Summary of Agency Proposals Related to Accountable Care Organizations and the Medicare Shared Savings Program

I. Executive Summary

On March 31, 2011, the Centers for Medicare & Medicaid Services (CMS) released the proposed rule “Medicare Shared Savings Program: Accountable Care Organizations.” The proposed rule would implement section 3022 of the Affordable Care Act (ACA), which established a Medicare program-wide option for providers of services and suppliers to create Accountable Care Organizations (ACOs). The long-awaited proposed rule is the product of significant collaboration between CMS, the Department of Health and Human Services Office of the Inspector General (HHS OIG), the Federal Trade Commission (FTC) and the U.S. Department of Justice (DOJ), as well as substantial public input collected through a public workshop held October 5, 2010 and a request for information published on November 17, 2010.

In conjunction with the CMS proposed rule, the FTC and the Antitrust Division of the DOJ (collectively, the “antitrust agencies”) released a proposed statement of antitrust enforcement policy regarding ACOs participating in the Medicare Shared Savings Program; the HHS OIG released a notice with comment period proposing waivers of the Physician Self-Referral Law, the federal Anti-Kickback Statute and certain civil monetary penalty laws; and the Internal Revenue Service (IRS) released a notice soliciting comments as to whether existing guidance is sufficient for tax-exempt organizations planning to participate in ACOs, through the Medicare Shared Savings Program or other shared savings arrangements.

In brief, under CMS’ proposal, an ACO is a legal entity that is recognized and authorized under state law (with a taxpayer identification number or “TIN”), comprised of certain Medicare-enrolled providers and suppliers that work together to manage and coordinate care for Medicare fee-for-service beneficiaries and have a mechanism for shared governance. The types of providers and suppliers eligible to form an ACO include (1) “ACO professionals” (physicians, physician assistants, nurse practitioners and clinical nurse specialists) in group practice arrangements; (2) networks of individual practices of ACO professionals; (3) partnerships or joint venture agreements between hospitals and ACO professionals; (4) hospitals employing ACO professionals; and (5) critical access hospitals billing under Method II. ACOs that satisfy the eligibility criteria and enter into a 3-year agreement with CMS would be assigned a beneficiary population of at least 5,000, assigned retrospectively based on their use of primary care services for a particular year of the agreement. Participating ACOs may elect a “one-sided” or “two-sided” risk model: under the one-sided model, ACOs that meet all program

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requirements and quality standards and surpass an ACO-specific minimum savings rate below the ACO-specific benchmark would be eligible to receive up to 52.5 percent of the cost savings exceeding 2 percent of the ACO’s benchmark (with no downside risk); under the two-sided model, ACOs could receive up to 65 percent of any savings under the benchmark and would share any losses with CMS as well. Under CMS’ proposal, ACOs that elect the one-sided model would be transitioned to the two-sided model in year 3 of the agreement period. An ACO’s shared savings (and shared losses) percentage would be determined based on its reporting of and performance on 65 quality measures in 5 domains: (1) patient/caregiver experience; (2) care coordination; (3) patient safety; (4) preventive health; and (5) at-risk population/frail elderly health. These key elements and other proposals for implementing the Medicare Shared Savings Program are discussed in detail below.

In its regulatory impact analysis, CMS estimates that the total aggregate impact of net federal savings for 2012-2014 will be $510 million, calculated based on an estimated 75-150 participating ACOs. CMS estimates aggregate start-up investment and first year operating expenditures for ACOs at $131,643,825 to $263,287,650, depending on the number of participants. CMS presents a rough estimate of $1,755,251 in total average start-up investment and first-year operating expenditures for a participating ACO. Overall, CMS anticipates that 1.4 to 4 million Medicare beneficiaries will align with a participating ACO during the first three years of the program.

II. Provisions of the Medicare Shared Savings Program Proposed Rule

Below, we have summarized the provisions of the CMS proposed rule implementing the Medicare Shared Savings Program. The lettered sections follow the sections of the proposed rule (e.g. section A below corresponds with section II.A. of the proposed rule).

A. Organization of the Proposed Rule

The organization of this summary generally parallels the structure of the proposed rule, which addresses the following: A. Organization of the Proposed Rule; B. Eligibility and Governance; C. Establishing the 3-Year Agreement; D. Assignment of Medicare Fee-for-Service Beneficiaries; E. Quality and Other Reporting Requirements; F. Shared Savings Determination; G. Two-Sided Model; H. Monitoring and Termination of ACOs; I. Coordination with Other Agencies; J. Overlap with Other CMS Shared Savings Initiatives.

For purposes of the proposed rule, CMS proposes the following definitions:

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

B. Eligibility and Governance

Eligible Participants

Under the proposed rule, “eligible ACOs” include: (1) ACO professionals (physicians, physician assistants, nurse practitioners and clinical nurse specialists) 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.5 Although CAHs were not specified by the ACA as an eligible ACO, the ACA gave the Secretary authority to expand the list of eligible groups. Using this discretion, the Secretary added certain CAHs to the list of eligible ACOs. The Secretary also considered adding Federally Qualified Health Centers (FQHCs) and Rural Health Centers (RHCs) to the list of eligible participants; nevertheless, according to the proposed rule, CMS “currently lack[s] the requisite date elements (service code, physician, physician specialty, and specific attribution of services to the rendering health care profession) in the claims and payment systems” to allow their inclusion. Instead, however, the above listed eligible entities could establish ACOs that include additional Medicare-enrolled entities such as FQHCs, RHCs, post-acute facilities and other Medicare-enrolled providers and suppliers as “ACO participants.”

CMS is soliciting comment on the following: (1) the kinds of providers and suppliers that should or should not be included as potential ACO participants; (2) the potential benefits or concerns regarding including or not including certain provider or supplier types; (3) the administrative measures that would be needed to effectively implement and monitor particular partnerships; (4) other ways in which the Agency could employ the discretion provided to the Secretary to allow the independent participation of providers and suppliers not specifically mentioned in the statute, for example, through an ACO formed by a group of FQHCs and RHCs; and (5) any operational issues associated with the Agency’s proposal.

Legal Structure

Under the proposed rule, an ACO must be a legal entity (e.g., corporation, partnership, LLC) with a tax ID number (TIN) authorized to conduct business under state law and capable of: (a) receiving and distributing shared savings; (b) repaying shared losses; (c) establishing, reporting, and ensuring provider compliance with health care quality criteria, including quality performance standards; and (d) performing other required ACO functions.

CMS makes clear that the Agency is not proposing to require that the ACO itself be enrolled in the Medicare program, in contrast to this requirement for each ACO participant. Additionally, by proposing that each ACO must be constituted as a legal entity appropriately recognized and authorized under applicable State law, CMS is not proposing to require that existing legal entities appropriately recognized under State law must form a separate new entity. If the existing legal entity meets the eligibility requirements to be an ACO, it may operate as an

5 Under the “Method II” billing option, CAHs can elect to be paid for their outpatient CAH services at a rate equal to the sum of its facility fee paid on a reasonable cost basis and at 115% of the fee schedule for professional services otherwise included within outpatient critical access hospital services.
ACO, as long as it is recognized under applicable State law and is capable of receiving and distributing shared savings, repaying shared losses, and performing the other ACO functions identified in the statute and regulations, including the requirement for shared governance for ACO participants.

CMS is soliciting comment on whether the Agency should require all ACOs participating in the Shared Savings Program to be formed as a distinct legal entity appropriately recognized and authorized to conduct its business under applicable State law or whether an existing legal entity could be permitted to participate in the Shared Savings Program as an ACO, including entities that have similar arrangements with other payers. CMS also seeks input on other suitable legal structure requirements that the Agency should consider adding in the final rule or through subsequent rulemaking. Finally, CMS solicits comment on whether requirements for the creation of a separate entity would create disincentives for the formation of ACOs and whether there is an alternative requirement that could be used to achieve the aims of shared governance and decision-making and the ability to receive and distribute payments for shared savings.

Governance

Under the proposed rule, an ACO must have a “governing body” (e.g., a board of directors or other body that provides a mechanism for shared governance and decision-making for all ACO participants) comprised of ACO participants or their designated representatives and Medicare beneficiary representatives, with adequate authority to execute the statutory functions of an ACO and having broad responsibility for the ACO’s administrative, fiduciary, and clinical operations. In those instances where the ACO is comprised of a self-contained financially and clinically integrated entity that has a pre-existing board of directors or other governing body, such as a hospital that employs ACO professionals, CMS is also proposing that the ACO would not need to form a separate governing body, as long as that governing body is able to meet all other criteria required for ACO governing bodies. With regard to the composition of the governing body, CMS proposes that the ACO participants must hold at least 75 percent control of the governing body. In addition, each of the ACO participants must choose an appropriate representative from within its organization to represent them on the governing body.

CMS is requesting comment on whether requirements for the creation of a governing body as a mechanism for shared governance would create disincentives for the formation of ACOs and whether there is an alternative requirement that could be used to achieve the aims of shared governance and decision-making. CMS is also requesting comment on whether more or less than 75 percent control of the governing body being held by the ACO participants is an appropriate percentage. CMS also requests comment on whether the appropriate representative should be held by persons employed by and representing Medicare-enrolled tax ID numbers.

Leadership and Management Structure

Under the proposed rule, as part of its application, an ACO must submit supporting materials to CMS that demonstrate the ACO’s leadership and management structure, including clinical and administrative systems that support the goals of the Medicare Shared Savings Program and the aims of better care for individuals, better health for populations, and lower growth in expenditures.
Specifically, CMS proposes that ACOs meet the following criteria:

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

In order to determine an ACO’s compliance with these criteria, the proposed rule provides a detailed list of the supporting materials that must be submitted in the application—including documents that describe the ACO participants’ and ACO providers/suppliers’ rights and obligations, among other supporting documentation. Under the rule, CMS notes that ACOs with innovative leadership and management structures can describe an alternative mechanism, and in their application, must show how their leadership and management structure would achieve the same goals.

*CMS is soliciting comment on the requirement for submitting documents and whether an alternative method could be used to verify compliance with requirements. CMS is also seeking comment on the proposed leadership and management structure and whether the compliance burden will discourage participation, hinder innovative organizational structures, or whether there are alternative leadership and management structures.*

C. Establishing the 3-Year Agreement

Agreement Requirement

Under the proposed rule, in order to participate in the Medicare Shared Savings Program, an ACO must enter into an agreement with CMS. The participation agreement must be for a term of 3 years, starting on the January 1 following approval of an application or date specified in the agreement. CMS will determine whether to approve or deny applications from eligible organizations prior to the end of the calendar year in which the applications are submitted. CMS notes that there may be instances where an ACO might need to discontinue its participation in the Shared Savings Program prior to the end of the agreement period. In these cases, CMS proposes to require an ACO to give the Agency 60 days’ advance written notice of its intention to terminate its agreement and the effective date of its termination.
Additionally, if an ACO completes its 3-year agreement successfully, CMS proposes to refund in full any portion of shared savings withheld during the course of the 3-year agreement period that is not needed to offset losses (i.e., the 25 percent withhold of shared savings). In the event an ACO’s 3-year agreement is terminated before the completion of the 3 years, the Agency proposed to retain any portion of shared savings withheld.

Performance Period/Start Date

Unless otherwise specified, CMS proposes that the ACO’s annual performance period under the agreement must be the 12-month period beginning on January 1 of each year during the term of the agreement. In light of the short time frame for implementing the program for the first year, CMS is soliciting comment on any alternatives to a January 1, 2012 start date. The Agency notes that an alternative may be to add an additional start date of July 1 (for the first year of the program) and to allow the agreement period for ACOs with a July 1 start date to be increased to 3.5 years.

