Jackson Walker Health e-Brief

Accountable Care Organizations: Summary of CMS Proposed Rule

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I. INTRODUCTION

On March 31, 2011, the Centers for Medicare and Medicaid Services ("***CMS***") released the much anticipated proposed rule (the "***Proposed Rule***") which provides guidance regarding the formation and operation of Accountable Care Organizations ("***ACOs***"). Specifically, the Proposed Rule implements Sections 3022 and 10307 of the Affordable Care Act (the "***Act***") which required the Secretary of Health and Human Services (the "***Secretary***") to establish the Medicare Shared Saving Program ("***MSSP***"), intended to encourage the development of ACOs. The MSSP is a program which: (i) promotes accountability for a defined patient population and coordinates the delivery of items and services under Medicare Parts A and B; (ii) encourages investment in infrastructure; and (iii) redesigns care processes for high quality and efficient service delivery.

Under the provisions outlined in the Proposed Rule, providers and suppliers that participate in the MSSP can continue to receive traditional Medicare fee-for-service ("***Medicare FFS***") payments under Parts A and B, and also be eligible for additional payments based on meeting specified quality and saving requirements.

Related Proposals Issued by Other Agencies

Several other federal agencies simultaneously released proposals in connection with ACOs, all of which are discussed in detail in this e-Brief. These additional proposals include:

(i) a notice and request for comments released jointly by CMS and the U.S. Department of Health and Human Services Office of Inspector General ("***OIG***"), regarding possible waivers of application of the Stark law, the federal Anti-Kickback Statute, and certain civil monetary penalty law provisions to specified arrangements involving ACOs under the MSSP (the "***OIG Proposal***");

(ii) joint guidance from the U.S. Department of Justice ("***DOJ***") and Federal Trade Commission ("***FTC***") entitled a "Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program" which contemplates the concept of creating a "Safety Zone" for ACOs participating in the MSSP (the "***Policy Statement***"); and

(iii) a notice and solicitation of comments from the Internal Revenue Service ("***IRS***") related to tax-exempt organizations ("***IRS Proposal***").

Overview and Intent of MSSP

The Proposed Rule states that the MSSP creates a new way to deliver healthcare services, and is meant to achieve the following three goals:

(i) Better care for individuals. Specifically, the Proposed Rule indicates that this will include care that is based on the following six dimensions of quality: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity.

(ii) Better health for populations. Better health for populations is to be achieved by educating beneficiaries about the causes of ill health, including poor nutrition, physical inactivity, substance abuse and economic disparities. Further, the hope is that the ACO model will lead to more preventative care including, but not limited to, annual physicals and flu shots.

(iii) Lower growth in expenditures. CMS hopes that incentives of shared savings will encourage ACOs to eliminate waste and inefficiencies while not withholding any needed care from beneficiaries.

In this vein, CMS states that those entities that decide to become ACOs should aim to meet certain goals including: (i) putting the beneficiary and his or her family at the center of all its activities; (ii) ensuring coordination of care for beneficiaries regardless of time or place; (iii) paying special attention to care transition, especially as beneficiaries journey from one part of the healthcare system to another; (iv) managing resources carefully and respectfully; (v) being proactive in reaching out to patients with reminders and advice that can help them stay healthy and let them know when it is time for a check up or test; (vi) collecting, evaluating, and using data on healthcare process and outcomes to measure what it achieves for beneficiaries and communities overtime; and (vii) continually investing in the development and pride of its own workforce by maintaining and executing plans for helping build skill, knowledge, and teamwork.

Two ACO Models

Perhaps the biggest revelation in the Proposed Rule is the introduction of two financial models for ACOs to achieve shared saving under the MSSP. The two models are the shared saving model (the "***One-Sided Model***") and a shared savings/losses model (the "***Two-Sided Model***"). These models are discussed in greater detail in Section VII, but essentially, the One-Sided Model allows an ACO to benefit from the savings it generates, but not be penalized for having expenditures in excess of the benchmarked amounts. The Two-Sided Model also allows ACOs to benefit from the savings they generate, but holds ACOs accountable for expenditures in excess of the "benchmarks" by requiring the ACO to repay a share of the losses to CMS.

ACOs opting for the Two-Sided Model will immediately be rewarded with higher sharing rates. However, CMS states that the One-Sided Model may allow ACOs to gain much needed experience before transitioning to the Two-Sided Model, where it will be at greater risk for losing money. Regardless, the Proposed Rule indicates that all ACOs will be transitioned to the Two-Sided Model in the third year of their initial three (3) year commitment to the ACO Program. This mandatory transition is likely the second biggest revelation in the Proposed Rule.

In light of the financial risk, potential providers will have to determine if the ACO is the right vehicle for them. Entities must calculate if the potential shared savings available under the MSSP justifies the investment in infrastructure and the potential losses associated with the Two-Sided Model.

The deadline for submitting comments to CMS in connection with the Proposed Rule and the OIG Proposal is 5pm on June 6, 2011. The deadline for submitting comments in connection with both the Policy Statement and IRS Proposal is May 31, 2011.

II. ELIGIBILITY AND FORMATION

Definitions. The Act provided the definition of ACO Professional and the Proposed Rule provides new definitions for an ACO, an ACO Participant, and an ACO Provider/Supplier. These definitions are provided below:

- ***Accountable Care Organization*** means a legal entity that is recognized and authorized under applicable State law, as identified by a Taxpayer Identification Number ("***TIN***"), and comprised of an eligible group of ACO participants that work together to manage and coordinate care for Medicare FFS beneficiaries, and which has established a mechanism for shared governance that provides all ACO participants with an appropriate proportionate control over the ACO's decision making process.
- ***ACO Participant*** means a Medicare-enrolled provider of services and/or a supplier as indentified by a TIN, and that participates in an ACO.
- ***ACO Professional*** means a doctor of medicine or osteopathy or a "practitioner," which includes physician assistants, nurse practitioners, clinical nurse specialists, and several other primary care practitioners.
- ***ACO Provider/Supplier*** means 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.

A. Eligible ACO Participants

It is important to note that there is a distinction between the types of providers and suppliers that are eligible to form an ACO and those providers and suppliers that can participate as members of an ACO (*i.e.*, ACO Participants). In other words, many entities that are ACO Participants will not have the ability to form an ACO themselves, but will have the option of being a part of an ACO. Independent diagnostic testing facilities, for example, could be an ACO Participant, but could not form an ACO.

More specifically, the Act states that the following groups of providers and suppliers which have established a mechanism for "shared governance" are eligible to form ACOs: (i) ACO Professionals in group practices; (ii) networks of individual practices of ACO Professionals; (iii) partnerships or joint ventures between hospitals and ACO Professionals; (iv) hospitals employing ACO Professionals; and (v) other forms that the Secretary of Health and Human Services may deem appropriate. The Act also states that all ACOs must include primary care ACO professionals that are sufficient for the number of Medicare FFS beneficiaries assigned to the ACO and that at a minimum, the ACO shall have at least 5,000 beneficiaries assigned to it in order to be eligible to participate in the MSSP.

As a result, in order for one of the four categories of providers and suppliers identified by the Act to form an ACO, it will still be required to meet the additional criteria outlined by the Act to form an ACO including but not limited to: (i) meeting the shared governance requirements; and

(ii) having enough primary care ACO Professionals participating to have 5,000 beneficiaries assigned to the ACO.

Expanding the Number of Eligible ACO Participants

Using the authority granted by the Act, the Secretary explored the possibility of expanding the list of providers and suppliers who would be eligible to form an ACO. After much deliberation, the Secretary did decide to add Critical Access Hospitals that submit bills for both the facility and the professional services to its Medicare fiscal intermediary or its Medicare Part A/B MAC (referred to as method II) ("***Method II CAHs***") to the list of entities able to form ACOs.

Although Method II CAHs are the only entity that was specifically added to the list of entities eligible to form ACOs, the Proposed Rule states that the four statutory identified groups, as well as Method II CAHs, could establish an ACO with broader collaborations by including additional Medicare-enrolled entities such as FQHCs and RHCs and other Medicare-enrolled providers and suppliers as ACO Participants.

The Role of FQHCs and RHCs

The Secretary considered adding FQHCs and RHCs as entities eligible to form an ACO, but ultimately decided against this because of the information submitted by these entities when they bill claims. Under the Proposed Rule, and as discussed in more detail in Section IV, the assignment methodology chosen by CMS to assign beneficiaries to a particular ACO requires data that identifies: (i) the precise services rendered (that is, primary care HCPCS codes); (ii) the type of practitioner providing the service (that is, a MD/DO as opposed to NP, PA, or clinical nurse specialist); and (iii) and the physician specialty. However, FQHCs and RHCs do not report all of this data when they file claims with Medicare. For example, FQHCs do not report HCPCS codes with each claim billed and RHCs claims do not report HCPCS codes or the type of professional that provided the service.

Thus, in the absence of the data elements required for assignment of beneficiaries, CMS felt it was not possible for FQHCs and RHCs to participate in the MSSP by forming their own ACOs. Nevertheless, the Proposed Rule states that it will be possible for FQHCs and RHCs to join an ACO as an ACO Participant. In such case, the assignment of beneficiaries to ACOs in which FQHCs and RHCs are participating would have to be based solely on the data from other eligible ACO Professionals upon whom assignment can be based. Moreover, the Proposed Rule leaves the door open to allowing FQHCs and RHCs to form ACOs in the future stating that CMS may re-evaluate its position should it find a way to collect the requisite data from the organizations

CMS believes that by allowing the four providers and suppliers identified by the Act, and Method II CAHS to form ACOs while allowing other entities such as FQHC and RHC to act as ACO Participants, there will be more potential ACO configurations available to those desiring to form an ACO. Further, CMS believes by incorporating a broad range of health care providers and suppliers, including safety net suppliers such as FQHCs, RHCs, and Method II CAHs, ACOs will be able to offer more comprehensive care and better serve the needs of rural communities.

B. Reporting Requirements for ACO Professionals

The Proposed Rule provides that entities applying to participate in the MSSP must not only identify the TINs of the ACO and ACO Participants, but also list the national provider identifiers ("***NPIs***") associated with the ACO Provider/Suppliers, which would separately identify physicians that provide primary care. The Proposed Rule also proposes that ACOs will be responsible for maintaining and updating CMS on an annual basis of its ACO Participants and NPIs associated with the ACO Provider/Suppliers. In other words, every supplier or provider that participates in an ACO would have their NPI submitted to CMS by the ACO to show they are a participant in the ACO.

C. Structure/Governance

1. Introduction

Since the enactment of the Affordable Care Act and the introduction of the ACO concept, health care providers have desired to begin formation and implementation of their own ACO to "get ready" and "beat the competition." However, the big issue and major impediment in actually creating an ACO has been the question of what will actually qualify as an ACO under the Act and the final rules. The Proposed Rule begins to give guidance, but as noted below, due to CMS' desire to be flexible and CMS' uncertainty and concern with certain issues, CMS is specifically requesting comments on certain matters related to the formal structure and governance of an ACO. Therefore, additional structures may also qualify as an ACO under the final rules, and modification and/or addition of criteria for the currently proposed ACO structures may be added.

The Act requires that an ACO have "a formal legal structure that would allow the organization to receive and distribute payments for shared savings" to participating providers of services and suppliers. The Act also requires ACO participants to have a "mechanism for shared governance" in order to participate in the MSSP. Section 1899(b)(1)(a)-(d) specifies that the following four specific groups of providers or suppliers may participate as ACOs under the MSSP, if they have a mechanism for shared governance: (A) ACO professionals in group practice arrangements, (B) networks of individual practices of ACO professionals, (C) partnerships or joint venture arrangements between hospitals and ACO professionals, and (D) hospitals employing ACO professionals, in addition to other groups of providers of suppliers and suppliers as the Secretary determines appropriate.

