

**The Medicare Shared Savings Program:
Summaries of the Final Rule and Related Documents**

Table of Contents

| | |
|--|----|
| Introduction | 2 |
| CMS Final Rule on the Medicare Shared Savings Program | 3 |
| I. Background | 3 |
| II. Provisions of the Final Rule | 3 |
| A. Definitions | 3 |
| B. Eligibility and Governance | 4 |
| C. Establishing the Agreement with the Secretary | 10 |
| D. Provision of Aggregate and Beneficiary Identifiable Data | 12 |
| E. Assignment of Medicare Fee-for-Service Beneficiaries | 14 |
| F. Quality and Other Reporting Requirements | 17 |
| G. Shared Savings and Losses | 23 |
| H. Additional Program Requirements and Beneficiary Protections | 38 |
| III. Collection of Information Requirements | 47 |
| IV. Regulatory Impact Analysis | 47 |
| CMS-OIG Interim Final Rule on Waivers in Connection with the Shared Savings Program | 49 |
| FTC-DOJ Final Statement on Antitrust Policy Enforcement Regarding ACOs | 54 |
| IRS Fact Sheet on Tax-Exempt Organizations Participating in the Medicare Shared Savings Program | 58 |
| Notice and Other Details Regarding the Advance Payment Model for Certain ACOs | 62 |

Introduction

On October 20, 2011, the following documents were released relating to a new Medicare Shared Savings Program involving accountable care organizations (ACOs):

- A final rule issued by the Centers for Medicare & Medicaid Services (CMS), which will be published in the November 2, 2011 issue of the *Federal Register*;
- A joint CMS and Office of the Inspector General (OIG) interim final rule with comment period entitled Medicare Program; Final Waivers in Connection With the Shared Savings Program (also to be published on November 2, 2011);
- An Internal Revenue Service (IRS) Fact Sheet entitled “Tax-Exempt Organizations Participating in the Medicare Shared Savings Program through Accountable Care Organizations,” viewable on www.irs.gov;
- A Final Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Shared Savings Program issued by the Federal Trade Commission (FTC) and the Department of Justice (DOJ), collectively the Antitrust Agencies; and
- A notice and other details regarding an Advance Payment Model for certain ACOs participating in the Medicare Shared Savings Program (this notice will also be published on November 2, 2011).

A summary of each of these documents follows.

Medicare Shared Savings Program: Accountable Care Organizations

Summary of Final Rule

[CMS-1345-F]

I. Background

On October 20, 2011, the CMS put on public display a final rule implementing the Medicare Shared Savings Program, as mandated under §3022 of the Affordable Care Act (ACA). The final rule will be effective on January 2, 2011.

CMS received about 1,320 public comments on the related proposed rule published on April 7, 2011. The final rule differs in many significant ways from the proposed rule. CMS notes that it “tried to reduce or eliminate prescriptive or burdensome requirements that could discourage participation in the Shared Savings Program...[and that it has] also been vigilant in protecting the rights and benefits of [fee-for-service] FFS beneficiaries under traditional Medicare to maintain the same access to care and freedom of choice that existed prior to the implementation of this program.” Although many commenters asked CMS to issue an interim final rule, the agency found no benefit in doing so. CMS emphasizes at the outset that the Medicare Shared Savings Program is “a voluntary national program” and that “any and all groups of providers and suppliers that meet the eligibility criteria outlined in the final rule are invited to participate.”

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

A. Definitions

This section of the preamble to the final rule includes only 3 sentences. It is worth noting that CMS has made modest changes to the definitions of ACO, ACO participant, and ACO provider/supplier. For example, the definition of ACO now acknowledges that an ACO might be an entity recognized under applicable Federal or Tribal law (not just State law). And while CMS has retained very broad definitions of ACO participant and ACO provider/supplier, it has added, without explanation, a definition of “physician,” which it defines as a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Social Security Act). This could engender some confusion since this definition is narrower than the full definition of the term usually employed by Medicare. Nonetheless, the term appears to have significance only for beneficiary assignment to an ACO, which must be based on primary care services received from ACO professionals, and the statute authorizing the Shared Savings Program did limit this term to doctors of medicine and osteopathy and to certain non-physician practitioners (physician assistants, nurse practitioners, and clinical nurse specialists).

Other definitional issues and changes are addressed in subsequent sections of the final rule and covered in later sections of this summary.

B. Eligibility and Governance

1. General Requirements

CMS finalizes without change its proposed policy regarding an ACO's certification of accountability for the quality, cost, and overall care of assigned beneficiaries. CMS also finalizes language specifying that an ACO's agreement period may not be less than 3 years and requiring an authorized executive to sign the participation agreement after the ACO's participation has been approved by Medicare. The final rule makes no change to the requirement that an ACO have at least 5,000 assigned beneficiaries. CMS also finalizes the proposal to require organizations applying to be an ACO to provide the tax identification numbers (TINs) of its ACO participants and a list of the national provider identifiers (NPIs) of associated ACO providers/suppliers (and if approved as an ACO), to maintain, update, and annually report this information to CMS. CMS also finalizes its proposal to define an ACO operationally as a collection of Medicare enrolled TINs, defined as ACO participants.

CMS notes that the proposed rule had indicated that some ACO participants, those that bill for the primary care services on which CMS proposed to base assignment, would have to be exclusive to one ACO, for the purpose of Medicare beneficiary assignment, for the duration of an agreement period. This exclusivity is believed to be required since otherwise CMS would not know which ACO should receive an incentive payment for the participant's efforts on behalf of its assigned patient population. As discussed in more detail in section II.E below, the final rule now allows beneficiary assignment to be based, under certain circumstances, on primary care services provided by specialist physicians and certain non-physician practitioners. Thus, the final rule expands the exclusivity requirement to apply to each ACO participant TIN upon which beneficiary assignment is dependent, and also states that ACO participant TINs upon which beneficiary assignment is not dependent are not required to be exclusive to one Medicare Shared Savings Program ACO.

Unfortunately, in discussing the exclusivity requirement and beneficiary assignment generally, CMS refers to ACO participants, physicians, and ACO professionals, even though these terms are not necessarily interchangeable. Nonetheless, since beneficiary assignment is limited by statute to services provided by ACO professionals (a term that includes only individuals meeting the Medicare definition of "physician" found at section 1861(r)(1) of the Social Security Act plus certain non-physician practitioners), the exclusivity requirement should not apply to a TIN of ACO providers/suppliers meeting the Medicare definition of "physician" in sections 1861(r)(2), (3), and (4) of the Social Security

Act, unless such TIN also includes ACO professionals for which the exclusivity policy applies (e.g., primary care physicians in a multi-specialty group practice).

CMS also emphasizes that exclusivity of an ACO participant TIN to one ACO is not necessarily the same as exclusivity of individual practitioners (ACO providers/suppliers) to one ACO. For example, CMS says that exclusivity of an ACO participant leaves individual NPIs free to participate in multiple ACOs if they bill under several different TINs. The agency also notes that a member of a group practice that is an ACO participant, where billing is conducted on the basis of the group's TIN, "may move during the performance year from one group practice to another, or into solo practice, even if doing so involves moving from one ACO to another." CMS adds that "while solo practitioners who have joined an ACO as an ACO participant and upon whom assignment is based may move during the agreement period, they may not participate in another ACO for purposes of the Shared Savings Program unless they will be billing under a different TIN in that ACO" [emphasis added]. Despite all the preceding, readers should anticipate continuing confusion about the exclusivity policy and watch for further guidance from CMS, perhaps in the form of frequently asked questions (FAQs).

CMS rejects comments recommending that ACOs be required to demonstrate sufficiency in the number, type, and location of providers available to provide care to the beneficiaries, noting that beneficiaries assigned to an ACO may receive care from providers and suppliers both inside and outside the ACO.

CMS also rejects requests to define ACOs as a collection of NPIs (rather than TINs), arguing that TINs are more stable and that adopting NPIs would create much greater operational complexity. CMS adds that it is unable to allow, for example, a large health system with one TIN to include only parts of the system in an ACO. Similarly, it would not be permissible for some members of a group practice (billing under a single TIN) to participate in the Shared Savings Program while others do not.

2. Eligible Participants

The final rule adds Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) to the list of entities eligible to independently form ACOs. The five other eligible entities discussed in the proposed rule are also finalized. These are: (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; and (5) critical access hospitals (CAHs) that bill under Method II (under which a CAH submits bills for both facility and professional services). For both #3 and #4, the term hospital includes only acute care hospitals paid under the prospective payment system.

CMS rejects comments requesting that CAHs billing under Method I to be added to the list of entities eligible to independently form ACOs, but encourages such CAHs to participate in the Shared Savings Program by establishing partnerships or joint venture arrangements with ACO professionals, just like other hospitals. Similarly, in response to comments, CMS says it sees no need to design distinct ESRD- or cancer care-specific ACOs since neither of these provider types are excluded from participation in an ACO.

3. Legal Structure and Governance

Although many commenters opposed requiring ACOs formed among multiple participants to form a separate legal entity, the final rule insists that if an existing legal entity adds ACO participants that will remain independent legal entities (such as through a joint venture), it would have to create a new legal entity to do so. On the other hand, existing legal entities which are eligible to be ACOs are permitted to continue to use their existing legal structure as long as they meet other requirements of the Shared Savings Program.

In response to comments recommending that ACOs assuming insurance risk be required to meet all the consumer protection, market conduct, accreditation, solvency, and other requirements consistent with State laws, CMS says it disagrees that participating in the Shared Savings Program ultimately involves insurance risk, but then goes on to recommend that ACOs desiring to participate in Track 2 consult their State laws (as explained below, Track 2 offers the possibility of shared losses as well as shared savings). CMS also emphasizes that it is not preempting state laws; thus, to the extent that State law affects an ACO's operations, the ACO would be expected to comply with such requirements. For example, CMS is not requiring an ACO to be licensed as an ACO under State law unless State law requires such licensure.

In the final rule, CMS confirms that it will make shared savings payments directly to the ACO as identified by its TIN. CMS also says that it does not believe the agency has the legal authority to dictate how shared savings are distributed but it will require ACO applicants to indicate how they plan to use potential shared savings to meet the goals of the Shared Savings Program. The regulation text more specifically says that an applicant must indicate the following:

- How it plans to use shared savings, including criteria it plans to employ for distributing shared savings among its participants;
- How the proposed plan will achieve the specific goals of the program; and
- How the proposed plan will achieve the general aims of better care for individuals, better health for populations, and lower growth in expenditures.

CMS finalizes the requirement that an ACO must maintain an identifiable governing body with the authority to execute the functions of the ACO, including the definition of processes to promote evidence-based medicine and patient

engagement, report on quality and cost measures, and coordinating care. The final rule clarifies that an ACO's governing body must provide oversight and strategic direction, holding management accountable for meeting the goals of the ACO, which include the three-part aim, which CMS views as broader than responsibility for care delivery processes.

CMS emphasizes that the governing body of the ACO must be separate and unique to the ACO in the cases where the ACO comprises multiple, otherwise independent entities that are not under common control (for example, several independent physician group practices). However, CMS does not finalize its proposal that each ACO participant TIN or its representative be on the ACO's governing body. The agency instead requires an ACO to provide "meaningful participation" in the composition and control of the ACO's governing body for ACO participants or their designated representatives (reference to each ACO participant having "proportionate control" of the ACO governing body is dropped). The final rule requires ACOs to have a conflicts of interest policy for the governing body.

CMS retains a requirement that ACO participants have at least 75 percent control of an ACO's governing body (with the remaining 25% available for representatives of management companies, health plans, and third parties performing technology, systems, or administrative functions for the ACO, for example) but declines to specify how the voting control would be apportioned among ACO participants. CMS also finalizes a requirement that the governing body include at least one beneficiary representative. The final rule, however, allows applicants to the Shared Savings Program who do not meet the 75% or 1 beneficiary tests to demonstrate alternative "innovative ways" to address the requirements. For example, this approach could be used by existing entities, such as ACOs operating in States with Corporate Practice of Medicine restrictions, "to explain why they should not be required to reconfigure their board if they have other means of addressing the consumer perspective in governance."

CMS declines to impose further requirements on board composition, including mandating a specific role for nurses on the governing body, encouraging representation from local high-level public health officials, or requiring at least one board member to be a representative of a local hospital. Similarly, CMS rejects a comment recommending that ACOs be required to enact policies and procedures to ensure that physicians who participate in the ACO are free to exercise independent medical judgment.

4. Leadership and Management Structure

CMS finalizes its proposal that an ACO's operations be managed by an executive, officer, manager, or general partner, whose appointment and removal are under the control of the organization's governing body and whose leadership

team has demonstrated the ability to influence or direct clinical practice to improve efficiency, processes, and outcomes. CMS finalizes its proposal that an ACO have a senior-level medical director who is a board-certified physician, but drops the requirement that such individual be full time. This individual must be licensed in one of the States in which the ACO operates, and physically present on a regular basis at any clinic, office, or other location participating in the ACO.

CMS modifies the proposed requirement that an ACO have a physician-directed quality assurance and process improvement committee to instead require that an ACO establish and maintain an ongoing quality assurance and improvement program, led by an appropriately qualified health care professional (who need not be a physician).

The final rule requires ACO participants and ACO providers/suppliers to demonstrate a meaningful commitment to the mission of the ACO, which may be evidenced by financial or human investment, or by agreeing to comply with and implement the ACO's required processes and being accountable for meeting the ACO's performance standards.

Under the final rule, applicants to the Shared Savings Program must submit documents sufficient to describe the ACO participants' and ACO providers/suppliers' rights and obligations in the ACO, and supporting materials documenting the ACO's organization and management structure, including an organizational chart, a list of committees and their structures, and job descriptions for senior administrative and clinical leaders. Upon CMS request, the ACO may also be required to submit additional documents (e.g., charters, by-laws, and joint venture or other agreements).

CMS also finalizes its proposal allowing ACO applicants to describe innovative leadership and management structures that do not meet the final rule's leadership and management requirements.

CMS disagrees with a comment suggesting that participation in the Shared Savings Program is an undertaking of meaningful financial integration, in part because ACO participants and ACO providers/suppliers will continue to receive FFS payments.

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

The final rule significantly revises the structure and language of the proposed rule relating to required ACO processes and patient-centeredness criteria. First, ACOs will be required to define, establish, implement, and periodically update their processes to promote evidence-based medicine, and these guidelines must cover diagnoses with significant potential for the ACO to achieve quality improvements, taking into account the circumstances of individual beneficiaries.

Second, ACOs must define, establish, implement, and periodically update processes to promote patient engagement. More specifically, an applicant to the Shared Savings Program must describe how it intends to address the following: (1) evaluating the health needs of the ACO's assigned population; (2) communicating clinical knowledge/evidence-based medicine to beneficiaries; (3) beneficiary engagement and shared decision-making; and (4) written standards for beneficiary access and communication, and a process in place for beneficiaries to access their medical record.

Third, each ACO must define, establish, implement and periodically update its processes and infrastructure for its ACO participants and ACO providers/suppliers to internally report on quality and cost metrics to enable the ACO to monitor, provide feedback, and evaluate ACO participant and ACO provider/supplier performance and to use these results to improve care and service over time.