Timing and Process for Evaluating Shared Savings

Under the proposed rule, CMS will use a 6-month claims “run-out” period to calculate the benchmark and per-capita expenditures for the performance year. The claims run-out period is the time between when a Medicare-covered service has been furnished to a beneficiary and when the final payment is issued for the service.

CMS is soliciting comment on whether there are additional considerations that might make a 3-month claims period more appropriate. Additionally, CMS is concerned that some claims (for example, high cost claims) may be filed after the claims run-out period which would affect the accuracy of the amount of the shared savings payment. The Agency is considering, and seeks comment on, ways to address this issue, including applying an adjustment factor to account for incomplete claims, termination of the ACO’s agreement for ACOs found to be holding claims back, or attributing claims submitted after the run-out period to the following performance period.

Accountability for Beneficiaries

As part of the agreement, CMS proposes that an ACO executive who has the authority to bind the ACO must certify to the best of his or her knowledge, information, and belief that the ACO participants are willing to become accountable for, and to report to CMS on, the quality, cost, and overall care of the Medicare FFS beneficiaries assigned to the ACO.

Distribution of Savings

As part of an application, CMS proposes that an ACO must describe how: (a) it plans to use shared savings payments, including the criteria it plans to employ for distributing shared savings among its participants; (b) the proposed plan will achieve the specific goals of the program; and (c) the proposed plan will achieve the general aims of better care for individuals, better health for populations, and lower growth in expenditures.
Sufficient Number of Primary Care Providers and Beneficiaries

Under the proposed rule, CMS will deem an ACO to have a sufficient number of primary care physicians and beneficiaries if the number of beneficiaries historically assigned to the ACO participants is 5,000 or more. If at the end of a performance year, an ACO’s assigned population falls below 5,000, then that ACO will be issued a warning and placed on a corrective action plan (CAP); if the ACO’s assigned population has not returned to at least 5,000 by the end of the next performance year, then the agreement will be terminated and the ACO will not be eligible to share in savings for that year. *CMS is soliciting comment on this proposal and on other potential options addressing situations where the assigned beneficiary population falls below 5,000 during the course of an agreement period.*

Required Reporting on Participating ACO Professionals

Under the proposed rule, a participating ACO must maintain, update, and annually report to CMS the following: (a) each ACO participant’s TIN; and (b) each ACO providers/supplier’s National Provider Identifier and/or TIN.

Processes to Promote Evidence-Based Medicine, Patient Engagement, Reporting, and Coordination of Care

Under the proposed rule, an ACO must provide CMS with documentation of its plans to: (a) promote evidence-based medicine; (b) promote beneficiary engagement; (c) internally report quality and cost metrics; and (d) coordinate care. In carrying out strategies to optimize care coordination, CMS – under the proposed rule – prohibits the ACO from developing any policies that would restrict a beneficiary’s freedom to seek care from providers and suppliers outside the ACO. CMS notes that over time, as the Agency learns more about successful strategies in these areas, and gains more experience assessing specific critical elements for success, these requirements may be revised. *CMS is soliciting comment on whether more prescriptive criteria may be appropriate to meet the ACA-mandated goals of promoting evidenced-based medicine, patient engagement, reporting on quality and cost measures, and coordinated care.*

Patient-Centeredness Criteria

Under the proposed rule, an ACO should adopt a focus on patient-centeredness that is promoted by the governing body and integrated into practice by leadership and management working with the organization’s health care teams. Under the rule, an ACO must demonstrate patient-centeredness by meeting 8 specified criteria: (1) having a beneficiary experience of care survey in place; (2) involving patients in ACO governance; (3) having a process for evaluating the health needs of the ACO’s assigned population; (4) having systems in place to identify high-risk individuals and processes to develop individualized care plans for targeted patients populations; (5) having a mechanism in place for the coordination of care; (6) having a process in place for communicating clinical knowledge/evidence-based medicine to beneficiaries in a way that is understandable to them; (7) having written standards in place for beneficiary access and communication; and (8) having internal process in place for measuring clinical or service performance by physicians across the practices.

*CMS is soliciting comment on whether the patient centeredness criteria are sufficient to ensure that ACOs meet the eligibility requirement to demonstrate patient centeredness or*
whether there are additional patient centeredness criteria that should be added. CMS is also seeking comment on whether these criteria are burdensome and whether they might create disincentives to participate or make it difficult for small entities to participate.

ACO Marketing Guidelines

Under the proposed rule, any ACO marketing materials or activities and any changes to CMS-approved marketing materials or activities must be approved by CMS before use. The Agency defines ACO marketing materials, communications, and activities as including, but not limited to, general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, mailings, or other activities. These materials or activities must be approved by CMS if they are used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers regarding the ACO and its participation in the Shared Savings Program. The requirement would also apply to any materials or activities used by ACO participants or ACO providers/suppliers on behalf of the ACO to communicate about the ACO’s participation in the Shared Savings Program in any manner to Medicare beneficiaries. Finally, CMS proposes that an ACO that fails to adhere to these requirements may be placed under a CAP or terminated, at the Agency’s discretion.

Program Integrity Provisions

Compliance with Fraud and Abuse Laws. Under the proposed rule, ACOs must agree, and must require ACO participants, providers/suppliers, and contracted entities performing functions or services on behalf of the ACO to agree, or to comply with the federal criminal law; False Claims Act; Anti-Kickback Statute; Civil Monetary Penalties law; and the physician self-referral law.

Compliance Plan. ACOs must have a compliance plan that includes at least the following: (a) a designated compliance official or individual who is not legal counsel and who has the ability to report directly to the ACO’s governing body; (b) mechanisms for identifying and addressing compliance problems related to the ACO’s operations and performance; (c) a method for employees or contractors of the ACO, ACO participants, and ACO providers/suppliers to report suspected problems related to the ACO; (d) compliance training; (e) a requirement to report suspected violations of law to an appropriate law enforcement agency.

Compliance With Program Requirements. Under the proposed rule, the ACO maintains ultimate responsibility for compliance with all terms and conditions of its agreement – notwithstanding any relationships the ACO may have with other entities related to ACO activities. Additionally, as a condition of receiving a shared savings payment, an authorized representative with authority to legally bind the ACO must make a written request to CMS for payment in a document that certifies the ACO’s compliance with program requirements as well as the accuracy, completeness, and truthfulness of any information submitted by the ACO the ACO participants, or the ACO providers/suppliers to the Agency.

Conflicts of Interest. The ACO governing body must have a conflicts of interest policy that applies to members of the governing body.

Prohibition on Certain Required Referrals and Cost-Shifting. CMS is considering prohibiting ACOs and ACO participants from conditioning participation on referrals of federal
health care program business that the ACO or ACO participants know or should know is being provided to beneficiaries who are not assigned to the ACO.

CMS notes that although ACOs will not be subject to existing screening procedures for enrolling providers and suppliers, the Agency is nonetheless soliciting comments on the nature and extent of screening of ACOs and the screening results that would justify rejection of an application or increased scrutiny.

Data Sharing with CMS

Under the proposed rule, CMS will share aggregate and beneficiary identifiable data with ACOs if the ACO: (a) does not put unnecessary limitations or restrictions on use/disclosure of individually identifiable health information that it internally compiles from providers and suppliers both within and outside of the ACO; and (b) observes all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information and complies with the terms of the data use agreement.

Aggregate Data. Under the proposed rule, CMS will share aggregate data reports at the start of the agreement period based on the historical beneficiaries used to calculate the benchmark, and each quarter thereafter during the agreement period.

Quarterly reports will be based upon the most recent 12 months of data for beneficiaries that could potentially be assigned to the ACO. Data will not include beneficiary identifying information, but will include deidentified claims history of the services rendered for the ACO’s assigned FFS beneficiaries.

These aggregate data reports will include, when available, information such as: (1) financial performance; (2) quality performance scores; (3) aggregated metrics on the assigned beneficiary population; and (4) utilization data at the start of agreement period based on historical beneficiaries used to calculate the benchmark.

Identification of Historically Assigned Beneficiaries. At the beginning of the agreement period and end of each performance period, CMS will, upon the ACO’s request for the data for purposes of population-based activities relating to improving health or reducing health care costs, protocol development, case management, and care coordination, provide the following data about each historical beneficiary used to generate the ACO’s benchmark: beneficiary name; date of birth; gender; and Health Insurance Claim Number (“HICN”).

Sharing Beneficiary Identifiable Data. Subject to a beneficiary “opt-out”, CMS will, upon the ACO’s request, provide the ACO with monthly claims data for potentially assigned beneficiaries. The data must be for purposes of evaluating ACO provider/supplier performance, conducting quality assessment and improvement activities, and conducting population-based activities relating to improved health. In the proposed rule, CMS provides an extensive discussion of how these disclosures are permitted under both the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and thePrivacy Act of 1974.

To ensure beneficiaries have a meaningful opportunity to “opt-out” of having their claims data shared, the ACO may only request such claims data if the beneficiary has been seen in the
office of a participating primary care physician during the performance year; the beneficiary was informed about how the ACO intends to use the data; and the beneficiary did not “opt-out.” The “opt-out” requirement will not apply to the initial four data points that CMS will provide to ACOs (beneficiary name, date of birth, sex, and HICN).

**Part A, Part B, and Part D Data.** Under the proposed rule, the content of the data sets that CMS discloses will be the minimum data necessary for the ACO to effectively coordinate the care of its patient population. The minimum necessary Parts A and B data elements that CMS may disclose to an ACO include: beneficiary ID; date of birth; gender; date of death; claim ID; the from and through dates of service; the provider or supplier ID; and the claim payment type. The minimum necessary Part D data elements that CMS may disclose include: beneficiary ID; prescriber ID; drug service date; drug product service ID; quantity dispensed; days supplied; gross drug cost; brand name; generic name; drug strength; and indication if the drug is on the formulary, as designated by CMS. Similar to the process in which ACOs can receive the four beneficiary identifiable data points, to receive the Parts A, B, and D data, ACOs must meet similar disclosure and use criteria outlined above.

**Data Use Agreement.** Prior to receiving any beneficiary identifiable data, ACOs must enter into a data use agreement (“DUA”) with CMS. Under the DUA, the ACO would be prohibited from sharing the Medicare claims data provided by CMS with anyone outside the ACO, and from using the data in a manner in which a HIPAA covered entity could not without violating the HIPAA Privacy Rule.

In addition to requesting comment generally on all the above provisions, CMS is also seeking comment specifically on proposals related to the provision of both aggregate and beneficiary identifiable data to ACOs. The Agency is particularly interested in comments on the kinds and frequency of data that would be useful to ACOs, potential privacy and security issues, and the implications for sharing protected health information with ACOs, and the use of a beneficiary opt-out, as opposed to an opt-in, to obtain beneficiary consent to the sharing of their information.

**Changes during 3-Year Agreement Period**

**New Program Standards Established During Agreement Period.** Under the proposed rule, ACOs will be subject to all regulatory changes except: (a) eligibility requirements concerning the structure and governance of ACOs; (b) calculation of sharing rate; and (c) beneficiary assignment. If changes in law or regulations require an ACO to change its processes in a manner that affects the design of its care processes and delivery of care, changes to the quality of care, or changes in planned distribution of shared savings, the ACO will be required to submit to CMS a supplement to its original application. If an ACO cannot effectuate the changes needed to adhere to the regulatory modifications after being given an opportunity to act upon a CAP, the ACO would be terminated from the program.

**Significant Changes to the ACO During Agreement Period.** Under the proposed rule, during the 3-year agreement, an ACO may remove, but not add, ACO participants, and it may remove or add ACO providers/suppliers. The rule would require ACOs to notify CMS at least 30 days prior to any “significant change” – which occurs when an ACO is unable to fulfill its 3-year agreement due to: (1) deviation from its approved application; (2) a material change including changes in governing body composition; or (3) government-required reorganization as
a result of fraud or antitrust concerns. An ACO would be required to notify CMS within 30 days of the event for reevaluation of its eligibility.

