Accountable Care Organizations:
Summaries of the Proposed Regulation and Related Documents

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CMS Proposed Rule on the Medicare Shared Savings Program

I. Background

On March 31, 2011, the Centers for Medicare & Medicaid Services (CMS) and other Federal agencies released four documents relating to implementation of section 3022 of the Affordable Care Act (ACA), which mandates the establishment of a new Medicare Shared Savings Program by January 1, 2012. This program will provide a new option under which accountable care organizations (ACOs) meeting certain requirements can take responsibility for the care of Medicare beneficiaries assigned to them and qualify for shared savings (or losses) under various circumstances.

The four documents released on March 31 include the following:

- A proposed rule issued by CMS, to be published in the April 7, 2011 issue of the *Federal Register*, with a comment period ending June 6, 2011;

- A notice issued by CMS and the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) relating to waiver designs in connection with the Medicare Shared Savings Program and the Center for Medicare and Medicaid Innovation (CMMI or Innovation Center), also to be published in the April 7, 2011 issue of the *Federal Register* with a comment period ending June 6, 2011;

- A "Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program," jointly issued by the Federal Trade Commission (FTC) and the Department of Justice (DOJ), for which comments are due by May 31, 2011; and

- An Internal Revenue Service (IRS) notice soliciting comments regarding the need for additional tax guidance for tax-exempt organizations, including tax-exempt hospitals, participating in the Shared Savings Program, for which comments are due by May 31, 2011.

A summary of each of these documents follows.

In the background section of the proposed ACO regulation, CMS provides an overview of value-based purchasing and the statutory basis for the Medicare Shared Savings Program. CMS also describes the intent of the program, focusing especially on the need to achieve the three-part (or triple) aim of better

care for individuals, better health for populations, and lower growth in expenditures "by eliminating waste and inefficiencies while not withholding any needed care that helps beneficiaries." CMS also discusses related ACA provisions, especially section 3021, which required the establishment of a new CMMI. In particular, CMS notes its plan for the Innovation Center to explore alternative payment models for the Shared Savings Program (beyond those in the proposed rule) and its intent to move participants of the demonstration models that have a demonstrated track record of realizing shared savings and high quality performance into the Shared Savings Program in the future. Finally, CMS briefly discusses the Physician Group Practice (PGP) Demonstration, which it considers the agency's "first attempt at establishing a Shared Savings ACO model." Under the PGP demonstration, there were 32 quality markers and 6 of the 10 participating groups shared about $46 million in savings over the course of the first three years of the demonstration.

It is important to emphasize that CMS is inviting comment on all aspects of the proposed rule. In fact, for many design elements of the Medicare Shared Savings Program, the proposed rule describes two or more options, indicates CMS' current preference but, with rare exception, also indicates that CMS might adopt different policies in the final rule depending on the comments it receives. In fact, in many places in the proposed rule, CMS worries that its preferred policy might create disincentives for the formation of ACOs, discourage certain types of providers or suppliers from applying to become or participating in an ACO, or produce a range of other problems.

II. Provisions of the Proposed Rule

A. Organization of the Proposed Rule

This section defines three important terms as follows:

- *Accountable care organization*: a legal entity that is recognized and authorized under applicable State law, as identified by a Taxpayer Identification Number (TIN), and comprised of an eligible group (see II.B) of ACO participants that work together to manage and coordinate care for Medicare fee-for-service (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*: a Medicare-enrolled provider of services and/or a supplier (as identified by a TIN); and
- *ACO provider/supplier*: a provider of services and/or a supplier 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.

An example of an ACO participant would be a physician group practice. An example of an ACO supplier would be an individual physician within such a group practice. Note that the term "ACO participant" is significantly broader that the term "ACO professional" (found in section 3022 of the ACA), which includes only doctors of medicine, doctors of osteopathy, physician assistants, nurse practitioners and clinical nurse specialists.

B. Eligibility and Governance

The ACA had specified four groups capable of forming an ACO on their own. These were: (1) ACO professionals in group practice arrangements; (2) networks of individual practices of ACO professionals; (3) partnerships or joint venture arrangements between hospitals and ACO professionals; and (4) hospitals employing ACO professionals (for both #3 and #4, the term hospital includes only acute care hospitals paid under the prospective payment system). The ACA also gave discretion to the Secretary to add additional entities, and the proposed rule adds critical access hospitals (CAHs) that bill under Method II (under which a CAH submits bills for both facility and professional services). In addition, CMS emphasizes that while other providers and suppliers, such as Federal Qualified Health Centers (FQHCs), rural health centers (RHCs), and Medicare-enrolled providers and suppliers not meeting the definition of ACO professional, cannot form an ACO on their own, it is possible for them to participate in an ACO (and share in any relevant savings or losses).

CMS solicits comments on the following:

- The kinds of providers and suppliers that should or should not be included as potential ACO participants;
- The potential benefits or concerns regarding including or not including certain provider or supplier types;
- The administrative measures that would be needed to effectively implement and monitor particular partnerships;
- Other ways in which CMS could employ the discretion provided to the Secretary to allow the independent participation of providers and suppliers not specifically mentioned in the statute (e.g., through an ACO formed by a group of FQHCs and RHCs); and
- Any operational issues associated with CMS' proposal.

In terms of legal structure, CMS indicates that an ACO may be structured in a variety of ways, including as a corporation, partnership, limited liability company, foundation, or other entity permitted by State law. However, CMS emphasizes that an ACO must demonstrate a mechanism of shared governance that provides all ACO participants with an appropriate proportionate control over the ACO's decision making process.

The proposed rule specifies that each ACO must be constituted as a legal entity appropriately recognized and authorized to conduct its business under applicable

State law and it must have a TIN. Further, an ACO must be capable of—(1) receiving and distributing shared savings; (2) repaying shared losses; (3) establishing, reporting and ensuring ACO participant and ACO provider/supplier compliance with program requirements, including the quality performance standards; and (4) performing the other ACO functions identified in the statute. CMS is not proposing to require that the ACO itself be enrolled in the Medicare program, and the agency is not proposing to require that existing legal entities appropriately recognized under State law must form a separate new entity for the purpose of participating in the Shared Savings Program. However, CMS proposes that if an existing entity, such as a hospital employing ACO professionals, would like to include as ACO participants other providers of services and suppliers who are not already part of its existing legal structure, a separate entity would have to be established in order to provide all ACO participants a mechanism for shared governance and decision making.

Each ACO would have to certify that it is recognized as a legal entity under State law and authorized by the State to conduct its business. An ACO with operations in multiple States would have to certify that it is recognized as a legal entity in the State in which it was established and that it is authorized to conduct business in each State in which it operates.

The proposed rule observes that commonly used mechanisms for establishing shared governance are a board of directors, board of managers, or other similar governing bodies, and notes that all of these would be acceptable in the ACO context. Further, CMS notes that an ACO would not need to form a separate governing body as long as that governing body is able to meet all other criteria required for ACO governing bodies.

In terms of the composition of the ACO governing body, CMS proposes that the ACO participants must have at least 75 percent control of the ACO's governing body, with each of the ACO participants choosing an appropriate representative "from within its organization" (presumably meaning the ACO organization as a whole rather than each individual participant's organization, such as each individual physician group practice). CMS further proposes that ACOs be required to describe how they will partner with community stakeholders[*] as part of their application (with ACOs that have a community stakeholder organization serving on their governing body deemed to have satisfied this application criterion).

CMS proposes that ACOs meet the following criteria:

- The ACO's operations must be managed by an executive officer, manager, or general partner, whose appointment and removal are under the control of the organization's governing body.

[*] Community stakeholders (also referred to as community resources) include employers, commercial health plans, local businesses, State/local government agencies, local quality improvement organizations and collaboratives, such as health information exchanges.

- Clinical management and oversight must 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 (the regulation text adds that such individual must be "full-time").
- ACO participants and ACO providers/suppliers must demonstrate a meaningful commitment to the ACO's clinical integration program (this may include a meaningful financial investment in the ACO or a meaningful human investment, such as time and effort, in the ongoing operations of the ACO).
- The ACO must have a physician-directed quality assurance and process improvement committee, which would, among other things, hold ACO providers/suppliers accountable for meeting performance standards.
- The ACO must develop and implement evidence-based medical practice or clinical guidelines and processes covering diagnoses "with significant potential for the ACO to achieve quality and cost improvements," and ACO participants and ACO providers/suppliers would have to agree to comply with these guidelines and processes and be subject to performance evaluations and potential remedial actions.
- The ACO must have "an infrastructure, such as information technology, that enables the ACO to collect and evaluate data and provide feedback to ACO providers/suppliers across the entire organization" (later, CMS proposes to require that at least 50 percent of an ACO's primary care physicians be meaningful users of certified electronic health records (EHRs) by the beginning of the second year of the ACO's agreement with Medicare, *and seeks comments on whether a similar requirement should be apply to an ACO's hospitals).*

The above requirements notwithstanding, the proposed rule (including the regulation text) indicates that CMS retains the right to give consideration to an innovative ACO with a management structure not meeting the requirements.

The proposed rule also includes a long list of information that a prospective ACO would need to submit to CMS as part of its application. Among other things, the ACO would need to provide documentation describing its plans to: (1) promote evidence-based medicine; (2) promote beneficiary engagement ("the active participation of patients and their families in the process of making medical decisions"); (3) report internally on quality and cost metrics; and (4) coordinate care. CMS emphasizes that an ACO's care coordination processes must not impede the ability of a beneficiary to seek care from providers that are not participating in the ACO, or develop policies that restrict the exchange of medical records with such providers).

For the first round of the Shared Savings Program, CMS proposes to limit the participation agreements to a 3-year period. If an ACO were to discontinue its participation in the Shared Savings Program prior to the end of the agreement period, CMS proposes to require 60-day advance written notice to CMS. Further,

CMS proposes that such an organization would forfeit any withheld shared savings (discussed later in this summary).

CMS further proposes to require an ACO applicant to indicate as part of its application how potential shared savings would be used to promote accountability for its Medicare population and the coordination of their care as well as how the shared savings might be invested in infrastructure and redesigned care processes for high quality and efficient health care service delivery. It would also be expected to provide the criteria it plans to employ for distributing shared savings among ACO participants and ACO providers/suppliers, and how any shared savings will be used to align with the triple aim.

Under the proposed rule, an ACO would be determined to have a sufficient number of primary care ACO professionals to serve the number of Medicare beneficiaries assigned to it if the number of beneficiaries historically assigned over the three-year benchmarking period using the ACO participant TINs exceeds the 5,000 threshold each year. The proposed rule offers no alternative test *but invites comments on the issue.* If an ACO's assigned population falls below 5,000 Medicare beneficiaries, CMS proposes to issue a warning and place the ACO on a corrective action plan (which could, for example, include a plan to add more primary care providers to the ACO); the ACO would, however, remain eligible for shared savings for the performance year for which the warning was issued. If the ACO again fails to satisfy the minimum beneficiary requirement in the next performance year, CMS proposes to terminate its ACO participation agreement (and the ACO would not be eligible for shared savings for that year).

CMS further proposes that entities applying to participate as ACOs must provide the TINs of the ACO and ACO participants as well as a list of national provider identifiers (NPIs) associated with the ACO providers/suppliers, and separately identify the primary care physicians. ACOs would be required to maintain, update, and annually report to CMS the TINs of its ACO participants and the NPIs associated with the ACO providers/suppliers.

The ACA specifies that an ACO must demonstrate that it meets patient-centeredness criteria specified by the Secretary. The proposed rule notes that a patient-centered orientation could be defined as "care that incorporates the values…of transparency, individualization, recognition, respect, dignity, and choice in all matters, without exception, related to one's person, circumstances, and relationships in health care" and that patient-centered care "should extend not only to the patient but to the family and caregivers of the patient." The proposed rule states that an ACO would be considered patient-centered if it has all eight (8) of the following:

- A beneficiary experience of care survey in place (more specifically, the Clinician and Group Consumer Assessment of Health Providers and Systems (CAHPS) and an appropriate functional status survey module) and

a description in the ACO application of how the ACO will use the results to improve care over time;

- Patient involvement in ACO governance (that is, having at least 1 beneficiary on the ACO's governing body, provided that such beneficiary or an immediate family member does not have a conflict of interest and is not an ACO provider/supplier within the ACO's network);
- A process for evaluating the health needs of the ACO's assigned population, including consideration of diversity in its patient population, and a plan to address the needs of such population;
- Systems to identify high-risk individuals and processes to develop individualized care plans for targeted patient populations, including integration of community resources (employers, commercial health plans, local businesses, State/local government agencies, local quality improvement organizations or collaboratives, such as health information exchanges) to address individual needs;
- A mechanism for the coordination of care, including "a process in place (or clear path to develop such a process) to electronically exchange summary of care information when patients transition to another provider or setting of care, both within and outside the ACO";
- A process for communicating clinical knowledge/evidence-based medicine to beneficiaries in a way understandable to them;
- Written standards for beneficiary access and communication and a process for beneficiaries to access their medical record; and
- Internal processes for measuring clinical or service performance by physicians across the practices, and using these results to improve care and service over time.