2. Legal Entity

Comments received prior to the Proposed Rule requested CMS to be flexible in defining the required legal structure. In response, under the Proposed Rule CMS provides that an ACO must be a legal entity, but it "may be structured in a variety of ways, including as a corporation, partnership, limited liability company, foundation, or other entity permitted by State law." CMS defers to state law in recognition of a particular legal "entity," but provides that each ACO must be constituted as a legal entity appropriately recognized and authorized to conduct its business under applicable state law. The Proposed Rule requires each ACO to make specific certifications as to these requirements and actual documentary evidence may be required in the

application process. For ACOs that operate in more than one state, the ACO must separately make the certifications and provide documentary evidence as required by CMS for each state in which it operates.

Importantly, CMS also requires the ACO entity to have its own Tax Identification Number ("***TIN***"). Although the ACO is not enrolled in Medicare as a provider or supplier, the shared savings generated by the MSSP will be paid directly to the ACO, so that entity must have a TIN to receive such payments. Therefore, a mere contractual arrangement among Medicare providers and suppliers would not qualify as an ACO, as such arrangements are not a legal "entity" with a TIN.

In addition to being a legal entity recognized and authorized to do business under state law, 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 MSSP requirements, including the quality performance standards, and (4) performing the other ACO functions identified in the Act.

An important element in the MSSP is that the ACO entity itself will not necessarily be enrolled in the Medicare program. The ACO is the contracting vehicle for the MSSP, but actual Medicare covered services are delivered and billed by each individual ACO participant. An "***ACO participant***" is each Medicare-enrolled provider and supplier that joins together to form an ACO. In addition to the groups the Act specifically identifies, CMS proposes to use the Secretary's discretion to expand the list of eligible groups of providers and suppliers that may participate in the MSSP. CMS proposes that once an ACO exists, it may incorporate other groups of Medicare enrolled providers and suppliers, many of whom would not be able to form ACOs and participate in the MSSP independently. Regardless of whether ACO participants can meet MSSP eligibility requirements independently, the ACO itself must demonstrate "a mechanism of shared governance that provides all ACO participants with an appropriate proportionate control over the ACO's decision making process."

Prior comments raised the issue of whether ACO participants must form a new legal entity in order to qualify as an ACO and participate in the MSSP. In response, CMS states in the Proposed Rule that it presently is not proposing to require that existing legal entities appropriately recognized under state law must form a separate new legal entity for the purpose of participating in the MSSP. CMS also clearly states its intent to encourage participation by not-for-profit, community-based organizations. However, CMS expressed concern that the absence of a separate legal entity to operate the ACO may make it more difficult for CMS to audit and assess an ACO's performance. CMS specifically solicits comments on whether CMS should require all ACOs in the MSSP to be formed as a distinct legal entity or whether an existing legal entity could be permitted to participate. CMS also requests comments on whether requirements for the creation of a separate entity would create disincentives for the formation of ACOs and whether there is an alternative requirement that could be used to achieve the aims of shared governance and decision making and the ability to receive and distribute payments for shared savings.

In spite of the requested comments, the Proposed Rule does require 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 that are not then "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. This proposed requirement for a new entity under the identified circumstances apparently ignores the fact that many existing entities can create and issue new classes of membership or ownership and provide voting rights for the new participants. It will be interesting to see if the healthcare industry's corporate attorneys make this comment.

3. Governance and Governing Body

With respect to governance of the ACO entity, CMS believes that the governance mechanism should allow for appropriate proportionate control for ACO participants, give *each* ACO participant a voice in the ACO's decision making process, and be sufficient to meet the statutory requirements regarding clinical and administrative systems. CMS wants a mechanism that is transparent, accountable to the beneficiary community, and also accountable and responsive to the ACO participants and the ACO providers and suppliers they represent.

The Proposed Rule requires the ACO to establish and maintain a governing body with adequate authority to execute the statutory functions of an ACO. The governing body may be a board of directors, board of managers, or other similar governing body that provides a mechanism for shared governance and decision-making for all ACO participants, and the authority to execute an ACO's statutory functions. CMS intends that the governing body would be comprised of the ACO participants or their designated representatives, *including Medicare beneficiaries served by the ACO*, and possess broad responsibility for the ACO's administrative, fiduciary, and clinical operations. A requirement of Medicare beneficiary representation on the governing board is a significant new requirement, as many existing organizations would not have their patients formally represented and voting on the organization's governing board! Therefore, many existing organizations may want to consider forming a new legal entity with a separate governing board in order to address this public representation if this indeed becomes a formal requirement.

CMS also believes the governing body must be separate and unique to the ACO when the ACO participants are not already represented by an existing legal entity. In instances where the ACO is comprised of a self-contained financially and clinically integrated entity with a pre-existing board of directors or other governing body, the ACO would not need to form a separate governing body, as long as that governing body is able to meet all the other criteria for ACO governing bodies. In such case, the ACO would be required to provide evidence in its application that the pre-existing governing body would meet all other criteria for ACO governing bodies. In spite of CMS' current position to give ACOs flexibility in the creation of its governing body and to permit pre-existing governing bodies under some circumstances, CMS is concerned this would complicate CMS' monitoring and auditing of ACOs and solicits comments on this subject.

According to the Proposed Rule, ACO participants must have at least 75 percent control of the ACO's governing body, and each of the ACO participants must choose an appropriate

representative from within their own organization to represent them on the ACO's governing body. CMS solicits comments as to whether 75 percent is the appropriate percentage and whether the appropriate representative should be a person "employed by and representing Medicare-enrolled TINs" (as opposed perhaps to a lawyer or board member).

Consistent with its intent to encourage community participation in ACOs, CMS proposes that ACOs be required in their application to describe how they will partner with community stakeholders. ACOs that have a community stakeholder organization actually serving on their governing body would be deemed to have satisfied this criterion. As mentioned previously, ACOs will also be required to demonstrate a partnership with its Medicare beneficiaries by having beneficiary representation on the ACO governing body.

4. Leadership and Management Structure

The Act requires an eligible ACO to "have in place a leadership and management structure that includes clinical and administrative systems." CMS believes this structure should support the goals of the MSSP and the three-part aim of better care for individuals, better health for populations, and lower growth in expenditures. In this regard, CMS acknowledges the applicability of the parallel requirements of the FTC where healthcare providers must show they are integrated ventures that are likely to, or do, enable their participants to achieve cost efficiencies and quality improvements in providing services. For antitrust purposes, collaborations of competing healthcare providers may use either financial or clinical integration, or both, as means to achieve cost efficiencies and quality improvements. CMS believes it is in the public interest to "harmonize the eligibility criteria for ACOs that wish to participate in the Shared Savings Program with the similar antitrust criteria on clinical integration."

The Proposed Rule requires that ACOs meet the following "management" criteria:

(i) ACO operations would be managed by an executive, officer, manager, or general partner, whose appointment and removal are under control of the organization's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency process and outcomes.

(ii) Clinical management and oversight is conducted 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 the State.

(iii) ACO participants and ACO providers/suppliers would have a meaningful commitment to the ACO's clinical integration program to ensure likely success. Meaningful commitment may be a meaningful financial investment or a meaningful investment of time and effort in the ACO. (CMS, however, does not define "meaningful" in these contexts.)

(iv) The ACO would have a physician-directed quality assurance and process improvement committee to oversee an ongoing quality assurance and improvement program. Such quality assurance program would establish internal performance standards for quality of care and services, cost effectiveness, and

process and outcome improvements, and hold ACO providers and suppliers accountable for meeting those standards.

(v) The ACO would develop and implement evidence-based medical practice or clinical guidelines and processes for delivering care consistent with the three goals of better care for individuals, better health for populations, and lower growth in expenditures. ACO participants and ACO providers and suppliers must agree to comply with these guidelines and processes and be subject to performance evaluations and potential remedial action.

(vi) The ACO must have an infrastructure, such as information technology, that enables the ACO to collect and evaluate data and provide feedback to the ACO providers/suppliers across the entire organization.

CMS recognizes that it will be necessary for an ACO to include remedial process for ACO participants that fail to comply with the ACO procedures and performance standards, including the possibility of expulsion of those who are significant outliers. However, CMS cautions that expulsion cannot be used as a mechanism to avoid at-risk beneficiaries.

In order to determine an ACO's compliance with all of the legal structure and governance requirements, the Proposed Rules require submission of a laundry list of certain specific documentation for evidence of compliance with many of the criteria. In addition to the proposed documentary evidence that must be submitted as part of the application process, upon request by CMS, an ACO would be required to provide other specifically identified documents and descriptions set forth in the Proposed Rule.

III. CONTRACTING AND APPLICATION PROCESS

Among the requirements established by the Affordable Care Act is the requirement that the ACO enter into an agreement with CMS to participate in the MSSP for not less than a 3-year period. This section briefly summarizes the ACO application requirements and processes.

A. Application Process

In order to enter into an agreement to participate in the MSSP, the ACO will be required to submit a completed application. While no form of application yet has been proposed, CMS indicates, in various places throughout the Proposed Rule that it will require the following to be submitted with the application:

- Evidence that the ACO is recognized as a legal entity in its state of incorporation and that it is authorized to conduct business in each state in which it operates;
- Copies of each of the following documents:
  - All documents describing the ACO participants' and ACO providers/suppliers' rights and obligations in the ACO, and the shared savings that will encourage adherence to the quality assurance and improvement program and the evidenced-based clinical guidelines;

  - Documents that describe the scope and scale of the quality assurance and clinical integration program;
  - Supporting materials documenting the ACO's organization and management structure;
  - Evidence that the ACO has a licensed, board-certified physician as its medical director and that a principal CMS liaison is identified in its leadership structure;
  - Evidence that the governing body includes persons who represent the ACO participants, and that these ACO participants hold at least 75% control of the governing body;
  - Documents effectuating the ACO's formation and operation, if requested by CMS; and
  - Descriptions of the remedial processes that will apply when ACO participants and ACO providers/suppliers fail to comply with the ACO's internal procedures and performance standards, if requested by CMS;
- Description of how the ACO will partner with community stakeholders;
- Description of how the ACO plans to use potential shared savings to meet the goals of the MSSP;
- Description of the ACO's plans to (i) promote evidence-based medicine, (ii) promote beneficiary engagement, (iii) report internally on quality and cost metrics, and (iv) coordinate care;
- Description of how the ACO will use the results of its beneficiary experience of care survey to improve care over time;
- Description of how the ACO would consider diversity in its patient population and plans to address its population needs;
- Written standards for beneficiary access and communication and description of the process for beneficiaries to access their medical records;
- Description of the process for evaluating the health needs of the ACO's Medicare population;
- Description of its individualized care program, along with a sample care plan and explanation of how this program is used to promote improved outcomes for, at a minimum, the ACO's high-risk and multiple chronic condition patients;
- Disclosure of the percent of shared losses that each ACO participant will be responsible for and copies of signed agreements with its ACO participants establishing such liabilities;
- Documentation of the ACO's repayment mechanism for approval by CMS; and
- If applicable, a letter from the reviewing antitrust agency confirming that it has no present intent to challenge or recommend challenging the proposed ACO.

B. Agreement Length and Start Dates

Though the Affordable Care Act provides that agreements to participate in the MSSP shall be for a period of "not less than" three years, the Proposed Rule provides that the first round of agreements will all be for three years. CMS does not provide for longer agreements at this time (with one exception, which is discussed below).