CMS would then be required to review the ACO’s notification and make one of the following determinations: (1) the ACO may continue to operate under the new structure with savings calculations for the performance year based upon the updated list of ACO participant TINs; (2) the ACO structure is so different from the initially approved ACO that it must submit a new application, and, if applicable, undergo an antitrust review; (3) the ACO is materially different from the initially approved ACO because of the inclusion of additional ACO providers and suppliers such that the ACO must obtain an antitrust review and a letter from the reviewing Antitrust Agency stating that it has no present intent to challenge, or to recommend challenging, the ACO; (4) the ACO no longer meets the eligibility criteria for the program and its 3-year agreement must be terminated; or (5) CMS and the ACO may mutually decide to terminate the agreement.

Future Participation of Previous Shared Savings Program Participants. The ACO must disclose to CMS whether the ACO, its ACO participants, or its ACO providers/suppliers have participated in Medicare under the same or a different name, or is related to or has an affiliation with another Shared Savings Program ACO. The ACO must specify whether the related ACO was terminated or withdrew voluntarily. If the ACO was terminated, the applicant must identify the cause and what safeguards are now in place to enable the applicant ACO to participate in the program.

D. Assignment of Medicare Fee-for-Service Beneficiaries

As discussed above, ACOs must serve at least 5,000 beneficiaries to participate in the Medicare Shared Savings Program. CMS describes “assignment” as the operational process by which Medicare will determine whether a beneficiary has received a sufficient level of requisite primary care services from physicians associated with a specific ACO such that that ACO may be designated as exercising basic responsibility for the beneficiary’s care. Beneficiaries will retain free choice of providers both within and outside of the ACO, but CMS will align beneficiaries to an ACO to assess the ACO’s eligibility for shared savings.

Assignment Mechanics and Underlying Definitions

CMS proposes to identify ACOs operationally as a collection of Medicare-enrolled TINs practicing as a group practice arrangement or network. For example, a single group practice would be identified by its TIN, and a collection of practices forming an ACO would be identified by a set of TINs. Beneficiaries would be assigned to an ACO through a TIN based only on the primary care services they received from primary care physicians billing under that TIN and not from other ACO professionals such as physician assistants or nurse practitioners. CMS is also proposing to require organizations applying to be an ACO to list National Provider Identification (NPI) numbers for all ACO professionals, including a list that identifies physicians that provide primary care.

ACO professionals on whom beneficiary assignment is based (i.e. primary care providers) must be exclusive to one ACO agreement. Other ACO participants (e.g., acute care hospitals, surgical and medical specialists, RHCs and FQHCs) could participate in multiple ACOs. CMS is concerned that requiring exclusivity would diminish competition in the market.
CMS considered multiple options for defining primary care services for purposes of assignment. CMS is proposing a definition that considers both the care and the services provided. CMS proposes to define “primary care practitioner” as a physician who has a specialty designation of internal medicine, general practice, family practice, or geriatric medicine. “Primary care services” would be defined on the basis of the selected set of HCPCS codes established under section 5501 of the ACA for purposes of providing an incentive payment for primary care services (including G-codes associated with the annual wellness visit and Welcome to Medicare visit). CMS proposes to assign beneficiaries based on appropriate primary care services received from physicians designated as primary care providers. CMS solicits comments on this proposal, an alternative “step-wise” option which would also capture primary care services provided by specialists, and other options that may better address the delivery of primary care services by specialists.

CMS proposes to assign beneficiaries to an ACO if they receive a plurality (as opposed to a majority) of their primary care services (based on accumulated allowed charges, rather than a simple service count) from primary care physicians within that ACO. CMS believes that a majority rule would be too strict. CMS welcomes comments on the proposed plurality rule and on whether there should be a minimum threshold number of primary care services that a beneficiary should receive from the ACO to be assigned to it.

Retrospective Beneficiary Assignment

CMS is proposing retrospective beneficiary assignment, meaning that beneficiaries would be assigned at the end of the performance year. Although it considered prospective beneficiary assignment, CMS did not want to encourage ACOs to limit their care improvement activities to a subset of patients and felt it was critical to assess ACO performance based on patients seen in the performance year rather than an earlier period. To balance retrospective assignment, CMS proposes to prospectively provide aggregate beneficiary level data for the population of Medicare beneficiaries that would have been assigned (had the ACO existed) during the benchmark period. According to CMS, this will allow ACOs to have information on the population for which they will likely be responsible. CMS solicits comments on the combined approach of retrospective assignment for purposes of determining eligibility for shared savings balanced by the provision of data from the benchmark period. CMS also seeks comments on alternative assignment approaches.

Beneficiary Information and Notification

CMS intends to develop a communications plan to give beneficiaries information about their utilization of services furnished by ACO participants and the possibility of being assigned to an ACO. Under the Proposed Rule, ACOs would be required to post signs in the facilities of participating ACO providers/suppliers indicating their participation in the Shared Savings Program and to make standardized written information available to beneficiaries they serve. ACOs would further be required to give beneficiaries a form allowing them to opt out of having their data shared among ACO participants. ACOs would also be required to inform beneficiaries if they will no longer be participating in the Shared Savings Program. CMS seeks comments on the appropriate form and content of beneficiary notification and the most important items to communicate to beneficiaries.
E. Quality and Other Reporting Requirements

Under the Proposed Rule, ACOs that do not meet quality performance standards will not be eligible for shared savings. Quality scores would serve as the basis for assessing, benchmarking, rewarding and improving ACO quality performance.

Proposed Quality Measures

CMS proposes using quality measures in the following five domains: (1) Patient/Caregiver Experience; (2) Care Coordination; (3) Patient Safety; (4) Preventive Health; and (5) At-Risk Population/Frail Elderly Health. For the first performance period, CMS is proposing a total of 65 measures for ACOs, which are listed in the Appendix to this summary. As noted in the Appendix, many of the proposed measures are National Quality Forum (NQF) measures. Others are drawn from existing programs, such as the Electronic Health Record (EHR) Incentive Program or the Physician Quality Reporting System (PQRS).

Quality measures for the remaining 2 years of the 3 year agreement will be proposed in future rulemaking. CMS indicates that expanded measures may address highly prevalent conditions of interest and may add measures of hospital-based care and measures for care furnished in other settings. CMS is interested in measuring success in the delivery of high-quality health care at the individual and population levels.

For the first year only, an ACO will be considered to meet the ACO Quality Performance Standard if it has fully and accurately reported on applicable quality measures. In later years, an ACO will have to both report quality measures and achieve performance at a minimum attainment level, as discussed below. Under the Proposed Rule, ACOs that fail to meet the minimum attainment level for 1 or more domains would receive a warning and re-evaluation in the following year. The agreement of an ACO that continues to underperform in the next year would be terminated. If an ACO does not report 1 or more measures, CMS would request the data by a specified date. An ACO’s agreement could be terminated for failure to report the requested data.

CMS invites comments on the implications of including or excluding any proposed measure, suggested variations or substitutions that are substantially equivalent to the proposed measures, whether the list of proposed measures should be narrowed, and whether any of the proposed measures should be considered for quality monitoring purposes only. CMS also seeks comment on a process for retiring or adjusting the weights of domains, modules, or measures over time.

Data Submission

The mechanics of data submission for the proposed quality measures will vary, as indicated in the Appendix. CMS proposes to derive claims-based measures from claims submitted, without additional ACO reporting. Other measures will be reported through the CAHPS survey or other established mechanisms. CMS proposes to create a CMS-specific data collection tool and a survey tool for certain proposed measures. Specifically, CMS is proposing use of the Group Practice Reporting Option (GRPO) Data Collection Tool (incorporated from the Physician Quality Reporting System) to allow ACOs to submit clinical information from EHRs, registries, and administrative data sources required for measurement reporting. Through
a GRPO audit process, CMS plans to audit random samples of 30 beneficiaries for each of the quality measure domains/measure sets. As discussed below, elsewhere in the Proposed Rule, CMS proposes that at least 50% of an ACO’s primary care physicians must be “meaningful EHR users.” CMS intends to develop the capability of the GPRO web-based tool to interface with EHR technology, such that EHR data could directly populate the ACO GPRO tool with required quality data. CMS solicits comments on the proposed data submission requirements.

Quality Performance Standards

CMS proposes to score ACOs based on performance in each domain. Aggregated domain scores would determine the ACO’s eligibility for sharing savings and the percentage of savings that the ACO will share. For each measure, CMS proposes to set a performance benchmark and a minimum attainment level. Based on its percentile in terms of the FFS/MA rate, an ACO would be awarded between 0 and 2 points for performance on each measure. The minimum attainment level is proposed at 30 percent or the 30th percentile. Performance equal to or greater than the minimum attainment level, but less than the performance benchmark, would be awarded points based on a sliding scale. Two measures, the diabetes and coronary artery disease composites, would instead be scored on an “all or nothing” basis, as noted in the Appendix. CMS’s intent in using “all or nothing” scoring on these composites is to signal that failure to perform any element of a process is unacceptable.

Once each measure is scored, CMS proposes to divide the points earned by the ACO across all measures in a domain by the total points available in that domain. CMS proposes aggregating the resulting quality domain scores into a single overall ACO performance score. All domains would be weighted equally in determining an ACO’s overall score. The overall score would be used to calculate the ACO’s final sharing rate. To be eligible for the maximum shared savings percentage under either the one-sided or two-sided risk model (discussed below), an ACO would have to obtain all available quality points. CMS further proposes that ACOs must report completely and accurately on all measures within all domains to be deemed eligible for shared savings consideration.

As an alternative to the proposal discussed above for establishing quality performance standards, CMS discusses the option of setting a minimum quality threshold. Under this approach, an ACO would be eligible for the maximum shared savings percentage/sharing rate if its performance was at or above the 50th percentile for each domain. CMS seeks comments on its proposal for quality performance standards and the alternative minimum quality threshold option. Within these options, CMS seeks comment on the appropriateness of weighting all domains equally in determining an ACO’s quality performance or whether certain domains and/or specific measures should be weighted more heavily. CMS also invites comment on alternatives that would blend these two approaches.

In the first year of the Shared Savings Program, CMS proposes to set the quality performance standard at the reporting level, meaning ACOs could receive full quality points for 100 percent complete and accurate reporting on all quality measures. Via future rulemaking, CMS plans to raise the quality performance standard requirements beginning in the second program year, when actual performance on the reported measures would be considered in determining whether an ACO is eligible to receive any shared savings. CMS seeks comments on this proposal. In addition, CMS seeks comment on the proposal for all of the proposed quality
Incorporation of Physician Quality Reporting System (PQRS) Reporting Requirements and Meaningful Use Requirements

CMS proposes to incorporate a PQRS group practice reporting option (GPRO) under the Shared Savings Program. Eligible professionals that are ACO participant providers/suppliers would constitute a group practice for purposes of qualifying for a PQRS incentive under the Shared Savings Program. The ACO would report and submit data on behalf of the eligible professionals in an effort to qualify for the PQRS incentive as a group practice. Thus, eligible professionals within an ACO would qualify for the PQRS incentive as a group practice rather than as individuals. CMS proposes to incorporate certain aspects of the criteria for satisfactory reporting under the 2011 PQRS GPRO I option (as described at 75 Fed. Reg. 73506), with several modifications. CMS seeks comments on its proposal to incorporate PQRS requirements and payments and certain related metrics under the Shared Savings Program.

