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Life Sciences Health Industry Alert

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Summary and Analysis of Medicare's Shared Savings Program for Accountable Care Organizations

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Introduction

The Patient Protection and Affordable Care Act ("PPACA"), enacted in March 2010, requires that the Secretary ("Secretary") of the Department of Health & Human Services ("HHS") establish a Medicare "Shared Savings Program" by January 1, 2012.[1] The Shared Savings Program is intended to encourage physicians, hospitals, and certain other types of providers and suppliers to form accountable care organizations ("ACOs") to provide cost-effective, coordinated care to Medicare beneficiaries. At a basic level, an ACO is a network of physicians, hospitals, and other health providers that work together to improve the quality of health care services and reduce costs. The PPACA constructed the foundation of the ACO program under Medicare, but instead of establishing the details of the program in the statute, Congress authorized the Secretary to determine the parameters of the Shared Savings Program through rulemaking. Physicians, hospitals, physician groups, other providers, policymakers, and many other stakeholders in the health care industry have

eagerly anticipated the issuance of the ACO proposed rule. On March 31, 2011, under the authority of the Secretary, the Centers for Medicare & Medicaid Services ("CMS") issued the proposed rule.

The proposed rule addresses numerous policy and operational issues associated with the formation of an ACO, beneficiary assignment to an ACO, the establishment of quality standards, the calculation of incentive payments, and the monitoring of ACOs, among many other issues. However, because CMS requests comment on almost every aspect of the proposed rule, it is clear that the proposed rule is very much a proposal that is subject to change in the final rule. In addition to the CMS proposed rule, the federal government released several other documents related to ACOs, including:

- CMS and the Office of Inspector General ("OIG") jointly issued a notice with comment period discussing the waiver of the physician self-referral law, the anti-kickback statute, and certain provisions of the civil monetary penalty law in connection with the Medicare Shared Savings Program (*see* http://www.gpo.gov/fdsys/pkg/FR-2011-04-07/pdf/2011-7884.pdf).
- The Federal Trade Commission ("FTC") and the Department of Justice ("DOJ") jointly issued an Antitrust Policy Statement titled, "Proposed Statement of Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program" (*see* http://www.ftc.gov/os/fedreg/2011/03/110331acofrn.pdf).
- The Internal Revenue Service ("IRS") issued a notice requesting comments regarding the need for guidance on participation by tax-exempt organizations in ACOs (*see* http://www.irs.gov/pub/irs-drop/n-11-20.pdf).

The CMS proposed rule was published in the April 7, 2011 issue of the *Federal Register*.[2] The jointly issued CMS/OIG notice with comment period discussing the waiver of the physician self-referral law, the anti-kickback statute, and certain provisions of the civil monetary penalty law in connection with the Medicare Shared Savings Program was also published in the April 7, 2011 issue of the *Federal Register*.[3] CMS will accept comments on the proposed rule and the notice with comment period discussing the proposed waiver until June 6, 2011, and will respond to comments and issue a final rule and a final waiver later this year. CMS anticipates that the Shared Savings Program will begin operating January 1, 2012, as mandated by the PPACA.

This Client Alert first provides a brief overview of the ACO model, then summarizes the proposed rule, listing areas of comment solicited by CMS and identifying the practical impact of the proposed rule, as well as questions and concerns that may emerge. Finally, this Client Alert summarizes the jointly issued CMS and OIG notice with comment period discussing the waiver of the physician self-referral law, the anti-kickback statute, and certain provisions of the civil monetary penalty law in connection with the Medicare Shared Savings Program.

This Client Alert provides a summary and analysis of those provisions of the proposed rule and the proposed waiver that we believe are of greatest interest to health care providers, and medical device and pharmaceutical manufacturers. We would be pleased to provide further analyses for individuals or organizations considering participation in the Medicare Shared Savings Program, or to assist in developing comments to the proposed rule and/or the proposed waiver.

Overview of the ACO Model

ACO Basics

An ACO is an arrangement among health providers "who collectively agree to accept accountability for the cost and quality of care delivered to a specific set of patients."[4] Since surfacing as an idea in 2006, policymakers have touted ACOs as a way to promote integration while avoiding some of the perceived problems of past efforts, such as concerns of incentives to deny care and restrictions in provider choice under the managed care model.[5] Part of the promise of the ACO model is that it offers an approach for improved efficiency and quality in care without requiring a radical change in either the payment system currently utilized or current referral patterns.[6] As an article outlining ACOs states:

> The essence of an ACO lies less in its organizational form than in elements of its delivery and operation that enable "accountable" care, specifically its: capacity to deliver the continuum of care, grounded in strong primary care; payment that rewards specific improvements in quality as well as slower cost growth; and reliable measures of patients' health to assure that savings are achieved through improvements in care.[7]

If the Shared Savings Program under Medicare is successful, it is likely that the ACO model, or a similar model that results in more effective payment and service delivery, will spread to other

institutions that pay for health care and the patients those institutions cover. In fact, in a February 3 letter to governors, the Secretary of HHS, Kathleen Sebelius, urged states to use the ACO model in their Medicaid programs.[8] Further, the PPACA established a pediatric ACO demonstration project.[9] Finally, a number of states and private insurers have adopted or are considering ACO programs.[10]

General Concerns Regarding Medicare's Shared Savings Program

There are a number of potential concerns to consider when reviewing the proposed ACO rule. First, the shared savings of ACOs might not offset revenue lost from reduced patient utilization of services. In light of this concern, it is important to note the split, between CMS and an ACO, of the savings incurred by an ACO arrangement. It is also imperative that each provider considering the formation of an ACO or contemplating joining an ACO deliberate over the specific agreement governing how the savings will be distributed among providers that partake in a specific ACO. Another concern regarding ACOs is that a few, highly integrated ACOs could capture a large share of the market, dramatically lowering utilization rates for other providers. An additional issue related to the formation of an ACO is that the reporting requirements under the statute essentially mandate data systems and an organizational structure that a small physician group might not have the resources to create.

An ACO's quality performance score will have a significant impact on whether it qualifies for a shared savings payment and the amount of payment. Accordingly, providers and suppliers considering participation in an ACO should carefully consider whether the proposed ACO can exceed the minimum threshold of performance in the quality measures. CMS proposes 65 quality measures for year one with new measures to be identified in future rulemaking. Because the quality measures identified by CMS determine the financial performance of the ACO, providers and suppliers that choose to form an ACO are likely to devote significant resources to achieving the specific benchmarks identified by CMS. Further, under the proposed rule, at least 50 percent of the primary care physicians participating in an ACO must be "meaningful EHR users" by the start of the second year in order to continue participation in the program.

ACOs will be required to provide a detailed analysis of their respective market shares, and if an ACO's market share exceeds a 50 percent threshold, it will be required to obtain approval from federal antitrust enforcement agencies before participating in the Shared Savings Program. An additional concern is the narrowness of the proposed waiver from compliance with the federal Stark law, anti-kickback statute, and civil monetary penalty. Finally, the success of ACOs requires that patients perceive ACOs favorably and desire to participate in an ACO.[11]

Summary of the ACO Rule

Introduction and Important Definitions

Introduction

CMS requests comment on almost every aspect of its proposed rule. Thus, it seems clear that this proposed rule is, in fact, a proposal. Stakeholders who wish to provide comment on the proposed rule must do so ***no later than 5 p.m. ET June 6, 2011***.