The Proposed Rule also provides that all agreements will have a start date of January 1. This means that instead of establishing a system for rolling or semiannual start dates, CMS instead proposes to establish a system that creates "cohorts" of ACOs which would be simultaneously evaluated for eligibility to participate in the program and which would each have agreements that take effect on the same date each year. CMS proposes this structure to provide for a more streamlined process for agreement renewal and performance analysis, evaluation and monitoring. Unfortunately, this means that regardless of when an ACO is prepared to enter into an agreement to participate in the MSSP, it must wait until the next cohort is evaluated and accepted into the program. This may create unreasonably long wait times for some ACOs to enter into the program.

If all agreements begin on January 1 of each year, CMS will propose one application deadline, and applications will be considered and either rejected or accepted by CMS by the end of the year in which the application was submitted. CMS has not yet established this annual application deadline. Once a deadline has been established, ACOs that do not submit a complete application by the deadline are deemed not to have submitted an application at all and may submit a complete application for consideration with the next cohort.

ACO applicants will not be subject to existing screens in place for providers and suppliers enrolling in Medicare because the ACO will not be enrolling in Medicare. However, CMS is considering screening ACOs during the application process with regard to their program integrity history, and will look for any history of program exclusions or other sanctions and any affiliations with individuals or entities that have a history of program integrity issues. If CMS finds program integrity issues, the ACO may have its application rejected or may be subject to additional safeguards during the term of its agreement.

CMS acknowledges the administrative hurdles for ACO applicants in preparing applications for January 1, 2012 and solicits comments for start dates during the first year of the program. One proposal included in the Proposed Rule is to include an additional start date in 2012 of July 1. ACOs that have agreements effective July 1, 2012 would have 3.5 year agreements, which would be the only exception during the first round to the 3-year agreement period. For administrative purposes, these ACOs would have an 18-month "first year" so that they would end up on the January 1 year with the other cohorts.

C. Agreement Requirements

If the ACO is approved for participation in the MSSP, an executive officer of the ACO will be required to certify, by executing and returning the agreement to CMS, that all of the ACO participants agree to the requirements set forth in the agreement. CMS intends that all ACOs, ACO participants, and ACO providers/suppliers with direct or indirect obligations under the

MSSP be subject to the requirements of the agreement and that all certifications submitted on behalf of the ACO in connection with its participation in the MSSP extend to all parties with obligations to which the particular certification applies. CMS has not articulated how such obligations or certifications would extend down to each party, but has solicited comments on the best way to achieve this end.

CMS also establishes many other requirements for ACOs in the Proposed Rules. Among these requirements are that the ACO establish a conflicts of interest policy and a compliance plan, and that all marketing materials, communications, and activities be approved by CMS before they are used on behalf of the ACO. The ACO's compliance plan must include, at a minimum: (i) a designated compliance official, (ii) a mechanism for identifying and addressing compliance problems, (iii) a method for employees and contractors to report suspected problems, (iv) compliance training, and (v) a requirement to report suspected violations. The ACO may use or build on an existing compliance program or it may coordinate compliance efforts with any of its ACO providers/suppliers. CMS makes it clear that it does not intend that an ACO engage in duplicative efforts to fulfill these compliance requirements.

The Accountable Care Act makes clear that all ACOs must be patient-centered. In connection with this, CMS requires that all marketing materials, communications, and activities related to the ACO and its participation in the MSSP be approved by CMS before use. This pre-approval requirement will extend to all materials or activities that are used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers regarding the ACO and its participation in the MSSP, including all general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, mailings, or other activities. Exceptions to pre-approval of ACO marketing include beneficiary communications that are informational materials, those that are 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 individual health related issues, and educational information on specific medical conditions, and all exceptions to the definition of "marketing" under the HIPAA Privacy Rule.

IV. ASSIGNING MEDICARE BENEFICIARIES

A crucial aspect of the MSSP is how CMS will assign Medicare FFS beneficiaries to each participating ACO. The Statute requires that an ACO have a minimum of 5,000 beneficiaries, and if the ACO's number of assigned beneficiaries falls below 5,000, there will be adverse consequences to the ACO. However, unlike HMOs enrolling Medicare beneficiaries in Medicare Advantage plans, the ACO has no direct participation or influence in the beneficiary assignment process. Pursuant to the Act and the Proposed Rule, that process is controlled by CMS and the Medicare FFS beneficiary's freedom of choice. Furthermore, the decision for assignment of beneficiaries by CMS is final and cannot be appealed by administrative or judicial means. Yet, an ACO's ability to continue participation in the MSSP and achieve shared savings for additional payment is dependent upon the number and type of beneficiaries assigned to that ACO by CMS and the beneficiaries' election to stay with that ACO.

Section 1899(c) of the Social Security Act requires the Secretary to "determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on their utilization of primary care services… by an ACO professional…". "ACO professional" includes both physicians and non-physician practitioners (such as APNs, PAs and NPs), but for purposes of beneficiary assignment to an ACO, the Statute requires that CMS consider only beneficiaries' utilization of primary care services rendered *by physicians*. Therefore, the inclusion of non-physician ACO professionals is a factor in determining an entity's eligibility to participate in the MSSP, but assignment of beneficiaries to ACOs will be determined only on the basis of primary care services provided by ACO professionals who are primary care physicians.

CMS notes that the term "assignment" used in this context refers only to an operational process by which Medicare will determine whether *a beneficiary has chosen* to receive a sufficient level of the requisite primary care services from physicians associated with a specific ACO. CMS notes that "assignment…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 services." CMS prefers to characterize the process of assignment more as an "alignment" of beneficiaries with an ACO as the exercise of free choice by beneficiaries in the physicians and other health care providers and suppliers from whom they receive their services.

A. Operational Identification

The first step in assigning beneficiaries is to establish a clear operational method of identifying an ACO that correctly associates its healthcare professionals and providers with the ACO. CMS believes two data sources could be used to identify the specific providers of services and suppliers participating in as ACOs: (1) their National Provider Identifier ("***NPI***") and (2) their tax identification number ("***TIN***"), which may be either an employer identification number or social security number.

After considering both approaches, CMS proposes to identify an ACO operationally as a collection of Medicare-enrolled TINs. Under this approach, beneficiaries are assigned to an ACO through a TIN based on the primary care services they received from physicians billing under that TIN. CMS also proposes that ACO professionals within the respective TIN on which the beneficiary assignment is based will be *exclusive* to one ACO agreement in the MSSP. *This exclusivity will apply only to the primary care physicians* by whom beneficiary assignment is established.

In contrast, ACO participant TINs upon which beneficiary assignment is not dependent (e.g., acute care hospitals, surgical and medical specialties, RHCs, and FQHCs) would be required to agree to participate in a particular ACO for the term of the three-year agreement, *but would not be restricted to participation in a single ACO*. Therefore, hospitals, specialist physicians, and other non-primary care physician providers may participate in more than one ACO provided they agree to participate for the three-year term of the ACO's agreement with CMS. CMS' rationale for this non-exclusivity is to permit competition, promote access to providers, not create a system where a single ACO may dominate the market, and address situations where certain areas lack physicians.

CMS believes TIN level data alone will not be entirely sufficient for a number of purposes of the MSSP (e.g., NPI information will be necessary in monitoring ACO activities). Therefore, CMS also would require that organizations applying to be an ACO provide a list of associated NPIs for all ACO professionals (including a list that separately identifies its primary care physicians), in addition to providing its TIN. CMS reasons that defining the ACO operationally as a group of Medicare-enrolled TINs, while also collecting NPI information associated with those TINs, allows CMS to link the beneficiary, type of service provided, and the type of physician providing the services for purposes of beneficiary assignment to an ACO in the manner required by the Statute. In CMS' estimation it also provides the best and most stable data for its purposes in operating the MSSP while taking advantage of infrastructure and methodologies already in place, thereby reducing the administrative burden on participating providers and suppliers.

B. Definition of Primary Care Services

CMS considered three options with respect to defining "primary care services" for purposes of assigning beneficiaries under the MSSP: (1) assignment of beneficiaries based upon a predefined set of primary care services, (2) assignment of beneficiaries based upon both a predefined set of primary care services and a predefined group of primary care providers, and (3) assignment of beneficiaries in a step-wise fashion. Under the step-wise option, beneficiary assignment would proceed by first identifying primary care physicians who are providing primary care services, and then identifying specialists who are providing these same services.

The first option considered would assign beneficiaries by defining primary care services on the basis of the select set of E&M services (specifically those defined as primary care services in section 5501 of the Act), and including G-codes associated with the annual wellness visit and Welcome to Medicare benefit, regardless of provider specialty. The second option is to assign beneficiaries to physicians designated as primary care providers who are providing the appropriate primary care services to beneficiaries (defining primary care services in the same manner as option one). The third option is to assign beneficiaries in the step-wise fashion.

CMS chose the second option because CMS believes this option best aligns with other provisions of the Act related to primary care by placing a priority on the services of designated primary care physicians. However, CMS expresses concern that this approach may not adequately account for primary care services provided by specialists, and may also make it difficult to obtain the minimum number of beneficiaries to form an ACO in geographic regions with primary care shortages. Therefore, CMS invites specific comments on this approach.

C. Prospective vs. Retrospective Beneficiary Assignment

A contentious issue is when assignment occurs. CMS evaluated two basic options for assigning beneficiaries to an ACO to calculate eligibility for shared savings for a "performance year." The first option is for beneficiary assignment to occur prospectively at the beginning of a performance year, based on utilization data demonstrating the provision of primary care services to beneficiaries in prior periods. The second option is for beneficiary assignment to occur retrospectively at the end of the performance year, based on utilization data demonstrating the provision of primary care services to beneficiaries by ACO physicians during the performance

year. In the prior comments received, it appears most comments supported the prospective assignment of beneficiaries. The reasoning by many advocates was that it is essential to population management to be able to profile a population, identify individuals at high risk, develop outreach programs, and proactively work with patients and their families to establish care plans. Only if you know who is in your population can you effectively coordinate the care for such individuals.

Advocates of retrospective assignment (at the end of the performance year) point out that many patients during the year come in or out of Medicare eligibility, they join Medicare Advantage plans, and they move in or out of the service area. Statistics under the Physician Group Practice demonstration showed that approximately 25% of the patient population varies from year to year. Thus, the argument is that, even prospective assignment must ultimately be adjusted retrospectively due to these factors. Moreover, CMS fears that ACO participants might focus only on the identified ACO population, to the detriment of other beneficiaries in their practice or hospital. CMS reasons that "ACO participants and ACO providers/suppliers should have incentives to treat all patients equally, using standardized evidence-based care processes, to improve the quality and efficiency of all of the care they provide, and in the end they should see positive results in the retrospectively assigned population."

CMS thus concluded that the retrospective approach was compelling. However, CMS took note of comments suggesting the use of retrospective alignment for determining utilization and shared savings, but prospective assignment for purposes of CMS sharing aggregate beneficiary identifiable data with ACOs in order to help them plan for their expected patient population. Therefore, CMS proposes the combined approach of retrospective beneficiary assignment for purposes of determining eligibility for shared savings balanced by the provision of aggregate beneficiary level data for the assigned population of Medicare beneficiaries during the benchmark period. CMS will prospectively provide ACOs with a list of beneficiary names, date of birth, sex, and other information derived from the assignment algorithm used to generate the three-year benchmark. CMS believes providing data on those beneficiaries assigned to an ACO in the benchmark period is a good compromise that will allow ACOs to have information on the population they likely will be responsible for in order to plan for care improvements for such a population while not encouraging ACOs to limit their care improvement activities to only the subset of beneficiaries they believe will be assigned to them in the performance year.