Fourth, ACOs must define their care coordination processes across and among primary care physicians, specialists, and acute and post-acute providers. More specifically, an ACO: (1) must define its methods to manage care throughout an episode of care and during transitions; (2) must submit a description of its individualized care program as part of its application along with a sample care plan and explain how this program is used to promote improved outcomes for, at a minimum, its high-risk and multiple chronic condition patients; (3) should describe additional target populations that would benefit from individualized care plans; and (4) must describe in its application how the ACO will partner with community stakeholders. The final rule states that ACOs that have stakeholder organizations serving on their governing body will be deemed to have satisfied requirement #4. However, CMS rejects comments recommending that CMS require ACOs to have a contractual agreement with community-based organizations, preferring to give ACOs as much flexibility as possible.

6. Overlap with other CMS Shared Savings Initiatives

The ACA specifies that an organization participating in the Medicare Shared Savings Program may not also participate in certain other programs involving shared savings. This section of the final rule declares that an ACO could, therefore, not also participate in the following:

- The Independence at Home Medical Practice Pilot program;
- The Indiana Health Information Exchange demonstration and the North Carolina Community Care Network, both of which are Medicare Health Care Quality demonstration programs;
- The Multipayer Advanced Primary Care Practice demonstration if a shared savings arrangement has been chosen;
- The Care Management for High-Cost Beneficiaries Demonstration;
- Physician Group Practice (PGP) Transition demonstration; and
- The Pioneer ACO Model.

CMS notes, however, that an ACO provider/supplier who submits claims under multiple Medicare-enrolled TINs may participate in both the Shared Savings Program under one ACO participant TIN and another shared savings program under a different non-ACO participant TIN if the patient population is unique to each program.

CMS also says that “providers would be able to participate in both the Medicare Shared Savings Program and programs that focus on the integration of the Medicare and Medicaid programs for dually eligible individuals, specifically, State initiatives to integrate care for dually eligible individuals announced recently by the Medicare-Medicaid Coordination Office in partnership with the Innovation Center.” However, CMS will work closely with providers and States to prevent duplication of payment. Similarly, CMS states that “demonstrations that do not involve shared savings, such as the New Jersey gain sharing demonstration and others would not be considered overlapping for purposes of participation in the Shared Savings Program.”

More generally, CMS finalizes the proposal to implement a process for ensuring that savings associated with beneficiaries assigned to an ACO participating in the Shared Savings Program are not duplicated by savings earned in another Medicare program or demonstration involving shared savings.

The final rule briefly discusses the fact that all 10 PGP demonstration sites have agreed to participate in the PGP Transition Demonstration, and finalizes a proposal under which such sites could submit a condensed application form if they later sought to participate in the Shared Savings Program (as noted above, they may not participate in both the PGP Transition Demonstration and the Medicare Shared Savings Program).

C. Establishing the Agreement with the Secretary

1. Options for Start Date of the Performance Year

The final rule states that CMS will begin accepting applications from prospective ACOs shortly after January 1, 2012, and directs readers interested in more information about the application process to the following web address: <https://www.cms.gov/sharesavingsprogram>. The final rule also specifies that for the 2012 program year, there will be two possible start dates, April 1 and July 1. All ACOs that start in 2012 will have agreement periods that terminate at the end of 2015 (their first performance “year” will be considered to have 21 or 18 months, respectively). CMS adds that it will provide sub-regulatory guidance on the deadlines by which applications must be received in order to be considered for each respective start date.

2. Timing and Process for Evaluating Shared Savings

The final rule adopts a 3-month claims run-out period rather than the proposed 6-months for purposes of evaluating Medicare expenditures for a given year. CMS concludes that the minimal increased accuracy associated with 6 months of claims run-out does not justify the additional delay in the provision of quality metrics feedback and shared savings reconciliation. However, note that CMS intends to have its actuaries apply a completion percentage to the claims data, and to monitor ACO providers and suppliers for any deliberate delay in submission of claims; such deliberate behavior would be grounds for termination.

3. New Program Standards Established During the Agreement Period

CMS finalizes its proposal that ACOs be held responsible for all regulatory changes in policy, with the exception of: eligibility requirements concerning the structure and governance of ACOs, calculation of sharing rate, and beneficiary assignment. However, CMS modifies the proposal to allow ACOs to voluntarily terminate their agreement, without penalty, if they conclude that other regulatory changes impact their ability to continue to participate in the Shared Savings Program. CMS believes that this policy allows the program flexibility to improve over time while also providing a mechanism for ACOs to evaluate how regulatory changes impact their ability to continue participation in the program.

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

The final rule allows ACOs to add ACO participants during the agreement period (as well as subtract ACO participants and add or subtract ACO providers/suppliers, as originally proposed). ACOs will need to notify CMS of any additions/subtractions within 30 days. They must also notify CMS of any “significant change,” defined as an event that could cause an ACO to be unable to meet the eligibility or program requirements of the Shared Savings Program; reference to “material changes” has been dropped from the regulation. CMS adds that additions/subtractions and other changes could, for example, necessitate adjustments to the ACO’s benchmark but allow the ACO to continue participating in the Shared Savings Program.

5. Coordination with Other Agencies

CMS notes that waivers described in a separate interim final rule with comment will apply not only to the Shared Savings Program but also to the Innovation Center’s Advance Payment Model demonstration because ACOs participating in that model will also be participating in the Shared Savings Program.

CMS also notes that it has dropped a proposed requirement that certain ACOs undergo a mandatory review by the Antitrust Agencies and submit a letter from a reviewing Antitrust Agency confirming that it has no present intent to challenge or

recommend challenging such ACO on antitrust grounds. CMS adds that the Antitrust Agencies will offer a voluntary, expedited antitrust review to any newly formed ACO before it is approved to participate in the Shared Savings Program. CMS explicitly states that it will accept an ACO into the Shared Savings Program regardless of whether it voluntarily obtains a letter from the Antitrust Agencies and regardless of the contents of any letter it may have voluntarily obtained from them, assuming that the ACO meets all eligibility requirements. CMS further emphasizes that the acceptance of an ACO into the Shared Savings Program represents no judgment by CMS about the ACO's compliance with the antitrust laws or the ACO's competitive impact in a commercial market.

CMS will provide the Antitrust Agencies with aggregate Medicare claims data that will allow them to calculate the primary service area (PSA) shares for ACOs participating in the Shared Savings Program. It will also require ACOs formed after March 23, 2010 to agree, as part of their application to participate in the Shared Savings Program, to permit CMS to share a copy of their application with the Antitrust Agencies. CMS says that the claims data and ACO applications will help the Antitrust Agencies to monitor ACOs and take enforcement actions.

In response to several comments recommending that CMS monitor ACOs' per capita health care cost, for both Medicare beneficiaries and commercial patients, or otherwise build a more robust system to monitor for cost shifting, CMS says that it has requested that the Antitrust Agencies conduct a study examining how ACOs participating in the Shared Savings Program have affected the quality and price of health care in private markets. CMS anticipates using the results of this study to evaluate whether the agency should, in the future, consider competition concerns more explicitly in the Shared Savings Program application review process.

D. Provision of Aggregate and Beneficiary Identifiable Data

1. CMS Data Sharing with ACOs

CMS finalizes without change the proposal to share with ACOs aggregate Medicare data relating to historically assigned (now referred to as preliminary prospectively assigned) beneficiaries. However, the agency notes, in response to comments, this it is not possible to provide these data in "real time," prior to the submission and approval of an ACO application and the ACO signing its participation agreement, as customized reports for each ACO, or linked to specific quality indicators.

CMS also finalizes the proposal to provide each ACO with a list of beneficiary names, dates of birth, sex and health insurance claim number (HICN) derived from the beneficiaries whose data was used to generate the preliminary prospective aggregate reports, and modifies the proposal to provide similar

information in conjunction with each quarterly data report, based upon the most recent 12 months of data.

CMS also finalizes the proposal to provide ACOs with certain beneficiary-identifiable claims data on a monthly basis while allowing beneficiaries to opt out of such data sharing (that is, to object to CMS sharing beneficiary-identifiable claims data with the ACO to which the beneficiary has been preliminarily assigned). Prior to receiving such beneficiary identifiable claims data, ACOs must enter into a Data Use Agreement (DUA) and compliance with the DUA will be a condition of the ACO's participation in the Shared Savings Program. The ACO will also be required to explain how it intends the 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. The proposed rule has specified a list of minimally necessary data elements for Medicare Part A, Part B and Part D claim types but CMS now clarifies that these data elements are not the only ones that could be requested by an ACO provided it demonstrates the necessity of receiving additional information. CMS further agrees with commenters to add provider identity (by addition of NPI and TIN) and place of service code to the list of minimum necessary data elements but the regulation text only adds NPI and TIN. CMS also notes that an ACO may allow a vendor to receive claims information on its behalf (as a business associate or subcontractor of a business associate), but the ACO must assume responsibility for that vendor's use and disclosures of the data.

2. Beneficiary Opt-Out

As noted above, the final rule retains the proposed option under which beneficiaries could opt-out of data sharing with respect to beneficiary-identifiable claims data, which CMS is otherwise prepared to share with ACOs. Note, too, that ACOs will have the option of contacting beneficiaries from the list of preliminarily prospectively assigned beneficiaries (in advance of the point of care) in order to notify them of the ACO's participation in the program and their intent to request beneficiary identifiable data. After a period of 30 days from the date the ACO provides such notification, ACOs will be able to request beneficiary identifiable data from CMS absent an opt-out request from the beneficiary. The ACO would be responsible for repeating the notification and opportunity to decline sharing information during the next face-to-face encounter with the beneficiary in order to ensure transparency, beneficiary engagement, and meaningful choice. While not discussed explicitly in the final rule, it appears that beneficiaries would need to make a contact with CMS or a CMS contractor in order to exercise their opt-out decision. Also, CMS explicitly states, in either the preamble or the regulation text that a beneficiary's opt out decision would not affect the content of aggregate data reports provided to ACOs or CMS' intent to provide ACOs with certain beneficiary identifiers for preliminarily prospectively assigned beneficiaries.

CMS acknowledges that many commenters objected to this opt-out option and offered various alternatives, including removing those beneficiaries who elect to decline to have their data shared from ACO performance assessment, requiring beneficiaries who choose to decline to participate in data sharing from continuing to seek care from an ACO participant, allowing ACOs to refuse care to beneficiaries who choose to decline data sharing, and making the beneficiary's choice to receive care from an ACO provider/supplier an automatic opt-in for data sharing. CMS rejects all these suggestions and argues that beneficiaries should have some control over who has access to their personal health information for purposes of the shared savings program without affecting their assignment to an ACO or precluding their receipt of care from ACO participants. CMS also rejects a formal opt-in approach because it would involve significant paperwork burdens.

CMS acknowledges comments requesting that beneficiary-identifiable data be provided in advance of an ACO's participation in the Shared Savings Program but CMS responds that the legal bases for the disclosure of such data would not be applicable prior to the start of the ACO's participation in the program.

E. Assignment of Medicare Fee-for-Service Beneficiaries

1. Definition of Primary Care Services

The statute requires assignment of a beneficiary to an ACO to be based on the utilization of primary care services. CMS finalizes its proposal to define primary care services as the set of services identified by the following HCPCS codes: 99201 through 99215, 99304 through 99340, 99341 through 99350, the Welcome to Medicare visit (G0402), and the annual wellness visits (G0438 and G0439). This corresponds to office or other outpatient visits, nursing facility, domiciliary or rest home visits and related services, home visits, and certain preventive care visits. In addition, CMS now plans to establish a cross-walk for these codes to certain revenue center codes used by FQHCs and RHCs so that their services can be included in the ACO assignment process.* These revenue codes are 0521 (clinic visit by member to RHC/FQHC), 0522 (home visit by RHC/FQHC practitioner), 0524 (visit by RHC/FQHC practitioner to a member, in a covered Part A stay at the SNF), and 0525 (visit by RHC/FQHC practitioner to a member in an SNF (not in a covered Part A stay) or NF or ICF MR or other residential facility). To determine whether these revenue codes represent primary care services, CMS will use Attending Provider NPI information on the claim (with "Attending Provider" defined as "the individual who has overall responsibility for the patient's medical care and treatment reported in this claim/encounter"), require FQHCs/RHCs to attest to which NPIs represent physicians that provide direct patient primary care services, and assume that each such physician is functioning as a primary care physician. CMS adds that

* Starting in 2011, FQHC claims must include HCPCS codes to identify the specific services provided in order for CMS to develop a prospective payment system for FQHCs. Hence, the need to rely on revenue codes to identify primary care services will be time-limited in the case of FQHCs.

over the longer term, it will consider establishing definitions for data fields on the claims submitted by FQHCs/RHCs, which could be used to identify the type of practitioner providing the service.

CMS rejects comments recommending the addition of other codes to the list of primary care services, including inpatient hospital visit codes (99221-99223, and 99231-99233), inpatient consultation codes (99251-99255) and observation services (99218-99220 and 99224-99226), arguing that such services do not constitute primary care. CMS adds that the code set being adopted in the final rule represents the best approximation of primary care services based upon relevant precedents and the information at hand but that the agency will monitor the issue and consider adjustments if warranted.

CMS finalizes its proposal to define primary care physicians to encompass the following specialties: family practice, general practice, geriatrics and internal medicine. However, the final rule provides for a two-step process for deciding whether to attribute a beneficiary to an ACO. In the first step, a beneficiary will be assigned to an ACO if the allowed charges for primary care services furnished by primary care physicians who are providers/suppliers of that ACO are greater than the allowed charges for primary care services furnished by primary care physicians who are providers/suppliers of other ACOs, and greater than the allowed charges for primary care services provided by primary care physicians who are unaffiliated with any ACO (identified by Medicare-enrolled TINs or other unique identifiers, as appropriate). In the second step, a beneficiary will be assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by all ACO professionals who are ACO providers/suppliers in the ACO are greater than the allowed charges for primary care services furnished by ACO professionals who are ACO providers/suppliers in any other ACO and allowed charges for primary care services furnished by physicians, nurse practitioners, physician assistants and clinical nurse specialists who are not affiliated with an ACO. This obviously means that beneficiary assignment to an ACO can now be based on services provided by specialist physicians and certain non-physician practitioners. Moreover, as noted under section II.B above, this beneficiary assignment methodology will mean that ACO participant TINs upon which beneficiary assignment is dependent will need to be exclusive to one ACO.

CMS rejects a suggestion to add “preventive care specialist” to the list of primary care physicians saying that it is following the designations of primary care physicians established under section 5501 of the ACA (mandating Medicare bonus payments for primary care physicians), which does not include this specialty.

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

The final rule provides for prospective assignment of beneficiaries to ACOs in a preliminary manner (what the final rule describes as preliminary or preliminarily prospectively assigned beneficiaries) at the beginning of a performance year based on the most recent data available, and this assignment will be updated quarterly based on the most recent 12 months of data. However, final assignment will continue to be retrospective (as originally proposed), and determined at the end of each performance year based on data from that year. Nonetheless, CMS believes that the prospective assignment, though only preliminary in nature, will assist ACOs in managing their patients.

CMS acknowledges that most commenters favored prospective assignment of Medicare beneficiaries to ACOs. CMS rejects comments recommending that beneficiary assignment to ACOs should actually be more like a process of beneficiary enrollment (as used under the Medicare Advantage (MA) program), or a “gatekeeper” model for ACOs, emphasizing that an essential element of the Shared Savings program is the absence of any “lock-in” restrictions or other impediments for beneficiaries that seek services from specialist physicians and other practitioners of their choice. CMS also rejects comments recommending a prospective approach under which patients would volunteer to be part of an ACO, saying that this would completely sever the connection between assignment and actual utilization of primary care services, which would conflict with statutory requirements. Further, CMS disagrees with those commenters who argued that beneficiaries should be required to opt out of an ACO in order to preserve adequate beneficiary free choice. CMS also rejects a comment recommending that ACOs be given the option of excluding from assignment certain patients, such as those expected to get a high percentage of their care from non-primary care physicians, arguing that beneficiaries with serious conditions may receive the greatest benefits from greater accountability, enhanced coordination, and redesigned care processes. Lastly, CMS notes that it will study the results of the Pioneer ACO Model very carefully and consider in its next rulemaking whether to revise its approach to ACO assignment in the Shared Savings Program in the light of those interim results.