In the preamble to the proposed rule, CMS declares its intent to promote accountability for a population of Medicare beneficiaries, improve the coordination of fee-for-service ("FFS") items and services, encourage investment in infrastructure and redesigned care processes for high-quality and efficient service delivery, and incentivize higher value care. The Shared Savings Program has a three-part aim that consists of the following:

- Better care for individuals—as described by all six dimensions of quality in the Institute of Medicine report: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity
- Better health for populations with respect to educating beneficiaries about the upstream causes of ill health—like poor nutrition, physician inactivity, substance abuse, economic disparities—as well as the importance of preventive services such as annual physicals and flu shots
- Lower growth in expenditures by eliminating waste and inefficiencies while not withholding any needed care that helps beneficiaries

In introducing the rule, CMS discusses related PPACA provisions, including the establishment of the Center for Medicare and Medicaid Innovation ("CMMI"). It explains that it plans to use CMMI to explore alternative payment models for the Shared Savings Program, and that it plans to make the alternative payment models developed by the CMMI available to Shared Savings Program

participants through future rulemaking. Unfortunately, the proposed rule does not provide any further detail about these potential alternative payment models.

CMS also remarks on the Physician Group Practice Demonstration as it relates to the Shared Savings Program. CMS notes that "over the course of the first three years, six of the ten groups shared in approximately $46 million in savings."[12]

Important Definitions

CMS proposes the following definitions:

- **Accountable care organization (ACO)**: 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 have established a mechanism for shared governance that provides all ACO participants with an appropriate proportionate control over the ACO's decision making process.
- **ACO participant**: a Medicare-enrolled provider of services and/or a supplier.
- **ACO provider/supplier**: a provider of services and/or a supplier that bills for items and services it furnishes to Medicare beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare rules and regulations.
- **ACO professional**: an ACO provider/supplier who is either of the following: (1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action, including an osteopathic practitioner within the scope of his or her practice as defined by State law; (2) a practitioner who is one of the following: (i) a physician assistant; (ii) a nurse practitioner; or (iii) a clinical nurse.[13]

Eligibility to Form ACOs, Legal Structure, Governance, Leadership and Management Structure and Operations

Who Can Form an ACO?

According to the proposed rule, an ACO may include the following types of groups of providers and suppliers of Medicare-covered services, provided that they have established a "mechanism for shared governance":

- ACO professionals (*i.e.*, physicians or practitioners such as physician assistants, nurse practitioners, and clinical nurse specialists)
- Networks of individual practices of ACO professionals
- Partnerships or joint venture agreements between hospitals and ACO professionals
- Hospitals employing ACO professionals
- Such other groups of providers of services and suppliers as the Secretary determines appropriate

In addition to the foregoing, CMS has exercised its statutory authority to allow certain critical access hospitals ("CAHs") to form ACOs independently. In order to independently form an ACO, a CAH must bill under "method II," whereby a CAH submits bills for both the facility and the professional services to its Medicare fiscal intermediary or its Medicare Part A/B Medicare Administrative Contractor ("MAC"). Because CAHs that bill under the "standard method" do not submit claims with information on individual practitioners or the type of health professional that provided a specific service, these CAHs could not independently form an ACO.

In the preamble to the proposed rule, CMS emphasizes that ACO configurations can encompass a broad range of providers and suppliers, including post-acute care facilities, federally qualified health centers ("FQHCs"), rural health centers ("RHCs"), and CAHs. It also points out that it proposes to provide an incentive of an increased percentage of shared savings for ACOs that include FQHCs and RHCs because of the "special role that these entities play in the health care delivery system, especially in providing care to otherwise underserved and vulnerable populations."[14]

Antitrust Concerns

The proposed rule creates a structure for addressing antitrust concerns based on the ACO participants' combined share of health care services in the relevant "primary service area." Under the proposed rule, if an ACO has greater than 50 percent of the primary service area share for any common service that two or more ACO participants provide, it must either: (1) meet the Rural

Exception articulated in the Antitrust Policy Statement[15] or other controlling guidance from the antitrust agencies, or (2) request an expedited antitrust review from the antitrust agencies (the Department of Justice, "DOJ," and the Federal Trade Commission, "FTC") confirming that the agencies have no present intent to challenge or to recommend challenge to the proposed ACO, and then submit this letter to CMS as part of its application to participate in the Shared Savings Program. If an ACO has greater than 30 percent and less than or equal to 50 percent of the primary service area share for any common service that two or more ACO participants provide, it must either: (1) meet the Rural Exception articulated in the Antitrust Policy Statement or other controlling guidance from the antitrust agencies; (2) request an expedited antitrust review from the antitrust agencies confirming that the agencies have no present intent to challenge or to recommend challenge to the proposed ACO and submit this letter to CMS; (3) begin to operate and follow a list of conduct restrictions; or (4) begin to operate and remain subject to an antitrust investigation. If an ACO has less than 30 percent of the primary service area share for any common service that two or more ACO participants provide, it qualifies for a safety zone and is not subject to antitrust review.

Under the proposed rule, if an ACO makes any material changes to its ACO participants or ACO providers/suppliers, then it must submit recalculated primary service area shares for common services that two or more ACO participants provide. If the revised primary service area share is greater than 50 percent, the ACO would be subject to review or re-review by an antitrust agency. Further, if an ACO receives a letter from an antitrust agency stating that the antitrust agency will likely challenge or recommend challenging the ACO, then the ACO will be ineligible to participate in the Shared Savings Program.

Legal Structure and Governance

The proposed rule would require that ACOs meet the following requirements: (1) be a legal entity that is recognized and authorized to conduct its business under applicable state law; (2) have a taxpayer identification number ("TIN"); (3) consist of an eligible group of ACO participants (discussed in Part II.A above); and (4) have a mechanism for shared governance.

Legal Entity

CMS proposes to require that an ACO be an organization that is recognized and authorized to conduct its business under applicable state law and is capable of: (1) receiving and distributing shared savings; (2) repaying shared losses; (3) establishing, reporting, and ensuring ACO participant and ACO provider/supplier compliance with program requirements, including quality performance standards; and (4) performing other ACO functions identified in the statute.

The preamble of the proposed rule stipulates that CMS would not require that existing legal entities appropriately recognized under state law form a new and separate legal entity to participate in the Shared Savings Program. As an example, the preamble states that a hospital employing ACO professionals may be eligible to participate as an ACO in the Shared Savings Program without developing a new legal entity. However, CMS further states that if an existing entity would like to incorporate providers and suppliers that are not currently part of its existing legal structure, the entity must establish a new legal entity in order to provide all ACO participants with a mechanism for shared governance and decision making.

In its application, a proposed ACO would be required to provide evidence that it is recognized as a legal entity in the state in which it was established, and that it is authorized to conduct business in each state in which it operates.

Taxpayer Identification Number

The proposed rule would require that an ACO have a taxpayer identification number. Further, the proposed rule states that CMS would pay the ACO's shared savings to that TIN. ACOs would be required to report to CMS the TINs of all ACO participants, in addition to the list of associated National Provider Identifiers ("NPIs"), at the beginning of each performance year.

Mechanism for Shared Governance

CMS proposes an ACO be required to establish and maintain a governing body such as a board of directors, board of managers, or any other governing body that provides a mechanism for shared governance and decision making for all ACO participants. Further, CMS states that an ACO's governance mechanism "should allow for appropriate proportionate control for ACO participants, giving each ACO participant a voice in the ACO's decision making process, and be sufficient to meet the statutory requirements regarding clinical and administrative systems."[16]

CMS proposes that an ACO would not need to form a new and separate governing body, as long as its current governing body is able to meet all other criteria required for an ACO governing body. If an entity is not forming a new governing body, it would be required to show in its application that it meets all other criteria required for ACO governing bodies.