With respect to the above requirements, CMS invites comments on a number of issues, including whether the minimum standard for beneficiary participation on ACO governing bodies should call for a minimum number of beneficiaries or a minimum proportion of beneficiary control over the governing body. CMS also invites comments on the possible role of a separate Medicare beneficiary advisory panel or committee (including its potential for substituting for the required inclusion of a beneficiary representative on an ACO's governing body).

CMS further proposes that all ACO marketing materials and activities must be approved by CMS prior to use. The regulation text defines "marketing materials and activities" as including, but not being limited to, "general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, data sharing opt out letters, mailings, or other activities conducted by or on behalf of the ACO, or by ACO participants, or ACO providers/suppliers participating in the ACO, or by other individuals on behalf of the ACO or its participating providers and suppliers when used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers regarding the Shared

Savings Program."[*] Further, before any changes can be made to any approved materials, the revised materials would first have to be approved by CMS. The proposed rule warns that an ACO that fails to adhere to these requirements may be placed under a corrective action plan or terminated, at CMS' discretion.

In addition, the proposed rule includes a number of program integrity requirements. An ACO would be required to have a compliance plan that includes elements common in the compliance industry (e.g., a designated compliance official and mechanisms for identifying and addressing compliance problems). An authorized representative of the ACO who has the ability to legally bind the ACO, such as its chief executive officer (CEO) or chief financial officer (CFO), would be required to certify the accuracy, completeness, and truthfulness of information contained in its Shared Savings Program application, 3-year agreement, and submissions of quality data and other information. Such an authorized representative would similarly have to make a written request to CMS for payment of shared savings. Also, if data submitted to CMS are generated by ACO participants or another individual or entity, or a contractor, or subcontractor of the ACO or the ACO participants, such ACO participant, individual, entity, contractor, or subcontractor must similarly certify the accuracy, completeness, and truthfulness of the data and provide the government with access to such data for audit, evaluation, and inspection. Further, an ACO must have a conflicts of interest policy that applies to members of its governing body (which must require members of the governing body to disclose relevant financial interests).

C. Establishing the 3-Year Agreement with the Secretary

CMS proposes to adopt an annual ACO application period during which a cohort of ACO applicants would be evaluated, and further proposes that the performance years be based on the calendar year. This presumably means that the first cohort of ACOs would be approved for a start date of January 1, 2012. *CMS invites comments on alternative start dates and notes that one option might be to add an additional start date of July 1, 2012 (with a 3.5 year agreement period, with the first performance year defined as 18 months).*

For purposes of evaluating shared savings (that is, for calculating the applicable benchmark and per capita expenditures for the performance year), CMS proposes to use a 6-month claims run-out period (the time between when a Medicare-covered service has been furnished and when the final payment is actually issued for the service). This would be expected to produce a completion

[*] The regulation text adds that the following beneficiary communications are not marketing materials and activities: information materials customized or limited to a subset of beneficiaries; materials that do not include information about the ACO or providers in the ACO; materials that cover beneficiary-specific billing and claims issues or other specific health-related issues; or educational information on specific medical conditions (for example, flu shot reminders), or referrals for Medicare covered items and services.

percentage of about 99.5 percent for physician services and 99 percent for Part A services. Nonetheless, CMS is still concerned that some claims (for example, high cost claims) might be filed after the claims run-out period and is considering ways to address this issue, including applying an adjustment factor determined by CMS actuaries to account for incomplete claims. In any event, a 6-month claims run-out period means that final decisions about shared savings (and losses) would not occur until many months after the end of each performance period.

To help ACOs accomplish the goals of the Shared Savings Program, CMS proposes to share three separate types of data. First, in advance of an ACO's first performance year (for beneficiaries who would have been assigned to an ACO based on historical data) and at quarterly intervals thereafter (based on the most recent 12 months of data from potentially assigned beneficiaries), CMS proposes to provide aggregate (not beneficiary identifiable) data reports. These data reports would include de-identified claims history of the services rendered for an ACO's historically assigned or potentially assigned beneficiaries, and, when available, financial performance, quality performance scores, and aggregated metrics on the relevant beneficiary population.

Second, at the beginning of the agreement period and at the end of each performance period, CMS would, upon the ACO's request, provide four data elements (beneficiary name, date of birth, sex, and Health Insurance Claim Number (HIC); the regulation text omits sex but this is clearly inadvertent) about each beneficiary who would have been assigned to the ACO based on historic data (at the beginning of the first performance year) or who was assigned during a given performance period (at the end of each performance year). These data elements would expressly be provided to ACOs only for purposes of population-based activities relating to improving health or reducing health care costs, protocol development, case management, and care coordination. CMS explicitly notes that ACOs, their ACO participants and their ACO providers/suppliers would be able to use the four data elements "to communicate with individuals on the list to describe available services and for case management and care coordination purposes."

Third, CMS also proposes to give ACOs the option of requesting certain beneficiary identifiable claims data (only the minimum data necessary to accomplish specified purposes) on a monthly basis, in the form of a standardized data set about the beneficiaries currently being serviced by the ACO participants and ACO providers/suppliers. For this purpose, CMS proposes to limit the beneficiaries covered by such data sets to those who have received a service from a primary care physician participating in the ACO during the performance year, and who have not opted out of having CMS share their claims data with the ACO (see below for further discussion of the opt-out option). Further, for Medicare Parts A and B, the minimum necessary data set may 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. For Medicare Part D, the minimum necessary data elements may 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.[*] An ACO requesting these beneficiary identifiable data would be required to explain how it intends to use the data to evaluate the performance of ACO participants and ACO providers/suppliers, conduct quality assessment and improvement activities, and conduct population-based activities to improve the health of its assigned beneficiary population. Requesting ACOs would also have to enter into a Data Use Agreement.

The proposed rule also specifies that ACOs will generally be subject to future changes in Medicare regulations that occur during an agreement period except in the following program areas: eligibility requirements concerning the structure and governance of ACOs, calculation of sharing rate, and beneficiary assignment. If regulatory modifications to which an ACO must comply "effectuate changes in the processes associated with an ACO pertaining to design, delivery, and quality of care," an ACO will be required to submit to CMS for review and approval an explanation of how the ACO will address key changes in processes resulting from the regulatory modifications.

The proposed rule states that adding ACO participants during the course of an ACO's three-year agreement could cause the ACO to "deviate from its approved application and jeopardize the ACO's eligibility since the ACO would differ from its approved application and could be subject to further antitrust review." CMS, therefore, proposes that an ACO may not add ACO participants during the course of the three-year agreement, but it could remove ACO participants and it could add/subtract ACO providers/suppliers. In other words, an ACO could not add a single physician group practice during the entire three-year agreement (even if some group practices were dropped) but additional physicians could join an existing group practice that was already participating in the ACO. In any event, when an ACO reorganizes its structure by excluding ACO participants or by adding or excluding ACO providers/suppliers, deviates from its approved application, changes information contained in its approved application, or experiences other changes which may make it unable to complete its three-year agreement, it would be required to notify CMS within 30 days of the event for reevaluation of its eligibility to continue to participate in the Shared Savings Program.

Finally, the proposed rule speaks to several issues relating to future participation of previously terminated and certain other previous Shared Savings Program participants. ACO applicants would be required to disclose to CMS whether the ACO, its ACO participants, or its ACO providers/suppliers have previously

[*] CMS emphasizes that it will not disclose any patient information related to alcohol and substance abuse without the patient's written consent.

participated in the Shared Savings Program under the same or a different name, and specify whether it was terminated or withdrew voluntarily from the program. Further, if the previous history involved termination, the applicant must identify the cause of termination and what safeguards are now in place. Moreover, a previously terminated ACO (or one that voluntarily withdrew from the Shared Savings Program) would not be allowed to begin a new 3-year agreement until the original agreement period has lapsed. In addition, an ACO that experienced a net loss during its first 3-year agreement period would not be allowed to reapply to participate in the Shared Savings Program.

D. Assignment of Medicare Fee-For-Service Beneficiaries

CMS proposes to assign Medicare beneficiaries to an ACO retrospectively (that is, at the end of each performance period). The agency further proposes to assign beneficiaries to an ACO if they received a plurality of their primary care services (defined below and based on an analysis of allowed charges, not units of service) from primary care physicians (also defined below) within that ACO. The test, then, is whether they received more primary care from that ACO than any other provider.

To operationalize the above beneficiary assignment methodology, CMS proposes to identify an ACO as a collection of Medicare enrolled TINs (each of which CMS claims can be systematically linked to an individual physician specialty code, although the agency does not indicate how it will handle multi-specialty group practices). CMS further proposes that ACO professionals within the respective TIN on which beneficiary assignment is based (that is, primary care physicians) will be exclusive to one ACO agreement. All other providers and suppliers would be free to participate in more than one ACO (if they did participate in an ACO, they would be required to agree to participate for the term of the 3-year agreement).

For purposes of beneficiary assignment, primary care services are defined to include services identified by Healthcare Common Procedure Coding System (HCPCS) codes 99201 through 99215 (office or other outpatient visits), 99304 through 99340 (nursing facility, domiciliary or rest home visits and related services), and 99341 through 99350 (home visits), as well as the Welcome to Medicare visit (G0402) and the annual wellness visits (G0438 and G0439). Further, primary care physicians would be defined to include doctors of medicine and osteopathy in internal medicine, family practice, general practice and geriatric medicine.

CMS welcomes comments on whether there should be a minimum threshold number of primary care services that a beneficiary should receive from physicians in the ACO in order to be assigned to the ACO under the plurality rule and if so, where that minimum threshold should be set.

CMS emphasizes that the term "assignment" (with respect to the ACO program) "in no way implies any limits, restrictions, or diminishment of the rights of Medicare FFS beneficiaries to exercise complete freedom of choice in the physicians and other health care practitioners and suppliers from whom they receive their services." In fact, CMS prefers to characterize the process as an "alignment" of the assigned beneficiary with a given ACO.

In the proposed rule, CMS notes that it intends to develop a communications plan, including educational materials and other forms of outreach, to help educate beneficiaries about the Shared Savings Program. CMS also proposes to require ACOs to post signs in the facilities of participating ACO providers/suppliers indicating the participation of the providers/suppliers in the program and to make available standardized written information to Medicare FFS beneficiaries whom they serve. This standardized information would provide written notice to beneficiaries of both their participation in the program and the potential for CMS to share beneficiary identifiable data with ACOs when a beneficiary receives services from a physician on whom assignment to the ACO is based. CMS says it also plans to instruct ACOs to supply a form allowing beneficiaries to opt-out of having their data shared. This form would be provided to each beneficiary as part of their office visit with a primary care physician, and must include a phone number, fax or email for beneficiaries to contact and request that their data not be shared. This proposed plan would mean that the beneficiary would need to take additional action (make a phone call or send a fax or email), presumably after leaving the physician's office. Note, too, that this "opt out" has nothing to do with whether or not a beneficiary can continue to see a primary care physician participating in an ACO.

CMS also proposes that ACOs be required to provide timely notice to beneficiaries if they will no longer be participating in the Shared Savings Program, and this notice should include the effective date of the termination of their agreement with CMS (no specific deadline is given for such "timely" notice).

E. Quality and Other Reporting Requirements

CMS proposes to use 65 performance measures in year 1 of the ACO program, with ACOs required to report full and accurate data for those measures, but not meet any specific performance target. For subsequent performance periods, ACOs will be expected to exceed certain minimum performance levels for each ACO performance measure then in use. In this regard, while Table 1 of the proposed rule lists 65 measures in 5 domains (patient/caregiver experience, care coordination, patient safety, preventive health, and at-risk population/frail elderly health), CMS notes that the quality measures for years 2 and 3 of the 3-year agreement period "will be proposed in future rulemaking."