3. Majority vs. Plurality Rule for Beneficiary Assignment

The final rule maintains the proposed plurality test for determining beneficiary assignment to an ACO (that is, whether a beneficiary receives more primary care from that ACO than from any other provider), and finalizes the proposal to use allowed charges rather than service counts under this test. CMS modifies the regulation text to reflect its intention for the plurality test to calculate total allowed charges for each non-ACO provider for purposes of determining where the beneficiary received the plurality of his or her primary care services. In other words, each non-ACO TIN will be considered as a separate entity for purposes of

determining where a beneficiary received the plurality of his or her primary care services (rather than considering all non-ACO TINs in the aggregate).

A number of commenters recommended majority assignment but CMS argues that such a standard would necessarily result in the assignment of fewer beneficiaries to each ACO. In response to concerns about the assignment of “snowbirds” who spend parts of each year in different locations, CMS argues that this poses a much smaller problem in the Shared Savings Program than in other programs such as MA because “the assignment methodology under the Shared Savings Program is essentially self-correcting for the effects of seasonal migrations and extensive travel, since it directly reflects where a beneficiary receives the plurality of his or her primary care services. A beneficiary who travels or resides in more than one location will not be assigned to an ACO unless he or she receives the plurality of primary care from that ACO.”

CMS also rejects calls for establishing a variety of thresholds for beneficiary assignment purposes, including limiting assignment to beneficiaries who have received at least two or three primary care visits from an ACO, or for whom the plurality of services represents at least 20 to as much as 50 percent of primary care services. CMS believes that such thresholds would necessarily result in the assignment of fewer beneficiaries to ACOs.

Commenters suggested alternatives to use of allowed charges in determining beneficiary assignment, including use of visit counts and work relative value units (RVUs), with the latter intended to sidestep, for example, the issue of lower Medicare payments for primary care services provided by nurse practitioners and clinical nurse specialists. CMS responds that it has successfully used allowed charges under the PGP Demonstration and that this approach generally does not require tie-breaker rules. With respect to the use of work RVUs, CMS believes that such an approach would preclude using FQHC/RHC services in the beneficiary assignment process. As it is, CMS notes that allowed charges for FQHC/RHC services will be based on interim payments, since any subsequent adjustments following settlement of FQHC/RHC cost reports would not be available in time. CMS does say that it will continue to consider the alternative of using RVUs as it gains experience under the Shared Savings Program.

F. Quality and Other Reporting Requirements

1. Measures and Measure Domains

CMS adopts 33 quality measures instead of the 65 measures it originally proposed. CMS says this is being done to reduce the burden of the quality reporting at the start of the Shared Savings Program. CMS adds that it has sought to avoid measure redundancy, remove operationally complex measures, select final measures with a predominantly ambulatory care focus, and include only the most high impact measures.

The 33 measures fall into 4 equally weighted domains, instead of the original 5 (the care coordination and patient safety domains have now been combined). Table 1 of the final rule lists the measures by domain, indicates how data for each measure will be collected (by patient survey, claims, electronic health record (EHR) incentive program reporting or via the Group Practice Reporting Option (GPRO) Web interface), and also indicates whether ACOs must simply report measure data in a given year (Reporting) or achieve at least a minimum level of performance in that year (Performance). Excerpts from Table 1 are shown below. Note that the final rule indicates that CMS will fund and administer the Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys (from which 7 of the measures are derived) for the first two calendar years of the Shared Savings Program (2012 and 2013). After that, ACOs will be expected to select from among CMS-certified vendors and pay such vendors to administer the survey and report results using standardized procedures developed by CMS. CMS adds that it will develop and refine these standardized procedures over the next 18 to 24 months. CMS also plans to add an Access to Specialists module to the CAHPS survey.

Table 1 Measures for Use In Establishing Quality Performance Standards that ACOs Must Meet for Shared Savings

| Measure # and Title | NQF Measure #/Measure Steward | Method of Data Submission |
|--|-------------------------------|---------------------------------|
| Patient/Care Giver Experience Domain | | |
| 1. CAHPS: Getting Timely Care, Appointments, and Information | NQF #5 AHRQ | Survey |
| 2. CAHPS: How Well Your Doctors Communicate | NQF #5 AHRQ | Survey |
| 3. CAHPS: Patients' Rating of Doctor | NQF #5 AHRQ | Survey |
| 4. CAHPS: Access to Specialists | NQF #5 AHRQ | Survey |
| 5. CAHPS: Health Promotion and Education | NQF #5 AHRQ | Survey |
| 6. CAHPS: Shared Decision Making | NQF #5 AHRQ | Survey |
| 7. CAHPS: Health Status/Functional Status | NQF #6 AHRQ | Survey |
| Care Coordination/Patient Safety Domain | | |
| 8. Risk-Standardized, All Condition Readmission* | NQF #TBD CMS | Claims |
| 9. Ambulatory Sensitive Condition Admissions: Chronic Obstructive Pulmonary Disease (AHRQ Prevention Quality Indicator (PQI) #5) | NQF #275 AHRQ | Claims |
| 10. Ambulatory Sensitive Conditions Admissions: Congestive Heart Failure (AHRQ PQI #8) | NQF #277 AHRQ | Claims |
| 11. Percent of PCPs who Successfully Qualify for an EHR Incentive Program Payment | CMS | EHR Incentive Program Reporting |
| 12. Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility | NQF #97 AMA-PCPI/NCQA | GPRO Web Interface |
| 13. Falls: Screening for Fall Risk | NQF #101 NCQA | GPRO Web Interface |
| Preventive Health Domain | | |
| 14. Influenza Immunization | NQF #41 AMA-PCPI | GPRO Web Interface |
| 15. Pneumococcal Vaccination | NQF #43 NCQA | GPRO Web Interface |

| Measure # and Title | NQF Measure #/Measure Steward | Method of Data Submission |
|---|---|----------------------------------|
| 16. Adult Weight Screening and Follow-up | NQF #421 CMS | GPRO Web Interface |
| 17. Tobacco Use Assessment and Tobacco Cessation Intervention | NQF #28 AMA-PCPI | GPRO Web Interface |
| 18. Depression Screening | NQF #418 CMS | GPRO Web Interface |
| 19. Colorectal Cancer Screening | NQF #34 NCQA | GPRO Web Interface |
| 20. Mammography Screening | NQF #31 NCQA | GPRO Web Interface |
| 21. Proportion of Adults 18+ who had their Blood Pressure Measured within the preceding 2 years | CMS | GPRO Web Interface |
| At-Risk Population Domain | | |
| 22. Diabetes Composite (All or Nothing Scoring): Hemoglobin A1c Control (<8 percent) | NQF #0729 MN Community Measure | GPRO Web Interface |
| 23. Diabetes Composite (All or Nothing Scoring): Low Density Lipoprotein (<100) | NQF #0729 MN Community Measure | GPRO Web Interface |
| 24. Diabetes Composite (All or Nothing Scoring): Blood Pressure <140/90 | NQF #0729 MN Community Measure | GPRO Web Interface |
| 25. Diabetes Composite (All or Nothing Scoring): Tobacco Non Use | NQF #0729 MN Community Measure | GPRO Web Interface |
| 26. Diabetes Composite (All or Nothing Scoring): Aspirin Use | NQF #0729 MN Community Measure | GPRO Web Interface |
| 27. Diabetes Mellitus: Hemoglobin A1c Poor Control (>9 percent) | NQF #59 NCQA | GPRO Web Interface |
| 28. Hypertension: Blood Pressure Control | NQF #18 NCQA | GPRO Web Interface |
| 29. Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control <100 mg/dl | NQF #75 NCQA | GPRO Web Interface |
| 30. IVD: Use of Aspirin or Another Antithrombotic | NQF #68 NCQA | GPRO Web Interface |
| 31. Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction | NQF #83 AMA-PCPI | GPRO Web Interface |
| 32. Coronary Artery Disease (CAD) Composite (All or Nothing Scoring): Drug Therapy for Lowering LDL-Cholesterol | NQF #74 CMS (composite)/AMA-PCPI (individual component) | GPRO Web Interface |
| 33. CAD Composite (All or Nothing Scoring): Angiotension-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD) | NQF #66 CMS (composite)/AMA-PCPI (individual component) | GPRO Web Interface |

* Finalization of this measure is contingent upon the availability of measures specifications before the establishment of the Shared Savings Program on January 1, 2012.

For performance year 1, all measures are Reporting only. For performance year 2, measures #7, 8, 19, 20, 21, 31, 32, and 33 (8 measures) remain Reporting

only and the other measures are Performance measures. For performance year 3, all measures are Performance measures save for measure #7 (CAHPS: Health Status/Functional Status), which remains Reporting only, because CMS believes ACOs need to gain more experience with this measure.

CMS survey vendors will have responsibility for measuring the CAHPS patient experience measures, CMS will calculate the claims-based measures and the EHR Incentive Program measure, and ACOs will be directly responsible for reporting measures collected through the GPRO web interface. CMS notes that in 2010, 36 large group practices and integrated delivery systems used GPRO to report quality measures under the Physician Quality Reporting System (PQRS) and that the GPRO interface would allow ACOs to submit clinical information from EHRs, registries, and administrative data sources. For GPRO reporting, CMS will use the same sampling method used in the 2011 PQRS GPRO I (the random sample must consist of at least 411 assigned beneficiaries per measure set/domain or 100 percent of the assigned beneficiaries if the pool of eligible, GPRO-assigned beneficiaries is less than 411 for any measure set/domain). CMS finalizes its proposed validation methodology under which a random sample of 30 beneficiaries previously abstracted for each of the quality measure domains would be drawn and their medical records examined in two phases (8 records first, then 22 records if mismatches in numerator inclusions or denominator exclusions are found in phase 1), with a third phase of medical record auditing undertaken if the mismatch rate from phase 2 exceeds 10 percent. This validation methodology was used under the PGP Demonstration.

CMS expects to release specifications for most of the ACO quality measures during the 4th quarter of 2011 or the 1st quarter of 2012; the specifications for the CAHPS survey will be released later in 2012. CMS says this schedule is due, in part, to the fact that measures stewards frequently make their measures updates for a given year during the 4th quarter of the preceding year or the 1st quarter of the applicable year. The ACO measures specifications and reporting methodology will be provided in subregulatory guidance.

With respect to measure #11, Percent of Primary Care Physicians (PCPs) who Successfully Qualify for an EHR Incentive Program Payment, CMS says that qualifying for either Medicare or Medicaid EHR incentive payments would suffice.

CMS notes that while it has removed the hospital patient safety measures from the final ACO measure set, the agency plans to use the claims-based hospital measures as part of its ACO monitoring efforts.

CMS acknowledges receipt of a number of suggestions for additional measures and measure categories (e.g., measures of emergency room visits, perioperative care, cancer survivorship care, and risk-adjusted mortality measures for the entire ACO population, measures of appropriate use of new technologies, specialty care measures, measures that are more inclusive of non-physician

professionals (such as nurse practitioners and registered nurses) and a separate domain for palliative care). CMS says it is unable to add new measures in this final rule that were not proposed or that are not closely related to proposed measures, but promises to consider many of the suggestions received.

CMS rejects comments recommending use of “core” and “menu” sets of ACO measures, saying that it has reduced the number of required measures and believes that a menu approach would provide incentives for ACOs to select areas in which they are already performing well.

2. Scoring

Measure scoring is essentially the same as originally proposed, except that measure #11, Percent of PCPs who Successfully Qualify for an EHR Incentive Program Payment, is double-weighted to emphasize the importance of the measure. Nonetheless, CMS has modified its proposal such that meaningful use of EHRs by at least 50% of an ACO’s primary care providers by the start of the second performance year is no longer a condition of participation in the Shared Savings Program.

As originally proposed, points will be awarded on a sliding scale basis if a minimum attainment level is reached or exceeded for a measure, and this minimum attainment level will be set at a flat 30 percent or at the 30th percentile of national Medicare FFS or the MA rate, depending on what performance data are available. Maximum points will be awarded for performance at or above 90 percent or the 90th percentile. CMS plans to release performance benchmarks in sub-regulatory guidance at the start of the second year of the performance period as it phases in measures to pay for performance so that ACOs are aware of the actual performance rates they will need to achieve. Table 3 of the final rule, reproduced below, summarizes the measure scoring methodology.

Table 3: Sliding Scale Measure Scoring Approach

| ACO Performance Level | Quality Points (all measures except EHR) | EHR Measure Quality Points |
|---|--|----------------------------|
| 90+ percentile FFS/MA Rate or 90+ percent | 2 points | 4 points |
| 80+ percentile FFS/MA Rate or 80+ percent | 1.85 points | 3.7 points |
| 70+ percentile FFS/MA Rate or 70+ percent | 1.7 points | 3.4 points |
| 60+ percentile FFS/MA Rate or 60+ percent | 1.55 points | 3.1 points |
| 50+ percentile FFS/MA Rate or 50+ percent | 1.4 points | 2.8 points |
| 40+ percentile FFS/MA Rate or 40+ percent | 1.25 points | 2.5 points |
| 30+ percentile FFS/MA Rate or 30+ percent | 1.10 points | 2.2 points |
| <30 percentile FFS/MA Rate or <30 percent | No points | No points |

Note that “all or nothing” scoring will apply to the diabetes and coronary artery disease (CAD) composite measures (maximum points will be awarded if all the criteria are met and zero points if at least one criterion is not met).

Table 4 of the final rule, reproduced below, shows the number of individual performance measures per measure domain, indicates how these measures will be handled for scoring purposes, and gives the total potential points for each domain.

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

| Domain | Total Individual Measures | Total Measures for Scoring Purposes | Total Potential Points Per Domain | Domain Weights |
|--------------------------------------|---------------------------|--|-----------------------------------|----------------|
| Patient/Caregiver Experience | 7 | 1 measure with 6 survey module measures combined, plus 1 individual measure | 4 | 25% |
| Care Coordination/ Patient Safety | 6 | 6 measures, with the EHR measure doubled-weighted (4 points) | 14 | 25% |
| Preventive Health | 8 | 8 measures | 16 | 25% |
| At Risk Population | 12 | 7 measures, including 5 component diabetes composite measure and 2 component CAD composite measure | 14 | 25% |
| Total | 33 | 23 | 48 | 100% |

Rather than expecting ACOs to achieve the minimum attainment level on all performance measures in order to qualify for shared savings, the final rule requires ACOs to achieve the quality performance standard on 70 percent of the measures in each domain or it would be placed on a corrective action plan. If an ACO continued to underperform in the following year, CMS would terminate its agreement. This approach means that an ACO could fail one or more individual measures in each domain and still earn shared savings. However, in any year that an ACO scores a zero for an entire measure domain, it would not be eligible to share in any savings generated.

CMS also finalizes its proposal that if an ACO fails to report one or more measures, it will receive a written request to submit the required data by a specified date and provide reasonable explanation for its delay in reporting the required information. Failure to adequately respond to such a request would be grounds for terminating the ACO and thereby disqualify the ACO from sharing any savings.

