned beneficiaries. Having too few beneficiaries assigned to a participating ACO will impede determining whether changes in cost and quality measures are likely a reflection of normal variation rather than real improvement in the delivery of care. Section 1899(b)(2)(D) of the Act specifically provides that the composition of the ACO shall include sufficient numbers of ACO primary care professionals so that at least 5,000 beneficiaries are assigned to the ACO.

Primary care services can generally be defined based on the type of service provided or the type of provider specialty that provides the service. The PGP demonstration has helped inform assignment methodologies. Under the PGP demonstration, the assignment methodology incorporated outpatient evaluation and management (E&M) services provided by both primary care and specialist providers. One reason for this is that certain specialists (for example, cardiologists, endocrinologists, neurologists, oncologists) are often the principal primary care provider for elderly and chronically ill patients who do not otherwise have a primary care provider, and it is reasonable to expect them to take responsibility for these patients' care. Another reason is that the assignment methodology provided an opportunity for specialists to take responsibility for ensuring that their patients' primary care needs were being met even if the specialist provided care initially on a referral basis.

We would note that in defining primary care services, certain Affordable Care Act provisions also rely on a blend of the type of service and type of provider delivering the service. For example, section 5501 of the Affordable Care Act makes incentive payments available to primary care practitioners for whom primary care services account for at least 60 percent of the allowed charges under Part B. For purposes of this provision, a "primary care practitioner" is defined as a physician "who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine," or as a "nurse practitioner, clinical nurse specialist, or physician assistant." In that section, "primary care services" are defined as a set of services identified by these HCPCS codes: 99201 through 99215; 99304 through 99340; and 99341 through 99350. Additionally, we would 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.

In developing our proposal, we have 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 this 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 professional.

The first option would assign beneficiaries by defining "primary care services" on the basis of the select set of E&M services, specifically those defined as "primary care services" in section 5501 of the Affordable Care Act, and including G-codes associated with the annual wellness visit and Welcome to Medicare benefit regardless of provider specialty. This option would increase the number of potential beneficiaries assigned to the ACO in areas with primary care shortages (where specialists would necessarily be providing more primary care services as defined by the code set). It is also administratively straightforward, and we have experience with the similar methodology initially used in the PGP demonstration. However, assigning beneficiaries to ACOs based only on primary care services without distinction of caregiver specialty increases the likelihood of assigning beneficiaries to a specialist over a primary care provider. In addition, it would appear to be somewhat inconsistent with section 5501 of the Affordable Care Act, which, for purposes of establishing an incentive payment for primary care services, first defines a set of primary care practitioners, and then identifies a set of HCPCS codes as "primary care services." The primary care services are recognized for the incentive payment only when they are provided by primary care practitioners. It is dubious whether the codes identified in section 5501 of the Affordable Care Act alone, when they are not provided by primary care

doctors and other practitioners, truly constitute primary care services. Rather, these codes alone simply represent outpatient cognitive services (generally, consultations and office visits) that are provided for in all sorts of health care situations, including primary care but also specialty care, and are provided by many types of physicians. As such, this option has the potential to diminish the appropriate level of emphasis on a primary care core in the Shared Savings Program, by failing to place any priority on the services of designated primary care providers (for example, internal medicine, general practice, family practice, and geriatric medicine) in the assignment process.

The second option that we have considered is therefore 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 in the case of the first option, we would define "primary care services" on the basis of the select set of HCPCS codes identified in section 5501 of the Affordable Care Act, including G-codes associated with the annual wellness visit and Welcome to Medicare visit. This option more closely aligns the definition of primary care services with the definition in section 5501 of the Affordable Care Act. As in the case of the first option, this option would be relatively straightforward administratively. However, this option could reduce the number of beneficiaries assigned to an ACO, by excluding primary care services delivered by specialists, especially in some areas that may have shortages of primary care physicians but a relatively greater number of specialists. Consequently, this option could make it difficult for ACOs to form in some geographic regions with such primary care shortages.

The third option we have considered is to assign beneficiaries in a step-wise fashion. Under this 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 professional. This option would introduce a greater level of operational complexity compared to the two other options we considered. In addition, 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 specialists to whom beneficiaries are assigned would be required to be exclusive to one ACO. As noted previously, the ability of 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, a "step-wise approach" would not affect all specialists and it would reflect many of the advantages of the other two approaches, balancing the need for emphasis on a primary care core with a need for increased assignment numbers in areas with primary care shortages.

After considering these options, we are proposing the second option, which would assign beneficiaries with 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 believe that this option best aligns 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, this option places priority on the services of designated primary care physicians (for example, internal medicine, general practice, family practice, and geriatric medicine) in the assignment process. This option also allows ACOs to focus their efforts to coordinate and redesign care for patients seeing primary care providers and creates incentives for ACOs to establish primary care linkages for their patients who may not have a primary care provider. The option is also relatively straightforward administratively.

However, we are also concerned that this proposal may 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 are proposing 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 invite comments on this proposal and other options that may better address the delivery of primary care services by specialists. In the final rule, we could consider adopting another option; therefore we are seeking comments on the definition of primary care services approach as well as the "step-wise" approach as described previously.

3. 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 for shared savings with the Medicare program if the ACO meets performance standards established by the Secretary (which we discuss in section II.E. of this proposed 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 year of an agreement period each ACO will 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. We refer to each year for which such determinations must be made as a "performance year."

There are two basic options for assigning beneficiaries to an ACO to calculate eligibility for shared savings for 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.

Many observers and prospective ACO managers have argued that it is essential for an ACO to know who is included in its assigned population prior to the start of the performance year. While they intend to treat all patients the same, they assert that it is fundamental to population management to be able to profile a population, identify individuals at high risk, develop outreach programs, and proactively work with patients and their families to establish care plans. These observers also argue that, as with any well managed enterprise, it is essential to have operational goals and targets to manage effectively. Thus, they would like to be able to track prospective targeted expenses, in order to gauge their results as they go through the performance year. These observers also understand that even prospective assignment methodologies will require a retrospective definition of the population to adjust for a variety of changes in the population that occur during a performance year. Some current patients of the practice will

become eligible for Medicare. Some will join a Medicare Advantage (MA) plan and, although they may continue to receive care furnished by the ACO, these beneficiaries can no longer be considered part of the assigned population of the ACO for purposes of computing shared savings. Individuals will move in and out of the service area during the year. For all these reasons, any methodology will require a retrospective redefinition of the assigned population.

Advocates for the retrospective approach start with the observation that the actual population seen by a set of physicians changes significantly from year to year. Medicare FFS beneficiaries' right to see any enrolled physician typically leads to more year-to-year variability in treating physicians 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. Prospective assignment of a population seems inherently inaccurate from this perspective. If beneficiary assignment changes by 25 percent from year to year, a prospective assignment would not be an accurate reflection of those beneficiaries that were actually seen by physicians in the ACO during the performance year. Retrospective assignment of the population, on the other hand, appropriately holds the ACO accountable for the actual population it cared for during the performance year.

Proponents of the retrospective approach also make a second argument. They suggest that identifying a 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, ACOs should not be told who among their patients are likely to be in their assigned population. 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.

We believe 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 do not want to encourage ACOs to limit their care improvement activities to a subset of their patients that they believe may be assigned to them. Finally, we believe it is critical that the assessment of ACO performance in any year be based on patients who received the plurality of their primary care from the ACO in that year, rather than an earlier period. As noted previously, even under a prospective assignment approach, a retrospective redefinition of the assigned population to account for changes from prior periods would be required or the ACO would be held accountable for patients that it did not provide services for during the performance year. Under a prospective system, the assignment would have to be adjusted every year to account for beneficiaries entering and leaving FFS Medicare as well as for those patients who move in and out of the geographic area of the ACO, as well as potentially other adjustments such as when a beneficiary remains in the area but chooses to receive their care outside of the ACO based upon where the plurality of their primary care services are being performed. Considering the merits of both approaches, we believe that the retrospective approach to beneficiary assignment for purposes of determining eligibility for shared savings is compelling. We believe 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. In contrast, as we noted previously, a prospective approach has intrinsic inaccuracies, and requires additional adjustments in order to achieve the requisite level of accuracy for purposes of the Shared Savings Program.

In response to the November 17, 2010 RFI, of the few commenters favoring retrospective alignment, a group of commenters suggested the use of retrospective alignment for determining utilization and shared savings, but prospective assignment for purposes of CMS sharing beneficiary identifiable data with ACOs. We agree 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" will be helpful. We address our proposals for providing information to ACOs to help them understand their patient populations and better manage their care in section II.C. of this proposed rule.

Therefore, we are proposing 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 assigned population of Medicare beneficiaries during the benchmark period. (As we discuss in section II.C. of this proposed rule, we will provide ACOs with a list of beneficiary names, date of birth, sex, and other information derived from the assignment algorithm used to generate the 3-year benchmark.) Although the assignment methodology for the PGP demonstration was different from the proposed Shared Savings Program assignment methodology, when the PGP data is modeled with the Shared Savings Program assignment methodology, the assigned patient population would vary by approximately 25 percent from year to year. We believe that providing data on those beneficiaries that are assigned to an ACO in the benchmark period is a good compromise that will 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 not encouraging ACOs to limit their care improvement activities to only the subset of beneficiaries they believe will be assigned to them in the performance year. We believe that such a combined approach provides the best of both approaches while minimizing the disadvantages of either. ACO physicians will have the information they need to manage their population and estimate a target to manage towards, while they will still be encouraged to provide high-quality, efficient, and well-coordinated services to all Medicare FFS beneficiaries because they will not know for sure who will be in the assigned population. However, the ultimate evaluation of their effectiveness will be based on the actual population they served. We solicit comments on this combined approach of retrospective beneficiary assignment for purposes of determining eligibility for shared savings balanced by the provision of beneficiary data (names, date of birth, etc.) and aggregate beneficiary level data for the assigned population of Medicare beneficiaries during the benchmark period. We also seek comment on alternate assignment approaches, including the prospective method of assignment.

4. 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 is to make such an assignment on the basis of some percentage level of the primary care services a beneficiary receives from an ACO physician. The more specific issue under such an approach is whether to assign beneficiaries to the 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.

Alternatively, it could be argued that adopting a majority standard might enhance an ACO's sense of responsibility for its assigned patients, which is certainly consistent with the general goals of the Shared Savings Program. However, adopting a majority standard would likely somewhat reduce the number of beneficiaries assigned to an ACO and more beneficiaries would be unassigned to any ACO. On balance, we believe that a majority rule for assignment is too strict a standard to employ in a system where many Medicare beneficiaries may regularly receive primary care services from two or more primary care practitioners (for example, an internal medicine physician and a geriatric medicine physician). As such, this standard could undermine the development and sustainability of ACOs. Therefore, we are proposing 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 believe that the plurality rule provides a sufficient standard for assignment because it ensures that beneficiaries will be assigned to an ACO when they receive more primary care from that ACO than from any other provider. This will result in a greater number of beneficiaries assigned to ACOs, which may enhance the viability of the Shared Savings Program, especially in its initial years of operation. We welcome comments on our proposal to assign patients based upon a plurality rule. Additionally we would also welcome any comments on whether there should be a minimum threshold number of primary care services that a beneficiary should receive from physicians in the ACO in order to be assigned to the ACO under the plurality rule and if so, where that minimum threshold should be set.

Finally, we can determine when a beneficiary has received a plurality of primary care services from an ACO 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 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. 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 not require 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. 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. One possible tie-breaker for such cases is to assign the beneficiary to the ACO if it is the entity that most recently provided primary care services.

We propose 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.

5. Beneficiary Information and Notification

Section 1899(c) of the Act, as added by section 3022 of the Affordable Care Act, does not state whether beneficiaries should be informed in any way about the Shared Savings Program. Thus, it does not specify any information to be provided to beneficiaries about the Shared Savings Program in general, whether they are receiving services from an ACO participant or ACO provider/supplier, or whether they have been assigned to an ACO for purposes of determining that ACO's performance with respect to the quality standards and its possible shared savings under the Shared Savings Program.

As discussed previously, the term "assignment" as used in the statute for purposes of this provision 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. For example, if a beneficiary's physician becomes part of an ACO and the beneficiary does not wish to receive health care services under the ACO care coordination and management efforts, the beneficiary has the freedom of choice to go to a different physician. The continued exercise of free choice by beneficiaries in selecting the physicians and other health care practitioners from whom they receive their services is thus a presupposition of the Shared Savings Program. The exercise of free choice, however, can be undermined or even nullified if beneficiaries do not possess adequate information to assess the possible consequences of available choices, or to evaluate which available options are most consistent with their values and preferences concerning their own health care. We therefore believe that an important component of the Shared Savings Program must be timely and effective communication with beneficiaries concerning the Shared Savings Program, their potential

assignment to an ACO, and what that may mean for the beneficiaries' care.

Furthermore, 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 when beneficiaries are not aware of the new delivery system available from ACOs, and the possibility of being included in the population assigned to an ACO. In short, transparency must be a central feature of the Shared Savings Program.

Therefore, we intend to develop a communications plan, including educational materials and other forms of outreach, to provide beneficiaries in a timely manner with accurate, clear, and understandable information about the Shared Savings Program in general, about their utilization of services furnished by a provider or supplier participating in an ACO, about the possibility of their being assigned to an ACO for quality and shared savings purposes, and about the potential that their health information may be shared with the ACO, and their ability to opt-out of that data sharing. Accordingly, we will update the annual Medicare handbook to contain information about the Shared Savings Program, ACOs, and what receiving care from an ACO means for the Medicare FFS beneficiary.

One limitation on the timing of the information that we provide to beneficiaries arises from our proposal to assign beneficiaries to an ACO retroactively, that is, after the end of a performance year, on the basis of a beneficiary's actual primary care service utilization during the year. It is therefore not possible to inform beneficiaries of their assignment to an ACO in advance of the period in which they may seek services from the ACO. However, we believe that it is essential for beneficiaries to receive some form of advance notification that a physician or other provider from whom they are receiving services is participating in an ACO. The only practical manner in which such notification could be provided in a timely manner is to require ACOs to provide such notification to beneficiaries when they seek services from ACO providers/suppliers. Specifically, we propose to require ACOs to post signs in the facilities of participating ACO providers/suppliers indicating their participation in the Shared Savings Program and to make available standardized written information to Medicare FFS beneficiaries whom they serve. ACOs would provide standardized written notice to beneficiaries of both their participation in the Shared Savings Program and the potential for CMS to share beneficiary identifiable data with ACOs when a beneficiary receives services from a physician on whom assignment to ACO is based. We also plan to instruct ACOs to supply a form allowing beneficiaries to opt-out of having their data shared. The form would be provided to each beneficiary as part of their office visit with a primary care physician, and must include a phone number, fax or e-mail for beneficiaries to contact and request that their data not be shared.

Likewise, in instances where either an ACO chooses to no longer participate in the Shared Savings Program or we have terminated a participation agreement with an ACO, beneficiaries should be made aware of this change. Thus, we are proposing that ACOs be required to provide beneficiaries notice in a timely manner if they will no longer be participating in the Shared Savings Program. It should include the effective date of the termination of their agreement with us. As discussed in section II.C. of this proposed rule, we are also proposing to require an ACO seeking to terminate its participation in the Shared Savings Program to provide us with advanced notice.

We recognize that such a requirement could place an administrative burden on ACOs. However, we believe that such notification is essential to enhance patient engagement and understanding of their care. As discussed in section II.B. of this proposed rule, section 1899(b)(2)(H) of the Act requires that the "ACO * * * demonstrate to the Secretary that it meets patient-centeredness criteria specified by the Secretary * * *." We believe that providing notice of participation in or termination from the Shared Savings Program to beneficiaries is essential to the ability of beneficiaries to exercise free choice, and therefore would be an appropriate patient-centered criterion to be designated by the Secretary. In addition to notifying beneficiaries that they are seeking services from a provider or supplier participating in an ACO under the Shared Savings Program, this proposed notification will inform beneficiaries how assignment with an ACO is likely to affect (and not affect) the care they receive from the providers they have chosen. We seek comment on the appropriate form and content of this notification. For example, we seek comment on the utility of informing consumers about those objectives of the Shared Savings Program that might have the most impact on the beneficiary as a consumer of services from an ACO professional, such as the following:

- Easing the burden on consumers to coordinate their own care among different providers,
- Fostering follow-up with patients as they receive care from different providers,
- Facilitating greater dialogue between and among beneficiaries and providers about how health care is delivered, and
- Providing beneficiaries with quality measures by which they can evaluate the performance of their providers compared to regional and national norms.

We also seek comment on the most important items to communicate to beneficiaries about matters that will not change under the Shared Savings Program, including the fact that their cost-sharing will continue to be the same, and they remain free to seek care from providers of their choosing.

We welcome comments not only on our proposal to establish these notification requirements, but also on all matters concerning the appropriate form and content of such notification. If we adopt a notification requirement in the final rule, we will take comments on the issues such as the appropriate form and content of such a notification into account as we develop more detailed instructions for ACOs on beneficiary notification through guidance.

*E. Quality and Other Reporting Requirements*

1. Introduction

As discussed in section I. of this proposed rule, the intent of the Shared Savings Program is to: (1) Promote accountability to Medicare beneficiaries; (2) improve the coordination of FFS items and services; and (3) encourage investment in infrastructure and redesigned care processes to achieve high health care quality and efficient service delivery. In conjunction with the Shared Savings Program and other provisions of the Affordable Care Act, we have adopted three goals for improvement of the health care of Medicare beneficiaries and, by extension, of all Americans. These goals include: (1) Better care for individuals; (2) better health for populations; and (3) lower growth in expenditures. (We define better health care for individuals as health care that is safe, effective, patient-centered, timely, efficient, and equitable, as described in the IOM's six aims for changing U.S. health care delivery.)[14] This section of this

[14] Committee on Quality of Health Care in America, Institute of Medicine. Crossing the Quality

proposed rule pertains to the first two goals.

In this portion of the proposed regulation, we propose: (1) Measures to assess the quality of care furnished by an ACO; (2) requirements for data submission by ACOs; (3) quality performance standards; (4) the incorporation of reporting requirements under section 1848 of the Act for the Physician Quality Reporting System; and (5) requirements for public reporting by ACOs.

2. Proposed 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. 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 propose that an ACO be considered to have met the quality performance standard if they have reported quality measures and met the applicable performance criteria in accordance with the requirements detailed in rulemaking for each of the three performance years. We further propose 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 have listed the measures we propose to use to establish quality performance standards that ACOs must meet for shared savings for the first performance period in Table 1. Quality measures for the remaining two years of the 3-year agreement will be proposed in future rulemaking.

b. Considerations in Selecting Measures

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 volume. The Shared Savings Program is a critical element of our Medicare value-based purchasing initiative. In implementing these value-based purchasing initiatives, we seek to meet certain common goals, as follows:

1. Use of Measures

- Value-based payment systems and public reporting should rely on a mix of standards, processes, outcomes, and patient experience measures, including measures of care transitions and changes in patient functional status. Across all programs, we seek to move as quickly as possible to the use of outcome and patient experience measures. To the extent practicable and appropriate, these outcome and patient experience measures should be adjusted for risk or other appropriate patient population or provider characteristics.
- To the extent possible, and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across Medicare and Medicaid's public reporting and payment systems. We seek to evolve a focused core-set of measures appropriate to each specific provider category that reflects the level of care and the most important areas of service and measures for that provider.
- The collection of information should minimize the burden on providers to the extent possible. As part of that effort, we have begun and will continuously seek to align Shared Savings Program measures with the methods and measures included in the Medicare and Medicaid EHR Incentive Programs to enable the collection and reporting of performance information to be a seamless part of care delivery and the meaningful use of certified EHR technology.
- To the extent practicable, measures used by us should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures.

2. Scoring Methodology

- Providers should be scored on their overall achievement relative to national or other appropriate benchmarks. In addition, scoring methodologies should consider improvement as an independent goal.
- Measures or measurement domains need not be given equal weight, but over time, scoring methodologies should be more weighted towards outcome, patient experience and functional status measures.
- Scoring methodologies should be reliable, as straightforward as possible, and stable over time and enable consumers, providers, and payers to make meaningful distinctions among providers' performance.

Consistent with these value-based purchasing principles, our principal goal in selecting quality measures for ACOs is 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 in arriving at the proposed measures, prioritizing measures that meet the following:

- Address the goals we previously identified: Improving individual health and improving the health of populations.
- Address an array of quality domains, priorities, and aims, including the IOM six quality aims previously described and the National Quality Strategy, and other HHS priorities, such as prevention, care of chronic illness, treatment of high prevalence conditions such as cardiovascular disease, patient safety, patient and caregiver engagement, and care coordination.
- Support the goals for the Shared Savings Program, as stated in section 1899(a)(1) of the Act, of promoting provider accountability for a patient population, coordinating care furnished under Medicare Parts A and B, and encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Thus, measures should have high impact in terms of accountability and cost, particularly for vulnerable populations, when comparing beneficiary care received in ACOs to beneficiary care received in non-ACO Medicare FFS.
- Align with other Medicare incentive programs such as the Physician Quality Reporting System ("PQRS"; formerly known as the Physician Quality Reporting Initiative), Electronic Prescribing Incentive Program, Electronic Health Records (EHR) Incentive Programs, Hospital Inpatient Quality Reporting Program, and also Medicaid and private sector initiatives that align with the three-part aim.

Chasm: A New Health System for the 21st Century. Washington, DC, USA: National Academies Press; 2001.

• Include the quality performance standards that ACOs must meet in order to be eligible for shared savings, which should be well-established, correlate with improved patient outcomes, and be accepted by the professional and provider community, such as through National Quality Forum (NQF) endorsement.

• Are consistent across ACOs, regardless of ACO composition.

• Offer key opportunities for improvement in care and significantly impact the health status and outcomes of care for the Medicare beneficiaries served by the ACO.

• Are limited to those that have high impact, and/or are cross-cutting to the extent possible, with parsimony serving to focus clinical attention, and limiting the burden of data collection and reporting.

• Exhibit sensitivity to administrative burden and seek to become less burdensome over time.

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

Based upon the principles described, we are proposing 65 measures (see Table 1) for use in the calculation of the ACO Quality Performance Standard. We propose that ACOs will submit data on these measures using the process described later in this proposed rule and meet defined quality performance thresholds. We propose that ACOs be required to report quality measures and meet applicable performance criteria, as defined in rulemaking, for all 3 years within the 3-year agreement period to be considered as having met the quality performance standard. Specifically, for the first year of the program, we propose for the quality performance standard to be at the level of full and accurate measures reporting; for subsequent years, we propose the quality performance standard be based on a measures scale with a minimum attainment level as described in section II.E.4 of this proposed rule.

ACOs that do not meet the quality performance thresholds for all proposed measures would not be eligible for shared savings, regardless of how much per capita costs were reduced. Specifically, as discussed in section II.H. of this proposed rule, in those instances where an ACO fails to meet the minimum attainment level for 1 or more domains, we propose to give the ACO a warning and to re-evaluate the following year. If the ACO continues to underperform on the quality performance standards in the following year, the agreement will be terminated. We also propose that if an ACO fails to report 1 or more measures, we would send the ACO a written request to submit the required data by a specified date and to provide a reasonable written explanation for its delay in reporting the required information. If the ACO fails to report by the requested deadline and 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. We note 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. Termination from the Shared Savings Program is discussed further in sections II.H and II.C. of this proposed rule.

In addition to categorizing each of the proposed measures into the goals of better care for individuals and better health for populations, Table 1 includes the domain each of the proposed measures addresses, the measure title, a brief description of the data the measure captures, applicable Physician Quality Reporting System or EHR Incentive Programs information, the measure steward or, if applicable, NQF measure number, the proposed method of data submission for each measure, and the Measure Type. Under Measure Type, we have listed Patient Experience of Care, Process, or Outcome, consistent with the domains proposed in the Hospital Value Based Purchasing rule (76 FR 2457), for each of the proposed Shared Savings Program quality measures.

In an effort to provide focus to ACO quality improvement activity, we have identified 5 key domains within the dimensions of improved care and improved health that we propose will serve as the basis for assessing, benchmarking, rewarding, and improving ACO quality performance. These 5 domains are as follows:

• Better Care for Individuals:

++ Patient/Caregiver Experience

++ Care Coordination

++ Patient Safety

• Better Health for Populations:

++ Preventive Health

++ At-Risk Population/Frail Elderly Health

We note 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 will need to be refined in order to be applicable to an ACO population. However, we propose 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 plan to make the specifications for the proposed measures available on our Web site prior to the start of the Shared Savings Program.

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**Table 1. Proposed Measures for Use in Establishing Quality Performance Standards that ACOs Must Meet for Shared Savings**

| | Domain | Measure Title & Description | CMS Program, NQF Measure Number, Measure Steward | Method of Data Submission | Measure Type |
|---|---|---|---|---|---|
| **AIM: Better Care for Individuals** | | | | | |
| 1. | Patient/Care Giver Experience | **Clinician/Group CAHPS:** Getting Timely Care, Appointments, and Information | NQF #5 | Survey | Patient Experience of Care |
| 2. | Patient/Care Giver Experience | **Clinician/Group CAHPS:** How Well Your Doctors Communicate | NQF #5 | Survey | Patient Experience of Care |
| 3. | Patient/Care Giver Experience | **Clinician/Group CAHPS:** Helpful, Courteous, Respectful Office Staff | NQF #5 | Survey | Patient Experience of Care |
| 4. | Patient/Care Giver Experience | **Clinician/Group CAHPS:** Patients' Rating of Doctor | NQF #5 | Survey | Patient Experience of Care |
| 5. | Patient/Care Giver Experience | **Clinician/Group CAHPS:** Health Promotion and Education | NQF #5 | Survey | Patient Experience of Care |
| 6. | Patient/Care Giver Experience | **Clinician/Group CAHPS:** Shared Decision Making | NQF #5 | Survey | Patient Experience of Care |
| 7. | Patient/Care Giver Experience | **Medicare Advantage CAHPS:** Health Status/Functional Status | NQF #6 | Survey | Patient Experience of Care |
| 8. | Care Coordination/Transitions | **Risk-Standardized, All Condition Readmission:** The rate of readmissions within 30 days of discharge from an acute care hospital for assigned ACO beneficiary population. | CMS | Claims | Outcome |

| | Domain | Measure Title & Description | CMS Program, NQF Measure Number, Measure Steward | Method of Data Submission | Measure Type |
|---|---|---|---|---|---|
| 9. | Care Coordination/Transitions | **30 Day Post Discharge Physician Visit** | CMS | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |
| 10. | Care Coordination/Transitions | **Medication Reconciliation:** Reconciliation After Discharge from an Inpatient Facility Percentage of patients aged 65 years and older discharged from any inpatient facility (eg, hospital, skilled nursing facility, or rehabilitation facility) and seen within 60 days following discharge in the office by the physician providing on-going care who had a reconciliation of the discharge medications with the current medication list in the medical record documented. | NQF #554 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |
| 11. | Care Coordination/Transitions | **Care Transition Measure:** Uni-dimensional self-reported survey that measures the quality of preparation for care transitions. Namely: 1. Understanding one's self-care role in the post-hospital setting 2. Medication management 3. Having one's preferences incorporated into the care plan | NQF #228 or alternate | Survey or Group Practice Reporting Option (GPRO) Data Collection Tool | Patient Experience of Care |

| | Domain | Measure Title & Description | CMS Program, NQF Measure Number, Measure Steward | Method of Data Submission | Measure Type |
|---|---|---|---|---|---|
| 12. | Care Coordination | **Ambulatory Sensitive Conditions Admissions:**<br>**Diabetes, short-term complications**<br>(AHRQ Prevention Quality Indicator (PQI) #1)<br>All discharges of age 18 years and older with ICD-9-CM principal diagnosis code for short-term complications (ketoacidosis, hyperosmolarity, coma), per 100,000 population. | NQF #272 | Claims | Outcome |
| 13. | Care Coordination | **Ambulatory Sensitive Conditions Admissions:**<br>**Uncontrolled Diabetes**<br>(AHRQ Prevention Quality Indicator (PQI) #14)<br>All discharges of age 18 years and older with ICD-9-CM principal diagnosis code for uncontrolled diabetes, without mention of a short-term or long-term complication, per 100,000 population. | NQF # 638 | Claims | Outcome |
| 14. | Care Coordination | **Ambulatory Sensitive Conditions Admissions:**<br>**Chronic obstructive pulmonary disease**<br>(AHRQ Prevention Quality Indicator (PQI) #5)<br><br>All discharges of age 18 years and older with ICD-9-CM principal diagnosis code for COPD, per 100,000 population. | NQF #275 | Claims | Outcome |

| | Domain | Measure Title & Description | CMS Program, NQF Measure Number, Measure Steward | Method of Data Submission | Measure Type |
|---|---|---|---|---|---|
| 15. | Care Coordination | **Ambulatory Sensitive Conditions Admissions:**<br>**Congestive Heart Failure**<br>(AHRQ Prevention Quality Indicator (PQI) #8 )<br><br>All discharges of age 18 years and older with ICD-9-CM principal diagnosis code for CHF, per 100,000 population. | NQF #277 | Claims | Outcome |
| 16. | Care Coordination | **Ambulatory Sensitive Conditions Admissions:**<br>**Dehydration**<br>(AHRQ Prevention Quality Indicator (PQI) #10)<br><br>All discharges of age 18 years and older with ICD-9-CM principal diagnosis code for hypovolemia, per 100,000 population. | NQF # 280 | Claims | Outcome |
| 17. | Care Coordination | **Ambulatory Sensitive Conditions Admissions:**<br>**Bacterial pneumonia**<br>(AHRQ Prevention Quality Indicator (PQI) #11)<br><br>All non-maternal discharges of age 18 years and older with ICD-9-CM principal diagnosis code for bacterial pneumonia, per 100,000 population. | NQF # 279 | Claims | Outcome |

| | Domain | Measure Title & Description | CMS Program, NQF Measure Number, Measure Steward | Method of Data Submission | Measure Type |
|---|---|---|---|---|---|
| 18. | Care Coordination | **Ambulatory Sensitive Conditions Admissions:**<br>**Urinary infections**<br>(AHRQ Prevention Quality Indicator (PQI) #12)<br><br>All discharges of age 18 years and older with ICD-9-CM principal diagnosis code of urinary tract infection, per 100,000 population. | NQF # 281 | Claims | Outcome |
| 19. | Care Coordination/Information Systems | **% All Physicians Meeting Stage 1 HITECH Meaningful Use Requirements** | CMS | Group Practice Reporting Option (GPRO) Data Collection Tool / EHR Incentive Program Reporting | Process |
| 20. | Care Coordination/Information Systems | **% of PCPs Meeting Stage 1HITECH Meaningful Use Requirements** | CMS | Group Practice Reporting Option (GPRO) Data Collection Tool / EHR Incentive Program Reporting | Process |

| | Domain | Measure Title & Description | CMS Program, NQF Measure Number, Measure Steward | Method of Data Submission | Measure Type |
|---|---|---|---|---|---|
| 21. | Care Coordination/Information Systems | **% of PCPs Using Clinical Decision Support** | CMS<br><br>EHR Incentive Program – Core Measure | Group Practice Reporting Option (GPRO) Data Collection Tool/ EHR Incentive Program Reporting | Process |
| 22. | Care Coordination/Information Systems | **% of PCPs who are Successful Electronic Prescribers Under the eRx Incentive Program** | CMS<br><br>EHR Incentive Program – Core Measure | Group Practice Reporting Option (GPRO) Data Collection Tool / eRx Incentive Program Reporting | Process |
| 23. | Care Coordination/Information Systems | **Patient Registry Use** | CMS<br><br>EHR Incentive Program – Menu Set Measure | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |

| | Domain | Measure Title & Description | CMS Program, NQF Measure Number, Measure Steward | Method of Data Submission | Measure Type |
|---|---|---|---|---|---|
| 24. | Patient Safety | **Health Care Acquired Conditions Composite:**<br>• Foreign Object Retained After Surgery<br>• Air Embolism<br>• Blood Incompatibility<br>• Pressure Ulcer, Stages III and IV<br>• Falls and Trauma<br>• Catheter-Associated UTI<br>• Manifestations of Poor Glycemic Control<br>• Central Line Associated Blood Stream Infection (CLABSI)<br>• Surgical Site Infection<br>• AHRQ Patient Safety Indicator (PSI) 90 Complication/Patient Safety for Selected Indicators (composite)<br>o Accidental puncture or laceration<br>o Iatrogenic pneumothorax<br>o Postoperative DVT or PE<br>o Postoperative wound dehiscence<br>o Decubitus ulcer<br>o Selected infections due to medical care (PSI 07: Central Venus Catheter-related Bloodstream Infection)<br>o Postoperative hip fracture<br>o Postoperative sepsis | CMS (HACs), NQF #531 (AHRQ PSI) | Claims or CDC National Healthcare Safety Network | Outcome |

| | Domain | Measure Title & Description | CMS Program, NQF Measure Number, Measure Steward | Method of Data Submission | Measure Type |
|---|---|---|---|---|---|
| 25. | Patient Safety | **Health Care Acquired Conditions: CLABSI Bundle** | NQF #298 | Claims or CDC National Healthcare Safety Network | Process |
| **AIM: Better Health for Populations** | | | | | |
| 26. | Preventive Health | **Influenza Immunization:** Percentage of patients aged 50 years and older who received an influenza immunization during the flu season (September through February). | Physician Quality Reporting System Measure #110<br><br>EHR Incentive Program – Clinical Quality Measure<br><br>NQF #41 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |
| 27. | Preventive Health | **Pneumococcal Vaccination:** Percentage of patients aged 65 years and older who have ever received a pneumococcal vaccine. | Physician Quality Reporting System Measure #111<br><br>EHR Incentive Program – Clinical Quality Measure<br><br>NQF #44 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |

| | Domain | Measure Title & Description | CMS Program, NQF Measure Number, Measure Steward | Method of Data Submission | Measure Type |
|---|---|---|---|---|---|
| 28. | Preventive Health | **Mammography Screening:** Percentage of women aged 40 through 69 years who had a mammogram to screen for breast cancer within 24 months. | Physician Quality Reporting System Measure #112<br><br>EHR Incentive Program – Clinical Quality Measure<br><br>NQF #31 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |
| 29. | Preventive Health | **Colorectal Cancer Screening:** Percentage of patients aged 50 through 75 years who received the appropriate colorectal cancer screening. | Physician Quality Reporting System Measure #113<br><br>EHR Incentive Program – Clinical Quality Measure<br><br>NQF #34 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |

| | Domain | Measure Title & Description | CMS Program, NQF Measure Number, Measure Steward | Method of Data Submission | Measure Type |
|---|---|---|---|---|---|
| 30. | Preventive Health | **Cholesterol Management for Patients with Cardiovascular Conditions:**<br>• The percentage of members 18–75 years of age who were discharged alive for AMI, coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to the measurement year, who had each of the following during the measurement year.LDL-C screening<br>• LDL-C control (<100 mg/dL) | EHR Incentive Program – Clinical Quality Measure<br><br>NQF # 75 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process & Outcome |
| 31. | Preventive Health | **Adult Weight Screening and Follow-up**:<br>Percentage of patients aged 18 years and older with a calculated BMI in the past six months or during the current visit documented in the medical record AND if the most recent BMI is outside parameters, a follow-up plan is documented.<br>Parameters:<br>Age 65 and older BMI ≥ 30 or < 22;<br>Age 18-64 BMI ≥ 25 or < 18.5 | Physician Quality Reporting System Measure #128<br><br>EHR Incentive Program – Clinical Quality Measure<br><br>NQF #421 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |

| | Domain | Measure Title & Description | CMS Program, NQF Measure Number, Measure Steward | Method of Data Submission | Measure Type |
|---|---|---|---|---|---|
| 32. | Preventive Health | **Blood Pressure Measurement:**<br><br>Percentage of patient visits with blood pressure measurement recorded among all patient visits for patients aged > 18 years with diagnosed hypertension. | Physician Quality Reporting System #TBD<br><br>EHR Incentive Program – Clinical Quality Measure<br><br>NQF #13 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |
| 33. | Preventive Health | **Tobacco Use Assessment and Tobacco Cessation Intervention:**<br>Percentage of patients who were queried about tobacco use. Percentage of patients identified as tobacco users who received cessation intervention. | Physician Quality Reporting System #TBD<br><br>EHR Incentive Program – Clinical Quality Measure<br><br>NQF #28 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |
| 34. | Preventive Health | **Depression Screening:**<br><br>Percentage of patients aged 18 years and older screened for clinical depression using a standardized tool and follow up plan documented. | Physician Quality Reporting System #134<br><br>NQF #418 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |
| 35. | At Risk Population - Diabetes | **Diabetes Composite (All or Nothing Scoring):**<br>• Hemoglobin A1c Control (<8%)<br>• Low Density Lipoprotein (<100)<br>• Blood Pressure <140/90<br>• Tobacco Non Use<br>• Aspirin Use | NQF #575*, 64*, 61*, 28*, TBD | Group Practice Reporting Option (GPRO) Data Collection Tool | Process & Outcome |

| | Domain | Measure Title & Description | CMS Program, NQF Measure Number, Measure Steward | Method of Data Submission | Measure Type |
|---|---|---|---|---|---|
| 36. | At Risk Population – Diabetes | **Diabetes Mellitus: Hemoglobin A1c Control (<8%)**<br>Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent hemoglobin A1c less than 8.0%. | EHR Incentive Program – Clinical Quality Measure<br><br>NQF #575 | Group Practice Reporting Option (GPRO) Data Collection Tool | Outcome |
| 37. | At Risk Population – Diabetes | **Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus**<br><br>Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent LDL-C level in control (less than 100 mg/dl). | Physician Quality Reporting System Measure #2<br><br>EHR Incentive Program – Clinical Quality Measure<br><br>NQF #64 | Group Practice Reporting Option (GPRO) Data Collection Tool | Outcome |
| 38. | At Risk Population - Diabetes | **Diabetes Mellitus: Tobacco Non Use**<br>Tobacco use assessment and cessation | Physician Quality Reporting System #TBD<br><br>EHR Incentive Program – Clinical Quality Measure<br><br>NQF #28 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |
| 39. | At Risk Population - Diabetes | **Diabetes Mellitus: Aspirin Use**<br>Daily aspirin use for patients with diabetes & cardiovascular disease | NQF TBD | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |

| | Domain | Measure Title & Description | CMS Program, NQF Measure Number, Measure Steward | Method of Data Submission | Measure Type |
|---|---|---|---|---|---|
| 40. | At Risk Population - Diabetes | **Diabetes Mellitus: Hemoglobin A1c Poor Control(>9%):** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent hemoglobin A1c greater than 9.0%. | Physician Quality Reporting System Measure #1<br><br>EHR Incentive Program – Clinical Quality Measure<br><br>NQF #59 | Group Practice Reporting Option (GPRO) Data Collection Tool | Outcome |
| 41. | At Risk Population - Diabetes | **Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus:** Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent blood pressure in control (less than 140/90 mmHg). | Physician Quality Reporting System Measure #3<br><br>EHR Incentive Program – Clinical Quality Measure<br><br>NQF #61 | Group Practice Reporting Option (GPRO) Data Collection Tool | Outcome |
| 42. | At Risk Population - Diabetes | **Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients** Percentage of patients aged 18 through 75 years with diabetes mellitus who received urine protein screening or medical attention for nephropathy during at least one office visit within 12 months. | Physician Quality Reporting System Measure #119<br><br>EHR Incentive Program – Clinical Quality Measure<br><br>NQF #62 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |

| | Domain | Measure Title & Description | CMS Program, NQF Measure Number, Measure Steward | Method of Data Submission | Measure Type |
|---|---|---|---|---|---|
| 43. | At Risk Population - Diabetes | **Diabetes Mellitus: Dilated Eye Exam in Diabetic Patients**<br><br>Percentage of patients aged 18 through 75 years with a diagnosis of diabetes mellitus who had a dilated eye exam. | Physician Quality Reporting System Measure #117<br><br>EHR Incentive Program – Clinical Quality Measure<br><br>NQF #55 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |
| 44. | At Risk Population - Diabetes | **Diabetes Mellitus: Foot Exam**<br><br>The percentage of patients aged 18 through 75 years with diabetes who had a foot examination. | Physician Quality Reporting System Measure #163<br><br>EHR Incentive Program – Clinical Quality Measure<br><br>NQF #56 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |
| 45. | At Risk Population - Heart Failure | **Heart Failure: Left Ventricular Function (LVF) Assessment**<br><br>Percentage of patients aged 18 years and older with a diagnosis of heart failure who have quantitative or qualitative results of LVF assessment recorded. | Physician Quality Reporting System Measure #198<br><br>NQF # 79 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |

| | Domain | Measure Title & Description | CMS Program, NQF Measure Number, Measure Steward | Method of Data Submission | Measure Type |
|---|---|---|---|---|---|
| 46. | At Risk Population - Heart Failure | **Heart Failure: Left Ventricular Function (LVF) Testing**<br><br>Percentage of patients with LVF testing during the current year for patients hospitalized with a principal diagnosis of heart failure (HF) during the measurement period. | Physician Quality Reporting System Measure #228<br><br>CMS | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |
| 47. | At Risk Population - Heart Failure | **Heart Failure: Weight Measurement**<br><br>Percentage of patient visits for patients aged 18 years and older with a diagnosis of heart failure with weight measurement recorded. | Physician Quality Reporting System #227<br><br>NQF # 85 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |
| 48. | At Risk Population - Heart Failure | **Heart Failure: Patient Education**<br><br>Percentage of patients aged 18 years and older with a diagnosis of heart failure who were provided with patient education on disease management and health behavior changes during one or more visit(s) within 12 months. | Physician Quality Reporting System #199<br><br>NQF # 82 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |
| 49. | At Risk Population - Heart Failure | **Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)**<br><br>Percentage of patients aged 18 years and older with a diagnosis of heart failure who also have LVSD (LVEF < 40%) and who were prescribed beta-blocker therapy. | Physician Quality Reporting System Measure # 8<br><br>EHR Incentive Program – Clinical Quality Measure<br><br>NQF #83 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |

| | Domain | Measure Title & Description | CMS Program, NQF Measure Number, Measure Steward | Method of Data Submission | Measure Type |
|---|---|---|---|---|---|
| 50. | At Risk Population - Heart Failure | **Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)**<br><br>Percentage of patients aged 18 years and older with a diagnosis of heart failure and LVSD (LVEF < 40%) who were prescribed ACE inhibitor or ARB therapy. | Physician Quality Reporting System Measure #5<br><br>EHR Incentive Program – Clinical Quality Measure<br><br>NQF #81 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |
| 51. | At Risk Population - Heart Failure | **Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation**<br><br>Percentage of all patients aged 18 and older with a diagnosis of heart failure and paroxysmal or chronic atrial fibrillation who were prescribed warfarin therapy. | Physician Quality Reporting System Measure #200<br><br>EHR Incentive Program – Clinical Quality Measure<br><br>NQF #84 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |

| | Domain | Measure Title & Description | CMS Program, NQF Measure Number, Measure Steward | Method of Data Submission | Measure Type |
|---|---|---|---|---|---|
| 52. | At Risk Population – Coronary Artery Disease | **Coronary Artery Disease (CAD) Composite: All or Nothing Scoring**<br>• Oral Antiplatelet Therapy Prescribed for Patients with CAD<br>• Drug Therapy for Lowering LDL-Cholesterol<br>• Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI)<br>• LDL Level <100 mg/dl<br>• 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 #67, 74, 70, 64, 66 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process & Outcome |
| 53. | At Risk Population – Coronary Artery Disease | **Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD**<br><br>Percentage of patients aged 18 years and older with a diagnosis of CAD who were prescribed oral antiplatelet therapy. | Physician Quality Reporting System Measure # 6<br><br>EHR Incentive Program – Clinical Quality Measure<br><br>NQF #67 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |

| | Domain | Measure Title & Description | CMS Program, NQF Measure Number, Measure Steward | Method of Data Submission | Measure Type |
|---|---|---|---|---|---|
| 54. | At Risk Population – Coronary Artery Disease | **Coronary Artery Disease (CAD): Drug Therapy for Lowering LDL-Cholesterol**<br><br>Percentage of patients aged 18 years and older with a diagnosis of CAD who were prescribed a lipid-lowering therapy (based on current ACC/AHA guidelines).<br><br>The LDL-C treatment goal is <100 mg/dl. Persons with established coronary heart disease (CHD) who have a baseline LDL-C 130 mg/dl should be started on a cholesterol-lowering drug simultaneously with therapeutic lifestyle changes and control of nonlipid risk factors (National Cholesterol Education Program (NCEP). | Physician Quality Reporting System #197<br><br>EHR Incentive Program – Clinical Quality Measure<br><br>NQF #74 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |
| 55. | At Risk Population – Coronary Artery Disease | **Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI)**<br><br>Percentage of patients aged 18 years and older with a diagnosis of CAD and prior MI who were prescribed beta-blocker therapy. | Physician Quality Reporting System Measure # 7<br><br>EHR Incentive Program – Clinical Quality Measure<br><br>NQF #70 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |
| 56. | At Risk Population – Coronary Artery Disease | **Coronary Artery Disease (CAD): LDL level < 100 mg/dl** | CMS | Group Practice Reporting Option (GPRO) Data Collection Tool | Outcome |

| | Domain | Measure Title & Description | CMS Program, NQF Measure Number, Measure Steward | Method of Data Submission | Measure Type |
|---|---|---|---|---|---|
| 57. | At Risk Population – Coronary Artery Disease | **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 Systolic Dysfunction (LVSD)**<br><br>Percentage of patients aged 18 years and older with a diagnosis of CAD who also have diabetes mellitus and/or LVSD (LVEF < 40%) who were prescribed ACE inhibitor or ARB therapy. | Physician Quality Reporting System Measure #118<br><br>NQF #66 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |
| 58. | At Risk Population – Hypertension | **Hypertension (HTN): Blood Pressure Control**<br><br>Percentage of patients with last BP < 140/90 mmHg | Physician Quality Reporting System #TBD<br><br>EHR Incentive Program – Clinical Quality Measure<br><br>NQF #18 | Group Practice Reporting Option (GPRO) Data Collection Tool | Outcome |
| 59. | At Risk Population – Hypertension | **Hypertension (HTN): Plan of Care**<br><br>Percentage of patient visits for patients aged 18 years and older with a diagnosis of HTN with either systolic blood pressure ≥ 140 mmHg or diastolic blood pressure ≥ 90 mmHg with documented plan of care for hypertension. | Physician Quality Reporting System #TBD<br><br>NQF # 17 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |

| | Domain | Measure Title & Description | CMS Program, NQF Measure Number, Measure Steward | Method of Data Submission | Measure Type |
|---|---|---|---|---|---|
| 60. | At Risk Population – COPD | **Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation**<br><br>Percentage of patients aged 18 years and older with a diagnosis of COPD who had spirometry evaluation results documented. | Physician Quality Reporting System Measure # 51<br><br>NQF #91 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |
| 61. | At Risk Population – COPD | **Chronic Obstructive Pulmonary Disease (COPD): Smoking Cessation Counseling Received** | CMS | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |
| 62. | At Risk Population – COPD | **Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy based on FEV1**<br><br>Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV1/FVC less than 70% and have symptoms who were prescribed an inhaled bronchodilator. | Physician Quality Reporting System Measure # 52<br><br>NQF #102 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |
| 63. | At Risk Population – Frail Elderly | **Falls: Screening for Fall Risk**<br><br>Percentage of patients aged 65 years and older who were screened for fall risk at least once within 12 months | NQF #101 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |

| | Domain | Measure Title & Description | CMS Program, NQF Measure Number, Measure Steward | Method of Data Submission | Measure Type |
|---|---|---|---|---|---|
| 64. | At Risk Population – Frail Elderly | **Osteoporosis Management in Women Who had a Fracture**<br><br>Percentage of women 65 years and older who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat or prevent osteoporosis in the 6 months after the date of fracture | NQF #53 | Group Practice Reporting Option (GPRO) Data Collection Tool | Process |
| 65. | At Risk Population – Frail Elderly | **Monthly INR for Beneficiaries on Warfarin**<br>Average percentage of monthly intervals in which Part D beneficiaries with claims for warfarin do not receive an INR test during the measurement period | NQF #555 | Claims | Process |

*Individual measure within composite measure is used in the EHR Incentive Program.

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Information on Physician Quality Reporting System measures are available at: *http://www.cms.gov/pqri/*. Information on EHR Incentive Program measures are available at: *https://www.cms.gov/EHRIncentivePrograms/*. Information on quality measures used by the Hospital Inpatient Quality Reporting Program are available at: *http://www.cms.gov/HospitalQualityInits/08_HospitalRHQDAPU.asp*.

As illustrated in the "Method of Data Submission" column of Table 1, we propose to calculate results for the first program year measures via claims, the Group Practice Reporting Option (GPRO) data collection tool, as discussed in section II.E.4. of this proposed rule, and survey instruments. The ACO GPRO tool would be a new tool based on the data collection tool currently used in the Physician Quality Reporting System (formerly known as the Physician Quality Reporting Initiative) group practice reporting option (GPRO) and Physician Group Practice (PGP) demonstration.

In subsequent program years through additional rulemaking, we would expect to refine and expand the ACO measures to enhance our ability to assess the quality of care furnished by ACOs participating in the Shared Savings Program and expand measures reporting mechanisms to include those that are directly EHR-based. Specifically, we expect to expand the measures through future rulemaking to include other highly prevalent conditions and areas of interest, such as frailty, as well as measures of caregiver experience. In addition to ambulatory measures, we would expect to add measures of hospital-based care and quality measures for care furnished in other settings, such as home health services and nursing homes. To the extent consistent with the Shared Savings Program requirements under section 1899 of the Act, we also anticipate the ACO quality measures will evolve over time in an effort to achieve our quality program alignment goal of developing a single quality measure set that could be used by ACOs operating across a wide variety of payers, including those dealing with Medicaid, the Children's Health Insurance Program (CHIP), and Special Needs Plans.

We invite comments on the implication of including or excluding any proposed measure or measures in the calculation of the ACO Quality Performance Standard. Commenters may suggest variations or substitutions that are substantially equivalent to the proposed measures. However, without future rulemaking, we cannot consider measures that do not substantially cover the same patient populations, processes, or outcomes addressed by the existing measures outlined in this proposed rule. We invite comment on whether the list of proposed measures should be narrowed, and also invite comments on whether any of the measures we proposed in Table 1 for calculating the ACO Quality Performance Standard should be excluded for scoring purposes and/or instead be considered for quality monitoring purposes only. Finally, we also seek comment on a process for retiring or adjusting the weights of domains, modules, or measures over time.

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. Most of the proposed measures identified in Table 1 can be derived from CMS systems and calculated for the assigned patient population the ACO serves. Most of the measures are consistent with those reported for the Physician Quality Reporting System, others will rely on eRx and HITECH program data, and some may rely on Hospital Compare or the Centers for Disease Control and Prevention National Healthcare Safety Network data. However, we recognize 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 instance, measures dealing with laboratory results are not conducive to claims-based reporting, since claims typically include diagnosis and procedure codes but not specific test results. For this reason, we propose to make available a CMS-specified data collection tool and a survey tool for certain proposed measures (that is, those measures in Table 1 where the proposed method of data submission is listed as "GPRO").

We also propose that for some measures ACOs collect data via survey instruments. As noted previously, we plan to continually align the ACO reporting requirements with those required for the EHR Incentive Program and leverage the infrastructure and measures specifications being developed for that program. We propose that during the year following the first performance period, each ACO would be required to report via the GPRO tool, as applicable, the proposed quality measures listed in Table 1 with respect to services furnished during the performance period. We propose 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. Survey data would also reflect care received during the first performance period. For future performance periods, we intend to use rulemaking to update the quality measure requirements and mechanisms.

We welcome comments on the proposed data submission requirements. We also seek 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.

b. GPRO Tool

In 2010, 36 large group practices and integrated delivery systems used the GPRO tool to report 26 quality measures for an assigned patient population under the Physician Quality Reporting System. The GPRO tool 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 tool would allow ACOs to submit clinical information from EHRs, registries, and administrative data sources required for measurement reporting. The tool reduces 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. We propose that the existing GPRO tool be built out, refined, and upgraded to support clinical data collection and measurement reporting and feedback to ACOs under the Shared Savings Program.

For the measures with "GPRO" listed as the method of data collection in Table 1, we plan 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 Physician Quality Reporting System GPRO I, as described later in the document. Assigned beneficiaries, for purposes of the GPRO tool, would be limited to those Medicare FFS beneficiaries assigned to the ACO, as discussed in Section II.D.

For the measures with "GPRO" listed as the method of data collection in

Table 1, we also plan to provide each ACO with access to a database (that is, the GPRO data collection tool) that will include a sample of its assigned beneficiary population and the GPRO quality measures listed in Table 1. We plan to pre-populate the data collection tool 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.

Identical to the sampling method used in the 2011 Physician Quality Reporting System GPRO I, we plan to 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 plan to require the ACO to report on 100 percent, or all, of the assigned beneficiaries. For each measure set/domain within the GPRO tool, the ACO would be required to report information on the assigned beneficiaries in the order in which they appear consecutively in the ACO's sample.

Some GPRO measures will not rely on beneficiary data but rather on ACO attestation. GPRO measures relying on attestation include those in the Care Coordination domain that pertain to HITECH Meaningful Use, the Electronic Prescribing Incentive Program, and patient registry use. We plan to validate GPRO attestations through CMS data from the EHR Incentive Program and Electronic Prescribing Incentive Program.

For the other measures, that we propose be reported via the GPRO tool, we propose to retain the right to validate the data entered into the tool. In the event we were to audit the data entered into the GPRO tool, we propose to do so via a data validation process based on the one used in phase I of the PGP demonstration, as described later in the document.

In the GPRO audit process, we plan to 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 propose 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 propose that the ACO will not be given credit for meeting the quality target for any measures for which this mismatch rate still exists. We note that the 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, per the Monitoring section of this proposed rule.

We invite comment on the proposed quality data submission requirements and on the administrative burden associated with reporting.

c. Certified EHR Technology

In July 2010, HHS published final rules for the EHR Incentive Programs. Included within the final regulations were certain clinical quality measures for which eligible professionals and eligible hospitals are responsible. We have noted in Table 1, the proposed Shared Savings Program quality measures currently included in the EHR Incentive Programs and will continue to further align the measures between the two programs. Given that we have proposed in Section II.E.6 that at least 50 percent of an ACO's PCPs are "meaningful EHR users" as that term is defined in 42 CFR 495.4 by the start of the second Shared Savings Program performance year in order to continue participation in the Shared Savings Program, our intent is to develop the capability of the GPRO web-based tool to interface with EHR technology, such that EHR data could directly populate the ACO GPRO tool with the required quality data. As we intend to further align both the Shared Savings Program and EHR incentive program through subsequent rulemaking, we anticipate that certified EHR technology (including certified EHR modules capable of reporting clinical quality measures) will be an additional measures reporting mechanism used by ACOs under the Shared Savings Program for future program years.

4. Quality Performance Standards

a. General

Before an ACO can share in any savings created, it must demonstrate that it is delivering high quality care. Thus, 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.E.3 of this proposed rule, we propose to use the 65 measures in Table 1 to establish the quality performance standards that ACOs must meet in order to be eligible for shared savings.

We considered two alternative options for establishing quality standards: Rewards for better performance, and a minimum quality threshold for shared savings. The performance score approach rewards ACOs for better quality with larger percentages of shared savings. The threshold approach ensures that ACOs exceed minimum standards for the quality of care, but allows full shared savings if ACOs meet the minimum. We propose the performance score approach and seek comment on the threshold approach.

b. Option 1—Performance Scoring

Under the first option, we would use quality performance standards to arrive at a total performance score for an ACO. We would organize the measures by domain, as discussed in section II.E.5.b. of this proposed rule. The performance on each measure will be scored, as discussed in section II.E.5.c. of this proposed rule. The scores for the measures will be rolled up into a score by each domain as discussed in section II.E.5.d. of this proposed rule. ACOs will receive performance feedback at both the individual measure and domain level. The percentage of points earned for each domain will be aggregated using the weighting method discussed in section II.E.5.d. of this proposed rule to arrive at a single percentage that will be applied to determine the quality sharing rate for which the ACO is eligible. The aggregated domain scores will 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 discussed in Section II. G, Two-Side

Model. We also discuss our proposal to set the quality performance standard in the first year of the Shared Savings Program at the reporting level and set the standard at a higher level in subsequent years in section II.E.5.e. of this proposed rule.

(1) Measure Domains and Measures Included in the Domains

The 65 quality performance standard measures in Table 1 are subdivided into 5 domains, as discussed in section II.E.3.c. of this proposed rule. The domains include: (1) Patient/Caregiver Experience; (2) Care Coordination; (3) Patient Safety; (4) Preventive Health; (5) At-Risk Population/Frail Elderly Health. The At-Risk Population Care domain would include the following chronic diseases: Diabetes mellitus (DM); heart failure (HF); coronary artery disease (CAD); hypertension; and chronic obstructive pulmonary disorder (COPD). The measures from Table 1 that are included in each domain are as indicated in Table 2.

**Table 2: Five Measure Domains for Quality Performance Standard**

| Domain | Category | Table 1 Measures (Total) |
|---|---|---|
| 1. Patient/Caregiver Experience | | 1-7 (7 measures) |
| 2. Care Coordination | | 8-23 (16 measures) |
| 3. Patient Safety | | 24-25 (2 measures) |
| 4. Preventive Health | | 26-34 (9 measures ) |
| 5. At-Risk Population/Frail Elderly Health | Diabetes | 35-65 (31 measures) |
| | Heart Failure | |
| | Coronary Artery Disease | |
| | Hypertension | |
| | Chronic Obstructive Pulmonary Disorder | |
| | Frail Elderly | |

(2) Methodology for Calculating a Performance Score for Each Measure Within a Domain

We propose that an ACO will receive a performance score on each measure included in Table 1. For the first year of the Shared Savings Program, these scores would be for informational purposes, since we propose to set the quality performance standard at the reporting level. We propose setting benchmarks for each measure using Medicare FFS claims data, MA quality performance rates, or, where appropriate, the corresponding percent performance rates that an ACO will be required to demonstrate. For each measure, we propose to set a performance benchmark and a minimum attainment level as defined in Table 3. 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 annual MA quality performance data and set the benchmark accordingly. Furthermore, since MA quality performance rates utilize both claims and clinical data, we propose to use those rates when they are available.

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 will be aware of the benchmarks they must achieve to receive the maximum quality score. In future program years, we anticipate that actual ACO performance will be used to update the benchmarks. As discussed in section II.H of this proposed rule, 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 propose to 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 propose 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.

**Table 3: Sliding Scale Measure Scoring Approach**

| ACO Performance Level | Quality Points |
|---|---|
| 90+ percentile FFS/MA Rate or 90+ percent | 2 points |
| 80+ percentile FFS/MA Rate or 80+ percent | 1.85 points |
| 70+ percentile FFS/MA Rate or 70+ percent | 1.7 points |
| 60+ percentile FFS/MA Rate or 60+ percent | 1.55 points |
| 50+ percentile FFS/MA Rate or 50+ percent | 1.4 points |
| 40+ percentile FFS/MA Rate or 40+ percent | 1.25 points |
| 30+ percentile FFS/MA Rate or 30+ percent | 1.10 point |
| <30 percentile FFS/MA Rate or <30 percent | No points |

We propose that performance below the minimum attainment level would earn zero points for that measure under both the one-sided and two-sided risk models. Performance equal to or greater than the minimum attainment level but less than the performance benchmark shall receive points on a sliding scale based on the level of performance, for those measures in which the points scale applies. Table 3 represents the approach that we are currently considering. We also are considering setting the initial minimum attainment level for both the one-sided and two-sided shared savings models at 30 percent or the 30th percentile of Medicare FFS or the MA rate, depending on what performance data are available.

Measures 35 and 52 in Table 1 include diabetes and coronary artery disease composite measures in which we propose "all or nothing" scoring. We propose that measures designated as all or nothing measures receive the maximum available points if all criteria are met and zero points if at least one of the criteria are not met. We define "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 5 submeasures within the diabetes composite and all 5 submeasures within the CAD composite would need to be reported in order to earn points for these 2 composite measures. The intent of all or nothing scoring is to signal to providers that failing to perform any element of a process is unacceptable and will result in a "zero" score for quality for that measure. We believe that incorporating all or nothing scoring concepts into the ACO quality performance standard would provide greater insight into the use of these methodologies, drive ACOs to aggressively improve their population's health, and encourage future development of composite measures.

However, we also recognize 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 in the Medicare population given the difficulty in attaining targets for individuals with multiple chronic conditions and complications that may not be adequately addressed in denominator exclusions. Therefore, in addition to scoring the diabetes and CAD composites, we also propose scoring the sub measures within the diabetes and CAD composites individually.

Measure #24 is a hospital acquired conditions (HACs) composite, in which we propose a summation of the events included within the measure and attributing the rate to the same scale used for other measures described in Table 3. We do not propose all or nothing scoring for this composite, since the HACs are rare events. Because the HACs are rare events, we believe that grouping them into one measure will make the measure more meaningful for ACOs, which will have smaller populations and, therefore, should have even fewer HAC events than a hospital would experience for its total population outside of the Shared Savings Program. We also believe grouping the HACs into one measure reduces the HACs' impact on the ACO's overall quality performance score. We intend 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 propose setting a quality standard for each domain at the reporting level. For subsequent program years, we plan to calculate the percentage of points an ACO earns for each domain after determining the points earned for each measure. We plan 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 pre-defined number of points based on the number of individual measures in the domain, as shown in Table 4.

**Table 4: Total Points for Each Domain within the Quality Performance Standard**

| Domain | Category | Table 1 Measures (Total) | One-Sided Model – Total Potential Points Per Domain | Two-Sided Risk Model – Total Potential Points Per Domain |
|---|---|---|---|---|
| 1. Patient/Caregiver Experience | | 1-7 (7 measures) | 14 | 14 |
| 2. Care Coordination | | 8-23 (16 measures) | 32 | 32 |
| 3. Patient Safety | | 24-25 (2 measures) | 4 | 4 |
| 4. Preventive Health | | 26-34 (9 measures ) | 18 | 18 |
| 5. At-Risk Population/Frail Elderly Health | Diabetes | 35-65 (31 measures) | 62 | 62 |
| | Heart Failure | | | |
| | Coronary Artery Disease | | | |
| | Hypertension | | | |
| | Chronic Obstructive Pulmonary Disorder | | | |
| | Frail Elderly | | | |
| **Total Quality Points Available** | | | 130 | 130 |
| **Total Potential Shared Savings** | | | **50%** | **60%** |

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. 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. That is, full and accurate reporting of the quality measures in the first year of the Shared Savings Program will result in an ACO earning 60 or 50 percent of shareable savings, depending on whether the ACO is in the two-sided or one-sided model. For future program years, the percent of potential shareable savings will vary on the ACO's performance on the measures as compared with the measure benchmarks.

For example, the preventive health domain has 9 measures and would be worth a maximum of 18 points (that is, 9 measures × 2 points equals 18 quality points). We propose the sliding scale in Table 3 for determining points earned for each measure. As mentioned previously, we propose calculating the percentage of points an ACO earns for each domain by dividing the points earned by the total points available, yielding a percentage. For example, if an ACO earns 16.2 out of 18 points in the preventive health domain, the ACO earned 90 percent of the points for the preventive health domain (16.2 divided by 18 equals .90). Assuming the ACO is operating under the two-sided shared savings model and earns 90 percent of the quality performance points across all five domains and generates shared savings, it would receive 90 percent of the ACO's share of the savings or 54 percent of the total savings generated. That is, achieving 90 percent of the potential 60 percent of shared savings an ACO can earn under the two-sided model, means the ACO could earn 54 percent of the total savings generated. Under the one-sided model, achieving 90 percent of the potential 50 percent of shared savings, means the ACO could earn 45 percent of the shareable savings generated.

Under both the one-sided and two-sided shared savings models, the quality measures domain scoring methodology treats all domains equally regardless of the number of measures within the domain. We believe the key benefit of weighting the domains equally is that it does not create a preference for any one domain, which we believe is important as we expect ACOs to vary in composition, and, as a result, to place more emphasis on different domains. We also considered weighting the domains to emphasize priority conditions or areas in order to emphasize (or de-emphasize) certain measures that are more difficult (or easy) to achieve without needing to change the scoring methodology. This method would require judgment about which domains are more important than others, which may not be appropriate. Equal weighting contains an implicit judgment that domains such as patient/caregiver experience of care and patient safety are equally important to the quality of care. Accordingly, we believe ACOs should seek to address all aspects of patient care in order to improve the overall quality of care under the Medicare program. 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 propose aggregating 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 as described in section II.F. of this proposed rule. 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.

We also propose that ACOs must report completely and accurately on all measures within all domains to be deemed eligible for shared savings consideration. We believe this is important as it requires ACOs to address all domains and be accountable across the continuum of care. If the ACO demonstrates sufficient cost savings in addition to meeting the quality performance requirements, the ACO would be deemed eligible for shared savings. We believe that this methodology provides a sufficient incentive for quality improvement targeted to specific domains and allows ACOs of varying compositions, which may be stronger in some domains than others, to receive some level of shared savings. In addition to this proposed domain-based scoring methodology, we considered several other options for assessing the quality performance of ACOs. We considered scoring measures individually under a method that would weight all measures equally. Each measure would be worth the maximum points available as described previously for a total maximum possible points for each ACO. This system would avoid overweighting or underweighting measures due to the number of measures in a domain. We also considered weighting quality measures by their clinical importance. More important quality measures would account for a greater proportion of shared savings. Outcome measures such as hospital-acquired infections and readmissions would be worth more than process measures. This would avoid overweighting or underweighting measures due to their domain, and account for clinical importance.

However, we did not think either of these approaches would be consistent with a larger measurement strategy of driving better health for populations and better care for individuals overall for the ACO beneficiary population, since we believe population health is better assessed across domains that encompass a variety of measures that apply to beneficiaries with different needs.

(4) The Quality Performance Standard Level

We propose to set the quality performance standard of the first year of the Shared Savings Program at the reporting level. That is, under the one-sided model, we propose that an ACO would receive 50 percent of shared savings (provided that the ACO realizes sufficient cost savings under the methodology described in the Shared Savings Determination section of this proposed rule) based on 100 percent complete and accurate reporting on all quality measures. Similarly, we propose that under the two-sided risk model, ACOs would receive 60 percent of shared savings (provided that the ACO realizes sufficient cost savings under the methodology described in the section II.G. of this proposed rule) based on 100 percent complete and accurate reporting on all quality measures. We believe setting the quality performance standard for the first year of the Shared Savings Program at full and accurate reporting allows 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. It also would provide CMS with the opportunity to learn about the process, establish and refine benchmarks on ACO reported data, and establish improvement targets using data reporting for the first performance year. Setting the quality performance standard at the reporting level is also consistent with other value-based purchasing programs that have started out initially as pay for reporting programs.

Via future rulemaking, we plan to raise the quality performance standard requirements beginning in the second program year, when actual performance on the reported measures would be considered in determining whether an ACO is eligible to receive any shared savings (provided, that the ACO realizes cost savings under the methodology described in the Shared Savings Determination section of this proposed rule). We believe this approach is 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."

c. Option 2: Quality Threshold

Under the second option, we would establish a minimum quality threshold for participating ACOs. If an ACO exceeded the quality threshold, it would retain the full shared savings percentage attributable to quality under this proposed rule (50 percent for one-sided risk, and 60 percent for two-sided risk). If an ACO did not meet the minimum quality standards in a performance year, it would not be eligible for shared savings. Furthermore, as discussed in section II.H. of this proposed rule and with respect to the performance standards option, if an ACO that fails to meet the minimum threshold during a performance year, we propose to give the ACO a warning, an opportunity for correction, and follow the termination process described in the Monitoring section if the ACO continues to underperform.

(1) Minimum Quality Threshold

Alternatively, we could establish the minimum quality threshold using the same set of quality measures and domains outlined in Table 1. We would also use the benchmarks for performance described in Table 3, established using claims data from FFS Medicare or the Medicare Advantage program. The minimum quality threshold would be performance at or above the 50th percentile (on the performance standards described in Table 3) for each domain: patient/caregiver experience; care coordination; patient safety; preventive health; and at-risk population/frail elderly. If an ACO meets these thresholds, it would be eligible for the full 50 percent of shared savings attributable to quality for those participating in the one-sided model, and the full 60 percent for those participating in the two-sided model. If an ACO failed to meet this threshold, it would not be eligible for shared savings. We expect that the quality threshold will increase over time in future rulemaking, under the requirement to improve the quality of care furnished by the ACO under section 1899(b)(3)(C) of the Act. We solicit comment on this approach and the appropriate threshold level, and on the pros and cons of the minimum threshold approach.

(2) Considerations in Establishing a Quality Threshold

The quality threshold option has advantages and disadvantages compared with the performance standard option. Under the performance standard option, an ACO could receive rewards for higher quality based on outcomes in one or two domains (for example, patient/caregiver experience and preventive care), while having very low quality in others (for example, patient safety). This is true for individual measures (for example, healthcare-acquired infections) as well. Setting a minimum threshold ensures that all ACOs meet basic standards on all quality measures, with a special emphasis on patient safety. An ACO's quality outcomes may vary from year to year due to factors outside of its control, meaning that performance-based standards could reward ACOs due to random variability. A threshold established at a basic level of quality acknowledged to be minimally necessary presents less of a risk of being triggered due to random variation, as opposed to truly poor performance. Finally, for ACOs meeting

the threshold, their shared savings percentage attributable to quality would be fixed and certain. This would increase incentives, achieve savings, and present more certainty on potential investment returns for organizations considering whether or not to become ACOs.

A quality threshold also presents disadvantages. Under this model, once an ACO is certain that it has met the minimum threshold, there is no incentive to continue improving quality; in effect, the quality incentives would be the same as under traditional FFS. ACOs may even have an incentive to reduce quality to just above the minimum. Additionally, an ACO would not be rewarded for improving quality outcomes on specific measures once it was confident that the minimum was exceeded.

In addition to proposing these two options, we also considered establishing performance standards for the overarching goals (of improving health care for individuals and populations) or a single performance standard to measure overall ACO performance. However, we believe that such aggregated scores may not be meaningful or useful for the ACO, since the general goals of improving health for individuals and populations are not as actionable as, for instance, a specific goal of lowering patients' LDL cholesterol levels. For the patient experience domain measures, we also considered weighting more heavily the responses of beneficiaries who have sought care with the ACO providers longer than the responses of those who are newer to the ACO providers. Finally, we considered an option that would permit the ACO to satisfy the quality performance standards based on peer to peer benchmarking. Under this approach the quality measure benchmarks would be set based on all ACOs' performance during the year. However, the main reason we did not propose this option is that, for measures in which most ACOs achieve high performance levels, minor changes in performance could determine whether an ACO achieves the performance benchmark. Thus, there would be little incentive to improve quality beyond the level necessary to share in savings. Additionally, our proposed approach enables us to reward improvement over the minimum attainment level by allowing the ACO to share in greater savings as they improve over time.