CMS proposes that ACOs be required to report quality measures and meet applicable performance criteria for all 3 years within the 3-year agreement period

to be considered as having met the quality performance standard. Further, if an ACO fails to report quality measures by the requested deadline and does not provide a reasonable explanation for delayed reporting, CMS says it would immediately terminate the ACO. Moreover, since meeting the quality standard is a condition for sharing in any savings, an ACO would be disqualified from sharing in savings in each year in which it underperforms.

Table 1 of the proposed rule includes the domain each of the proposed measures addresses, the measure title, a brief description of the data the measure captures, applicable Physician Quality Reporting System (PQRS) or EHR Incentive Programs information, the measure steward or, if applicable, the National Quality Forum (NQF) measure number, the proposed method of data submission for each measure (survey instruments, claims, or the Group Practice Reporting (GPRO) data collection tool), and the Measure Type (patient experience of care, process or outcome). Under the GPRO data reporting option, a sampling methodology is used, with requisite data submitted for a sample of beneficiaries. CMS proposes to retain the right to validate the data entered into the GPRO reporting tool and describes an audit process under which the medical records of a small sample of beneficiaries would be examined (first, 8 records to check for mismatches, then another 22 records if mismatches were found in phase 1, and finally corrective action if mismatches are found in more than 10 percent of the medical records in phase 2). CMS also indicates that it will make the specifications for the proposed measures available on its website prior to the start of the Shared Savings Program, and warns that the specifications for some of the measures will need to be refined to apply to an ACO population.

CMS says it expects to refine and expand the list of ACO performance measures (in subsequent program years through additional rulemaking) and to expand measure reporting mechanisms to include those that are directly EHR-based. The agency also expects that the ACO quality measures will evolve over time with the goal of developing a single measure set that could be used by ACOs operating across a wide variety of payers. In terms of the measures included in Table 1 of the proposed rule, CMS warns that, in the near-term (that is, absent a new rulemaking cycle), the agency will not be able to consider measures "that do not substantially cover the same patient populations, processes, or outcomes addressed by the existing measures outlined in the proposed rule." In other words, the final rule might drop measures from Table 1 or make modest, relatively technical changes to those measures, but not add substantially different measures. This is the same approach CMS has taken when seeking comment on various performance measure sets, including those used under the PQRS.

CMS proposes to set benchmarks for each proposed measure using Medicare FFS, Medicare Advantage or ACO performance data (depending on availability). ACOs would be required to report completely and accurately on all measures within all domains to be deemed eligible for shared savings consideration. Each

measure would have a minimum attainment level. ACOs would have to exceed the minimum attainment level (generally set at 30 percent or the 30th percentile of the Medicare FFS or Medicare Advantage rate) for each measure in a domain for the domain to be eligible for shared savings.* Further, all domains must have a score above the minimum attainment level in order for the domain to be eligible for shared savings, and an ACO is eligible for shared savings only if it has satisfied the quality performance requirements for each domain.

CMS further proposes to use a sliding scale measure scoring approach for performance above the minimum attainment level, with better performance receiving more points, thereby qualifying better performing ACOs to receive a greater share of any savings. Under the proposed scoring methodology, each of the 5 domains would be worth a pre-defined number of points (for a total of 130 possible points). All domains would be equally weighted regardless of the number of measures within the domain. The aggregated domain scores would determine an ACO's eligibility for sharing up to 50 percent of the total savings generated by the ACO under the one-sided model or up to 60 percent of the total savings under the two-sided model (see II.G. below for further details).

CMS invites comments on whether ACOs would be required to only report a subset of the measures in Table 1, based on their level of readiness for the Shared Savings Program.

Table 2 of the proposed rule, reproduced below, lists the 5 measure domains and the number of measures in each domain.

Table 2: Five Measure Domains for Quality Performance Standard

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

* CMS proposes "all or nothing" scoring for two measures in Table 1.

CMS proposes that for ACOs that meet the quality performance standard under the Shared Savings Program for the first performance year (where only data reporting is required), their eligible professionals under the PQRS will be deemed to have qualified for incentive payments under the PQRS (equal to 0.5 percent of the eligible professionals' total estimated Medicare Part B physician fee schedule allowed charges for covered professional services furnished during the first performance period). CMS intends to discuss in future rulemaking the policy for incorporating the PQRS incentive under the Shared Savings Program for subsequent years. At this time, CMS is not proposing to incorporate incentive payments for the EHR Incentive Program or the Electronic Prescribing Incentive Program under the Shared Savings Program. Professionals in ACOs may still separately participate in those other incentive programs.

Finally, CMS proposes to require ACOs to publicly report the following information in a standardized format that the agency will make available through subregulatory guidance:

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

F. Shared Savings Determination

ACOs that meet the quality performance standards established by the Secretary, as discussed in the previous section, and that achieve savings compared to a benchmark of expected average per capita Medicare fee-for-service (FFS) expenditures, will share in a portion of the Medicare savings. Section 1899(d) of the statute provides for a pure one-sided shared savings approach, with entities assuming no risk in the event expenditures exceed the benchmark, and section 1899(i) gives the Secretary authority to create a risk-based option. The proposed rule creates two tracks. Under the first track, ACOs can participate in a one-sided, shared savings-only model for the first two years of the 3-year agreement and not be responsible for any portion of losses above the expenditure target. In the third year of the agreement, however, these ACOs would be automatically transitioned to the two-sided model and payments would be reconciled as if the ACO was in the first year of the two-sided model. Quality scoring, however, would still be based on the methods for the third year of the two-sided model and not revert back to the first year standard for full and accurate reporting. Going

forward, Track 1 ACOs wishing to continue to participate in the Shared Savings Program would only have the option of participating in Track 2, the two-sided risk model.

More experienced ACOs that are willing to share in losses with greater opportunity for reward may elect to enter the two-sided model under Track 2 immediately. Such an ACO would be under the two-sided model for all three years of its agreement period and would be eligible for higher sharing rates than would be available under the one-sided model.

The statute requires that the Secretary:

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

Identifying expenditure data for the benchmark

Establishing an expenditure benchmark involves: (1) determining the patient population to be used for the historical expenditure experience; (2) making appropriate adjustments in spending levels for beneficiary characteristics such as demographic factors and/or health status; (3) determining whether any other adjustments to the 3-year benchmark are warranted, such as to avoid potentially disadvantaging various types of providers (for example, hospitals that receive Medicare disproportionate share hospital payments (DSH hospitals) or teaching hospitals that receive indirect graduate medical education (IME) payments) or ACOs located in high cost, or low cost, areas; and (4) identifying the method for trending the 3-year benchmark forward to the start of the agreement period, and subsequently for updating the benchmark for each of the 3 performance years of the agreement period with the ACO. Each ACO's benchmark level will be reset at the start of each new agreement period.

The proposed rule invites public comment on two options for identifying the patient population which will be used to set the benchmark level. Under Option 1, the option which CMS proposes to use, an ACO's benchmark would be based on Part A and B FFS expenditures on behalf of beneficiaries who would have been assigned to the ACO in each of the 3 years prior to the start of an ACO's

agreement period using the ACO participants' taxpayer identification numbers (TINs). Under Option 2, the benchmark would be based on the expenditures of beneficiaries who are actually assigned to the ACO during each performance year, with the expenditures still being those incurred in the 3 years immediately preceding the ACO's agreement period for those assigned beneficiaries.

Option 1:

i. Use the claim records of ACO participants to determine a list of beneficiaries who received a plurality of their primary care services from primary care physicians participating in the ACO in each of the prior 3 most recent available years. This is accomplished by applying the same methodology that is used to assign beneficiaries to ACOs, as discussed in section D above.
ii. Use the per capita Part A and B FFS expenditures for these beneficiaries in each of these 3 prior years to estimate the benchmark.
iii. To minimize variation from catastrophically large claims, truncate an assigned beneficiary's total annual per capita expenditures at the 99th percentile as determined for each benchmark year (for example, roughly $100,000 in 2008). The proposed rule also would truncate an assigned beneficiary's total annual per capita expenditures at the 99th percentile as determined for each subsequent performance year.
iv. Use Office of the Actuary national Medicare expenditure data for each of the years making up the benchmark to determine an appropriate growth index and trend the benchmark years' expenditures to benchmark year 3 (BY3) dollars.
v. Use health status measures for the beneficiary population in each of the years making up the benchmark to establish health status indices for each year and adjust so they are restated to reflect BY3 risk.
vi. Compute a 3-year risk- and growth-trend adjusted per capita expenditure amount for the patient populations in each of the 3 benchmark years by combining the initial per capita expenditures for each year with the respective growth and health status indices. This yields risk adjusted per capita expenditures for beneficiaries historically assigned to the ACO in each of the 3 years used to establish the benchmark stated in BY3 risk and expenditure amounts.
vii. Weight the most recent year of the benchmark, BY3, at 60 percent, BY2 at 30 percent and BY1 at 10 percent to ensure that the benchmark more accurately reflects the latest expenditure and health status of the ACO's assigned beneficiary population. CMS states that this weighting results in a more accurate benchmark and permits lower MSRs.
viii. Update the benchmark for each performance year by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program using actual claims and expenditure data for Medicare patients from the Office of the Actuary. The proposed rule notes that this approach for updating the

benchmark avoids current law issues associated with Medicare expenditure projections, such as arise with the physician update, since it uses the actual claims and expenditure experience to calculate the factor used to update the benchmark for purposes of annual reconciliation.

ix. The benchmark and its associated computations would be rebased only at the start of a new agreement period.

CMS proposes to provide an ACO, at its request, with aggregated data and information on beneficiaries that would historically have been assigned to the ACO and, as a result, have a likelihood of being assigned during the agreement period. The proposed rule acknowledges that an ACO's population or its composition of ACO providers/suppliers may change over time so that the assigned population would diverge from the benchmark population, potentially affecting the comparability of performance measurement. Based on modeling of the PGP demonstration data using the proposed primary care-based assignment methodology, CMS found that assignment of beneficiaries varies from year-to-year, with about 25 percent of those assigned in one year not being assigned in the subsequent year (due to relocation, death, participation in MA, or changes in their choice of care professionals).

CMS notes that some of the beneficiaries whose expenditures would be included in the benchmark would not be reflected in the assigned ACO population during the performance years of the agreement period. It also observes that the Option 1 benchmark approach could provide unwanted incentives to seek and/or avoid specific beneficiaries during the agreement period so that average expenditures would more likely be less than for the beneficiaries included in the benchmark. *For these reasons, CMS invites comments on a second option for determining the benchmark.*

Option 2:

i. For beneficiaries actually assigned to the ACO during the agreement period, calculate their per capita Parts A and B FFS expenditures during each of the 3 years immediately preceding the first year of the agreement period.

ii. Trend these amounts to the start of the agreement period and adjust the benchmark for "beneficiary characteristics" and health status as specified above in steps ii through vi of Option 1.

iii. Update the benchmark for each performance year by the projected absolute amount of growth in national per capita expenditures, as specified above in step viii of Option 1.

iv. Apply special rules for beneficiaries without 3 full years of immediately prior Medicare eligibility (such as beneficiaries who were not 68 in their first year assigned to the ACO).
   – For assigned beneficiaries with less than one full year of prior Medicare experience, CMS either would substitute the average per

capita FFS expenditures for all Medicare beneficiaries during the year they are first assigned to the ACO (adjusted for health status) for their own expenditures, or CMS would exclude their experience from the shared savings computations.

- For assigned beneficiaries with more than 12 months prior Medicare experience but less than 36 months, CMS either would compute a weighted-average (using number of months as the weight) that blends their prior expenditure experience and the average per capita FFS expenditures for all Medicare beneficiaries during the year before the first year they are assigned to the ACO (adjusted for health status), or CMS would use only their prior expenditure experience.

v. For the second and third year of the agreement period, CMS would not make any adjustments for assigned beneficiaries who were also assigned in the first year of the ACO agreement period.

vi. Adjust the benchmark for the second and third year of the agreement for beneficiaries who are newly-assigned in those years and for previously assigned beneficiaries who are no longer assigned to the ACO. The adjustment would add the experience of the newly-assigned beneficiaries (as step iv describes for the first year) for the 3 years prior to the agreement period and would remove the prior experience of the no-longer assigned beneficiaries.

vii. For beneficiaries who were assigned during the first year, not assigned during the second year, and then again assigned during the third year of the ACO's agreement period, the prior expenditure experience that would be used to adjust the benchmark in the third year would be the same amount initially used for their first year of assignment.

viii. Option 2 also requires an adjustment for assigned beneficiaries who die during an agreement year in recognition that their average monthly expenditures are often higher during this last year of life. The proposed rule notes that approximately 5 percent of all Medicare beneficiaries die in a single year.