D. Majority vs. Plurality Rule

The Statute requires beneficiary assignment to an ACO on the basis of the beneficiaries' utilization of primary care services, but does not prescribe the criteria or methodology for such assignment. CMS believes the obvious general approach is to make the assignment of beneficiaries on the basis of some percentage level of the primary care services a beneficiary receives from an ACO physician. The issue is whether to assign beneficiaries to an ACO when they receive a plurality of their primary care services from that ACO (the plurality rule), or to adopt a stricter standard whereby a beneficiary will be assigned to an ACO only when that beneficiary receives a majority of their primary care services from an ACO (the majority rule). CMS believes that a majority rule for assignment is too strict a standard in a system where many Medicare beneficiaries may regularly receive primary care services from two or more primary

care practitioners (e.g., an internal medicine and a geriatric medicine physician). Therefore, CMS proposes to use the plurality rule and assign beneficiaries to an ACO if they receive a plurality of their primary care services from primary care physicians within that ACO.

For purposes of determining the plurality of primary care services, CMS proposes to implement a method using the plurality of "allowed charges" of primary care services. CMS believes charges are a reasonable proxy for the resource use of the underlying primary care services and that using a plurality of allowed charges assigns beneficiaries to an ACO according to the intensity of their primary care interactions, and not simply the frequency of such services. Beneficiaries will thus be assigned to the ACO which has as an ACO Participant a primary care physician from whom that beneficiary received the plurality of their primary care services (by charges) for the performance year.

E. Beneficiary Information and Notification

The Statute does not specify whether beneficiaries should be informed in any way about the MSSP. It does not require that any information be provided to beneficiaries about the MSSP, such as whether they are receiving services from an ACO, or whether they even have been assigned to an ACO. However, CMS believes that the beneficiaries' freedom of choice as to who will provide their care is undermined or nullified if beneficiaries do not possess adequate information to assess the possible consequences of available choices, so CMS is firm that transparency be a central feature of the MSSP.

In the Proposed Rule, CMS states its intention to develop a communications plan (including educational materials and other forms of outreach) to provide beneficiaries in a timely manner with accurate, clear, and understandable information about the MSSP and their options. CMS proposes to require ACOs to post signs in the facilities of participating ACO providers/suppliers indicating their participation in the MSSP and to make available standardized written information to beneficiaries whom they serve. CMS also plans to develop notice requirements whereby beneficiaries are timely notified in instances where either an ACO chooses no longer to participate in the MSSP or CMS has terminated an ACO's participation agreement. CMS also proposes that an ACO seeking to terminate its participation in the MSSP must provide CMS with advance notice. CMS seeks comment on the appropriate form and content of notices to beneficiaries. If CMS adopts a notification requirement in the final rule, CMS says it will take comments on the issues, such as the appropriate form and content of such notifications, as they develop more detailed instructions for ACOs on beneficiary notification.

V. PATIENT FOCUSED CARE

A central statutory theme of the MSSP is that ACOs must provide quality, patient-centered care. The MSSP establishes several standards that ACOs must meet with regard to how patient care is provided, with a focus on processes and methods to: (1) promote evidence-based medicine, (2) promote patient engagement, (3) report on quality and cost measures, and (4) coordinate care. In the Proposed Rule, CMS considered whether it should set specific patient-focused criteria that an ACO must satisfy. CMS ultimately determined that such a prescriptive approach would be premature and could impede innovation. Thus, under the Proposed Rule, an ACO must provide

documentation in its application describing how it plans to promote evidence-based medicine and patient engagement, report internally on quality and costs measures, and coordinate care.

CMS defines evidence-based medicine "as the application of the best available evidence gained from the scientific method to clinical decision-making." According to CMS, the promotion of evidence-based medicine should be achieved through the establishment and implementation of guidelines, which are regularly assessed and updated, based on the best available evidence as to the effectiveness of medical treatments. The second standard, the promotion of "patient engagement," involves engaging patients and their families in the medical decision-making process. Patient engagement measures may include the use of tools and methods with which the patient can assess the merits of treatment options in the context of the patient's values and convictions. It may also include methods for fostering "health literacy," which includes the possession of basic knowledge about maintaining good health, managing existing conditions, and avoiding preventable conditions.

CMS suggests that the third standard, reporting on quality and costs measures, may be achieved through an ACO's development of capabilities to allow it to monitor and appropriately modify costs and quality levels internally. The fourth standard requires an ACO to define processes to coordinate care through the use of telehealth, remote patient monitoring, and other such enabling technologies. Coordination of care should promote integration and consistency of care for a patient across primary care physicians, specialists, and other providers and suppliers—particularly during a hospital discharge or transition from primary to specialty care. CMS warns, however, that an ACO's strategies to coordinate care should not impede the ability of a beneficiary to seek care from providers outside the ACO.

The Affordable Care Act also requires ACOs to demonstrate that they meet the "patient-centeredness criteria" specified by CMS. The Proposed Rule loosely defines a patient-centered, or "person-centered," orientation "as care that incorporates the values (to the extent the informed, individual patient desires it) of transparency, individualism, recognition, respect, dignity, and choice in all matters, without exception, related to one's person, circumstances, and relationships in health care." According to CMS, one goal of the MSSP is to have ACOs adopt a patient-centered focus that is promoted by the ACO's governing body and integrated into its leadership and management.

CMS establishes the following patient-centered principles for ACOs:

- Care should be individualized based on the beneficiary's needs, preferences, values, and priorities.
- Beneficiaries should have access to their own medical records and sufficient clinical knowledge to make informed decisions about their care.
- Beneficiaries (and their families or caregivers, if applicable) should be encouraged to make choices regarding their care based on information provided by their ACOs and their own values.
- The ACO should routinely assess and seek to improve beneficiary and family/caregiver experience of care.

- Care should be integrated with the beneficiary's community resources.
- Transitions among ACO providers—and between providers inside and outside the ACO—should be supported by processes including the electronic exchange of information.

Patient Centered Criteria

Based on these principles, the Proposed Rule includes a list of patient-centered criteria, *all* of which an ACO must demonstrate to participate in the MSSP. In the commentary to the Proposed Rule, CMS describes eight criteria, but the Proposed Rule itself lists the following nine. Whatever the number, CMS is soliciting comments as to whether the list should be narrowed, expanded, or otherwise revised.

1. ***Beneficiary Experience of Care Survey***. An ACO must have a beneficiary experience of care survey in place and must describe in its application how it will use the results to improve care over time. ACOs will also be required to submit plans to CMS as to how they will improve areas the survey identifies as weak.

2. ***Patient Involvement in ACO Governance***. Beneficiaries must be involved in ACO governance. Specifically, an ACO must have a beneficiary served by the ACO on its governing body to satisfy this criterion.

3. ***Evaluation of Population Health Needs and Consideration of Diversity***. ACOs must describe in their application their process for evaluating the needs of their Medicare population. Although not required, CMS suggests that ACOs may find existing recommendations by the National Committee for Quality Assurance and other groups for evaluating population health and diversity useful.

4. ***Individualized Care Plans and Integration of Community Resources***. An ACO must have a system in place to identify high-risk individuals and develop individualized care plans for targeted patient populations. As part of the application process, an ACO must submit a description of its individualized care program, submit a sample care plan, and describe how its promote improved outcomes for high-risk and multiple chronic condition patients.

5. ***Coordination of Care Mechanism***. The ACO must be able to electronically exchange care information when patients change providers, either inside or outside of the ACO, in a manner consistent with "meaningful use" requirements under the EHR Incentive program.

6. ***Process for Communicating Knowledge/Evidence-Based Medicine to Beneficiaries***. This process must ensure that the communication is understandable to beneficiaries.

7. ***Process for Beneficiary Engagement and Shared Decision-Making***. This process must engage beneficiaries and their families/caregivers, if applicable, in the medical

decision-making process in a manner that takes into account the beneficiaries' needs, preferences, values, and priorities.

8. ***Standards for Beneficiary Access and Communication***. The ACO must have in place written standards allowing beneficiaries to access their medical record.

9. ***Internal Processes for Measuring Physician Clinical and Service Performance***. ACO internal processes must measure clinical and service performance by physicians across practices within the ACO, and the ACO must use the results to improve care and service over time.

CMS recognizes that the patient-centeredness criteria discussed above overlap in some areas with the processes ACOs are required to establish in order to demonstrate eligibility to participate in the MSSP. For example, having a beneficiary on the ACO's governing board is required for eligibility and also satisfies the proposed patient-centered criterion on patient involvement in ACO governance. CMS believes this overlap will reduce the burden on ACO in meeting eligibility and patient-centeredness requirements. Again, however, CMS is also soliciting comments as to whether these criteria should be narrowed, expanded, or otherwise revised.

VI. PERFORMANCE AND QUALITY MEASUREMENTS

Some believe the heart of the ACO program is the implementation of performance standards for ACOs. In order for an ACO to participate in Shared Savings, not only must those savings exist, but the ACO must meet certain quality performance and reporting requirements. The proposed rule both establishes standards, and outlines the methodology for measuring ACO performance, to indicate whether an ACO has met the quality performance goals in order for an ACO to be eligible for shared savings.

CMS considered two alternatives for establishing quality standards. Under the "performance score approach," an ACO's performance score is calculated and the ACO is rewarded with increased shared savings for better performance on quality measures. The "quality threshold approach" establishes a minimum quality threshold that allows an ACO to fully participate in shared savings if the ACO meets the minimum threshold. Not surprisingly, CMS proposes to use the performance score approach, but invites comment on the threshold approach. Both the performance score approach and the threshold approach are based on the same quality measures, require the same reporting by the ACO, and use the same benchmarks described below.

A. Performance Standards

CMS is proposing 65 distinct quality measures for use in the calculation of the ACO Quality Performance Standard. The tables published by CMS in the Proposed Rule are far too lengthy to be reproduced here, but the quality measures essentially are divided into five "domains", including: i) Patient/Caregiver Experience, ii) Care Coordination, iii) Patient Safety, iv) Preventive Health, and v) At-Risk Population/Frail Elderly Health. The Patient Experience domain for example, may ask patients "How Well Does Your Doctor Communicate? The

Preventive Health domain might ask the "Percentage of patients aged 50 years and older who received an influenza immunization during the most recent flu season (September through February)." The questions are designed to elicit measurable data that can result in objective scoring for each ACO.

B. Reporting Tools

CMS proposes to collect the data used to score the quality measures via a variety of data collection tools. For example, the quality measures under the Patient/Caregiver Experience Domain will rely exclusively on patient/caregiver survey data. CMS states that it will make available a CMS-specified survey tool for the collection of survey data by the ACO.

CMS proposes to collect much of the data for the other quality measures using a newly developed tool, the Group Practice Reporting Option ("***GPRO***"). The GPRO is a tool tested in 2010 by 36 large group physician practices to collect 26 quality measures for an assigned patient population under the Physician Quality Reporting System. CMS proposes to provide the GPRO tool and access to a database that will include a sample of the ACO's assigned beneficiary population. CMS will pre-populate the GPRO data collection tool with the beneficiaries' demographic and utilization information based on their Medicare claims data. The ACO will be required to populate the remaining data fields necessary for capturing quality measure information on each of the beneficiaries.

Some GPRO measures will not rely on beneficiary data but rather on ACO attestation. GPRO measures relying on attestation include those in the Care Coordination domain that pertain to HITECH Meaningful Use, the Electronic Prescribing Incentive Program, and patient registry use. CMS plans to validate GPRO attestations through CMS data from the EHR Incentive Program and Electronic Prescribing Incentive Program. Additionally, CMS intends to validate the data reported using the GPRO tool by audits. All ACOs will be required to report using the GPRO tool by the first year following the first performance period of the Shared Savings Program.