We also considered permitting ACOs to report a subset of the measures in Table 1, based on their level of readiness to participate in the Shared Savings Program. ACOs seeking to participate in the Shared Savings Program may vary with respect to their readiness to function in the Shared Savings Program, with respect 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. However, consistent with the overall goals of the Shared Savings Program discussed in section I. of this proposed rule, we believe that ACOs participating in the Shared Savings Program should seek to improve quality across a variety of measures addressing a range of domains, not only for those areas in which they are currently able or comfortable to report, hence our proposal to require 100 percent reporting for the measures in Table 1 to satisfactorily meet the quality performance requirements under the Shared Savings Program

We propose the performance scoring option and invite comment on this option as well as the quality threshold option. Within these options, we seek comment on the appropriateness of weighting all domains equally in determining an ACO's quality performance or whether certain domains and/or specific measures should be weighted more heavily. We also invite comment on alternatives that would blend these two approaches. For example, under the two-sided model, allowing ACOs that generate savings to increase their share of savings with higher quality scores (Option 1) but using a threshold approach (Option 2) when calculating losses so that higher quality does not reduce an ACO's share of any losses. Such an approach would have the effect of essentially applying a minimum sharing rate for losses (for example, 50 percent) and could appropriately reflect the goal of the Shared Savings Program to reward high quality and efficient care, by providing a greater reward when high quality care is also efficient and less relief for high quality care that is not efficient. Alternatively, the threshold option could be utilized in the two-sided model so that if the threshold score for the two-sided model resulted in 60% shared savings, it would also result in 60 percent shared losses, creating a symmetrical two-sided model. Another example of a blended approach would be to use the threshold approach (Option 2) for the first 3 years of the Shared Savings Program and then, as experience is gained and measures are further aligned, transition to performance scoring (Option 1). We also invite comment on the proposal to set the quality performance standard of the first program year at the reporting level and to raise the standard to reflect performance in subsequent years. We also invite comment on the proposed quality measures scoring methodologies under the one-sided and two-sided risk models. In addition, we invite comment on our proposal to have all quality measures listed in Table 1 required of all ACOs, and the alternative under which ACOs would be required to only report a subset of the measures in Table 1, based on their level of readiness for the Shared Savings Program.

5. Incorporation of Other Reporting Requirements Related to the Physician Quality Reporting System and Electronic Health Records Technology Under Section 1848 of the Act

Medicare provides multiple incentive payment options for providers to report and use clinical information more proactively in their practices. 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, 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 for determining whether to make such payments." Under this authority, we propose to incorporate certain reporting requirements and payments related to the Physician Quality Reporting System into the Shared Savings Program for "eligible professionals" within an ACO. 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-language pathologist; or (4) a qualified audiologist.

We propose to incorporate a Physician Quality Reporting System group practice reporting option (GPRO) under the Shared Savings Program and further propose that the eligible professionals that are ACO participant providers/suppliers would constitute a group practice for purposes of qualifying for a Physician Quality

Reporting System incentive under the Shared Savings Program. Specifically, eligible professionals would be required to submit data through the ACO on the quality measures proposed in Table 1 using the GPRO tool and methodology described in section II.E.3. of this proposed rule to qualify for the Physician Quality Reporting System incentive under the Shared Savings Program. We propose that the ACO would report and submit data on behalf of the eligible professionals in an effort to qualify for the Physician Quality Reporting System incentive as a group practice; that is, eligible professionals within an ACO would qualify for the Physician Quality Reporting System incentive as a group practice, and not as individuals. In addition, we propose a calendar year reporting period from January 1 through December 31, for purposes of the Physician Quality Reporting System incentive under the Shared Savings Program.

With regard to the requirements for satisfactory reporting for purposes of earning the Physician Quality Reporting System incentive under the Shared Savings Program, we propose to incorporate certain aspects of the criteria for satisfactory reporting under the 2011 Physician Quality Reporting System GPRO I option (75 FR 73506), with a few modifications. In particular, we propose the following criteria for satisfactory reporting for purposes of the Physician Quality Reporting System incentive for the first performance period under the Shared Savings Program:

- ACOs, on behalf of its EPs, would need to report on all measures included in the data collection tool;
- Beneficiaries will be assigned to the ACO using the methodology described in the Assignment section of this 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, measure 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 will need to be completed for all domains, measure sets, and measures described in Table 1.

Accordingly, eligible professionals within an ACO that satisfactorily report the measures proposed in Table 1 during the reporting period would qualify under the Shared Savings Program for a Physician Quality Reporting System incentive equal to 0.5 percent of the ACO's eligible professionals' total estimated Medicare Part B PFS allowed charges for covered professional services furnished 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 under the ACO participant's TINs.

We plan to align the incorporated Physician Quality Reporting System requirements with the general Shared Savings Program reporting requirements, such that no extra reporting is actually required in order for eligible professionals or the ACO to earn the Physician Quality Reporting System 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, the Physician Quality Reporting System eligible professionals within such ACOs will be considered eligible for the Physician Quality Reporting System incentive under the Shared Savings Program for that year. This means ACOs will need to report on all measures proposed in Table 1 in order to receive both the Shared Savings Program shared savings and Physician Quality Reporting System incentive. 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 Physician Quality Reporting System 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 intend to discuss the policy for incorporating the Physician Quality Reporting System incentive under the Shared Savings Program for subsequent years in future rulemaking.

We note that ACOs will be eligible for the Physician Quality Reporting System incentive under the Shared Savings Program to the extent that they contain eligible professionals as defined under § 414.90(b). As a result, not all ACOs will necessarily be eligible for the Physician Quality Reporting System incentive under the Shared Savings Program. A complete list of Physician Quality Reporting System eligible professionals (EP) is available at: *http://www.cms.gov/PQRI/Downloads/EligibleProfessionals.pdf.* In addition, similar to traditional Physician Quality Reporting System, an EP could not qualify for the Physician Quality Reporting System incentive as both a group that is part of an ACO and as an individual. Furthermore, EPs could not qualify for a Physician Quality Reporting System incentive under both the Physician Quality Reporting System under the Shared Savings Program and the traditional Physician Quality Reporting System. For purposes of analysis and payment, we intend to use TINs and National Provider Identification numbers similar to what we have done in the traditional Physician Quality Reporting System (75 FR 40169), and we will provide such details in guidance.

At this time, we are not proposing to incorporate such payments for the EHR Incentive Program or Electronic Prescribing Incentive Program under the Shared Savings Program. Professionals in ACOs may still separately participate in those other incentive programs. However, we propose to require in 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 eligible professionals and hospitals and the eRx Incentive Program, as illustrated in Table 1. Metrics related to successful participation in the EHR Incentive Program and the eRx Incentive Program includes scoring the percentage of "meaningful users" of certified EHR technology, as defined in our regulations, and the percentage of those professionals that meet the criteria for the eRx incentive, as measures that are part of the quality performance standard. These measures would be subject to the same points scale and 30 percent or 30th percentile minimum attainment level previously described in table D3. We note that including metrics based on EHR Incentive Program and eRx Incentive Program data does not in any way duplicate or replace specific program measures within each of the two respective programs or allow eligible professionals to satisfy the requirements of either of the two programs through the Shared Savings Program. To receive incentive payments under the EHR incentive or eRx programs (or to avoid payment adjustments), eligible professionals will be required to meet all the requirements of the respective EHR and eRx programs. In addition, as a Shared Savings Program requirement separate from the quality measures reporting discussed previously, we propose

requiring that at least 50 percent of an ACO's primary care physicians are determined to be "meaningful EHR users" as that term is defined in 42 CFR 495.4 as defined in the HITECH Act and subsequent Medicare regulations 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 believe these approaches would foster incentives for improving and delivering high quality care by engaging providers in performance based quality incentive programs; and encourage adoption of EHRs. The requirement that at least 50 percent of ACO primary care physicians be meaningful users represents a first step towards achieving our objective of incenting full participation of ACOs' providers in the EHR Incentive Program over time. For subsequent years, we anticipate proposing greater alignment between the Shared Savings Program and the EHR Incentive program through future rulemaking. We considered several other options for incorporating other program reporting requirements into the Shared Savings Program. One option was to incorporate Physician Quality Reporting System into the Shared Savings Program via a scaled approach, in which how the ACO performs on the quality measures under the Shared Savings Program would determine the amount of Physician Quality Reporting System incentive an ACO could earn. However, we thought this approach would be burdensome and confusing to providers who are used to a different approach under the traditional Physician Quality Reporting System. We also considered proposing to limit incorporation of the Physician Quality Reporting System incentive under the Shared Savings Program to the ACO's group practices that were used for beneficiary assignment rather than to all group practices associated with an ACO. However, we thought expanding the Physician Quality Reporting System incentive under the Shared Savings Program to all participant TINs within an ACO would be more efficient for EPs participating in both traditional Physician Quality Reporting System and the Physician Quality Reporting System and the Physician Quality Reporting System incentive under the Shared Savings Program. This way ACOs would report one way for the Physician Quality Reporting System for all of its ACO providers/suppliers who are eligible professionals; that is, for purposes of qualifying for the Physician Quality Reporting System incentive, the ACO would not need to report one way for the TINs used for beneficiary assignment and another way for the TINs not used for assignment. Another option we considered was to incorporate the eRx Incentive Program's incentive requirements and payments into the Shared Savings Program. However, we are not proposing to incorporate the eRx incentive requirements and payments under the Shared Savings Program since the eRx incentive ends after 2013. We believe it would be burdensome to require ACOs to incorporate the eRx incentive requirements for only a 2-year period.

In concert with the proposal for 50 percent of primary care physicians to be meaningful EHR users by the second performance year, we seek 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 request public comment related to circumstances where the ACO may only include one eligible hospital or no hospital and whether we would need to provide an exclusion or exemption in such a circumstance.

We also considered limiting the metrics related to percentage of meaningful users to be applicable to the Medicare EHR Incentive Program only, since presumably ACO providers/suppliers may see a high proportion of Medicare FFS patients. However, we realize that ACO providers/suppliers eligible for the EHR incentive may seek to qualify for the EHR incentive through any of the EHR Incentive Programs available to Medicare and Medicaid eligible professionals and hospitals. Finally, we considered incorporating EHR Incentive Program's incentive requirements into the Shared Savings Program, however, per the previous discussion, we did not believe the program was ready for incorporation at this time. Furthermore, we are proposing that ACOs report quality measures as a group, and the EHR Incentive program does not include a group reporting option at this time.

We invite comment on our proposal to incorporate Physician Quality Reporting System requirements and payments and certain metrics related to under the Shared Savings Program, as well as the options discussed previously that we considered.

6. Public Reporting

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. Examples of existing efforts that improve transparency include Hospital Compare, which enables patients along with their family and health care providers to compare the quality of care provided in the hospitals that agree to submit data on the quality of certain services they provide for certain conditions. Hospital Compare displays the following kinds of information:

- Rates for process of care measures that show whether or not hospitals provide some of the care that is recommended for patients being treated for a heart attack, heart failure, pneumonia, asthma (children only) or patients having surgery.
- Information on hospital outcome of care measures, including 30-day risk adjusted death (mortality) and readmission rates.
- Data collected from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey, reflecting patients' hospital experiences.
- Medicare inpatient hospital payment information.
- The number of Medicare patients treated for certain illnesses or diagnoses (as reported by Medicare severity-diagnosis related groups (MS–DRGs)).

(For more information, see the Hospital Compare Web site at *http://www.hospitalcompare.hhs.gov/hospital-search.aspx?AspxAutoDetectCookieSupport=1.*)

Similarly, Nursing Home Compare reports detailed information about every Medicare and Medicaid-certified nursing home in the country. Nursing Home Compare includes comparative information on health inspection results such as: (1) An assessment of the care of residents; (2) the process of care; (3) staff and resident interactions; and (4) the nursing home environment; (5) nursing home staffing; and quality measures. (For more information, see the Nursing Home Compare Web site at *http://www.medicare.gov/NHCompare/Include/DataSection/Questions/SearchCriteriaNEW.asp?version=default&browser=*

*IE%7C6%7CWinXP&language=English&defaultstatus=0&pagelist=Home&CookiesEnabledStatus=True.*)

The Affordable Care Act included several new initiatives that will expand transparency in the Medicare program. Among these, section 3003 of the Affordable Care Act will make aggregate information on physician resource use publicly available; section 3004 of the Affordable Care Act will make quality data relating to long-term care hospitals, inpatient rehabilitation facilities, and hospices publicly available; and section 3005 of the Affordable Care Act will make quality data for certain cancer hospitals publicly available. Similarly, section 10331 of the Affordable Care Act requires the Secretary to develop a Physician Compare Internet Web site by January 1, 2011 with information on physicians enrolled in the Medicare program and other eligible professionals who participate in the Physician Quality Reporting Initiative. Not later than January 1, 2013, the Secretary must also implement a plan for making information on quality and patient experience measures publicly available. Further, in developing this plan and as determined appropriate, the Secretary must consider the plan to transition to a value-based purchasing program for physicians and other practitioners developed under section 131 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275). Section 10332 of the Affordable Care Act requires the Secretary to make certain standardized claims data under Medicare Parts A, B, and D available to entities qualified by the Secretary to use these data to evaluate the performance of providers of services and suppliers on measures of quality, efficiency, effectiveness, and resource use.

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 ACOs to be willing to "become accountable for the quality, cost, and overall care" of the Medicare beneficiaries assigned to it.

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 by making available information that enables ACO professionals to assess their performance relative to their peers, and creates incentives for those professionals to improve their performance. For example, the transparency of outcomes that results when consumers have access to publicly reported performance information could be an important catalyst for providers to continually seek to improve their performance. Further, many other stakeholders, including health plans, employers, and policy makers have an interest in knowing the degree to which different health care delivery models are effective in improving quality and reducing costs. Timely dissemination of reports on ACO quality and cost performance will contribute to the dialogue, at the national, regional and local level, on how to drive improvement and innovation in health care.

Therefore, 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—specifically, information regarding: (1) Providers and suppliers participating in the ACO; (2) parties sharing in the governance of the ACO; (3) quality performance standard scores; and (4) general information on how an ACO shares savings with its members. We are proposing that certain information regarding the operations of the ACO would be subject to public reporting to the extent administratively feasible and permitted by law. Specifically, we propose that the following information regarding the ACO be publicly reported:

- Name and location.
- Primary contact.
- Organizational information including—
  - ++ ACO participants;
  - ++ Identification of ACO participants in joint ventures between ACO professionals and hospitals;
  - ++ Identification of the ACO participant representatives on its governing body; and
  - ++ Associated committees and committee leadership.
- Shared savings information including—
  - ++ Shared savings performance payment received by ACOs or shared losses payable to us; and
  - ++ 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.
- Quality performance standard scores.

In the interest of transparency, it is important that the ACO make available to the public information on its accountability for the quality, cost, and the overall care furnished to its assigned beneficiary population. We are proposing that each ACO be responsible for making this information available to the public in a standardized format that we will make available through subregulatory guidance. This requirement would be included in each ACO's 3-year agreement.

We seek comments on our proposals, including whether the proposed list includes elements that should not be required, or excludes elements that are important for achieving transparency or meaningful public disclosure within the Shared Savings Program and whether we should standardize the format or allow ACOs the flexibility to try different and innovative approaches for providing this information to beneficiaries. We welcome comment on these requirements and new reporting requirement recommendations that could be considered for future program years through future rulemaking. Also, we seek comment on whether ACOs themselves should be required to make this information publicly available or whether ACOs should report this information to us, and we would then make this information publicly available.

7. Aligning ACO Quality Measures With Other Laws and Regulations

The standards for Accountable Care Organizations proposed in this rule are among the first quality standards for doctors and health care organizations established under the Affordable Care Act. As such, we believe that they represent an opportunity to continue a robust discussion between the Federal government, affected parties such as physicians, hospitals, and patients, and all other stakeholders on developing and aligning the best possible framework for ensuring quality care. The Act directs the Department to promulgate quality standards and require accountability or reporting in several sections. It calls for a National Quality Strategy that was released on March 21, 2011. We have already proposed standards for inpatient hospitals and the Medicaid program through rulemaking, as well as the standards for ACOs outlined in this rule. These standards affect different constituencies, including physicians, hospitals, other providers, and patients and their families. As such, we have proposed distinct domains and

categories of quality measures, and different frameworks for rewarding performance, under each Affordable Care Act program as illustrated in Table 5.

**Table 5: Quality Frameworks for Affordable Care Act Programs**

| Domain |
|---|
| **Proposed for Medicare Shared Savings Program: Accountable Care Organizations** |
| Patient/Caregiver Experience |
| Care Coordination |
| Patient Safety |
| Preventive Health |
| At-Risk Population/Frail Elderly Health |
| **Proposed for Initial Core Set of Health Quality Measures for Medicaid-Eligible Adults** |
| Prevention and health promotion |
| Management of Acute Conditions |
| Management of Chronic Conditions |
| Family Experiences of Care |
| Availability |
| **Proposed for Hospital Inpatient Value-Based Purchasing Program** |
| Process Measures |
| Outcome Measures |
| Survey Measures |
| **National Health Care Quality Strategy and Plan** |
| Patient-centeredness and family engagement |
| Eliminating disparities in care |
| Better care |
| Affordable care |
| Healthy communities |

While these quality domains and categories—and the parties that they affect—overlap in a number of areas, each set of standards has different domains, categories, and specific measures. We recognize that 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. We seek 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 seek 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.

*F. Shared Savings Determination*

1. Background

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 ACOs 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.E. of proposed 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 the 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 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 payment models.

We considered 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 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 risk might be more accessible and attract smaller group participation. However, as some commenters suggest, 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 of health care delivery and cost. Therefore, we considered whether we should instead focus on our authority under section 1899(i) of the Act to create a 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 option 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 risk-based approach under section 1899(i) of the Act. The hybrid approach would have the advantage of providing 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 while also 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.

Based on the input of commenters on the November 17, 2010 RFI, other stakeholders and policy experts we are proposing to implement a hybrid approach. Specifically, we are proposing that ACOs participating in the Shared Savings Program will 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 will 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 any losses that may be generated as well as savings. The portion of shared losses that the ACO would be at risk for in the third year of the agreement is further described in section II.G. of this proposed rule. 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.

Track 2: More experienced ACOs that are ready to share in losses with greater opportunity for reward may elect to immediately enter the two-sided model (as discussed in section II.G. of this proposed rule). An ACO participating in Track 2 would be under the two-sided model for all three 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.

Unless specifically noted, the elements discussed in the rest of this section will apply to both the one-sided and two-sided models. Section II.G. of this proposed rule provides additional detail regarding aspects of the two-sided model that are not discussed in this section.

We seek comment on our proposal and the alternatives discussed previously.

2. Overview of Shared Savings Determination

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 FFS 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 will 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 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.E. of this proposed 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 (that is, assigning patients to ACOs for purposes of quality and financial performance measurement) 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, such as to avoid potentially disadvantaging various types of providers (for example, hospitals that receive Medicare disproportionate share hospital payments (DSH hospitals) or teaching hospitals that receive indirect graduate medical education (IME) payments) or ACOs located in high cost, or low cost, areas; 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 of the 3 performance years of the agreement period with the ACO.

Second, we must compare the benchmark to the assigned beneficiary per capita Medicare expenditures in each performance year under the agreement period 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 above 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 proposals for addressing them, in this section.

3. Establishing an Expenditure Benchmark

a. Background

Section 1899(d)(1)(B)(ii) of the Act specifies several requirements with regard to establishing an ACO's benchmark.

- 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."

A useful way to view the benchmark is as a surrogate measure of what the Medicare FFS Parts A and B expenditures would otherwise have been in the absence of the ACO. Once the savings realized by the ACO exceed a margin for normal variation in expenditures from year-to-year (what we call the MSR described in more detail later in this proposed rule), the difference between actual expenditures of the ACO's assigned beneficiaries during each year of the agreement period and its benchmark (updated, according to statute as described in more detail later in the document) should reflect how well the ACO is coordinating care for these beneficiaries and improving the overall efficiency of their care.

An accurate benchmark estimate is important in order to ensure that an ACO that successfully coordinates care and achieves real savings is rewarded with shared savings. Similarly, an accurate benchmark estimate helps to ensure that shared savings are not inadvertently paid to an ACO that does not successfully coordinate care well or that has not achieved savings in excess of normal variation in annual expenditures.

We have considered two legally permissible approaches to meeting the statutory language for estimating the benchmark, which we will call Option 1 and Option 2 in this proposed rule. Both approaches involve benchmarks that are 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, the benchmark would also be reset at the start of each agreement period. However, a key difference between these two approaches is the beneficiary population used to determine expenditures for purposes of the benchmark. Specifically, under Option 1, we would estimate 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. In contrast, under Option 2, the benchmark would be based on the Parts A and B FFS expenditures of beneficiaries, who are actually assigned to the ACO during each performance year, with the expenditures being those incurred in the 3 years immediately preceding the ACO's agreement period for those assigned beneficiaries. We describe these two options later in this document. In this proposed rule, we are proposing Option 1 to establish each ACO's benchmark; however, we solicit comments on both options.

b. Option 1

Under Option 1, we would estimate the benchmark for an ACO for an agreement period starting with the TINs of ACO participants identified at the start of the agreement period. The same rules that will be used to determine assignment of beneficiaries to ACOs during the agreement period would be applied to these data. Accordingly, consistent with the assignment methodology proposed in section II.D. of this proposed rule, we would use the claim records of these ACO participants to determine a list of beneficiaries who received a plurality of their primary care services from primary care physicians participating in the ACO in each of the prior 3 most recent available years.

Using the per capita Parts A and B FFS expenditures for beneficiaries that would have been assigned to the ACO in each of these 3 prior years, we will estimate a fixed benchmark that is adjusted for overall growth and beneficiary characteristics, including health status using prospective HCC adjustments (as discussed in section 3 later in this document). This benchmark would then be updated annually during the agreement period, according to statute, based on the absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program.

- The first step in this process is to calculate annual Parts A and B FFS per capita expenditures for the beneficiaries who would have been assigned for each of the benchmark years. To minimize variation from catastrophically large claims, we would 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 (for example roughly $100,000 in 2008). We would also truncate an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile as

determined for each subsequent performance year.

• Next, using our Office of the Actuary national Medicare expenditure data for each of the years making up the benchmark, we would determine an appropriate growth index and trend them to benchmark year 3 (BY3) dollars. Our proposed method for trending expenditures is discussed in section II.F.7.of this proposed rule.

• Using health status measures for the beneficiary population in each of the years making up the benchmark, we would establish health status indices for each year and adjust so they are restated to reflect BY3 risk. Our approach to account for health status is discussed section II.F.3. of this proposed rule.

• Next, we would compute a 3-year risk-and growth-trend adjusted per capita expenditure amount for the patient populations in each of the 3 benchmark years by combining the initial per capita expenditures for each year with the respective growth and health status indices. This yields risk adjusted per capita expenditures for beneficiaries historically assigned to the ACO in each of the 3 years used to establish the benchmark stated in BY3 risk and expenditure amounts.

• We propose to weight the most recent year of the benchmark, BY3 at 60 percent, BY2 at 30 percent and BY1 at 10 percent so that we can ensure the benchmark reflects more accurately the latest expenditure and health status of the ACO's assigned beneficiary population. This weighting allows us to establish lower MSRs since the weighting results in a more accurate benchmark.

• Last, as required by statute, for each performance year we would update 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 FFS program using data from our Office of the Actuary. This approach for updating the benchmark avoids current law issues associated with Medicare expenditure projections since it uses the actual claims and expenditure experience for Medicare patients to calculate the factor used to update the benchmark for purposes of annual reconciliation. Consistent with the statutory requirement, the benchmark and its associated computations would only be rebased at the start of a new agreement period.

As described in section II.C. of this proposed rule, if requested by the ACO, we are proposing to provide the ACO with aggregated data and information on beneficiaries that would historically have been assigned to the ACO and, as a result, have a likelihood of being assigned during the agreement period.

It is possible that to the extent that an ACO's population or its composition of ACO providers/suppliers change over time, the assigned population could diverge from the benchmark population, potentially affecting the comparability of performance measurement. Modeling the PGP demonstration data using the proposed primary care based assignment methodology revealed that assignment of beneficiaries varies from year-to-year, with about 25 percent of those assigned in one year not being assigned in the subsequent year (due to relocation, death, participation in MA, or changes in their choice of care professionals). This was consistent across organizations participating in the demonstration which were also geographically diverse. We believe the approach to establishing the benchmark described previously would provide a relatively accurate reflection of the average population of Medicare FFS beneficiaries that receive their care from the ACO participants during the ACO agreement period. However, because the FFS population served by the ACO changes from year to year, some of the beneficiaries whose expenditures would be included in the benchmark with this approach would not be reflected in the population assigned to the ACO during the years of the ACO agreement period. It is also possible that this benchmark approach could provide unwanted incentives to seek and/or avoid specific beneficiaries during the agreement period so that average expenditures would more likely be less than for their historical beneficiaries included in the benchmark. Therefore we also considered a second option that relies on developing a benchmark based on the populations of specific beneficiaries who are actually assigned to the ACO during the agreement period.

c. Option 2

Under this option, for each beneficiary assigned to the ACO during the agreement period, we would calculate their per capita Parts A and B FFS expenditures during each of the 3 years immediately preceding the first year of the agreement period. These amounts would be trended to the start of the agreement period as was described for Option 1, that is, since Option 2 also requires risk adjustment, we will adjust the benchmark for health status using the same prospective CMS–Hierarchal Condition Category (CMS–HCC) risk adjuster and apply it to calculate the benchmark in the same manner as described for Option 1.

To meet the statutory requirement to adjust the benchmark for "beneficiary characteristics" we would adjust the annual per capita expenditures to account for changes in health status.

For beneficiaries without 3 full years of immediately-prior Medicare eligibility (such as beneficiaries who were not 68 in their first year assigned to the ACO), a further adjustment would be necessary under this option.

• For those beneficiaries with less than one full year of prior Medicare experience, we would either—

++ Use a substitute for their own expenditures in the update amount within the benchmark, that is, substitute the average per capita FFS expenditures for all Medicare beneficiaries during the year they are first assigned to the ACO, adjusted for health status (as described later in the document in section 3); or

++ Exclude their experience from the shared savings computations.

• For those assigned beneficiaries with more than 12 months prior Medicare experience but less than 36 months we also have two choices:

++ Compute a weighted-average (using number of months as the weight) that blends.

—Their prior expenditure experience and

—The average per capita Parts A and B FFS expenditures for all Medicare beneficiaries during the year before the first year they are assigned to the ACO, adjusted for health status; or

++ Use only their prior expenditure experience.

We seek comments about these adjustment approaches and solicit other approaches we might consider.

After the benchmark is adjusted for beneficiary health status, the benchmark would also be updated by the applicable projected amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program as was described for Option 1.

For the second and third year of the agreement period, we would make no further adjustments for assigned beneficiaries who were also assigned in the first year of the ACO agreement period. However, in the second and third year of the agreement, there will also be newly-assigned beneficiaries as well as previously-assigned beneficiaries who are no longer assigned to the ACO. The benchmark would be adjusted to account for these changes. We would adjust the benchmark by adding the experience of the newly-assigned beneficiaries (as discussed previously for the first year) for the 3 years prior to the agreement period, and

by removing the prior experience of the no-longer assigned beneficiaries. In the case of a beneficiary who was assigned during the first year, not assigned during the second year, and then again assigned during the third year of the ACO's agreement period, the prior expenditure experience that would be used to adjust the benchmark in the third year would be the same amount initially used for their first year of assignment. These adjustments would yield a benchmark for each ACO that is estimated using beneficiary expenditures for the three years prior to the agreement period for only those beneficiaries that were actually assigned to the ACO during that year of the agreement period.

Additionally, Option 2 would require an adjustment for assigned beneficiaries who die during an agreement year. We know that approximately 5 percent of all Medicare beneficiaries die in a single year, and that their average monthly expenditures are often higher during this last year of life compared to the immediately preceding years. For these beneficiaries, the benchmark might therefore not be a fair basis for comparison with actual expenditures for purposes of determining shared savings, which could create incentives for ACOs to avoid assignment of beneficiaries who may be in their last year of life or treat such beneficiaries differently. This would not be the case for Option 1 as that benchmark approach would include the average per capita costs of beneficiaries who died during the benchmark period. We are therefore considering one of two methods to adjust for this beneficiary characteristic within Option 2.

Under the first method for adjusting for decedents, we would propose to exclude the expenditures of deceased beneficiaries from actual expenditures during the agreement period. We believe this approach would best avoid concerns about creating incentives for ACOs to avoid assignment of beneficiaries in their last year of life or treat such beneficiaries differently. In a second method for adjusting for decedents, we would compare average expenditures for each deceased beneficiary during the agreement year to the average expenditures for beneficiaries included in the benchmark.

- If the agreement year's expenditures were 5 percent or less above the benchmark, we would make no adjustment;
- If the agreement year's expenditures were greater than 5 percent above the benchmark, we would need to decide upon an acceptable method to adjust the accumulated expenditures for deceased beneficiaries.

Of these two methods for adjusting for decedents during the course of the performance year under Option 2, our preference is for the first method. However, we invite comments on both of these methods, and any others that might be suggested for adjusting for decedents during the course of the performance year under Option 2.

The second method is intended to address the implications of changes to an ACO's population over time, but this option would require additional data adjustments and computations that are not required under the first method.

However, to the extent that average per capita expenditures for all beneficiaries differs from the average for the geographic area in which an ACO operates, the first method previously discussed would effectively be imputing a value that is likely to be somewhat higher or lower than would actually be expected for that ACO. Alternatively, excluding the experience of beneficiaries with less than 1 full year of experience from the shared savings computations as contemplated in the second method previously discussed, would reduce the size of an ACO's beneficiary population, increasing the MSR that would be needed before an ACO would be eligible to share savings. This could have the effect of discouraging participation among smaller ACOs, for example, in rural areas. Likewise, we would expect a similar impact on an ACO's MSR if deceased beneficiaries were excluded from the shared savings computations as is previously proposed.

d. Summary

We believe both Option 1 and Option 2 are legally permissible approaches to setting the expenditure benchmark, adjusting for beneficiary characteristics, and updating by the projected absolute amount of growth in national per capita expenditures. We also believe that both approaches can establish viable benchmarks to measure ACO performance over time and provide incentives for ACOs to improve their processes and outcomes during the agreement period.

We are proposing to adopt Option 1 for establishing ACO benchmarks, but seek comments on the merits and limitations of both options, particularly with respect to how each approach might affect the willingness of ACOs or particular types of ACO to participate in the Shared Savings Program, create incentives for ACOs to seek or avoid certain kinds of beneficiaries, and impact Medicare expenditures. Moreover, we will continue to examine the merits and potential effects of both options over the next several months. If, based on our findings and the comments received in response to this proposal, we determine that Option 2 would be a more appropriate method for establishing a benchmark, we would expect to adopt that option in the final rule.

4. Adjusting the Benchmark and 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 of treating a patient mix with better health status than the patient population reflected in the benchmark. On the other hand, some organizations may share in savings on a risk adjusted basis but would not have shared in savings if expenditures were not risk adjusted.

Beneficiary health status can be measured using various tools, under which beneficiaries are typically assigned "risk scores" that reflect their demographic and diagnostic conditions and offer an estimate of the relative extent to which they are likely to utilize medical services compared to other beneficiaries. Performance payments are a function of the ACO's success in controlling expenditure growth and changes in the health status of the assigned population, thus they are sensitive to changes in risk scores. However, an ACO's ability to share in savings can be affected not only by changes in the health status of a 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. 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 ACOs organizational structure that would affect the case mix of assigned patients rather than apparent changes arising from the manner in which ACO providers/suppliers code diagnoses. Thus, 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.

The statute clearly calls for the characteristics of the beneficiaries assigned to an ACO to be taken into account in estimating both an ACO's benchmark and its expenditures during the agreement period. This requirement helps to ensure that quality and efficiency in the delivery of health care services are the basis for realizing and sharing savings under the Shared Savings Program. Because we want to create an environment where ACOs are encouraged to effectively coordinate care for beneficiaries with complex illnesses, and not create an environment where ACOs have incentive to avoid these types of beneficiaries, we believe that relative health status is one such beneficiary characteristic that should be reflected in the calculation of average per capita expenditures for purposes of both the benchmark and actual expenditures during the agreement period. We have considered two basic options for risk adjusting the average per capita expenditures in order to reflect beneficiary characteristics.

One option is to employ a method that considers 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 is to employ a methodology that incorporates diagnostic information, specifically the CMS–HCC prospective risk adjustment model that has been used under the MA program. In addition to demographic variables, the CMS–HCC prospective risk adjustment model uses beneficiaries' prior year diagnoses to develop risk scores that are then applied to their current year expenditures. The model is widely accepted by payers and providers, and risk scores are annually calculated for all Medicare beneficiaries by us, so readily available data can be incorporated into the Shared Savings Program. Additional information on the CMS–HCC model can be found in the Advance Notice of Methodological Changes for Calendar Year (CY) 2011 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2011 Call Letter, which can be found at *http://www.cms.gov/MedicareAdvtgSpecRateStats/Downloads/Advance2011.pdf* and *http://www.cms.gov/MedicareAdvtgSpecRateStats/Downloads/Announcement2011.pdf*.

As discussed previously, a key issue when using a risk adjustment model that incorporates diagnosis data is that risk scores can be affected not just by changes in the health status of the population but also by changes in coding intensity and by the mix of specialists and providers furnishing services. The experience in MA clearly shows that health plans can significantly increase the HCC score of their populations by focusing on more complete coding. Similarly, our experience with the PGP demonstration shows that participating sites have an incentive to code more fully or intensely because of the potential impact on performance payments, to provide more accurate measurement and reporting of quality measures, as well as to provide for more complete and accurate information that can be used for population management.

If we adopt a risk adjustment methodology in the Shared Savings Program that incorporates diagnostic data, we expect that ACOs would have a similar incentive to code more fully for purposes of population management, quality reporting and to optimize their risk scores for the purpose of achieving shared savings. Because they are responsible for the delivery of care, and can control the information included in Parts A and B claims, the ACO providers/suppliers could potentially increase the risk scores for their FFS patients by more completely reporting diagnoses. The practical effect of increasing risk scores would be to decrease the actual annual expenditures compared to the benchmark, because the benchmark would be increased to reflect changes in the ACO's risk score, while actual expenditures would not change. As a result, the ACO's chances of demonstrating savings and receiving a shared savings payment would improve. Behaviors such as these could allow an ACO to achieve apparent savings by coding changes alone and without improved methods of beneficiary care.

We have made adjustments to account for the upward trend in risk scores in other programs. For example, for the MA program we make adjustments to account for the upward trend in FFS diagnostic coding and CMS–HCC model changes through normalization factors and coding intensity adjustments. Another approach to addressing this upward trend in diagnostic coding would be to incorporate an annual cap in the amount of risk score growth we would allow for each ACO. One option for setting the annual cap could be setting a fixed growth percentage for all ACOs, and any increase in risk score growth above the cap would be negated. A challenge to this approach would be determining a generally acceptable sized cap. A second option would be to 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. This would establish an annual cap, that is based on experience specific to each individual ACO and would thus result in an individually calculated cap for each ACO. Yet another alternative we considered for addressing the upward trend in coding intensity would be to use a methodology similar to the MA methodology that would reduce the amount of growth in the risk scores for beneficiaries assigned to the ACOs, but continue to allow increases. However, modeling this approach showed that it would reward those organizations with exceptionally high risk score growth while penalizing organizations that do not engage in efforts to more completely and accurately code since their risk score growth could go negative if they did not code sufficiently intensively.

A model that uses beneficiary demographic factors alone would avoid this issue, and may be simpler administratively precisely because it employs a more restricted range of factors. We have therefore also considered implementing the MA "new enrollee" demographic risk adjustment model. This model includes adjustments for age, sex, Medicaid enrollment status and originally disabled status. Such a model, however, would not take into account the health status of the assigned beneficiaries which could have a particularly 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. Therefore, we are proposing to adjust Medicare expenditure amounts by employing the CMS–HCC model used in the MA program.