CMS invites comment on two alternatives for adjusting the benchmark for beneficiaries who die during an agreement year. Under the first method, which CMS prefers, it would exclude the expenditures of deceased beneficiaries from actual expenditures during the agreement period – an approach which it indicates might best address concerns about creating incentives for ACOs to avoid assignment of beneficiaries in their last year of life or to treat such beneficiaries differently. Under the alternative method for adjusting for decedents, CMS would compare average expenditures for each deceased beneficiary during the agreement year to the average expenditures for beneficiaries included in the benchmark. If the agreement year's expenditures were 5 percent or less above the benchmark, no adjustment would be made; if the agreement year's expenditures were greater than 5 percent above the benchmark, CMS would adjust the accumulated expenditures for deceased beneficiaries by a yet-to-be-developed methodology.

Option 2 would yield a benchmark for each ACO that is estimated using beneficiary expenditures for the three years prior to the agreement period for only those beneficiaries that were actually assigned to the ACO during that year of the agreement period.

CMS seeks comments about these adjustment approaches and solicits other approaches that it might consider, noting that it proposes adopting Option 1 but could adopt Option 2 in the final rule based on comments.

Adjusting the Benchmark and Average Per Capita Expenditures for Beneficiary Characteristics

Changes in the case mix of assigned patients stemming from changes in the health status of assigned patients or changes in the ACO's organizational structure could affect expenditures. CMS considered alternative risk-adjustment options to account for this impact. One basic approach would consider only patient demographic factors, such as age, sex, Medicaid status, and the basis for Medicare entitlement (that is, age, disability or ESRD), without incorporating diagnostic information; the alternative approach would incorporate diagnostic information based on the CMS Hierarchal Condition Category (CMS-HCC) prospective risk adjustment model that has been used in the MA program and, according to CMS, is widely accepted by payers and providers. The CMS-HCC prospective risk adjustment model uses beneficiaries' prior year diagnoses to develop risk scores that are then applied to their current year expenditures. Since CMS annually calculates risk scores using the CMS-HCC model for all Medicare beneficiaries, readily available data can be incorporated into the Shared Savings Program. Additional information on the CMS-HCC model can be found in the Advance Notice of Methodological Changes for Calendar Year (CY) 2011 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2011 Call Letter, which can be found at: http://www.cms.gov/MedicareAdvtgSpecRateStats/Downloads/Advance2011.pdf and http://www.cms.gov/MedicareAdvtgSpecRateStats/Downloads/Announcement2011.pdf.

CMS rejected a model that would adjust only for beneficiary demographic factors because it would not take into account the health status of the assigned beneficiaries and could potentially have an adverse effect on ACOs which include providers and suppliers that typically treat a comparatively sick beneficiary population, including academic medical centers and tertiary care centers. For the proposed rule, CMS adjusts Medicare expenditure amounts based on the CMS-HCC model used in the MA program.

Incorporating adjustments based on diagnostic information in the Shared Savings Program carries the potential for changes in coding completeness and intensity to affect payments. Based on experience in MA and with the PGP

demonstration, CMS concluded that both health plans and PGP participants were able to increase the HCC score of their populations significantly by focusing on more complete coding. To address coding improvement, CMS observes that it expects an ACO's average population risk scores to be stable over time and therefore it proposes to calculate a single benchmark risk score for each ACO. The same risk score will be applied throughout the agreement period. The benchmark risk score is calculated by applying the CMS-HCC model to the assigned beneficiary population attributed in each year of the 3-year benchmark. Changes in the assigned beneficiary population risk score relative to the 3-year benchmark period during the performance year will not be incorporated. Thus, the effects of changes in coding intensity during the performance years (compared to the benchmark) will not be reflected in program costs.

The proposed rule discusses and invites comments on this and other options to adjust for coding improvements, including normalization factors and coding intensity adjustments similar to those used in the MA program, an annual cap in the amount of risk score growth which would be allowed for each ACO, and establishing a risk score for an ACO's assigned population during the agreement period based on the calculated risk score of beneficiaries who were used to calculate the ACO's benchmark.

Technical Adjustments to the Benchmark

The law provides that the benchmark will be adjusted for "such other factors as the Secretary determines appropriate." The factors considered and CMS's proposed rule policies are summarized in the table below:

Factor	Possible Rationale for Adjustment to Exclude Them	Proposed Rule Policy
Remove additional payments for indirect medical education (IME) and disproportionate share (DSH)	Higher payments provided to hospitals receiving these payments could provide ACOs with a strong incentive to realize savings simply by avoiding referrals to such hospitals	Does not exclude these payments citing lack of statutory authority. Also 1) removal would result in an artificial and incomplete representation of actual Medicare spending; 2) the trend adjustment during the performance period is based on absolute amount of growth in national per capita expenditures, including these payments; and 3) all relevant Medicare costs should be included in an ACO's benchmark to maintain sufficient incentives for ACOs to ensure their assigned beneficiaries receive care in the most appropriate settings

Factor	Possible Rationale for Adjustment to Exclude Them	Proposed Rule Policy
Geographic payment adjustments (e.g., the IPPS wage index and the physician fee schedule geographic practice cost index (GPCI))	Timing of temporary legislative changes to these adjustment factors (such as a rural floor) could result in differences between an ACO's benchmark and the performance years, thus influencing the ACO's ability to realize savings under the program	Does not exclude these adjustments citing lack of statutory authority. As with IME and DSH, the law grants authority to remove them from the benchmark but not from the performance period expenditure calculations
Bonus payments and penalties related to value-based purchasing initiatives such as the PQRS and the Health Information Technology for Economic and Clinical Health (HITECH) Act, which encourages hospital and physician adoption of EHRs	Incentive payments and penalties can differentially affect the benchmark and actual expenditures in the performance period, and thus influence an ACO's ability to realize savings. Including these payments could create perverse incentives so that participation in the Shared Savings Program might adversely affect the performance of providers and suppliers with respect to other important Medicare efforts like value-based purchasing and HITECH	Excludes expenditures or savings for incentive payments and penalties under section 1848 (PQRS, e-Prescribing, and the EHR incentives for eligible professionals under the HITECH Act) from the computations of both benchmark and actual expenditures during the agreement period. Due to lack of statutory authority, does not exclude expenditures or savings for incentive payments and penalties not under section 1848, such as EHR incentive payments to hospitals and the Hospital Inpatient Value-Based Purchasing Program, which are made under section 1886, and EHR incentive payments to CAHs, which are made under section 1814

Trending Forward Prior Years' Experience to Obtain an Initial Benchmark

The statute directs use of "the most recent 3 years of per-beneficiary expenditures for parts A and B services" to estimate a benchmark for each ACO, and the per capita costs for each year must be trended forward to current year dollars to obtain the benchmark for the first agreement period. The benchmark is subsequently updated for each year of the agreement period based on the "projected absolute amount of growth in national per capita expenditures for parts A and B services" under the FFS program as estimated by the Secretary.

The statute does not specify the trending factor to be used in estimating the initial benchmark. Often prior years' expenditures would be increased using a

percentage growth factor, but CMS also considered using a flat dollar amount equivalent to the absolute amount of growth in per capita expenditures under the FFS program. Use of a growth rate rather than a flat dollar amount would more accurately reflect each ACO's historical experience and would neither raise the bar for ACOs in historically higher growth rate areas nor lower it for ACOs in lower growth areas. But it also can be argued that it would perpetuate current regional differences in medical expenditures. A flat amount adjustment provides a stronger incentive for ACO development in areas with historically lower expenditures and growth rates, but potential ACOs in areas with historically higher growth rates could be reluctant to participate in the program given the challenge to reduce their growth rate. CMS proposes to use growth rates rather than a flat dollar amount. As a hypothetical example, CMS discusses use of 2011, 2012 and 2013 claims year data to set the benchmark for an ACO starting its agreement period in 2014. Under such an approach, the 2011 and 2012 data would be trended forward so that all benchmark dollars would be in 2013 dollars.

Similar considerations apply to the choice of using a national rate versus a local or State rate. A national rate could disproportionately encourage the development of ACOs in areas with low historical growth rates and discourage development of ACOs in areas with historically higher growth rates above the national average. CMS considered an option to trend the benchmark by the lower of the national projected growth rate or the State or local growth rate but decided to propose trending forward the fixed benchmark based on a national growth rate in Medicare Parts A and B expenditures for FFS beneficiaries.

The proposed rule invites comments on these issues.

Updating the Benchmark During the Agreement Period

The law requires that the benchmark be "updated by the projected absolute amount of growth in national per capita expenditures" during the agreement period, an approach that will mitigate some of the regional differences in Medicare spending among ACOs. In the second and third years of an agreement period, using a flat dollar increase, which would be the same for all ACOs, provides a relatively higher expenditure benchmark for low growth low spending ACOs and a relatively lower benchmark for high growth high spending ACOs. Generally, an ACO can more likely share in savings when its actual expenditures are judged against a higher benchmark. Thus, with a flat dollar increase to the benchmark, ACOs in high cost high growth areas must reduce their rate of growth more to bring their costs more in line with the national average.

CMS considered but rejected using its authority under Section 1899(i) to update the benchmark by the lower of the national projected absolute amount of growth in national per capita expenditures or the local/State projected absolute amount of growth in per capita expenditures. Applying more localized growth factors

would reflect the expenditure and growth patterns within the geographic area served by ACO participants and ACO providers/suppliers, potentially providing a more accurate estimate of the updated benchmark based on the area from which the ACO derives its patient population. Under this alternative approach, CMS could cap the update at the projected absolute amount of growth in national per capita expenditures so that the update would not disproportionately benefit higher cost/higher growth rate areas which might have a potentially greater ability to realize savings from current levels due to better care coordination and efficiency. At the same time, using the lower local/State rate rather than the national flat-dollar update for low-spending, low-growth areas would ensure that the Shared Savings Program retains appropriate incentives for ACOs in low-cost areas, as well as for those in high-cost areas.

CMS invites comment on this alternative option.

Minimum Savings Rate (MSR)

The law stipulates that an ACO is eligible to receive payment for shared savings "only if the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries is at least the percent specified by the Secretary below the applicable benchmark . . . ." The Secretary is directed to "determine the appropriate percent… to account for normal variation in expenditures under this title, based upon the number of Medicare fee-for-service beneficiaries assigned to an ACO." If an ACO achieves savings in excess of this minimum savings rate (MSR) and meets the quality standards established by the Secretary, the ACO may be paid a percent (as determined appropriate by the Secretary) of the difference between its average per capita Medicare expenditures in a year, adjusted for beneficiary characteristics, and the benchmark. Beyond this shared savings, the remainder of the difference is retained by the Medicare program. A higher MSR would increase confidence that the shared savings amounts reflect the real quality and efficiency gains, and offer greater protection to the Medicare Trust Funds, but also could discourage potentially successful ACOs, especially physician organized ACOs and smaller ACOs in rural areas, from participating in the program. Under the PGP demonstration, the MSR was set initially at a flat 2 percent of the benchmark, regardless of the number of assigned beneficiaries, and PGP practices received back 80 percent of the savings achieved in excess of the MSR.

For the one-sided risk model, CMS proposes a sliding scale confidence interval (CI) based on the number of assigned beneficiaries. The MSR would be established for each ACO based on a confidence interval determined by the size of the ACO. The proposed rule sets the confidence interval to 90 percent for ACOs of 5,000 beneficiaries, resulting in an MSR of 3.9 percent. For ACOs with 20,000 and 50,000 beneficiaries, it sets the confidence interval to 95 percent and 99 percent, respectively, resulting in MSRs of 2.5 percent and 2.2 percent. Depending on its performance on quality measures, an ACO in the one-sided

model that exceeds its MSR would be eligible to share up to 50 percent of the savings (all savings in excess of 2 percent, no matter what an individual ACO's MSR was).

Table 6 displays the minimum savings rate an ACO must achieve before savings could be shared based on the number of its assigned beneficiaries. Table 6 shows the MSR at both the high and low end of each range of ACO population size. A particular ACO would be assigned a linearly interpolated MSR given its exact number of beneficiaries. For example, an ACO with 7,500 beneficiaries would be assigned an MSR of 3.3 percent because it lies at the midpoint between 7,000 and 7,999 beneficiaries, sizes at which the MSR would be 3.4 percent and 3.2 percent, respectively. For ACOs serving more than 60,000 aligned beneficiaries, CMS proposes that the MSR would not be allowed to fall below 2 percent.