CMS proposes that an ACO should be operated and directed by Medicare-enrolled entities that directly provide health care services to beneficiaries, and specifically that ACO participants must have at least 75 percent control of the ACO's governing body. Further, at least one Medicare beneficiary served by the ACO who has no conflict of interest (and no family member with a conflict of interest) must serve on the governing body.

Leadership and Management Structure

Requirements

CMS proposes that an ACO must have a leadership and management structure that includes clinical and administrative systems. Thus, an ACO must meet the following criteria: (1) have an executive, officer, manager, or general partner who manages operations, whose appointment and removal are under control of the organization's governing body, and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency processes and outcomes; (2) have a senior-level medical director who would manage clinical management and oversight; (3) participants must have a meaningful commitment to the ACO's clinical integration, through a meaningful financial investment or a meaningful human investment; (4) have a physician-directed quality assurance and process improvement committee that would oversee an ongoing quality assurance and improvement program; (5) develop and implement evidence-based medical practice or clinical guidelines and processes for delivering care consistent with the goals of the proposed regulation; and (6) have an infrastructure, such as information technology, that allows the ACO to collect and evaluate data and provide feedback to the ACO providers/suppliers across the entire organization. CMS proposes that ACOs with "innovative leadership and management structures" would have the opportunity to develop an alternative leadership and management structure than what is described above, but it must describe in its application how the ACO will perform the leadership and management functions without the specific leadership regime the proposed rule outlines.

Application Process

In order to determine an ACO's compliance with the above-mentioned requirements, CMS proposes to mandate the following in the ACO application process: (1) ACO documents that describe the ACO participants' and ACO providers/suppliers' rights and obligations in the ACO; (2) documents that describe the scope and scale of the quality assurance and clinical integration program; (3) supporting materials documenting the ACO's organization and management structure; (4) evidence that the ACO has a board-certified physician as its medical director; and (5) evidence that the governing body includes persons who represent the ACO participants, and that these participants account for at least 75 percent control of the governing board.

Operational Issues

Three-Year Agreement Period

CMS proposes that in order for an ACO to participate in the Shared Savings Program, it must enter into a participation agreement with CMS for a three-year period. Further, all ACO participants and ACO providers/suppliers with direct or indirect obligations under the Shared Savings Program would be subject to the requirements of the above-mentioned participation agreement.

Further, CMS proposes that the requisite three-year agreement period will begin January 1 following approval of an application, and that the ACO's performance periods under the agreement will begin January 1 of each respective year during the agreement period.

How ACO Shares Savings

An ACO can use its own discretion to determine how savings are shared among ACO participants. However, CMS would require that an ACO indicate, as part of its application, how it plans to use potential shared savings to meet the goals of the Shared Savings Program.

Mandatory Minimum of 5,000 Medicare Beneficiaries

An ACO under the Shared Savings Program is required to serve at least 5,000 Medicare beneficiaries. However, in the event the number of Medicare beneficiaries falls below 5,000 during

the agreement period with CMS, CMS would issue a warning and place the ACO on a corrective action plan. If the ACO fails to meet the 5,000 beneficiaries floor by the completion of the next performance year, CMS would terminate the ACO's participation agreement and the ACO would not receive any shared savings for that performance year.

Evidence-based Medicine, Beneficiary Engagement, Quality and Cost Metrics, and Care Coordination

CMS proposes that in order to participate in the Shared Savings Program, an ACO must provide documentation in its application describing its plans to: (1) promote evidence-based medicine; (2) promote beneficiary engagement; (3) report internally on quality and cost metrics; and (4) coordinate care.

Patient-Centeredness

CMS further proposes that an ACO would be required to demonstrate its focus on patient care. It proposes that an ACO would be considered patient-centered if it has all of the following: (1) a beneficiary care survey in place; (2) patient involvement in ACO governance; (3) a process for evaluating the health needs of the ACO's assigned population; (4) systems in place to identify high-risk individuals; (5) a mechanism in place for the coordination of care; (6) a process in place for communicating clinical knowledge/evidence-based medicine to beneficiaries in a way that is understandable to them; (7) a process in place for beneficiary engagement and shared decision-making that takes into account the beneficiaries' unique needs, preferences, values, and priorities; (8) written standards in place for beneficiary access and communication, and a process in place for beneficiaries to access their medical record; and (9) internal processes in place for measuring clinical or service performance by physicians across practices. CMS proposes that ACOs be required to use the Clinician and Group survey developed by the Consumer Assessment of Healthcare Providers and Systems ("CAHPS") program, and also that an appropriate functional status survey module is incorporated into the CAHPS survey. In addition, in order to show that an ACO has a process for evaluating the health needs of the ACO's assigned population, the applying ACO must describe, in its application, its processes for evaluating the health needs of its Medicare population, including a consideration for diversity, and a plan to address the needs of its Medicare population.

Program Integrity Requirements

CMS proposes to mandate that an ACO have a compliance plan that addresses how the ACO will comply with applicable legal requirements. The compliance plan must contain the following five elements: (1) a designated compliance official or individual who is not legal counsel to the ACO and who reports directly to the ACO's governing body; (2) mechanisms for identifying and addressing compliance programs related to the ACO's operations and performance; (3) a method for employees or contracts of the ACO or ACO providers/suppliers to report suspected problems related to the ACO; (4) compliance training of the ACO's employees and contractors; and (5) a requirement to report suspected violations of law to an appropriate law enforcement agency. It is important to note that the requirement that an ACO have a designated compliance official or individual who "is not legal counsel" to the ACO and who reports directly to the ACO's governing body does not preclude an attorney from serving as the compliance officer, but likely prohibits the general counsel of an organization from serving as the compliance officer.

Further, the ACO would be responsible for complying with its three-year agreement with CMS. In addition, the ACO must certify the accuracy, completeness, and truthfulness of information contained in its Shared Savings Program application, three-year agreement, and submission of quality data and other information. As a condition of receiving shared savings, the ACO must make a written request to CMS, certifying that it adhered to the program requirements, and again certify the accuracy, completeness, and truthfulness of information provided by the ACO to CMS. CMS also proposes that the ACO must develop a conflicts-of-interest policy that applies to members of the governing body.

Areas Where CMS Solicits Comments

CMS solicits comments on almost every aspect of the proposed rule. With respect to the eligibility to form ACOs, legal structure, governance, and operations CMS seeks comments in the following areas:

- What providers, suppliers, and groups can form ACOs
- The kinds of providers and suppliers that should or should not be included as potential ACO participants