The CMS–HCC model more accurately predicts health care expenditures than the demographic-

only model as it accounts for variation in case complexity and severity. In addition, incorporating diagnosis data in the risk adjustment model will encourage ACOs to maintain complete and accurate medical documentation which could result in better information for population management, care coordination, and quality improvement. ACOs will have an incentive to code more completely and accurately, as is the case with MA plans, and behaviors such as these could allow an ACO to achieve apparent savings by coding changes alone and without improved methods of beneficiary care. We do not want to create an environment that rewards ACOs for achieving apparent savings by coding changes alone. Additionally, we expect the ACO's average population risk scores to be stable over time, given that there is 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 an incentive to increase coding. As a result, we believe the benchmark risk adjustment score for the ACO's historically assigned beneficiary population will 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 propose to calculate a single benchmark risk score for each ACO. The same risk score will then be applied throughout the agreement period to the annual assigned patient populations per capita expenditures for assigned beneficiaries. The benchmark risk score will be calculated by applying the CMS–HCC model to the assigned beneficiary population attributed in each year of the 3-year benchmark. However, changes in the assigned beneficiary population risk score from the 3-year benchmark period during the performance year will not be incorporated. By not incorporating the effects of changes in coding intensity during the performance years (versus the benchmark), we will protect the program from costs due to greater diagnosis coding intensity in ACOs.

We welcome comments on this proposal including comments on alternative approaches such as using the MA "new enrollee" demographic risk adjustment model for risk adjusting in the Shared Savings Program or applying a coding intensity cap on annual growth in the risk scores of an ACO's assigned beneficiary population.

We intend to monitor and evaluate the issue of more complete and accurate coding as we gain experience with the Shared Savings Program, and would consider making revisions and adaptations to the final risk adjustment model through future rulemaking if they are warranted. Further, to assure the appropriateness of ACO coding practices and our methodology for risk adjusting, we are also proposing to retain our option to audit ACOs especially those ACOs with high levels of risk score growth relative to their peers and adjust the risk scores used for purposes of establishing the 3-year benchmark accordingly. We seek comment on this proposal.

5. Technical Adjustments to the Benchmark: Impact of IME and DSH

Section 1899(d)(1)(B)(ii) of the Act states that "Such benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate * * *." Several factors in the Medicare FFS payment systems can affect an ACO's ability to realize savings by adjusting payment rates and thus affecting both expenditures during the benchmark period and each subsequent performance year. Additionally, changes in these payment factors, between the benchmark and performance years can also influence whether an ACO realizes savings or incurs losses under the program.

Teaching hospitals receive additional payment to support medical education through an indirect medical education (IME) adjustment. In addition, hospitals that serve a disproportionate share of low-income beneficiaries also receive additional payments, referred to as the Medicare disproportionate share hospital (DSH) adjustment. Many hospitals, especially academic medical centers, receive both these adjustments, which can provide substantial increases in their Medicare payments compared to hospitals that do not qualify for these adjustments. 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.

We have 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, section 1899(d)(1)(B)(i) of the Act only provides authority to adjust expenditures in the performance period for beneficiary characteristics and does not provide authority to adjust for "other factors". Therefore, while we may adjust the benchmark under this provision by removing IME and DSH payments, we could not also do so in our calculation of performance year expenditures. If we were to remove IME and DSH payments from the benchmark, the benchmark would be set artificially lower relative to the performance period, thus making it more difficult for an ACO to overcome and achieve savings under this program. In addition, excluding these payments would result in an artificial and incomplete representation of actual spending of Medicare Trust Fund dollars. Further, 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 a national standard ("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. Additionally, we believe 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. For example, ACOs that include teaching and/or DSH hospitals in their network might be more interested in joining the program if we do not remove these payments from the calculations. This is because including these payments would result in higher benchmarks against which such ACOs would work to achieve savings, and such ACOs may be able to earn back a portion of forgone IME/DSH payments in the form of shared savings in cases where a referral to a less intensive setting is most appropriate for the beneficiary.

Thus, we are not proposing to remove IME and DSH payments from the per capita costs included in the benchmark for an ACO. However, we invite comments on this issue, especially on how including or excluding these payments in the benchmark could likely affect access to medically necessary services provided at teaching/DSH hospitals. We will consider comments on this issue carefully, and in the light of these comments, we could adopt a policy in the final rule of adjusting the benchmark calculation in order to prevent any adverse effects on access to services at these hospitals.

6. Technical Adjustments to the Benchmark: Impact of Geographic Payment Adjustments on the Calculation of the Benchmark

Similarly, another factor in the Medicare FFS payment systems that could affect an ACO's ability to realize savings is the geographic payment adjustment (for example, the IPPS wage index adjustments and the physician fee schedule geographic practice cost index (GPCI) adjustments) that is generally made to payments under these systems. These adjustments increase and decrease payments under these systems to account for the different costs of providing care in different areas of the country. Further, 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.

As in the case of IME and DSH adjustments, we have considered removing these geographic payment adjustments from the calculation of the benchmark and actual expenditures. However, as with IME and DSH payments, we only have statutory authority under section 1899(d)(1)(B) of the Act to remove them from the benchmark and thus we cannot remove them from performance period expenditure calculations. Consistent with our proposed treatment of IME and DSH payments, we are not proposing to remove geographic payment adjustments from the calculation of benchmark expenditures. Again, we welcome comments on this issue and will especially consider comments on the likely impact of this proposal in areas that are affected by temporary geographic adjustments. After consideration of the comments, we could adopt a policy in the final rule of adjusting the benchmark calculation to remove the effects of these geographic payment adjustments.

7. Technical Adjustments to the Benchmark: Impact of Bonus Payments and Penalties on the Calculation of the Benchmark and Actual Expenditures

Medicare bonus payments are available and penalties may be imposed through value-based purchasing initiatives such as the Physician Quality Reporting System and the Health Information Technology for Economic and Clinical Health (HITECH) Act, which encourages hospital and physician adoption of electronic health records (EHR), and provides for penalties in subsequent years for those that do not demonstrate meaningful use of EHR. 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. As such, 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, such as the value-based purchasing and HITECH initiatives.

Section 1899(b)(3)(D) of the Act provides authority for the Secretary to incorporate, as the Secretary determines appropriate, the reporting requirements and incentive payments related to the Physician Quality Reporting System, eRx, EHR, and other similar initiatives under section 1848 of the Act. The statute provides that these incentive payments "shall not be taken into consideration when calculating any payments otherwise made under subsection (d)." Additionally, we believe it is important to ensure that these various programs' incentives are properly aligned so that their interactions support rather than impede each of the programs' goals.

Thus, consistent with our statutory authority, we are proposing to exclude Medicare expenditures or savings for incentive payments and penalties under section 1848 of the Act for value-based purchasing initiatives such as Physician Quality Reporting System, eRx, and the EHR incentives for eligible professionals under the HITECH Act from the computations of both benchmark and actual expenditures during the agreement period. We believe that excluding these costs and savings will reduce the chances that incentives that were intended to encourage and reward participation in one Medicare program would discourage full participation in another. We seek comments on this proposal.

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 not under section 1848 of the Act from benchmark and actual expenditures. Therefore, payments that are reflected in Part A and B claims for services furnished to assigned FFS beneficiaries, such as EHR incentive payments to hospitals and 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, (or any incentive payments not made under section 1848 of the Act) would be counted in both the computation of actual expenditures and benchmark expenditures for Part A and B costs.

8. Trending Forward Prior Years' Experience To Obtain an Initial Benchmark

Section 1899(d)(1)(B)(ii) of the Act requires the use of "the most recent 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. This benchmark is subsequently updated 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. Flat Dollar vs Growth Rate as a Benchmark Trending Factor

The statute does not specify the trending factor to be used in estimating the initial benchmark. Typically, prior years would be increased using a percentage growth factor. 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. The first option is to trend these expenditures forward using growth rates in expenditures for Parts A and B services for FFS beneficiaries. The second option is to trend 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.

An advantage of the first option is that the use of a growth rate, as opposed to a flat dollar amount, would more accurately reflect each ACO's historical experience. That is, in contrast to a flat dollar amount, this option would neither raise the bar for ACOs in historically higher growth rate areas nor lower it for ACOs in lower growth areas. At the same time, it could be argued that this option perpetuates current regional differences in medical expenditures. An advantage of the second option, using the flat dollar amount equivalent to the absolute amount of growth in per capita expenditures for Medicare Parts A and B under the FFS program, is that it is more consistent with the method designated by the under section 1899(d)(1)(B)(ii) of the statute for updating the benchmark (as described later in this proposed rule) during the agreement period. This option also provides 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.

On balance, we believe 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 are proposing 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. For example, we would use 2011, 2012 and 2013 claims year data to set the benchmark for an ACO starting its agreement period in 2014. The 2011 and 2012 data would be trended forward using the factor described later in this proposed rule so that all benchmark dollars would be in 2013 dollars. We welcome comments on this proposal, and especially on whether the other option that we considered to trend the benchmark by the flat dollar amount would be more consistent with our proposal to update the benchmark as specified under section 1899(d)(1)(B)(ii), as discussed in the next section.

b. National vs Local Growth Rate as a Benchmark Trending Factor

Under the option described previously, we could trend per beneficiary expenditures forward using national or local growth factors. Using the national growth rate in Medicare A and B FFS expenditures would appear to be more consistent with the methodology that, as specified in section 1899(d)(1)(B)(ii) of the Act incorporates the absolute amount of growth in per capita expenditures for Medicare Parts A and B nationwide under the FFS program in updating each ACO's benchmark. 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 later in this proposed rule the national average that would benefit from having a relatively higher base, which increases the chances for shared saving, while relatively discouraging development of ACOs in areas with historically higher growth rates above the national average that would have a relatively lower base.

In contrast, 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 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 would balance providing a more accurate reflection of local experience with not rewarding historical growth higher than the average. This method also instills strong saving incentives for ACOs in both high-cost growth and low-cost growth areas.

After considering both of these alternatives, we are proposing to employ the national growth rate in Medicare Parts A and B expenditures for FFS beneficiaries for trending forward the fixed benchmark. We believe this approach will help to ensure that ACOs in both high spending, high growth and low spending, low growth areas will have appropriate incentives to participate in the Shared Savings Program, while also moving toward establishing a national standard for calculating and measuring ACO financial performance. We seek comment on this proposal and on the alternatives to using a national growth rate as outlined previously.

9. Updating the Benchmark During the Agreement Period

Section 1899(d)(1)(B)(ii) states that the benchmark shall be "updated by the projected absolute amount of growth in national per capita expenditures". We believe that Congress demonstrated an interest in mitigating some of the regional differences in Medicare spending among ACOs by requiring the use of a flat dollar amount equivalent of the absolute amount of growth in national FFS expenditures to update the benchmark for the agreement period. In effect, 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.

However, we also considered our authority under Section 1899(i) for an alternative option. Specifically, we considered an option 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. Incorporating more localized growth factors reflects the expenditure and growth patterns within the geographic area served by ACO participants and ACO providers/suppliers, 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 prevents the update from disproportionately allowing relatively larger dollar-amount updates for high-spending areas that potentially have a stronger ability to improve care coordination and efficiency from current levels. Not using the national flat-dollar update for low-spending, low-growth areas ensures that the Medicare Shared Savings Program instills strong saving incentives for ACOs in low-cost areas, as well as for those in high-cost areas. Also, as noted in section V.C.1. of this proposed rule, using the national flat-dollar update as specified in section 1899(d)(1)(B)(ii) for all ACOs could contribute to selective

program participation that could result in Medicare costs due to an increase in the amount of bonus payments for unearned savings.

In keeping with section 1899(d)(1)(B)(ii) of the Act, we are proposing to update the benchmark by the projected absolute amount of growth in national per capita expenditures. We believe this approach will help to ensure that ACOs in both high spending, high growth and low spending, low growth areas will have appropriate incentives to participate in the Shared Savings Program. We seek comment on this proposal and on the alternative to update 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 under section 1899(i) of the Act.

10. Minimum Savings Rate (MSR) and Sharing Rate

Section 1899(d)(1)(B)(i) of the Act provides that "an ACO shall be eligible to receive payment for shared savings under paragraph (2) 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 * * *." That provision further states 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)(1)(B)(ii) 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."

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, 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 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 the real quality and efficiency gains, and offer greater protection to the Medicare Trust Funds. However, due to the larger barrier to achieve 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.

We believe 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. For the one-sided model we are proposing 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.

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.E. of this proposed rule. 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.

In order to improve the opportunity for groups of solo and small practices to participate in the Shared Savings Program, we are proposing 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 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 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.

The MSRs are 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 propose to set the confidence interval to 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 propose to set the confidence interval to 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 propose blending the MSRs between the two neighboring confidence intervals, resulting in the MSRs as shown in Table 6. We specify 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 their 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 aligned beneficiaries, we propose that the MSR would not be allowed to fall below 2 percent. This lower bound is 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 propose to use in the two-sided model and is the minimum level that was used in the PGP Demonstration for groups regardless of size which also provided a lower MSR for smaller physician groups participating in the demonstration.

We considered using a flat 95 percent confidence interval for organizations which is a recognized standard for measuring statistical differences, but as previously noted, because we believe that many smaller physician-driven and rural ACOs have the potential to improve the quality and efficiency of care, we were concerned about the impact on the ability of these ACOs to participate in the Shared Savings Program. We also wanted to protect the Medicare Trust Funds against large organizations coming together solely for purposes of aggregating their number of assigned beneficiaries in order to have smaller MSRs to be able to achieve the minimum required savings levels and share in savings with little or no actual improvement in the quality and efficiency of care provided to beneficiaries.

The proposed confidence intervals were determined assuming that the variation in the per capita expenditure growth for a particular ACO is equal to the variation in per capita expenditure growth nationally. This is not 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 overstate the relative confidence associated with an increasing group size. This is compensated for in two ways: (1) The 2 percent floor; and (2) increasing the confidence interval as group size increases.

**Table 6. Minimum Savings Rate and Confidence Intervals by Number of Assigned Beneficiaries (One-Sided Model)**

| Number Beneficiaries | MSR (low end of assigned beneficiaries) | MSR (high end of assigned beneficiaries) |
|---|---|---|
| 5,000 - 5,999 | 3.9% | 3.6% |
| 6,000 - 6,999 | 3.6% | 3.4% |
| 7,000 - 7,999 | 3.4% | 3.2% |
| 8,000 - 8,999 | 3.2% | 3.1% |
| 9,000 - 9,999 | 3.1% | 3.0% |
| 10,000 - 14,999 | 3.0% | 2.7% |
| 15,000 - 19,999 | 2.7% | 2.5% |
| 20,000 – 49,999 | 2.5% | 2.2% |
| 50,000 – 59,999 | 2.2% | 2.0% |
| 60,000 + | 2.0% | |

We welcome comments on the most appropriate means to establish the MSR for an ACO, including the appropriate confidence intervals.

11. Net Sharing Rate

Section 1899(d)(2) 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 could 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 the MSR was exceeded. 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 have concerns that sharing on first dollar could result in sharing on unearned savings rather than on savings achieved by the ACO for redesigned care processes.

Therefore, we considered another alternative which would be to 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 in the previous section, 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 share savings in excess of a certain threshold. ACOs meeting certain criteria could be exempted from this provision and be 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 participants. Additionally, we have experience with this model through the PGP demonstration.

We are proposing the third option, that is, we propose that once an ACO has surpassed its MSR, the ACO would share in savings beyond a certain threshold. We further propose 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 (earned quality performance sharing rate and additional increases for including FQHCs and/or RHCs) would be applied to net savings above this 2 percent threshold in order to determine the shared savings amount. We believe that this threshold protects the program from sharing unearned savings and helps 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 right away (and be eligible for greater reward) of the two-sided model. As such, we are proposing that ACOs that meet the following criteria would be exempt from the 2 percent net savings threshold and would instead share on first dollar savings under the one-sided model. We propose to exempt ACOs with less than 10,000 assigned beneficiaries in the most recent year for which we have complete claims data (for instance, 2012 for 2014 program participation) and that meet one of the following:

- The ACO is comprised only of ACO professionals in group practice arrangements or networks of individual practices of ACO professionals.
- 75 percent or more of the ACO's assigned beneficiaries reside in counties outside a Metropolitan Statistical Area (MSA) in the most recent year for which we have complete claims data.
- 50 percent or more of the ACO's assigned beneficiaries were assigned to the ACO on the basis of primary care services received from a Method II CAH.
- 50 percent or more of the beneficiaries assigned to the ACO had at least one encounter with an ACO participant FQHC and/or RHC in the most recent year for which we have complete claims data, that is, the ACO has met criteria for receiving full potential additional payment as described later in this proposed rule.

We invite comment on these proposals and the other options considered.

12. Additional Shared Savings Payments for Including FQHCs and/or RHCs

We are also proposing that an ACO in the one-sided model can receive an increase in its shared savings rate of up to 2.5 percentage points during the first 2 years of its agreement, for including a strong FQHC and/or RHC presence within the structure of the ACO. (See section II.G. of this proposed rule for details surrounding the two-sided model which provides for a 5 percentage point increase for including FQHCs or RHCs or both.)

FQHCs and RHCs have long delivered comprehensive, high-quality primary health care to patients regardless of their ability to pay, and increase access to health care through innovative models of community-based, comprehensive primary health care that focus on outreach, disease prevention, and patient education activities. FQHCs provide high-quality care to rural and urban populations alike by focusing attention on improving public health through preventive care in addition to direct patient care. Not only do health centers provide critical, high quality primary care in the Nation's neediest areas, but reports have shown that the

health center model of care can reduce the use of costlier providers of care, such as emergency departments and hospitals. Currently, more than 1,100 such health centers operate over 7,900 service delivery sites that provide care to nearly 19 million patients in every State, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin.

Despite serving less healthy and more vulnerable populations, research indicates that these health centers have achieved considerable success in increasing access to care, improving health outcomes for patients, reducing health disparities, and containing health care costs. For example, regarding FQHCs, data show health center Medicaid patients were 11 percent less likely to be inappropriately hospitalized and 19 percent less likely to visit the emergency room inappropriately than Medicaid beneficiaries who had another provider as their usual source of care.[15]

RHCs improve access to primary care in underserved rural areas through the use of interdisciplinary team· based care. Currently, more than 3,800 such RHCs provide care to more than 1.6 million Medicare beneficiaries throughout the United States. RHCs provide critical, quality primary care to Medicare beneficiaries and others most in need in underserved areas. Research has shown that RHCs not only provide care at costs significantly less than other providers of care, such as emergency departments and hospitals, but also reduce use of those providers. Additionally, research on RHCs has shown that:

- Among older adults, the presence of an RHC in the county reduced ambulatory care sensitive (ACS) conditions admission rates, compared to counties in which an RHC was not present.[16]
- RHCs offer financially accessible care to low income individuals; 96 percent of independent RHCs surveyed offer free care, sliding fee scales, or both.[17]

Accordingly, because FQHCs and RHCs are unable to participate independently in this program, we believe providing incentives to ACOs that include FQHCs and/or RHCs as ACO participants is in the interest of the Shared Savings Program as incorporation of these types of entities will promote care coordination and the delivery of efficient, high-quality health care. Therefore, we are proposing, for the one-sided model, up to a 2.5 percentage point increase in the sharing rate for ACOs that include these entities as ACO participants. We propose establishing a sliding-scale payment, outlined in the following table, based on the number of Medicare FFS beneficiaries with one or more visit at an ACO's participant FQHC or RHC during the performance year.

**Table 7: Sliding Scale Payment Based on Number of Beneficiary Visits at an ACO's 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) |
|---|---|
| 1-10% | 0.5 |
| 11-20% | 1 |
| 21-30% | 1.5 |
| 31-40% | 2 |
| 41-50% | 2.5 |

We are also proposing 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.

The statutory definition of FQHCs at section 1861(aa)(4) of the Act includes FQHCs receiving grant support under section 330 of the Public Health Service Act, so-called FQHC look-a-likes, and outpatient health programs/facilities operated by tribal organizations. Our regulations at 42 CFR 405.2401(b) include this statutory definition of FQHCs. Similarly, § 405.2401(b) reflects the statutory definition of RHCs in section 1861(aa)(2) of the Act. We therefore propose to define FQHCs and RHCs, for the purpose of awarding this payment preference, as these terms are defined in § 405.2401(b) of our regulations. We seek comments on alternate options for establishing a payment preference with 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.

We are also interested in encouraging providers who serve a large portion of dual eligible beneficiaries to participate in the Medicare Shared Savings Program. 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 fee-for-service 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. The Affordable Care Act recognizes the unique status of dual eligible beneficiaries and includes several provisions to address their special

[15] Falik M. *et al*. Comparative Effectiveness of Health Centers as Regular Source of Care. Journal of Ambulatory Care Management 2006; 29(1): 24–35.

[16] Probst, J.C., Laditka, J., and Laditka, S. (2009). "Community Health Center and Rural Health Clinic Presence Associated With Lower County-Level Hospitalization Rates for Ambulatory Care Sensitive Conditions." South Carolina Rural Health Research Center.

[17] Hartley, D., Gale, J. Leighton, A. and Bratesman, S. (2010). "Are Rural Health Clinics Part of the Rural Safety Net?" Muskie School of Public Service; Maine Rural Health Research Center.

needs. For instance, section 2602 of the Affordable Care Act established a Federal Coordinated Health Care Office within CMS to bring together officers and employees of the Medicare and Medicaid programs at CMS to: (1) more effectively integrate benefits under the Medicare and Medicaid programs; and (2) improve the coordination between the Federal government and States for individuals eligible for benefits under both such programs in order to ensure that these individuals receive full access to the items and services to which they are entitled under titles XVIII and XIX of the Act.

Additionally 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 believe 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 are seeking comment on methods to provide preference to ACOs that serve a large dual-eligible population or that enter and maintain similar arrangements with other payers. Specifically we seek comment regarding suggestions to encourage accountability for dual-eligible beneficiaries and participation in similar arrangements with other types of payers.

13. Withholding Performance Payments To Offset Future Losses

Over the course of the program, an ACO may earn performance payments in some years and incur losses in other years. The issue is whether the full amount of shared savings payments should be paid in the year they are accrued, 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 discussed in section II.G. of this proposed rule, we propose that an ACO may use a withhold of their earned shared savings payment as one option for demonstrating an adequate repayment mechanism in the event they incur shareable losses. As discussed in sections II.B. and II.I. of this proposed rule, we believe the requirement that ACOs be willing to commit to a 3-year 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 here furthers that intent. Since we want to encourage ACOs to participate for all 3 years of their agreements, protect the Medicare program against losses, and ensure ACOs have an adequate repayment mechanism in the event they incur losses under either the one-sided or two-sided model, we are proposing a flat 25 percent withholding rate will be applied annually to any earned performance payment. Under the two-sided model as discussed in Section II.G. of this proposed rule, we propose that an ACO may withhold an additional portion of its earned performance payment as a mechanism to demonstrate an adequate repayment mechanism in the event they incur shareable losses. Furthermore, we propose that at the end of each agreement period, positive balances will be returned to the ACO. However, if the ACO does not complete its 3-year agreement, the ACO would forfeit any savings withheld.

14. Performance Payment Limit

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, we must propose the maximum performance payment an ACO may receive in any given performance year in this proposed rule. In determining what would constitute an appropriate limit, we believe 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 risk. ACOs seeking to participate in the Shared Savings Program will vary with respect to their readiness to function under a risk model with respect 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 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. 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 cap 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 a goal as important as achieving savings in the Shared Savings Program. Providing an incentive for ACOs to invest to improve quality and efficiency of care needs to be balanced against providing an overly large incentive where an ACO may be encouraged to generate savings resulting from inappropriate limitations on necessary care. A higher cap 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 cap 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 cap on ACO shared savings. (Since the maximum shared savings potentially realized by an ACO under the one-sided model is 52.5 percent, a 7.5-percent limit on the ACO share implies an expectation that overall savings may be as high as approximately 14 percent; a 10-percent limit implies a savings expectation of approximately 19 percent.) On the other hand, such a higher limit may provide some incentive for ACO providers/suppliers to reduce utilization inappropriately, which could potentially be harmful to beneficiaries

We believe 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 have merit. Accordingly we are proposing 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, in order to encourage ACOs to assume risk and participate in the two-sided model, as described in section II.G. of this proposed rule, we are proposing, 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 two-sided model is 65 percent, a 10-percent limit on the ACO share implies an expectation that overall savings may be as high as approximately 15 percent). We are soliciting comments on these proposed payment limits and on whether a higher limit—for example, 10 percent for all ACOs—would be more appropriate in the light of the considerations discussed previously and other considerations that commenters may wish to raise. We also seek 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 will consider this information and the implications for a differential cap based on ACO readiness in future rulemaking cycles.

Regardless of what limit is adopted in the final rule, we plan to monitor beneficiary access and utilization of services, and the potential contribution of the performance limit to any inappropriate reductions in services. Our proposals related to monitoring and addressing ACO performance can be found in Section II.H. of this proposed rule. Furthermore, 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 the final rule.

*G. Two-Sided Model*

Section 1899 of the Act implements a voluntary program that provides incentives for group of providers of services and suppliers to work together to improve the quality and efficiency of care for a FFS beneficiary population in exchange for a share in any savings generated from their effort. Section 1899(i) of the Act authorizes the Secretary to use other payment models in addition to the shared savings model outlined in section 1899(d) of the Act under which we only share savings with ACOs. This provision authorizes the Secretary to select a partial capitation model or any other payment model that the Secretary determines would improve the quality and efficiency of items and services furnished to Medicare fee-for-service beneficiaries. In addition, section 1115A of the Act, as amended by 3021 of the Affordable Care Act, authorizes the Center for Medicare and Medicaid Innovation (Innovation Center) to test innovative payment and service delivery models, which could include alternative ACO payment models.

In the November 17, 2010 **Federal Register**, we solicited public comment on a number of issues including the types of alternative payment models we should consider in addition to the model laid out in section 1899(d) of the Act, either in the Shared Savings Program under the authority provided in 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 payment models.

Most comments received in response to this question favored our use of alternative payment models. A number of commenters suggested risk-based models such as partial capitation (an up-front fixed dollar amount for a sub-set of Medicare services rendered by a provider per beneficiary per period of time) or global payment (an up-front fixed dollar amount for all Medicare-covered services required per beneficiary per period of time). Commenters proposed both one-sided shared savings models (to ease providers of services and suppliers into this payment model) and models that would allow ACOs to share in savings and be held accountable for losses (two-sided models).

Taking these comments into account, we are proposing that ACOs could elect the two-sided model for their initial agreement period, to become accountable for losses and in order to be eligible for higher sharing rates than would be available under the one-sided model, beginning in their first performance year. In addition, we are also proposing that ACOs that initially elect the one-sided model would be reconciled annually for the first 2 years of the 3-year agreement using the one-sided model and automatically transitioned to the two-sided model for the third year of their agreement. This approach gives ACOs an option of two tracks for their initial agreement period, thereby providing an opportunity for organizations more experienced with care coordination and risk models, that are ready to accept risk to enter a sharing arrangement that provides greater reward for greater responsibility in year 1, while also providing 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 more risk.

1. Risk-Based Payment Models

In section II.F of this proposed rule, we describe in detail the one-sided model, under which ACOs share in savings but are not accountable for repaying any losses if actual expenditures exceed the benchmark. While we believe this model holds promise for creating substantial improvement in quality and cost, many commenters on the November 17, 2010 RFI, and other stakeholders urged us to include risk-based arrangements where ACOs would also be accountable for downside risk. Policy experts have also suggested that incorporating downside risk-based models into the Shared Savings Program would provide a stronger lever than a one-sided model for encouraging ACOs to achieve

efficiencies and attain the program's transformative goals.[18]

Risk-based arrangements may take many forms. Two models considered for inclusion in the Shared Savings Program were two-sided risk arrangements (shared savings and losses) and partial capitation. Real-world examples of these models vary widely, according to the terms of specific provider-payer initiatives they encompass. Partial capitation refers to a payment system that incorporates elements of both capitation and FFS. Section 1899(i) of the Act defines partial capitation as a model "* * * in which an ACO is at financial risk for some, but not all, of the items and services covered under Parts A and B, such as at risk for some or all physicians' services or all items and services under Part B." Our intent is to design and test partial capitation models in the Innovation Center first in order to gain more experience, introduce them to providers of services and suppliers, and refine them before adopting them more widely in the Shared Savings Program.

In a two-sided model based around FFS within the Shared Savings Program, ACOs would accept the downside risk for losses once the minimum loss rate is exceeded (the equivalent of the minimum savings rate that must be exceeded in order to share in savings under the Shared Savings Program). ACOs' exposure to downside risk could also be limited by the creation of risk corridors that establish a maximum shared loss cap. We are proposing to make available a two-sided model in the Shared Savings Program to foster ACOs' accountability for greater risk with a greater opportunity for reward. ACOs may elect to enter the one-sided model (Track 1) or elect the two-sided model (Track 2). An ACO that elects Track 1 would automatically be transitioned to the two-sided model for the third year of its agreement. Thus, in the third year of the ACO's agreement under Track 1, the methodology used to reconcile ACOs under the first year of the two-sided model would apply except ACOs must meet the quality performance standard that applies in the third year (as opposed to the first year standard of full and accurate reporting). A key attribute of FFS is beneficiary freedom of choice to choose any provider they wish which will be maintained under both the one-sided and two-sided models.

There are pros and cons of risk-based arrangements. Providers of services and suppliers engaged in a risk-based payment arrangement, compared to a one-sided shared savings structure, have a stronger incentive to control spending and achieve efficiencies. This is consistent with the antitrust perspective that participants in financially integrated organizations have the incentive to cooperate in controlling costs and improving quality by managing the provision of services; such that to demonstrate financial integration, participants in a collaboration must share substantial financial risk, as discussed in section II.B of this proposed rule. Risk-based arrangements offer payers a chance to control spending, either through the recoupment of excess expenditures (losses) in two-sided risk arrangements, or through capitated payments. However, since providers of services and suppliers have an increased motivation to control spending and achieve efficiencies under a risk-based model, it would be reasonable to anticipate an increase in negative incentives such as incentives to stint on care or undersupply services, shift costs (for instance through changes in referral patterns), as well as increased incentives for providers of services and suppliers to avoid at risk beneficiaries. In the 1990's, California providers' willingness to take risk led to the rapid expansion and failure of many under-capitalized risk-bearing physician organizations. This experience illustrates that risk-bearing arrangements have broad implications for provider relationships (namely leading to the integration of providers through mergers and acquisitions); the financial solvency of provider organizations and therefore the stability of health care markets and patients' access to care; as well as leverage between providers and private payers.[19] For these reasons, risk-based arrangements require greater assurance of providers' financial solvency in order to repay Medicare for excess expenditures that may be incurred, as well as greater beneficiary protections, for example by heightened monitoring to detect inappropriate short-cutting of care and avoidance of at-risk beneficiaries. In addition, proper safeguards may be needed to address the risk of conduct violating fraud and abuse laws.

Incorporation of downside risk into the Shared Savings Program, while retaining a FFS base, has been encouraged by commenters on the November 17, 2010 RFI (including MedPAC), other stakeholders and policy experts as an entry point for moving ACOs to risk-based arrangements. MedPAC suggested offering a two-sided risk model in addition to the one-sided model, and over time, making the two-sided model the dominant or only option available to program participants. Further, to encourage ACOs to participate in the two-sided model, MedPAC recommended that it could be distinguished from the one-sided model by features such as a larger share of savings and risk corridors to protect ACOs from high levels of losses.[20]

A relevant example of a two-sided risk arrangement in a FFS setting is Blue Cross Blue Shield of Massachusetts' (BCBSMA) Alternative Quality Contract, an initiative that engages groups of providers for HMO or PPO beneficiaries. Under this contract, providers continue to be paid on a FFS basis. Each group's yearly expenditures are compared against a predetermined global budget, factoring in the level of risk the group has agreed to take on; the group is paid any surplus or repays BCBSMA for any deficit. Groups can earn bonuses based on quality performance targets, and achieved savings, and also earn significant quality bonuses.[21]

Given these considerations, we believe payment models where ACOs bear a degree of financial risk hold the potential to induce more meaningful systematic change in the behavior of groups of providers of services and suppliers compared to a one-sided model. We propose to develop an option for an ACO to either enter into a two-sided model within the Shared Savings Program initially or enter into the one-sided model within the Shared Savings Program initially and be transitioned to the two-sided model in year 3 of its initial 3-year agreement. We believe this proposal strikes a balance between stakeholders' requests for risk-based arrangements with the implications for beneficiary protections and market stability posed by capitated models and the operational complexity of creating

[18] *See e.g.,* Robert A. Berenson, "Shared Savings Program for Accountable Care Organizations: A Bridge to Nowhere?" The American Journal of Managed Care, Vol 16, No. 10 (October 2010).

[19] *See* Robert A. Berenson, Paul B. Ginsburg and Nicole Kemper, "Unchecked Provider Clout in California Foreshadows Challenges To Health Reform" Health Affairs, April 2010; James C. Robinson & Emma L. Dolan, "Accountable Care Organizations in California: Lessons for the National Debate on Delivery System Reform" Integrated Healthcare Association, White Paper (2010).

[20] Letter from Glenn M. Hackbarth, Chairman MedPAC, to Dr. Donald M. Berwick, Administrator, Centers for Medicare and Medicaid Services, November 22, 2010 (File Code CMS–1345–NC).

[21] Michael E. Chernew et al. "Private-Payer Innovation In Massachusetts: The 'Alternative Quality Contract' " Health Affairs (January 2011).

these arrangements in a FFS environment. As we develop experience with other risk-based models, for example through the Innovation Center, we expect to consider incorporating additional payment models into the Shared Savings Program through future rule making.

2. Two Tracks Provide Incremental Approach to Incorporating Risk

We considered several options about how to incorporate a two-sided model into the Shared Savings Program. The major options we considered are as follows:

- Basing the program on a two-sided model, thereby requiring all participants to accept risk from the first program year.
- Allowing applicants to choose between program tracks, either a one-sided model or two-sided model, for the duration of the agreement.
- Allowing a choice of tracks, but requiring ACOs electing the one-sided model to transition to the two-sided model during their initial agreement period.

Requiring all ACOs to initially take downside risk would likely inhibit the participation of some interested entities. Potential Shared Savings Program applicants will likely include providers and suppliers with different levels of experience with risk-based payment arrangements and with different levels of financial footing, reflecting the heterogeneity of providers and suppliers and provider arrangements that exist in the nation's health care system. The comments on the November 17, 2010 RFI reflect this diversity, but in sum, favored our adoption of a flexible approach that recognizes the different levels of ACOs' readiness to take on risk. For instance, organizations experienced with integrated care and risk-based arrangements, with available financial reserves, may be ready and willing to accept risk beginning in the first program year. Others urged against program requirements which could preclude small/solo practices and safety net providers, from entering the Shared Savings Program. These comments underscored the scenario in which ACOs, otherwise capable of meeting the program's requirements, may initially lack the experience and capital to accept significant downside risk.

However, allowing ACOs to choose from either a one-sided model or a two-sided model also creates some concerns. Some ACOs capable of taking risk may take advantage of the option that allows for gain by realizing savings without any risk for incurring added costs. We believe it important that all Shared Savings Program participants quickly move to taking on downside risk. We believe that payment models where ACOs bear a degree of financial risk have the potential to induce more meaningful systematic change in providers' and suppliers' behavior. Additionally, by introducing a risk model, we believe we will 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 propose that applicants will 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. Thereafter, those ACOs can only participate under the two-sided model for any subsequent agreement periods. Alternatively, under Track 2, an ACO may enter the two-sided model option immediately for a full 3-year agreement period. Those ACOs must also participate in the two-sided model thereafter in subsequent agreement periods. Thus an ACO may only participate for a maximum of two 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 believe that this approach addresses the concerns we have identified. Incorporating both a one-sided and two-sided model into the Shared Savings Program provides a path forward for diverse organizations to gain experience with redesigning care processes and assuming accountability for the quality of care and financial outcomes of the populations they serve. Requiring those who enter the program on Track 1 to migrate to the two-sided model encourages organizations to take on greater risk with the opportunity for greater reward. We invite comments 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.