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

Number Beneficiaries	MSR (low end of assigned beneficiaries)	MSR (high end of assigned beneficiaries)
5,000 - 5,999	3.90%	3.60%
6,000 - 6,999	3.60%	3.40%
7,000 - 7,999	3.40%	3.20%
8,000 - 8,999	3.20%	3.10%
9,000 - 9,999	3.10%	3.00%
10,000 - 14,999	3.00%	2.70%
15,000 - 19,999	2.70%	2.50%
20,000 – 49,999	2.50%	2.20%
50,000 – 59,999	2.20%	2.00%
60,000 +	2.00%	

Determination of Shared Savings

The proposed rule sets out several other policies for determining the amount of shared savings. These are described in the table below for the one-sided model and in the next section for the two-sided model.

Factor	Proposed Rule Policy for One-Sided Model	*Other Options Considered and On Which Comments Are Sought*
Net savings threshold above which shared savings are calculated	ACOs that exceed the MSR would be eligible to share in net savings above a 2-percent threshold, calculated as 2 percent of its updated benchmark. The sharing rate (earned quality performance sharing rate, up to 50 percent, and additional increases for including FQHCs and/or RHCs) would be applied to net savings above this 2 percent threshold in order to determine the shared savings amount.	1) Permit the ACO to share on first dollar savings once the MSR was exceeded 2) Share with the ACO only those savings in excess of the MSR
Waiver of net savings threshold for calculating savings	Exempt certain ACOs from the 2 percent net savings threshold and provide first dollar savings to them. Qualifying ACOs must satisfy at least <u>one</u> of the criteria listed below (following this table) <u>and</u> have less than 10,000 assigned beneficiaries in the most recent year for which CMS has complete claims data	None
Additional shared savings payments for including FQHCs and/or RHCs	Provide up to a 2.5 percentage point increase in the sharing rate for ACOs that include these entities as ACO participants	Comments are sought on alternate options for establishing a payment preference with sliding scale for ACOs that include FQHCs or RHCs as ACO participants, including suggestions for the appropriate method to measure FQHC/RHC involvement and the appropriate level of incentives
Encouraging providers who serve a large portion of dual eligible beneficiaries to participate in the Shared Savings Program	None specified	Comments are sought on methods to provide preference to ACOs that serve a large dual-eligible population
Giving preference to ACOs who are participating in similar arrangements with other payers	None specified	Comments are sought on methods to provide preference to ACOs that have similar arrangements with other payers

Factor	Proposed Rule Policy for One-Sided Model	*Other Options Considered and On Which Comments Are Sought*
Withholding performance payments to offset future losses	Apply a flat 25 percent withholding rate annually to any earned performance payment. At the end of each agreement period, positive balances will be returned to the ACO. If the ACO does not complete its 3-year agreement, the ACO would forfeit any savings withheld.	None. Under the PGP demonstration, a flat 25 percent was withheld from annual earned performance payments
Performance payment limit on the total amount of shared savings that may be paid to an ACO. Such limit is required by Section 1899(d)(2)	Establish a payment limit at 7.5 percent of an ACO's benchmark for the first 2 years of the agreement under the one-sided model. In the 3rd year, the payment limit would be 10 percent, as proposed for the two-sided model. CMS notes that the shared savings might represent a higher proportion of Medicare payments to the ACO because the cap is based on a percentage of the ACO's benchmark, not its payments. For example, an ACO that does not include a hospital might realize a relatively higher proportion of shared savings as a percentage of its Medicare revenue	1) Set the limit at 5 percent of the ACO's Part A and Part B expenditure target, as in the PGP Demonstration 2) Adopt a higher limit, such as 10 or 15 percent 3) Vary the limit by the readiness of the ACO to take on greater responsibility and risk

The proposed waiver of the two percent net savings threshold (shown in the above table) is intended to recognize the challenges faced by smaller physician-driven ACOs and ACOs caring for underserved populations in accessing capital, coordinating care and creating the infrastructure necessary, and to encourage their successful participation in the Shared Savings Program. Qualifying ACOs must have less than 10,000 assigned beneficiaries and satisfy at least one of the criteria listed below:

i) The ACO is comprised only of ACO professionals in group practice arrangements or networks of individual practices of ACO professionals;
ii) 75 percent or more of the ACO's assigned beneficiaries reside in counties outside a Metropolitan Statistical Area (MSA) in the most recent year for which CMS has complete claims data;
iii) 50 percent or more of the ACO's assigned beneficiaries were assigned to the ACO on the basis of primary care services received from a Method II CAH;
iv) 50 percent or more of the beneficiaries assigned to the ACO had at least one encounter with an ACO participant FQHC and/or RHC in the most recent year for which CMS has complete claims data.

The additional shared savings for ACOs that include an FQHC and/or RHC within the structure of the ACO recognize the contributions of these entities in delivering comprehensive, high-quality primary health care to patients regardless of their ability to pay, and in increasing access to health care through innovative models of community-based care. CMS believes that incentives for ACOs to include FQHCs and RHCs also are indicated because these entities are unable to participate independently in the Shared Savings Program. Table 7 shows the percentage increase in the shared savings rate which an ACO can earn based on the number of Medicare FFS beneficiaries with one or more visits at the ACO's participant FQHC or RHC during the performance year.

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

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

The proposed rule defines FQHCs and RHCs as these terms are defined in §405.2401(b) of Medicare regulations. This definition encompasses FQHCs receiving grant support under section 330 of the Public Health Service Act as well as so-called FQHC look-a-likes and outpatient health programs/facilities operated by tribal organizations.

G. Two-Sided Model

CMS proposes a two-sided shared savings model using the authority of Section 1899(i). ACOs could elect the two-sided model for their initial agreement period to be eligible for higher sharing rates, but also would become accountable for losses. ACOs that initially elect the one-sided model would be reconciled annually for the first 2 years of the 3-year agreement using the one-sided model and automatically transitioned to the two-sided model for the third year of their agreement, and any agreement extensions would be available only under the two-sided model. CMS notes that the two-sided model would provide ACOs with greater incentives to achieve efficiencies and attain the program's transformative goals but also acknowledges the inherent risks from possible negative incentives to stint on care or undersupply services, shift costs (for instance through changes in referral patterns), or avoid high risk beneficiaries.

The proposed rule does not adopt additional beneficiary notification and protections, eligibility requirements, monitoring procedures, or quality performance measurement and scoring policies for ACOs participating under the two-sided model, but CMS invites comments on all of these issues.

The proposed rule states that although CMS is not adopting partial capitation models in this proposed rule, it will design and test such models in the Innovation Center in order to gain experience and refine them before adopting them more widely in the Shared Savings Program. Partial capitation is a model "… in which an ACO is at financial risk for some, but not all, of the items and services covered under Parts A and B, such as at risk for some or all physicians' services or all items and services under Part B."

The policies and methodologies established for the one-sided model, including beneficiary assignment and benchmark establishment and updating, would apply also to the two-sided model except as described in the table and discussion below. The two-sided model includes a proposed sharing rate of up to 60 percent (based on quality performance). Each of the 5 quality measure domains, discussed in section E above, would continue to be equally weighted. As discussed in section E, CMS proposes to apply a sliding scale for determining points earned for each measure under both the one-sided and two-sided models. Finally, as also discussed in section E, the quality performance standard for the first year of the Shared Savings Program will be set at full and accurate reporting.

ACOs participating in the two-sided model would be:

- subject to a fixed minimum savings rate of 2 percent, rather than a variable rate dependent on ACO enrollment as in the one-sided model, and a fixed minimum loss rate of 2 percent;
- able to share in gross savings on a first dollar basis once the MSR is exceeded; the final sharing rate (defined as the quality performance sharing rate and any additional increases for including FQHCs and/or RHCs) would be applied to an ACO's total savings that exceed its benchmark;
- eligible for increased savings for including FQHCs and/or RHCs as ACO participants at a percentage add-on that is double the amount available under the one-sided model and that is based on a sliding scale increase of up to 5 percentage points;
- responsible for a portion of the excess expenditures above the benchmark based on their quality performance and inclusion of FQHCs and/or RHCs;
- not responsible for repaying Medicare for excess expenditures within the minimum loss rate; and
- responsible for paying excess expenditures exceeding the minimum loss rate with excess expenditures calculated by multiplying the amount of excess above the benchmark by one minus the final sharing rate, as described below.

Table 8 of the proposed rule provides an overview comparison of the two models.

Table 8: Shared Savings Program Overview (reordered)

Design Element	One-Sided Model (performance years 1 & 2)	Two-Sided Model
Quality Scoring	Sharing rate up to 50 percent based on quality performance	Sharing rate up to 60 percent based on quality performance
FQHC/RHC Participation Incentives	Up to 2.5 percentage points	Up to 5 percentage points
Shared Savings	Savings shared once MSR is exceeded; unless exempted, share in savings net of a 2 percent threshold; up to 52.5 percent of net savings up to cap	Savings shared once MSR is exceeded, with no 2 percent threshold; up to 65 percent of gross savings up to cap
Maximum Sharing Rate	52.5 percent	65 percent
Minimum Savings Rate	Varies by population	Flat 2 percent regardless of size
Minimum Loss Rate	None	Flat 2 percent regardless of size
Maximum Sharing Cap	Payment capped at 7.5 percent of ACO's benchmark	Payments capped at 10 percent of ACO's benchmark
Shared Losses	None	First dollar shared losses once the minimum loss rate is exceeded. Cap on the amount of losses to be shared is phased in over three years starting at 5 percent in year 1; 7.5 percent in year 2; and 10 percent in year 3. Losses in excess of the annual cap would not be shared. Actual amount of shared losses would be based on final sharing rate that reflects ACO quality performance and any additional incentives for including FQHCs and/or RHCs using the following methodology (1 minus final sharing rate)

Calculating Sharing in Losses

Because the quality performance standard for the first year of the Shared Savings Program is set at full and accurate reporting, the shared loss rate in the first year for ACOs which meet this quality standard but do not qualify for increases based on FQHC/RHC participation will be 40 percent (one minus the savings rate of 60 percent). The shared loss rate can be as low as 35 percent if the ACO is eligible for the maximum quality and other adjustments to its savings rate (that is, 1 minus 65 percent). On the other hand, the shared loss rate could be much higher, as high as 100 percent, if an ACO scores poorly on the quality measures and does not receive any extra credit for involving FQHCs and/or RHCs.

ACOs would be responsible for paying the shared loss rate percentage of excess expenditures up to the annual loss cap, which is set as a percentage of the benchmark: 5 percent, 7.5 percent and 10 percent respectively across the first 3 years for Track 2 ACOs; an ACO in Track 1 who has entered the third year of its initial agreement period would be liable for an amount not to exceed the percentage of the first year of the two-sided model, or 5 percent.

The proposed rule includes an example of application of the shared loss rate. If an ACO's annual average per capita benchmark for assigned beneficiaries is $8,000, the maximum amount of losses for which it would be responsible in the first year is 5 percent of its benchmark, 7.5 percent the second year, and 10 percent the third year. Therefore, the ACO's maximum per capita liability could range from $400 to $800 per assigned beneficiary. Actual liability depends on the ACO's actual final sharing rate incorporating its quality performance and any increases for inclusion of FQHCs and/or RHCs. If the ACO had actual costs for its assigned beneficiaries of $8800, it would have a per capita loss of $800. The following table shows how much of the loss the ACO would be responsible to pay back under the program based on its final sharing rate, as determined by its quality performance and additional increases for FQHC/RHC participation.