CMS agrees with a comment suggesting that the agency gradually raise the minimum attainment level in order to continue to incentivize quality improvement over time and adds that this would be done through future rulemaking. CMS

rejects comments recommending the use of regional rather than national performance benchmarks.

CMS specifies that if an ACO, on behalf of its eligible professionals (EPs), satisfactorily reports ACO GPRO measures, the EPs' ACO participant TINs will receive the PQRS incentive payments. In other words, no extra reporting would be required in order for EPs to earn the PQRS incentive, even if the ACO is not eligible for shared savings. Further, EPs in an ACO that starts its agreement in April or July of 2012 will also qualify for the 2012 PQRS incentive under the Shared Savings Program by satisfactorily reporting the ACO GPRO measures for the full 2012 PQRS calendar year reporting period. Note that under this policy, PQRS incentive payments would not be conditioned on reporting all ACO quality measures (that is, from claims, CAHPS, and the CMS administrative data relating to the EHR incentive program). CMS clarifies that ACO participant TINs that wish to qualify for PQRS need to participate as group practices in the PQRS under the Shared Savings Program and may not separately participate in or earn a PQRS incentive under the traditional PQRS. CMS adds that it intends that reporting on the GPRO quality measures under the Shared Savings Program will also fulfill the reporting requirements for purposes of avoiding the payment adjustment that begins in 2015 for EPs failing to report PQRS data; this issue will be addressed in more detail in future rulemaking.

G. Shared Savings and Losses

1. Authority For and Selection of Shared Savings/Losses Model

ACOs meeting the quality performance standards discussed in the previous section and achieving savings compared to a benchmark of expected average per capita Medicare FFS expenditures will share in a portion of the Medicare savings. Section 1899(d) of the statute provides for a pure one-sided shared savings approach, with entities assuming no risk if expenditures exceed the benchmark; section 1899(i) gives the Secretary authority to create a risk-based option.

As in the proposed rule, the final rule offers ACOs a choice of two tracks. Under Track 1, ACOs can participate in a one-sided, shared savings-only model and not be responsible for any portion of losses above the expenditure target. In response to the overwhelming majority of comments objecting to the proposed rule's requirement that Track 1 ACOs would be transitioned automatically to the two-sided model in the third year of their agreement, the final rule allows Track 1 ACOs to remain under the one-sided model for all three years of the initial agreement period, which begins in 2012 and ends December 31, 2015.

As in the proposed rule, the final rule allows ACOs that are willing to share in both savings and losses, should they occur, to have greater opportunity for reward by electing the two-sided model under Track 2. Such an ACO would be

eligible for higher sharing rates than are available under the one-sided model. All ACOs could participate only under the two-sided model in agreement periods subsequent to the initial agreement period. CMS believes 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 and will elicit applicants who are more serious about their commitment to achieving the program's goals around accountability for the care of Medicare beneficiaries. CMS also notes that ACOs can decide whether to continue to participate in subsequent agreement periods.

In response to comments, the final rule allows continued participation in the ACO model by ACOs electing to do so who experience a net loss during their first agreement period. CMS will require ACOs, which experience a net loss in their initial agreement period and apply to participate in a subsequent agreement period, to identify in their application the cause(s) for the net loss and to identify safeguards which they have implemented to enable the ACO to potentially achieve savings in its next agreement period. The final rule's policies on monitoring and termination will help to ensure that ACOs that underperform on the quality standards do not continue in the program. The agency also will monitor this aspect of the program closely, and may revise its policy in future rulemaking.

CMS disagrees with suggestions from many commenters to use the authority under section 1899(i) to include additional alternative payment models in the ACO program. Suggestions included ones that would provide for blended fee-for-service payments; prospective payments; episode/case rate payments; bundled payments; patient-centered medical homes and surgical homes payment models; payments based on global budgets; full capitation; partial capitation such as condition-specific capitation; and enhanced FFS payments for care management, such as care coordination fees, as well as telephone calls and other non-face-to-face services. Other commenters sought targeted payment models for certain types of ACOs, such as small physician-only ACOs, especially those in rural areas; or to support care for particular types of patients, such as dual eligible beneficiaries. CMS declined all of these alternatives, noting that they are untested and could be considered under the Innovation Center. The final rule also rejected using the section 1899(f) authority to waive the requirements of the SGR methodology for ACO participants believing such a waiver to be unnecessary for successful implementation of ACOs.

2. Shared Savings and Losses Determination

a. Overview of Shared Savings and Losses Determination

The statute requires the Secretary to:

- 1) establish a per capita Medicare expenditure benchmark based on payments made for services under Parts A and B, adjusted for beneficiary characteristics;

- 2) compare the benchmark to per capita Medicare expenditures, adjusted for beneficiary characteristics, for the assigned beneficiaries in each performance year under the agreement period in order to determine the amount of any savings or excess expenditures;
- 3) establish the percentage that expenditures must be below the applicable benchmark "to account for normal variation in expenditures..., based upon the number of Medicare fee-for-service beneficiaries assigned to an ACO" (CMS refers to this percentage as the "minimum savings rate" (MSR));
- 4) determine the appropriate "sharing rate" for ACOs that have realized savings against the benchmark above the MSR; and
- 5) establish limits on the total amount of shared savings that may be paid to an ACO, which CMS calls the "sharing cap."

The table on the following pages, copied from the final rule, compares the key features of the proposed and final rules.

TABLE 5. SHARED SAVINGS PROGRAM OVERVIEW

| Issue | One-Sided Model | | Two-Sided Model | |
|---|---|---|---|--|
| | Proposed Rule | Final Rule | Proposed Rule | Final Rule |
| Transition to Two-Sided Model | Transition in third year of first agreement period | First agreement period under one-sided model. Subsequent agreement periods under two-sided model | Not Applicable | Not Applicable |
| Benchmark | Option 1 reset at the start of each agreement period. | Finalizing proposal | Option 1 reset at the start of each agreement period. | Finalizing proposal. |
| Adjustments for health status and demographic changes | Benchmark expenditures adjusted based on CMS-HCC model. | Historical benchmark expenditures adjusted based on CMS-HCC model. Performance year: newly assigned beneficiaries adjusted using CMS-HCC model; continuously assigned beneficiaries (using demographic factors alone unless CMS-HCC risk scores result in a lower risk score). Updated benchmark adjusted relative to the risk profile of the performance year. | Benchmark expenditures adjusted based on CMS-HCC model. | Historical benchmark expenditures adjusted based on CMS-HCC model. Performance year : newly assigned beneficiaries adjusted using CMS-HCC model; continuously assigned beneficiaries (using demographic factors alone unless CMS-HCC risk scores result in a lower risk score). Updated benchmark adjusted relative to the risk profile of the performance year. |
| Adjustments for IME and DSH | Include IME and DSH payments | IME and DSH excluded from benchmark and performance expenditures | Include IME and DSH payments | IME and DSH excluded from benchmark and performance expenditures |

| Issue | One-Sided Model | | Two-Sided Model | |
|---|---|---|---|---|
| | Proposed Rule | Final Rule | Proposed Rule | Final Rule |
| Payments outside Part A and B claims excluded from benchmark and performance year expenditures; | Exclude GME, PQRS, eRx, and EHR incentive payments for eligible professionals, and EHR incentive payments for hospitals | Finalize proposal | Exclude GME, PQRS, eRx, and EHR incentive payments for eligible professionals, and EHR incentive payments for hospitals | Finalize proposal |
| Other adjustments | Include other adjustment based in Part A and B claims such as geographic payment adjustments and HVBP payments | Finalize proposal | Include other adjustment based in Part A and B claims such as geographic payment adjustments and HVBP payments | Finalize proposal |
| Maximum Sharing Rate | Up to 52.5 percent based on the maximum quality score plus incentives for FQHC/RHC participation | Up to 50 percent based on the maximum quality score | Up to 65 percent based on the maximum quality score plus incentives for FQHC/RHC participation | Up to 60 percent based on the maximum quality score |
| Quality Sharing Rate | Up to 50 percent based on quality performance | Finalizing proposal | Up to 60 percent based on quality performance | Finalizing proposal |
| Participation Incentives | Up to 2.5 percentage points for inclusion of FQHCs and RHCs | No additional incentives | Up to 5 percentage points for inclusion of FQHCs and RHCs | No additional incentives |

| Issue | One-Sided Model | | Two-Sided Model | |
|------------------------------|--|---|---|--|
| | Proposed Rule | Final Rule | Proposed Rule | Final Rule |
| Minimum Savings Rate | 2.0 percent to 3.9 percent depending on number of assigned beneficiaries | Finalizing proposal based on number of assigned beneficiaries | Flat 2 percent | Finalizing proposal: Flat 2 percent |
| Minimum Loss Rate | 2.0 percent | Shared losses removed from Track 1 | 2.0 percent | Finalizing proposal |
| Performance Payment Limit | 7.5 percent. | 10 percent | 10 percent | 15 percent |
| Performance payment withhold | 25 percent | No withhold | 25 percent | No withhold |
| Shared Savings | Sharing above 2 percent threshold once MSR is exceeded | First dollar sharing once MSR is met or exceeded. | First dollar sharing once MSR is exceeded. | First dollar sharing once MSR is met or exceeded. |
| Shared Loss Rate | One minus final sharing rate | Shared losses removed from Track 1 | One minus final sharing rate | One minus final sharing rate applied to first dollar losses once minimum loss rate is met or exceeded; shared loss rate not to exceed 60 percent |
| Loss Sharing Limit | 5 percent in first risk bearing year (year 3). | Shared losses removed from Track 1. | Limit on the amount of losses to be shared phased in over 3 years starting at 5 percent in year 1; 7.5 percent in year 2; and 10 percent in year 3. Losses in excess of the annual limit would not be shared. | Finalizing proposal |

As shown in the preceding table and described in succeeding sections, the final rule includes numerous changes urged by commenters to improve the financial attractiveness of the program – i.e, the reward to risk ratio for participating in the program – in an attempt to encourage broad participation by providers and suppliers, particularly those likely to comprise smaller ACOs, such as small and medium sized physician practices; small hospitals and safety net providers, particularly those serving rural areas; and providers serving high risk patients (for example, dual eligibles and oncology patients).

b. Establishing the Benchmark

The final rule largely adopts the methodology laid out in the proposed rule for establishing an ACO's initial benchmark based on the Parts A and B FFS expenditures of beneficiaries who would have been assigned to the ACO in any of the 3 years prior to the start of an ACO's agreement period using the ACO participants' TINs identified at the start of the agreement period. CMS will calculate benchmark expenditures by categorizing beneficiaries in the following four cost categories, in this order: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. The benchmarking methodology will apply to all ACOs, including those consisting of FQHCs and/or RHCs (either independently or in partnership with other eligible entities).

The aforementioned policies reflect changes made due to commenters' suggestions for taking a categorical approach to sorting beneficiaries and establishing the benchmark. The categorical approach will be used not only to establish the benchmark, but also to update the benchmark and to calculate expenditures in the performance years.

CMS also finalizes these proposals:

- to truncate an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile of national Medicare FFS expenditures as determined for each benchmark and performance year;
- to weight the most recent year of the benchmark, BY3 (i.e., benchmark year 3, the most recent prior year) at 60 percent, BY2 at 30 percent and BY1 at 10 percent; and
- to reset the benchmark at the start of each agreement period.

As noted earlier, CMS will use a 3-month run-out of claims data and a completion factor to calculate benchmark expenditures.

The preamble notes that the final rule's adoption of a step-wise approach to beneficiary assignment, which is described in section II.E above, addresses commenters' issues concerning situations in which primary care services are provided principally by specialists. CMS believes that the final rule strikes a balance by maintaining the primary care-centric approach to assignment while

recognizing the necessary and appropriate role of specialists in providing primary care services.

Only a few commenters expressed a preference concerning the two options described in the proposed rule for selecting the benchmark patient population. CMS finalizes the proposed rule Option 1, which generates “a statistically stable” expenditure benchmark based on the average population cared for by the ACO participants during the preceding 3 years. In contrast, Option 2, which is not finalized, would have based the benchmark on the Parts A and B FFS expenditures of individual beneficiaries actually assigned to the ACO during each performance year, with the benchmark expenditures being those incurred in the 3 years immediately preceding the ACO's agreement period for each of those assigned beneficiaries. The preamble cites a preference for using a benchmarking methodology based on an ACO's actual assigned population, such as Option 2, or an alternative suggested by the Medicare Payment Advisory Commission (MedPAC), or the approach proposed by CMS for Pioneer Model ACOs. CMS, however, cites insufficient experience with such a model and affirms its support for the Innovation Center's testing of this benchmarking approach through the Pioneer Model ACO initiative for possible later adoption in the principal shared savings program.

CMS makes no changes in response to concerns that setting the benchmark based on historical data disadvantages low-cost, efficient providers, including rural providers, or may discourage them from participating in the ACO program. The preamble notes that section 1899(d)(1)(B)(ii) clearly states that "The Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per-beneficiary expenditures for parts A and B services for Medicare fee-for-service beneficiaries assigned to the ACO." Finally, CMS rejects alternatives offered to not reset the benchmark for ACOs that continue in the program after the first agreement period, or to limit how far the baseline could move from one agreement period to the next. It observes that a fundamental purpose of the Shared Savings Program is to provide incentives for ACOs to strive continually to make further advances in the quality and efficiency of the care they provide.

c. Adjusting the Benchmark and Actual Expenditures

(1) Adjusting Benchmark and Performance Year Average per Capita Expenditures for Beneficiary Characteristics

CMS finalizes its proposal to risk adjust historical benchmark expenditures of an ACO using the CMS-HCC model, with modifications to make certain additional risk adjustments to performance year assigned beneficiaries. The proposed rule had capped growth in risk adjustments during the agreement/performance years at zero percent, but commenters, including MedPAC, raised significant concerns that this might create incentives for ACO providers to encourage existing patients

who are costly to seek care elsewhere as well as to avoid taking on new patients that could be costly. Another commenter suggested that accurate risk adjustment is especially important for providers, such as academic medical centers, that disproportionately treat the sickest and most complex patients.

In response, the final rule annually updates an ACO's CMS-Hierarchical Condition Category (HCC) prospective risk scores to fully reflect changes in severity and case mix for newly assigned beneficiaries. CMS, however, will adjust for severity and case mix for the continuously assigned population relative to the historical benchmark using only demographic factors unless the continuously assigned population shows a decline in its CMS-HCC prospective risk scores, in which instance CMS will lower the risk score for this population. A "newly assigned beneficiary" is a beneficiary assigned in the current performance year who was neither assigned nor received a primary care service from any of the ACO's participants during the most recent prior calendar year. A "continuously assigned beneficiary" is a beneficiary assigned to the ACO in the current performance year who was either assigned to or received a primary care service from any of the ACO's participants during the most recent prior calendar year.

CMS also accepts a suggestion to adjust benchmark expenditures based on the risk profile of the beneficiaries actually assigned for the performance year; the ACO's updated benchmark will be restated using the appropriate performance year risk profile to ensure fairness recognizing changes in the level of risk among the ACO's assigned beneficiaries.

As noted previously, CMS will determine benchmark expenditures for each of the following four categories of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. CMS also finalizes its proposals to monitor and evaluate changes pertaining to more complete and accurate coding for possible future rule making; to use an audit process to assure the appropriateness of ACO coding practices; and to adjust ACO risk scores. It will monitor HCC scores for beneficiaries assigned in the prior year that are not assigned in the current performance year, and may make a more explicit adjustment for this population in future rule making.