3. Elements of the Two-Sided Model

In developing the elements of a two-sided model under the Shared Savings Program, we propose to employ, as feasible and appropriate, the elements of the one-sided model that we have described in detail in the rest of this proposed rule. At the same time, it will be necessary to develop some policies for the two-sided model that would not be necessary under a one-sided model, for example, a methodology for determining shared losses. In addition, we believe that it is also appropriate to adapt some of the elements of the one-sided model to the somewhat different circumstances and incentives under which ACOs sharing two-sided risk would operate. Specifically, 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 both appropriate and essential to provide greater incentives for organizations that participate in the two-sided model. For example, as we describe below, we believe that it is appropriate to provide a higher shared savings 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 the discussion that follows, it can be assumed that the features of the one-sided model we have proposed in this rule would also apply under the two-sided model, unless we specifically state otherwise. In general, we are proposing the same eligibility requirements and methodologies for the two-sided model as we have proposed for the one-sided model. That is, we propose 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 under the two-sided model that we have described under the one-sided model. However, as we discuss below, we are adding some requirements in order to provide further assurance about the ability of an ACO which will be operating under the two-sided model to repay the Medicare program in the case of incurred losses.

The following table provides a summary comparison of the program's two models:

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**Table 8: Shared Savings Program Overview**

| Design Element | One-Sided Model (performance years 1 & 2) | Two-Sided Model |
|---|---|---|
| **Maximum Sharing Rate** | 52.5 percent | 65 percent |
| **Quality Scoring** | Sharing rate up to 50 percent based on quality performance. | Sharing rate up to 60 percent based on quality performance |
| **FQHC/RHC Participation Incentives** | Up to 2.5 percentage points | Up to 5 percentage points |
| **Minimum Savings Rate** | Varies by population | Flat 2 percent regardless of size. |
| **Minimum Loss Rate** | None | Flat 2 percent regardless of size |
| **Maximum Sharing Cap** | Payment capped at 7.5 percent of ACO's benchmark | Payments capped at 10 percent of ACO's benchmark |
| **Shared Savings** | Savings shared once MSR is exceeded; unless exempted, share in savings net of a 2 percent threshold; up to 52.5 percent of net savings up to cap. | Savings shared once MSR is exceeded; up to 65 percent of gross savings up to cap. |
| **Shared Losses** | None | First dollar shared losses once the minimum loss rate is exceeded. Cap on the amount of losses to be shared phased in over three 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 cap would not be shared. Actual amount of shared losses would be based on final sharing rate that reflects ACO quality performance and any additional incentives for including FQHCs and/or RHCs using the following methodology (1 minus final sharing rate). |

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a. Beneficiary Notification and Protections

Because we believe participants in risk models have an increased incentive to lower costs, we also recognize there may also be an increased incentive for ACOs to avoid at-risk beneficiaries. We believe that the monitoring procedures that we are proposing as discussed in section II.H. of this proposed rule, in combination with our proposed use of a retrospective beneficiary assignment methodology and proposed beneficiary notification requirements, are 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 invite comments on the sufficiency of these proposed monitoring procedures as well as additional areas and mechanisms for monitoring two-sided model ACOs.

b. Eligibility Requirements

We believe the eligibility requirements for ACOs we are proposing for the one-sided model, as discussed in section II.B. of this proposed rule, in combination with the proposed requirement that ACOs entering the two-sided model receive our approval of their repayment

mechanisms, are sufficient to ensure the ability of ACOs to pay CMS in the event they incur losses. We invite comments on whether additional eligibility requirements are necessary for ensuring that ACOs entering the two-sided model would be capable of repaying us if actual expenditures exceed their benchmark.

c. Quality Performance Measurement and Scoring

We believe that the comprehensive quality performance standards that we have proposed for the one-sided model are also appropriate for the two-sided model. However, it is worth emphasizing in this context that we place great importance on the quality aspects of the Shared Savings Program, and that the quality standards take on even greater importance for ensuring high quality of care for beneficiaries since we are proposing to incorporate a requirement that all ACOs participating in the Shared Savings Program accept risk either beginning in year 1 or year 3 of their initial agreement period. Therefore, in order to provide greater incentives for organizations to participate under the two-sided model, we are proposing higher shared savings rates under the two-sided model. Specifically, we are proposing a sharing rate of up to 60 percent (based on quality performance) under this model, compared to a sharing rate of up to 50 percent under the one-sided model, as discussed in section II.E. of this proposed rule. We propose that each of the 5 quality measure domains in Table 2 would continue to be equally weighted. Thus, each domain would be worth 12 percent of the savings generated by the ACO. That is, 5 domains × 12 percent equals 60 percent of the total savings generated by the ACO. Under this model, high performers in quality scoring would continue to earn more than lower quality performers. As discussed in section II.E. of the proposed rule, Table 3 illustrates our proposed sliding scale for determining points earned for each measure; we are proposing that under the two-sided model ACOs, like one-sided model ACOs, could earn a maximum of 2 points per measure.

As discussed in section II.E. of this proposed rule, the quality performance standard for the first year of the Shared Savings Program will be set at full and accurate reporting. For the purposes of determining the shared savings rate for Track 2 ACOs, ACOs which meet this standard will obtain the maximum savings rate for quality performance (60 percent). As previously proposed, under Track 1, ACOs will be reconciled using the methodology under the one-sided model for the first and second year of the agreement. In the third year of the ACO's agreement under Track 1, the methodology used to reconcile ACOs under the first year of the two-sided model would apply for payment purposes. With respect to the quality performance standard, Track 1 ACOs in the third year of their agreement must meet the quality performance standard that applies in the third program year, as opposed to the first year standard of full and accurate reporting.

We considered a number of alternatives to incorporating features that mirror the quality performance standard proposed for the one-sided model into determining the shared savings and shared losses under the two-sided model. That is, as proposed, under the two-sided model ACOs could increase their share of savings or decrease their amount of losses with higher quality scores. Alternatives track to the options considered for establishing the quality performance standard discussed in section II.E. of this proposed rule. An alternative is to take a threshold approach to measuring quality performance for the purpose of determining the amount of shared savings or losses. A third option is to use a blend of these two options, by allowing ACOs to increase their share of savings with higher quality scores but use a threshold approach when calculating losses, so that higher quality does not reduce an ACO's share of any losses. We seek comment on these alternate approaches.

d. Shared Savings Methodology

As discussed in Section II.F. of this proposed rule, we are proposing that ACOs choosing to participate in the one-sided model could share savings if they exceed a minimum savings rate (MSR). For those ACOs whose savings exceed the MSR in the one-sided model, we are proposing 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 are also proposing 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 this 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.

For purposes of the two-sided model, we are proposing to adopt the same methodology for determining shared savings, with some changes and incentives outlined below. In comparison to the one-sided model, the ACOs participating in the two-sided model would: (1) Have increased incentive payments for the same quality performance and including FQHCs and/or RHCs as ACO participants; (2) would be subject to a fixed minimum savings rate and minimum loss rate of 2 percent and would share in gross savings once the MSR is exceeded; and (3) would be responsible for a portion of the excess expenditures above the benchmark based on their quality performance and inclusion of FQHCs and/or RHCs. ACOs with excess expenditures within the minimum loss rate would not be responsible for repaying Medicare. ACOs with expenditures exceeding the minimum loss rate would be responsible for paying excess expenditures calculated by multiplying the amount of excess above the benchmark by one minus the final sharing rate. The final sharing rate is defined as the quality performance sharing rate plus the percentage points for including FQHCs and/or RHCs as ACO participants. ACOs would be responsible for paying the percentage of excess expenditures up to the annual loss cap which is measured as a percentage of the benchmark: 5 percent, 7.5 percent and 10 percent respectively across the first 3 years for Track 2 ACOs; an ACO in Track 1 who has entered the third year of its initial agreement period would be liable for an amount not to exceed the percentage of the first year of the two-sided model, that is, it would not exceed 5 percent.

(1) Minimum Savings Rate

We believe 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 believe that it is more appropriate to employ a fixed minimum savings rate under this model. First, the greater predictability of a fixed minimum savings rate 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 Physician Group Practice demonstration and consistent with the lowest applicable MSR under the one-sided model, we are proposing to adopt a fixed 2 percent MSR for organizations operating under this model, in place of the variable

minimum savings rate for organizations operating under the one-sided model.

(2) Additional Shared Savings Payments

In the one-sided model described previously in this proposed rule, we propose to increase an ACO's share in savings for including FQHCs and/or RHCs as ACO participants. To further increase the ACO's reward for taking risk, we are proposing to double this amount, awarding a sliding scale increase of up to 5 percentage points for including FQHCs and/or RHCs as ACO participants in an ACO participating in the two-sided model, compared to 2.5 percentage points available under the one-sided model.

(3) Net Sharing Rate

As discussed in section II.F. of this proposed rule, we considered several options for the amount of savings an ACO could receive under the one-sided model. These options included requiring the ACO to exceed the MSR and then sharing either on a first dollar basis or sharing with the ACO savings in excess of a threshold amount. We proposed that for the first 2 years of the agreement for the one-sided model that ACOs which exceed the MSR would be eligible to share in savings net of a 2 percent threshold, calculated as 2 percent of their benchmark. We further proposed that small ACOs under the one-sided model which meet certain criteria (namely, physician-driven ACOs, rural ACOs, and ACOs caring for underserved populations) which generate savings that exceed the MSR will be eligible to share in savings on a first dollar basis.

We considered the same options on limiting the amount of savings an ACO could receive under the two-sided model. A number of factors favored allowing two-sided model ACOs to share on first dollar savings. For one, ACOs participating in the two-sided model are assuming the risk of losses due to normal year-to-year variations in Medicare beneficiaries' claims expenditures. 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, we propose that two-sided model ACOs which generate savings that exceed the MSR will be eligible to share in savings on a first dollar basis. Thus, under the two-sided model, the final sharing rate (quality performance sharing rate and any additional increases for including FQHCs and/or RHCs) would be applied to an ACO's total savings that exceed its benchmark.

(4) Calculating Sharing in Losses

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. As discussed previously, we considered several options for calculating the amount of shared losses, tracking the options considered for establishing the quality performance standard. While a methodology for determining shared losses is obviously not necessary under a one-sided model, we have mirrored the structure and features of the shared savings methodology as much as possible to the determination of loss sharing. Thus, for purposes of the loss-sharing methodology, we propose adopting a similar structure of minimum loss rate (the equivalent of minimum savings rate on the savings side), shared loss cap, and adjustments to the shared loss percentage based on the ACO's quality performance and inclusion of FQHCs and/or RHCs.

As noted previously, we are proposing a minimum loss rate for purposes of computing shared losses when an ACO's actual expenditures exceed its benchmark. As in the case of shared savings, we believe that 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. Further, we are also proposing a cap on the loss sharing rate under the two-sided model, as we discuss later in this proposed rule.

In addition, as in the determination of shared savings, we are proposing to adjust the loss sharing rate by considering several factors related to performance and behavior. These factors would include: (1) Performance on quality measures; and (2) any additional adjustment for including FQHCs and/or RHCs as ACO participants. However, in order to recognize these factors appropriately in the determination of the shared loss rate, these factors must operate as decreases in the ACO's shared loss rate, rather than as the increases that they represent in the determination of the shared savings rate.

For example, a two-sided model ACO that realizes savings against its benchmark may qualify for a final sharing rate of up to 65 percent if it is eligible for the maximum adjustments. In this case, the 65 percent final sharing rate is comprised of the savings rate of up to 60 percent for quality performance, plus 5 percentage points for including FQHCs and/or RHCs as ACO participants.

On the other hand, a two-sided model ACO that experiences actual expenditures in excess of its benchmark may qualify for a shared loss rate as low as 35 percent of total losses if it is eligible for the maximum adjustments to its shared loss rate. So, for example, if the ACO obtained maximum points for its quality performance, and also received the maximum adjustment for including FQHCs and/or RHCs as ACO participants, it would have a sharing rate of 65 percent for purposes of sharing in savings. But since there are losses, the quality performance and inclusion of FQHCs and/or RHCs should be taken into consideration when calculating losses owed to the program. Accordingly, under our proposed methodology we would multiply the total losses by 1 minus the 65 percent final sharing rate, or 35 percent, making the ACO responsible for only 35 percent of the amount of losses.

As discussed in section II.E. of this proposed rule, the quality performance standard for the first year of the Shared Savings Program will be set at full and accurate reporting. Therefore, for the purposes of determining the loss sharing rate, two-sided model ACOs which meet this standard will obtain the maximum savings rate for quality performance (60 percent), making them responsible for 40 percent of any losses under the methodology previously described, absent any increases in the sharing rate for FQHC/RHC participation.

(5) Maximum Shared Savings and Shared Loss Caps

We are proposing a maximum shared loss cap, so that the shared losses that an ACO might be required to return to the Medicare program under this model could not exceed a designated percentage of an ACO's benchmark in any performance year. However, in order to provide a greater incentive for organizations to participate in the Shared Savings Program under the two-sided model, we are proposing to phase in this shared loss cap over a 3-year period. Specifically, we are proposing a shared loss cap of 5 percent of the benchmark in the first year of the Shared Savings Program, 7.5 percent in the second year, and 10 percent in the third year.

ACOs electing the one-sided model that are transitioned to the two-sided model in the third year of their agreement would be subject to the 5 percent cap on losses since they would be considered to be in their first year under the two-sided model.

Additionally, as discussed previously, we are proposing a higher maximum shared savings cap under the two-sided model, so that shared savings payment under this model could not exceed 10 percent of an ACO's benchmark, compared to 7.5 percent under the one-sided model.

An example of estimating an ACO's maximum potential downside risk and estimating the ACO's yearly losses is as follows. If the ACO's annual average per capita benchmark for assigned beneficiaries is $8,000 the maximum amount of losses an ACO would be responsible for the first year is 5 percent of its benchmark, 7.5 percent the second year, and 10 percent the third year. Therefore, the ACO's maximum per capita liability could range from $400 to $800 per assigned beneficiary. Actual liability depends on the ACO's actual final sharing rate which incorporates its quality performance and any increases for inclusion of FQHCs and/or RHCs.

Continuing this example, if an ACO with a benchmark of $8,000 per capita has actual costs for its assigned beneficiaries of $8,800, it would have a per capita loss of $800. The following table presents how much of the loss the ACO would be responsible to pay back under the program based on its final sharing rate, as determined by its quality performance, and assuming no additional increases for FQHC/RHC participation.

**Table 9: Examples of Loss Estimates in Dollars Per Beneficiary**

| Final Sharing Rate | Annual Per Capita Loss | First Year Cap (5% of benchmark) | Payment Due CMS |
|---|---|---|---|
| 40% | $800 (1-0.4) = $480 | $400 | $400 |
| 50% | $800 (1-0.5) = $400 | $400 | $400 |
| 60% | $800 (1-0.6) = $320 | $400 | $320 |

(e) Ensuring ACO Repayment of Shared Losses

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. Financial protection requirements for other entities with which CMS does business provide examples of potential mechanisms for recouping payment. In order to enroll in and bill the Medicare program, some Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers are required to obtain a surety bond. Home Health Agencies (HHA) entering into the Medicare program must have available sufficient "initial reserve operating funds" at the time of application submission—and at all times during the enrollment process up to the expiration of the 3-month period following the conveyance of Medicare billing privileges. CMS, through an intermediary, determines the amount of the HHA's required initial reserve operating funds using reported cost and visit data from submitted cost reports for the first full year of operation from at least three HHAs that the intermediary serves that are comparable to the HHA.

As discussed in section II.F. of this proposed rule, we propose a flat 25 percent withholding rate will be applied annually to an ACO's earned performance payment. We propose that this withholding serve as a component of the repayment mechanism ACOs will need to establish to ensure their ability to repay Medicare for incurred losses. We propose that we would apply the withheld amount towards repayment of an ACO's losses. However, we recognize that the 25 percent withholding of shared savings may be inadequate to cover the total amount of shared losses, particularly if a Track 2 ACO experiences losses in its first year. In order to more fully ensure that the Medicare program is paid back in the event that an ACO incurs losses, we have considered a number of options, including the following:

- Recoup funds from the ACO and require the ACO to obtain reinsurance, place ACO funds in escrow, obtain surety bonds, or establish a line of credit as evidenced by a letter of credit that the Medicare program can draw upon.
- Recoup funds from an ACO via the ACO's participants. We would require the ACO to disclose on its application the percentage of shared losses that each ACO participant would be responsible for, and the ACO would provide copies of signed agreements with its ACO participants, establishing their liability. We would require ACO participants to agree to have their future Medicare payments reduced by the amount reflected in the agreement. We note that such arrangements, to the extent they involve remuneration between referral sources and those seeking referrals, may raise liability issues under the physician self-referral law and anti-kickback statute. CMS and the OIG have solicited comments on how best to approach this issue in the Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center, also released today.
- Withhold an additional portion of any annual shared savings payments (on top of the proposed flat 25 percent withhold discussed in section II.F. of this proposed rule in order to guard against losses in subsequent years. This could be done in combination with other alternatives in order to guard against any losses incurred by ACOs that have not previously received shared savings sufficient to offset such losses.
- Permit ACOs to specify how they would repay us, for example through one or more of the previously noted recoupment options.

We further considered requiring an ACO to establish a self-executing method of repaying losses, using one or more of the aforementioned options, to demonstrate its ability to repay a prescribed portion of its possible losses. Another option we considered was to require 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).

After considering these options, we propose to require that an ACO establish a self-executing method for repaying losses to the Medicare program by indicating that funds may be recouped from Medicare payments to the ACO's participants, 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 repayment mechanism, such as those previously discussed. This proposal assures operational simplicity without establishing eligibility requirements that might discourage ACOs with limited risk-bearing experience from entering Track 2.

We considered several options for determining the adequacy of an ACO's recoupment mechanism. One option would be to require ACOs to demonstrate an ability to repay the maximum amount of possible losses, 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. Such a requirement could be prohibitively burdensome given that ACOs may need to demonstrate their ability to repay a large amount of capital and potentially excessive given that ACOs' loss rates would be reduced to account for quality performance and inclusion of FQHCs and/or RHCs and ACOs have a limited probability of incurring the maximum possible losses. Another option, potentially equally as effective as the first but less onerous, would be to require ACOs to demonstrate their ability to repay losses, defined as a percentage of the benchmark but below the annual loss cap. Either option would require the ACO to estimate anticipated losses, and for CMS to confirm this amount against the ACO's benchmark (once available). Given the anticipated variation in ACO composition and regional variations in cost, there may be numerous ways of accurately estimating an ACO's maximum potential downside risk. We further recognize that an ACO's assigned number of beneficiaries may vary from year to year. Given the potential for fluctuation in the size of an ACO's assigned population, and the increase in the cap on shared losses in the second and third years under Track 2, the sufficiency of the ACO's repayment mechanism would need to be periodically reassessed to ensure its adequacy.

We propose that an ACO must demonstrate having established a repayment mechanism, using one or more of the recoupment methods proposed previously, sufficient to ensure repayment of losses equal to at least 1 percent of per capita expenditures for its assigned beneficiaries from the most recent year available. We further propose that we will 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 propose that an ACO must demonstrate the adequacy of this repayment mechanism annually, prior to the start of each performance year in which it takes risk, to ensure that it is adequate to cover the anticipated number of assigned Medicare beneficiaries. An ACO must 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 the ACO's losses. We would ensure that an ACO maintains an adequate repayment mechanism through monitoring activities. We invite comments on this proposal and on the other options we have considered, as well as alternate suggestions for assuring risk-bearing ACOs have an appropriate amount of available funds to repay potential losses.

We further propose 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 Track 2 would be required to submit this documentation as part of its initial application. An ACO applying for Track 1 would also be required to submit this documentation as part of its Shared Savings Program application since Track 1 ACOs will be required to transition to the two-sided model in the third year. We believe it is important that ACOs electing Track 1 can demonstrate that they can fulfill the requirements for the full three year agreement period and that we do not create an incentive for ACOs to terminate their agreements prior to the start of the third year under Track 1. As a result, it is important to ensure that prior to entry into the Shared Savings Program, the ACO has an appropriate plan for how it will repay any losses incurred during the third year of its agreement when it is automatically transitioned to the two-sided model.

To the extent that an ACO's repayment mechanism does not enable us to fully recoup the losses for a given performance year, we propose 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 invite comments on this proposal and on other options that we have considered, as well as alternate suggestions for assuring that any losses by ACOs participating in the two-sided model can be recouped, the processes for recouping losses from these ACOs and/or their ACO participants, and the appropriate amount of available funds a risk-bearing ACO should be required to have.

(f) Future Participation of Under-Performing Organizations

As discussed in section II.C. of this proposed rule, we propose that an ACO which experiences a net loss during its first 3-year agreement period may not reapply to participate in the Shared Savings Program because it has been unsuccessful in lowering the growth in Medicare expenditures and/or its activities contributed in increases in Medicare expenditure growth. We believe this proposal is a means for ensuring that under-performing organizations do not continue to increase Medicare expenditure growth. We seek comment on this proposal and whether denying continued participation in the Shared Savings Program for ACOs that under-perform would create disincentives for the formation of ACOs. We are specifically interested in whether this requirement will create disincentives for participation among smaller ACOs.

(g) Public Reporting

We believe that the public reporting requirements proposed under the one-sided model should also apply to the two-sided model. One such proposed requirement is for ACOs to report publicly on the shared savings received by ACOs. Given that the purpose of this proposed requirement is to enhance transparency of the program we further propose that ACOs under the two-sided model publicly report on their amount of losses, if any. We invite comments on this proposed public reporting requirement and whether, for the purpose of ensuring transparency, there is any additional information that would be important for two-sided model ACOs to publicly report.

(h) Impact on States

Finally, we emphasize that, under our proposal for a two-sided model 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 risk against the benchmark would be solely between the Medicare program and the ACO. We do 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 note 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 seek 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.

4. Verification of Savings and Losses

We will notify an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due. Similarly, we will provide written notification to an ACO of the amount of shared losses, if any, that it must pay to the program. We propose that an ACO must make payment in full to CMS of any shared losses within 30 days of receipt of notification. Because we will calculate amounts due to, or owed by, the ACO on the basis of information submitted by the ACO, we propose that the ACO must certify the accuracy, completeness, and truthfulness of such information. We propose that, as a condition of receiving a shared savings payment, the ACO must submit to us a written request for the shared savings payment amount. The written request must certify the ACO's compliance with program requirements for the relevant performance period as well as the accuracy, completeness, and truthfulness of any information submitted to us by the ACO, or its ACO participants, or the ACO providers/suppliers, or another entity, including the accuracy, completeness, and truthfulness of TINs used to assign patients, any quality data or other information or data relied upon by us in determining the ACO's eligibility for, and the amount of, the shared savings payment. In the case of an ACO participating in the two-sided model that has incurred shared losses, we propose to require submission of a similar certification at such time that would provide us with assurance of the ACO's compliance with program requirements for the relevant performance period and the accuracy, completeness, and truthfulness of any data or other information submitted by the ACO upon which we rely in calculating the amount of shared losses.

*H. Monitoring and Termination of ACOs*

Section 1899(d)(3) of the Act, as added by section 3022 of the Affordable Care 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." We discuss later in the document our proposal to monitor ACOs for avoidance of at-risk beneficiaries and to take appropriate corrective actions when ACOs are found to have engaged in this prohibited conduct, including termination where necessary.

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. As discussed later in the document, we propose to monitor ACO performance with respect to our proposed quality standards. Subsequently, we discuss our proposal to terminate ACOs that fail to meet quality performance standards which are described in section II.E. of this proposed rule.

Section 1899 of the Act sets forth a number of requirements for ACOs, and authorizes the Secretary to promulgate additional criteria that ACOs must satisfy in order to be eligible to participate in the Shared Savings Program. The statute does not prescribe procedures for monitoring nor what factors we should consider in imposing sanctions against an ACO, including termination of its 3-year agreement for reasons beyond avoiding patients at risk and not meeting established quality standards. Based on our experience with other Medicare programs, as discussed this proposed rule, we believe it is important for patient protection and to effectuate the Shared Savings Program that we monitor an ACO to determine if it meets additional Shared Savings Program requirements not set forth in section 1899 of the Act and take actions such as termination with ACOs that are not in compliance with additional Shared Savings Program requirements that are not set forth in section 1899 of the Act. We discuss our proposal to monitor ACO performance with respect to these requirements and to terminate or otherwise sanction ACOs that are not in compliance with the requirements of the Shared Savings Program.

In implementing other Medicare programs, including the MA and the Medicare Prescription Drug programs, we have gained extensive experience in monitoring organizational, provider, and supplier behavior with respect to compliance with Medicare program and program integrity requirements, quality measurement, and avoidance of particular types of beneficiaries. For purposes of the Shared Savings Program, we propose to employ many of the methods we have developed for purposes of the MA and Medicare prescription drug programs to monitor and assess ACOs and their participating providers and suppliers. In general, 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.
- Assessment and following up investigation of beneficiary and provider complaints.
- Audits (including, for example, analysis of claims, chart review, beneficiary surveys, coding audits).

If based upon the monitoring activities described previously we conclude that an ACO's performance may subject the ACO to termination from the Shared Savings Program, we are proposing that CMS in its sole discretion, may 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 of the specific performance at issue.
- Request a corrective action plan (CAP) from the ACO.
- Place the ACO on a special monitoring plan.

We are seeking comment on additional actions that may be appropriate prior to termination.

A number of factors may trigger heightened oversight of ACOs by us, including conditions specified as the bases for terminating the agreement described in this proposed rule. Further, we anticipate close examination of ACOs that incur large losses to the Medicare program.

In order to ensure that we have the information necessary to conduct appropriate monitoring and oversight of ACOs, it will be necessary for ACOs, ACO participants, and ACO providers/suppliers, and other contracted entities performing services and functions on behalf of the ACO to 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, and inspections of their activities. A "contracted entity performing services or functions on behalf of the ACO" would include any party that enters into

an arrangement with an ACO to provide services (including administrative, management, or clinical services) to the ACO or health care services to the beneficiaries assigned to the ACO. It also includes any party that enters into an arrangement with an entity is in an arrangement with the ACO down to the level of the ultimate provider of services.

We are proposing that an ACO, ACO participant, ACO providers/suppliers, and contracted entities performing services and functions on behalf of the ACO, will be required to maintain and give us, the Department of Health and Human Services (DHHS), the Comptroller General, the Federal Government or their designees, the right to inspect 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, and inspection of the ACO's compliance with Shared Savings Program requirements and the ACO's right to any shared savings payment. We propose that such books, contracts, records, documents, and other evidence be maintained by the ACO for a period of 10 years from the end of the agreement period or from the date of completion of any audit, evaluation, or inspection, whichever is later, unless we determine there is a special need to retain a particular record or group of records for a longer period and notify the ACO organization at least 30 days before the normal disposition date. If there has been a termination, dispute, or allegation of fraud or similar fault by the ACO organization or its members, we propose that the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, fraud, or similar fault. We further propose that if we determine that there is a reasonable possibility of fraud or similar fault, we may inspect, evaluate, and audit the ACO organization at any time. If as a result of any inspection, evaluation, or audit, we determine that the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO has been determined in error, we reserve the right to reopen the initial determination and issue a revised initial determination.

We further propose that ACOs include terms in their agreements with ACO participants, ACO providers/suppliers, and the ACO and contracted entities performing services and functions on behalf of the ACO requiring them to comply with the same record retention requirements and to make such books, contracts, records, documents, and other evidence available to the government upon request. Notwithstanding any arrangements between or among an ACO, ACO participants, ACO providers/suppliers, and contracted entities performing services and functions on behalf of the ACO, the ACO shall have ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its agreement with CMS, including the record retention requirement.

1. Monitoring Avoidance of At-Risk Beneficiaries

As noted previously, 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 believe such patients are those beneficiaries who have a high risk score on the CMS–HCC risk adjustment model, are considered high cost due to having two or more hospitalizations or emergency room visits each year, are dually eligible for Medicare and Medicaid, have a high utilization pattern, have one or more chronic conditions (such as, for example, diabetes, heart failure, coronary artery disease, chronic obstructive pulmonary disease, depression, dementia, end stage renal disease) or beneficiaries who have a recent diagnosis (for example, newly diagnosed cancer) that is expected to result in an increased cost.

Such beneficiaries might be appropriately targeted by an ACO to implement care improvement strategies to coordinate their care more efficiently. However, high-cost beneficiaries are also potentially at-risk for inappropriate avoidance by an ACO because the ACO may believe that it will be more likely to realize shared savings against its benchmark costs if it can avoid having higher-cost patients assigned to it during a performance year. We seek comment on this definition of "at-risk beneficiary" and whether other beneficiary characteristics should be considered in determining whether a beneficiary is "at-risk."

To identify ACOs that could be avoiding at-risk beneficiaries, we propose to use a combination of methods that would begin with an analysis of claims and examination of other beneficiary-level documentation (for example, beneficiary satisfaction surveys, medical record audits, beneficiary and provider complaints) 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 the beneficiary or the ACO (including ACO participants and ACO providers/suppliers) in order to determine whether avoidance of at-risk beneficiaries has occurred. If as a result of our analysis we conclude that an ACO has been avoiding at-risk beneficiaries during a performance year, we propose to notify the ACO of our determination and to require the ACO to submit a corrective action plan (CAP) for our approval. The CAP must address actions the ACO will take to ensure that the ACO, ACO participants, and ACO providers/suppliers cease avoidance of at-risk beneficiaries and must be implemented as approved. In addition, we propose that the ACO will 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 propose that the ACO would not receive shared savings payments while it is under the CAP regardless of the period of performance in question and that the ACO would not be eligible to earn any shared savings for the period during which it is under the CAP for avoiding at-risk beneficiaries.

We solicit comments on whether lesser sanctions may be appropriate when an ACO avoids at-risk beneficiaries, such as the cessation of, or a reduction in, the assignment of new beneficiaries to the ACO, a reduction in the amount of the shared savings payment, or a fine for each instance of at-risk beneficiary avoidance.

2. Monitoring Compliance With Quality Performance Standards

Section 1899(d)(4) of the Act further authorizes the Secretary to terminate an agreement with an ACO that does not meet the established quality performance standards. To identify ACOs that are not meeting the quality performance standards, we will review the ACO's submission of quality measurement data. We may request additional documentation from an ACO or its ACO participants or ACO providers/supplier, as appropriate. In those instances where an ACO fails to meet the minimum attainment level for one or more domains, we propose to give the ACO a warning and to re-evaluate the following year. If the ACO continues to underperform on the quality performance standards in the

following year, the agreement will be terminated. We also propose that if an ACO fails to report one or more measures, we would send the ACO a written request to submit the required data by a specified date and to provide a reasonable written explanation for its delay in reporting the required information. If the ACO fails to report by the requested deadline and does not provide a reasonable explanation for delayed reporting, we would immediately terminate the ACO for failing to report quality measures. We further propose 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 note 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.

3. Terminating an ACO Agreement

There are a number of important program requirements that ACOs must satisfy in order to be eligible to participate in the Shared Savings Program. As a result, in addition to the statutory provisions at section 1899(d)(3) and (d)(4) of the Act regarding termination for avoidance of at-risk beneficiaries and for failure to meet the quality standards, we believe the agreement with an ACO should be contingent upon that ACO continuing to meet the requirements for eligibility to participate in the Shared Savings Program. Accordingly, we propose that an ACO's failure to continue to meet the eligibility requirements for participation in the Shared Savings Program should also result in an ACO's termination from the Shared Savings Program. As described in section II.F. of this proposed rule, termination of an ACO from the Shared Savings Program by us or at the ACOs request for any reason will result in loss of the mandatory 25 percent withhold of shared savings.

Therefore, we are proposing that based upon monitoring and assessing ACO operations (including ACO participants and ACO providers/suppliers), we may terminate an agreement with an ACO before the end of the 3-year agreement period for any of the following reasons:

- Avoidance of at-risk beneficiaries as described previously.
- Failure to meet the Shared Savings Program's quality performance standard as described previously.
- Any material change impacting ability to meet eligibility requirements, including but not limited to the following:

++ Changes in ACO participants that are the basis for beneficiary assignment.

++ Increase in ACO provider/supplier composition that results in a reviewing Antitrust Agency to state it is likely to challenge or recommend challenging the ACO.

++ Changes in the ACO's leadership and management structure that result in an inability to perform the functions discussed in section II.B. of this proposed rule.

++ Sanctions or other actions taken against the ACO, its ACO participants, and ACO providers/suppliers, or contracted entities performing services or functions on behalf of the ACO, by an accrediting organization, or by a State, Federal or local government agency.

- Failure of the ACO to effectuate required regulatory changes during the agreement period after given the opportunity for a CAP.
- Failure of an ACO to demonstrate that it has adequate resources in place to repay losses and to maintain those resources for the agreement period.
- Noncompliance with requirements regarding beneficiary notification of provider/supplier participation in an ACO.
- Failure to completely and accurately report or failure to make timely corrections.
- Material noncompliance, or a pattern of noncompliance, with public reporting and other CMS reporting requirements.
- Limiting or restricting internally compiled beneficiary summary of care or medical records from providers and suppliers both within and outside of the ACO, to the extent permitted by law (for example, not sharing beneficiary medical records with providers or suppliers not participating in the ACO from whom the beneficiary chooses to receive care).
- Failure to offer beneficiaries the option to opt out of sharing claims information.
- Improper use or disclosure of claims information received from us in violation of the HIPAA Privacy Rule, Medicare Part D Data Rule, Privacy Act, the data use agreement, or other applicable laws or regulations.
- Violation of physician self-referral prohibition, civil monetary penalty laws, anti-kickback statute, other antifraud laws, antitrust laws, or other applicable Medicare laws, rules, or regulations that are relevant to ACO operations.
- Submission to us of false, inaccurate, or incomplete data and or information, including but not limited to, information provided in the Shared Savings Program application, quality data, financial data, and information regarding the distribution of shared savings.
- Failure to submit payment due to us in a timely manner.
- Use of marketing materials or activities or other beneficiary communications subject to approval that have not been approved by us as discussed in section II.B.11.of this proposed rule.

Furthermore, 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 are proposing to require an ACO to provide us with a 60-day notice if it chooses to terminate its agreement. 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. As described in section II.F.of this proposed rule, the ACO would forfeit its mandatory 25 percent withhold of shared savings.

Finally, we propose that an ACO that has been terminated from the Shared Savings Program may apply to participate in the Shared Savings Program again at the end of the original 3-year agreement period. To be eligible to participate in the Shared Savings Program, 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. We have proposed in section II.G. of this proposed rule, that ACOs may only have one agreement period involving the one-sided model, thus ACOs with corrected deficiencies that wish to reenter the program only have the option to do so under the two-sided model.

For violations that we consider minor in nature and pose no immediate risk or harm to beneficiaries or impact on care, we propose to allow ACOs the opportunity to submit a corrective action plan (CAP) before termination. We further propose that the ACO must submit a CAP for our approval by the deadline indicated on the notice of violation. The CAP must address what actions the ACO will take to ensure that the ACO, ACO participants, ACO providers/suppliers, and entities performing services or functions on

behalf of the ACO will correct any deficiencies to remain in compliance with Shared Savings Program requirements. The CAP must be implemented as approved. The ACO's performance will be monitored during the CAP process. Failure of the ACO to submit, obtain approval for, or implement a CAP may result in termination of the agreement. Failure of the ACO to demonstrate improved performance upon completion of the CAP may result in termination. We seek comments on our proposal, including any additional conditions that could merit the termination of an ACO agreement.