In the Proposed Rule, CMS is not proposing to incorporate EHR Incentive Program or Electronic Prescribing (eRx) Incentive Program payments under the Shared Savings Program. Professionals in ACOs could separately participate in these programs. CMS is proposing, as a Shared Savings Program requirement separate from the quality measures discussed above, that at least 50 percent of an ACO’s primary care physicians must be determined to be “meaningful EHR users” by the start of the second performance year in order to continue participation in the Shared Savings Program. “Meaningful use” is used as defined in 42 C.F.R. 495.4, pursuant to the HITECH Act and subsequent Medicare regulations. For subsequent years, CMS anticipates proposing greater alignment between the Shared Savings Program and the EHR Incentive program. CMS seeks comment on this proposal and on whether to require 50 percent of eligible hospitals that are ACO providers/suppliers to achieve meaningful use of certified EHR technology by the start of the second performance year. Related to this option, CMS seeks comments on circumstances where the ACO may only include one eligible hospital or no hospital and whether an exclusion or exemption would be needed in such a circumstance.

In the Proposed Rule, CMS discusses further aligning ACO quality measures with other laws and regulations. CMS seeks comment on the best way to align quality domains, categories, specific measures, and rewards across Federal healthcare programs and whether quality standards in different ACA programs should use the same definition of domains, categories, specific measures, and rewards for performance.

Requirements for Public Reporting

CMS is proposing that certain information regarding the operations of an ACO would be subject to public reporting. Specifically, an ACO would publicly report:

- Name and location;
- Primary contact;
- Organizational information (including: ACO participants; identification of ACO participants in joint ventures between ACO professionals and hospitals; identification of the ACO participant representatives on its governing body; and associated committees and committee leadership);
• Shared savings information (including: shared savings performance payment received by the ACO or shared losses payable to CMS; and total proportion of shared savings invested in infrastructure, redesigned care processes and other resources required to support the three-part aim goals of better health for populations, better care for individuals and lower growth in expenditures, including the proportion distributed among ACO participants); and
• Quality performance standard scores.

Each ACO would be responsible for making this information available to the public in a standardized format to be provided in subregulatory guidance. CMS seeks comments on this proposal, including whether the listed elements for reporting capture information important for achieving transparency and meaningful public disclosure. CMS also seeks comment on whether ACOs themselves should be required to make this information publicly available or whether ACOs should report this information to CMS for dissemination.

F. Shared Savings Determination

Two “Tracks” for ACO Participation

CMS has proposed a “hybrid approach” to implementing the Medicare Shared Savings Program, combining elements of the “one-sided” model contemplated by §1899(d) of the ACA and a risk-based approach under §1899(i). Thus, CMS has proposed two “tracks” from which participating ACOs may choose:

• Track 1: Under Track 1, shared savings would be reconciled annually for the first 2 years of the 3-year agreement using a “one-sided” shared savings approach, meaning ACOs would not held responsible for any portion of losses above the expenditure target. In the third year of the agreement, Track 1 ACOs would transition to the “two-sided” model and would be required to share any losses, as well as savings, with CMS. ACOs that wish to continue participating in the Shared Savings Program would be required to participate in the two-sided model going forward after the first 3-year agreement ends.
• Track 2: For “more experienced ACOs,” Track 2 places ACOs immediately in the “two-sided” model for all 3 years of the agreement period. Track 2 ACOs would therefore share in losses with CMS beginning in year 1, but would be eligible for higher rates of shared savings than those available under the one-sided model.

Overview of Shared Savings Determination

ACOs will be eligible to receive shared savings payments if they meet all contract requirements and quality performance standards, and achieve savings exceeding the ACO’s “minimum savings rate”—a specified percentage below its “benchmark.” An ACO’s benchmark is a measure of what the Medicare FFS Parts A and B expenditures would have been in the absence of the ACO. Thus, the benchmark is essentially the baseline measure of Parts A and B expenditures against which the ACO’s financial performance will be compared in each year of the agreement. ACOs that exceed their minimum savings rate (that is, spend a certain percentage below the benchmark) will share the savings with CMS at the ACO’s applicable “sharing rate”—the percentage of the total savings that an ACO receives. Under CMS’ proposal, the sharing rate
would be based on the ACO’s level of quality performance and the extent to which it has included FQHCs and RHCs in the ACO. Savings payments would be limited by the “sharing cap.” Track 1 and Track 2 ACOs would be subject to the same mechanism for determining the benchmark but would have different minimum savings rates, sharing rates and sharing caps. In addition, Track 2 ACOs and Track 1 ACOs in the third year of their agreement would be subject to shared losses (as described in section G, below).

Establishing an Expenditure Benchmark

CMS considered two “legally permissible” methods of setting ACOs’ benchmarks. Under “Option 1” (ultimately selected by CMS in the proposed rule), an ACO’s benchmark would be estimated based on the Parts A and B FFS expenditures of beneficiaries who would have been assigned to the ACO in each of the 3 years prior to the start of an ACO’s agreements period, based on claims submitted using ACO participants’ TINs. Under “Option 2,” the benchmark would be based on Parts A and B FFS expenditures of the beneficiaries actually assigned to the ACO during each performance year, with the expenditures being those incurred in the 3 years preceding the ACO’s agreement period. Both options’ benchmarks would be derived from prior expenditures adjusted for certain beneficiary characteristics and other factors; updated year to year by the projected absolute amount of growth in national per capita expenditures; and reset at the start of each agreement period. Thus, the primary difference in the options is the population whose claims history will be the basis for the benchmark. CMS seeks comments on both options for determining ACO benchmarks.

Under Option 1, CMS would use the claims records of ACO participants to determine the list of beneficiaries who received a plurality of their primary care services from primary care physicians in the ACO in each of the prior 3 most recent available years. Annual per capita Parts A and B FFS expenditures for the assigned population would be calculated, truncating an assigned beneficiary’s expenditures at the 99th percentile to minimize variation from catastrophically large claims. Using CMS Office of the Actuary national Medicare expenditure data, CMS would determine a growth index and trend each year’s expenditures to benchmark year 3 dollars (trending described below). Then CMS would establish health status indices for each benchmark year and adjust them to reflect benchmark year 3 risk (risk adjustment methodology described below). CMS would then compute a 3-year risk- and growth trend-adjusted per capita expenditure amount by combining the initial per capita expenditures for each year with the respective growth and health status indices. CMS would weight benchmark year 3 at 60 percent, benchmark year 2 at 30 percent and benchmark year 1 at 10 percent to more accurately reflect the latest spending and health status, yielding the initial benchmark that applies to the ACO. For each performance year, the benchmark would be updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B FFS services, as required by the statute.

CMS notes that it is possible that the assigned population could diverge from the benchmark population, potentially affecting the comparability of performance measurement. Data from the Physician Group Practice Demonstration showed that 25 percent of the beneficiaries assigned in one year were not assigned in the subsequent year due to relocation, death, participation in Medicare Advantage (MA), or changes in choice of care professionals. While CMS believes Option 1 would be a “relatively accurate” reflection of the average population of assigned beneficiaries, some beneficiaries whose expenditures would be included in the benchmark would not be reflected in the assigned population and it is possible that this
approach could provide an incentive to seek or avoid specific beneficiaries in order to reduce expenditures in the agreement period.

Thus, under Option 2, CMS would use the claims experience (for the 3 years prior to the agreement period) of the beneficiaries actually assigned to the ACO to establish the benchmark (trended forward and risk-adjusted as under Option 1). In the second and third years of the agreement period, CMS would adjust the benchmark to account for newly-assigned beneficiaries and beneficiaries no longer assigned to the ACO, as well as for beneficiaries who died during an agreement year. CMS presents two options for adjusting for decedents under Option 2, opting to exclude the expenditures of deceased beneficiaries from actual expenditures during the agreement period.

Adjusting the Benchmark and Average Per Capita Expenditures for Beneficiary Characteristics

CMS considered two options for risk adjusting average per capita expenditures to reflect beneficiary characteristics: (1) consider only demographic factors (e.g., age, sex, Medicaid status and basis for Medicare entitlement); or (2) consider both demographic factors and diagnostic information under the CMS-HCC prospective risk adjustment model used in the Medicare Advantage program. The first option would be administratively simpler and avoid issues of coding intensity, but CMS has proposed to adjust Medicare expenditure amounts by employing the CMS-HCC model used in the MA program. Reasoning that an ACO’s average population risk score would be stable in case mix over time, and that CMS does not want to incentivize ACOs to achieve “savings” by increasing their coding intensity, CMS has proposed that a single benchmark risk score be calculated for each ACO and applied throughout the agreement period. The benchmark risk score would be calculated by applying the CMS-HCC model to the assigned population attributed in each year of the 3-year benchmark, but changes in the assigned beneficiary population risk score from the benchmark period during the performance year would not be incorporated. CMS requests comments on this proposed methodology and alternative approaches, including using the MA “new enrollee” demographic risk adjustment model or applying a coding intensity cap on annual growth in the risk scores of an ACO’s assigned population.

Technical Adjustments to the Benchmark

As authorized under the statute, CMS considered whether to make adjustments to the benchmark for several “other factors,” ultimately deciding in the proposed rule to adjust only for expenditures and savings for certain incentive payments and penalties under section 1848 of the Social Security Act. CMS considered removing indirect medical education (IME) and disproportionate share hospital (DSH) payments from both the benchmark and calculation of actual expenditures, but determined that the statute only provides authority to adjust expenditures in the agreement period for beneficiary characteristics and not for “other factors.” Similarly, for geographic adjustments such as the IPPS wage index and physician fee schedule geographic practice cost index adjustments, CMS considered but decided against removing these adjustments from the calculation of the benchmark and actual expenditures due to the lack of statutory authority referenced above.
On the other hand, CMS is proposing to exclude from the computation of both benchmark and actual expenditures in the agreement period the expenditures or savings for incentive payments and penalties under section 1848 for value-based purchasing initiatives such as the PQRS, eRx and EHR programs for eligible professionals under the HITECH Act because the statute gives CMS the authority to incorporate the reporting requirements and incentive payments of these section 1848 initiatives, as appropriate. CMS states that the statute does not give it authority for such exclusion for initiatives not under section 1848; thus, EHR incentive payments to hospitals and the hospital inpatient value-based purchasing program would be included in the benchmark and actual expenditure calculations.

Trending Forward Prior Years’ Experience to Obtain an Initial Benchmark

As an ACO’s benchmark is based on the most recent 3 years of beneficiary expenditures for Parts A and B services, the per capita costs for each year must be trended forward to current year dollars and averaged (using the 60-30-10 weighting approach as described above) to obtain the benchmark for the first agreement period (the “initial benchmark”). CMS considered two options for trending forward the expenditures: (1) using growth rates in expenditures for Parts A and B services for FFS beneficiaries; or (2) using a flat dollar amount equivalent to the absolute growth in per capita expenditures for Parts A and B FFS services. CMS has proposed the former. For example, an ACO starting its agreement period in 2014 would have its benchmark based on 2011, 2012 and 2013 claims data; the 2011 and 2012 data would be trended forward so all benchmark dollars would be in 2013 dollars. Furthermore, CMS has proposed to use a national growth rate as opposed to the lower of the national or state/local growth rate. CMS welcomes comments on these proposals.

Updating the Benchmark during the Agreement Period

Under the statute, CMS is directed to update the benchmark by the “projected absolute amount of growth in national per capita expenditures,” which would mean a flat dollar increase, which is the same for all ACOs, in years 2 and 3 of the agreement period. CMS considered but did not decide to use its authority under section 1899(i) to use an alternative option that would update the benchmark by the lower of the national absolute amount of growth or the state/local amount (which could potentially provide a more accurate estimate in lower growth areas). CMS proposes the former option—to update the benchmark by the projected absolute amount of growth in national per capita expenditures—and seeks comment on the proposal and alternative.