In addition to the GPRO tool, CMS proposes to collect data for the quality measures from Medicare claims submitted for services furnished during the first performance period. Claims-based data will not impose any additional reporting requirements on the ACO. CMS also intends to collect data from that reported in connection with the EHR Incentive Program, the Physician and Hospital Inpatient Quality Reporting Systems, eRx and HITECH program data, Hospital Compare, or the Centers for Disease Control and Prevention National Healthcare Safety Network. Because CMS intends to rely on EHR data, by the start of the second Shared Savings Program performance year, 50% of an ACO's primary care providers must be "meaningful EHR users."

C. Timing of Implementation of Quality and Performance Measures

ACOs must report on 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. Specifically, for the first year of the program, CMS proposes that the quality performance standard will be deemed to have been met if the ACO submits full and accurate reporting on 100% of the 65 quality measures. Therefore, under the One-Sided Model, an ACO

that meets the 100% reporting requirement will receive the full 50% of shared savings; under the Two-Sided Model, an ACO will receive the full 60% if the ACO demonstrates sufficient cost savings to be eligible. The Proposed Rules implies that even during the first year, an ACO's failure to meet the 100% reporting requirement will result in an ACO's ineligibility for any shared savings. Although during the first year of the Shared Savings Program an ACO will receive a performance score of each of the 65 quality measures, these performance scores will be for informational purposes only.

For the second and third years, in addition to meeting the requirement to completely and accurately report, an ACO must meet a minimum attainment level in each of the five domains based on performance benchmarks to be established by CMS for each of the 65 quality measures. ACOs that do not meet the quality performance thresholds for all proposed quality measures will be ineligible for shared savings, regardless of how much per capita costs were reduced. The minimum performance threshold using the quality performance scoring method is currently set at 30%. Therefore, the ACO must achieve an average of 30% or above in each of the five domains.

D. Performance Scoring Option (CMS Preferred Option)

Under the performance scoring option, each quality measure will be given a score from zero to two points. The score for each measure is based on comparing a benchmark that will be set by CMS for each quality measure based on data from Medicare fee for services ("***FFS***") and Medicare Advantage ("***MA***") claims data. The benchmarks will be established using the most currently available data source and most recent available year of FFS and MA data prior to the start of the Shared Savings Program annual agreement periods. Consequently, the proposed rules do not establish specific benchmarks for each quality measure. Rather, the benchmarks will be made available to ACOs prior to the start of the Shared Savings Program and for each annual performance year thereafter. Therefore, ACOs will not be aware of the benchmarks they must achieve to receive shared savings until after they have entered the Shared Savings Program.

CMS proposes that the points for each of the 65 quality measures will be based on the ACO achieving a sliding scale percentage of the benchmark for each quality measure. For example, if an ACO's data for a quality measure (collected using the reporting tools described above) is in the 90+ percentile of the benchmark set by CMS, the ACO will receive the maximum score of two points. At the 30+ percentile of the benchmark, the ACO will receive 1.10 points. For performance below the 30th percentile, the ACO will receive no points for a quality measure.

There are certain quality measures that will be scored on what CMS terms the "all or nothing" method. Quality measures 35 (diabetes) and 52 (coronary artery disease) contain five "sub-measures." Under the "all or nothing" measures, if the benchmarks for *all* of the sub-measures are met, the ACO receives 2 points (the maximum). If *one* of the sub-measures is not met, the ACO will receive zero points.

Once points have been awarded for each performance measure, the points for each domain will be aggregated. Therefore, since there are 7 performance measures in the Patient/Caregiver domain, the ACO can earn a maximum of 14 points for that domain. The total points achieved in each domain will be compared to the maximum points for that domain to give a percentage

score. The domain percentage scores will be weighted equally. All domain scores for an ACO will be averaged together equally to calculate the overall quality score that will be used to calculate the ACO's final sharing score. Table 3 reflects an example of the calculation of the overall quality score for an ACO assuming that the ACO received 1.4 points for all measures based on performance at the 50+ percentile level of the bench mark and received 2 points for the 2 all or nothing measures

Table

1. Patient/Caregiver Experience	1-7 (7 measures)	7 x 1.4=9.8 ÷ 14=.70
2. Care Coordination	8-23 (16 measures)	16 x 1.4=22.4 ÷ 30=.70
3. Patient Safety	24-25 (2 measures)	2 x 1.4=2.8 ÷ 4=.70
4. Preventive Health	26-34 (9 measures)	9 x 1.4=12.6 ÷ 18=.70
5. At-Risk Population / Frail Elderly Health	35-65 (31) measures)	29 x 1.4=40.6 + 4=44.6 ÷ 64=.697
	Total quality score	.699

Under the foregoing example, an ACO on the one-sided savings model would receive 34.95% of the shared savings (69.9% of 50%= 34.95%). Under the Two-Sided Model, the ACO would receive 41.9% of the shared savings (69.9% of 60%= 41.9%).

E. Minimum Quality Threshold Option

CMS also considered a simpler option of establishing a minimum quality threshold for participating ACOs. Under this option, if an ACO meets or exceeds the minimum quality threshold, it would retain the full shared percentage savings under either the one or two-sided plans. If the ACO fails to meet the minimum quality threshold, the ACO would not be eligible for shared savings. CMS does not favor the minimum quality threshold option but invited comments regarding the use of this option as well as options that would blend the performance scoring and minimum quality threshold options.

F. Additional Incentives Based on Reporting Requirements

CMS proposes that "eligible professionals" ("***EPs***") that are ACO participant providers/ suppliers will constitute a group practice for purposes of qualifying for a Physician Quality Reporting System ("***PQRS***") incentive. An eligible professional is any of the following:

> (1) a physician; (2) A physician assistant, nurse practitioner, or clinical nurse specialist; (3) A certified registered nurse; (4) A certified nurse-midwife; (5) A clinical social worker; (6) A clinical psychologist; (7) A registered dietitian or nutrition professional; (8) a physical or occupation therapist or a qualified speech-language pathologist; or (9) a qualified audiologist.

These EPs will be eligible for a PQRS incentive which will be in addition to the ACO's shared savings. The ACO will report and submit data on behalf of the EPs using the GPRO in an effort to qualify them for the PQRS incentive equal to .5 % of the ACO's eligible professionals' total

estimated Medicare Part B physician fee schedule allowed charges for covered professional services furnished during the first performance period. The ACO must meet the ACO quality performance standards in order for the EPs to qualify for the PQRS incentive. The ACO's EPs would not be eligible for both a PQRS incentive under the Shared Savings Program and the traditional PQRS incentive program.

CMS is not proposing to incorporate incentive payments under the EHR Incentive Program or the Electronic Prescribing Incentive Program into the Shared Savings Program until 2013. Professionals in ACOs may still separately participate in those other incentive programs.

G. Public Reporting

CMS believes that several aspects of an ACO's operation and performance should be transparent to the public—specifically, information regarding: (1) providers and suppliers participating in the ACO; (2) parties sharing in the governance of the ACO; (3) quality performance standard scores, and (4) general information on how an ACO shares savings with its members. Therefore, CMS is proposing that the following information regarding an ACO be publicly reported:

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

Each ACO will be responsible for making this information available to the public in a standardized format that CMS will make available through additional guidance. The public reporting requirement will be included in each ACO's 3-year agreement.

VII. REIMBURSEMENT MODELS AND SHARED SAVINGS

A. Reimbursement Overview

As the title of new Section 1899 makes clear, the core element to the Medicare Shared Savings Program is the opportunity for ACO participants to realize additional Medicare reimbursement from effectively managing and coordinating the care of their Medicare fee for service patient population. Any savings from what Medicare would ordinarily pay for such patient population would be shared between the program and the ACO.

Under the basic ACO model established by Congress, the ACO has no down-side risk. The Affordable Care Act simply provides that Medicare will continue to make Part A and Part B payments to ACO providers and suppliers "in the same manner as they would otherwise be made," and then stipulates that eligible ACO's (those meeting established performance standards) may receive shared savings generated under the program.

CMS, however, under the authority of section 1899(i) of the Social Security Act (added by Section 10307 of the Affordable Care Act), adds a risk reimbursement model for ACOs. Section 1899(i) allows the Secretary to substitute for the basic model either a partial capitation reimbursement model, or "any payment model that the Secretary determines will improve the quality and efficiency of items and services furnished under this title." With that broad authority, CMS proposes a "two-sided" risk model to complement the basic no risk model. CMS calls these options Track 1 and Track 2.

Track 1, according to CMS, is intended as an "entry point for organizations with less experience with risk models, such as some physician-driven organizations or smaller ACOs." The premise is that such ACOs will gain experience with population management before transitioning to a risk-based model. Under Track 1, the ACO initially shares in savings under the "one-sided" approach specified in the law, namely, that the ACO shares 50% of the savings, but bears no risk for excess expenditures.

Track 2 (the Two-Sided Model) has the advantage of providing an opportunity for more experienced ACOs that are able to risk sharing in losses to enter a sharing arrangement that provides greater reward for greater responsibility. Under Track 2, the ACO bears two-sided risk from the beginning. More experienced ACOs that are ready to share in losses with greater opportunity for reward may elect to immediately enter the Two-Sided Model. An ACO participating in Track 2 would be under the Two-Sided Model for all three years of its agreement period. Under this model, the ACO is eligible for higher sharing rates (60% instead of 50%) than available under the One-Sided Model.

Importantly for those ACOs seeking to participate, however, in the third year of participation, all ACO's are transitioned to a Track 2 model. That is, even a Track 1 ACO assumes the downside risk in year three and after.

B. Benchmarks

In order to calculate actual savings in Medicare expenditures attributable to the efforts of ACOs, CMS first must establish average spending benchmarks against which savings will be measured. CMS notes that benchmarks can be thought of as a "surrogate measure of what the Medicare FFS Parts A and B expenditures would otherwise have been in the absence of the ACO." The law requires that the benchmark "must use the most recent available 3 years of per-beneficiary expenditures for parts A and B services for Medicare fee-for-service beneficiaries assigned to the ACO", adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate. Finally, benchmarks must be updated by the projected absolute amount of growth in Medicare spending, as estimated by the Secretary. The benchmarks are reset at the start of each ACO contract year.

After exhaustively analyzing two possible options, CMS has elected to establish benchmarks based upon the past three years expenditure data for the Medicare beneficiaries who would have been assigned to the ACO for those years, based upon the number of beneficiaries who received a plurality of their primary care services in each of the three years from ACO primary care doctors. This is the same methodology pursuant to which beneficiaries are assigned to the ACOs in the first place.

The benchmarks are adjusted for the health status of beneficiaries, using the CMS-HCC prospective risk adjustment model used in the Medicare Advantage program. The CMS-HCC model uses beneficiaries' actual prior year diagnoses to develop risk scores that are then applied to current year expenditures. Acknowledging the greater complexity of care required, a higher risk score raises the expenditure benchmark, thus increasing the likelihood that an ACO may be able to generate savings from the elevated benchmark.

CMS notes that its experience in the Medicare Advantage program is that health plans are far more careful to include all pertinent diagnoses for a patient in order to raise the risk scores accordingly. It notes that it will retain the option to audit those ACOs with high levels of risk growth relative to their peers, and adjust such risk scores as required.

Finally, benchmarks are weighted so that the most recent of the three years is weighted more than twice as much as the first two years. They also are adjusted for the projected absolute amount of growth in Medicare spending, and trended forward to be expressed in current year dollars.