(2) Technical Adjustments to the Benchmark and Performance Year Expenditures

CMS finalizes its proposal to compute average per capita Medicare expenditures under the ACO using payments made from the Medicare Trust Funds for services under Parts A and B for assigned Medicare FFS beneficiaries, including individual beneficiary identifiable payments made under a demonstration, pilot, or time limited program. It will calculate ACO expenditures for the previously noted four categories of beneficiaries and will make technical adjustments as described in the table below comparing proposed and final rule policies.

| Factor | Proposed Rule Policy | Final Rule Policy |
|---|---|---|
| Remove additional payments for indirect medical education (IME) and disproportionate share (DSH) | Does not exclude these payments citing lack of statutory authority and additional policy rationale. | Responding to commenters' substantial concerns, CMS will exclude IME and DSH from both benchmark and performance year expenditures. The final rule also clarifies that payments for direct graduate medical education are made outside of the payments for Parts A and B claims and thus are not be included in an ACO's benchmark and performance year expenditures. |
| Geographic payment adjustments (e.g., the IPPS wage index and the physician fee schedule geographic practice cost index (GPCI)) | Does not exclude these adjustments citing lack of statutory authority. | Finalizes the proposed rule policy but may evaluate further in future rule making. |
| Bonus payments and penalties related to value-based purchasing initiatives such as the PQRS and the Health Information Technology for Economic and Clinical Health (HITECH) Act, which encourages hospital and physician adoption of EHRs | Excludes expenditures or savings for incentive payments and penalties under section 1848 (PQRS, e-Prescribing, and the EHR incentives for eligible professionals under the HITECH Act) from the computations of both benchmark and performance year expenditures. Due to lack of statutory authority, does not exclude expenditures or savings for incentive payments and penalties not under section 1848, such as EHR incentive payments to hospitals and the Hospital Inpatient Value-Based Purchasing Program, which are made under section 1886, and EHR incentive payments to CAHs, which are made under section 1814 | Finalizes the proposed rule policies relating to physician incentive payments and also excludes the EHR incentive payments made to hospitals (but not payments made under the Hospital Value-Based Purchasing Program). |

The final rule does not accept commenters' suggestions for making several additional types of adjustments, including:

- costs of preventive services from an ACO's benchmark and spending calculations to avoid incentives to withhold preventive care;
- costs of urgent care center visits from ACO's benchmark and performance year expenditures to avoid creating incentives for ACOs to refer their non-emergent patients to their own emergency departments instead of to urgent care centers in the community;
- costs of beneficiaries who seek care outside the ACO;
- new technology payments under the Inpatient Prospective Payment System and transitional pass through payment expenditures under the Outpatient Prospective Payment System for drugs, biologicals and devices. Commenters urged exclusion of these payments to avoid incentives for ACOs to underuse new technologies and therapies;
- rural health payment adjustments under which CMS reimburses some providers under alternative, specialized methodologies due to their designation as rural or critical access facilities;
- primary care incentive payments under the primary care incentive program established by the ACA; and
- TEFRA relief payments, the inclusion of which could provide incentives for ACOs to avoid forming joint ventures with and including cancer centers.

CMS also rejected suggestions that it offer a process to allow individual ACOs to petition for specific benchmark adjustments for conditions that might be relevant to their providers or beneficiaries, but would not be relevant to all ACOs. Other commenters recommended that CMS consider Part D spending in its calculation of benchmark and performance year expenditures to address potential incentives to shift expenditures from Parts A and B to Part D. Concerning the latter, CMS notes that the statute clearly requires it to consider only payments made for services under Parts A and B and it cites its quality measurement and program monitoring activities as a means to detect inappropriate changes in practice patterns.

(3) Trending Forward Prior Year's Experience to Obtain an Initial Benchmark

CMS finalizes its proposal 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. It will trend BY1 and BY2 forward, based on the applicable growth rate, to BY3 dollars. To trend forward the benchmark, CMS will utilize separate cost categories for the four subpopulations of beneficiaries: ESRD; disabled; aged/dual eligible Medicare and Medicaid beneficiaries; and aged/non-dual eligible Medicare and Medicaid beneficiaries. The preamble notes that trending historical expenditures for these four categories provides a more complete and accurate benchmark for an ACO since it more accurately captures the proportion of ACO assigned patients that make up these categories,

their expenditure growth patterns, and changes in the health status of these patients over time.

CMS finalized using national growth rates rather than local, regional or state growth rates despite concerns raised by some commenters that using a national growth rate might discourage participation of ACOs in higher cost areas, including areas where many academic medical centers are located, where there is a high prevalence of chronic illness, or in states that have increased health care spending due to initiatives to expand health insurance coverage. Using the same trending factor for all ACOs will provide a relatively higher expenditure benchmark for low-growth/low spending ACOs and a relatively lower benchmark for high growth/high spending ACOs. According to CMS, ACOs in high cost/high growth areas will have an incentive to reduce their rate of growth more to bring their costs more in line with the national average; while ACOs in low cost low growth areas have an incentive to continue to maintain or improve their overall lower spending levels.

d. Updating the Benchmark During the Agreement Period

To update the benchmark during the agreement/performance period, CMS finalizes its proposal to base the update on the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program using data from CMS' Office of the Actuary. In updating the benchmark, CMS will make calculations for separate cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible and aged/non-dual eligible. CMS explains that its use of 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. ACOs in high cost/high growth areas will need to reduce their rate of growth to closer to the national average. The final rule decision to make calculations for separate cost categories for each of the four beneficiary sub-populations corresponds to a commenter citing experience from the physician group practice demonstration and urging separate benchmarks for specific groups of beneficiaries, specifically the aged, disabled and ESRD populations. The preamble observes that applying national growth dollars separately to each of the benchmark strata reflects the different expected growth rates for these types of beneficiaries.

e. Determining Shared Savings

Minimum Savings Rate: The minimum savings rate (MSR) is the amount of savings below the benchmark that the ACO must achieve in order to qualify for shared savings. It is set, in part, to account for normal variation in expenditures

based on the number of beneficiaries assigned to the ACO, in order to assure that savings are real savings and not just random statistical changes. CMS confirms without change in the final rule its proposed minimum savings rates for both one-sided and two-sided models.

For the one-sided model, the MSR varies by the number of assigned beneficiaries, because there is more statistical variation expected with a small number of beneficiaries than with a larger number of beneficiaries. The MSR for the one-sided model is as follows:

| Minimum Savings Rate, One-Sided Model, by Number of Assigned Beneficiaries | | |
|---|--|---|
| Number of 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 % | |

For the two-sided model, CMS retains the 2.0 percent MSR established in the proposed rule.

CMS responds to comments and concerns that the higher MSRs for smaller ACOs in the one-sided model would discourage smaller ACOs from participating, as well as comments that there should be no MSR at all. CMS notes again its statistical concern about random variation in costs, and notes that the flat, 2.0 percent MSR for the two sided model is accompanied by the shared risk in that model.

Quality Performance Sharing Rate: The quality performance sharing rate is the maximum share of savings, if any, that an ACO can retain, depending on its performance on the quality measures. CMS confirms in the final rule its proposed maximum sharing rates:

- one-sided model: 50 percent quality performance sharing rate;
- two-sided model: 60 percent quality performance sharing rate.

CMS responds to comments suggesting higher sharing rates, and in particular higher rates for the two-sided model, by noting that it modifies the quality performance standards themselves, as well as some other elements of the financial model, to make the program more attractive to providers.

Additional Shared Savings Payments: CMS in the final rule provides for no additional shared savings incentives beyond the quality performance sharing rate. In the proposed rule, it had provided for a sliding scale increase in the quality performance sharing rate for ACOs based on the portion of beneficiary visits at FQHCs or RHCs. Because the final rule, unlike the proposed rule, sets up a mechanism for FQHCs and RHCs to be participating ACO providers, with beneficiaries served by such providers assigned to the ACO, CMS no longer sees the need for this separate incentive. In addition, CMS rejects comments calling for additional sharing incentives for ACOs serving dual Medicaid/Medicare eligibles or other special populations. CMS notes that it will study the effect of assignment of such individuals to ACOs and may use the information in developing future models through the Innovation Center.

Net Sharing Rate: The final rule provides that ACOs in both the one-sided and two-sided models will share in “first dollar” savings once the ACO has achieved the MSR. That means that, while the ACO must first achieve a MSR of 2.0 percent to 3.9 percent (depending on its size or if it is one- or two-sided), it fully shares in all savings (including the initial 2.0 percent to 3.9 percent) once that threshold has been reached.

The final rule is consistent with the proposed rule for the two-sided model, but it does provide a greater share of savings than in the proposed rule for ACOs in the one-sided model. For one-sided model (Track 1), the proposed rule had set out a threshold of 2 percent for shared savings. That meant that once the ACO met the MSR, it would share only in the savings above the 2 percent threshold. CMS revised the policy in response to comments about the need to encourage smaller ACOs to participate, and as part of the broader package of initiatives to make the one-sided model more attractive.

Performance Payment Limits: The final rule sets a performance payment limit of 10 percent of the ACO’s updated benchmark under the one-sided model, and 15 percent under the two-sided model. Those are increases, in response to comments, from the 7.5 percent limit in the proposed rule for the one-sided model and 10 percent for the two-sided model. CMS rejected comments to eliminate the limits altogether.

f. Calculating Shared Losses

Minimum Loss Rate: CMS maintains in the final rule its proposal that, in the two-sided model, losses must exceed the updated benchmark by at least 2 percent for the ACO to be responsible for sharing losses.

Shared Loss Rate: CMS ensures that the final rule provides a maximum shared loss rate that mirrors the maximum shared savings rate. It would be calculated as 1 minus the shared savings rate (the shared savings rate is up to 50% in the one-sided model and up to 60% in the two-sided model). It applies to “first dollar”

losses once the minimum loss rate is achieved. CMS is, in the final rule, capping the shared loss rate at 60 percent, because of comments that under the methodology in the proposed rule, an ACO with very low quality scores could, in theory, be subject to sharing up to 100 percent of losses, which would not mirror the shared savings rate.

g. Limits on Shared Losses

The final rule maintains the limit on the amount of shared losses set out in the proposed rule:

- 1st performance year: 5 percent of updated benchmark;
- 2nd performance year: 7.5 percent of updated benchmark;
- 3rd performance year: 10 percent of updated benchmark.

h. Ensuring ACO Repayment of Shared Losses

The final rule retains proposed policies requiring mechanisms to ensure that an ACO can repay shared losses. That means that an ACO applying for the two-sided model must submit to CMS for approval documentation that it is capable of repaying any losses. It must include details for how it would repay amounts up to 1 percent of the ACO's total per capita Medicare Part A and Part B spending for assigned beneficiaries. It may demonstrate that ability through reinsurance, escrow funds, surety bonds, a line of credit, or another appropriate repayment mechanism.

CMS will not carry forward losses into future performance periods.

i. Timing of Repayment

The final rule requires that ACO's repay CMS for any shared losses within 90 days of receipt of notification. This is an increase over the proposed repayment period of 30 days, in response to comments expressing concern about the 30 day period.

j. Withholding Performance Payments

The final rule eliminates the proposed rule's requirement that CMS withhold 25 percent of any shared savings, in response to numerous comments and concerns. There is no 25 percent withhold in the final rule.

k. Determining First Year Performance for ACOs beginning April 1 or July 1, 2012

As noted earlier in this summary, ACO's starting either April 1 or July 1, 2012 will have an initial performance year that extends through December 31, 2013, a performance period of 21 or 18 months. In response to comments that ACOs

should receive more rapid initial feedback, CMS in the final rule provides such ACOs the option to request, in their initial application, an interim payment calculation, with final reconciliation at the completion of the full performance period.

Interim calculation: for those ACOs requesting the interim calculation:

- CMS compares the first 12 months of experience with a historical benchmark updated to take into account changes in health status and demographics.
- Quality performance is based on GPRO quality data for CY 2012.

ACOs, including those in the one-sided model, must have a mechanism to repay any interim payment if the final reconciliation determines that the interim calculation yielded an overpayment. The repayment mechanism requirement is the same as the previously described requirement for repayment of shared losses.

First performance year reconciliation: The full reconciliation takes into account the full 21 months (for those starting April 1, 2012) or 18 months (for those starting July 1, 2012).

3. Impact on States

CMS sought comments in the proposed rule on whether the ACO program would trigger the application of any State insurance laws and how CMS could work with ACOs and States to minimize any burden. Commenters raised issues and recommendations ranging from the applicability of state insurance laws to the need for HMO licenses, and federal preemption of State laws, to malpractice concerns and recommendations.

CMS emphasizes again in the final rule that the Medicare program retains the insurance risk and responsibility for paying claims for services. It stresses that ACOs participating in the Shared Savings Program are very different from health plans. It will consider these issues in future rulemaking should it become aware of any unexpected program issues that render States responsible for bearing any of the costs resulting from the operation of the ACO program.

H. Additional Program Requirements and Beneficiary Protections

In this section, CMS discusses certain requirements that they believe will protect beneficiaries by ensuring patient engagement and transparency, and discusses how ACOs will be monitored for compliance with program requirements, what actions will be taken against ACOs that are not in compliance, and program integrity requirements.

1. Beneficiary Protection

Beneficiary Notification: In the final rule, CMS notes that it intends to develop a communications plan, including educational materials and other forms of outreach, to help educate beneficiaries about the Shared Savings Program. CMS also finalizes the proposal to require ACOs to post signs in the facilities of participating ACO providers/suppliers indicating the participation of the providers/suppliers in the program and to make available standardized written information to Medicare FFS beneficiaries whom they serve.

In response to comments, all standardized written information provided by CMS will be in compliance with the Plain Writing Act of 2010. CMS clarifies that the standardized written notices must be furnished in settings in which FFS beneficiaries are receiving primary care services. Because of the revised policy of preliminary prospective assignment (Section II.E. of the final rule), CMS is revising the advance notification policy to allow an ACO the option of notifying beneficiaries who appear on the preliminary prospective assignment list and quarterly assignment lists of the ACO's participation in the Shared Savings Program.

To minimize beneficiary confusion and reduce burden on ACOs and their providers/suppliers, CMS is modifying the proposed rule and finalizes that in instances where either an ACO does not renew its agreement or an ACO's participation agreement is terminated, ACOs will not be required to provide beneficiaries notices that the ACO, its ACO participants and its ACO providers/suppliers will no longer be participating in the Shared Savings Program. This change also extends to ACO participants and ACO providers/suppliers that terminate participation in an ACO.

ACO Marketing Guidelines: The regulation text in the proposed rule defined "marketing materials and activities" as including, but 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." [†] Based on comments, CMS finalizes the definition to also include social media, such as Twitter or Facebook. CMS also revises the regulation to add additional beneficiary protections.

[†] The regulation text adds that the following beneficiary communications are not marketing materials and activities: information 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.

In response to comments about the operational burden associated with prior approval of any marketing materials, the final rule provides that marketing materials and activities may be used or conducted 5 business days following their submission to CMS, provided that the ACO certifies compliance with applicable marketing requirements and CMS does not disapprove the materials and activities. CMS can disapprove the marketing materials and activities at any time, including after the expiration of the initial 5 day review period. The marketing materials or activities disapproved by CMS must be discontinued. Based on comments, CMS is revising the regulation to specify that all marketing materials and activities must use template language when available, must comply with the prohibition set forth in the ACA (section 425.304(a)) regarding certain beneficiary inducements, must not be used in a discriminatory manner or for discriminatory purposes and must not be inaccurate or misleading. ACOs that fail to adhere to these requirements may be placed under a corrective action plan or terminated, at CMS' discretion.