Minimum Savings Rate (MSR) and Sharing Rate

The amount of shared savings an ACO receives depends on (1) its minimum savings rate (MSR) and (2) its sharing rate. The MSR is the percentage below the benchmark that CMS has determined will “account for normal variation in expenditures” in the Medicare program. The sharing rate is determined based on quality performance (as described in section E above) and is the percentage of the available savings that an ACO receives. CMS explains that expenditures may have normal variations years to year; thus an MSR is needed to assure that the ACO’s financial performance is the result of its interventions rather than normal variation. CMS proposes to use a sliding scale confidence interval (CI) based on the size of the ACO’s assigned population to determine the MSR for ACOs in the one-sided model (ACOs in the two-sided model would have a flat 2 percent MSR). The MSRs are estimated “to provide confidence that an ACO with a given number of beneficiaries and assumed to be of average national baseline
per-capita expenditure and expenditure growth rate would be unlikely to achieve a shared savings payment by random chance alone.”

CMS proposes to set the CI to 90 percent for ACOs of 5,000 beneficiaries; 95 percent for ACOs of 20,000 beneficiaries; and 99 percent for ACOs of 50,000 beneficiaries. These CIs produce MSRs ranging from 3.9 percent down to 2.2 percent. For ACOs of sizes in between these levels, the resulting MSRs would be blended and each ACO would be assigned a linearly-interpolated MSR based on its exact number of beneficiaries (see ranges in the table below). For ACOs of more than 60,000 beneficiaries, the MSR would not be allowed to fall below 2.0 percent.

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

<table>
<thead>
<tr>
<th>Number of Beneficiaries</th>
<th>MSR (low end of assigned beneficiaries)</th>
<th>MSR (high end of assigned beneficiaries)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5,000 – 5,999</td>
<td>3.9%</td>
<td>3.6%</td>
</tr>
<tr>
<td>6,000 – 6,999</td>
<td>3.6%</td>
<td>3.4%</td>
</tr>
<tr>
<td>7,000 – 7,999</td>
<td>3.4%</td>
<td>3.2%</td>
</tr>
<tr>
<td>8,000 – 8,999</td>
<td>3.2%</td>
<td>3.1%</td>
</tr>
<tr>
<td>9,000 – 9,999</td>
<td>3.1%</td>
<td>3.0%</td>
</tr>
<tr>
<td>10,000 – 14,999</td>
<td>3.0%</td>
<td>2.7%</td>
</tr>
<tr>
<td>15,000 – 19,999</td>
<td>2.7%</td>
<td>2.5%</td>
</tr>
<tr>
<td>20,000 – 49,999</td>
<td>2.5%</td>
<td>2.2%</td>
</tr>
<tr>
<td>50,000 – 59,999</td>
<td>2.2%</td>
<td>2.0%</td>
</tr>
<tr>
<td>60,000 +</td>
<td>2.0%</td>
<td></td>
</tr>
</tbody>
</table>

**Net Sharing Rate**

CMS considered several options for determining the portion of the savings an ACO may share with CMS, including (1) sharing on first-dollar savings once the MSR is exceeded; (2) sharing only the savings in excess of the MSR; or (3) sharing savings in excess of a specific threshold (once the MSR is exceeded). For one-sided model ACOs, CMS has proposed the third option—to share with ACOs the savings in excess of 2 percent of the ACO’s benchmark. Thus, an ACO in the one-sided model that surpasses its MSR would be eligible to share the savings that exceed 2 percent of its benchmark. CMS has proposed to exempt from this 2 percent threshold ACOs with fewer than 10,000 beneficiaries that meet one of the following criteria:

- The ACO is comprised of only ACO professionals in group practices or networks of individual practices of ACO professionals;
- 75 percent of more of the assigned beneficiaries reside in counties outside a Metropolitan Statistical Area in the most recent year of complete claims data;
- 50 percent or more of assigned beneficiaries were assigned to the ACO on the basis of primary care services received from a Method II CAH; or
- 50 percent or more of the assigned beneficiaries had at least one encounter with an ACO participant FQHC and/or RHC in the most recent year of complete claims data.
Additional Shared Savings Payments for Including FQHCs and/or RHCs

CMS proposes that ACOs in the one-sided model may receive an increase in its sharing rate of up to 2.5 percentage points for including a “strong FQHC and/or RHC presence within the structure of the ACO.” A sliding scale increase would apply, based on the number of beneficiaries with one or more visits at an ACO’s participating FQHC or RHC during the performance year, as determined according to the table below:

Table 7: Sliding Scale Payment Based on Number of Beneficiary Visits at an ACO's Participant FOHC or RHC

<table>
<thead>
<tr>
<th>Percentage of ACO Assigned Beneficiaries With 1 or More Visits to an ACO participant FOHC/RHC During the Performance Year</th>
<th>Percentage Point Increase in Shared Savings Rate (One-Sided Model)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-10%</td>
<td>0.5</td>
</tr>
<tr>
<td>11-20%</td>
<td>1</td>
</tr>
<tr>
<td>21-30%</td>
<td>1.5</td>
</tr>
<tr>
<td>31-40%</td>
<td>2</td>
</tr>
<tr>
<td>41-50%</td>
<td>2.5</td>
</tr>
</tbody>
</table>

CMS seeks comment on alternate options for establishing a payment preference with a sliding scale for ACOs that include FQHCs or RHCs, including suggestions for the appropriate method to measure these entities’ involvements (CMS proposes that ACOs specifically identify these entities’ TINs in their initial and annual reporting and other provider identifiers to assure their proper identification for the purpose of awarding the payment preference). CMS also seeks comment on methods to provide preference to ACOs that serve a large dual-eligible population or ACOs that are participating in “similar arrangements” (e.g. shared savings arrangements) with other payers.

Withholding Performance Payments to Offset Future Losses

In order to encourage ACOs to participate for all 3 years of their agreements, protect the Medicare program against losses, and ensure ACOs have an adequate repayment mechanism in the event they incur losses, CMS is proposing to apply a flat 25 percent withholding rate to any shared savings payment for which an ACO is eligible. Withheld amounts would be returned to ACOs at the end of each agreement period, but would be forfeited if the ACO does not complete its 3-year agreement.

Performance Payment Limit

As required by statute, CMS is proposing a limit on the total amount of shared savings that may be paid to an ACO. CMS considered potential limits on shared savings of 5, 10 and 15 percent of an ACO’s benchmark, weighing the incentives for participation, quality and efficiency each cap would provide. CMS is proposing a cap of 7.5 percent of an ACO’s benchmark for the first two years of the agreement for ACOs under the one-sided model and a cap of 10 percent for ACOs in the two-sided model. CMS seeks comment on these proposed limits and on whether and how differential limits should be established based on an ACO’s readiness to take on greater responsibility and risk.
G. Two-Sided Model

Taking into account comments from policy experts (including MedPAC) and the public in response to CMS’ request for information and other open forums, CMS has proposed the two tracks/risk models previously described. CMS states the belief that “payment models where ACOs bear a degree of financial risk hold the potential to induce more meaningful systematic change in the behavior of groups of providers of services and suppliers compared to a one-sided model” and that its proposal of two tracks “strikes a balance between stakeholders’ requests for risk-based arrangements with the implications for beneficiary protections and market stability posed by capitated models and the operational complexity of creating these arrangements in a FFS environment. CMS also considered a partial capitation model and states that it intends to “design and test partial capitation models in the Innovation Center first in order to gain more experience, introduce them to providers of services and suppliers, and refine them before adopting them more widely in the Shared Savings Program.”

Under the two-sided model, CMS proposes to employ, as feasible and appropriate, the elements of the one-sided model described above. Key differences include sharing of losses for the duration of the 3-year agreement and providing greater incentives through a higher shared savings rate. The same eligibility criteria, beneficiary assignment methodology, benchmark and update methodology, quality performance standards, data reporting requirements, data sharing provisions, monitoring for avoidance of at-risk beneficiaries, and transparency requirements apply under both the one-sided and two-sided models. The following table summarizes the two models:
To provide a greater incentive for organizations to participate in the two-sided model, CMS is proposing a higher sharing rate for ACOs that elect this model. Specifically, CMS is proposing a sharing rate of up to 60 percent based on quality performance (as compared to up to 50 percent for one-sided model ACOs). Each of the 5 quality measure domains would continue to be equally weighted as under the one-sided model, meaning each domain would be worth 12 percent of the savings generated by the ACO, and ACOs could earn a maximum of 2 points per measure, as under the one-sided model. As for one-sided model ACOs, the quality performance standard in the first year of the Shared Savings Program would be set at full and accurate reporting; those track 2 ACOs that fully and accurately report in the first year of the program will have the maximum sharing rate for quality performance: 60 percent. CMS considered for track 2 the same alternatives to the quality performance standard that it considered for track 1 (e.g. a threshold approach to measuring quality performance and a blend of these two options wherein ACOs could increase their shared savings with higher quality scores but use a threshold approach to calculate losses). \textit{CMS requests comments on these alternate approaches.}
Shared Savings and Losses under the Two-Sided Model

CMS proposes to use the same methodology for determining shared savings for ACOs in the two-sided model as would be used for ACOs in the one-sided model with the following key differences:

- Increased sharing rate for the same quality performance (possible 60 percent as compared to 50 percent under the one-sided model);
- Higher additional sharing rate percentage add-on for including FQHCs and/or RHCs as ACO participants (possible 5 additional percentage points as compared to possible 2.5 additional percentage points under the one-sided model);
- Fixed minimum savings rate (MSR) of 2 percent (as compared with variable MSR based on ACO size under the one-sided model) and fixed minimum loss rate of 2 percent;
- Share in gross savings (or “first-dollar” savings) once the MSR is exceeded (as compared to sharing only the savings exceeding 2 percent of the benchmark for non-exempted ACOs under the one-sided model);
- Share in gross losses (or “first-dollar” losses), once the minimum loss rate is exceeded, at a rate of 100 percent minus the sharing rate (as compared with no shared losses in years 1 and 2 for track 1 ACOs);
- Sharing cap of 10 percent of benchmark (as compared with 7.5 percent for one-sided model ACOs); and
- Maximum loss amount or “shared loss cap” phased in over three years of track 2 ACO agreement: 5 percent of benchmark in year 1, 7.5 percent in year 2, and 10 percent in year 3 (as compared with no shared losses for track 1 ACOs in years 1 and 2 of the agreement and a 5 percent loss cap for track 1 ACOs in year 3 of the agreement).

Ensuring ACO Repayment of Shared Losses

To ensure that ACOs under the two-sided model are capable of repaying CMS for shared losses, CMS established the flat 25 percent withholding rate for all shared savings payments. This applies to both track 1 and track 2 ACOs. However, CMS states that this amount could be inadequate, particularly if a track 2 ACO experiences losses in the first year. CMS therefore proposes to require that an ACO establish a self-executing method for repaying losses equal to at least 1 percent of per capita expenditures for its assigned beneficiaries from the most recent year available. Repayment mechanisms could include indicating the funds may be recouped from Medicare payments to the ACO’s participants, obtaining reinsurance, placing funds in escrow, obtaining surety bonds, establishing a line of credit as evidenced by a letter of credit the Medicare program can draw upon, or establishing another repayment mechanism. CMS proposes that it will determine the adequacy of an ACO’s repayment mechanism prior to its entering a participation period in the Shared Savings Program, as well as annually prior to the start of each performance year in which it takes risk. ACOs in either track would need to submit documentation of such repayment mechanism as part of the application. If an ACO’s repayment mechanism does not allow CMS to fully recoup losses for a given year, CMS proposes to carry forward unpaid losses into subsequent performance years.