4. Reconsideration Review Process

Section 1899(g) of the Act, as added by section 3022 of the Affordable Care Act, states that there shall be no administrative or judicial review of the following actions:

- Specification of criteria for meeting quality performance standards under section 1899(a)(1)(B) of the Act.
- Assessment of quality of care furnished by an ACO and the establishment of quality performance standards under section 1899(b)(3) of the Act.
- Assignment of Medicare FFS beneficiaries to an ACO under section 1899(c) of the Act.
- Determination of whether an ACO is eligible for shared savings under section 1899(d)(2) of the Act), the amount of shared savings, including the determination of the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries assigned to the ACO and the average benchmark for the ACO under section 1899(d)(1)(B) of the Act.
- Percent of shared savings specified by the Secretary under section 1899(d)(2) of the Act and any limit on the total amount of shared savings.
- Termination of an ACO under section 1899(d)(4) of the Act for failure to meet quality performance standards.

The statute is otherwise silent regarding an ACO's right to contest decisions on such matters as eligibility to participate in the Shared Savings Program or termination for avoidance of at-risk beneficiaries. Accordingly, we believe it is important to establish a fair administrative process by which ACOs may request review of decisions, such as the denial of an ACO application or the termination of an existing ACO agreement for reasons other than those exempted by statute. An administrative reconsideration process provides an opportunity to resolve disputes quickly and efficiently, and creates an administrative record that can serve as the basis for any further review of the agency's decision.

Based on our experiences with the Medicare durable medical equipment prosthetics orthotics and supplies (DMEPOS) competitive bidding program and the MA Part C and D programs, we are proposing to implement reconsideration review procedure similar to the review process used by those programs for initial determinations that are not precluded from administrative or judicial review by statute. These initial determinations would include the denial of an ACO application or the termination of an ACO participation agreement. Under this proposal, if we deny a Shared Savings Program application, the applicant would be able to request reconsideration of our determination from a CMS reconsideration official. This process would not apply to applicants who are rejected on the grounds that their certified application was not submitted by the required deadline, because in this situation no valid application would have been submitted. In the case where an ACO has entered a 3-year agreement and subsequently met criteria for termination, we will give the ACO notification of our initial determination to terminate the agreement. The ACO would be able to request an independent review from a CMS reconsideration official who will reconsider the initial determination.

We propose that if an ACO or ACO applicant wants to request a review by a CMS reconsideration official of an adverse initial determination, it must submit a written request by an authorized official for receipt by CMS within 15 days of the adverse initial determination. If the 15th day is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day. Failure to submit a request for a reconsideration review within 15 days will result in denial of the request for a review.

Reconsideration reviews are scheduled at the discretion of the review official and may be held orally (that is, in person, by telephone or other electronic means) or on the record (review submitted documentation). The ACO or ACO applicant will receive acknowledgement of the reconsideration request that will outline the review procedures. The burden of proof would be on the ACO or ACO applicant to demonstrate to the reconsideration official with convincing evidence that the termination or application denial is not consistent with CMS' regulations or statutory authority. The ACO or ACO applicant may not use the reconsideration process to submit required documentation as evidence for the record that was not previously submitted to CMS by the applicable deadline. Furthermore, the reconsideration official will only consider evidence for the record that is submitted in the required format and in the timeframes indicated in the acknowledgement notification, unless additional information is requested by the official. Following the review, the reconsideration official will issue a recommended decision.

We further propose that if the ACO or ACO applicant disagrees with the recommendation of the reconsideration official, it will have an opportunity to request a record review of the initial determination and recommendation of the reconsideration official by an independent CMS official who was not involved in the initial determination or the reconsideration review process. An ACO or ACO applicant that wishes to request an on the record review of the reconsideration official's recommendation must submit an explanation of why it disagrees with the recommendation in the timeframe and in the format indicated in the recommendation letter. The CMS official may also review the recommendation of the reconsideration official on his or her own motion. The on the record review process will be based only on evidence presented for the reconsideration review. The CMS official will review the recommendation of the reconsideration official and the supporting materials and make a final agency determination.

If an ACO applicant requests a review of a decision to deny its application, and our initial determination is upheld, the application will be considered to have been denied based on the effective date of the original notice of denial. An ACO that requests a reconsideration review of an initial determination to terminate its participation in the Shared Savings Program will be permitted to continue to participate during the review process. However, if our initial determination to terminate the agreement with the ACO is upheld, the decision to terminate the agreement is effective as of the date indicated in the initial notice of termination.

An ACO whose Shared Savings Program application has been denied or whose Shared Savings Program agreement has been terminated due to a determination made by a reviewing antitrust agency may not contest the merits of the antitrust agency's determination through the reconsideration review process proposed in this rule. Furthermore, the

reconsideration review process proposed in this rule shall not be construed to negate, diminish, or otherwise alter the applicability of existing laws, rules, and regulations or determinations made by other government agencies.

We invite public comment, in general, on the structures and procedure of an appropriate review process for ACOs terminated for avoidance of at-risk beneficiaries or other reasons not exempted from review by statute.

*I. Coordination With Other Agencies*

As mentioned previously, in developing the Shared Savings Program, and in response to stakeholder concerns, we have worked very 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 the implementation of the program. The result of this effort is the release of three documents with which potential participants are strongly encouraged to become familiar. These documents include: (1) A joint CMS and DHHS Office of Inspector General (OIG) Medicare Program; 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 Antitrust Policy Statement issued by the FTC and DOJ (collectively, the Antitrust Agencies). In addition, we are proposing to preserve the benefits of competition for Medicare beneficiaries by precluding newly formed ACOs with market power from participating in the Shared Savings Program.

1. 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 have jointly published elsewhere in this **Federal Register** a Medicare Program, Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center, which describes and solicits public input regarding possible waivers of the application of certain CMP law provisions, the Federal anti-kickback statute, and the physician self-referral law to specified financial arrangements involving ACOs under the Shared Savings Program. In addition, section 1115A(d)(1) of the Act, as added by section 3021 of the Affordable Care Act, authorizes the Secretary to waive the same fraud and abuse laws, among others, as necessary solely for the purposes of carrying out the provisions of section 1115A of the Act with respect to the testing of certain innovative payment and service delivery models by the Innovation Center. The notice with comment period published elsewhere in this **Federal Register** also solicits public input regarding that separate waiver authority.

We expect that the waivers applicable to ACOs participating in the Shared Savings Program will be issued concurrently with our publication of the Shared Savings Program final rule. The requirements of the Shared Savings Program final rule will bear on the scope of any waivers granted for the Shared Savings Program. Because of the close nexus between the final regulations governing the structure and operation of ACOs under the Shared Savings Program and the development of waivers necessary to carry out the provisions of the Shared Savings Program, CMS and OIG may, when crafting waivers applicable to the Shared Savings Program, consider comments submitted in response to this Shared Savings Program proposed rule and the provisions of the Shared Savings Program final rule. Conversely, we may consider comments received in response to the joint notice with comment period when drafting the Shared Savings Program final rule. Members of the public submitting comment on this proposed regulation should consider commenting on the proposed waivers, as well.

2. IRS Guidance Relating to Tax-Exempt Organizations

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 intends to solicit 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. The IRS also intends to solicit comments concerning what guidance, if any, is necessary for tax-exempt organizations participating in ACOs that conduct activities unrelated to the Shared Savings Program.

We plan to continue to work with the IRS to ensure a coordinated and aligned interagency effort in the implementation of the program. Nothing in this proposed rule should be construed to modify, impair, or supersede the applicability of any of the Federal tax laws. For further guidance, tax-exempt organizations and ACOs should review the IRS notice and solicitation of public comment.

3. Antitrust Policy Statement

Concurrently with the issuance of this Shared Savings Program proposed rule, the Antitrust Agencies have issued a proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (Antitrust Policy Statement). The Antitrust Policy Statement applies to collaborations among otherwise independent providers and provider groups formed after March 23, 2010 that have otherwise been approved to participate, or seek to participate, as ACOs in the Shared Savings Program.

The Antitrust Policy Statement sets forth an antitrust "Safety Zone" for certain ACOs. Specifically, the Antitrust Policy Statement provides that the Antitrust Agencies, absent extraordinary circumstances, will not challenge an ACO that otherwise meets the CMS criteria to participate in the Shared Savings Program if ACO participants that provide the same service (common service) have a combined share of 30 percent or less of each common service in each ACO participant's Primary Service Area (PSA), wherever two or more ACO participants provide that service to patients from that PSA. Also, under the Rural Exception set forth in the Antitrust Policy Statement, ACOs may qualify for the Safety Zone under certain circumstances even if their combined PSA share for common services would be greater than 30 percent. The Antitrust Policy Statement further provides that an ACO outside the Safety Zone may proceed without scrutiny by the Antitrust Agencies if its combined PSA share for each common service, wherever two or more ACO

participants provide that service to patients from that PSA, is less than or equal to 50 percent. An ACO in this category is also highly unlikely to present competitive concerns if it avoids certain specified conduct. The Antitrust Policy Statement explains, however, that for ACOs that do not meet the Rural Exception, a combined PSA share for common services of more than 50 percent provides a valuable indication of an ACO's potential for competitive harm.

The Antitrust Policy Statement outlines a methodology by which ACOs can calculate their shares of common services (that is, the same services provided by two or more ACO participants) provided to patients from the same PSA. The common services consist of physician specialties, major diagnostic categories ("MDCs") for inpatient settings, and outpatient categories for outpatient settings. We will make public the information necessary to designate common services and to calculate the pertinent PSA shares.

We plan to continue to work with the Antitrust Agencies to determine the extent to which additional action may be appropriate with regard to ACOs in the Shared Savings Program. Nothing in this proposed rule should be construed to modify, impair, or supersede the applicability of any of the Federal antitrust laws. For further guidance, ACOs should review the Antitrust Policy Statement.

*4. Prohibition Against Shared Savings Program Participation by ACOs With Market Power*

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

In light of the Antitrust Agency Policy Statement, we propose to require that, except for an ACO that qualifies for the rural exception articulated in the Policy Statement, an 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 must submit to us, as part of its Shared Savings Program application, a letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or recommend challenging, the proposed ACO. Absent such a letter, the proposed ACO will not be eligible to participate in the Shared Savings Program. In addition, the Antitrust Policy Statement explains that ACOs that are outside the Safety Zone and below the 50 percent mandatory review threshold frequently may be procompetitive. It highlights how ACOs in this category that do not impede the functioning of a competitive market and that engage in procompetitive activities will not raise competitive concerns and may proceed without Agency scrutiny. However, to provide additional antitrust guidance, the Antitrust Policy Statement identifies five types of conduct that an ACO can avoid to significantly reduce the likelihood of an antitrust investigation. An ACO in this category that desires further certainty regarding the application of the antitrust laws to its formation and planned operation also can seek an expedited review from the Antitrust Agencies, similar to the mandatory review described previously. Such an ACO will 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 propose that an ACO that falls within the Safety Zone would not be required to obtain an Antitrust Agency review as a condition of participation. As noted in the Antitrust Policy Statement, the Antitrust Agencies are committed to providing expedited reviews for ACOs that exceed the 50 percent threshold and for those ACOs that fall below the 50 percent threshold and seek greater antitrust certainty. The procedures for obtaining such review are set forth in the Antitrust Policy Statement.

| ACO PSA Share | Review Process |
|---|---|
| **≤ 30 percent (with a rural exception)** | *Safety Zone* -- No antitrust review necessary by the Antitrust Agencies |
| **>30 percent and ≤50 percent** | *Expedited review, compliance with list of conduct restrictions, or proceed without antitrust assurances* –<br>ACOs may:<br>1. Request an expedited review by the Antitrust Agencies and submit letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or recommend challenging the ACO,<br>2. Begin to operate and abide by a list of conduct restrictions, reducing significantly the likelihood of an antitrust investigation, or<br>3. Begin to operate and remain subject to antitrust investigation if it presents competitive concerns. |
| **>50 percent** | *Required expedited review* -- ACO must seek review by the Antitrust Agencies to assess likelihood of procompetitive and anticompetitive effects. ACO eligibility to participate in Shared Savings Program is contingent on the ACO's submission of a letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or recommend challenging the proposed ACO. |

Additionally, we recognize there may be instances during the 3-year agreement period where there is a material change (as discussed in section II. C.) in the participant and/or provider/supplier composition of an ACO. When this occurs, we have proposed that the ACO must notify us of the change within 30 days and that the ACO must recalculate and report at that time their PSA shares for common services that two or more independent ACO participants provide to patients from the same PSA. We propose that if any revised PSA share is calculated to be greater than 50 percent, the ACO will be subject to mandatory review or re-review by the Antitrust Agencies in order to maintain the benefits of competition for Medicare beneficiaries and eligibility to participate in the Shared Savings Program. Finally, we propose that if the ACO fails to obtain a letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or recommend challenging the ACO, the ACO will be terminated from the Shared Savings Program.

The purpose of requiring Antitrust Agency confirmation that it has no present intent to challenge or recommend challenging the ACO as a condition of participation is two-fold. First, the proposal ensures that ACOs participating in the Shared Savings Program will not present competitive problems that could subject them to antitrust challenge that may prevent them from completing the term of their 3-year agreement with us. Section 1899(b)(2)(B) of the Act provides that ACOs shall enter into an agreement with the Secretary to participate in the program for not less than a 3-year period. We believe the requirement that ACOs be willing and able to commit to a 3-year 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 here furthers that intent.

Second, the proposal maintains competition for the benefit of Medicare beneficiaries by reducing the potential for the creation of ACOs with market power. As discussed in more detail later in the document, we believe 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 a variety of providers. Furthermore, competition benefits the Shared Savings Program by allowing the opportunity for the formation of two or more ACOs in an area, which could accelerate advancements in quality and efficiency. All of these benefits to Medicare patients would be reduced or eliminated if we allow ACOs to participate in the Shared Savings Program when their participation would create market power.

b. Competition and Quality of Care

Because Medicare prices are regulated, ACOs participating in the Shared Savings Program will not compete on the basis of price. Nevertheless, economic theory and competition policy suggest that these ACOs will compete to serve Medicare beneficiaries on the basis of nonprice dimensions such as quality of care, innovations that improve care, and choice in treatment options. Empirical studies of the Medicare program confirm this theory and demonstrate that, where prices are fixed, competition among health care providers produces higher quality for consumers.[22] The most prominent study of markets with fixed prices examined the impact of market concentration on mortality for Medicare heart attack patients. The study found that mortality was significantly higher for patients in more concentrated markets.[23] A later study had similar findings in that high-risk Medicare patients' heart attack mortality was higher in highly concentrated markets, while there was no such effect for low-risk patients.[24] Overall, the evidence suggests that competition in the presence of regulated prices fosters improved quality.

The means by which competition fosters improvements in quality, innovation, and choice for Medicare patients can vary. For example, competition among ACOs can:

- Motivate innovation in the use of existing treatment and care protocols and the development of new protocols. ACOs with better quality would be expected to attract more patients, and ACOs with both better quality and lower costs would obtain a greater percentage of shared savings.
- Accelerate the development of evidence-based best practices. In some instances, physicians may differ on the best course of treatment in a given case. In the early stages of developing evidence-based best practices, there may be no way to know which practice or care protocols among several alternatives would be most effective. An ACO with market power may have less incentive to test alternative practices or care protocols.
- Raise the likelihood of preserving alternatives in the market, ultimately leading to the emergency of better procedures and treatments.
- Provide better benchmarks for quality improvements. For example, although a single ACO might claim that environmental or demographic factors limit what it can achieve in the treatment of certain illnesses, a comparison among multiple ACOs in the same service area could better ensure that the best standards possible under prevailing conditions are being met.

c. Competition, Price, and Access To Care

A concern with potential ACO market power in the commercial (as well as the Medicare) market is warranted, because recent commentary suggests that health care providers are more likely to create ACOs under the Shared Savings Program if they can use the same ACOs to serve both Medicare beneficiaries and patients covered by commercial insurance.[25] If we permitted the creation of ACOs with market power to operate in the Shared Savings Program, those ACOs would likely operate in the commercial market as well. In the commercial market, however, prices are not regulated, so newly created ACOs with market power could raise prices to private purchasers and payers of health care insurance above competitive levels.

Higher commercial prices create disparities in payment rates between commercial purchasers and payers compared to Medicare rates. As reported in a study by MedPAC staff, hospitals with high payments from private payers had high levels of overall profitability.[26] Similarly, ACOs may wish to increase the profitable private patients they serve and, as a result, reduce the number of

[22] *See* Daniel P. Kessler & Mark B. McClellan, *Is Hospital Competition Socially Wasteful*? 115 Quarterly Journal of Econ. 577 (2000); Daniel P. Kessler & Jeffrey J. Geppert, *The Effects of Competition on Variation in the Quality and Cost of Medical Care,* 14 Journal of Econ. and Mgmt. Strategy 575 (2005). See also Abigail Tay *Assessing Competition in Hospital Care Markets: The Importance of Accounting for Quality Differentiation* 34 RAND Journal of Econ. 786 (2003).

[23] Daniel P. Kessler & Mark B. McClellan, *Is Hospital Competition Socially Wasteful*? 115 Quarterly Journal of Econ., 577 (2000).

[24] Daniel P. Kessler & Jeffrey J. Geppert, *The Effects of Competition on Variation in the Quality and Cost of Medical Care* 14 Journal of Econ. and Mgmt. Strategy, 575 (2005).

[25] Federal Trade Commision & Department of Health and Human Services, Medicare Program; Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-kickback, and Civil Monetary Penalty (CMP) Laws, 75 FR 57039.

[26] *Report to Congress: Medicare Payment Policy,* 111th Cong. (2010), *available at http://www.medpac.gov/documents/Mar10_EntireReport.pdf.*

Medicare beneficiaries they serve. In this way, commercial price increases resulting from newly created ACOs with market power could limit access to care for Medicare beneficiaries. Our proposal to require ACOs that exceed the 50 percent threshold to undergo a mandatory antitrust review seeks to ensure that there are sufficient providers to allow the formation of competing ACOs to serve Medicare beneficiaries.

In summary, we believe that it is reasonable and appropriate to make approval of an ACO's Shared Savings Program application and continuation in the program contingent on the absence of a determination by the reviewing Antitrust Agency that it is likely to challenge or recommend challenging the ACO, or in the case of an ACO that exceeds the 50 percent threshold, on the ACO's submission of written confirmation from the reviewing Antitrust Agency that it has no present intent to challenge or recommend challenging the ACO.

We plan to continue to work with the Antitrust Agencies to determine the extent to which additional actions may be appropriate with regard to ACOs participating in the Shared Savings Program. We will also work closely with the Innovation Center (which is charged with considering whether the models it tests demonstrate effective linkage with other public and private sector payers) and will use the results from the ACO models it tests to inform possible future rulemaking that may be necessary in order to maintain ACO competition for the benefit of Medicare beneficiaries. Nothing in these regulations shall be construed to modify, impair, or supersede the applicability of the antitrust laws.

*J. Overlap With Other CMS Shared Savings Initiatives*

1. Duplication in Participation in Medicare Shared Savings Programs

The statute includes a provision that precludes duplication in participation in shared savings programs. 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)(A) and (B) of the statute, as added by section 3022 of the Affordable Care 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."

Other shared savings programs that include the opportunity for Medicare-enrolled TINs to earn payment, in the form of shared savings, for savings to Medicare for Part A and B services rendered to Medicare FFS beneficiaries would be considered duplicative. We have determined that the following existing shared savings programs overlap with the Shared Savings Program and therefore, a Medicare-enrolled TIN may not participate in both the Shared Savings Program and one of the following:

- Independence at Home Medical Practice Demonstration program, as established by section 3024 of the Affordable Care Act.
- Medicare Health Care Quality Demonstration Programs, as established by section 646 of the Medicare Modernization Act.
- Medical home demonstrations with a shared savings element: Currently, the only such Medicare demonstration that includes a shared savings component is the multi-payer advanced primary care demonstration
- Physician Group Practice Transition Demonstration.

Additional programs, demonstrations, or models with a shared savings component may be introduced in the Medicare program in the future. Interested parties should check the CMS Web site for an updated list to ensure that a provider or supplier participating in the Shared Savings Program does not participate in another Medicare program or demonstarion involving shared savings.

The prohibition against duplication in participation in shared savings programs applies only to programs that involve shared savings under Medicare, and the following are examples of such programs established by the Affordable Care Act which are unlikely to generate duplicative shared savings:

- State initiatives to provide health homes for Medicaid enrollees with chronic conditions as authorized under section 2703 of the Affordable Care Act.
- Program to establish community health teams to support patient-centered medical homes under section 3502 of the Affordable Care Act.

We believe a principal reason underlying the prohibition against participation in multiple shared savings programs is to prevent a provider or supplier from being rewarded twice for achieving savings in the cost of care provided to the same beneficiary. As discussed in section II.D. of this proposed rule, we propose that beneficiaries will be assigned to an ACO based upon the TIN of the ACO participant from which they receive the plurality of their primary care services. 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 shared savings programs, we do not believe it is appropriate to extend this prohibition to individual providers and suppliers. We explore alternative provider incentives, payment arrangements and care delivery mechanisms through its shared savings programs, often specific to subsets of Medicare or Medicaid beneficiaries. To further our understanding of the delivery of cost effective and high quality care, and to ensure beneficiaries receive the most appropriate care possible relative to their needs, individual practitioners should have the opportunity to concurrently participate in multiple shared savings programs. 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 different TIN that is not an ACO participant since there would be no duplication in beneficiary assignment; and therefore, no duplication in shared savings.

We propose 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 will compare the participating TINs in the program with those 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 propose working with the developers of the respective demonstrations and initiatives to devise an appropriate method to ensure no duplication in shared savings payment. Applications for participation in the Shared Savings Program that include TINs that are already participating in another Medicare shared savings program will be rejected.

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

The PGP demonstration, authorized under section 1866A of the Act, was our first experience with a shared savings program in Medicare. The PGP demonstration serves as a model for many aspects of the Shared Savings Program. Section 1899(k) of the Act speaks directly to the treatment of the PGP demonstration. "During the period beginning on the date of the enactment of this section and ending on the date the program is established, the Secretary may enter into an agreement with an ACO under the demonstration under section 1866A of the Act, subject to rebasing and other modifications deemed appropriate by the Secretary." As the final performance year of the initial five year PGP demonstration concluded in March 2010, this section of the Affordable Care Act authorizes the Secretary to extend the PGP demonstration.

It is likely that the 10 physician groups in the PGP demonstration will be uniquely situated and qualified to be among the organizations which are ready to become early participants in the Shared Savings Program. As noted 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 would be permitted to participate in either the PGP demonstration or the Shared Savings Program under section 1899 of the Act, but could not participate in both. 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.

We believe it is appropriate to consider what transition process should be available for those PGP demonstration sites that wish to participate in the Shared Savings Program. We do not believe that automatically transferring the PGP demonstration sites into the Shared Savings Program is appropriate because we are concerned that some of the PGP demonstration participants may be incapable of meeting the Shared Savings Program's requirements, thereby jeopardizing the participant's ability to achieve the overall goals associated with the Shared Savings Program, including the ability to achieve shared savings. On the other hand, requiring the PGP sites to undergo the same application process as all other entities would not account for our familiarity with these organizations, and their experience with redesigning care processes and improving quality in a shared savings setting. In addition, requiring the sites to undergo the full application process could potentially deter qualified sites that are currently participating in the PGP demonstration from transitioning from the PGP demonstration to the Shared Savings Program.

We propose that should a PGP site decide to apply for participation to the Shared Savings Program, we will 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. For instance, the condensed application would ensure that the PGP site satisfies the eligibility requirements of the Shared Savings Program, as follows:

- Establishing a shared governance structure and leadership and management structure according to program requirements;
- Providing documentation around processes for quality management and patient engagement, and patient-centeredness criteria as described in section II.B of this proposed rule.

However, it should be noted that some PGP sites applying to the Shared Savings Program may not constitute a newly created ACO and therefore would be exempt from the antitrust review described previously in the Coordination With Other Agencies section of this preamble.

3. 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, as amended by section 3021 of the Affordable Care 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.

As mentioned previously, section 1899(b)(4) of the Act also restricts providers of services and suppliers from participating in both the Shared Savings Program and other 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 shared savings models tested by the Innovation Center. Similarly, we will also take steps to ensure there is a methodology to avoid duplication of 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.

Finally, the Innovation Center is seeking input on how it can best test different payment models that provide financial and technical assistance to groups of providers and suppliers that may wish to develop into an ACO.

## III. Collection of Information Requirements

As stated in section 3022 of the Affordable Care Act, Chapter 35 of title 44, United States Code, shall not apply to the Shared Savings Program.

Consequently, the information collection requirements contained in this proposed rule need not be reviewed by the Office of Management and Budget.

## IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

## V. Regulatory Impact Analysis

### *A. Introduction*

We have examined the impacts of this proposed 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 rule has been designated an "economically" significant rule, under section 3(f)(1) of Executive Order 12866. 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 proposed 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 proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, pre-empts State law, or otherwise has Federalism implications. We do not believe that there is anything in this proposed rule that either explicitly or implicitly pre-empts any State law, and furthermore we do not believe that this proposed rule will have a substantial direct effect on State or local governments, preempt States law, or otherwise have a Federalism implication.

### *B. Statement of Need*

This proposed 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 of 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. 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 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 accepting risk while maintaining sufficient incentive to encourage providers to participate in the one-sided model, providing an entry point to risk-oriented models.

As detailed in Table 10, we estimate a total aggregate median impact of $510 million in net Federal savings for CYs 2012 through 2014 from the implementation of the Shared Savings Program. (An estimate produced by the Office of the Actuary on April 22, 2010 showed no net impact only because the statute by itself lacked enough detail to allow for scoring.) The 10th and 90th percentiles of the estimate distribution, for the same time period, show net savings of $960 million and $170 million. These estimated impacts represent the effect on Federal transfers. The estimated aggregate cost for start-up investment and first year operating expenditures for ACOs in the Shared Savings Program range from $131,643,825 to $263,287,650, assuming 75 to 150 ACOs participating in the Shared Savings Program. Furthermore, the Shared Savings Program would benefit beneficiaries since the program requires 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 demonstrate a dedication and focus toward patient-centered care. Accordingly, we have prepared a RIA that to the best of our ability presents the costs and benefits of this proposed rule. We solicit comment on the assumptions and analysis presented throughout this regulatory impact section.

**Table 10: Estimated Net Federal Savings, Costs and Benefits, Years 1-3**

| Federal Savings | Year 1 | Year 2 | Year 3 | Total (Years 1-3) |
|---|---|---|---|---|
| 90th Percentile | $30 Million | $90 Million | $50 Million | $170 Million |
| Median | $100 Million | $210 Million | $200 Million | $510 Million |
| 10th Percentile | $190 Million | $380 Million | $390 Million | $960 Million |
| Costs | Total ACO start-up investment and first year operating expenditures average from $131,643,825 to $263,287,650, for the estimated range of 75-150 participating ACOs. | | | |
| Benefits | Improved healthcare delivery and quality of care and better communication to beneficiaries through patient centered-care. | | | |

As discussed in the preamble of this proposed rule, the Shared Savings Program establishes a program whereby groups of suppliers and providers can work together through ACOs that would assume responsibility for managing and coordinating the care of groups of traditional FFS Medicare patients. 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 years 1 and 2 without the risk of being responsible for repaying any losses if actual expenditures exceed the benchmark, followed by a third year offering a higher percentage of shared savings but also risk for excess expenditures above the benchmark. The second option (two-sided model) provides an opportunity for receiving a higher percentage of shared savings for all 3 years, but with potential liability in each of the 3 years for annual expenditures that exceed the benchmark.

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 program design and other 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 10. In this way, we can evaluate the full range of potential outcomes based on all combinations of the many factors that will affect the financial impact, and with an indication of the likelihood of these outcomes. It is important to note that these indications do not represent formal statistical probabilities in the usual sense, since basis for 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 11, 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 $510 million in net savings over CYs 2012 through 2014. Approximately 97 percent of the stochastic trials resulted in a net savings to the Medicare program, while the other 3 percent produced a net cost. At the extremes, the greatest simulated savings was approximately $1,960 million, while the greatest simulated cost was $270 million.

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 we finalize the Shared Savings Program provisions, and 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 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 development.

*C. 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 possible approaches. The optional two-sided risk model, and the requirement for all other ACOs to accept downside risk in their third program year, both provide stronger incentives than a shared savings only approach. For example, under the one-sided model, a provider's worst-case outcome is the failure to earn shared-savings. A provider would operate under the significant possibility that there would be no impact on their Medicare reimbursement. The two-sided risk model, however, presents liability for excessive expenditures, significantly increasing a provider's perceived likelihood that aggregate Medicare revenue will depend on the level of efficiency with which they operate. In addition, the two-sided model offers a lower minimum savings rate and a greater sharing percentage, both of which enhance the incentive for efficiency. However, participating ACOs may be more likely to choose the one-sided model for the first 2 years and thereby avoid the potential for financial loss if expenditures experience a significant upward fluctuation or if efficiency improvements are less effective than planned.

In the third year of their first agreement period, as noted previously, all ACOs that participate in the one-sided model during the first 2 years of the agreement period will be required to transition to the two-sided risk model. We believe certain participating ACOs may choose to terminate their agreement early after the first 2 years. For example, ACOs in Track 1 that failed to meet the expenditure growth targets in the first 2 years (but were protected from penalties by being in the one-sided model), would likely reconsider their continuing participation. Certain other ACOs, such as those in higher-cost areas of the country, could also terminate their agreement if they anticipate that the national growth formula, relative to their local baseline cost, puts them in jeopardy of experiencing losses in the third year. (Under section 2899(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.

While shared FFS savings, even with optional liability for a portion of excess expenditures, offers less incentive to reduce costs or improve efficiency 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, managing care furnished by providers and suppliers outside the ACO, lack of similar contracts with other payers, achieving buy-in from ACO providers and 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 the ACO.

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. The assumptions identified and stochastically modeled include the following:

- Number of participating ACO provider groups.
- Size mix of participating ACOs.
- Type of ACO that would consider accepting risk under the two-sided risk option.
- 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 national average.
- Number and profile of providers and suppliers unavailable to participate in the Shared Savings Program due to participation in ACO models tested by the Innovation Center.
- Range of savings for participating ACOs within the first three years of the program.
- 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 1.5 to 4 million Medicare beneficiaries would align with a participating ACO during the first three years of the program. We assumed ACOs to be more likely to participate from markets exhibiting baseline per-capita FFS expenditures above the national average. 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.

Of particular relevance 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 Program shared savings payments even in the absence of any efficiency gains. Similarly, some ACOs could find that in the determination of shared savings by factors such as prevailing per-capita expenditure growth in their service area that is higher than the national average overshadows their hard-fought efficiency gains.

b. Detailed Stochastic Modeling Results

Table 11 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 2014 is a net savings of $510 million. This amount represents the "best estimate" of the 3-year financial impact of the Shared Savings Program initiative. It is important to note, however, the relatively wide range of possible outcomes. Overall, 97 percent of the stochastic trials resulted in net program savings, and the other 3 percent represented cost increases. The 10th and 90th percentiles of the estimated

distribution show net savings of $960 million and $170 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 billion in savings or $270 million in costs.

Our Office of the Actuary (OACT) prepared the stochastic model and resulting financial estimates. OACT believes that the median result of $510 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 proposed rule. However, OACT emphasizes the possibility of outcomes that differ substantially from the median estimate, as illustrated by the estimate distribution. With the adoption of final program provisions and 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 1.5 to 4 million beneficiaries to participating ACOs over the first 3 years. 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 11—Stochastic Distribution for Estimated Total 3-Year Net Savings (–) or Costs (+)**

(Dollar amounts in millions)

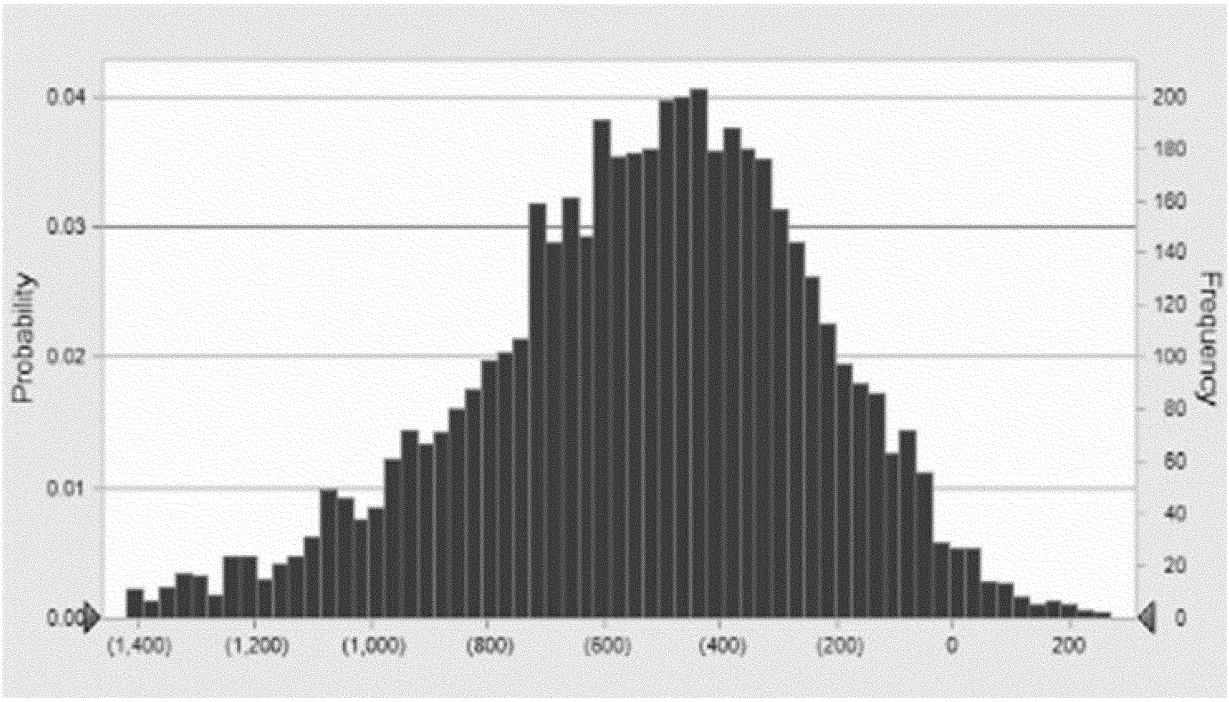
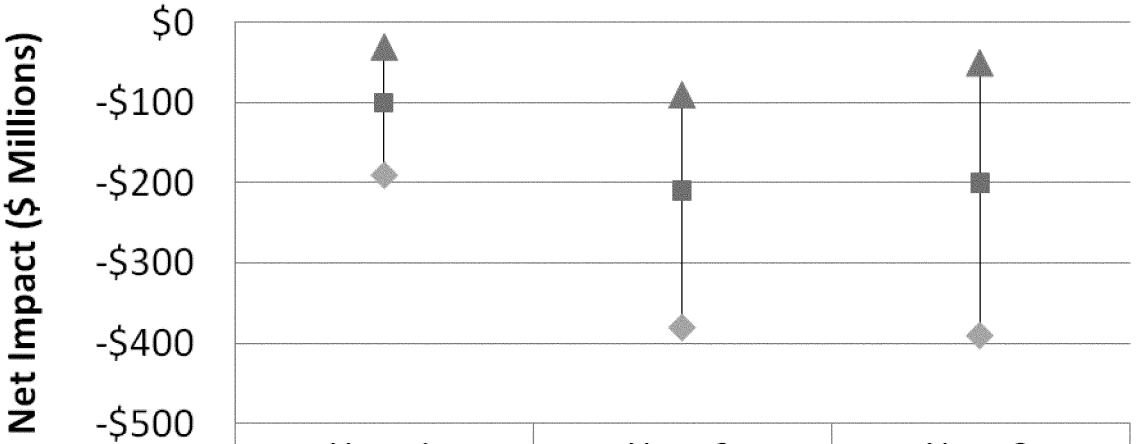



Table 12 shows the median estimated financial effects for the Shared Savings Program initiative, and the associated 10th and 90th percentile ranges, broken out for each of the first 3 years. For the first year, 2012, the median projection indicates a $100 million savings, primarily because the ACO cost-efficiency initiatives are generally not assumed to have matured, but a number of provider groups that benefit from favorable random claim fluctuations or from low baseline expenditure relative to the national average would receive shared saving payments. By the second and third years, 2013 and 2014, of the projection, the median estimates indicate net savings of $210 million and $200 million, respectively, from increased cost-saving effectiveness offset in part by shared savings paid due to random variation and the (increasing) variation in the accuracy of updated national targets compared to actual local growth as well as participation and sharing percentage changes resulting from mandatory transition to two-sided risk in the third year. As a result, the projections for years 2 and 3 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.