- The potential benefits or concerns regarding including or not including certain provider or supplier types
- The administrative measures that would be needed to effectively implement and monitor particular partnerships
- Other ways in which CMS could employ the discretion provided to the Secretary to allow the independent participation of providers and suppliers not specifically mentioned in the statute, for example, through an ACO formed by a group of FQHCs and RHCs
- Any operational issues associated with its proposal
- The requirement that all ACOs participating in the Shared Savings Program be formed as a distinct legal entity appropriately recognized and authorized to conduct business under applicable state law, or if an existing legal entity could be permitted to participate in the Shared Savings Program as an ACO, including entities that have similar arrangements with other payors
- The required legal structure, and other suitable legal structure requirements
- Whether the requirement for the creation of a separate entity creates disincentives for the formation of ACOs, and whether there is an alternative that would not result in such disincentives
- Whether allowing existing entities to be ACOs would complicate its monitoring and auditing of the ACO
- Whether requirements for the creation of a governing body as a mechanism for shared governance would create disincentives for the formation of ACOs, and whether there is an alternative requirement that could be used to achieve the aims of shared governance and decision making
- Whether more or less than 75 percent control of the governing body being held by the ACO participants is an appropriate percentage
- Whether the representative positions should be held by persons employed by and representing Medicare-enrolled TINs
- The proposed leadership and management structure, and whether the compliance burden associated with these requirements will discourage participation in the Shared Savings Program
- Whether other or alternative leadership and management requirements would enable ACOs to fulfill the goals of the Shared Savings Program
- The requirement for the submission of certain documents described in the proposed rule, and whether the compliance burden associated with these requirements will discourage participation
- Whether the initial agreement period for an ACO should be more than three years
- Any additional measures or alternative means that would satisfy the agreement requirement beyond what is specified in the proposed rule
- The proposal to make shared savings payments directly to the ACO, as identified by its TIN, and to make shared savings payments to a non-Medicare-enrolled entity
- How to determine whether an ACO has a sufficient number of primary care ACO professionals to serve the number of Medicare beneficiaries assigned to it
- How to address the situation where an ACO's assigned Medicare beneficiary population falls below 5,000, and other potential options for this situation
- Whether more prescriptive criteria may be appropriate to meet the statutorily mandated development of defined processes to: promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care
- Requiring ACOs to use the Clinician and Group CAHPS survey, and whether other existing survey tools would be more appropriate for ACO quality assessment
- The inclusion of a Medicare beneficiary serviced by the ACO on the governing body, whether the requirement for beneficiary participation should include a minimum standard for such beneficiary participation on ACO governing bodies, and the possible role of a Medicare beneficiary advisory panel or committee in promoting the goal of engaging patients in ACO governance
- The proposal requiring an ACO to have a process for evaluating the health needs of the population, including consideration of diversity in its patient populations, and a plan to address the needs of its population

- Whether ACOs should be required to demonstrate use of individualized care plans for targeted beneficiary populations in order to be eligible for the Shared Savings Program
- Whether ACOs should be required in their applications to describe how they will partner with community stakeholders
- The proposed conflicts-of-interest policy, including the scope and content of such a policy
- The nature and scope of screening of ACOs applying to the Shared Savings Program, and the screening results that would justify a rejection of an application or increased scrutiny
- Any alternatives to a January 1 start date that would allow the greatest number of qualified organizations to apply to participate in the first year of the program

Analysis and Potential Issues for Comments

- The requirements for formation, governance and operation are quite onerous, and may present a fundamental challenge to a participation in a Shared Savings Program, particularly for smaller, unintegrated health care providers.
- Each ACO participant will need to carefully deliberate the ACO's shared saving distribution within the ACO, and ACO participants will need to consider how to apportion both risks and rewards.
- CMS is proposing to allow ACOs flexibility to meet requirements regarding evidence-based medicine, beneficiary engagement, quality and cost metrics, and care coordination. It is important to consider whether more prescriptive criteria should be required in these areas.

Beneficiary Assignment to ACOs

Introduction

CMS notes in the preamble and in the proposed rule that a Medicare beneficiary's assignment to a particular ACO in no way limits, restricts, or diminishes the right of a beneficiary to exercise freedom of choice when choosing providers or suppliers. CMS proposes a retrospective assignment process, meaning that an ACO would not know who its assigned Medicare beneficiaries were until the end of each performance year.

CMS proposes to assign beneficiaries based on the following process: (1) identify all primary care physicians who participated in an ACO during a performance year; (2) at the end of each performance year, determine all beneficiaries who received primary care services from primary care physicians in the ACO; (3) determine the total charges related to primary care services that each of the beneficiaries identified in step two received from any provider or supplier during the performance year; (4) for each beneficiary, add together charges derived from primary care services provided by primary care physicians in each ACO; and (5) assign a beneficiary to an ACO if the beneficiary has received a plurality of his or her primary care services from a primary care physician who participates in a particular ACO.

Operational Identification of an ACO and Identification of Primary Care Physicians Who Participate in an ACO

CMS proposes to identify primary care physicians assigned to a particular ACO through their TINs. Thus, in terms of assignment, an ACO will be identified as a collection of Medicare-enrolled TINs. For example, a single group practice that participates in an ACO will be identified by its TIN, while a network of independent practices that join to form an ACO will be identified by the set of TINs of the practices constituting the ACO. Under the proposed rule, CMS would require that ACO applicants provide not only ACO participant TINs, but also a list of associated NPIs for all ACO professionals. Further, the ACO would be required to provide CMS a NPI list that specifically identifies primary care physicians.

Beneficiaries would be assigned to an ACO through a TIN based on the primary care services received from physicians billing under that TIN. It is important to note that CMS proposes that ACO professionals who become the basis of a beneficiary's assignment must be exclusive to one ACO agreement in the Shared Savings Program. This means that primary care physicians, defined as physicians practicing in internal medicine, geriatric medicine, family practice, and general practice, must be exclusive to one ACO. This exclusivity applies only to primary care physicians. Other ACO participants, such hospitals, surgeons, radiologists, and other medical specialists, are required to agree to participate for the full three-year term of an ACO's agreement, but would not be restricted to participating in a single ACO.

What are Considered Primary Care Services?

CMS proposes to assign Medicare beneficiaries to ACOs based on their utilization of primary care services provided by primary care physicians. Thus, it is important to understand what are considered primary care services under the proposed rule. CMS proposes to define "primary care services" on the basis of the set of HCPCS codes identified in section 5501 of the PPACA, including the G-codes associated with the annual wellness visit and Welcome to Medicare visit.[17] The codes that CMS has identified as "primary care services" generally cover routine office visits, wellness visits, patient home visits, and visits to patients in nursing facilities or rest homes.

Retrospective Assignment

CMS proposes to retrospectively assign beneficiaries to an ACO. What this means is that beneficiaries would be assigned to an ACO 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. CMS proposes, however, to provide an ACO with a list of beneficiary names, date of birth, sex, and other information derived from the data used to develop the ACO's benchmark. CMS states that it believes that by providing the data it uses to develop the ACO's benchmark, it will provide an ACO with a good idea of its likely patient population while encouraging ACOs to improve care provided to the entire patient population.

Assigning Beneficiaries Based on a Plurality of Primary Care Services Received

CMS proposes to assign beneficiaries to an ACO if they receive a plurality of their primary care services from primary care physicians within that ACO. What this means is that a beneficiary will be assigned to an ACO if he or she received more primary care (determined by allowed primary care services charges) from that ACO than any other provider during the course of the performance year.

Beneficiary Notification

The proposed rule would require ACO participants to post signs in each of their facilities and provide written notification for beneficiaries about their participation in the Medicare Shared Savings Program. CMS also states in the preamble that it intends to develop a "communications plan," which would provide Medicare beneficiaries with general information regarding the Shared Savings Program. Further, CMS plans to instruct ACOs to supply a form allowing beneficiaries to opt-out of having their data shared. These opt-out forms would be provided to a beneficiary during an office visit with a primary care physician, and would include a phone number, fax, or email for beneficiaries to contact in order to request that their data not be shared. Finally, ACOs would be required to inform Medicare beneficiaries should they choose to no longer participate in the Shared Savings Program.