C. Minimum Savings Rate

Once the benchmarks have been established, as required by the law, CMS proposes what it terms a minimum savings rate ("***MSR***") as the amount *below* the benchmark which must be achieved before shared savings will begin to accrue. Rather than first dollar savings, Congress contemplated that ordinary yearly fluctuations in Medicare expenditures might contribute to apparent "savings", and instructed the Secretary to calculate such a percent based upon such normal fluctuations based upon the number of beneficiaries assigned to the ACO. CMS has determined that larger more experienced ACOs are likely to experience fewer fluctuations than smaller ACOs, and created an MSR scale varying from 3.9% for the smallest ACOs (with 5,000

beneficiaries) to 2.0% for the very largest ACOs (with 60,000+ beneficiaries). Thus the smallest ACOs must achieve savings at least 3.9% below their benchmark before any shared savings payments can be made.

D. Net Sharing Rate

Once the MSR has been realized (thus triggering eligibility for savings), CMS proposes to share any savings in excess of 2% below the benchmark (the "***Net Savings Rate***"). CMS considered first dollar savings, and also considered only savings in excess of the MSR. The compromise allows all ACOs to begin to share in savings in excess of 2%, so long as the performance Standards are met, and the MSR is exceeded. A sample calculation for a small Track 1 ACO appears below.

Sample Savings Calculation

A. Benchmark	$30,000,000 (5,000 patients x $6,000 "benchmark")	
B. Expenditures for Year	$27,500,000	
C. Actual Savings	$ 2,500,000	
D. MSR (3.9%)	$ 1,170,000	
E. Net Sharing Rate (2%)	$ 600,000	
F. Sharing Rate	(Track 1-50%)	
G. Shared Savings	$ 950,000	((C-E) x F)
H. Withhold (25%)	$ 237,500	
I. Shared Savings Payment	$ 712,500	(G-H)

E. Timing of Payments

The Affordable Care Act does not specify when the shared savings determination should be made. Some commenters have told CMS that ACO's need timely feedback on their performance in order to develop and implement improvements in care delivery. In developing the Proposed Rule, CMS thus has been "attentive to the importance of determining shared savings payments and providing feedback to ACOs on their performance in a timely manner while at the same time not sacrificing the accuracy needed to calculate per capita expenditures."

The savings calculation must account for the length of time between when a service is rendered and when payment is made. This "claims run out" period determines the accuracy of the data. The longer the claims run out, the more reliable the expenditure data. CMS proposes a 6-month claims run out period to calculate the benchmark and per capita expenditures for the performance year. According to CMS, "although the use of a 6-month claims run out will delay the computation of shared savings payments and the provision of feedback to participating ACOs, the trade-off for a more accurate calculation of per capita costs is warranted." CMS invites comment, however, on whether a 3-month period is more appropriate.

Overall, the language in the Proposed Rule is unclear as to when CMS will actually declare and pay shared savings, or will pay previously withheld amounts. The final rule will need to clarify the details of exactly how and when such payments will be made.

F. Additional Shared Savings

Under its general authority under the law, CMS proposes additional payments to Track 1 ACOs that contract with federally qualified health centers ("***FQHC***") or rural health clinics ("***RHCs***"), where a minimum number of ACO beneficiaries receive at least one episode of care from such FQHCs and RHCs. CMS cites data showing that such organizations not only provide comprehensive, quality care to an at risk population, but such care results in significant savings by reducing the use of costlier sites of care such as hospital emergency rooms. CMS proposes on a sliding scale that ACOs may receive an increase of as much as 2.5% in their Sharing Rate by effectively utilizing FQHCs or RHCs as part of their delivery model.

G. Savings Ceilings

The Affordable Care Act requires the Secretary to "establish limits on the total amount of shared savings that may be paid to an ACO …." Conceptually, the limit should provide a significant opportunity for ACOs to receive legitimate shared savings generated from quality improvements and better coordination and management of care, but avoid creating incentives for excessive reductions in utilization which could be harmful to beneficiaries. The proposed ceiling for a Track 1 ACO will be 7.5% of its benchmark (which assumes overall savings of 15% below the Net Sharing Rate level), while Track 2 ACOs may receive as much as 10% of their benchmark.

H. Withholding

CMS notes that over the course of the program, an ACO might earn performance payments in some years and incur losses in other years. Thus, the issue is whether CMS will pay the full amount of shared savings payments in the year they are accrued, or whether some portion would be withheld to offset potential future losses. Since the original statute did not contemplate a risk-based reimbursement model, there is no statutory guidance available. Believing that guaranteeing that ACOs participating in the Two-Sided Model will be capable of repaying CMS for costs that exceed their benchmark is a critical program requirement, CMS thus proposes a 25% withholding rate to be applied annually to an ACO's earned performance payment as a hedge against future losses. An ACO earning a $1,000,000 shared savings amount thus will only receive $750,000.

CMS suggests that withholding is only one component of the repayment mechanism ACOs will need to establish to ensure their ability to repay Medicare for incurred losses. If an ACO completes its 3-year agreement successfully, CMS will refund in full any portion of shared savings withheld during the course of the agreement period that is not needed to offset losses. Alternatively, in the event an ACO's 3-year agreement is terminated before the completion of the 3 years, CMS proposes to retain any portion of shared savings withheld.

I. Losses Under Track 2 "Two-Sided" Model

For ACOs electing Track 2 status at the outset, and for Track 1 ACOs entering year three of their agreement, CMS proposes a risk formula where the ACO assumes some of the risk if expenditures exceed the benchmark. Once expenditures exceed a "minimum loss rate" above the benchmark (2%), the ACO shares first dollar losses above that point. The calculation of such

losses favors the ACO, however. For example, if the ACO met all the relevant performance standards, and would have qualified for a 60% savings payment had there been savings, the loss that must be shared is the inverse of that amount, or 40%. CMS reasons that if the ACO achieves the performance and quality standards that are an important element of the MSSP, the ACO should be recognized for that fact, even if overall losses occur. Thus, even if expenditures exceed the benchmarks, the ACO receives some credit for achieving quality standards. Finally, losses are capped at 5% in year 1, 7.5% in year 2, and 10% in year 3. Any losses in excess of the annual cap would not be shared.

J. Conclusion

Although the Affordable Care Act predicated the ACO program on a no risk (one-sided) reimbursement model, the addition of Section 1899(i) allows CMS broad discretion to promulgate a broad risk-based model that eventually applies to all ACOs. Those choosing Track 2 will share losses beginning immediately, while those entering under Track 1 automatically convert to Track 2 in year 3 and beyond. The downside risk for losses is an integral element of CMS' model, and providers seeking to participate as an ACO must engage in sophisticated modeling to assure themselves it is a risk worth taking.

VIII. PRIVACY AND DATA COLLECTION

In order for ACOs to deliver their intended benefits of cost savings, greater accountability of providers, and improved coordination of care, it will be necessary that ACO members be able to share data among themselves. Additionally, in order for ACOs to track the provision of care, and for CMS to be able to determine whether a particular ACO is entitled to incentive compensation for meeting goals of reducing costs, ACOs and their members will need to be able to receive information from CMS relating to the past level of care provided to the beneficiaries for which the ACO is responsible. Both types of information exchanges (among ACO participants and from CMS to the ACOs) raise implications under the medical record privacy provisions of the Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated thereunder ("***HIPAA***"), as well as under the Federal Privacy Act of 1974.

With respect to the exchange of individually identifiable health information among the hospitals, physicians, and other providers in an ACO, the Proposed Rule anticipates that most of this information will be exchanged in connection with either the treatment of the individual, payment for the care of the individual, or the "health care operations" of the ACO members. To the extent the ACO members receiving the information are not providers, or in the event of exchanges of information between provider ACO members and the ACO itself, it is likely that the non-provider members (or the ACO entity itself) would be acting as "business associates" of the provider ACO members. In either case, the Proposed Rule anticipates that any such exchanges would be allowed under HIPAA as either "treatment, payment, or health care operations" disclosures or as disclosures to a business associate.

Much of the information to be provided to the ACOs by CMS will be aggregated data, which likely will not include individually identifiable information that would raise HIPAA concerns.

However, some information will be provided that identifies the beneficiaries assigned to the ACO, and that information would be subject to HIPAA restrictions. CMS has determined in the Proposed Rule that the disclosure of this information from CMS to the ACO would be allowed under HIPAA pursuant to the "health care operations" exception. CMS also addresses the Federal Privacy Act in the Proposed Rule, and comes to the conclusion that the disclosures from CMS to the ACOs would be allowed.

The Proposed Rule also anticipates that ACOs may seek more specific claims data in order to improve efficiency and measure the costs of care being delivered. CMS will be able to provide this additional data, but only if the ACO agrees to a Data Use Agreement restricting the use of the additional data.

Finally, CMS notes that, while CMS believes it has the authority under HIPAA to release beneficiary data to ACOs, it also notes that individual Medicare or Medicaid beneficiaries should have control over whether their information is so disclosed. Therefore, the Proposed Rule contemplates an "opt-out" mechanism that would allow beneficiaries to decide that their personal information should not be shared by CMS. In those instances, ACO providers would still be able to exchange information among themselves (as is customary under current law) for treatment of the patient or for payment or health care operations purposes, but would not receive data from CMS regarding that patient's past receipt of care or treatment.

IX. COORDINATION WITH OTHER AGENCIES

A. Federal Law Waivers

1. Antitrust Agencies

Congress anticipated that the implementation of ACOs might require the waiver of existing laws or regulations relating to payments for referrals and related laws. The Act itself provides that "The Secretary may waive such provisions of sections 1128A [civil monetary penalties] and 1128B [anti kickback and other criminal penalties] and title XVIII [Medicare] of this Act as may be necessary to carry out the provisions of this section."

What Congress failed to address was the effect of the antitrust laws on the implementation of the MSSP. Inherent in the ACO concept is that competing groups of providers will align themselves to jointly provide and coordinate care for a defined Medicare population, thus raising antitrust concerns.

Federal antitrust laws treat naked price-fixing or market allocation agreements as *per se* violations of the law. Competing groups of cardiologists, for example, may not jointly negotiate contracts with managed care plans. Joint price agreements among competing providers are evaluated under a "Rule of Reason", however, if the providers are financially or clinically integrated, and the joint pricing agreement is reasonably necessary to accomplish the procompetitive benefits of the proposed arrangement. A rule of reason analysis evaluates whether the proposed arrangement has any substantial anticompetitive effects, and if so, whether the procompetitive benefits of the combination are likely to outweigh such effects.

The Department of Justice and the Federal Trade Commission (the "***Antitrust Agencies***") share joint jurisdiction enforcing the antitrust laws. The Antitrust Agencies have been involved for many months in the discussions with CMS surrounding ACOs, and on March 31st simultaneously with the Proposed Rule published a "Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program." (the "***Policy Statement***"). As the Antitrust Agencies note in the Policy Statement:

> "The [Antitrust] Agencies recognize that ACOs may generate opportunities for health care providers to innovate in both the Medicare and commercial markets and achieve for many consumers the benefits Congress intended for Medicare beneficiaries through the Shared Savings Program. Therefore, to maximize and foster opportunities for ACO innovation, the Agencies wish … to clarify the antitrust analysis of newly formed collaborations among independent providers that seek to become ACOs in the Shared Savings Program…….[N]ot all such ACOs are likely to benefit consumers [however], and under certain conditions ACOs could reduce competition and harm consumers through higher prices or lower quality of care. Thus, the antitrust analysis ….. must remain sufficiently rigorous to protect both Medicare beneficiaries and commercially insured patients from potential anticompetitive harm."