Final Sharing Rate	Annual Per Capita Loss	First Year Cap (5% of benchmark)	Per Capita Payment Due CMS
40%	$800 times (1-0.4) = $480	$400	$400
50%	$800 times (1-0.5) = $400	$400	$400
60%	$800 times (1-0.6) = $320	$400	$320
65%	$800 times (1-0.65) = $280	$400	$280

Ensuring ACO Repayment of Shared Losses

CMS proposes that a flat 25 percent withholding rate be applied annually to an ACO's earned performance payment under the two-sided model, the same withhold that applies to the one-sided model. Noting that the 25 percent withhold

may be inadequate to cover the total amount of shared losses, particularly if a Track 2 ACO experiences losses in its first year, the proposed rule establishes several additional requirements. In general, an ACO must:

- establish a self-executing method for repaying losses to the Medicare program by indicating that funds may be recouped from Medicare payments to the ACO's participants, obtaining reinsurance, placing funds in escrow, obtaining surety bonds, establishing a line of credit as evidenced by a letter of credit that the Medicare program can draw upon, or establishing another repayment mechanism;
- demonstrate having established a repayment mechanism, using one or more of the recoupment methods, sufficient to ensure repayment of losses equal to at least 1 percent of per capita expenditures for its assigned beneficiaries from the most recent year available. CMS will determine the adequacy of an ACO's repayment mechanism prior to its entrance into a period of participation in the Shared Savings Program;
- submit documentation of such a repayment mechanism for CMS approval; an ACO applying for Track 1 also would be required to submit this documentation as part of its application since Track 1 ACOs will be required to transition to the two-sided model in the third year;
- certify the ACO's compliance with program requirements for the relevant performance period as well as the accuracy, completeness, and truthfulness of any information submitted to CMS by the ACO, or its ACO participants, or the ACO providers/suppliers, or another entity, including the accuracy, completeness, and truthfulness of TINs used to assign patients, any quality data or other information or data used to determine the ACO's eligibility for, and the amount of, the shared savings payment; and
- make payment in full to CMS of any shared losses within 30 days of receipt of notification.

CMS proposes to carry forward unpaid losses into subsequent performance years (to be recouped either against additional financial reserves, or by offsetting shared savings earned by the ACO). An ACO which experiences a net loss during its first 3-year agreement period may not reapply to participate in the Shared Savings Program.

CMS invites comments on these proposals and on other options or suggestions for assuring that any losses by ACOs participating in the two-sided model can be recouped, on the processes for recouping losses from these ACOs and/or their ACO participants, and on the appropriate amount of available funds a risk-bearing ACO should be required to have. It also seeks comment on whether any of its proposals for the two-sided model in particular, or the Shared Savings Program in general, would trigger the application of any State insurance laws, the adequacy of the provisions that it has set forth, and the ways that the agency can work with ACOs and States to minimize the burden of any additional regulation.

H. Monitoring and Termination of ACOs

CMS proposes to use methods developed for the Medicare Advantage and Medicare Prescription Drug program to monitor and assess ACOs and their participating providers and suppliers. Those include analysis of financial and quality data, site visits, assessment and investigation of beneficiary and provider complaints, and audits.

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

CMS requests comment on other actions that might be appropriate prior to termination.

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

CMS could inspect, evaluate and audit the ACO at any time if it determines that there is a reasonable possibility of fraud or similar fault. If CMS determines that the amount of shared savings or shared losses has been determined in error, then it reserves the right to reopen and revise the initial determination.

Monitoring avoidance of at-risk beneficiaries: CMS proposes to monitor ACOs to identify trends and patterns that suggest avoidance of at-risk beneficiaries and to determine the appropriate sanction, including termination. At-risk beneficiaries are defined as those who:

- have a high risk score on the CMS-HCC risk adjustment model;
- are considered high cost due to having two or more hospitalizations or ER visits each year;
- are dually eligible for Medicare and Medicaid;
- have a high utilization pattern;
- have one or more chronic conditions; or
- have a recent diagnosis, such as cancer, that is expected to result in high cost.

CMS seeks comment on this definition and whether other beneficiary characteristics should be considered.

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

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

The ACO would not receive shared savings payments while it is under such a CAP, regardless of the period of performance, and would not be eligible to earn shared savings during a period it is under the CAP. If CMS determines that the ACO continues to avoid at-risk beneficiaries, CMS would terminate it from the Shared Savings Program.

CMS solicits comments on whether lesser sanctions may be appropriate, such as cessation or reduction in the assignment of new beneficiaries, reduction in the amount of shared savings, or a fine.

Monitoring compliance with quality performance standards: CMS proposes to monitor compliance with quality performance standards by reviewing the ACO's submission of data and requesting additional documentation if appropriate. If an ACO fails to meet the minimum attainment level for one or more domains, CMS would give the ACA a warning and reevaluate it the next year. If it continues to underperform, it would be terminated. If the ACO fails to report, CMS would send a request for the required data. If the ACO fails to resubmit without a reasonable explanation, or exhibits a pattern of incomplete or inaccurate reporting, it may be terminated. An ACO would be disqualified from shared savings in any year in which it underperforms.

Terminating an ACO agreement: CMS proposes to terminate an ACO before the end of the three-year agreement for any of more than fifteen listed reasons, including the two statutory provisions noted above (avoidance of at-risk beneficiaries and failure to meet quality performance standards) as well as other types of failures and non-compliance with program requirements. In the event of minor violations, ACOs could submit a CAP. CMS would monitor performance during the CAP process. Failure to submit, obtain approval, implement, or demonstrate improved performance under, a CAP may result in termination.

CMS proposes that an ACO provide a 60-day notice if the ACO elects to terminate its agreement. The ACO must notify CMS, and all of its participants and providers/suppliers, who would in turn be required to notify beneficiaries in a timely manner.

Termination for any reason (by CMS or at the election of the ACO) would result in the loss of the mandatory 25 percent withhold of shared savings.

A terminated ACO may apply to participate in the Shared Savings program again at the end of the original three-year agreement period. It must demonstrate that it has corrected deficiencies, and has processes in place to remain in compliance. An ACO may only have one period with a one-sided model, so ACOs that seek to re-enter would have to pursue the two-sided model.

CMS seeks comments on its proposals for termination, including any additional conditions that could merit termination.

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

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

CMS proposes an administrative reconsideration review procedure for denials of initial applications or terminations for reasons other than those precluded from review by statute. If CMS denies an initial application (for a reason other than it not being submitted by the required deadline), or notifies an ACO of a termination, the ACO may, within 15 days, request reconsideration from a CMS reconsideration official. Reconsiderations are scheduled at the discretion of the review official. The burden of proof is on the ACO to demonstrate that the application denial or termination is not consistent with CMS regulations or statute. The ACO may not submit required documentation as evidence that was not previously submitted to CMS. Following review, the reconsideration official would issue a recommended decision.

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

This reconsideration review process does not apply in the case of an application denial or a termination due to a determination by a reviewing anti-trust agency, nor does it alter determinations made by other governmental entities.

CMS invites public comment on the appropriate review process for ACOs terminated for avoidance of at-risk beneficiaries or other reasons not exempted by statute.

I. Coordination with Other Agencies

CMS' proposed rule is accompanied by the simultaneous release of three other federal documents (which are reviewed in detail elsewhere in this summary):

- a joint CMS/OIG statement on Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center;
- an IRS Notice on tax guidance for tax-exempt organizations seeking to participate;
- a proposed Antitrust Policy Statement issued by the FTC and DOJ.

CMS notes that those commenting on its proposed rule may also wish to comment on these other documents.

Waivers of CMP, Anti-Kickback and Physician Self-Referral Laws (see separate summary later in this document): CMS and OIG have issued a notice with comment period to request public input on possible waivers for specified financial arrangements involving ACOs.

IRS Guidance Relating to Tax-Exempt Organizations (see separate summary later in this document): The IRS is soliciting public comment on whether its existing guidance relating to tax-exempt organizations is sufficient for those planning to participate in an ACO, and if not, what additional guidance is needed.

Antitrust Policy Statement (see separate summary later in this document): The FTC and DOJ have issued a proposed Antitrust Policy Statement applying to ACOs. It proposes an antitrust "Safety Zone" for certain ACOs if participants have a combined market share of 30 percent or less of each common service in each primary service area (PSA), and provides guidance for those with market share above 30 percent but less than 50 percent. In that situation, the ACO may either: request an expedited review by the Antitrust Agencies and submit a letter from the reviewing agency that it has no present intent to challenge the ACO; begin to operate and abide by a list of conduct restrictions that would reduce significantly the likelihood of antitrust investigation; or begin to operate without antitrust assurances. CMS will make public the information necessary to designate common services and to calculate the pertinent shares.

An ACO with a market share above 50 percent for any common service (unless it qualifies for a rural exception under the proposed Antitrust Statement) must submit to CMS a letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or recommend challenging the proposed ACO. In the absence of such a letter, CMS would not approve the application. CMS would also not approve an application if a reviewing Antitrust Agency determines that it is likely to challenge as anticompetitive any other ACO (including those below that 50 percent market share threshold).

The ACO must notify CMS of any material change in the composition of an ACO during a three-year agreement period and recalculate and report its market shares for common services. If any revised market share exceeds the 50 percent threshold, the ACO would be subject to mandatory review by the Antitrust Agencies. CMS would terminate the ACO if it fails to obtain a letter from the reviewing Antitrust Agency confirming that the agency has no intent to challenge the ACO.

J. Overlap with Other CMS Shared Savings Initiatives

CMS proposes to implement the statutory prohibition against duplication in participation with other shared savings initiatives by requiring that a Medicare enrolled-TIN may not participate in the Shared Savings Program if it participates in any of the following:

- Independence at Home Medicare Practice Demonstration Program (section 3024 of ACA);
- Medicare Health Care Quality Demonstration Programs (section 646 of the Medicare Modernization Act);
- Medicare medical home demonstrations with a shared savings element (currently the only such example is the multi-payer advanced primary care demonstration); or
- Physician Group Practice Transition Demonstration.

The prohibition applies only to shared savings under Medicare, and CMS notes that it is unlikely to apply to programs such as State initiatives to provide health homes for Medicaid enrollees with chronic conditions (section 2703 of the ACA) or community health teams to support patient-centered medical homes (section 3502 of the ACA).

CMS proposes that the prohibition against duplicate participation not be extended to individual providers and suppliers. More specifically, CMS proposes that an ACO provider or 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 the relevant Medicare-enrolled TINs do not participate in both programs.

Transition of the Physician Group Practice (PGP) Demonstration: PGP sites would be eligible to participate in the PGP demonstration or the Shared Savings Program, but not both. CMS proposes a condensed application form for PGP sites that wish to apply for participation in the Shared Savings Program.

Overlap with the CMMI Shared Savings Model: CMMI will be testing different ACO payment models, and CMS will coordinate to assure that there is no duplication of participation in shared savings programs.

CMS is seeking comments for how CMMI can best test different models that provide technical and financial assistance to groups that may wish to develop into an ACO.

III. Collection of Information Requirements

Under the statute authorizing the Shared Savings Program (section 3022 of the ACA), the information collection requirements in the proposed rule do not need to be reviewed by the Office of Management and Budget.

IV. Response to Comments

CMS will not respond to or acknowledge comments individually, but will consider all comments received by June 6, 2011 and respond to the comments in the preamble to subsequent documents.

V. Regulatory Impact Analysis

A. Introduction

CMS reviews the various requirements under federal law and Executive Orders for proposed regulations.

- Executive Order 12866 requires a Regulatory Impact Analysis (RIA), assessing costs and benefits in the case of major rules with economically significant impact ($100 million or more in any year). This rule has been designated an "economically" significant rule and includes a RIA.

- CMS has determined that the proposed rule does not include any mandate that would result in spending by State, local or tribal governments in the aggregate, or by the private sector above the threshold of $136 million in any one year under Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA), so the agency does not need to assess anticipated costs and benefits. CMS acknowledges that there will be costs borne by the private sector but participation in the program is voluntary and is not mandated.

- CMS does not believe the proposed rule imposes direct costs on State and local governments, preempts State law or otherwise has a Federalism implication.

B. Statement of Need

CMS solicits comments on the assumptions and analysis presented throughout the regulatory impact section.

The estimated net federal savings, costs and benefits are summarized below (Additional information is summarized in Section V.C., Anticipated Effects.) These estimates assume:

- 75 to 150 ACOs participating in the Shared Savings Program
- 1.5 to 4 million Medicare beneficiaries assigned to those ACOs

Net Federal Savings: The total aggregated median impact is $510 million in net Federal savings for CY 2012 through 2014 from implementation of the Shared Savings Program.

- The median estimate includes the net of : (1) reduced actual Medicare expenditures due to more efficient care; (2) shared savings payments to ACOs; and (3) payments to CMS for shared losses when actual expenditures exceed the benchmark.
- As the Shared Savings Program provisions become finalized and the actual number and characteristics of participating ACOs becomes known, the range of financial outcomes may differ substantially from the median estimate.

Table 1: Estimated Net Federal Savings in Millions, Years 1-3

Federal Savings	Year 1	Year 2	Year 3	Total
90th Percentile	$30	$90	$50	$170
Median	$100	$210	$200	$510
10th Percentile	$190	$380	$390	$960

Aggregate Costs For Start-up Investments and First Year Operations: Total estimates for ACOs (assuming 75-150) range from $131,683,825 to $263,287,650. These estimates are based on information from a Government Accountability Office (GAO) report (GAO-08-65) on the Physician Group Practice (PGP) demonstration.