Areas Where CMS Solicits Comments

CMS solicits comments on almost every aspect of the proposed rule. With respect to the assignment of beneficiaries, CMS seeks comments in the following areas:

- Requiring ACOs to report TINs and NPIs associated with each ACO provider/supplier
- The definition of primary care services, as well as the "step-wise" approach it describes in the proposed rule
- Assigning beneficiaries to physicians designated as primary care physicians, and other options that may address the delivery of primary care services by specialists
- Retrospective assignment of beneficiaries, combined with the provision of beneficiary data used to create the benchmark
- Alternative approaches to beneficiary assignment, including the prospective method of assignment
- Assigning patients to an ACO based upon a plurality rule
- Whether there should be a minimum threshold number of primary care services that a beneficiary should receive from physicians in the ACO in order to be assigned to an ACO, and if so, what that minimum threshold should be
- What the appropriate form and content of the Shared Savings Program notification to Medicare beneficiaries will be
- The utility of informing beneficiaries of the objectives of the Shared Savings Program, particularly those objectives that might have the most impact on them

- What the most important issues to communicate to beneficiaries about the Shared Savings Program are
- The proposed notification requirements

Analysis and Potential Issues for Comments

- The definition of primary care services in the proposed rule could make it difficult for ACOs to form in areas that have a shortage of primary care physicians, and further, any primary care services provided by specialists would not be considered when assigning beneficiaries.
- The proposed rule's focus on primary care services in beneficiary assignment obligates an ACO to develop a strong primary care network.
- Under retrospective assignment, an ACO would not know which beneficiaries it is responsible for until after the performance year. Without knowing which beneficiaries it will be responsible for during the course of each performance year, it would be difficult for an ACO to provide the best care to its ACO beneficiary population and to develop set operational goals. Thus, it would be important for an ACO to develop and implement broad-based care coordination, evidence-based medicine protocols, patient engagement processes, and other quality-improvement policies and procedures in order to best serve its entire patient population.
- Because an ACO's beneficiary population is assigned based on a plurality of primary care services, an ACO-assigned beneficiary could still receive much of his or her care outside of an ACO. This could make it difficult for an ACO to manage an assigned beneficiary's care.
- CMS seeks comment on the utility of informing beneficiaries of the objectives of the Shared Savings Program, particularly those objectives that might have the most impact on beneficiaries. CMS does not describe how, or whether, any notification would include an explicit discussion of how the ACO can receive shared savings if it reduces cost. It is important to consider whether the general beneficiary notification CMS proposes are sufficient, or if the additional disclosures are needed, specifically with regard to shared savings and potential referrals.

Payments to ACOs—How Savings and Losses Are Shared

Introduction

ACO participants would continue to receive payment under the original Medicare FFS program under Parts A and B in the same manner as they would otherwise be made. In addition, ACOs would receive payment for shared Medicare savings, *if* the ACO both (1) meets the quality performance standard discussed in Part V below, and (2) demonstrates that it has achieved savings against a benchmark of expected average per capita Medicare FFS expenditures.

In the proposed rule, ACOs participating in the Shared Savings Program have two potential tracks. In Track One, ACOs would not be responsible for any shared losses above the expenditure target in years one and two of the three-year ACO agreement. However, in the third year of the three-year agreement, an ACO would be required to share any losses. ACOs participating in Track One would be eligible for a smaller percentage of shared savings, with a maximum sharing rate of 52.5 percent. The proposed rule refers to this as the "one-sided" payment model. In Track Two, ACOs would be required to share any losses in all three years of its agreement period, but would also be eligible for a higher percentage of shared savings, with a maximum sharing rate of 65 percent. The proposed rule refers to this as the "two-sided" payment model. In the preamble, CMS notes that it has developed a two-track system so that it provides "an entry point for organizations with less experience with risk models, such as some physician-driven organizations or smaller ACOs, to gain experience with population management before transitioning to a risk-based model while also providing an opportunity for more experienced ACOs that are ready to share in losses to enter a sharing agreement that provides greater reward for greater responsibility."[18] CMS also notes in the preamble that it plans to design and test partial capitation models in the CMMI before adopting partial capitation methods more widely in the Shared Savings Program, but contains little specific information on this approach.

Establishing an Expenditure Benchmark

CMS proposes to establish the expenditure benchmark for an ACO by computing per capita expenditures for beneficiaries who would have been assigned to the ACO in each of the prior three most recent, available years, using a six-month claims run-out.[19] This benchmark would be updated annually during the three-year agreement period, based on the absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program.

How Beneficiaries Are Assigned to Establish a Benchmark

Beneficiaries would be assigned to an ACO for benchmark purposes in the same way that beneficiaries are assigned to an ACO for other purposes. Specifically, CMS would use the claims records of the ACO participants to determine a list of beneficiaries who received a plurality of their primary care services from primary care physicians participating in the ACO in each of the prior three most recent, available years.

How the Benchmark Would Be Computed

CMS would establish a benchmark by determining Parts A and B FFS per capita expenditures, adjusted for overall growth and beneficiary characteristics, for the beneficiaries that would be assigned to the ACO for the three prior years. In an attempt to minimize variation from catastrophically large claims, CMS would cut an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile, as determined for each benchmark year and for each subsequent performance year. The actual benchmark would be the weighted average of the three years' averages, after trending and risk adjusting, with the greatest weight assigned to the most recent year.

Adjusting for "Beneficiary Characteristics"

The proposed rule suggests adjusting the Medicare expenditure amounts by employing the CMS-Hierarchal Condition Category ("CMS-HCC") model used in the Medicare Advantage program. The CMS-HCC model uses demographic variables in addition to beneficiaries' prior year diagnoses to develop risk scores that then are applied to current year expenditures. CMS would calculate a single benchmark risk score for each ACO, and would not incorporate changes in the assigned beneficiary population risk score that occur during the performance year. CMS believes that using this model would: (1) "encourage ACOs to maintain complete and accurate documentation"; (2) prevent creating "an environment that rewards ACOs for achieving apparent savings by coding changes alone"; (3) "be a reasonable approximation of the actual risk score for the beneficiary population assigned to the ACO during the agreement period"; and (4) "protect the program from costs due to greater diagnosis coding intensity in ACOs."[20]

Other Adjustments

CMS does not propose to remove indirect medical education ("IME") and disproportionate share hospital ("DSH") payments from per capita costs included in the benchmark for an ACO. In the preamble, CMS explains that because it cannot remove IME and DSH payments in the calculation of performance year expenditures, "[i]f we were to remove IME and DSH payments from the benchmark, the benchmark would be set artificially lower relative to the performance period, thus making it more difficult for an ACO to overcome and achieve savings under the program."[21]

In addition, CMS does not propose to remove geographic payment adjustments from the calculation of benchmark expenditures. Further, consistent with the PPACA, CMS proposes to exclude Medicare expenditures or savings for incentive payments and penalties related to value-based purchasing initiatives such as Physician Quality Reporting System, eRx, and the EHR incentives for eligible professionals under the HITECH Act. However, certain incentive payments, such as EHR incentive payments to hospitals and critical access hospitals, and the Hospital Inpatient Value-Based Purchasing Program, would be counted in both the computation of actual expenditures and benchmark expenditures for Part A and B costs.

*Obtaining an Initial Benchmark—Trending Forward Prior Years' Experience*s

CMS proposes to establish an initial expenditure benchmark by trending forward the most recent three years of per-beneficiary expenditures using the national growth rates per beneficiary expenditures for Parts A and B services. The preamble to the proposed rule provides an example of how this trending would work in practice: "We would use the 2011, 2012 and 2013 claims year data to set the benchmark for an ACO starting its agreement period in 2014. The 2011 and 2012 data would be trended forward [using national growth rate in Medicare Parts A and B expenditures for FFS beneficiaries] so that all benchmark dollars would be in 2013 dollars." Using the national growth index, CMS would trend the expenditures to determine a benchmark for year three in a dollar amount. This dollar amount would then be adjusted, as described in Sections 2.a and 2.b above, to reflect benchmark year three risk-adjusted per capita expenditures for beneficiaries historically assigned to the ACO in each of the three years used to establish the benchmark stated in BY3 risk and expenditure amounts.