Public Reporting and Transparency: CMS finalizes the requirement that ACOs publicly report the following information in a standardized format that the agency will make available through subregulatory guidance:

- Name and location;
- Primary contact;
- Organizational information, including ACO participants, identification of ACO participants in joint ventures between ACO professionals and hospitals, identification of each member of the governing body, and associated committees and committee leadership;
- Shared savings information, including shared savings performance payments received by ACOs or shared losses payable to CMS, and the total proportion of shared savings invested in infrastructure, redesigned care processes and other resources required to support the three-part aim, including the proportion distributed among ACO participants; and
- Quality performance standard scores.

CMS expects the reporting of quality performance standards will align with the proposed new public reporting requirements under the PQRS. Because an ACO will be considered a group practice, CMS intends to report ACO quality performance GPRO measures on Physician Compare with other PQRS group practices. This is contingent upon the final policies in the CY 2012 Physician Fee Schedule final rule and CMS will issue guidance to ACOs about public reporting of the quality performance scores.

2. Program Monitoring

CMS finalizes without substantive change the proposal to use the many methods available to monitor ACO performance and ensure program integrity. This includes analysis of financial and quality data, site visits, assessment and investigation of beneficiary and provider complaints, and audits. CMS notes that

as a practical matter, they may choose to target resources to audit or monitor certain organizations or compliance with certain program requirements. ACOs, ACO participants, ACO providers/suppliers and other contracted entities must give the appropriate federal agencies the right to inspect their books and records. CMS could inspect, evaluate and audit the ACO at any time if it determines that there is a reasonable possibility of fraud or similar fault.

Because the Shared Savings Program is built on the FFS system, and beneficiaries retain all the rights and benefits under traditional FFS Medicare, CMS does not believe it is necessary to impose the same protections or network adequacy requirements that are part of the MA program.

CMS could take any or all of the following actions if it concludes that an ACO's performance may subject it to termination: provide a warning notice; request a corrective action plan (CAP); or place the ACO on a special monitoring plan.

Monitoring Avoidance of At-Risk Beneficiaries: In response to comments, CMS finalizes at-risk beneficiaries as those 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 ER visits each year;
- are dually eligible for Medicare and Medicaid;
- have a high utilization pattern;
- have one or more chronic conditions; or
- have a recent diagnosis, such as cancer, that is expected to result in high cost.
- entitled to Medicaid because of disability; or
- have a diagnosis of mental health or substance abuse disorder.

CMS believes that its definition is general enough to include most of the specific suggestions made by commenters to include specific diseases and chronic conditions. CMS disagrees with comments that beneficiaries with limited proficiency in English should be included in the definition since limited English proficiency should not put patients at high risks for significant increases in health care costs.

CMS finalizes its proposal to use a combination of methods to monitor for avoidance of at-risk beneficiaries, including analysis of claims, examination of other beneficiary-level documentation, and further investigation and follow-up with the beneficiary or ACO, including its participants and providers/suppliers. If CMS determines that an ACO has been avoiding at-risk beneficiaries, it would:

- Notify the ACO;
- Require submission of a CAP for approval; and
- Re-evaluate the ACO during and at the end of the CAP.

The ACO would not receive shared savings payments while it is under such a CAP, regardless of the period of performance, and would not be eligible to earn

shared savings during a period it is under the CAP. If CMS determines that the ACO continues to avoid at-risk beneficiaries, CMS would terminate it from the Shared Savings Program. In response to commenter concerns, CMS modifies the proposal to retain the right to terminate an ACO immediately in appropriate cases. CMS disagrees with comments that additional grievance mechanisms need to be developed specific for ACOs. CMS does acknowledge comments about the use of lesser sanctions and says it may consider lesser sanctions as the agency gains experience with the program.

Monitoring compliance with quality performance standards: CMS finalizes its proposal to monitor compliance with quality performance standards by reviewing the ACO's submission of data and requesting additional documentation if appropriate. If an ACO fails to meet the minimum attainment level for one or more domains, CMS would give the ACA a warning and reevaluate it the next year. If it continues to underperform, it would be terminated. If the ACO fails to report, CMS would send a request for the required data. If the ACO fails to resubmit without a reasonable explanation, or exhibits a pattern of incomplete or inaccurate reporting, it may be terminated. An ACO would be disqualified from shared savings in any year in which it underperforms. In response to comments, depending on the nature and severity of the noncompliance, the final rule permits for immediate termination or a CAP in addition to a warning letter for ACOs who are underperforming on quality performance standards.

3. Program Integrity Requirements

Compliance Plan: An ACO would be required to have a compliance plan that includes elements common in the compliance industry (e.g., a designated compliance official and mechanisms for identifying and addressing compliance problems). The final rule allows an ACO to coordinate and streamline compliance efforts with the ACO participants and ACO providers/suppliers. A provision requiring compliance plans to be updated periodically reflects changes in law. In response to comments, CMS provides that "probable" instead of "suspected" violations of law should be reported to law enforcement. CMS also clarifies that although both legal counsel to the ACO and the compliance officer may have a legal education, legal counsel to the ACO and the compliance officer must be different individuals. ACOs may use their current compliance officer and the compliance officer must report directly to the ACO's governing body. CMS declines to specify how various organizations should work together to develop their compliance plans to allow flexibility and innovation. CMS also refers providers to the HHS OIG for information about industry best practices for compliance programs.

Compliance with Program Requirements: CMS finalizes that the ACO maintains ultimate responsibility for compliance with all terms and conditions of its participation agreement with CMS. An authorized representative of the ACO who has the ability to legally bind the ACO, such as its chief executive officer (CEO)

or chief financial officer (CFO), would be required to 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. Also, if data submitted to CMS 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. In response to comments, CMS clarifies that the certification language may include “to the best of my knowledge or belief” or similar language appearing in other Medicare certifications. In response to concerns about burdensome processes for requesting payment of shared savings, CMS finalizes a simpler process which requires ACOs to submit annual certifications to CMS by the timeframes CMS will establish through guidance. If the ACO or one of its ACO participants or ACO providers/suppliers becomes aware that incorrect information was submitted during the performance year, corrected information must be submitted before the recertification.

Conflict of Interest: CMS finalizes, without any change, the requirement that the ACO governing body have a conflict of interest policy, which must require members of the governing body to disclose relevant financial interests. CMS cites the IRS for samples of conflict of interest policies.

Screening of ACO Applicants: CMS finalizes, without any change, screening requirements for ACOs during the Shared Savings Program application process with regard to 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 and ACO participants that are eligible to enroll in Medicare will be subject to screening in accordance with applicable regulations, and their program integrity experience will be considered when the application is reviewed. For ACOs that are not eligible to enroll in Medicare, CMS will consider the ACO’s program integrity history. Due to statutory limitations, CMS is not able to apply the provisions of the Medicare screening rules to ACOs that are not eligible to enroll in Medicare. CMS clarifies that the screening process will be based upon information submitted with the application. An ACO whose screening reveals a history of program integrity issues and/or affiliations with individuals or entities with a history of program integrity issues may have their application rejected from the Shared Savings Program or have additional safeguards imposed.

Prohibition on Certain Required Referrals and Cost Shifting: CMS remains 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. To address the risk of inappropriate cost-shifting within Medicare and other Federal health care

programs, the final rule prohibits 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. The final rule specifies that this prohibition does not apply to referrals made by employees or contractors who are operating within the scope of their employment or contractual arrangement to the employer or contracting entity, provided that the employees and contractors remain free to make referrals without restrictions or limitations if the patient expresses a preference, the patient's insurer determines the provider, or the referral is not in the patient's best medical interests in the judgment of the referring party. For example, an employer, such as a hospital, may require its employees to refer to the hospital's laboratory or imaging center, provided that the referring party is free to honor patient choice, insurer requirements, and the medical best interests of the patients. CMS understands commenters' concerns that the agency should have strict prohibition against any behavior that limits referrals to professionals who are not participants in the ACO but are concerned that a strict prohibition may disrupt arrangements that are permitted under the physician self referral law. As part of ACO monitoring activities, CMS will monitor if ACOs are interfering with the beneficiary's freedom of choice by improperly limiting or restricting referrals.

In response to comments about potential cost shifting of drug costs from Part B to Part D, CMS will include patterns of shifting drug costs within its ACO monitoring activities. CMS notes that health care providers in an ACO that participate in the 340B program must continue to meet all the requirements of the 340B statute; a 340B provider is prohibited from purchasing or transferring drugs to non-340B entities and patients of non-340B providers, including those that are part of an ACO. CMS will consult with the Health Resources and Services Administration (HRSA) to determine if additional monitoring is needed for ACOs participating in the 340B program. CMS also acknowledges concerns about issues related to market power and intends to monitor available data to detect patterns of cost shifting by ACOs. CMS will work, as appropriate, with FTC, DOJ, and the HHS OIG if patterns of inappropriate cost shifting are reported.

Record Retention: ACOs, ACO participants, ACO providers/suppliers and other contracted entities must give the appropriate federal agencies the right to inspect their books and records. Other contracted entities include any party with an arrangement with the ACO to provide administrative, management or clinical services. They must retain records for 10 years from the end of the agreement period, or, if later, from the date of completion of any audit, evaluation or inspection, or if CMS determines and notifies the ACO of a longer retention period. CMS finalizes that retention is additionally extended for up to six years after the resolution of any termination, dispute, allegation of fraud or similar fault by the ACO.

In response to comments about the time duration, CMS states that these record retention and audit requirements are consistent with other Medicare programs. CMS declines to specify a records retention plan and allows ACOs flexibility to develop appropriate policies. CMS clarifies that as a result of any inspection, evaluation or audit it is determined that the amount of shared savings or shared losses has been calculated in error, CMS reserves the right to reopen the initial determination and issue a revised initial determination. In addition, the record retention requirements in this rule do not put any restrictions on the OIG's authority.

Beneficiary Inducements: The final rule prohibits an ACO, its ACO participants, and its ACO providers/suppliers from providing gifts, cash or other remunerations as inducements for receiving services or remaining in an ACO or with a particular provider within the ACO. Based on comments, CMS is allowing an ACO, its ACO participants, and its ACO providers/suppliers to provide to beneficiaries items or services for free or below fair-market value if specific conditions are met. The ACO must be in good standing under its participation agreement, there is a reasonable connection between the items or services and the medical care of the beneficiary, and the items or services are in-kind and either are preventive care items or services or advance adherence to either a treatment regime, drug regime, follow-up care plan or management of a chronic disease or condition. For example, an ACO provider may give blood pressure monitors to patients with hypertension in order to encourage regular blood pressure monitoring.

4. Terminating an ACO Agreement

The final rule specifies that CMS may terminate an ACO before the end of the three-year agreement for: noncompliance with eligibility and other ACO requirements, which are discussed throughout this summary (the proposed rule listed each possible reason separately but the final rule takes a simpler approach); the imposition of sanctions or other actions taken against the ACO by an accrediting organization, State, Federal or local government agency leading to inability of the ACO to comply with Shared Savings Program requirements; and violations of the physician self-referral prohibition, civil monetary penalties law, Federal anti-kickback statute, antitrust laws, or any other applicable Medicare laws, rules, or regulations that are relevant to ACO operations. CMS clarifies that they will provide the ACO with notice of termination. CMS also clarifies that an ACO agreement may be terminated if its providers are excluded by the OIG or have their Medicare privileges to participate in Medicare revoked.

CMS finalizes the rule that ACOs may voluntarily terminate and will be required to provide CMS and all of its ACO participants, ACO providers/suppliers, and other individuals or entities performing services related to ACO activities with a 60-day notice of its decision to terminate its participation in the Shared Savings Program. CMS disagrees with comments that this time period should be extended. Based on comments, ACOs would not be required to notify

beneficiaries of the ACO's decision to withdraw from the program. CMS clarifies that an ACO that terminates its participation agreement early will not share in any savings for the performance year during which it notifies CMS of its decision to terminate the participation agreement.

CMS also finalizes the requirement that an ACO must produce a corrective action plan (CAP) prior to termination for minor violations that CMS does not believe pose immediate risk of harm to beneficiaries or impact care. An ACO must submit a CAP to CMS by the deadline indicated on the notice of violation. Failure of the ACO to meet the related CAP requirements and failure to demonstrate improved performance may result in termination. Further, the ACO would not be eligible to earn any shared savings for the period during which it is under a CAP.

Finally, CMS finalizes several issues relating to future participation of previously terminated and certain other previous Shared Savings Program participants. ACO applicants would be required to disclose to CMS whether the ACO, its ACO participants, or its ACO providers/suppliers have previously participated in the Shared Savings Program under the same or a different name, and specify whether it was terminated or withdrew voluntarily from the program. Further, if the previous history involved termination, the applicant must identify the cause of termination and what safeguards are now in place. Moreover, a previously terminated ACO (or one that voluntarily withdrew from the Shared Savings Program) would not be allowed to begin a new 3-year agreement until the original agreement period has lapsed. In addition, an ACO that experienced a net loss during its first 3-year agreement period would not be allowed to reapply to participate in the Shared Savings Program before the conclusion of their initial agreement period.

5. Reconsideration Review Process

CMS notes that the ACA precludes administrative or judicial review of several decisions:

- specification of criteria for meeting quality performance standards;
- assessment of quality of care;
- assignment of beneficiaries to an ACO;
- determination of eligibility for or the amount of shared savings or the average benchmarks;
- the percent of shared savings and any limit on total shared savings;
- termination of an ACO for failing to meet quality performance standards.

CMS finalizes an administrative reconsideration review procedure for denials of initial applications or terminations for reasons other than those precluded from review by statute. If CMS denies an initial application (for a reason other than it not being submitted by the required deadline), or notifies an ACO of a termination, the ACO may, within 15 days, request reconsideration from a CMS

reconsideration official. Reconsiderations are scheduled at the discretion of the review official. The burden of proof is on the ACO to demonstrate that the application denial or termination is not consistent with CMS regulations or statute. The ACO may not submit required documentation as evidence that was not previously submitted to CMS. Following review, the reconsideration official would issue a recommended decision.

If the ACO disagrees with that decision, it may request a record review by an independent CMS official in a timeframe and format set out in the reconsideration letter. If upheld, an application denial or an ACO termination is effective on the date indicated in the initial notice.

In the final rule, CMS eliminates the specific provisions related to review of determinations made by a reviewing antitrust agency as no longer applicable because of revisions to the procedures for Antitrust review (section II.C of the final rule).

III. Collection of Information Requirements

The MSSP statute provides that information collection requirements do not apply to the MSSP.

IV. Regulatory Impact Analysis

CMS reviews in the final rule, as it did in the proposed rule, the requirements for a regulatory impact analysis, and updates the analysis based on the provisions of the final rule. CMS extends the period of the analysis from the three-year period 2012-2014 in the proposed rule to the four-year period 2012-2015 in the final rule because of the extension of the initial performance period to include either the 18 – or 21- month period ending December 31, 2013.

CMS projects a greater range of uncertainty around the potential take-up and beneficiary participation based on the final rule, and notes that as the actual number of participating ACOs and their characteristics become known, the range of financial outcomes will narrow.

| ACO Participation | | |
|---|--------------------------------------|-----------------------------------|
| Assumptions | Proposed Rule (2012-2014) | Final Rule (2012-2015) |
| Number of participating ACOs | 75 – 150 | 50 - 270 |
| Number of Medicare beneficiaries assigned to ACOs | 1.5 – 4.0 million | 1.0 – 5.0 million |

CMS assumes that most participating ACOs will opt for the one-sided model in order to avoid the potential for financial loss and while still building organizational experience. It assumes that ACOs will be equally likely to participate in markets

with FFS expenditures above, at, and below the national average, in contrast to the assumption in the proposed rule that participation was more likely in high-cost markets.