**Table 12—Stochastic Distribution for Estimated Net Savings (–) or Costs (+), Years 1-3**

(Dollar amounts in millions)




| | Year 1 | Year 2 | Year 3 |
|---|---|---|---|
| ▲ 90th %-ile | -$30 | -$90 | -$50 |
| ■ median | -$100 | -$210 | -$200 |
| ◆ 10th %-ile | -$190 | -$380 | -$390 |

c. Further Consideration

The impact analysis shown is only for the first 3-year 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. A risk exists that by ACOs in low-cost areas could dominate the Shared Savings Program, where participation could be a relatively risk-free opportunity to achieve shared savings simply due to the generous benchmark presented by national average "flat-dollar" growth. On the other hand, the first 3-year agreement period ACOs could 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 3 years of the program, does not incorporate either of these longer-run scenarios, but both remain possibilities—subject to the final program design and implementation. At this time, an impact estimate expanded to include performance beyond the initial 3-year 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. Patient-centered care is a concept that focuses healthcare delivery and communication on the patient and those who are close to the patient and bases the care and communication delivered around the needs of the beneficiary, thus benefitting the beneficiary community. This program does not affect the beneficiary's freedom of choice regarding providers or care. 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 beneficiary impacts would be maximized as the ACO meets the mission of the Shared Savings Program, as established by the Affordable Care Act and embraces the following 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. F, Shared Savings Determination, of this proposed rule, how well it improves and delivers high quality care outlined in the quality measurement and reporting methodology in section II.E. of this proposed rule, and in meeting program requirements for patient centered care outlined in the eligibility section II.B. of this proposed rule.

Therefore, because of the accountability of ACOs 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, August 2009) showed that over the first three years of the PGP Demonstration, physician groups increased their quality scores an average of 10 percentage points on the 10 diabetes measures, 11 percentage points on the ten congestive heart failure measures, 6 percentage points on the coronary artery disease measures, 10 percentage points on the cancer screening measures, and 1 percentage point on the 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 can be examined by comparing the values of the seven claimsbased 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 that program participation will create.

The proposed rule allows for flexibility regarding the specific structure of an ACO and, as such, we expect the costs to vary greatly. Furthermore, beyond the statutorily required assignment of at least 5,000 Medicare beneficiaries to an ACO, the size of ACOs will also vary in relation to beneficiary participation and associated cost. 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, 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 nonphysician 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.

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 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 present a rough estimate of

$1,755,251, based on the GAO findings to reflect the total average start-up investment and first year operating expenditures for a participant in the Shared Savings Program. Lastly, assuming a range of expected ACOs participating in the Shared Savings Program at 75 to 150 yields an estimated aggregate cost, for ACO start-up investment and first year operating expenditures in the Shared Savings Program, in the range of $131,643,825 to $263,287,650.

Participating in the Shared Savings Program will require groups of providers and suppliers to (among other things): invest in or improve upon information technology systems, focus on evidence-based medicine, improve care coordination and quality and generally refine all processes of caring for their patients and community. While, as we discussed previously, there will be a financial cost placed on ACOs in order to do so, 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 proposed rule, there will be an opportunity for financial reward for success in the program in the form of shared savings. The estimated bonuses paid are a median of $800 million over 3 years, with $560 million and $1,130 million reflecting the 10th and 90th percentiles. Also, participating ACO's will be assuming a risk of a financial penalty for failing to achieve savings (that is, if actual expenditures exceed the benchmark). The estimated penalties paid are a median of $40 million over 3 years, with $10 million and $80 million reflecting the 10th and 90th percentiles. (It is important to note that the given percentiles for bonuses, penalties, and net impacts are independently tabulated and therefore are not additive across the three parameters.) The actuality of the risk is dependent on which of the two options an ACO selects for their first agreement period. 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. We anticipate that not all ACOs will achieve shared savings and some will incur a financial loss, due to requirement to repay a share of actual expenditures in excess of their benchmark.

As is previously stated, we expect the costs and benefits of establishing and maintaining an ACO to vary and solicit comment on this issue, including total ACO expenditures for start-up investment and annual operating costs for the 3 years of the Shared Savings Program.

*D. Alternatives Considered*

The proposed 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 on 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 minimum of 5,000 assigned beneficiaries, as is described in the preamble, we are proposing a sliding minimum percentage and confidence interval for the savings threshold based on the size of an ACO. This proposal is a balance of protecting the program from paying out savings based on random variation, while allowing attainable thresholds for smaller sized potential ACOs and thus encouraging participation from various sized entities.

The preceding preamble provides descriptions of the various statutory provisions that are addressed, identifies those policies when discretion has been allowed and exercised, presents the rationales for our proposals and, where relevant, alternatives that were considered. An important example involves 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 hospitals (as will occur under current law at the end of FY 2011) then ACO-attributed claims incurred in a 508 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. However, as we have previously noted, the statute provides authority for adjustment to the benchmark for "such other factors as the Secretary determines appropriate."

Another design element involves the method for constructing a participating ACO's benchmark. One proposed method employs a similar approach to that used in the CMS PGP Demonstration and is based on risk-adjusting to take into account changes in the health status of the population between the benchmark period and performance year. If HCC risk adjustments are specified in the final program then it must be applied in a manner that does not reward ACOs for more complete and accurate coding of their assigned patient population to protect the program from costs due to paying shared savings as a result of greater diagnosis coding intensity in ACOs than would occur for a comparable group of beneficiaries receiving care outside an ACO.

Finally, a key design element involves the method for establishing quality standards. We propose aggregating the quality domain scores into a single overall ACO score used to calculate the ACOs final sharing rate for purposes of determining shared savings or shared losses as described in section II.E of this proposed 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 methodology that would have differing incentives for improving clinical outcomes such as: Scoring measures individually under a method that would weight all measures equally as well as weighting 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 to realize the full shared savings. By design this approach could ensure higher net savings to the Medicare program, depending on the quality threshold and sharing percentage chosen.

The provisions adopted in the final Shared Savings Program rule may differ from the current proposals, possibly resulting in material changes in the projected financial impact of the program. We solicit comment on other potentially effective and reasonably feasible alternatives especially those that reduce burdens and maintain flexibility and freedom of choice for the public.

*E. 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 13, we have prepared an accounting statement showing the classification of transfers, benefits and

costs associated with the provisions of this proposed rule. Because of the uncertainties identified in establishing the economic impact estimates, we intend to update the estimates in the final rule.

**TABLE 13: Accounting Statement: Estimated Transfers, Benefits and Costs (CY 2012 to CY 2014**

| Category | TRANSFERS | | | |
|---|---|---|---|---|
| **Annualized Monetized Transfers** | Year Dollar | Units Discount Rate | | Notes |
| | 2011 | 7% | 3% | These estimates represent the range of annualized impact on the Medicare Program for CYs 2012 - 2014. |
| | Primary Estimate | -$167.72 million | -$169.01 million | |
| | 90th Percentile Estimate | -$56.19 million | -$56.46 million | |
| | 10th Percentile Estimate | -$315.45 million | -$318.02 million | |
| From/To | Federal Government to ACO Providers | | | |
| **Category** | **BENEFITS** | | | |
| **Qualitative Benefits** | Improved healthcare delivery and communication to beneficiaries through patient centered-care. | | | |
| **Category** | **COSTS** | | | |
| **Costs** | Total ACO start-up investment and first year operating expenditures average from $131,643,825 to $263,287,650, for the estimated range of 75-150 participating ACOs. | | | |

*F. Conclusion*

As a result of this proposed rule, the median estimate of the financial impact from implementation of the Shared Savings Program, for CYs 2012 through 2014, is a net savings of $510 million. Although this is the "best estimate" for the 3-year financial impact of the Shared Savings Program initiative, a relatively wide range of possible outcomes exists. Overall, 80 percent of the stochastic trials resulted in net program savings, and the other 30 percent represented cost increases. The 10th and 90th percentiles of the estimate distribution show net savings of $960 million and $170 million, respectively, suggesting a 10-percent likelihood that the actual impact would exceed the respective percentile amounts. In the extreme scenarios, the results were as large as $1,960 million in savings or $270 million in costs. Lastly, the estimated aggregate cost for ACO start-up investment and first year operating expenditures in the Shared Savings Program range from $131,643,825 to $263,287,650, based on an assumed 75 to 150 ACOs participating in the Shared Savings Program.

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

**List of Subjects in 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 proposes to amend 42 CFR Chapter IV by adding part 425 to read as follows:

**SUBCHAPTER B—MEDICARE PROGRAM**

## PART 425—MEDICARE SHARED SAVINGS PROGRAM

Sec.

**Subpart A—General Provisions**

425.2 Basis and scope.
425.4 Definitions.

**Subpart B—Shared Savings Program Requirements**

425.5 Eligibility and governance requirements.
425.6 Assignment of Medicare fee-for-service beneficiaries to ACOs.
425.7 Payment and treatment of savings.
425.8 ACO quality and continuous improvement goals.
425.9 Measures to assess the quality of care furnished by an ACO.
425.10 Calculating the ACO quality performance score and determining shared savings eligibility.
425.11 Incorporating other reporting requirements related to the Physician Quality Reporting System and electronic health records technology.
425.12 Monitoring.
425.13 Actions prior to termination.
425.14 Termination, suspension, and repayment of Shared Savings.
425.15 Reconsideration review process.
425.16 Audits and record retention.
425.17 Requirements for data submission by ACOs.
425.18 The 3-year agreement with CMS.
425.19 Data sharing with ACOs.
425.20 New program standards established during the 3-year agreement period.
425.21 Managing significant changes to the ACO during the agreement period.
425.22 Future participation of previous Shared Savings Program participants.
425.23 Public reporting and transparency.
425.24 Overlap with other CMS shared savings initiatives.

### Subpart A—General Provisions

**§ 425.2 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 parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient services. 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 (ACO). ACOs that meet quality performance standards established by the Secretary are eligible to receive payments for shared savings. During years in which the ACO is participating in a two-sided model, the ACO may be required to share losses.

(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) Program requirements, including quality and other reporting requirements.

(3) The method for assigning Medicare fee-for-service beneficiaries to ACOs.

(4) Payment criteria and methodologies (one-sided model and two-sided model).

(5) Compliance monitoring and sanctions for noncompliance.

(6) Reconsideration of adverse determinations.

**§ 425.4 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 law, as identified by a Taxpayer Identification Number (TIN), and comprised of an eligible group (as defined at § 425.5(b)) of ACO participants that work together to manage and coordinate care for Medicare fee-for-service beneficiaries and have established a mechanism for shared governance that provides all ACO participants with an appropriate proportionate control over the ACO's decision-making process.

*ACO participant* means a provider (as defined in § 400.202) or a supplier (as defined at § 400.202), as identified by a TIN.

*ACO provider/supplier* means—

(1) A provider (as defined in § 400.202); or

(2) A supplier (as defined at § 400.202) that bills for items and services it furnishes to Medicare beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare rules and regulations.

*ACO professional* means an ACO provider/supplier who is either of the following:

(1) A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action, including an osteopathic practitioner within the scope of his or her practice as defined by State law.

(2) A practitioner who is one of the following:

(i) A physician assistant (as defined at § 410.74(a)(2)).

(ii) A nurse practitioner (as defined at § 410.75(b)).

(iii) A clinical nurse specialist (as defined at § 410.76(b)).

*Antitrust Agency* means the Department of Justice or Federal Trade Commission.

*Antitrust Policy Statement* means the Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program issued by the antitrust agencies.

*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 primary care physician(s) 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 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 each year;

(3) Is dually eligible for Medicare and Medicaid;

(4) Has a high utilization pattern; or

(5) Has had a recent diagnosis that is expected to result in increased cost.

*CAP* means a corrective action plan.

*Covered professional services* has the same meaning give these terms under section 1848(k)(3) of the Act.

*Eligible professional* has the meanings given this term under section 1848(k)(3) of the Act.

*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, or other activities conducted by or on behalf of the ACO, or by ACO participants, or ACO providers/suppliers participating in the ACO, or by other individuals on behalf of the ACO or its participating providers and suppliers 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: Informational materials customized or limited to a subset of beneficiaries; materials that do not include information about the ACO or providers in the ACO; materials that cover beneficiary-specific billing and claims issues or other specific health-related issues; or educational information on specific medical conditions (for example, flu shot reminders), or referrals for Medicare covered items and services.

*Medicare fee-for-service beneficiary* means an individual who is—

(1) Enrolled in the original Medicare fee-for-service program under 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.

*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 the provisions of § 425.7(c).

*Physician Quality Reporting System* means the system established under section 1848(k) of the Act.

*Primary care physician* means a physician (as defined at § 410.20(b)(1)) who has a primary specialty designation of internal medicine, general practice, family practice, or geriatric medicine.

*Primary care services* mean the set of services identified by the following HCPCS codes: 99201 through 99215, 99304 through 99340, and 99341 through 99350, G0402 (the code for the Welcome to Medicare visit); and G0438 and G0439 (codes for the annual wellness visits).

*Reporting period* means January 1 through December 31.

*TIN* means Federal taxpayer identification number.

*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 the provisions of § 425.7(d).

## Subpart B—Shared Savings Program Requirements

**§ 425.5 Eligibility and governance requirements.**

(a) *General requirements.* (1) 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 participates in the Shared Savings Program and meets the criteria specified in this part.

(2) ACOs that exceed a minimum savings rate established under § 425.7(c)(2) and (d)(2), meet the minimum quality performance standards established under § 425.10, and otherwise maintain their eligibility to participate in the Shared Savings Program under this section are eligible to receive payments for shared savings under § 425.7 of this subpart.

(3) ACOs that operate under the two-sided model established in this section must share losses with the Medicare program under § 425.7 of this subpart.

(b) *Eligible providers and suppliers.* The following ACO participants, which must have established a mechanism for

shared governance, are eligible, separately or in combination, to form ACOs that may 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) Providers or suppliers otherwise recognized under the Act that are not ACO professionals or hospitals, as defined in § 425.4.

(6) CAHs that bill under Method II (as described in § 413.70(b)(3))

(c) *Reporting of TINs.* (1) Each ACO must report to CMS the TINs of the ACO participants comprising the ACO along with a list of associated National Provider Identifiers (NPIs), at the beginning of each performance year and at other such times as specified by CMS.

(2) 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.

(3) ACO participant TINs upon which beneficiary assignment is not dependent are required to commit to a 3-year agreement to the ACO, and the ACO participant must not be required to be exclusive to a single ACO.

(d) *Other requirements.* (1) *Accountability for beneficiaries.* As part of its application and 3-year agreement, the ACO must certify that the providers and suppliers forming the ACO have agreed to become accountable for and report to CMS on the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO. Each ACO must make information on its accountability for quality, cost, and the overall care of its assigned population available to the public in a standardized format, as determined by CMS.

(2) *Coordination of Antitrust Agency review.* (i) Except for an ACO that qualifies for the Rural Exception articulated in the Antitrust Policy Statement or other controlling guidance from the antitrust agencies, an ACO with a Primary Service Area (PSA) share, as described in the Antitrust Policy Statement, greater than 50 percent for any common service that two or more ACO participants provide to patients from the same PSA must do both of the following:

(A) Request an expedited antitrust review from the Antitrust Agencies.

(B) Submit, as part of its application, a letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or to recommend challenging the proposed ACO.

(ii) Except for an ACO that qualifies for the Rural Exception articulated in the Antitrust Policy Statement, or other controlling guidance from the antitrust agencies, an ACO with a PSA share, as described in the Antitrust Policy Statement, greater than 30 percent and less than or equal to 50 percent may do one of the following:

(A) Request an expedited antitrust review from the Antitrust Agencies.

(B) Submit a letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or to recommend challenging the proposed ACO.

(C) Begin to operate and abide by a list of conduct restrictions, reducing significantly the likelihood of antitrust concern.

(D) Begin to operate and remain subject to antitrust investigation if it presents competitive concerns.

(iii) An ACO must notify CMS at least 30 days before any material change within the 3-year agreement period of its ACO participants or ACO providers/suppliers and must submit recalculated PSA shares for common services that two or more independent ACO participants provide to patients from the same PSA. If any revised PSA share is calculated to be greater than 50 percent, the ACO will be subject to review or re-review by an Antitrust Agency in order to remain eligible to participate in the Shared Savings Program.

(iv)(A) If an ACO receives a letter from a reviewing Antitrust Agency stating that the Antitrust Agency will likely challenge or recommend challenging the ACO, then the ACO will be ineligible to participate in the Shared Savings Program.

(B) The ACO must promptly inform CMS if it receives such a letter at any time from an Antitrust Agency.

*(3) Agreement requirements.* (i) 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 3-year agreement.

(ii) The 3-year agreement must require the ACO to comply with the provisions in this part in order to participate in the Shared Savings Program.

(iii) All contracts or arrangements between or among the ACO, ACO participants, ACO providers/suppliers, and other entities furnishing services related to ACO activities must require compliance with the requirements and conditions of this part, including those specified in the 3-year agreement. The ACO must provide a copy of the 3-year agreement to these individuals and entities.

(iv)(A) The ACO must certify the accuracy, completeness, and truthfulness of its information contained in the following:

(*1*) Shared Savings Program application.

(*2*) 3-year agreement.

(*3*) Submissions of quality data and other information.

(B) Certification must be made at the time the ACO submits the following:

(*1*) Application to participate in the Shared Savings Program.

(*2*) Executes the 3-year agreement.

(*3*) Submits any information, including quality data, on which shared savings payments or shared losses are calculated.

(C) Certification must be signed by an individual with the authority to legally bind the ACO (for example the ACO's chief executive officer (CEO) or chief financial officer (CFO)).

(v) The ACO must establish partnerships with community stakeholders in order to advance the three-part aim of better care for individuals, better health for populations, and lower growth in expenditures.

(vi) The ACO must agree, and must require its ACO participants, ACO providers/suppliers, and contracted entities performing functions or services on behalf of the ACO to agree, or to comply with applicable provisions of the following:

(A) Federal criminal law.

(B) The False Claims Act (31 U.S.C. 3729 et seq.).

(C) The anti-kickback statute (42 U.S.C. 1320a–7b(b)).

(D) The civil monetary penalties law (42 U.S.C. 1320a–7a).

(E) The physician self-referral law (42 U.S.C. 1395nn).

(vii)(A) The ACO must agree, as a condition of receiving any shared saving payment and participating in the program, that an individual with the authority to legally bind the ACO must certify that any data or information requested by or submitted to CMS is accurate, complete, and truthful.

(B) If data or information is generated by an entity other than the ACO, such entity must similarly certify the accuracy, completeness, and truthfulness of the information or data.

(4) *Marketing materials.* (i) Any ACO marketing materials or activities, as defined in § 425.4, must be approved by CMS before use.

(ii) Any changes to CMS-approved marketing materials or activities must be approved by CMS before use.

(5) *Notice of ACO participation.* (i) ACO participants must notify beneficiaries that their ACO providers/suppliers are participating in an ACO.

(ii) Except as specified in paragraph § 412.1(a)(1) of this section, all beneficiary communications any materials or activities used by ACO participants or ACO providers/suppliers on behalf of the ACO to communicate about the ACO in any manner to Medicare beneficiaries, must be approved by CMS before use.

(6) *Tracks during agreement periods.* (i) For its initial agreement period, an ACO may elect to operate under one of the following tracks:

(A) *Track 1.* Under Track 1, the ACO operates under the one-sided model (as described under § 425.7(c) of this part) for 2 years, and under the two-sided model (as described under § 425.7(d) of this part) for the third year. In the third year of the ACO's agreement under Track 1, the methodology used to reconcile ACOs under the first year of the two-sided model would apply except ACOs must meet the quality performance standard that applies in the third year.

(B) *Track 2.* Under Track 2, the ACO operates under the two-sided model (as described under § 425.7(d) of this part), sharing both savings and losses with the Medicare program for 3 years.

(ii) For subsequent agreement periods, an ACO may operate only under the two-sided model, sharing both savings and losses with the Medicare program (as described in § 425.7(d) of this part).

(iii) In both models an ACO's share in savings will be subject to 25 percent withholding in order to help ensure repayment of any losses to the Medicare program. The withheld amount will be applied towards repayment of an ACO's losses.

(iv) ACOs must obtain reinsurance, place funds in escrow, obtain surety bonds, establish a line of credit as evidenced by a letter of credit that the Medicare program can draw upon, or establish another appropriate repayment mechanism in order to ensure repayment of any losses to the Medicare program in advance of entering a period of participation in the Shared Savings Program under the two-sided model.

(v) An ACO that is applying for participation in the Shared Savings Program must, as part of its application, submit documentation of such a repayment mechanism for approval by CMS. This documentation must include details supporting the adequacy of the mechanism for repaying losses equal to at least 1 percent of the ACO's per capita expenditures for its assigned beneficiaries from the most recent year available.

(iv) CMS will determine the adequacy of an ACO's repayment mechanism.

(v) An ACO must demonstrate the adequacy of this repayment mechanism annually, prior to the start of each performance year in which it takes risk.

(vi) To the extent that such an ACO's repayment mechanism does not enable CMS to fully recoup the losses for a given performance year, any unpaid losses will be carried forward into subsequent performance years and agreement periods (to be recouped either against additional financial reserves, or offset by shared savings earned by the ACO).

(7) *Legal structure.* (i) An ACO must be constituted as a legal entity for purposes of all of the following:

(A) Receiving and distributing shared savings.

(B) Repaying shared losses.

(C) Establishing, reporting, and ensuring provider compliance with health care quality criteria, including quality performance standards.

(D) Other ACO functions identified in this part.

(ii) An ACO must 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.

(8) *Shared governance.* (i) An ACO must establish and maintain a governing body with adequate authority to execute the functions of an ACO as defined under this part, including but not limited to, the definition of processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care.

(ii) The governing body must be comprised of the following:

(A) ACO participants or their designated representatives.

(B) Medicare beneficiary representative(s) served by the ACO who do not have a conflict of interest with the ACO, and who have no immediate family member with conflict of interest with the ACO.

(iii) The governing body must have and possess broad responsibility for the ACO's administrative, fiduciary, and clinical operations.

(iv) At least 75 percent control of the ACO's governing body must be held by ACO participants. Each ACO participant must choose an appropriate representative from within its organization to represent them on the governing body and each ACO participant must have appropriate proportionate control over governing body decision making.

(v)(A) The members of the governing body may serve in a similar or complementary manner for an existing participant in the ACO.

(B) The governing body of the ACO must be separate and unique to the ACO in cases where the ACO comprises multiple, otherwise independent entities (for example, several independent physician group practices).

(C) The ACO must provide evidence within its application that the governing body is a separate legal entity.

(vi)(A) Except as specified in paragraph (d)(8)(vi)(b) of this section, a separate governing body must be established.

(B) If the ACO is comprised of a single entity that is financially and clinically integrated, and if at least 75 percent control of the entity's governing body is comprised of representatives of the entity, the ACO governing body may be the same as the governing body of that entity, provided it satisfies the other requirements of this section.

(9) *Leadership and management structure.* (i) As part of its application process, an ACO must submit supporting materials to CMS that demonstrate the ACO's leadership and management structure, including 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.

(ii) The ACO's operations must 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.

(iii) Clinical management and oversight must be managed by a full-time senior-level medical director who is physically present on a regular basis in an established ACO location, and who is a board-certified physician and licensed in the State in which the ACO operates.

(iv) ACO participants and ACO providers/suppliers must have a meaningful commitment to the ACO's clinical integration program to ensure its likely success. Meaningful commitment may include, for example, a meaningful financial investment in the ACO or a meaningful 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

participant and provider/supplier to make the clinical integration program succeed.

(v) A physician-directed quality assurance and process improvement committee must oversee an ongoing action-oriented quality assurance and improvement program. The quality assurance program must establish internal performance standards for quality of care and services, cost effectiveness, and process and outcome improvements, and hold ACO's providers/suppliers accountable for meeting the performance standards. The program must have processes and procedures in place to identify and correct poor compliance with such standards and to promote continuous quality improvements.

(vi) The ACO must implement evidence-based medical practice or clinical guidelines and processes for delivering care consistent with the aims of better care for individuals, better health for populations, and lower growth in health care expenditures. The guidelines and care delivery processes must cover diagnoses with significant potential for the ACO to achieve quality and cost improvements, taking into account the circumstances of individual beneficiaries.

(vii) ACO participants and providers/suppliers must agree to comply with these guidelines and processes and to be subject to performance evaluations and potential remedial actions, including their expulsion from the ACO. The ACO must have policies and procedures for expulsion of ACO participants and ACO provider/suppliers from the ACO.

(viii) The ACO must have an infrastructure, such as information technology (which may include EHR technology certified to the standards and implementation specifications adopted by the Secretary for the purposes of the meaningful use EHR incentive programs), that enables the ACO to collect and evaluate data and provide feedback to ACO participants and ACO providers/suppliers across the entire ACO, including providing information to influence care at the point of care.

(ix) The supporting materials that are submitted in the application must include all of the following:

(A) ACO documents (for example, participation agreements, employment contracts, and operating policies) that describe the ACO participants' rights and obligations in the ACO, including distribution of shared savings to encourage ACO participants and ACO providers/suppliers to adhere to the quality assurance and improvement program and the evidenced-based clinical guidelines.

(B) 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, such as the internal performance standards and the processes for monitoring and evaluating performance.

(C) 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.

(D) 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.

(E) Evidence that the governing body is comprised of representatives the ACO participants who form the ACO, and that these ACO participants comprise at least 75 percent of the governing body.

(F) Upon request, the ACO must provide copies of all documents effectuating the ACO's formation and operation, including, without limitation the following:

(*1*) Charters.

(*2*) By-laws.

(*3*) Articles of incorporation.

(*4*) Partnership agreement.

(*5*) Joint venture agreement.

(*6*) Management or asset purchase agreements.

(*7*) Financial statements and records.

(*8*) Descriptions of the remedial processes that will apply if an ACO participant or an ACO provider/supplier fails to comply with the ACO's internal procedures and performance standards, including a CAP and the circumstances under which expulsion from the ACO could occur.

(G) 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.

(H) A description of how the ACO will partner with community stakeholders.

(I) Written standards for beneficiary access and communication. These standards must include the ACO's process for beneficiaries to access their medical record.

(x) CMS retains the right to give consideration to an innovative ACO with a management structure not meeting these requirements.

(10) *Compliance plan.* (i) The ACO must have a compliance plan that includes at least the following elements:

(A) A designated compliance official or individual who is not legal counsel and who has the ability to report directly to the ACO's governing body.

(B) Mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance.

(C) A method for employees or contractors of the ACO, ACO participants, and ACO providers/suppliers to report suspected problems related to the ACO.

(D) Compliance training for the ACO, the ACO participants, and the ACO providers/suppliers.

(E) A requirement to report suspected violations of law to an appropriate law enforcement agency.

(ii) To achieve an effective compliance program, an ACO may consider coordinating its compliance efforts with existing compliance efforts of its ACO providers/suppliers.

(11) *Distribution of savings.* As part of its application to participate in the Shared Savings Program, an ACO must describe how:

(i) It plans to use shared savings payments, including the criteria it plans to employ for distributing shared savings among its participants.

(ii) The proposed plan will achieve the specific goals of the Shared Savings Program.

(iii) The proposed plan will achieve the general aims of better care for individuals, better health for populations, and lower growth in expenditures.

(12) *Written request for shared savings payment.* (i) After receipt of notification from CMS of the anticipated shared savings payment or amount of shared losses, an individual with the authority to legally bind the ACO (such as the ACO's CEO or CFO), must make a written request to CMS for payment of the shared savings (or acknowledge the amount of shared losses) in a document that certifies the ACO's compliance with program requirements as well as the accuracy, completeness, and truthfulness of any information submitted directly or indirectly by the ACO, its ACO participants, the ACO providers/suppliers, or any other entity 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 or the amount owed by the ACO to CMS.

(ii) If such data are generated or submitted by ACO participants, ACO providers/suppliers, or another entity,

such ACO participant, ACO provider/supplier, must similarly certify the accuracy, completeness, and truthfulness of the data and provide the government with access to such data for audit, evaluation, investigation, and inspection.

(13) *Sufficient number of primary care providers and beneficiaries.* (i) CMS will deem an ACO to have a sufficient number of primary care physicians and beneficiaries if the number of beneficiaries historically assigned to the ACO participants using the assignment methodology in § 425.6 is 5,000 or more.

(ii) If at the end of a performance year, an ACO's assigned population falls below 5,000, then that ACO will be issued a warning and placed on a CAP.

(A) While under the CAP, an ACO remains eligible for shared savings and losses during that performance year.

(B) If the ACO's assigned population has not returned to at least 5,000 by the end of the next performance year, then that ACO's agreement will be terminated and the ACO will not be eligible to share in savings for that year.

(14) *Required reporting on participating ACO professionals.* A participating ACO must maintain, update, and annually report to CMS a list of the following:

(i) Each ACO participant's TIN.

(ii) Each ACO providers/supplier's NPI and/or TIN.

(15) *Required processes and patient-centeredness criteria.* (i) *Required processes.* In its application to participate in the Shared Savings Program, an ACO must provide CMS with documentation of its plans to do all of the following:

(A) Promote evidence-based medicine.

(B) Promote beneficiary engagement.

(C) Internally report quality and cost metrics.

(D) Coordinate care.

(ii) *Patient-centeredness criteria.* (A) An ACO should 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.

(B) An ACO must demonstrate patient-centeredness by addressing all of the following areas:

(*1*) Have a beneficiary experience of care survey in place (using the Clinician and Group CAHPS survey, including an appropriate functional status survey module) and describe how the ACO will use the results to improve care over time.

(*2*) Patient involvement in ACO governance.

(*3*) 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.

(*4*) Systems in place to identify and update high-risk individuals and processes to develop individualized care plans for targeted patient populations including integration of community resources to address individual needs.

(*i*) Such plans must promote improved outcomes for, at a minimum, high-risk and multiple chronic condition patients, and as appropriate, other patients with chronic conditions.

(*ii*) The plan must be tailored to the beneficiary's health and psychosocial needs, account for beneficiary preferences and values, and identify community and other resources to support the beneficiary in following the plan.

(*5*) A mechanism in place for the coordination of care (for example, via use of enabling technologies or care coordinators).

(*i*) The ACO is required to describe its mechanism for coordinating care for Medicare beneficiaries.

(*ii*) The ACO should have a process in place (or clear path to develop such a process) to exchange summary of care information when patients transition to another provider or setting of care, both within and outside the ACO.

(*iii*) For providers enrolled in the electronic exchange of information, this process must be consistent with meaningful use requirements under the Medicare EHR Incentive Program (as described in part 495 of this chapter).

(*6*) A process in place for communicating clinical knowledge/evidence-based medicine to beneficiaries in a way that is understandable to them.

(*7*) A process in place for beneficiary engagement and shared decision-making that takes into account the beneficiaries' unique needs, preferences, values, and priorities.

(*8*) Written standards in place for beneficiary access and communication, and a process in place for beneficiaries to access their medical record.

(*9*) 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.

**§ 425.6 Assignment of Medicare fee-for-service beneficiaries to ACOs.**

(a) *General rule.* (1) Medicare fee-for-service beneficiaries are assigned to an ACO based on their utilization of primary care services provided under this title by a primary care physician who is an ACO provider/supplier during the performance year for which shared savings are to be determined.

(2) 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, and for determining whether an ACO has achieved savings under § 425.7 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.

(b) *Assignment methodology.* CMS employs the following methodology to assign Medicare beneficiaries to an ACO:

(1) For each ACO, identify all primary care physicians as defined in § 425.4 of this part who were an ACO participant during the performance year.

(2) At the end of each performance year, determine all beneficiaries who received services from primary care physicians in the ACO, as determined under paragraph (b)(1) of this section.

(3) Determine the total allowed charges for the primary care services (as identified by HCPCS code in the definition of primary care services under § 425.4 of this section) that each of the beneficiaries identified in paragraph (b)(2) received from any provider or supplier during the performance year.

(4) For each beneficiary, add together the allowed charges for the primary care services provided by the primary care physicians (identified in paragraph (b)(1) of this section) in each ACO (identified in paragraph (b)(1) of this section).

(5) Assign a beneficiary to an ACO if the beneficiary has received a plurality of his or her primary care services, as determined by the sum of allowed charges for those services under paragraph (b)(4) of this section, from primary care physicians identified under paragraph (b)(1) of this section, who are an ACO participant.

(c) *Beneficiary information and notification.* ACO participants will post signs in each of their facilities and provide written notification for beneficiaries about their participation in the Shared Savings Program.

**§ 425.7 Payment and treatment of savings.**

(a) *Establishing a benchmark.* (1) Using a 6-months claims run-out, CMS will retrospectively estimate and update an ACO's benchmark for an agreement period starting with ACO participants identified at the start of the agreement period.

(2) Using the claim records of ACO participants and applying the methodology for assigning beneficiaries

in § 425.6 of this part, CMS will compute per capita expenditures for beneficiaries who would have been assigned to the ACO in any of the prior three most recent available years.

(b) *Computing per capita Medicare Part A and Part B expenditures and updating the benchmark.* In computing these per capita expenditures, CMS uses the per capita Parts A and B fee-for-service expenditures for beneficiaries that would have been assigned to the ACO in each of these 3 prior years, we will estimate a fixed benchmark that is adjusted for overall growth and beneficiary characteristics, including health status using prospective HCC adjustments. This benchmark will then be updated annually during the agreement period, according to statute, based on the absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program. CMS will do all of the following:

(1) Calculate annual Parts A and B fee-for-service per capita expenditures for the beneficiaries who would have been assigned for each of the benchmark years. To minimize variation from catastrophically large claims, CMS truncates an assigned beneficiary's total—

(i) Parts A and B fee-for-service per capita expenditures at the 99th percentile as determined for each benchmark year.

(2) Using CMS Office of the Actuary national Medicare expenditure data for each of the years making up the benchmark, CMS determines national growth trend indices and trend them to the third benchmark year (BY3) dollars.

(3) Using health status measures for the beneficiary population in each of the years making up the benchmark, CMS establishes health status indices for each year and adjust these indices so they are restated in BY3 risk.

(4) CMS computes a 3-year risk-and growth-trend adjusted per capita expenditure amount for the patient populations in each of the 3 benchmark years by combining the initial per capita expenditures for each year with the respective growth and health status indices. The result is risk adjusted per capita expenditures for beneficiaries historically assigned to the ACO in each of the 3 years used to establish the benchmark stated in BY3 risk and expenditure amounts, and assigned patient populations.

(5) CMS weights the most recent year of the benchmark, BY3 at 60 percent, BY2 at 30 percent and BY1 at 10 percent to ensure that the benchmark reflects more accurately the latest expenditure and health status of the ACO's assigned beneficiary population.

(6) 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's Office of the Actuary.

(7) In performing these steps, CMS does not take into consideration expenditure increases or decreases under Section 1848 related to value-based purchasing programs or the HITECH Act; specifically, any of the following:

(i) Physician Quality Reporting Initiative as provided in § 414.90.