CMS would weight the most recent year of the benchmark, BY3, at 60 percent, would weight BY2 at 30 percent, and would weight BY1 at 10 percent to "ensure that the benchmark reflects more accurately the latest expenditure and health status of the ACO's assigned beneficiary population."[22]

Updating the Benchmark During the Agreement Period

The proposed rule would result in the initial benchmark being updated in the second and third years of an ACO's agreement period. The initial benchmark would be updated by the projected absolute amount of growth in national per capita expenditures.

Minimum Savings Rate

The proposed rule establishes a minimum savings rate ("MSR") that must be exceeded in order to qualify for shared savings. In the preamble of the proposed rule, CMS states, "The MSR should be set in a way that gives us some assurances that the ACO's performance is a result of its interventions, not normal variation."[23] The MSR, in combination with the savings rate, discussed below, will determine the amount of shared savings that an ACO can receive (if it meets the quality performance standards discussed in Part IV and otherwise maintains its eligibility to participate in the Shared Savings Program).

The minimum savings rate is a percentage of the benchmark that ACO expenditure savings must exceed in order for an ACO to qualify for shared savings in any given year. Under the proposed rule, ACOs in the one-sided payment model that have smaller populations, resulting in greater variation in expenditures, would have a larger MSR. ACOs in the one-sided payment model that have larger populations, and therefore have less variation in expenditures, have a smaller MSR. The MSR percentage is based on a statistical confidence interval ranging from 90 percent for small ACOs to 99 percent for larger ACOs. The confidence interval reflects at what point CMS can be sure that the savings are real, not the result of a fluke or randomness. A chart reflecting the MSR proposal for the one-sided payment model is set forth in the proposed rule, and is copied below.

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

Under the two-sided approach, CMS proposed a flat, 2 percent minimum savings rate.

Net Sharing Rate

As previously mentioned, CMS proposes that all ACOs must exceed the MSR to be eligible for savings. Further, CMS proposes that ACOs will only share in savings in excess of a certain threshold; however, certain ACOs will be exempted from the threshold. The threshold level proposed by CMS is the following: ACOs that exceed the MSR would be eligible to share in net savings above a 2 percent threshold, calculated as 2 percent of its benchmark (updated according to statute). The sharing rate would be applied to net savings above this 2 percent threshold in order to determine the shared savings amount.

The final sharing rate is defined as the quality performance sharing rate plus the percentage points for including FQHCs and/or RHCs as ACO participants.

Exempted ACOs

ACOs that meet any one of the following criteria would be exempt from the 2 percent net savings threshold and would instead share on first-dollar savings under the one-sided model:

- Less than 10,000 assigned beneficiaries in the most recent year for which CMS has complete claims data
- ACO is made up of only ACO professionals in group practice arrangements or networks of individual practices of ACO professionals
- 75 percent or more of the ACO's assigned beneficiaries reside in counties outside of a Metropolitan Statistical Area for the most recent year for which CMS has complete claims data
- 50 percent or more of the ACO's assigned beneficiaries were assigned to the ACO on the basis of primary care services received from a Method II critical access hospital
- 50 percent or more of the beneficiaries assigned to the ACO had at least one encounter with an ACO participant FQHC and/or RHC in the most recent year for which we have complete claims data

Additional Shared Savings Payments—Inclusion of FQHCs and/or RHCs

An ACO can achieve an increase in its shared savings rate for including a strong FQHC and/or RHC presence within the structure of the ACO. ACOs that participate in the one-sided payment model can receive an increased shared savings rate of up to 2.5 percentage points during the first two years of the agreement. CMS proposes a sliding scale of increased payment for ACOs participating in the one-sided payment model, based on the percentage of ACO-assigned beneficiaries with one or more visits to an ACO-participating FQHC/RHC during the performance year. The table below represents the sliding scale for ACOs participating in the one-sided payment model:

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

An ACO that participates in the two-sided payment model can also receive an increased shared savings rate of up to five percentage points if it includes a RHC or FQHC within its structure. The table below represents the sliding scale for ACOs participating in the two-sided payment model:

Percentage of ACO Assigned Beneficiaries With One or More Visits to an ACO Participant FQHC/RHC During the Performance Year	Percentage Point Increase in Shared Savings Rate (One-Sided Model)
1-10%	1.0
11-20%	2.0
21-30%	3.0
31-40%	4.0
41-50%	5.0

Withholding Rate and Recoupment of Losses

CMS proposes that a flat, 25 percent withholding rate would be applied annually to any earned performance payment. In the preamble, CMS states that this withholding rate is proposed because it "want[s] to encourage ACOs to participate for all three years of their agreements, protect the Medicare program against losses, and ensure ACOs have an adequate repayment mechanism in the event they incur losses under either the one-sided or two-sided [payment] model."[24]

Under the two-sided payment model, an ACO may withhold an additional, self-determined portion of its earned performance payment in the event that it incurs shareable losses in the future. CMS proposes that at the end of a three-year agreement period, it will return the positive balance of the shared savings withheld to the ACO. However, if the ACO does not complete its three-year agreement, the ACO would forfeit any savings withheld.

CMS proposes to require that an ACO establish a self-executing method for repaying losses to the Medicare program by doing any of the following: (1) indicating that funds may be recouped from Medicare payments to the ACO's participants; (2) obtaining reinsurance; (3) placing funds in escrow; (4) obtaining surety bonds; (5) establishing a line of credit as evidenced by a letter of credit that the Medicare program can draw upon; or (6) establishing another repayment mechanism. As part of the Shared Savings Program application process, an ACO participating in either the one-sided or two-sided payment model would be required to submit documentation of such a repayment mechanism, including details supporting the adequacy of such a repayment mechanism for repaying the ACO's maximum potential downside risk exposure for CMS' approval. CMS further proposes that an ACO must demonstrate that it can ensure repayment of losses equal to at least 1 percent of per capita expenditures for its assigned beneficiaries in the most recent available year. CMS would determine the adequacy of an ACO's repayment mechanism prior to an ACO participating in the Shared Savings Program, and then the ACO must demonstrate the adequacy of this repayment mechanism annually, prior to the start of each performance year. CMS proposes that it would ensure that an ACO maintains an adequate repayment mechanism through "monitoring activities."

CMS further proposes that if an ACO's repayment mechanism does not enable it to fully recoup the losses from a given performance year, it will carry forward any unpaid losses into subsequent performance years. The losses would then be recouped either against additional financial reserves, or by offsetting shared savings earned by the ACO.

Cap on Shared Savings

CMS proposes to establish a payment limit of 7.5 percent of an ACO's benchmark for the first two years of the ACO agreement for the one-sided model. For the two-sided model and the third year of the one-sided model, CMS proposed to establish a payment limit of 10 percent of an ACO's benchmark.

Further Explanation of the One-Sided and Two-Sided Payment Models

Shared Savings Program applicants will have the option of choosing between a one-sided payment model and a two-sided payment model. ACOs that participate in the one-sided payment model will have to transition to the two-sided payment model in the third year of their agreement period, and must participate in the two-sided payment model in any future agreement periods. ACOs that participate in the two-sided payment model will also only be able to participate in the two-sided payment model in any future agreement periods.