CMS projects lower net federal savings under the proposed rule, with its median savings estimate declining from \$510 million (over three years) in the proposed rule to \$470 million (over four years) in the final rule. That is because of the greater program generosity, in particular the first-dollar sharing in savings below the benchmark, as well as the easing of program requirements.

| Net Federal Savings, in millions | | |
|---|--------------------------------------|-----------------------------------|
| Net Federal Savings | Proposed Rule (2012-2014) | Final Rule (2012-2015) |
| 90 th Percentile | \$170 | \$0 |
| Median | \$510 | \$470 |
| 10 th Percentile | \$960 | \$940 |

CMS projects start-up costs for individual ACOs will average \$0.58 million, slightly higher than the \$0.49 million estimate in the proposed rule, and retains its estimate that annual operating costs will average \$1.27 million.

| ACO Start-Up and Annual Operating Costs, in millions | | |
|---|--------------------------------------|-----------------------------------|
| | Proposed Rule (2012-2014) | Final Rule (2012-2015) |
| Average Amount Per ACO | | |
| Start-Up Costs | \$0.49 | \$0.58 |
| Annual Operating Costs | \$1.27 | \$1.27 |
| Aggregate Start-Up and Operating Costs: range | \$132 - \$263 | \$92 - \$499 |

CMS projects an increase in median bonus payments to \$1.31 billion, compared with the \$800 median estimate of bonus payments in the proposed rule.

| ACO Bonus Payments, in millions | | |
|--|--------------------------------------|-----------------------------------|
| | Proposed Rule (2012-2014) | Final Rule (2012-2015) |
| Bonus Payments | | |
| 90 th Percentile | \$1,130 | \$1,900 |
| Median | \$800 | \$1,310 |
| 10 th Percentile | \$560 | \$890 |

CMS' median projection is that there would be no collected penalties in this initial period, compared with the \$40 million median estimate in the proposed rule. That is largely because of the elimination of year three risk in the Track 1, one-sided model.

Medicare Program; Final Waivers in Connection With the Shared Savings Program

CMS/OIG Interim Final Rule with Comment Period

[CMS-1439-IFC]

I. Background

On October 20, 2011, the Centers for Medicare & Medicaid Services (CMS) and the Office of the Inspector General (OIG) of the Department of Health and Human Services (hereinafter "the Agencies") made available for public inspection an interim final rule with comment period relating to waivers of the physician self-referral law, the federal anti-kickback statute, and certain civil money penalty (CMP) provisions of law to specified arrangements involving ACOs in connection with the Medicare Shared Savings Program (MSSP), including ACOs participating in the Advance Payment Initiative, to be published in the November 2, 2011 issue of the *Federal Register* with a comment period ending January 3, 2012.

The interim final rule differs significantly from the proposed rule which the Agencies refer to as the Waiver Design Notice. The Agencies reiterate the goal of applying fraud and abuse laws in a manner that does not unduly impede development of beneficial ACOs but that also ensures that ACO arrangements are not misused for fraudulent or abusive purposes that harm Medicare beneficiaries or Federal health care programs. However, the Agencies are very responsive to commenters who argued for far greater flexibility under the waivers and for broader application of those waivers, and in response, the Agencies finalize 5 waivers. Two of the waivers, relating to shared savings, are derived from the Waiver Design Notice but are broadened and arguably easier to satisfy. The Agencies also establish three additional waivers that address ACO financial and other arrangements outside of shared savings that are important to carry out the MSSP: a pre-participation waiver, a participation waiver, and a patient incentives waiver.

The waivers under the interim final rule apply only with respect to ACOs participating under the MSSP, and include ACOs participating in the Advance Payment Initiative; waivers for CMMI demonstration projects, including the Pioneer ACO, will be issued separately through guidance. The Agencies remind stakeholders that current exceptions and safe harbors under the fraud and abuse laws that may apply to ACOs and underscore that the waivers for ACOs under the MSSP do not apply to other provisions of Federal or State law not specifically waived, such as the internal Revenue Code. The Agencies provide consistency across fraud and abuse laws and again in response to comments largely provide uniform application of waivers to all qualified ACOs, ACO participants, and ACO providers and suppliers under the MSSP. One consistent requirement under the waivers is that the ACO have entered into a participation agreement (or in the

case of a pre-participation waiver bona fide intent and initial steps to apply as an MSSP ACO participant) with CMS and remain in good standing under the agreement. **The Agencies seek comment on whether an ACO under a corrective action plan should be required to be in compliance with that plan as a waiver condition.**

While accommodating many requests of stakeholders to provide broader waivers and greater flexibility to encourage innovation under the MSSP, the Agencies caution stakeholders to apply a reasoned approach to their interpretation of the conditions of the waivers and note they will closely monitor ACOs for the first 18 months with the intent to narrow the waivers for future applicants and renewing ACOs. Additionally, **the Agencies seek comment on many provisions of the interim final rule with respect to the waivers generally, and with more specificity with respect to waiver conditions and on the impact on beneficiaries as well as program integrity.**

II. Waivers

The Agencies decline to codify the waivers in the Code of Federal Regulations and will instead post them to their respective Internet Websites. A consistent requirement under the waivers is that arrangements be reasonably related to the purposes of the MSSP which is substituted for the necessary and directly related standard for waivers in the Waiver Designs Notice. The Agencies decline to define or provide examples of how to meet this standard and instead indicate that parties should be able to clearly articulate the nexus of any arrangement to MSSP purposes, but **the Agencies seek comment on whether and how to define this standard.** The Agencies provide a definition of MSSP purposes which is largely taken from the statute (viz. promoting accountability for the quality and cost of care; managing and coordinating care through the ACO, and encouraging investment in infrastructure and redesigned care processes for high quality, efficient delivery of care) and provide further specific examples.

Shared Savings Distribution Waiver

The shared savings distribution waiver protects distributions and uses of shared savings earned by an ACO from the Physician Self-Referral Law, the Anti-Kickback Statute, and the Gainsharing CMP. It applies with respect to distributions of shared savings to or among the ACO, ACO participants and ACO providers and suppliers (ACO parties) that are earned during the agreement (even if distributed or used after the agreement) and includes downstream distributions between and among the ACO parties. The waiver would also protect use of shared savings for activities that are reasonably related to MSSP purposes, including payment to parties outside the ACO other than outside referring physicians who are not compensated for activities reasonably related to MSSP purposes. With respect to the Gainsharing CMP, the Agencies retain the requirement that payment from a hospital to a physician may not be made

knowingly to induce the physician to reduce or limit medically necessary items or services.

The Agencies decline to provide specific waiver protection for shared savings distributed to or used by an MSSP participating ACO that the ACO earns from a comparable shared savings program with a commercial plan and **solicit comment on this.**

Compliance with Physician Self-Referral Law Waiver

This waiver protects any financial relationship between or among an ACO, its ACO participants, and its ACO providers and suppliers from the Physician Self-Referral Law, the Anti-Kickback Statute, and the Gainsharing CMP if the financial relationship is reasonably related to MSSP purposes and the financial relationship fully complies with a Physician Self-Referral Law exception. The waiver applies until the participation agreement, including renewals, expires or terminates, but the Agencies are considering providing an additional 3 to 12 months continuation period and **seek comment on this.**

Pre-Participation and Participation Waivers

These waivers apply with respect to the Physician Self-Referral Law, the Anti-Kickback Statute, and the Gainsharing CMP, and are intended to facilitate the participation of ACOs in the MSSP by protecting bona fide investment, start-up, operating and other arrangements of ACOs intending to participate or participating in the MSSP. They are designed to provide seamless protection to the ACO for a period before entering into a participation agreement with CMS and during that agreement. The waivers apply to arrangements within the ACO as well as ACO-related arrangements with outside providers and suppliers that coordinate or manage care for beneficiaries of the ACO; **the Agencies seek comment on whether outside party arrangements should be excluded.**

The Agencies provide safeguards by imposing specific responsibilities of the governing body to authorize arrangements (by first making a bona fide determination that the arrangement is reasonably related to MSSP purposes), by providing transparency through public disclosure (on a ACO Internet web site) describing the arrangement, and by requiring clear documentation retained for 10 years and available for audit. The governing body must be independent and has the duty to ensure arrangements further MSSP purposes and are not arrangements for the benefit of individual or business interests of ACO participants or ACO providers and suppliers and to clearly articulate their rationale. The Agencies **solicit comment on whether they should specify particular methods for governing bodies to make determinations and authorize these arrangements; they also seek comment on minimally burdensome methods of public disclosure and whether disclosure requirements should be more specific in the waiver text.**

Pre-participation waivers apply with respect to start-up arrangements of an ACO before CMS approves an application from the ACO to participate in the MSSP; insofar as these types of arrangements occur after entering into a participation agreement, protection is afforded them under the participation waiver. The Agencies define start-up arrangements as being any items, services, facilities, or goods (including non-medical items, services, facilities, or goods) used to create or develop an ACO that are provided by the ACO, ACO participants, or ACO providers or suppliers, and include subsidies for the same. The Agencies provide numerous examples of these arrangements and **seek comment on the definition generally as well as specific input as to whether it provides for sufficient innovation to create or develop ACOs.** ACOs, ACO participants, and ACO providers and suppliers, for purposes of this waiver are those individuals or entities that would meet the applicable definition under a participation agreement; however, drug and device manufacturers and distributors as well as DME suppliers and home health suppliers are not covered by this waiver.

A pre-participation waiver has numerous conditions, among them that parties are acting in good faith to develop an MSSP participating ACO in a target year and submit a completed application; that parties are taking diligent steps to develop that ACO; that there is contemporaneous documentation of the arrangement, the governing body's authorization, and the diligent steps; that there is public disclosure; and in the case of failure to submit an application by the deadline, a satisfactory explanation of the cause of the failure. Generally, the waiver period begins one year preceding the application date for the target year and ends on the start date of the agreement; in the case of a denied application, the waiver period ends 6 months after the date of denial (referred to as the tail period). The Agencies note that an ACO may only use the pre-participation waiver once.

Participation waivers apply to any arrangement of an ACO, its participants or providers and suppliers. They have fewer conditions, **about which the Agencies seek comment**, in part because the ACO is under a participation agreement and required to be in good standing. The governing body must still make its duly authorized bona fide determination and authorize the arrangement and contemporaneously document all the above, identify all parties to the arrangement as well as its purpose and financial terms, and publicly disclose a description of the arrangement. The waiver period begins on the date of the participation agreement and ends 6 months after its expiration (including renewals) or voluntary termination, unless involuntarily terminated in which case the waiver ends on the date of the termination notice.

Patient Incentives Waivers

The patient incentives waiver protects the provision of certain free or below fair market value items and services furnished to beneficiaries by an ACO, its ACO participants, or its ACO providers or suppliers from the Beneficiary Inducements

CMP and Anti-Kickback Statute. The waiver applies to preventive services (which the Agencies do not define **but seek comment on whether a definition should be provided**); to services to advance adherence to treatment regime, drug regime, or follow-up care plan; or management of chronic disease or condition. There must be a reasonable connection between services furnished and medical care of the beneficiary, and the services must be in-kind—financial incentives are not protected under the waiver. The waiver is not limited to beneficiaries assigned to the ACO **and the Agencies seek comment on whether it should be limited to assigned beneficiaries**. The waiver does not extend to free or below fair market value items and services from manufacturers or other vendors provided to beneficiaries, the ACO, ACO participants, or ACO providers and suppliers, but would protect items or services given to beneficiaries by the ACO, ACO participants, or ACO providers and suppliers received at discounted rates from manufacturers or vendors (other than through discount arrangements).

The waiver period begins on the date of the participation agreement and ends on its expiration (including renewals) or termination. ACO beneficiaries may retain items received during the agreement period and continue to receive services initiated during the agreement period that continue past the expiration or termination date. Incentives that fit within an existing safe harbor or exception are also permitted and do not require the protection of this waiver.

III. Additional Public Comment

Notwithstanding the provision of significant additional room for innovation, the Agencies emphasize this they intend to fully protect the program and beneficiaries from kickbacks and referral payments, monitoring closely for overutilization, increased, and substandard or poor quality care. As noted above, they intend to narrow the waivers for "undesirable effects" (the interim final rule includes several examples), and modified waivers would apply to new applicants or renewing ACOs after July 2013. The Agencies also **seek comment on all of the following:**

- **The narrowing of waivers**
- **Other categories of arrangements that require waiver protection**
- **How to define any categories identified above and what additional limits should apply**

Comments are due by January 3, 2012, and should include a reference to file code CMS-1439-IFC. Comments may be delivered electronically at <http://www.regulations.gov> (commenters should follow the "Submit a comment" instructions). Comments may also be delivered by regular mail to the following address: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1439-IFC, P.O. Box 8013, Baltimore, MD 21244-8013.

FTC/DOJ Final Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program

I. Background

On October 20, 2011, the Federal Trade Commission (FTC) and the Department of Justice (DOJ) (hereinafter “the Agencies”) issued a final version of a joint policy statement describing the enforcement policy on the application of antitrust laws to accountable care organizations (ACOs) participating under the Medicare Shared Savings Program (MSSP). There is no comment period. Unlike the CMS and OIG interim final rule on waivers of the fraud and abuse laws, the final joint policy statement is largely consistent with the proposed antitrust policy statement; however in response to public comment there are two significant changes. First, the provision calling for mandatory expedited review for collaborations with one or more Primary Service Areas (PSAs) with greater than 50 percent share of a common service has been dropped because CMS in its MSSP final rule no longer requires the review as a condition of entry into the program. Second, with the exception of voluntary expedited 90-day review, the entire final policy statement applies to all provider collaborations eligible and intending, or approved, to participate in the MSSP; it is no longer restricted to new collaborations (those formed on or after March 23, 2010 that have not yet participated in the MSSP). However, voluntary expedited 90-day review will only be available to new collaborations.

The Agencies state they will be closely monitoring the competitive effects of ACOs using data and information from CMS, including copies of ACO applications as well as aggregate claims data on allowed charges and fee-for-service payments for all MSSP ACOs, and further caution they will vigilantly monitor complaints on ACO formation or conduct. The final policy statement does not apply to either mergers or to single, fully integrated entities.

The Agencies conclude that eligibility criteria applicable to an ACO under the CMS final MSSP rule are consistent with clinical integration indicia the Agencies apply under the Health Care Statements used to evaluate collaborations among providers. The Agencies determined that an ACO that meets the CMS eligibility criteria is likely to be a bona fide arrangement, and if it applies the same arrangements in the commercial market, its integration criteria are sufficiently rigorous so that joint negotiations with private-sector payers will be treated as subordinate and reasonably related to the ACO’s primary purposes of improving health care services. The Agencies indicate they are willing to consider other proposals for clinical integration by reason of CMS regulations that allow an ACO to propose alternative methods to establish clinical management and oversight of the ACO.

The Agencies will apply a rule of reason analysis to an ACO participating under the MSSP and will apply the same analysis to the ACO in the commercial market if it uses the same governance and leadership structure as well as the same clinical and administrative processes under the MSSP. The rule of reason analysis evaluates whether an ACO collaboration is likely to have substantial anticompetitive effects and, if so, whether the ACO's potential procompetitive efficiencies are likely to outweigh those effects. The greater the likely anticompetitive effects, the greater the likely efficiencies must be to pass muster under the antitrust laws.