Impact on States

CMS emphasizes that under the two-sided model, the Medicare program retains the insurance risk and the responsibility for paying claims for the services furnished to Medicare
beneficiaries, and that the agreement to share risk against the benchmark would be solely between the Medicare program and the ACO. CMS does not intend its proposals to render states responsible for bearing any costs resulting from the operation of the program. However, CMS notes and seeks comment on the fact that some states may regulate risk bearing entities such as ACOs under the two-sided model and seeks comment on whether its proposals would trigger the application of state insurance laws.

Verification of Savings and Losses

CMS states that it will notify an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and the amount; CMS will also notify an ACO in writing regarding shared losses the ACO must pay back. CMS proposes that ACOs make payment in full within 30 days of the notice. CMS also proposes that, as a condition of receiving a shared savings payment, the ACO must submit a written request for the payment amount, which must certify the ACO’s compliance with program requirements for the performance period as well as the accuracy, completeness, and truthfulness of information submitted. A similar certification would be required for ACOs that experience shared losses.

H. Monitoring and Termination of ACOs

Under the statute, CMS is authorized to impose an appropriate sanction, including termination from the program, if it determines an ACO has “taken steps to avoid patients at risk in order to reduce the likelihood of increasing costs to the ACO.” CMS is also authorized to terminate an agreement with an ACO that does not meet the established quality performance standards. CMS proposes to monitor ACOs for both of these occurrences and to take appropriate action (which could include termination). In addition, CMS is authorized to promulgate additional criteria that ACOs must satisfy in order to be eligible to participate. Although the statute does not prescribe procedures for monitoring ACOs, or the factors to consider in imposing sanctions, CMS believes such monitoring is important for patient protection and to determine if program requirements are met.

In general, CMS proposes to employ methods used for monitoring MA and Part D contracts for purposes of the Shared Savings Program, such as analysis of financial and quality data, site visits, assessment and investigation of beneficiary and provider complaints and audits (e.g. claims analysis, chart review, beneficiary surveys, coding audits). If, based on these monitoring activities, CMS concludes that an ACO’s performance may subject it to termination, CMS proposes that in its sole discretion it may (1) provide a warning notice to the ACO of the specific performance at issue; (2) request a CAP; or (3) place the ACO on a special monitoring plan. CMS states that a number of factors may trigger heightened oversight, including conditions specified as the bases for termination (described below) and potentially ACOs that incur large losses to the Medicare program.

CMS proposes a number of recordkeeping and inspection rules applicable to ACOs, ACO participants, ACO providers/suppliers and contracted entities (defines as any party that enters into an arrangement with an ACO to provide services to the ACO or its assigned beneficiaries). Books, contracts, records, documents and other evidence would need to be maintained for a period of 10 years from the end of the agreement period or from the date of completion of any audit, evaluation, or inspection, whichever is latter, unless CMS determines there is a special need to retain records longer and notifies the ACO at least 30 days before the normal disposition.
date. CMS proposes that it may inspect, evaluate and audit an ACO at any time if there is a reasonable probability of fraud or similar fault.

Monitoring Avoidance of At-Risk Beneficiaries

CMS defines “patients at risk” as those beneficiaries who have a high CMS-HCC risk score, 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 (e.g. diabetes, heart failure, COPD, depression), or beneficiaries with a recent diagnosis (e.g. cancer) that is expected to result in increased cost. To identify ACOs that could be avoiding at-risk beneficiaries, CMS proposes to use a combination of methods beginning with claims analysis and examination of beneficiary-level documentation, the results of which could lead to further investigation and follow-up with the beneficiary or the ACO. If CMS concludes that avoidance has occurred, CMS proposes to notify the ACO of the determination and require the ACO to submit a CAP for CMS’ approval, followed by reevaluation during and at the end of the CAP. The ACO would be terminated if found to have continued avoiding at-risk beneficiaries. CMS also proposes that the ACO would not be eligible for shared savings while under the CAP.

Monitoring Compliance with Quality Performance Standards

To identify ACOs that are not meeting the quality performance standards, CMS proposes to review the ACO’s submission of quality measurement data and may request additional documentation as appropriate. When an ACO fails to meet a minimum attainment level for one or more domains, CMS would give a warning and reevaluate the following year. If underperformance continues, the agreement would be terminated. If an ACO fails to report one or more measures, CMS would send a written request to submit the required data by a specified date and provide a reasonable explanation for the delay. If the ACO fails to report by the deadline and does not provide a reasonable explanation, the agreement would be terminated immediately. Finally, ACOs that have a pattern of inaccurate or incomplete reporting or fail to make timely corrections may be terminated. In each year of underperformance, the ACO would be disqualified from sharing savings.

Terminating an ACO Agreement

CMS proposes authority to terminate agreements with ACOs on the basis of the above violations listed in the statute, as well as for failure to continue to meet the eligibility requirements for participation in the Shared Savings Program. Thus, CMS proposes that it may terminate an agreement prior to the end of the 3-year agreement period for a variety of reasons, including those described above; any material change impacting the ACO’s ability to meet eligibility requirements (e.g. changes in ACO participants that are the basis for beneficiary assignment, increase in ACO provider/supplier composition that results in an Antitrust Agency statement that it is likely to challenge the ACO); failure of the ACO to effectuate required regulatory changes after given the opportunity for a CAP; failure of the ACO to demonstrate
adequate resources to repay losses; noncompliance with beneficiary notification requirements; and for many other reasons.

CMS proposes to require 60-day notice if an ACO chooses to terminate its agreement. The ACO would be required to notify CMS of its decision and all ACO participants and ACO providers/suppliers, who would then need to notify beneficiaries. In this situation, the ACO would forfeit its 25 percent withhold of shared savings.

CMS proposes that an ACO that was terminated may apply to participate again at the end of the original 3-year agreement period. To be eligible, the ACO must show in its application that it has corrected the deficiencies that caused the termination and has compliance processes in place. Reentry into the Shared Savings Program may only occur through the two-sided model.

For minor violations, CMS proposes that ACOs may submit a CAP prior to termination; failure to demonstrate improvement upon completion of the CAP may result in termination.

Reconsideration Review Process

CMS proposes to establish a fair administrative process for requesting review of decisions for reasons other than those exempted by statute, which are: criteria for meeting quality performance standards; assessment of quality of care furnished; assignment of beneficiaries; determination of an ACO’s eligibility for shared savings and the amount (including determination of benchmarks and expenditures); percent of and cap on shared savings; and termination for failure to meet quality performance standards. Thus, CMS proposes to implement a reconsideration review process for initial determinations not precluded from review: (1) denial of an ACO application; or (2) termination of an ACO participation agreement. An applicant who was denied or an ACO that was terminated may request reconsideration or independent review by a CMS reconsideration official. These parties must submit a written request within 15 days of the initial determination. Reconsideration reviews are scheduled at the discretion of the official and may be held orally or on the record. The burden of proof would be on the ACO or applicant to demonstrate with convincing evidence that the termination or application denial is not consistent with CMS’ regulations or statutory authority.

Following the review, the official will issue a recommended decision. If the ACO or applicant disagrees with the recommendation, it may request a record review by an independent CMS official not previously involved with the case. This official will review the recommendation of the reconsideration official and supporting materials and make a final agency determination.

I. Coordination with Other Agencies

This section of the proposed rule describes the agency documents issued in conjunction with the proposed rule. These documents are summarized in sections III, IV and V, below.

J. Overlap with Other CMS Shared Savings Initiatives

ACOs will be precluded from duplicate participation in “shared savings programs.” In the Proposed Rule, CMS identifies the following programs as shared savings programs, meaning that a provider participating in the Medicare Shared Savings Program could not also participate in one of these programs:
- The Independence at Home Medical Practice Demonstration program;
- Medicare Health Care Quality Demonstration Programs;
- Medical home demonstrations with a shared savings element (i.e. the multi-payer advanced primary care demonstration); and
- The Physician Group Practice (PGP) Transition Demonstration.

CMS further identifies the following programs as examples of programs which are unlikely to generate duplicative shared savings, meaning that a provider could participate in both the Medicare Shared Savings Program and these programs:

- State initiatives to provide health homes for Medicaid enrollees with chronic conditions as authorized under section 2703 of the ACA; and
- The program to establish community health teams to support patient-centered medical homes under section 3502 of the ACA.

CMS further advises that an ACO provider/supplier who submits claims under multiple Medicare-enrolled TINs may participate in both the Shared Savings Program and another shared savings program if the patient population is unique to each program and if none of the relevant Medicare-enrolled TINs participate in both programs. Applications for participation in the Shared Savings Program that include TINs that are already participating in another Medicare shared savings program will be rejected.

CMS notes that, within the Center for Medicare and Medicaid Innovation (the Innovation Center), it may be possible to test different payment models, provide assistance to groups of providers and suppliers that wish to develop into an ACO, or enhance CMS’s understanding of different benchmarking methods. Innovation Center experience with different ACO payment models is anticipated to enable CMS to use proven methods to enhance and improve the Shared Savings Program over time.

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

The Proposed Rule also includes discussion of transition of PGP Demonstration Sites into the Medicare Shared Savings Program.

### III. Waiver of Fraud and Abuse Laws

In conjunction with issuance of the Medicare Shared Savings Program proposed rule issued by CMS, the HHS Office of the Inspector General (OIG) released a notice with comment period on related waivers. The OIG expects to issue waivers applicable to ACOs participating in the Medicare Shared Savings Program concurrently with CMS’s publication of a final rule. In the notice, the OIG discusses stakeholder concerns regarding restrictions imposed by the Physician Self-Referral Law, the Federal anti-kickback statute, and the civil monetary penalty (CMP) provision addressing hospital payments to physicians to reduce or limit services, as they relate to formation of ACOs. The OIG describes its waiver authority under Section 1899(f) of the Social Security Act (added by the ACA) as specific to the Medicare Shared Savings Program and not pertaining to other similar integrated-care delivery models. The OIG indicates that is may consider waivers, exceptions, or safe harbors for other types of ACOs at a later date.
The OIG proposes the following waivers for ACOs participating in the Medicare Shared Savings Program:

- Waiver of application of the Physician Self-Referral Law to distributions of shared savings: (1) among ACO, participants, and providers/suppliers; or (2) for activities necessary for and directly related to the ACO’s participation in and operations under the Shared Savings Program.

- Waiver of application of the Anti-Kickback Statute with respect to:
  - Distributions of shared savings: (1) among ACO participants and providers/suppliers; or (2) for activities necessary for and directly related to an ACO’s participation in the Shared Savings Program.
  - Any financial relationship between or among the ACO, participants, and providers/suppliers necessary for and directly related to the ACO’s participation in and operations under the Shared Savings Program.

- Waiver of application of the prohibition on hospital payments to physicians to induce reductions or limitation of services with respect to:
  - Distributions of shared savings from a hospital to a physician, provided that: (1) the payments are not made knowingly to induce the physician to reduce or limit medically necessary items or services; and (2) the hospital and physician are ACO participants or providers/suppliers.
  - Any financial relationship between or among the ACO, participants, and providers/suppliers necessary for and directly related to the ACO’s participation in and operations under the Shared Savings Program that implicates the Physician-Self Referral Law and fully complies with an exception.

These waivers would apply uniformly to all qualified ACOs and participants in the Medicare Shared Savings Program during the term of an ACO’s agreement. An agreement with CMS to participate in the Medicare Shared Savings Program and compliance with that agreement by ACOs, ACO participants, and ACO providers/suppliers would be threshold qualifications for these proposed waivers.