The following chart provides a summary of the comparisons between the one-sided and two-sided payment models:

Design Element	One-Sided Model (performance years 1 & 2)	Two-Sided Model
Maximum Sharing Rate	52.5 percent	65 percent
Quality Scoring	Sharing rate up to 50 percent based on quality performance	Sharing rate up to 60 percent based on quality performance
FQHC/RHC		
Participation Incentives	Up to 2.5 percentage points	Up to 5 percentage points
Minimum Savings Rate	Varies by population	Flat 2 percent regardless of size
Minimum Loss Rate	None	Flat 2 percent regardless of size
Maximum Sharing Cap	Payment capped at 7.5 percent of ACO's benchmark	Payments capped at 10 percent of ACO's benchmark
Shared Savings	Savings shared once MSR is exceeded; unless exempted, share in savings net of a 2 percent threshold; up to 52.5 percent of net savings up to cap	Savings shared once MSR is exceeded; up to 65 percent of gross savings up to cap

Shared Losses	None	First dollar shared losses once the minimum loss rate is exceeded. Cap on the amount of losses to be shared phased in over three years starting at 5 percent in year 1; 7.5 percent in year 2; and 10 percent in year 3. Losses in excess of the annual cap would not be shared. Actual amount of shared losses would be based on final sharing rate that reflects ACO quality performance and any additional incentives for including FQHCs and/or RHCs using the following methodology (1 minus final sharing rate).

In order to provide greater incentives for organizations to participate under the two-sided model, CMS proposes higher shared saving rates under the two-sided payment model. The shared savings rate under the two-sided payment model will be 65 percent, at most (60 percent if there is no FQHC or RHC participation in the ACO). The shared savings rate under the one-sided payment model will be 52.5 percent, at most (50 percent if there is no FQHC or RHC participation in the ACO). Overall shared savings for both payment models are dependent on performance in quality standards, as described further in Section V below. Another incentive for ACOs participating in the two-sided payment model is that a two-sided payment model ACO would be subject to a fixed minimum savings rate and minimum loss rate of 2 percent, sharing in gross savings once the 2 percent MSR is exceeded.

In the third year of an ACO's agreement under the one-sided payment model, the methodology used to reconcile an ACO's payment under the first year of the two-sided model would apply for payment purposes, but the ACO must meet the quality performance standard that applies to the third program year.

Sharing Losses

Minimum Loss Rate

Similar to shared savings, CMS is proposing a minimum loss rate for purposes of computing shared losses when an ACO's actual expenditure exceeds its benchmark. According to CMS, "[l]osses must exceed some minimum percentage around the benchmark in order to provide sufficient confidence that the losses experienced during a given performance year are not simply the result of random variation."[25]

Cap on Shared Losses

CMS proposes a maximum shared loss cap, meaning that the shared losses that an ACO might be required to return to the Medicare program under this model could not exceed a designated percentage of an ACO's benchmark in any performance year. CMS proposes a phased-in shared loss cap of: 5 percent in the first year of the Shared Savings Program; 7.5 percent in the second year of the Program; and 10 percent in the third year of the Program. ACOs that participate in the one-sided payment model under the Program would be subject to a 5 percent cap in the third year of the Program.

Adjustments to Loss Sharing Rate

CMS proposes to adjust the loss sharing rate by considering several factors, including performance on quality measures and any additional adjustment for including FQHCs and/or RHCs as ACO participants.

The proposed rule's preamble contains the following example of how a shared loss rate may be adjusted:

> So, for example, if the ACO obtained maximum points for including FQHCs and/or RHCs as ACO participants, it would have a sharing rate of 65 percent for purposes of sharing in savings. But since there are losses, the quality performance and inclusion of FQHCs and/or RHCs should be taken into consideration when calculating losses owed to the program. Accordingly, under our proposed methodology, we would multiply the total losses by 1 minus

the 65 percent final sharing rate, or 35 percent, making the ACO responsible for only 35 percent of the amount of losses.[26]

During the first year of the Shared Savings Program, the quality performance standard is set at full and accurate reporting. Therefore, in the first year, ACOs that fully and accurately report will attain the quality performance standard, and thus would only be responsible for 40 percent of any losses, absent any increases in the sharing rate for FQHC/RHC participation.

Areas Where CMS Solicits Comments

CMS solicits comments on almost every aspect of the proposed rule. With respect to setting a benchmark, shared savings, and shared losses, CMS seeks comments in the following areas:

- The one-sided and two-sided payment models, other alternatives it discusses in the proposed rule, and this proposal and other options for incorporating a two-sided model into the Shared Savings Program, including mechanisms for transitioning ACOs to two-sided risk arrangements
- How to set a benchmark and the other benchmark options, and both the merits and limitations of such options, particularly with respect to how each approach might affect the willingness of ACOs or particular types of ACO to participate in the Shared Savings Program, create incentives for ACOs to seek or avoid certain kinds of beneficiaries, and impact Medicare expenditures
- How to adjust the benchmark, and other approaches that could be used to adjust the benchmark, and alternative approaches such as using the MA ''new enrollee'' demographic risk adjustment model for risk adjusting in the Shared Savings Program, or applying a coding intensity cap on annual growth in the risk scores of an ACO's assigned beneficiary population
- Methods to adjust for decedents under benchmark setting Option 2, and any others that might be suggested for adjusting for decedents during the course of the performance year under Option 2
- The proposal to audit ACOs, especially those ACOs with high levels of risk-score growth relative to their peers, and to adjust the risk scores used for purposes of establishing the three-year benchmark accordingly
- The proposal to include DSH and IME payments from the per capita costs included in the benchmark of an ACO, especially on how including or excluding these payments in the benchmark could likely affect access to medically necessary services provided at teaching/DSH hospitals
- The proposal to include the geographic payment adjustments from the calculation of benchmark expenditures, particularly the likely impact of this proposal in areas that are affected by temporary geographic adjustments
- Excluding incentive payments and penalties related to value-based purchasing initiatives such as Physician Quality Reporting System, eRx, and the EHR incentives for eligible professionals under the HITECH Act from the computations of both benchmark and actual expenditures during the agreement period
- The proposal to trend forward the most recent three years of per-beneficiary expenditures using growth rates in per beneficiary expenditures for Parts A and B services, and the other option that it considered to trend the benchmark by the flat dollar amount
- The proposal to update the benchmark by the projected absolute amount of growth in national per capita expenditures, and the alternative to update by the lower of the national projected absolute amount of growth in national per capita expenditures or the local/state projected absolute amount of growth in per capita expenditures
- The most appropriate means to set minimum savings rate, including whether or not the confidence intervals are appropriate
- The net sharing rate proposal, and proposed exemptions for net sharing rate
- Alternate options for establishing a payment preference with sliding scale for ACOs that include FQHCs or RHCs as ACO participants, including suggestions for the appropriate method to measure FQHC/RHC involvement and the appropriate level of incentives
- Methods to provide preference to ACOs that serve a large dual-eligible population, or that enter and maintain similar arrangements with other payers
- The proposed payment limits and on whether a higher limit—for example, 10 percent for all ACOs—would be more appropriate, and whether differential limits should be established based on an ACO's readiness

- The sufficiency of the proposed risk-avoidance monitoring procedures and additional areas and mechanisms for monitoring two-sided model ACOs
- Whether additional eligibility requirements are necessary for ensuring that ACOs entering the two-sided model would be capable of repaying CMS if actual expenditures exceed their benchmark
- The proposed method of assuring that risk-bearing ACOs have an appropriate amount of available funds to repay losses, in addition to other options CMS considered
- Alternate suggestions for assuring that any losses by ACOs participating in the two-sided model can be recouped, the processes for recouping losses from these ACOs and/or their ACO participants, and the appropriate amount of available funds a risk-bearing ACO should be required to have

Analysis and Potential Issues for Comments

- The proposed rule allows ACOs to participate in either a one-sided payment model or a two-sided payment model. In both models, however, an ACO will inevitably incur downside financial risk. Incurring financial risk with respect to beneficiaries who are unknown to an ACO (because of retrospective assignment) should be considered in any provider or supplier's decision to join or form an ACO.
- Providers and suppliers forming an ACO should carefully consider whether to participate in the one-sided payment model or the two-sided payment model. Smaller, less sophisticated ACOs should likely opt for the one-sided payment model, whereas larger, more sophisticated ACOs should likely opt for the two-sided payment model.
- ACOs that operate in areas that have a growth rate above the growth rate in national per capita expenditures might be disadvantaged by CMS proposing to update the benchmarks by the annual growth rate in national per capita expenditures. On the other hand, ACOs that operate in areas that have a growth rate below the national per capita expenditures might benefit from this.
- The incentives to include RHCs and FQHCs are great, provide an obvious incentive for ACOs to include such entities in their group, and further to ensure that patients who participate in an ACO utilize RHCs and FQHCs.
- Developing a successful ACO will require a significant investment. Having an automatic 25 percent of shared savings withheld will likely hurt ACOs that would rely on savings to cover their costs. This automatic withholding could create cash flow problems for some ACOs.