The Policy Statement is intended to ensure that health care providers have the guidance needed to form procompetitive ACOs that participate in both the Medicare and commercial markets. The Policy Statement describes (l) the ACOs to which the guidance will apply; (2) when the Agencies will apply rule of reason treatment to those ACOs; (3) an antitrust safety zone; (4) the Agency review of ACOs exceeding a 50 percent share threshold mandated by CMS under the Shared Savings Program; and (5) options for ACOs to obtain additional antitrust certainty if they are outside the safety zone and below the mandatory review threshold. The Policy Statement applies only to ACOs formed on or after March 23, 2010 that seek to contract with CMS in the MSSP program.

The Antitrust Agencies believe that CMS's proposed eligibility criteria for ACOs are "broadly consistent" with the clinical integration guidelines previously published by the Antitrust Agencies. Thus, they conclude, "organizations meeting the CMS criteria for approval as an ACO are reasonably likely to be bona fide arrangements intended to improve the quality, and reduce the costs, of providing medical and other health care services through their participants' joint efforts", and thus will not be challenged by the Antitrust Agencies.

The Policy Statement goes on to expand favorable treatment specifically to the commercial payor market, concluding that rule of reason treatment will be afforded to an MSSP ACO also participating in the commercial market, provided that the ACO uses the same governance and leadership structure and clinical and administrative processes as it uses to qualify for and participate in the MSSP. This rule of reason treatment will apply to the ACO for the duration of its participation in the Shared Savings Program.

Safety Zones

The Policy Statement sets forth an antitrust "Safety Zone" for certain ACOs. Specifically, the Antitrust Agencies, absent extraordinary circumstances, will not challenge an ACO that otherwise meets the CMS criteria to participate in the MSSP if ACO participants that provide the same or a common service (wherever two or more ACO participants provide that common service to patients) have a combined share of 30 percent or less of each common service in each ACO participant's Primary Service Area (PSA). This safety zone is particularly applicable to hospitals or large medical groups. If a hospital system has greater than a 30% market share (not unusual in many markets), that system likely will be the only hospital in the ACO.

Rural ACOs have an additional safety zone. An ACO may include one physician per specialty from each rural county (as defined by the U.S. Census Bureau) on a non-exclusive basis and qualify for the safety zone, even if the inclusion of these physicians causes the ACO's share of any common service to exceed 30 percent. Likewise, an ACO may include Rural Hospitals on a non-exclusive basis and qualify for the safety zone, even if the inclusion of a Rural Hospital causes the ACO's share of any common service to exceed 30 percent in any ACO participant's PSA for that service.

The Policy Statement also includes a "Dominant Provider" limitation which provides that any provider participating in an ACO with greater than a 50% market share within its PSA (assuming no one else provides that service) must be nonexclusive to the ACO, and may not restrict a commercial payor's ability to contract or deal with that or other ACOs.

Antitrust Agency Review

CMS in the Proposed Rule prohibits ACOs which do not meet the rural exception from participating in the MSSP if they exceed a 50% market share for any common service, unless they first obtain a mandatory Antitrust Agency review. The ACO must provide to CMS a letter from one of the Antitrust Agencies stating that the reviewing Agency has no present intention to challenge or recommend challenging the ACO under the antitrust laws. The Antitrust Agencies have committed to providing expedited review of such requests.

Conclusion

The guidance in the Policy Statement is fairly clear and straightforward, and has the advantage (unlike the IRS guidance discussed below) of applying directly to commercial payors as well as the MSSP. The math and market analysis, however, can be exceedingly complex. In evaluating participation in the ACO, ACO organizers must engage in careful market share analysis in order to determine which providers and suppliers will be invited to join the ACO.

2. Stark, Anti-Kickback, and Gainsharing CMP

The basic concept of the ACO involves providers working together and sharing reimbursement gained from cost savings. However, this concept is in direct conflict with the primary regulatory

structure of the healthcare industry: preventing referral-receiving providers of services such as hospitals from providing financial incentives to referral-generating providers such as physicians. The only way to reconcile these structures is to waive the applicability of regulatory schemes such as the Stark Law, Anti-Kickback Statute, and Gainsharing CMP. The Act specifically states that "[t]he Secretary [of HHS] may waive requirements of Section 1128A and 1128B and title XVIII of [the] Act as may be necessary to carry out the provisions of" the Act.

The OIG Proposal specifically outlines regulatory waivers of three components of federal fraud and abuse laws: the Stark Law (42 USC 1395nn)("***Stark Law***"), the Anti-Kickback Statute (42 USC 1320a-7b(b))("***Anti-Kickback Stature***"), and the Prohibition on Hospital Payments to Physicians to Induce Reduction or Limitation of Services (sometimes referred to as the Gainsharing Civil Money Penalty or "***Gainsharing CMP***") (42 USC 1320a-7a(b)). Unless an exception or safe harbor applies, (i) the Stark Law prohibits referrals for certain designated health services if a financial relationship exists; (ii) the Anti-Kickback Statute prohibits payments for referrals for any services paid for by a government program; and (iii) the Gainsharing CMP prohibits payments by hospitals to doctors intended to reduce or limit the provision of services to governmental payment program patients.

In connection with the publication of the Proposed Rule, the HHS OIG published a special rule outlining the waiver of these three regulatory prohibitions in connection with ACO payments. The OIG Proposal is divided into two primary sections: one granting waivers, and another seeking comments on the existing waivers and possible new ones. In the OIG Proposal, waivers are granted to certain payments that might otherwise violate the Stark Law, Anti-Kickback Statute, or Gainsharing CMP (the "***Fraud and Abuse Prohibitions***"). Unlike waivers for certain insurance plans under some other provisions of the Affordable Care Act, these waivers are granted automatically to all ACO arrangements, and do not need to be applied for specifically.

Stark Law Waiver. The only activities that are subject to the Stark Law waiver are payments of Shared Savings Program funds. Specifically, the OIG Proposal waives applicability of the Stark Law to (i) distributions of Shared Savings Program funds to or among ACO participants, or (ii) the distribution of Shared Savings Program funds in connection with activities necessary for or directly related to ACO participation. This waiver applies only to Shared Savings Program distributions; any other payment or financial arrangement must meet an existing Stark Law exception. The waiver is also very limited in respect to payments to providers outside of the ACO; those payments are only subject to the waiver if they are both necessary for, and directly related to, the ACO's participation in the Shared Savings Program.

Anti-Kickback Statute Waiver. The OIG Proposal waives the Anti-Kickback Statute prohibitions in the same situations as are described in the Stark Law Waiver, but also waives the prohibitions of the Anti-Kickback Statute with respect to any other financial relationships among ACOs, ACO Participants and ACO providers/suppliers if the relationship is both necessary for and directly related to the ACO's participation in the Shared Savings Program. Therefore, the Anti-Kickback Statute waiver is broader than the Stark Law waiver.

Gainsharing CPM Waiver. The OIG Proposal waives the applicability of the Gainsharing CMP in connection with distributions of Shared Savings Program funds by a hospital

participating in an ACO and physicians participating in the same ACO, as long as the payment is not knowingly made to induce a physician to limit medically necessary services. The OIG Proposal also waives the Gainsharing CMP relating to other financial relationships among ACOs, their participants and providers/suppliers if the relationship is both necessary for and directly related to the ACO's participation in the Shared Savings Program, but only if it also meets a Stark Law exception.

Seeking Comments. The second component of the OIG Proposal seeks public comment and input on the proposed waivers and on the need for additional waivers. Specifically, the OIG Proposal seeks comments on the following matters:

- Arrangements relating to the establishment of the ACO;
- Arrangements among the ACO and ACO participants relating to ongoing operations of the ACO;
- Arrangements between the ACO or ACO participants and persons or entities outside the ACO;
- Distributions of shared savings or similar payments from private payers;
- Other financial arrangements where a waiver would be necessary;
- The duration and timing of waivers;
- Additional safeguards that might be necessary;
- The scope of the existing waivers;
- Special issues related to the two-sided risk model;
- Interaction of these waivers with the safe harbor for electronic health records; and
- The prohibition on beneficiary inducement.

The waivers granted in the OIG Proposal are extremely limited, and do not address many of the seemingly-obvious problems with the ACO concept in light of the Fraud and Abuse Prohibitions. The Stark Law waiver does not apply to any situation other than the distribution of Shared Savings Program funds; for example, payments by a hospital to establish an ACO that will include (and benefit) physicians on the medical staff of the hospital would not be subject to the Stark Law waiver. The Anti-Kickback Statute waiver is slightly broader, but the Gainsharing CMP waiver only applies to distributions of Shared Savings Program funds or arrangements that otherwise meet the existing Stark Law exceptions. The fact that the OIG Proposal specifically seeks additional commentary, and even lists specific areas for discussion, seems to indicate that the final rule may include many more waivers than are currently being offered. As currently drafted, the OIG Proposal will be of limited benefit to entities currently forming ACOs among otherwise unrelated providers.

3. IRS Issues Partial Guidance

In conjunction with the issuance by CMS of regulations regarding participating in the MSSP through an ACO, the Internal Revenue Service ("***IRS***") issued guidance [CLICK HERE] on the

effect of such participation by a 501(c)(3) organization on its federal tax exempt status. Unfortunately, the IRS left open some important issues that can adversely impact an organization's tax exempt status, requesting comments in lieu of giving direction. In Notice 2011-20 the IRS states the following:

(i) A tax exempt organization's participation in an ACO should not result in inurement or impermissible private benefit as long as certain conditions are met;

(ii) Any payments received by the tax exempt organization from an ACO will not be treated as unrelated business income tax ("***UBIT***") as long as the ACO meets all of the eligibility requirements established by CMS for participation in the ACO; and

(iii) The IRS explicitly declined to address the issue of whether an organization's participation in non-MSSP activities through an ACO is consistent with its tax exempt status or results in UBIT. Instead, the IRS solicits comments on these issues, thereby leaving a large area of risk for tax exempt organizations participating in ACOs.

Each of these matters is discussed below:

1. Inurement and Private Benefit. Under the Internal Revenue Code, no part of a tax exempt entity's income may inure to the benefit of its insiders, nor may such entity be operated for the benefit of private parties. In the case of a tax exempt entity's involvement in an ACO whose participants may be insiders, and which clearly results in the benefit of private persons, the IRS states that it will not consider such participation as inurement or impermissible private benefit if: (a) the terms of the tax exempt organization's participation are set forth in advance in a written agreement negotiated at arm's length; (b) CMS has accepted and has not terminated the ACO from the MSSP; (c) the tax exempt organization's share of economic benefits derived from the ACO is proportional to the benefits or contributions the tax exempt organization provides to the ACO; (d) the ownership interest received by the tax exempt entity is proportional and equal in value to its capital contributions to the ACO, and all returns of capital, allocations and distributions are made in proportion to such ownership interest; (e) the tax exempt organization's share of the ACO's losses does not exceed the share of ACO economic benefits to which it is entitled; and (f) all contracts and transactions entered into by the tax exempt entity by the ACO are at fair market value.

2. Unrelated Business Income. The Notice goes on to address the issue of whether monies received by a tax exempt organization from an ACO will be subject to UBIT. The Notice states that:

> "The IRS expects that, absent 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 such charitable purpose

> of lessening the burdens of government within the meaning of TREAS. REG. § 1.501(c)(3)-1(d)(2), as long as the ACO meets all of the eligibility requirements established by CMS for participation in the MSSP. Congress established the MSSP to be conducted through the ACOs in order to promote quality improvement and cross savings, thereby lessening the government's burden associated with providing Medicare benefits."