The OIG is soliciting comments on its proposed waivers and additional waivers that may be necessary. Specifically, the OIG is seeking input on:

- The necessary waivers for arrangements related to establishing the ACO;
- The necessary waivers for arrangements between or among ACO participants and/or ACO;
- The necessary waivers for arrangements between the ACO, its ACO participants, and/or its ACO providers/suppliers and outside individuals or entities;
- The necessary waivers for distributions of shared savings or similar payments received from private payers;
- Other financial arrangements for which a waiver would be necessary and where no current exception or safe harbor would apply;
- Duration of waivers;
- Additional safeguards that might be necessary for and effective to protect patients and the Federal health care programs;
• Whether the proposed waivers are too broad or too narrow, and recommended changes;
• Whether additional or different fraud and abuse waivers might be appropriate for ACOs participating in the two-sided risk model;
• Use of existing exception and safe harbor for electronic health records arrangements;
• Whether and under what circumstances waivers are needed related to the prohibition on inducements offered to Medicare and Medicaid beneficiaries;
• When the OIG should publish final waivers; and
• How the OIG should use its separate waiver authority related to CMMI demonstrations.

IV. Proposed Statement of Antitrust Enforcement Policy

Under the antitrust guidance issued jointly by the FTC and DOJ, the agencies will apply the “rule of reason” analysis (balancing benefits and harm of a collaboration between competing health care providers) to ACOs that satisfy the eligibility criteria established by CMS. The agencies have determined that CMS’ proposed eligibility criteria are broadly consistent with the indicia of clinical integration the agencies have previously set forth in the Health Care Statements and identified in the context of specific proposals from health care providers and that organizations meeting the CMS criteria are reasonably likely to be bona fide arrangements intended to improve the quality and reduce the costs of providing medical and other health care services through the participants’ joint efforts. Further, the agencies have determined that the integration criteria are sufficiently rigorous that joint negotiations with private-sector payers by a CMS-approved ACO that provides the same services in the commercial market will be treated as subordinate and reasonably related to the ACO’s primary purpose of improving health care services. Therefore, the agencies will apply rule of reason treatment to an ACO that, in the commercial market, uses the same governance and leadership structure and the same clinical and administrative processes as it uses to qualify for the Medicare Shared Savings Program.

The agencies have proposed three categories (as reflected in the table below) for evaluating whether an ACO raises anticompetitive concerns: (1) the “Safety Zone” in which independent ACO participating organizations have a combined share of 30 percent or less of each common service in their “primary service area” (PSA) and the ACO will not be challenged by the agencies absent extraordinary circumstances; (2) mandatory review in which the ACO participants have a combined share of more than 50 percent in any common service in the PSA, requiring expedited review (90 days) by the agencies; and (3) discretionary review in which the ACO participants have a combined share of between 30 percent and 50 percent for each common service, where the ACO may seek expedited review and is given guidance on types of anticompetitive conduct to avoid.
V. Treatment of Tax-Exempt Organizations

The Internal Revenue Service (IRS) released Notice 2011-20 in conjunction with CMS’s Medicare Shared Savings Program proposed rule. The IRS is soliciting comments on whether existing guidance for tax-exempt organizations is sufficient for tax-exempt organizations planning to participate in the Medicare Shared Savings Program. The IRS is also interested in what criteria or requirements should be analyzed in determining whether participation by a tax-exempt organization in the Medicare Shared Savings Program through an ACO is consistent with tax-exempt status under § 501(c)(3) and whether the tax exempt organization is receiving unrelated business income.

The IRS advises that, to avoid adverse tax consequences, the tax-exempt organization must ensure that its participation in the Shared Savings Program is structured so as not to result in its net earnings inuring to the benefit of its insiders or in its being operated for the benefit of private parties participating in the ACO. Because of CMS regulation and oversight, the IRS generally expects that it will not consider a tax-exempt organization’s participation in an ACO to result in inurement or impermissible private benefit to the private party ACO in various circumstances listed in the Notice.

Although the issue may arise, the IRS expects that activities generating shared savings payments received by a tax-exempt organization participating in an ACO will generally be substantially related to the performance of the organization’s charitable purposes, meaning that such payments will likely not be subject to unrelated business income tax (UBIT).

The IRS also solicits comments on whether guidance is needed regarding the tax implications for tax-exempt organizations participating in shared savings arrangements, with commercial health insurance payers or others, through ACOs outside of the Medicare Shared Savings Program.