Benefits For Beneficiaries: Improved health care delivery, quality of care and better communications.

C. Anticipated Effects

CMS acknowledges that this voluntary program could result in a wide range of possible outcomes for Medicare. For example:

- Some participating ACOs may choose to reconsider participation in year 3 because they failed to meet the expenditure growth targets in the prior years.

- ACOs in higher-cost areas of the country could terminate in the third year if they anticipate that the national growth formula, relative to their

local baseline cost, puts them in jeopardy of experiencing losses. CMS will update ACO benchmarks by the estimated annual increase in the absolute amount of national average Medicare Part A and Part B expenditures, expressed as a flat dollar amount for each year (Section 2899(d) of the Act). Updates to ACO benchmarks in percentage terms will be higher in low-cost areas of the country and lower in high-cost areas. This could contribute to selective program participation by ACOs favored by the national flat-dollar growth target.

- Many potential ACOs might need more than 3 years to achieve comprehensive efficiency gains and acknowledge challenges associated with development of comprehensive efficiency gains.

The CMS Office of the Actuary prepared a stochastic model that incorporates assumed probability distribution for each key variable that will affect the overall financial impact of the Shared Savings Program. A Monte Carlo simulation approach was used and the process was repeated for a total of 5000 random trials tabulating the resulting individual cost or savings estimates. Approximately 97 percent of the stochastic trials resulted in a net savings and 3 percent produced a net cost.

Assumptions modeled included:

- Number of participating ACO provider groups
- Size mix of participating ACOs
- Type of ACO that would consider risk under the two-sided risk option
- Participating ACOs' current level of integration
- Baseline per-capita costs for prospective ACOs, relative to national average
- Number and profile of providers and suppliers unavailable to participate in the program due to participation in ACO models tested by CMMI
- Range of savings for participating ACOS within the first 3 years of the program
- Local variation in expected claims cost growth relative to the national average
- Quality reporting scores and resulting attained sharing (or loss) percentages

The model also assumed:

- 1.5 to 4 million Medicare beneficiaries
- ACOs more likely to participate from markets with baseline per-capita FFS expenditures above the national average
- The level of savings generated by an ACO positively correlate to the achieved quality performance score and resulting sharing percentage

CMS notes the high degree of variability observed for local per-capita cost growth rates relative to the national average ”flat dollar” growth used to update ACO benchmarks.

The analysis does not include the impact that the Shared Savings Program will have on revenues from Part B beneficiary premiums or adjustments to MA payment rates.

For the first year, 2012, the median projection indicates a $100 million savings, primarily because the ACO cost-efficiency initiatives are generally not assumed to have matured, but provider groups could benefit from random claim fluctuations or from low baseline expenditures relative to the national average and receive shared savings payments.

By 2013 and 2014, the median estimates reflect increased cost-savings effectiveness offset in part by shared savings due to random variation, variation in accuracy of updated national targets compared to actual local growth and transition to two-sided risk in the third year. Projections cover a wider range of possible outcomes.

The impact analysis is only for the first 3-year agreement period.

Impact on Beneficiaries
Important aspects cited that benefit beneficiaries and support improved beneficiary care are:

- The program does not affect the beneficiary’s freedom of choice regarding providers or care.

- The ACO requirement of reporting quality measures and patient-experience surveys which contribute to successful performance.

- The program will include monitoring and auditing processes to protect beneficiary choice and ensure beneficiaries receive appropriate care.

- The Medicare PGP Demonstration shows that measuring quality and providing incentives can result in redesigned care processes which improve patient care processes and outcomes.

Impact on Providers and Suppliers
CMS solicits comments on the issue of costs and benefits of establishing and maintaining an ACO including total ACO expenditures for start-up investment and annual operating costs for the 3 years of the Shared Savings Program.

While provider and supplier participation in the Shared Savings Program will be voluntary, CMS examined the potential costs of program participation. The

proposed rule allows for flexibility of the ACO-specific structure and CMS expects costs to vary greatly.

CMS used information from the GAO to demonstrate that the expected range of investment varies greatly across ACOs and to provide the potential scope of investment. CMS expects the PGP-related costs may be a subset of the investment required for an ACO.

CMS estimates are summarized below. Given that percentiles for bonuses, penalties, and net impacts are independently calculated, they are not additive across the three parameters.

Total Average Start-up Investment and First Year Operating Expenditures

- Rough estimate of $1,755,251 for a participant in the Shared Savings Program.
- Assuming a range of expected ACO participation at 75 to 150 yields an estimated aggregate cost for start up and first year operating expenditures in the range of $131,643,825 to $263,287,650.

Financial Reward

- The estimated bonuses paid are a median of $800 million over 3 years, with $560 million and $1,130 million reflecting the 10^{th} and 90^{th} percentiles.

Financial Penalty

- The estimated penalties paid are a median of $40 million over 3 years, with $10 million and $80 million reflecting the 10^{th} and 90^{th} percentiles.

D. Alternatives Considered

Many tenets of the program are statutorily mandated and allow for limited, if any, flexibility. When there was flexibility, decisions regarding alternatives were based on a balance between creating the least possible negative impact on the stakeholders and on fitting the vision of the program within given operational constraints.

CMS solicits comments on other potentially effective and reasonably feasible alternatives that reduce burdens and maintain flexibility and freedom of choice.

For example, ACA mandates an ACO be large enough to care for a minimum of 5,000 assigned beneficiaries, and CMS is proposing a sliding minimum percentage and confidence interval for the savings threshold based on the size of an ACO.

Other examples included adjustments to an ACO's benchmark for changes in FFS price adjustments, the method for constructing a participating ACO's benchmark, and the method for establishing quality standards.

E. Accounting Statement and Table

CMS provides the required Accounting Statement of Costs and Savings

F. Conclusion

The median estimate of the financial impact from implementation of the Shared Savings Program for CY 2012 through 2014 is a net savings of $510 million. This is the "best estimate" for the 3 year financial impact. The 10th and 90th percentiles of the estimate distribution show net savings of $960 million and $170 million, respectively, suggesting a 10-percent likelihood that the actual impact would exceed the respective percentile amounts. In the extreme scenarios, the results were as large as $1,960 million in savings or $270 million in costs.

The estimated aggregate cost for ACO start-up investment and first year operating expenditures range from $131,643,825 to $263,287,650 based on assuming 75 to 150 participating ACOs.

CMS/OIG Notice with Comment Period Relating to Waiver Designs in Connection with the Medicare Shared Savings Program and the Center for Medicare and Medicaid Innovation

I. Background

On March 31, 2011, the Centers for Medicare & Medicaid Services (CMS) and the Office of the Inspector General (OIG) of the Department of Health and Human Services released a notice relating to possible waivers of the physician self-referral law, the federal anti-kickback statute, and civil money penalties that prohibit hospital payments to physicians to reduce or limit services in connection with the Medicare Shared Savings Program and the Center for Medicare and Medicaid Innovation (CMMI or Innovation Center), to be published in the April 7, 2011 issue of the *Federal Register* with a comment period ending June 6, 2011.

CMS and OIG state as their goal the application of fraud and abuse laws in a manner that does not unduly impede development of beneficial ACOs but that also ensures that ACO arrangements are not misused for fraudulent or abusive purposes that harm patients or Federal health care programs. CMS and OIG expect to issue waivers concurrently with the publication of the CMS final rule for the Medicare Shared Savings Program (MSSP) in part due to likely modifications in that final rule that will impact the scope of waivers. CMS and OIG indicate that each agency will review pertinent comments the other agency receives in developing final guidance and regulations.

The waiver authority provided under the MSSP applies only with respect to ACOs participating under the MSSP, but OIG notes it may consider other waiver authority provided under the Affordable Care Act at a later date for ACOs under other programs (such as Medicaid pediatric ACOs or ACOs under demonstrations or pilot projects of the CMMI), other integrated-care delivery models, or other financial arrangements. CMS and OIG also note that there are current exceptions and safe harbors under the fraud and abuse laws that may apply to ACOs. The agencies also underscore that proposed waivers for ACOs under the MSSP do not apply to other provisions of Federal or State law not specifically waived, and remind potential applicants that financial arrangements not covered by a waiver must meet existing requirements under law. The agencies seek consistency across fraud and abuse laws when possible and will provide uniform application of waivers to all qualified ACOs, ACO participants, and ACO providers and suppliers under the MSSP. The agencies also note that waivers apply only insofar as an ACO enters into an agreement with CMS to participate in the MSSP and complies with the terms and conditions of the agreement, the statute, and implementing regulations.

II. Proposed Waivers

Physician Self-Referral law

CMS proposes to waive under the MSSP limitations on physician self-referral *only with respect to distribution of shared savings received from CMS under the MSSP* as follows:

- Distributions to or among ACO participants, ACO providers and suppliers, and individuals and entities who are ACO participants, ACO providers and suppliers for the year when savings are earned; or
- Distributions for activities necessary AND directly related to ACO participation and operation under the program.

All other financial relationships involving physicians must satisfy an existing Stark exception (e.g. fair market value, personal services, or indirect compensation). CMS' stated intention is to protect financial relationships created by the distribution of shared savings both within and outside an ACO; however, with respect to distributions outside the ACO, those distributions must closely relate to ACO statutory requirements. CMS notes the waiver will only protect shared savings distributions for referring physicians outside the ACO if those physicians are paid using funds from the shared savings and paid for activities necessary for and directly related to ACO participation in and operations under the MSSP.

Federal Anti-Kickback statute

OIG proposes to waive the federal anti-kickback statute for distribution of shared savings received from CMS under the MSSP (consistent with the requirements for a waiver of the physician self-referral law proposed by CMS described above) and for a financial relationship covered under an existing exception to the physician self-referral law.

Ordinarily, compliance with an exception to the physician self-referral law does not immunize a physician from anti-kickback concerns, but under this waiver OIG would afford that protection because of the specific safeguards of the MSSP. Thus a financial arrangement that implicates the physician self-referral law among ACO participants, providers and suppliers will qualify for a waiver of the federal anti-kickback statute if the arrangement is necessary and directly related to ACO participation and operation under the MSSP and if it fits squarely within a physician self-referral law exception.

OIG notes that failure to qualify for a proposed waiver does not mean the arrangement is automatically illegal under anti-kickback rules, but the financial arrangement must comply with the law and the OIG would likely also review it under the physician self-referral law for a possible violation.

Civil Money Penalties that Prohibit Hospital Payments to Physicians to Reduce or Limit Services (Gainsharing CMP)

Consistent with the OIG proposed waiver for the federal anti-kickback statute described above, OIG proposes to waive application of the gainsharing CMP for distribution of shared savings and for financial relationships covered under an existing exception to the physician self-referral law. With respect to the proposed waiver for distribution of shared savings received by an ACO from CMS, those distributions made from a hospital to a physician are protected if—

- The payments are not knowingly made to induce the physician to reduce or limit medically necessary items and services; and
- The hospital and the physician are (or were) ACO participants, or ACO provider/suppliers during the year in which shared savings were earned.

Duration of Waivers

A waiver related to distributions of shared savings would apply to distributions earned during the term of the agreement even if the distribution occurs after the expiration of that agreement. A waiver in compliance with a physician self-referral exception would apply during the term of the ACO's agreement to participate in the MSSP.

III. Public Comment on Additional Waiver Design Considerations

CMS and OIG generally seek comments on waivers for financial arrangements necessary to carry out the MSSP; comments must explain how waivers or waiver modifications or additions for financial arrangements would be necessary to carry out the MSSP and why those financial arrangements would not qualify for existing safe harbors or exceptions. Specific topics for comment include the following:

- Arrangements establishing ACOs: whether it is necessary to waive some or all laws for 1) ACO formation, 2) ACO governance and administrative requirements, or 3) building technological or administrative capacity (including training) to achieve quality and cost goals.
- Arrangements for ongoing operation of ACOs: whether these laws should be waived for financial arrangements (in addition to arrangements for distribution of shared savings) among ACO participants, providers and suppliers that are necessary for and directly related to 1) operating the ACO or 2) achieving integrated care, costs savings, and quality goals.
- Arrangements between ACOs and outside individuals and entities: whether the laws should be waived for financial arrangements that are necessary for and directly related to 1) establishing the ACO or 2) achieving integrated care, costs savings, and quality goals.
- Distribution of shared savings/similar payments from private payers: whether such a waiver is necessary and advisable, and the suggested scope and design of the waiver.