II. Analysis Used for ACOs Meeting CMS Eligibility Criteria

The Agencies will evaluate an ACO's share of common services in each ACO participant's PSA using the framework set forth in the proposed policy statement. Common services are described as services provided by two or more ACO participants to patients within a PSA. The Agencies again note that a higher ACO share of the services within a PSA indicates a greater risk the ACO will be anticompetitive, absent competing ACOs or sufficient unaffiliated providers and physicians. A PSA is the lowest number of contiguous postal zip codes from which an ACO participant draws at least 75 percent of its patients for the service involved. The final policy statement establishes an antitrust safety zone and, for ACOs outside the antitrust safety zone, guidance as well as voluntary expedited 90-day review for new collaborations.

Antitrust safety zone

ACOs within the antitrust safety zone (combined share of 30 percent or less of each common service in each participant's PSA where two or more ACO participants provide that service to patients in the PSA) are highly unlikely to raise significant competitive concerns, and the Agencies will not challenge them absent extraordinary circumstances (for example collusion or improper sharing of competitively sensitive information for sales outside the ACO). To qualify for treatment in the antitrust safety zone, any hospital or ambulatory surgery center in the ACO must be non-exclusive. There are special rules for ACOs in rural areas such that an ACO may include, on a non-exclusive basis, one physician per specialty, and critical access hospitals, sole community hospitals and acute care hospitals with fewer than 50 beds located in a rural area and 35 miles away from another acute care hospital, from each rural county even if including the physician or hospital causes the ACO's share of common services to exceed 30 percent in any ACO participant's PSA. To qualify for the rural exception, the physician or physician group practice primary office (the office in which the majority of patient visits occur) must be located in a zip code classified as isolated rural or other small rural according to the Washington, Wyoming, Alaska, Montana, Idaho (WWAMI) Rural Health Research Center of the University of Washington's seven category classification. Further, physician group practices must be treating patients as a fully integrated practice group as of the date of the

final policy statement and may not increase the number of physicians in the practice during the period of the ACO agreement; the agencies further note that Federally Qualified Health Centers and Rural Health Clinics are, for this purpose, considered physician group practices.

Additionally, if an ACO includes a participant with more than a 50 percent share in its PSA of any service that no other ACO participant provides to patients in that PSA (referred to as a dominant provider), that participant must be non-exclusive to the ACO. The Agencies caution that the ACO must be non-exclusive in fact—not just in name.

The safety zone treatment applies for the duration of the ACO agreement as long as it meets the safety zone requirements, though the agency notes that an ACO will not lose safety zone status solely because it attracts more patients.

ACOs Outside the Safety Zone

While an ACO outside the safety zone may be procompetitive and lawful, it is not clear whether it will provide the benefits intended under the MSSP (high quality, cost effective care) or whether it will reduce consumer choice and value and increase price. Thus the Agencies caution that if it appears that an ACO's formation or conduct appears to be anticompetitive, the Agencies may investigate. While the new collaborations are not under a legal obligation to seek expedited 90-day review from the Agencies, they may do so. Review requires the submission of a significant amount of documentation, including the completed application to CMS and all supporting documentation. The Agencies will make public both the request letter and the response, and remind ACOs that if during the review the Agencies determine that an ACO's formation or conduct may be anticompetitive, they will investigate and may take enforcement action as appropriate.

The Agencies provide guidance on 5 types of conduct to avoid to reduce the likelihood of an antitrust investigation. The first applies to all ACOs, including those falling within the safety zone. ACOs should refrain from and establish appropriate firewalls against conduct that may facilitate collusion among ACO participants in the sale of competing services outside the ACO, such as sharing among ACO provider participants sensitive price or other data that could be used to set prices or other terms for services provided outside the ACO.

With respect to ACOs outside the safety zone, the Agencies identify four types of conduct that may raise competitive concerns:

1. Preventing or discouraging private payers from directing or incentivizing patients to choose certain providers, including providers not participating in the ACO, through anti-steering, guaranteed inclusion, product participation, price parity or similar contract provisions.

2. Tying sales of ACO services to the private payer's purchase of other services from providers outside the ACO and vice versa.
3. Contracting on an exclusive basis with other ACO physicians, hospitals, ASCs, or other providers.
4. Restricting a private payer's ability to make cost, quality, efficiency, and performance information available to its enrollees for evaluation and selection of providers if that information is similar to the measures used under the MSSP.

Calculation of PSA Shares

To calculate PSA shares of common services, the ACO applicant must:

- a. Identify each service provided by at least two independent ACO participants.
 - A service is—
 - i. For physicians, the physician primary specialty,
 - ii. For inpatient facilities, a major diagnostic category, and
 - iii. For outpatient facilities, an outpatient category as defined by CMS.

The Policy Statement does not apply to other types of providers, such as clinical laboratories or nursing homes.
- b. Identify the PSA for each common service for each participant in the ACO.
- c. Separately for each common service, calculate the ACO's PSA share in each PSA in which at least two participants serve patients for that service during the most recent calendar year for which data are available.
 - i. For physicians' services, the ACO's share of Medicare fee-for-service (FFS) allowed charges,
 - ii. For inpatient services, the ACO's share of state-level all-payer hospital discharge data; for states without all-payer hospital discharge data, the ACO's share of Medicare FFS payments during the most recent federal fiscal year for which data are available (CMS will make the requisite data public), and
 - iii. For outpatient services, the ACO's share of Medicare FFS payments.

IRS Fact Sheet: Tax-Exempt Organizations Participating in the Medicare Shared Savings Program through Accountable Care Organizations

[FS-2011-11]

I. Background

On October 20, 2011, the Internal Revenue Service (IRS) released a fact sheet confirming that IRS Notice 2011-20, released April 18, 2011, continues to reflect IRS expectations regarding the Medicare Shared Savings Program (MSSP) and Accountable Care Organizations (ACOs) in light of the CMS MSSP final rule and that charitable organizations may rely on the guidance in that Notice. The fact sheet is in question and answer format and provides additional information for charitable organizations that wish to participate in the MSSP. The IRS does not solicit further comment.

II. Tax-Exempt Organization Participation in the MSSP Through ACOs

Prohibited Inurement or Impermissible Private Benefit

The IRS confirms that a charitable organization may participate in the MSSP through an ACO; however, to avoid adverse tax consequences, the charitable organization participating in the MSSP through an ACO must ensure that its participation agreement is structured so as not to result in its net earnings inuring to the benefit of the private shareholders or individuals of the tax-exempt organization (its insiders) or in its being operated for the benefit of private parties participating in the ACO, which the IRS determines based on all the facts and circumstances. The IRS expects, in part due to the requirements for and oversight of ACOs under the CMS final rule, that it will not consider the tax-exempt organization's participation to result in prohibited inurement or impermissible private benefit where all of the following conditions are met:

1. The participation terms are established in advance in a written agreement negotiated at arm's length.
2. CMS accepted the ACO into, and has not terminated it from, the program.
3. The tax-exempt organization's share of economic benefits from the ACO is proportional to the benefits or contributions it provides to the ACO.
4. The tax-exempt organization's share of ACO losses does not exceed the share of the tax-exempt organization's economic benefit from the ACO.
5. All contracts and transactions between the tax-exempt organization and the ACO and ACO participants are at fair market value.

The IRS expects that, as long as the participation agreement of a tax-exempt organization and the ACO is structured in accordance with the 5 factors noted above, no particular factor must be satisfied in all circumstances to prevent inurement or impermissible benefit. With respect to factor 1, the IRS does not expect the written agreement to state the precise share or exact amount of

shared savings distribution to the charitable organization; it does however expect the methodology for determining allocations to the tax-exempt participant to be set forth in that agreement. Further, termination of an ACO from the MSSP does not automatically jeopardize the status of a tax-exempt participant; relevant factors to the analysis include whether the ACO's activities after termination, which are non-MSSP activities, further a charitable purpose and whether they are attributed to the tax-exempt participant, for example in partnerships. With respect to requirements for proportionality of any ownership interests and capital contributions, and related distributions, in determining whether those interests and distributions meet factor 3, the IRS looks at the totality of the circumstances to determine whether the tax-exempt participant's share of economic benefits derived from the ACO is proportional to the benefits or contributions the tax-exempt participant provides to the ACO, using existing IRS guidance. The analysis under factor 3 takes into account all contributions made by the charitable organization and other ACO participants to the ACO, in whatever form and all economic benefits received by ACO participants, including shares of shared savings payments and any ownership interests.

In the case of an ACO treated as a partnership, the IRS does not necessarily require that the tax-exempt participants have control over the ACO to ensure that the ACO's participation in the Shared Savings Program furthers a charitable purpose noting that while control by tax-exempt participants is generally relevant, IRS looks to CMS regulation and oversight of the ACO to ensure that the ACO furthers the charitable purpose of lessening the burdens of government. However, should the tax-exempt participants in this type of ACO plan to engage in activities other than participation in the Shared Savings Program, the IRS counsels them to consult IRS guidance on joint ventures.

Tax on Unrelated Business Income

Whether the MSSP payments will be subject to tax on unrelated business income depends on whether the activities generating the MSSP payments are substantially related to the exercise or performance of the tax-exempt organization's charitable purpose that is the basis for its exemption under §501 of the Internal Revenue Code. The IRS expects generally that participation in the MSSP through an ACO will further the charitable purpose of lessening the burden of the government. The IRS confirms that, absent prohibited inurement or impermissible private benefit, any MSSP payments received by a tax-exempt organization from an ACO would derive from activities that are substantially related to the performance of the charitable purpose of lessening the burdens of government (the governmental burden being its responsibilities under the Medicare program) as long as the ACO meets all of the eligibility requirements established by CMS for participation in the MSSP.

With respect to whether activities unrelated to the MSSP are subject to tax on unrelated business income depends on the degree to which the activities are

related to the exercise or performance of a charitable purpose—if substantially related, then likely no tax obligation is generated for the tax-exempt participant. If not substantially related, there are a variety of factors, including type of income (dividends and interest may be excluded under section 512(b) of the Code) and special rules for partnerships that are taken into account.

ACO Conduct of Activities Unrelated to the MSSP

Insofar as an ACO conducts activities unrelated to the MSSP, for example operating under shared savings arrangements with other types of health insurance payers, these types of activities are not charitable in nature regardless of whether the agreement is related to a program intended to achieve cost savings in health care delivery. The IRS does recognize that certain non-MSSP activities may further or be substantially related to an exempt purpose (such as a shared savings arrangement under the Medicaid program or that provides care for the indigent). For ACOs treated as a partnership, the tax-exempt participants should again consult IRS guidance on joint ventures, specifically Revenue Rulings 2004-51 and 98-15, for examples that further charitable purposes of tax-exempt participants. IRS reiterates that not every activity that promotes health supports a tax exemption.

The conduct by an ACO of activities unrelated to the MSSP that do not further a charitable purpose may jeopardize the tax-exempt status of a tax-exempt participant. Whether those activities are attributable to the tax-exempt participant is significant but not necessarily dispositive as long as the ACO's non-charitable activities represent no more than an insubstantial part of the participant's total activities. But the IRS also notes that the presence of a single, substantial non-exempt purpose may jeopardize a participant's tax exempt status.

Tax Status of ACOs

An ACO that engages exclusively in MSSP activities may qualify as a tax-exempt (section 501(c)(3)) organization provided it satisfies all requirements under that section, unless it is treated as a partnership or disregarded for federal tax purposes. Additionally, an ACO that engages in both MSSP and non-MSSP activities may also qualify for tax exemption under section 501(c)(3) provided it engages exclusively in activities that accomplish one or more charitable purposes and meets all other section 501(c)(3) requirements.

Electronic Health Records Technology

The IRS clarifies that its May 2007 Memorandum relating to electronic health records (EHRs) does apply to a charitable organization (§ 501(c)(3) hospitals) participating in the MSSP through an ACO. Under the memorandum, the IRS does not treat the benefits a hospital provides to its medical staff physicians as inurement or impermissible private benefit where (a) the benefits fall within the

range of EHR software and technical support services permissible under HHS regulations, and (b) the hospital meets certain other specified requirements.

Medicare Program: Advanced Payment Model

Summary of Notice and Related Information

[CMS-5505-N]

CMS authored a notice (to be published in the November 2, 2011 issue of the *Federal Register*) announcing the testing of the Advanced Payment Model for certain accountable care organizations (ACOs) participating in the Medicare Shared Savings Program. The notice states that applicants for the Advanced Payment Model will need to submit their application by the application deadline(s) for the Medicare Shared Savings Program (along with their application for the Shared Savings Program itself). These deadlines have not yet been announced but CMS has indicated its intent to accept applications for the Medicare Shared Savings Program shortly after January 1, 2012.

The notice indicates that additional information about the Advanced Payment Model is available on the Center for Medicare and Medicaid Innovation web site at <http://www.innovations.cms.gov/areas-of-focus/seamless-and-coordinated-care-models/advance-payment>. The notice also states that questions regarding the Advance Payment Model or the application process should be sent to advpayaco@cms.hhs.gov.

According to CMS, the Advance Payment Model is an Innovation Center initiative for participants in the Medicare Shared Savings Program in need of prepayment of expected shared savings to build their capacity to provide high quality, coordinated care and generate cost savings. The Model will test whether and how pre-paying a portion of future shared savings could increase participation in the Medicare Shared Savings Program, and whether advance payments will increase the amount of and speed at which ACOs can effectively coordinate care to generate Medicare savings. Rural and physician-owned organizations are among the expected beneficiaries of the Advanced Payment Model.

Eligibility

A CMS fact sheet states that the Advance Payment ACO Model is open to only two types of organizations participating in the Shared Savings Program:

1. ACOs that do not include any inpatient facilities and have less than \$50 million in total annual revenue.
2. ACOs in which the only inpatient facilities are critical access hospitals and/or Medicare low-volume rural hospitals and have less than \$80 million in total annual revenue.

Further, only ACOs that enter the Shared Savings Program in April or July of 2012 will be eligible. And ACOs that are co-owned with a health plan will not be eligible.

The fact sheet notes that scoring criteria for evaluating applications will favor ACOs with the least access to capital, ACOs that serve rural populations, and ACOs that serve a significant number of Medicaid beneficiaries.

The notice explicitly states that organizations must be accepted for participation in the Medicare Shared Savings Program before they can be considered for the Advance Payment Model.

Structure of Payments

Under the Advance Payment Model, a participating ACO will receive three types of payments:

1. An upfront, fixed payment;
2. An upfront, variable payment, based on the number of its historically-assigned beneficiaries; and
3. A monthly payment of varying amount depending on the size of the ACO (and also based on the number of its historically-assigned beneficiaries).

The notice indicates that payments to selected ACOs will begin at the start of the first performance year and end at the settlement scheduled “the end of that performance year in June 2014.”

Recoupment of Advance Payments

The ACO fact sheet states that if an ACO participating in the Advance Payment Model does not generate sufficient savings to repay the advance payments as of the settlement scheduled for Shared Savings Program participants midway through ACOs' second performance year, CMS will recoup the balance from earned shared savings in the subsequent performance year. Rather importantly, CMS also notes that it will not pursue recoupment on any remaining balance of advance payments after the ACO completes the first agreement period. However, CMS adds that the agency will pursue full recoupment of advance payments from any ACO that does not complete the full, initial agreement period of the Shared Savings Program.