The result is that any income received by a tax exempt entity from participating in the MSSP from activities related to the MSSP, absent inurement or impermissible private benefit, is *by definition* related to such organization's tax exempt purpose and will not be treated as UBIT by the IRS.

3. Non-MSSP Activities. Finally, the IRS states its understanding that some tax exempt organizations might participate in ACOs conducting activities unrelated to the MSSP. The IRS specifically declines to address what effect such participation will have on an organization's tax exempt status. The IRS states that many non-MSSP activities conducted by or through an ACO are unlikely to lessen the burdens of government and would not, therefore, qualify as a charitable purpose by virtue of such activity. However, the IRS also recognizes that certain non-MSSP activities may further or be substantially related to an exempt purpose of the tax exempt entity, thereby allowing any monies generated by such activity to escape treatment as UBIT. The IRS uses the Notice to request comments regarding how a tax exempt organization's participation in particular non-MSSP activities through an ACO may further, or are substantially related to, an exempt purpose.

   The net effect is that an exempt organization that participates in non-MSSP related activities through an ACO could: (i) have the revenues generated by such activity be subjected to UBIT, or (ii) in the most extreme case, lose its tax exempt status. Instead of clearing the path to such participation by exempt entities, the IRS has delayed clarification. The advice for exempt organizations planning to participate in ACOs that engage in activities unrelated to the MSSP: send comments to the IRS and be careful. CAUTION.

B. State Law Waivers

Insurance Code and Proposed State Legislation

CMS states that under the proposed Two-Sided Model, the Medicare program retains the insurance risk and responsibility of paying claims for services provided to Medicare beneficiaries. Under the MSSP, the agreement to share risk is between the Medicare program and the ACO, and does not implicate payments for claims. Thus, CMS does not foresee that the MSSP implicates state insurance laws. CMS concedes, however, that some states may regulate risk-bearing entities such as ACOs, and it invites comments of whether any aspects of the Proposed Rule would trigger the application of state insurance laws.

There was considerable speculation that the Proposed Rule would address state insurance laws in more specific terms than it does. As the Proposed Rule is so new, the Texas Department of Insurance ("***TDI***") has not issued any formal comment on whether ACOs are subject to regulation under Texas state law. At least two bills currently before the Texas Legislature, however, may be relevant to Texas providers considering the ACO model.

Senate Bill 8 establishes "health care collaboratives" under a new Chapter 848 of the Texas Insurance Code. A "health care collaborative" is defined as an organization consisting of participating physicians, providers, or other entities, that is organized within a formal legal structure to provide or arrange to provide health care services, and is capable of receiving and distributing payments to participating physicians or health care providers. Under Chapter 848, health care collaboratives certified by TDI would be exempt from antitrust laws.

Under SB 8, a health care collaborative under Chapter 848 need not qualify as an ACO. Indeed, the bill provides that an organization is not required to be certified as a health care collaborative to the extent it provides health care services only as an ACO under contract with CMS. This is not to say that an entity could not qualify as both an ACO and a health care cooperative, but an entity need not do so. SB 8 is currently under consideration by the Senate Committee of Health and Human Services and faces weeks of discussion and possible amendment before it is even considered for passage. Texas providers interested in the idea of collaboration should follow the progress of this bill.

Texas physicians and other providers that participate in Medicaid or Texas CHIP should also be aware of another bill, Senate Bill 7, currently under consideration by the Texas Legislature. Similar to the theme underlying ACOs, SB 7 requires the Texas Health and Human Services Commission ("***HHSC***") to develop "quality-based payment systems" for compensating Medicaid and CHIP providers that align payment incentives with high-quality, cost-effective care, reward the use of evidence-based best practices, promote the coordination of care, encourage provider collaboration, promote effective care delivery models, and take into account the specific needs of recipient populations. Although SB 7 does not mandate the establishment of Medicaid or CHIP ACOs, it does provide HHSC considerable flexibility in designing quality-based payment systems that will affect Medicaid and CHIP providers in the state should this bill become law.

X. MONITORING AND TERMINATION OF ACO PARTICIPATION

In order to ensure compliance with the Accountable Care Act and the regulations, CMS will monitor ACOs during the term of their agreements for participation in the MSSP. In order to monitor the ACOs, CMS will utilize (i) data analysis, (ii) site visits, (iii) assessment and follow up of beneficiary and provider complaints, and (iv) audits, and reserves the ability to use any other means of monitoring that it deems necessary. An ACO that incurs large losses to Medicare will be subject to heightened oversight. In order to facilitate its monitoring of ACOs, CMS is imposing a 10-year document retention requirement on ACOs, ACO participants, ACO providers/suppliers, and all contracted entities performing services or functions on behalf of the ACO, which will include any party that enters into an agreement with an ACO to provide services to the ACO (including administrative services) or health care services to the beneficiaries assigned to the ACO.

A. Avoidance of Patients At-Risk

CMS has the authority to terminate agreements with ACOs for a variety of reasons. The Affordable Care Act specifically provides that ACO agreements may be terminated for avoidance of patients at-risk. Due to the model of sharing in savings, certain high cost beneficiaries may be at risk for avoidance by an ACO looking to maximize its savings against its benchmark costs. While the Affordable Care Act does not define "patients at-risk," this term is defined in the Proposed Rule as "beneficiaries who have a high risk score on the CMS-HCC risk adjustment model, are considered high cost due to having two or more hospitalizations or emergency room visits each year, are dually eligible for Medicare and Medicaid, have a high utilization pattern, have one or more chronic conditions (such as, for example, diabetes, heart failure, coronary artery disease, chronic obstructive pulmonary disease, depression, dementia, end stage renal disease) or beneficiaries who have a recent diagnosis (for example, newly diagnosed cancer) that is expected to result in an increased cost."

CMS has proposed to monitor the avoidance of these patients at-risk by analyzing claims and beneficiary-level documentation to identify trends and patterns of avoidance. It is not entirely clear what exactly CMS will be watching for as it monitors ACOs for this behavior, or how ACOs might avoid patients at-risk, due to the fact that beneficiaries are assigned to ACOs retrospectively by CMS. Nonetheless, if CMS identifies such a pattern and determines that an ACO is avoiding patients at-risk, it will require a Corrective Action Plan (a "***CAP***") from the ACO, which must include a plan to stop avoidance of these patients. During the period that an ACO is operating under its CAP, the ACO will not receive any shared savings, regardless of the period of performance related to the shared savings in question, and the ACO will not be eligible to earn any shared savings. CMS will re-evaluate the ACO at the end of its CAP to determine whether to terminate the ACO's agreement or allow it to continue participation in the MSSP.

B. Quality Performance Standards

The Affordable Care act also provides that agreements may be terminated for failure to meet the established quality performance standards. If an ACO fails to meet one or more quality performance standards, CMS will issue a warning to the ACO and re-evaluate the performance of the ACO the following year. If the ACO continues to underperform at the follow up evaluation, its agreement may be terminated.

An ACO that has been identified by CMS as failing to meet the quality performance standards is disqualified from sharing in savings in each year in which it underperforms. The Proposed Rule does not specify whether this disqualification is from receiving shared savings previously earned, earning shared savings, or both.

C. Additional Causes for Termination & Termination by ACOs

In addition to these statutory terminations, the Proposed Rule provides that failure to continue to meet the eligibility requirements for participation in the MSSP could result in termination of the ACO's agreement. Specifically, the Proposed Rule provides a laundry list of reasons for which an agreement may be terminated which includes the following:

- Failure of the ACO to effectuate required regulatory changes during the agreement period after being given the opportunity for a CAP.
- Failure of an ACO to demonstrate that it has adequate resources in place to repay losses and to maintain those resources for the agreement period or failure to submit payment due to CMS in a timely manner.
- Noncompliance with requirements regarding beneficiary notification of provider/supplier participation in an ACO.
- Material noncompliance, or a pattern of noncompliance, with public reporting and other CMS reporting requirements.
- Limiting or restricting internally compiled beneficiary summary of care or medical records from providers and suppliers both within and outside of the ACO, to the extent permitted by law (for example, not sharing beneficiary medical records with providers or suppliers not participating in the ACO from whom the beneficiary chooses to receive care).
- Violation of physician self-referral prohibition, civil monetary penalty laws, anti-kickback statute, other antifraud laws, antitrust laws, or other applicable Medicare laws, rules, or regulations that are relevant to ACO operations.
- Submission to CMS of false, inaccurate, or incomplete data or information, including information provided in the MSSP application, quality data, financial data, and information regarding the distribution of shared savings or failure to report quality measures.
- Use of marketing materials or activities or other beneficiary communications subject to approval that have not been approved by CMS.

The process for termination of an ACO's agreement by CMS may include giving notice to the ACO and, at its discretion, CMS may request a CAP from the ACO prior to terminating the agreement. Alternatively, CMS may place the ACO on a special monitoring plan prior to terminating its agreement.

In addition to termination of an agreement by CMS, an ACO may terminate its own agreement by providing at least 60 days written notice to CMS and giving notice to its ACO providers/suppliers. The ACO providers/suppliers are then obligated to notify the ACO's assigned beneficiaries of the ACO's decision to withdraw its participation in the MSSP.

If an ACO's agreement with CMS for participation in the MSSP is terminated for any reason, such termination will result in the automatic loss of the 25% withhold of shared savings discussed in Section VII. An ACO that has had its agreement terminated may re-apply for participation in the MSSP, but not before the end of its original 3-year agreement period. In its application, the ACO must demonstrate improvement in the areas for which the agreement was terminated. Because an ACO is permitted to have only one agreement under the One-Sided Model, an ACO that has had its agreement terminated will be permitted to re-enter the MSSP only under the Two-Sided Model.

D. Reconsideration Review Process

An ACO that has its agreement terminated for failure to meet established quality performance standards has no opportunity for administrative review as provided by Section 1899(d)(4) of the Social Security Act. For all other terminations, the Proposed Rule establishes an administrative process by which ACOs may request review. This administrative review process is applicable for all initial determinations, including rejection of an ACO's application for participation in the MSSP or termination of its agreement for reasons other than those statutorily prohibited from administrative review and actions taken due to determinations made by a reviewing anti-trust agency.

The administrative review process established in the Proposed Rule is similar to the DMEPOS competitive program and the Medicare Advantage Part C and D Programs, and includes reconsideration from a CMS reconsideration official, and a second review by an independent CMS official who was not involved in the initial determination or the subsequent reconsideration. The decision by the independent CMS official is not appealable and is CMS' final decision.

An ACO involved in the review process following notice of termination of its agreement from CMS will be permitted to participate in the MSSP until a final decision is reached. However, if the final decision is made to terminate the agreement, the effective date of termination will be the date indicated in CMS' initial notice to the ACO.

XI. CONCLUSION

While the concept of coordinated care is a viable one, whether ACOs will flourish and meet Congressional expectations is anyone's guess. CMS and related federal agencies have worked for months to deliver the Proposed Rule, scarcely nine months before the Congressional start date of January 1, 2012. The complexities in the rule are considerable, and many clarifications and modifications will be required prior to CMS issuing a Final Rule.

Potential ACOs have substantial work ahead of them to effectively analyze their markets, make assumptions about patient populations, determine market share of various physician specialties and hospitals, form and capitalize a new organization, integrate clinical recordkeeping capabilities, hire administrative staff, and conduct sophisticated financial modeling based on their best available information, in order to determine whether the ACO model is viable for them. All of that uncertainty is magnified since the number and identity of the Medicare population to be attributed to that ACO—hence the basis to calculate actual expenditures and savings—won't even be known until after January 1, 2013! In short, stay tuned for further developments.