- Scope of proposed waivers: whether the scope is too broad or narrow, and if so how to address that issue, and whether the standard that activities be “necessary and directly related to” ACO participation and operation is appropriate.
- Two-sided risk model: whether there should be a different or additional fraud and abuse waiver for ACOs under the two-sided risk model, including comments on relative risk of over or under utilization and of increased costs or stinting from the downside risk feature of two-sided risk.
- Electronic health records—whether a waiver should be provided under the program after the current exception and safe harbor sunset in 2013.
- Beneficiary inducements—whether there is a need for the OIG to waive the prohibition on beneficiary inducements in connection with the MSSP.

CMS and OIG also seek comment on the best exercise of the waiver authority granted to the Center for Medicare and Medicaid Innovation for demonstrations and pilots it operates.

Comments are due by June 6, 2011, and should include a reference to file code CMS-1345-NC2. Comments may be delivered electronically at http://www.regulations.gov (commenters should follow the "Submit a comment" instructions).
Comments may also be delivered by regular mail to the following address:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1345-NC2,
P.O. Box 8013,
Baltimore, MD 21244-8013.

FTC/DOJ Notice with Comment Period of Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program

I. Background

On March 31, 2011, the Federal Trade Commission (FTC) and the Department of Justice (DOJ) (hereinafter "the Agencies") released a notice Policy Statement proposing an enforcement policy on the application of antitrust laws to healthcare collaborations among otherwise independent providers and provider groups seeking to participate or participating as an accountable care organization (ACO) under the Medicare Shared Savings Program (MSSP) with a comment period ending May 31, 2011 (which is earlier than the deadline for comments on the CMS proposed rule and the CMS/OIG notice for waiver designs).

The Agencies note that eligibility criteria applicable to an ACO established under the CMS proposed rule to implement the MSSP are consistent with clinical integration indicia the Agencies apply under the Health Care Statements used to evaluate collaborations among providers. The Agencies determined that an ACO that meets the CMS eligibility criteria is likely to be a bona fide arrangement, and if it applies the same arrangements in the commercial market, its integration criteria are sufficiently rigorous so that joint negotiations with private-sector payers will be treated as subordinate and reasonably related to the ACO's primary purposes of improving health care services. The Agencies appeared reassured by the extensive monitoring by CMS of an ACO's cost, utilization and quality metrics under the MSSP.

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

The Agencies also note that the Policy Statement does not apply to collaborations formed before the date of the enactment of the Affordable Care Act (ACA) nor does it apply to ACOs created through mergers.

II. Analysis Used for ACOs Meeting CMS Eligibility Criteria

The Agencies will evaluate an ACO's share of services in each ACO participant's Primary Service Area (PSA) noting that a higher ACO share of the services within the PSA indicates a greater risk the ACO will be anticompetitive, absent

competing ACOs or sufficient unaffiliated providers and physicians. A PSA is the lowest number of contiguous postal zip codes from which an ACO participant draws at least 75 percent of its patients for the service involved. The Agencies establish three tiers to evaluate ACOs based on the combined share for each common service within PSAs, as follows:

- ACOs with combined shares of 30 percent or less (antitrust safety zone).
- ACOs with combined share of greater than 30 but not more than 50 percent (voluntary expedited review).
- ACOs with combined shares of greater than 50 percent (mandatory expedited review).

Common services are described as services provided by two or more ACO participants to patients within a PSA. For example, should two physician group practices form an ACO and each includes cardiologists and oncologists, cardiology and oncology would be common services.

Antitrust safety zone

ACOs within the antitrust safety zone are highly unlikely to raise significant competitive concerns, and the Agencies will not challenge them absent extraordinary circumstances. Thus no initial review by the Agencies is required, and the ACO is under no obligation to contact the Agencies. To qualify for treatment in the antitrust safety zone, any hospital or ambulatory surgery center in the ACO must be non-exclusive. There are special rules for ACOs in rural areas such that an ACO may include, on a non-exclusive basis, one physician per specialty, and critical access hospitals and sole community hospitals, from each rural county even if including the physician or hospital causes the ACO's share of common services to exceed 30 percent in any ACO participant's PSA. Additionally, if an ACO includes a participant with more than a 50 percent share in its PSA of any service that no other ACO participant provides to patients in that PSA (referred to as a dominant provider), that participant must be non-exclusive to the ACO.

ACOs Outside the Safety Zone but Not Above the 50 Percent PSA Share Threshold

While an ACO that falls under this tier may be procompetitive, it is not clear whether it will provide the benefits intended under the MSSP (high quality, cost effective care) or whether it will reduce consumer choice and value and increase price. Thus the Agencies caution that if it appears that an ACO's formation or conduct appears to be anticompetitive, the Agencies may investigate. While the ACO is not under a legal obligation to seek expedited review from the Agencies, it may do so. The Agencies have committed to completing each expedited review within 90 days.

For ACOs under this tier that do not elect to seek expedited review, the Agencies provide antitrust guidance that identifies five types of conduct the ACO should avoid to reduce the likelihood of an antitrust investigation, as follows:

1. Preventing or discouraging commercial payers from directing or incentivizing patients to choose certain providers through anti-steering, guaranteed inclusion, product participation, price parity or similar contract provisions.
2. Tying sales of ACO services to the commercial payer's purchase of other services from providers outside the ACO and vice versa.
3. Contracting on an exclusive basis with other ACO physician specialists, hospitals, ASCs, or other providers (note this does not apply to primary care physicians).
4. Restricting a commercial payer's ability to make cost, quality, efficiency, and performance information available to its enrollees for evaluation and selection of providers if that information is similar to the measures used under the MSSP.
5. Sharing among ACO provider participants sensitive price or other data that could be used to set prices or other terms for services provided outside the ACO.

ACOs Exceeding 50 Percent PSA Share Threshold

Unless it can qualify under the rural exception described above, an ACO with a PSA share of more than 50 percent may not participate under the MSSP unless after an expedited review, the applicable reviewing Agency indicates in writing that it has no present intention to challenge or recommend challenging the ACO under the antitrust laws.

While the 50 percent PSA share threshold indicates potential for competitive harm, the Agencies will consider any information that may indicate that the PSA shares may not reflect likely market share and information indicating substantial procompetitive effects. ACOs subject to expedited review must submit substantial documentation and information to the reviewing Agency, including the application to CMS; documents indicating the ability of ACO participants to compete; business strategies and plans to compete in the commercial and Medicare markets; ACO formation, if any, after enactment of the ACA; and information on PSA share calculation for each common service, restrictions on exchange of information on charges to commercial payers among ACO participants, the five largest commercial health plans/payers for ACO services, and the identity of other ACOs providing services in the PSA.

CMS will not approve any ACO under the MSSP that received a letter indicating the reviewing Agency is likely to challenge or recommend challenging the ACO if it proceeds. The Agencies note that, if approved, the ACO is well advised to follow the antitrust guidance on the five types of conduct to avoid (described above) to reduce the likelihood of antitrust concerns.

Calculation of PSA Shares

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

a. Identify each service provided by at least two independent ACO participants.

   A service is—

   i. For physicians, the physician primary specialty,
   ii. For inpatient facilities, a major diagnostic category, and
   iii. For outpatient facilities, an outpatient category as defined by CMS.

b. Identify the PSA for each common service for each participant in the ACO.
c. Calculate the ACO's PSA share for each common service in each PSA in which at least two participants serve patients for that service during the most recent calendar year for which data are available.
   i. For physicians services, the ACO's share of Medicare fee-for-service (FFS) allowed charges,
   ii. For inpatient services, the ACO's share of state-level all-payer hospital discharge data; for states without all-payer hospital discharge data, the ACO's share of Medicare FFS payments during the most recent federal fiscal year for which data are available, and
   iii. For outpatient services, the ACO's share of Medicare FFS payments.

III. Request for Comments

The Agencies seek comments as follows:

- Generally, whether the guidance in the proposed enforcement policy should be changed and why.
- With respect to the determination of PSA share, whether there are other sources of data in the case of physicians services rarely used by Medicare beneficiaries and in the case of inpatient hospital services in states where all-payer discharge data are not available.
- Whether the documents requested for an expedited review present an undue burden on ACO applicants.

Comments are due by May 31, 2011, and may be submitted electronically using the following link https://ftcpublic.commentworks.com/ftc/acoenforcementpolicy; or in paper form at the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex W), 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Comments should include the statement "Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program, Matter V100017" in the text and, for comments submitted by mail, also on the envelope.

IV. Paperwork Reduction Act

Though the MSSP is exempt from the Paperwork Reduction Act, the Agencies seek comment on the utility and burden associated with information required to be submitted for purposes of expedited review. The Agencies estimate that roughly 150 to 400 ACOs may be covered by the Policy Statement, and of that number perhaps 200 may submit requests for expedited review. The Agencies further estimate an average of 30 to 50 hours per applicant to gather and review the requisite information incurring labor costs ranging from $13,800 to $23,000. Annual capital and other non-labor costs are estimated to be minimal.

IRS Notice Considering Application of the Provisions of the Internal Revenue Code Governing Tax-Exempt Organizations to Hospitals or Other Health Care Organizations Recognized as 501(c)(3) Organizations Participating in the Medicare Shared Savings Program

I. Background

On March 31, 2011, the Internal Revenue Service (IRS) released a notice soliciting comments on the need for additional tax guidance for tax-exempt organizations, including tax-exempt hospitals, participating in the Medicare Shared Savings Program (MSSP). The IRS also solicits comments on the need for guidance regarding the tax implications for tax-exempt organizations participating in activities unrelated to the MSSP, including shared savings arrangements with commercial health insurance payers, through accountable care organizations (ACOs). The comment period ends May 31, 2011, which is earlier than the deadline for comments on the CMS proposed rule and the CMS/OIG notice for waiver designs.

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

Prohibited Inurement or Impermissible Private Benefit

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

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

Tax on Unrelated Business Income

The IRS notes that whether the MSSP payments will be subject to tax on unrelated business income depends on whether the activities generating the MSSP payments are substantially related to the exercise or performance of the

tax-exempt organization's charitable purposes that is the basis for its exemption under §501 of the Internal Revenue Code. Under Treasury regulations, the term charitable includes activities that lessen the burden of the government, and under IRS Revenue Rulings, the promotion of health is recognized as a charitable purpose. The IRS expects that, absent prohibited inurement or impermissible private benefit, any MSSP payments received by a tax-exempt organization from an ACO would derive from activities that are substantially related to the performance of the charitable purpose of lessening the burdens of government (the governmental burden being its responsibilities under the Medicare program) as long as the ACO meets all of the eligibility requirements established by CMS for participation in the MSSP.

The IRS solicits comment on the need for additional guidance for participation of a tax-exempt organization under the MSSP through ACOs, specifically with respect to the additional criteria or guidance needed to analyze whether that participation is consistent with tax-exempt status and whether the organization is receiving unrelated business income.

III. ACO Conduct of Activities Unrelated to the MSSP

Insofar as an ACO conducts activities unrelated to the MSSP, for example operating under shared savings arrangements with other types of health insurance payers, these types of activities are not charitable in nature regardless of whether the agreement is related to a program intended to achieve cost savings in health care delivery. The IRS does recognize that certain non-MSSP activities may further or be substantially related to an exempt purpose (such as a shared savings arrangement under the Medicaid program); *the IRS seeks comments on what guidance is necessary or appropriate for a tax-exempt organization's participation in non-MSSP activities.*

In particular, the IRS seeks comments describing the activities a tax-exempt organization might expect to participate in through an ACO and address under what rationale participation in such non-MSSP activities might further an exempt purpose and also what criteria, requirements, and safeguards would ensure the furtherance of such an exempt purpose, including how a participating tax-exempt organization will ensure that non-MSSP activities further an exempt purpose in the absence of safeguards similar to those present in the MSSP.

The IRS notes that comments on this issue should take into account the following principles under existing law:

1. Not every activity that promotes health supports a tax exemption.
2. If a tax-exempt organization is a partner (or member, in the case of an LLC) of an ACO treated as a partnership for federal tax purposes, the ACO's activities will be attributed to the tax-exempt organization for purposes of determining both whether the organization operates

exclusively for exempt purposes and whether it is engaged in an unrelated trade or business.

Comments are due by May 31, 2011 at the following address: Internal Revenue Service, SE:T:EO:RA:G (Notice 2011-20), P.O. Box 7604, Ben Franklin Station, Washington, DC 20044