(ii) Electronic prescribing program as provided in § 414.92.

(iii) HITECH Act incentives for eligible professionals as provided in § 495.102.

(c) *Determination of savings and shared savings rate for ACOs under the one-sided model.* (1) *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, adjusted for beneficiary characteristics, is below the applicable benchmark determined under paragraph (b) of this section. To minimize variation from catastrophically large claims, CMS truncates that assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile as determined for each performance year. 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 benchmark by more than a minimum savings rate established for the ACO under paragraph (c)(2) of this section.

(2) *Minimum savings rate (MSR).* CMS computes a minimum savings rate for each ACO based on the number of beneficiaries assigned to the ACO under § 425.6 of this part. The minimum savings rates for ACOs based on the numbers of assigned beneficiaries will be as follows:

| Number beneficiaries | MSR (low end of assigned beneficiaries) % | MSR (high end of assigned beneficiaries) % |
|---|---|---|
| 5,000–5,999 | 3.9 | 3.6 |
| 6,000–6,999 | 3.6 | 3.4 |
| 7,000–7,999 | 3.4 | 3.2 |
| 8,000–8,999 | 3.2 | 3.1 |
| 9,000–9,999 | 3.1 | 3.0 |
| 10,000–14,999 | 3.0 | 2.7 |
| 15,000–19,999 | 2.7 | 2.5 |
| 20,000–49,999 | 2.5 | 2.2 |
| 50,000–59,999 | 2.2 | 2.0 |
| 60,000 + | 2.0 | |

(3) *Qualification for shared savings payment.* In order to qualify for shared savings, an ACO must exceed its minimum savings rate determined under paragraph (c)(2) of this section, meet the minimum quality performance standards established under § 425.10 of this part, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(4) *Net savings threshold.* An ACO under the one-sided model that exceeds its minimum savings rate is eligible to share savings net 2 percent of its benchmark as determined under § 425.7(b). An ACO with fewer than 10,000 assigned beneficiaries in the most recent year for which CMS has complete claims data, and that meets any one of the following criteria, is exempt from the 2 percent net savings threshold adjustment under the one-sided model:

(i) All ACO participants are physicians or physician groups.

(ii) 75 percent or more of the ACO's assigned beneficiaries reside in counties outside an MSA in the most recent year for which CMS has complete claims data.

(iii) 50 percent or more of an ACO's assigned beneficiaries in the most recent year for which CMS has complete claims data were assigned on the basis of services received from Method II CAHs.

(iv) At least 50 percent of the assigned beneficiaries had at least one encounter with a participating FQHC or RHC in the most recent year for which CMS has complete claims data such that the ACO has achieved maximum sharing for this activity.

(5) *Final sharing rate.* The final sharing rate for an ACO in the one-sided model will be calculated by adding the ACO's earned quality performance sharing rate and any additional increase described in § 425.7(c)(6)) (up to the performance payment limit described in § 425.7(c)(7)).

(6) *Quality performance sharing rate.* An ACO that meets all the requirements for shared savings payments under the one-sided model will receive a shared savings payment based on quality performance of up to 50 percent, as determined on the basis of its quality performance under § 425.10 of this part.

(7) *Additional increase to the shared savings rate.* Under the one-sided model, an ACO's shared savings rate may be increased by up to 2.5 percentage points if the ACO includes a rural health clinic (RHC) or Federally qualified health center (FQHC) (as defined under § 405.2401(b) of this chapter) within its structure, determined on a sliding scale based on the number of assigned Medicare beneficiaries with one or more visit to an RHC or FQHC during the performance year. The sliding scale will operate according to the following table:

| Percentage of ACO assigned beneficiaries with 1 or more visits to an FQHC/RHC during the performance year | Percentage point increase in shared savings rate (one-sided model) |
|---|---|
| 1–10 | 0.5 |
| 11–20 | 1 |
| 21–30 | 1.5 |
| 31–40 | 2 |
| 41–50 | 2.5 |

(8) *Performance payment limit.* The amount of shared savings an eligible ACO receives under the one-sided model may not exceed 7.5 percent of its benchmark.

(d) *Determination of savings or losses, and shared savings or loss rates for ACOs under the two-sided model.* (1) 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, adjusted for beneficiary characteristics, is above or below the benchmark determined under paragraph (b) of this section. 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 for the performance year must be below or above the benchmark, respectively, by more than the minimum savings or loss rate under paragraph (d)(2) of this section.

(2) *Minimum savings or loss rate.* (i) 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 benchmark costs for the year by at least 2 percent.

(ii) 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 benchmark costs for the year.

(3) *Qualification for shared savings payment.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (d)(2) of this section, meet the minimum quality performance standards established under § 425.10 of this part, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(4) *Final sharing rate.* The final sharing rate for an ACO in the two-sided model will be calculated by adding the ACO's earned quality performance sharing rate under paragraph (d)(5) and any additional increase described in § 425.7(c)(6)) up to the performance payment limit described in § 425.7(d)(7).

(5) *Quality performance sharing rate.* An ACO that meets all the requirements for receiving shared savings payments under the two-sided model will receive a payment of up to 60 percent of all the savings under the benchmark as determined on the basis of its quality performance under § 425.10 of this part.

(6) *Additional increase to the shared savings rate.* Under the two-sided model, an ACO's shared savings rate may be increased by the following up to 5.0 percentage points if the ACO includes a RHC or FQHC (as these terms are defined under § 405.2401(b) of these regulations) within its structure, determined on a sliding scale based on the number of assigned Medicare beneficiaries with one or more visit to an RHC or FQHC during the performance year. The sliding scale will operate according to the following table:

| Percentage of ACO assigned beneficiaries with 1 or more visits to an FQHC/RHC during the performance year | Percentage point increase in shared savings rate (one-sided model) |
|---|---|
| 1–10 | 1.0 |
| 11–20 | 2.0 |
| 21–30 | 3.0 |
| 31–40 | 4.0 |
| 41–50 | 5.0 |

(7) *Performance payment limit.* The amount of shared savings an eligible ACO receives under the two-sided model may not exceed 10 percent of its benchmark.

(8) *Shared loss rate.* The shared loss rate for an ACO that is required to share losses with the Medicare program for expenditures over the benchmark with the Medicare program is determined based on the inverse of its final sharing rate described in paragraphs (d)(2) through (6) of this section (that is, 1 minus the shared savings rate determined under paragraphs (d)(2) through (6) of this section).

(9) *Loss recoupment limit.* The amount of shared losses for which an eligible ACO is liable may not exceed the following percentages of its benchmark as determined under paragraphs (a) and (b) of this section: 5 percent in the first year of participation in a two-sided model under the Shared Savings Program, 7.5 percent in the second year, and 10 percent in the third year. An ACO in Track 1 who has entered the third year of its agreement period would be liable for an amount not to exceed the percentage of the first year of the two-sided model, that is, it would not exceed 5 percent.

(e) *Notification of savings and losses.* 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. Similarly, CMS will provide written notification to an ACO of the amount of shared losses, if any, that it must pay to the program. If an ACO has shared losses, the ACO must make payment in full to CMS within 30 days of receipt of notification.

**§ 425.8 ACO quality and continuous improvement goals.**

(a) CMS defines quality and continuous improvement goals for ACOs.

(b) An ACO must meet the quality and continuous improvement goals defined

by CMS under paragraph (a) of this section in order to qualify for shared savings.

**§ 425.9 Measures to assess the quality of care furnished by an ACO.**

(a) *Selecting measures.* 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.

(b) *Quality measures for quality performance standards.* (1) CMS designates the measures for use in the calculation of the quality performance standard.

(2) ACOs must submit data on the measures determined under this paragraph (b) according to the method of submission established by CMS.

**§ 425.10 Calculating the ACO quality performance score and determining shared savings eligibility.**

(a) *Measure domains.* CMS groups individual quality performance standard measures into five domains:

(1) Patient/care giver experience.

(2) Care coordination.

(3) Patient safety.

(4) Preventative health.

(5) At-risk population/frail elderly health.

(b) *Methodology for calculating a performance score for each measure.* (1) CMS designates quality performance standards for each measure, including a performance benchmark and minimum attainment level and establishes a point scale for certain measures. Contingent upon data availability, quality measure performance benchmarks are defined by CMS based on Medicare fee-for-service, MA, or ACO performance data.

(i) For the first performance period under the Shared Savings Program, CMS defines the quality performance standard at the level of complete and accurate reporting.

(ii) For all subsequent years, CMS defines the quality performance based on measure scores.

(2) Performance below the minimum attainment level will receive zero points for that measure, for those measures in which the points scale applies.

(3) Performance equal to or greater than the minimum attainment level but less than the performance benchmark must receive points on a sliding scale based on the level of performance, for those measures in which the points scale applies.

(4) Those measures designated as all or nothing measures receive the maximum available points if all criteria are met and zero points if at least one of the criteria are not met.

(c) *Methodology for calculating a performance score for each domain.* CMS designates quality performance standards for each domain's contribution to an overall ACO performance score.

(d) *Shared savings eligibility.* If the ACO demonstrates to CMS that it has satisfied the quality performance requirements for each domain, the requirements of § 425.7 are satisfied, and the ACO meets all other applicable requirements, the ACO is eligible for shared savings. To satisfy the quality performance requirements for a domain:

(1) The ACO must report all measures within a domain, via the mechanisms determined by CMS, in order to be considered for shared savings for that domain.

(2) CMS scores individual measures based on data received.

(3) CMS adds the individual scores for each of the measures within the domain to determine the domain scores.

(i) Each of the 5 domains is equally weighted in determining an ACO's overall quality performance score, regardless of whether the ACO is in Track 1 or Track 2. All measures within a domain must have a score above the minimum attainment level determined by CMS in order for the domain to be eligible for shared savings.

(ii) If the ACO satisfies the quality performance standards for one or more domains, and also satisfies the requirements for realizing shared savings under § 425.7, the ACO may receive the proportion of those shared savings for which it qualifies.

(iii) CMS retains the right to audit and validate quality data reported by an ACO. In an audit, the ACO would be required to provide beneficiary medical record data as requested by CMS. The audit would consist of three phases of medical record review. 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.

(iv) 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 § 425.12.

(4) In the third year of the ACO's agreement under Track 1, the methodology used to reconcile ACOs under the first year of the two-sided model would apply except that ACOs must meet the quality performance standard that applies in the third year, as opposed to the first year standard of full and accurate reporting.

**§ 425.11 Incorporating other reporting requirements related to the Physician Quality Reporting System and electronic health records technology.**

(a) *Physician quality reporting system.* (1) ACOs, on behalf of their eligible professionals, must submit the measures determined under § 425.10(b) according to the method of submission established by CMS, to qualify for a Physician Quality Reporting System incentive under the Shared Savings Program.

(2) To qualify as a group practice for a Physician Quality Reporting System incentive under the Shared Savings Program, eligible professionals within an ACO must report the measures determined under § 425.10(b) during the reporting period according to the method of submission established by CMS under the Shared Savings Program.

(3) The Physician Quality Reporting System incentive under the Medicare Shared Savings Program is equal to 0.5 percent of the ACO's eligible professional's total estimated 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.

(b) *Electronic health records technology.* (1) At least 50 percent of an ACO's primary care physicians must be meaningful EHR users, using certified EHR technology as defined in § 495.4, in the HITECH Act and subsequent Medicare regulations by the start of the second performance year in order to continue participating in the Shared Savings Program.

(2) CMS may terminate an ACO agreement under § 425.14 of this part if fewer than 50 percent of an ACO's primary care physicians are not meaningfully EHR users, using certified EHR technology as defined in § 495.4, the HITECH Act and subsequent Medicare regulations by the start of the ACO's second performance year.

**§ 425.12 Monitoring.**

(a) *Monitoring of ACOs: General rule.* (1) CMS monitors and assesses the performance of ACOs and their participating providers/suppliers.

(2) CMS employs a range of methods to monitor and assess the performance of ACOs, 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 aggregated annual and quarterly reports.

(ii) Site visits.

(iii) Analysis of beneficiary and provider complaints.

(iv) Audits (including, for example, analysis of claims, chart review (medical record), beneficiary survey reviews, coding audits).

(b) *Monitoring ACO avoidance of at-risk beneficiaries.* To identify ACOs that could be avoiding at-risk beneficiaries, CMS uses a combination of the methods described in paragraph (a)(2) of this section (as appropriate) to identify trends and patterns suggestive of avoidance of at-risk beneficiaries. The results of these analyses may subsequently require further investigation and follow-up with the beneficiary or the ACO and its ACO providers/suppliers in order to substantiate cases of beneficiary avoidance. CMS may take the following actions as set forth in § 425.13(a)(4) of this part, if it determines that an ACO, its ACO participants, any ACO providers/suppliers, or contracted entities performing functions or services on behalf of the ACO avoids at-risk beneficiaries.

(1) The ACO is required to submit a CAP and implement the plan as approved by CMS as set forth in § 425.13(a)(2) of this part.

(i) The ACO will not receive any shared savings payments during the probation period, regardless of the period of performance for which savings were attributable to while under the CAP.

(ii) The ACO will not be eligible to receive shared savings for the performance period attributable to the time the ACO was under the CAP.

(iii) The ACO will not be eligible to earn shared savings attributable to the time the ACO is under the CAP.

(iv) The ACO will be re-evaluated during and after the CAP implementation period to determine if the ACO has continued to avoid at-risk beneficiaries.

(2) ACO may be terminated if CMS determines that the ACO has continued to avoid at-risk beneficiaries during or after the CAP as set forth in § 425.14 of this part.

(c) *Monitoring ACO compliance with quality performance standards.* To identify ACOs that are not meeting the quality performance standards, CMS will review the ACO's submission of quality measurement data under § 425.9(b)(2). CMS may request additional documentation from an ACO, ACO participants, or ACO providers/suppliers, as appropriate. CMS may take the following actions, in addition to actions set forth at § 425.13, if an ACO does not meet quality performance standards or fails to report on one or more quality measures.

(1) The ACO will be given a warning for the first time it fails to meet the minimum attainment level for one or more domain.

(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 may be terminated immediately or CMS may take an alternative action as set forth in § 425.13 of this part.

(3) 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 the ACO either to submit the required measure data, correct the data, and/or provide a written explanation as to why it did not report completely and accurately. If ACO still fails to report, fails to report by the requested deadline and/or does not provide reasonable explanation for not reporting, the ACO will be terminated immediately as set forth in § 425.14 of this part.

(4) An ACO that exhibits a pattern of inaccurate or incomplete reporting, or fails to make timely corrections following notice to resubmit, may be terminated from the program.

(d) *Monitoring changes to ACO eligibility requirements.* In order to ensure that the ACO continues to meet the eligibility requirements under § 425.5 of this part, CMS uses a combination of the methods described in paragraph (a) of this section (as appropriate).

(e) *Monitoring beneficiary notification of the provider and supplier's role in the ACO and the ability for the beneficiary to op-out of sharing claims data.* In order to ensure that the ACO is notifying beneficiaries concerning sharing of claims data as provided under § 425.15 of these regulations, and providing the opportunity for a beneficiary to opt-out of those data sharing arrangements, as required by that section, CMS uses a combination of the methods described in paragraph (a) of this section (as appropriate).

(f) *Monitoring ACO marketing materials and activities.* (1) CMS may monitor compliance with the requirement for approval of ACO marketing materials and activities set forth in § 425(d)(4).

(2) An ACO that fails to adhere to this requirement may be placed under a CAP or terminated as set forth in § 425.14 of this part, at the discretion of CMS.

**§ 425.13 Actions prior to termination.**

(a) If based upon the monitoring activities described in § 425.12, CMS concludes that an ACO's performance may subject the ACO to termination from the Shared Savings Program, CMS, in its sole discretion, may take one or more or all of the following actions prior to termination of the ACO from the Shared Savings Program.

(1) Provide a warning notice to the ACO of the specific performance at issue.

(2) Request a CAP from the ACO.

(i) The ACO must submit a CAP for CMS approval by CMS deadline indicated on the notice of violation.

(ii) The CAP must address what actions the ACO will take to ensure that the ACO, ACO participants, and ACO providers/suppliers and/or contracted entities performing services or functions on behalf of the ACO will correct any deficiencies and remain in compliance with Shared Savings Program requirements.

(iii) The ACO's performance will be monitored during the CAP process.

(iv) Failure to submit, obtain approval for, or implement a CAP may result in termination of the agreement.

(v) ACO failure to demonstrate improved performance upon completion of the CAP may result in termination.

(vi) This CAP process does not apply to determinations made by the Antitrust Agencies and 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.

(3) Place the ACO on a special monitoring plan.

(4) These procedures do not apply to either of the following:

(i) Determinations that an ACO has violated the Sherman antitrust act (15 U.S.C. 1), Clayton Act (15 U.S.C. 12), or the Federal Trade Commission Act (15 U.S.C. 45).

(ii) Determinations made by other government agencies.

(5) The procedures established under this section do not negate, diminish, or otherwise alter the applicability of existing laws, rules, and regulations.

**§ 425.14 Termination, suspension, and repayment of Shared Savings.**

(a) *Grounds for terminating an ACO agreement.* CMS may terminate an agreement with an ACO if the ACO, the ACO participants, the ACO providers/suppliers or contracted entities performing services or functions on behalf of the ACO:

(1) Avoid at-risk beneficiaries.

(2) Fail to meet quality performance standards.

(3) Fail to completely and accurately report information or fail to make timely corrections to reported information.

(4) Are not in compliance with eligibility requirements or have fallen

out of compliance with the requirements of the part because the ACO has undergone material changes that affect the ACO's eligibility to participate in the Shared Savings Program, including, but not limited to changes in governing body composition, a significant change (as defined in § 425.21(b)), and the imposition of sanctions or other actions taken against the ACO by an accrediting organization, State, Federal or local government agencies.

(5) Are unable to effectuate any required regulatory changes during the agreement period after given the opportunity for a CAP as set forth in § 425.20.

(6) Are not in compliance with requirements to notify beneficiaries of ACO provider/supplier participation in an ACO.

(7) Engage in material noncompliance, or demonstrates a pattern of noncompliance, with public reporting and other CMS reporting requirements.

(8) Fail to submit an approvable CAP, fail to implement an approved CAP, or fail to demonstrate improved performance after the implementation of a CAP.

(9) Violate the physician self-referral prohibition, civil monetary penalties (CMP) law, Anti-kickback statute, other antifraud and antitrust laws (or enter into a final judgement or other final resolution of antitrust charges by an Antitrust Agency), or any other applicable Medicare laws, rules, or regulations that are relevant to ACO operations.

(10) Submit to CMS false, inaccurate, or incomplete data and or information, including but not limited to, information provided in the Shared Savings Program application, quality data, financial data, and information regarding the distribution of shared savings.

(11) Use marketing materials or participate in activities or other beneficiary communications, that are subject to review and approval, that have not been approved by CMS.

(12) Fail to maintain an assigned beneficiary population of at least 5,000 beneficiaries.

(13) Fail to offer beneficiaries the option to opt-out of sharing claims information.

(14) Limit or restrict internally compiled beneficiary summary of care or medical records from other providers/suppliers both within and outside of the Shared Savings Program to the extent permitted by law.

(15) Improperly use or disclose claims information received from CMS in violation of the HIPAA Privacy Rule, Medicare Part D Data Rule, Privacy Act, or the data use agreement.

(16) Fail to demonstrate that the ACO has adequate resources in place to repay losses and to maintain those resources for the agreement period.

(b) *Reapplication after termination.* An ACO that has been terminated from the Shared Savings Program may apply to participate in the Shared Savings Program again only after the end of the original 3-year agreement period.

(i) To be eligible to participate in the Shared Savings Program, 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.

(ii) ACOs with corrected deficiencies that wish to reenter the program have the option to do so only under the two-sided model.

(c) *Forfeiture of mandatory withholding after termination.* If an agreement is terminated for any reason before the 3-year agreement period is completed, the ACO the ACO would forfeit its mandatory 25 percent withhold of shared savings.

(d) *Termination of an agreement by an ACO.* (1) ACO must notify CMS, its ACO participants, and other organizations of its decision to terminate 60 days before the date of termination.

(2) The ACO participants must notify beneficiaries of the ACO's decision to terminate in a timely manner.

(3) All termination notification materials must meet marketing guidelines as set forth at § 425.12(f).

(e) *Grounds for shared saving payment suspension.* If an ACO has been placed under a CAP because the ACO, ACO participants, ACO providers/suppliers, or contracted entities performing services or functions on behalf of the ACO were found to have avoided at-risk beneficiaries—

(1) The ACO must not receive shared savings payments while it is under the CAP, regardless of the period of performance it is attributable to; and

(2) The ACO is not eligible to earn any shared savings for the performance period attributable for the time the ACO was under the CAP.

**§ 425.15 Reconsideration review process.**

(a) There is no reconsideration, appeals, or other administrative or judicial review of the following determinations under this section:

(1) The specification of quality and performance standards under § 425.9 of this part.

(2) The assessment of the quality of care furnished by an ACO under the performance standards established in § 425.10.

(3) The assignment of Medicare fee-for-service beneficiaries under § 425.6 of this part.

(4) The determination of whether an ACO is eligible for shared savings under § 425.7(c) of this part, 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 § 425.7(a) and (b) of this part.

(5) The percent of shared savings specified by the Secretary and the limit on the total amount of shared savings established under § 425.7(c) of this part.

(6) The termination of an ACO for failure to meet the quality performance standards established under § 425.14 of this part.

(7) A determination made by the reviewing antitrust agency that it is likely to challenge or recommend challenging the ACO.

(b) An ACO may appeal an initial determination that is not prohibited from administrative or judicial review under paragraph (a) of this section 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 submitted documentation) at the discretion of the reconsideration official.

(3) The reconsideration official will send an acknowledgement of the reconsideration review request to the ACO and CMS that includes the following:

(A) Review procedures.

(B) Procedures for submission of evidence including format and timelines.

(C) Date, time and location of the review. 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 the parties to the reconsideration review notice of the change.

(4) 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 CMS' regulations or statutory authority.

(i) The reconsideration official's review will be based only on evidence submitted by the reconsideration official's requested deadline, unless requested by the reconsideration official.

(ii) Documentation submitted for the record as evidence cannot be documentation that was not previously submitted to CMS by its required applicable timelines and in the requested format.

(iii) All evidence submitted both from the applicant and CMS, in preparation for the reconsideration review will be shared with participating parties prior to the scheduled date of the hearing, as indicated in the acknowledgement notice.

(iv) All parties will be notified of the reconsideration official's recommendation.

(c) If any of the parties disagree with the recommendation of the reconsideration official, they 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.

(1) Any party that wishes to request an on the record review of the reconsideration official's recommendation must submit an explanation of why they disagree with the recommendation by the timeframe and in the format indicated on the recommendation letter.

(2) The on the record review process will be based only on evidence presented for the reconsideration review.

(3) The CMS official will consider the recommendation of the reconsideration official and make a final agency determination.

(d) CMS's decision after review of the reconsideration official's recommendation is final and binding.

(e) The review process under this section shall not be construed to negate, diminish, or otherwise alter the applicability of existing laws, rules, and regulations or determinations made by other government agencies.

(f) If CMS' initial decision to deny 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.

(g) An ACO that requests a reconsideration review for termination will remain operational throughout the review process. If CMS initial determination to terminate the agreement with the ACO is upheld, termination of the agreement is effective as indicated in the initial notice of termination.

(1) If CMS' 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.

(2) If CMS' 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.

**§ 425.16 Audits and record retention.**

(a) *Right to audit.* The ACO must agree, and must require its ACO participants, ACO providers/suppliers, and contracted entities performing services or functions on behalf of the ACO to agree, that the DHHS the Comptroller General, the OIG or their designees have the right to audit, inspect, and evaluate any books, contracts, records, documents and other evidence of the ACO, ACO participants, and ACO providers/suppliers, and other contracted entities that pertain to—

(1) The ACO's compliance with program requirements;

(2) The quality of services performed and determination of amount due to or from CMS under the contract; and

(3) The ability of the ACO to bear the risk of potential losses and to repay any losses to CMS.

(b) *Maintenance of records.* An ACO must agree, and must require its ACO participants, ACO providers/suppliers, and contracted entities performing functions or services on behalf of the ACO to agree to the following:

(1) To maintain and give DHHS, OIG, the Comptroller General, 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, 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;

(ii) There has been a termination, dispute, or allegation of fraud or similar fault by the ACO, its ACO participants, its ACO providers/suppliers, or contracted entities that perform functions or services on behalf of the ACO, 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.

(iii) There is a reasonable possibility of fraud or similar fault by the ACO or its participating providers/suppliers, or contracted entities performing services or functions on behalf of the ACO, in which case CMS may inspect, evaluate, and audit the ACO at any time.

(c) Notwithstanding any arrangements between or among an ACO, ACO participants, ACO providers/suppliers, and contracted entities performing functions or services on behalf of the ACO, 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.

**§ 425.17 Requirements for data submission by ACOs.**

(a) ACOs must submit data in a form and manner specified by CMS on the measures designated by CMS under § 425.9 of this part.

(b) ACOs that successfully must, on behalf of their eligible professionals, submit the measures designated by CMS under § 425.9 according to the method of submission established under the Shared Savings Program for purposes of the quality data requirements will be considered satisfactory reporters for purposes of the Physician Quality Reporting System incentive under § 425.11(a).

**§ 425.18 The 3-year agreement with CMS**

(a) *General rule.* In order to participate in the Shared Savings Program, an ACO must enter into an agreement with CMS. ACO applications must be submitted by the deadline established by CMS. CMS will determine whether to approve or deny applications from eligible organizations

prior to the end of the calendar year in which the applications are submitted.

(b) *An ACO's duration of agreement.* The participation agreement must be for a term of 3 years, starting on the January 1 following approval of an application or such other date specified in the agreement.

(c) *Performance period.* Unless otherwise specified, the ACO's annual performance period under the agreement must be the 12-month period beginning on January 1 of each year during the term of the agreement.

**§ 425.19 Data sharing with ACOs.**

(a) *General rules.* CMS shares both aggregate and beneficiary identifiable data with ACOs under the following general conditions:

(1) The ACO does not unnecessary limitations or restrictions on the use or disclosure of individually identifiable health information that it internally compiles from providers and suppliers both within and outside of the ACO.

(2) The ACO observes all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information and complies with the terms of the data use agreement described in paragraph (f) of this section.

(b) *Sharing aggregate data.* (1) CMS shares aggregate data (data that omits the 18 identifiers listed at 45 CFR 164.514(b) with ACOs as follows:

(i) Aggregate data reports at the start of the agreement period based on the historical beneficiaries used to calculate the benchmark, and each quarter thereafter during the agreement period.

(ii) Quarterly reports will be based upon the most recent 12 months of data for beneficiaries that could potentially be assigned to the ACO under the assignment methodology in § 425.6. These data will not include beneficiary identifying information, but will include de-identified claims history of the services rendered for the ACO's assigned FFS beneficiaries, as determined under § 425.6 of this part.

(2) These aggregate data reports will include, when available, the following information:

(i) Financial performance.

(ii) Quality performance scores.

(iii) Aggregated metrics on the assigned beneficiary population.

(iv) Utilization data at the start of the agreement period based on historical beneficiaries used to calculate the benchmark.

(c) Identification of historically assigned beneficiaries used to calculate the benchmark established under § 425.7.

(1) At the beginning of the agreement period, and at the end of each performance period, CMS will, upon the ACO's request for the data for purposes of population-based activities relating to improving health or reducing health care costs, protocol development, case management, and care coordination, provide the ACO the following data about each beneficiary that was included in the records used under § 425.7(a) and (b) of this part to generate the ACO's benchmark:

(i) Beneficiary names.

(ii) Date of birth.

(iii) HICN.

(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, 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.

(d) *Sharing beneficiary identifiable data.* Subject to the opt-out described in this paragraph (g) of this section, CMS will, upon the ACO's request for the data for purposes of evaluating ACO provider/supplier performance, conducting quality assessment and improvement activities, and conducting population-based activities relating to improved health, provide the ACO with monthly claims data for potentially assigned beneficiaries.

(1) If an ACO wishes to receive beneficiary identifiable claims data, it must either request these data as part of the application process or later submit a formal request for data.

(2) The ACO must certify that it is requesting claims data about either of the following:

(i) 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.

(ii) The patients of its HIPAA covered entity ACO participants 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.

(3) 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 assigned to the ACO, and that these data will not be used to reduce, limit or restrict care for specific beneficiaries.

(4) To ensure that beneficiaries have a meaningful opportunity to opt-out of having their claims data shared with the ACO, the ACO may only request such claims data about a beneficiary if—

(i) The beneficiary has been seen in the office of a participating primary care physician (as defined in § 425.4 of this part), during the performance year,

(ii) The beneficiary was informed about 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

(iii) The beneficiary did not exercise the opportunity to opt-out of having his/her claims data shared with the ACO as provided in paragraph (g) of the section.

(5) CMS will continue to provide ACOs with certain beneficiary identifiable claims data on a monthly basis, subject to beneficiary's opportunity to opt-out of the data sharing under paragraph (g) of this section.

(6) If an ACO requests beneficiary identifiable information, compliance with the terms of the data use agreement described in paragraph (f) of this section is a condition of an ACO's participation in the Shared Savings Program.

(e) *Minimum necessary data set.* (1) The minimum necessary Parts A and B data elements may include the following data elements:

(i) Beneficiary ID.

(ii) Date of birth.

(iii) Gender.

(iv) Date of death.

(v) Claim ID.

(vi) The from and through dates of service.

(vii) The provider or supplier ID.

(viii) The claim payment type.

(2) The minimum necessary Part D data elements may include the following data elements:

(i) Beneficiary ID.

(ii) Prescriber ID.

(iii) Drug service date.

(iv) Drug product service ID.

(v) Quantity dispensed.

(vi) Days supplied.

(vii) Gross drug cost.
(viii) Brand name.
(ix) Generic name.
(x) Drug strength.
(xi) Indication if the drug is on the formulary, as designated by CMS.

(f) *Data Use Agreement.* Prior to receiving any beneficiary identifiable data, ACOs must enter into a DUA with CMS. The DUA must—

(1) Specify that the ACO will comply with the limitations on the use and disclosure of individually identifiable health information that the HIPAA Privacy Rule places on HIPAA covered entities, as well as all other applicable privacy and confidentiality requirements;

(2) Prohibit the ACO from using the data received under the Shared Savings Program for any prohibited use of individually identifiable health information.

(3) Specify that if an 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, could potentially be terminated from the shared savings program as well as subject to additional sanctions and penalties available under the law.

(g) *Beneficiary opportunity to opt-out of claims data sharing.* (1) Prior to 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 opt-out of having his/her claims information shared with the ACO.

(2) The ACO must supply beneficiaries with a form allowing them to opt-out of data sharing. The form must be provided to each beneficiary as part of an office visit with a primary care physician as defined under § 425.4, whose services are used to assign beneficiaries to the ACO.

(3) This requirement will not apply to the initial four data points that CMS will provide to ACOs for individuals in the 3-year base data set (Beneficiary Name, Beneficiary DOB, Beneficiary Sex, and Beneficiary HICN) under paragraph (c) of this section.

**§ 425.20 New program standards established during the 3 year agreement period.**

(a)(1) ACOs will be subject to all statutory changes.

(2) ACOs will be 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 changes in law or regulations require, or otherwise cause an ACO to change its processes in a manner that affects the design of its care processes and delivery of care, changes to the quality of care, or changes in planned distribution of shared savings, the ACO will be required to submit to CMS for review and approval a supplement to its original application detailing how it will address key changes in processes resulting from these modifications.

(c) If an ACO cannot effectuate the changes needed to adhere to the regulatory modifications after being given an opportunity to act upon a CAP, the ACO would be terminated from the program.

(d) Nothing in the regulations under this part shall be construed to affect the payment, coverage, program integrity, and other requirements that apply to providers and suppliers under FFS Medicare.

**§ 425.21 Managing significant changes to the ACO during the agreement period.**

(a)(1) During the 3-year agreement, an ACO may remove, but not add, ACO participants (identified by TINs), and it may remove or add ACO providers/suppliers (identified by NPI and/or TIN).

(2) ACOs must notify CMS at least 30 days prior to any significant change, as defined in paragraph (b).

(3) CMS will review the ACO's notification and make one of the following determinations:

(i) The ACO may continue to operate under the new structure with savings calculations for the performance year based upon the updated list of ACO participant TINs.

(ii) The ACO structure is so different from the initially approved ACO that it must submit a new application, and, if applicable, undergo an antitrust review.

(iii) The ACO is materially different from the initially approved ACO because of the inclusion of additional ACO providers/suppliers such that, in order to continue in the program, the ACO must obtain an antitrust review and a letter from the reviewing Antitrust Agency stating that it has no present intent to challenge, or to recommend challenging, the ACO. An ACO's failure to timely request antitrust review shall be deemed to constitute voluntary termination of its 3-year agreement.

(iv) The ACO no longer meets the eligibility criteria for the program and its 3-year agreement must be terminated.

(v) CMS and the ACO may mutually decide to terminate the agreement.

(b) A "significant change" occurs when an ACO is unable to fulfill its 3-year agreement due to:

(i) Deviation from its approved application such as a reorganization of the ACO's legal structure or other changes in eligibility.

(ii) A material change as defined in § 425.14.

(iii) Government-required reorganization as a result of fraud or antitrust concerns.

(c) The ACO must notify CMS within 30 days of the event for reevaluation of its eligibility to continue to participate in the Shared Savings Program.

(d) ACO participants continue to be subject to all requirements applicable to fee-for-service Medicare, including routine CMS business operation updates, and changes in fee-for-service coverage decisions.

**§ 425.22 Future participation of previous Shared Savings Program participants.**

(a) The ACO must disclose to CMS whether the ACO, its ACO participants, or its ACO providers/suppliers have participated in the Medicare program under the same or a different name, or is related to or has an affiliation with another Shared Savings Program ACO. The ACO must specify whether the related ACO was terminated or withdrew voluntarily from the program.

(b) If the ACO was previously terminated from the program, the applicant must identify the cause of termination and what safeguards are now in place to enable the applicant ACO to participate in the program for the full of the three-year agreement period. For new ACOs, this should be disclosed on a prospective ACO's application. For ACOs that are already participating in the Shared Savings Program, this information should be included in the annual updates that the ACOs will provide to CMS on their ACO participants and ACO providers/suppliers.

**§ 425.23 Public reporting and transparency.**

For purposes of the shared savings program, each ACO will publicly report the following information regarding the ACO a standardized format specified by CMS:

(a) Name and location.
(b) Primary contact.
(c) Organizational information including all of the following:

(1) Participating providers of services and suppliers.

(2) Identification of participants in joint ventures between ACO professionals and hospitals.

(3) Identification of the representatives on its governing body.

(4) Associated committees and committee leadership.

(5) Quality performance standard scores.

(d) Shared savings or losses information, including the amount of any shared savings performance payment received by the ACOs or shared losses owed to CMS.

(e) Total proportion of shared savings that was distributed among ACO participants and total proportion that was used to support quality performance and the aims of better care for individuals, better health for populations, and lower growth in expenditures.

**§ 425.24 Overlap with other CMS Shared Savings initiatives.**

(a) Medicare providers and suppliers may not participate in the Shared Savings Program as ACO participants if they participate 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. CMS will review and reject an ACO's application if ACO participants are participating in another Medicare initiative that involves shared savings payments so that beneficiaries are assigned to only one such initiative and in order to avoid duplicate shared savings payments.

(b) PGP demonstration sites applying for participation to the Shared Savings Program will be required to complete a condensed application form.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: *March 24, 2011.*

**Donald M. Berwick,**

*Administrator, Centers for Medicare & Medicaid Services.*

Approved: *March 29, 2011.*

**Kathleen Sebelius,**

*Secretary.*

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