<table>
<thead>
<tr>
<th>ACO PSA Share</th>
<th>Review Process</th>
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<tbody>
<tr>
<td>≤ 30 percent (with a rural exception)</td>
<td>Safety Zone -- No antitrust review necessary by the Antitrust Agencies</td>
</tr>
<tr>
<td>&gt;30 percent and ≤ 50 percent</td>
<td>Expedited review, compliance with list of conduct restrictions, or proceed without antitrust assurances -- ACOs may: 1. Request an expedited review by the Antitrust Agencies and submit letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or recommend challenging the ACO. 2. Begin to operate and abide by a list of conduct restrictions, reducing significantly the likelihood of an antitrust investigation, or 3. Begin to operate and remain subject to antitrust investigation if it presents competitive concerns.</td>
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<tr>
<td>&gt;50 percent</td>
<td>Required expedited review -- ACO must seek review by the Antitrust Agencies to assess likelihood of procompetitive and anticompetitive effects. ACO eligibility to participate in Shared Savings Program is contingent on the ACO’s submission of a letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or recommend challenging the proposed ACO.</td>
</tr>
</tbody>
</table>
We hope you find this information useful. Please do not hesitate to contact us if you have questions or if you would like additional information.
## Appendix – Proposed Quality Measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>Source(s) of Measure</th>
<th>Submission Type</th>
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</thead>
<tbody>
<tr>
<td><strong>Patient/Caregiver Experience</strong></td>
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<tr>
<td>1. Clinician/Group CAHPS: Getting Timely Care, Appointments, and Information</td>
<td>NQF #5</td>
<td>Survey</td>
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<tr>
<td>2. Clinician/Group CAHPS: How Well Your Doctors Communicate</td>
<td>NQF #5</td>
<td>Survey</td>
</tr>
<tr>
<td>3. Clinician/Group CAHPS: Helpful, Courteous, Respectful Office Staff</td>
<td>NQF #5</td>
<td>Survey</td>
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<tr>
<td>4. Clinician/Group CAHPS: Patients' Rating of Doctor</td>
<td>NQF #5</td>
<td>Survey</td>
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<tr>
<td>5. Clinician/Group CAHPS: Health Promotion and Education</td>
<td>NQF #5</td>
<td>Survey</td>
</tr>
<tr>
<td>6. Clinician/Group CAHPS: Shared Decision Making</td>
<td>NQF #5</td>
<td>Survey</td>
</tr>
<tr>
<td>7. Medicare Advantage CAHPS: Health Status/Functional Status</td>
<td>NQF #6</td>
<td>Survey</td>
</tr>
<tr>
<td>8. Risk-Standardized, All Condition Readmission: The rate of readmissions within 30 days of discharge from an acute care hospital for assigned ACO beneficiary population.</td>
<td>CMS</td>
<td>Claims</td>
</tr>
<tr>
<td><strong>Care Coordination</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. 30 Day Post Discharge Physician Visit</td>
<td>CMS</td>
<td>GPRO</td>
</tr>
<tr>
<td>10. Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility Percentage of patients aged 65 years and older discharged from any inpatient facility (eg, hospital, skilled nursing facility, or rehabilitation facility) and seen within 60 days following discharge in the office by the physician providing ongoing care who had a reconciliation of the discharge medications with the current medication list in the medical record documented.</td>
<td>NQF # 554</td>
<td>GPRO</td>
</tr>
<tr>
<td>11. Care Transition Measure: Uni-dimensional self-reported survey that measures the quality of preparation for care transitions. Namely: (1) Understanding one's self-care role in the post-hospital setting; (2) Medication management; (3) Having one's preferences incorporated into the care plan.</td>
<td>NQF #228 or alternate</td>
<td>GPRO</td>
</tr>
<tr>
<td>12. Ambulatory Sensitive Conditions Admissions: Diabetes, short-term complications (AHRQ Prevention Quality Indicator (PQI) #1). All discharges of age 18 years and older with ICD-9-CM principal diagnosis code for short-term complications (ketoacidosis, hyperosmolarity, coma), per 100,000 population.</td>
<td>NQF #272</td>
<td>Claims</td>
</tr>
<tr>
<td>13. Ambulatory Sensitive Conditions Admissions: Uncontrolled Diabetes (AHRQ Prevention Quality Indicator (PQI) #14). All discharges of age 18 years and older with ICD-9-CM principal diagnosis code for uncontrolled diabetes, without mention of a short-term or long-term complication, per 100,000 population.</td>
<td>NQF # 638</td>
<td>Claims</td>
</tr>
<tr>
<td>14. Ambulatory Sensitive Conditions Admissions: Chronic obstructive pulmonary disease (AHRQ Prevention Quality Indicator (PQI) #5). All discharges of age 18 years and older with ICD-9-CM principal diagnosis code for COPD, per 100,000 population.</td>
<td>NQF #275</td>
<td>Claims</td>
</tr>
<tr>
<td>15. Ambulatory Sensitive Conditions Admissions: Congestive Heart Failure (AHRQ Prevention Quality Indicator (PQI) #8) All discharges of age 18 years and older with ICD-9-CM principal diagnosis code for CHF, per 100,000 population.</td>
<td>NQF #277</td>
<td>Claims</td>
</tr>
<tr>
<td>16. Ambulatory Sensitive Conditions Admissions: Dehydration (AHRQ Prevention Quality Indicator (PQI) #10). All discharges of age 18 years and older with ICD-9-CM principal diagnosis code for hypovolemia, per 100,000 population.</td>
<td>NQF # 280</td>
<td>Claims</td>
</tr>
<tr>
<td>17. Ambulatory Sensitive Conditions Admissions: Bacterial pneumonia (AHRQ Prevention Quality Indicator (PQI) #11). All non-maternal discharges of age 18 years and older with ICD-9-CM principal diagnosis code for bacterial pneumonia, per 100,000 population.</td>
<td>NQF # 279</td>
<td>Claims</td>
</tr>
<tr>
<td>18. Ambulatory Sensitive Conditions Admissions: Urinary infections (AHRQ Prevention Quality Indicator (PQI) #12). All discharges of age 18 years and older with ICD-9-CM principal diagnosis code of urinary tract infection, per 100,000 population.</td>
<td>NQF # 281</td>
<td>Claims</td>
</tr>
<tr>
<td>19. % All Physicians Meeting Stage 1 HITECH Meaningful Use Requirements</td>
<td>CMS</td>
<td>GPRO</td>
</tr>
<tr>
<td>20. % of PCPs Meeting Stage 1HITECH Meaningful Use Requirements</td>
<td>CMS</td>
<td>GPRO</td>
</tr>
<tr>
<td>21. % of PCPs Using Clinical Decision Support</td>
<td>CMS</td>
<td>EHR Incentive Program</td>
</tr>
<tr>
<td>Measure</td>
<td>Source(s) of Measure</td>
<td>Submission Type</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>22. % of PCPs who are Successful Electronic Prescribers Under the eRx Incentive Program</td>
<td>CMS</td>
<td>GPRO</td>
</tr>
<tr>
<td>23. Patient Registry Use</td>
<td>CMS</td>
<td>GPRO</td>
</tr>
<tr>
<td><strong>Patient Safety</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>24. Health Care Acquired Conditions Composite: Foreign Object Retained After Surgery; Air Embolism; Blood Incompatibility; Pressure Ulcer, Stages III and IV; Falls and Trauma; Catheter-Associated UTI; Manifestations of Poor Glycemic Control; Central Line Associated Blood Stream Infection (CLABSI); Surgical Site Infection; AHRQ Patient Safety Indicator (PSI) 90 Complication/Patient Safety for Selected Indicators (composite). [Additional detail omitted]</td>
<td>CMS (HACs)</td>
<td>Claims or CDC National Healthcare Safety Network</td>
</tr>
<tr>
<td>25. Health Care Acquired Conditions: CLABSI Bundle</td>
<td>NQF #298</td>
<td>Claims or CDC National Healthcare Safety Network</td>
</tr>
<tr>
<td><strong>Preventive Health</strong></td>
<td></td>
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</tr>
<tr>
<td>26. Influenza Immunization: Percentage of patients aged 50 years and older who received an influenza immunization during the flu season (September through February).</td>
<td>PQRS Measure #110</td>
<td>GPRO</td>
</tr>
<tr>
<td>27. Pneumococcal Vaccination: Percentage of patients aged 65 years and older who have ever received a pneumococcal vaccine.</td>
<td>PQRS Measure #111</td>
<td>GPRO</td>
</tr>
<tr>
<td>28. Mammography Screening: Percentage of women aged 40 through 69 years who had a mammogram to screen for breast cancer within 24 months.</td>
<td>PQRS Measure #112</td>
<td>GPRO</td>
</tr>
<tr>
<td>29. Colorectal Cancer Screening: Percentage of patients aged 50 through 75 years who received the appropriate colorectal cancer screening.</td>
<td>PQRS Measure #113</td>
<td>GPRO</td>
</tr>
<tr>
<td>30. Cholesterol Management for Patients with Cardiovascular Conditions: The percentage of members 18–75 years of age who were discharged alive for AMI, coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI) of the year prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to the measurement year, who had each of the following during the measurement year. LDL-C screening; LDL-C control (&lt;100 mg/dL)</td>
<td>EHR Incentive Program NQF # 75</td>
<td>GPRO</td>
</tr>
<tr>
<td>31. Adult Weight Screening and Followup: Percentage of patients aged 18 years and older with a calculated BMI in the past six months or during the current visit documented in the medical record AND if the most recent BMI is outside parameters, a follow-up plan is documented. Parameters: Age 65 and older BMI ≥ 30 or &lt; 22; Age 18-64 BMI ≥ 25 or &lt; 18.5</td>
<td>PQRS Measure #128</td>
<td>GPRO</td>
</tr>
<tr>
<td>32. Blood Pressure Measurement: Percentage of patient visits with blood pressure measurement recorded among all patient visits for patients aged &gt; 18 years with diagnosed hypertension.</td>
<td>PQRS Measure #TBD</td>
<td>GPRO</td>
</tr>
<tr>
<td>33. Tobacco Use Assessment and Tobacco Cessation Intervention: Percentage of patients who were queried about tobacco use; Percentage of patients identified as tobacco users who received cessation intervention.</td>
<td>PQRS Measure #TBD</td>
<td>GPRO</td>
</tr>
<tr>
<td>34. Depression Screening: Percentage of patients aged 18 years and older screened for clinical depression using a standardized tool and follow up plan documented.</td>
<td>PQRS Measure #134</td>
<td>GPRO</td>
</tr>
<tr>
<td><strong>At Risk Population/Frail Elderly Health</strong></td>
<td></td>
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</tr>
<tr>
<td>35. Diabetes Composite (All or Nothing Scoring): Hemoglobin A1c Control (&lt;8%); Low Density Lipoprotein (&lt;100); Blood</td>
<td>NQF #575*, 64*, 61*</td>
<td>GPRO</td>
</tr>
<tr>
<td>Measure</td>
<td>Source(s) of Measure</td>
<td>Submission Type</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Pressure &lt;140/90; Tobacco Non Use; Aspirin Use</td>
<td>EHR Incentive Program NQF #575</td>
<td>GPRO</td>
</tr>
<tr>
<td>36. Diabetes Mellitus: Hemoglobin A1c Control (&lt;8%): Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent hemoglobin A1c less than 8.0%.</td>
<td>EHR Incentive Program NQF #64</td>
<td>GPRO</td>
</tr>
<tr>
<td>37. Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus: Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent LDL-C level in control (less than 100 mg/dl).</td>
<td>PQRS Measure #2 EHR Incentive Program NQF #64</td>
<td>GPRO</td>
</tr>
<tr>
<td>38. Diabetes Mellitus: Tobacco Non Use: Tobacco use assessment and cessation</td>
<td>PQRS Measure #TBD EHR Incentive Program NQF #28</td>
<td>GPRO</td>
</tr>
<tr>
<td>40. Diabetes Mellitus: Hemoglobin A1c Poor Control (&gt;9%): Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent hemoglobin A1c greater than 9.0%.</td>
<td>PQRS Measure #1 EHR Incentive Program NQF #59</td>
<td>GPRO</td>
</tr>
<tr>
<td>41. Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus: Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent blood pressure in control (less than 140/90 mmHg).</td>
<td>PQRS Measure #3 EHR Incentive Program NQF #61</td>
<td>GPRO</td>
</tr>
<tr>
<td>42. Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients: Percentage of patients aged 18 through 75 years with diabetes mellitus who received urine protein screening or medical attention for nephropathy during at least one office visit within 12 months.</td>
<td>PQRS Measure #119 EHR Incentive Program NQF #62</td>
<td>GPRO</td>
</tr>
<tr>
<td>43. Diabetes Mellitus: Dilated Eye Exam in Diabetic Patients: Percentage of patients aged 18 through 75 years with a diagnosis of diabetes mellitus who had a dilated eye exam.</td>
<td>PQRS Measure #117 EHR Incentive Program NQF #55</td>
<td>GPRO</td>
</tr>
<tr>
<td>44. Diabetes Mellitus: Foot Exam: The percentage of patients aged 18 through 75 years with diabetes who had a foot examination.</td>
<td>PQRS Measure #163 EHR Incentive Program NQF #56</td>
<td>GPRO</td>
</tr>
<tr>
<td>45. Heart Failure: Left Ventricular Function (LVF) Assessment: Percentage of patients aged 18 years and older with a diagnosis of heart failure who have quantitative or qualitative results of LVF assessment recorded.</td>
<td>PQRS Measure #198 NQF #79</td>
<td>GPRO</td>
</tr>
<tr>
<td>46. Heart Failure: Left Ventricular Function (LVF) Testing: Percentage of patients with LVF testing during the current year for patients hospitalized with a principal diagnosis of heart failure (HF) during the measurement period.</td>
<td>PQRS Measure #228 CMS</td>
<td>GPRO</td>
</tr>
<tr>
<td>47. Heart Failure: Weight Measurement: Percentage of patient visits for patients aged 18 years and older with a diagnosis of heart failure with weight measurement recorded.</td>
<td>PQRS Measure #227 NQF #85</td>
<td>GPRO</td>
</tr>
<tr>
<td>48. Heart Failure: Patient Education: Percentage of patients aged 18 years and older with a diagnosis of heart failure who were provided patient education on disease management and health behavior changes during one or more visits within 12 months.</td>
<td>PQRS Measure #199 NQF #82</td>
<td>GPRO</td>
</tr>
<tr>
<td>49. Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of heart failure who also have LVSD (LVEF &lt; 40%) and who were prescribed beta-blocker therapy.</td>
<td>PQRS Measure #8 EHR Incentive Program NQF #83</td>
<td>GPRO</td>
</tr>
<tr>
<td>50. Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of heart failure and LVSD (LVEF &lt; 40%) who were prescribed ACE inhibitor or ARB therapy.</td>
<td>PQRS Measure #5 EHR Incentive Program NQF #81</td>
<td>GPRO</td>
</tr>
<tr>
<td>51. Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation: Percentage of all patients aged 18 and older with a diagnosis of heart failure and paroxysmal or chronic atrial fibrillation who were prescribed warfarin therapy.</td>
<td>PQRS Measure #200 EHR Incentive Program NQF #84</td>
<td>GPRO</td>
</tr>
<tr>
<td>52. Coronary Artery Disease (CAD) Composite (All or Nothing Scoring)</td>
<td>NQF #67, 74, 70, 64, 66</td>
<td>GPRO</td>
</tr>
<tr>
<td>Measure</td>
<td>Source(s) of Measure</td>
<td>Submission Type</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>53. Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD: Percentage of patients aged 18 years and older with a diagnosis of CAD who were prescribed oral antiplatelet therapy.</td>
<td>PQRS Measure #6 EHR Incentive Program NQF #67</td>
<td>GPRO</td>
</tr>
<tr>
<td>54. Coronary Artery Disease (CAD): Drug Therapy for Lowering LDL Cholesterol: Percentage of patients aged 18 years and older with a diagnosis of CAD who were prescribed a lipid-lowering therapy (based on current ACC/AHA guidelines). The LDL-C treatment goal is &lt;100 mg/dl. [Additional detail omitted]</td>
<td>PQRS Measure #197 EHR Incentive Program NQF #74</td>
<td>GPRO</td>
</tr>
<tr>
<td>55. Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI): Percentage of patients aged 18 years and older with a diagnosis of CAD and prior MI who were prescribed beta-blocker therapy.</td>
<td>PQRS Measure #7 EHR Incentive Program NQF #70</td>
<td>GPRO</td>
</tr>
<tr>
<td>56. Coronary Artery Disease (CAD): LDL level &lt; 100 mg/dl</td>
<td>CMS</td>
<td>GPRO</td>
</tr>
<tr>
<td>57. Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of CAD who also have diabetes mellitus and/or LVSD (LVEF &lt; 40%) who were prescribed ACE inhibitor or ARB therapy.</td>
<td>PQRS Measure #118 NQF #66</td>
<td>GPRO</td>
</tr>
<tr>
<td>58. Hypertension (HTN): Blood Pressure Control: Percentage of patients with last BP &lt; 140/90 mmHg</td>
<td>PQRS Measure #TBD EHR Incentive Program NQF #18</td>
<td>GPRO</td>
</tr>
<tr>
<td>59. Hypertension (HTN): Plan of Care: Percentage of patient visits for patients aged 18 years and older with a diagnosis of HTN with either systolic blood pressure ≥ 140 mmHg or diastolic blood pressure ≥ 90 mmHg with documented plan of care for hypertension.</td>
<td>PQRS Measure #TBD NQF # 17</td>
<td>GPRO</td>
</tr>
<tr>
<td>60. Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation: Percentage of patients aged 18 years and older with a diagnosis of COPD who had spirometry evaluation results documented.</td>
<td>PQRS Measure # 51 NQF #91</td>
<td>GPRO</td>
</tr>
<tr>
<td>61. Chronic Obstructive Pulmonary Disease (COPD): Smoking Cessation Counseling Received</td>
<td>CMS</td>
<td>GPRO</td>
</tr>
<tr>
<td>62. Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy based on FEV1: Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV1/FVC less than 70% and have symptoms who were prescribed an inhaled bronchodilator.</td>
<td>PQRS Measure # 52 NQF #102</td>
<td>GPRO</td>
</tr>
<tr>
<td>63. Falls: Screening for Fall Risk: Percentage of patients aged 65 years and older who were screened for fall risk at least once within 12 months.</td>
<td>NQF #101</td>
<td>GPRO</td>
</tr>
<tr>
<td>64. Osteoporosis Management in Women Who had a Fracture: Percentage of women 65 years and older who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat or prevent osteoporosis in the 6 months after the date of fracture</td>
<td>NQF #53</td>
<td>GPRO</td>
</tr>
<tr>
<td>65. Monthly INR for Beneficiaries on Warfarin: Average percentage of monthly intervals in which Part D beneficiaries with claims for warfarin do not receive an INR test during the measurement period</td>
<td>NQF #555</td>
<td>Claims</td>
</tr>
</tbody>
</table>