Quality

An ACO's ability to receive shared saving payments, and the amount of any payment, is largely dependant upon the ACO's performance score against a set of quality measures. In year one of the program, ACOs are required to report on ***all*** performance measures in order to qualify for shared saving payments. In years two and three, an ACO's score against the performance measures dictates the payment amount.

Quality Measures

For the first year of the Shared Saving Program, CMS proposes to establish 65 quality measures that are organized into five categories referred to as "domains." The domains include: (1) patient/caregiver experience; (2) care coordination; (3) patient safety; (4) preventative health; and (5) at-risk population. Of the 65 measures, 31 are within the domain for "at-risk population" and relate to major cost drivers such as diabetes treatment, heart failure, coronary artery disease and protecting the elderly from falls and fractures. Quality measures for the remaining two years of the three-year agreement will be proposed in future rulemaking.

The preamble to the proposed rule describes the 65 quality measures but does not list the measure specifications. Instead, CMS indicates that the specifications will align with existing measures to the extent possible, such as the existing measures in the Physician Quality Reporting System, the EHR Incentive Program, and the National Quality Forum measures. In relying heavily on existing quality measures, CMS did not propose measures that are explicitly related to cost savings or resource use that may be directly tied to the overuse or appropriateness of care. Similarly, the proposed quality measures do not directly address post-acute care beyond measures tied to the general coordination of care and patient safety. CMS emphasizes its intent to "refine and expand" the quality measures in future rulemaking and to expand the reporting mechanisms to include measures that are EHR-based. In particular, CMS indicates that the agency intends to "add measures of hospital-based care

and quality measures for care furnished in other settings, such as home health services and nursing homes."

Quality Performance Score

CMS proposes two alternative options for utilizing the quality standards in the Shared Savings Program: (1) tying rewards to better performance scores, or (2) establishing minimum quality thresholds for shared savings. In the proposed rule, CMS suggests that it will utilize the better performance score approach but seeks comment on the minimum threshold approach.

Better Performance Score Approach

Under the better performance score approach, ACOs must meet a minimum threshold of performance in the quality measures (*e.g.*, 30th percentile of performance) and achieve scores for higher performance in order to realize the financial gain. An ACO's failure to meet the minimum threshold performance for any of the 65 quality measures would result in a warning and may lead to termination from the program in a subsequent year if performance is not improved. In addition, ACO performance on each quality measure is scored with the score for each quality measure determined by either the absolute or relative benchmark, depending on the standard. For performance between the minimum threshold and the benchmark, the ACO would score points on a sliding scale based on a 2 point maximum for each of the 65 measures, as described in Table 3 of the preamble.

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

The scores for each quality measures are then added together within each of the five domains and divided by the maximum possible domain score to determine the relative performance in each domain. The domains are weighted equally in determining the ACOs total performance score. The performance score is then multiplied against the 50 percent shared savings pool for one-sided ACOs or 60 percent shared savings pool for two-sided ACOs.

Minimum Threshold Approach

Under the minimum threshold approach, ACOs must meet a minimum threshold of performance in all domains of the quality measures before payment from the shared savings pool is permitted. If an ACO fails to meet the minimum thresholds, no shared savings payment would be made and the ACO would be at risk of termination from the program. This approach would allow an ACO to achieve the full payment amount but does not reward improvement in the performance scores. CMS does not propose to use this alternative approach but has requested comments.

Incorporating Other Reporting Requirements Related to the Physician Quality Reporting System

CMS proposes to incorporate into the Shared Savings Program existing reporting requirements and payments related to the Physician Quality Reporting System. In particular, the Shared Savings Program would incorporate the Physician Quality Reporting System group practice reporting option ("GPRO") and allow ACO participant providers and suppliers to constitute a group practice for purposes of qualifying for a Physician Quality Reporting System incentive payment. Such eligible professionals would be required to submit data through the ACO on the quality measures using the GPRO tool. Conversely, CMS is not proposing to incorporate payments under the EHR Incentive Program or Electronic Proscribing Incentive Program. Professionals participating in those programs would separately qualify and pursue those incentive payments outside of the ACO program. However, the proposed quality measures do require that at least 50 percent of the ACO's primary care physicians be meaningful users of EHRs during the first year. In subsequent years, CMS

proposes to further align the Shared Savings Program and the EHR Incentive Program through future rulemaking.

Areas Where CMS Solicits Comments

CMS seeks comments on the following issues related to the proposed quality measures:

- Whether to include or exclude any proposed measure or measures in the calculation of the ACO Quality Performance Standard, including suggestions on variations or substitutions that are substantially equivalent to the proposed measures
- Whether the list of proposed measures should be narrowed;
- Whether any of the proposed measures for calculating the ACO Quality Performance Standard should be excluded for scoring purposes and/or instead be considered for quality monitoring purposes only
- How to retire or adjust the weights of domains, modules, or measures over time

Analysis and Potential Issues for Comments

- While many of the proposed quality measures may be familiar to a health care provider from the Physician Quality Reporting System, the EHR Incentive Program, or the National Quality Forum measures, several measures are new or are less frequently reported, such as the readmission measures.
- Any expansion of the quality measures in future rulemaking adds to the risk and uncertainty associated with participating in the Shared Savings Program. In particular, it is unclear what measures related to hospital-based care and post-acute care may be adopted.
- Quality performance scoring will reduce the total amount of shared savings payments from an ACO's cost reduction. Because an ACO is unlikely to achieve a perfect score in every quality measure, the quality performance scoring will reduce the payment made to the ACO.

Monitoring, Actions Prior to Termination, Termination, Reconsideration Review Process, and Auditing

Monitoring

CMS proposes to monitor and assess ACOs and their participating providers/suppliers. CMS would utilize a number of different measures to monitor ACOs, including: (1) analysis of specific financial and quality measurement data reported by ACOs, as well as aggregated annual and quarterly reports; (2) site visits; (3) analysis of beneficiary and provider complaints; and (4) audits. CMS would monitor ACOs for several, specific activities: (1) avoidance of at-risk beneficiaries; (2) compliance with quality performance standards; (3) changes to ACO eligibility requirements; (4) ACO marketing materials and activities; and (5) notification of the provider and supplier's role in the ACO, and the ability for beneficiaries to opt-out of sharing claims data.

This summary focuses on CMS' proposal to monitor ACOs and their participating providers/suppliers for the avoidance of at-risk beneficiaries. In the preamble, CMS describes what it means by at-risk beneficiaries:

> [W]e believe such patients are those beneficiaries who have a high risk score on the CMS–HCC risk adjustment model, are considered high cost due to having two or more hospitalizations or emergency room visits each year, are dually eligible for Medicare and Medicaid, have a high utilization pattern, have one or more chronic conditions (such as, for example, diabetes, heart failure, coronary artery disease, chronic obstructive pulmonary disease, depression, dementia, end stage renal disease) or beneficiaries who have a recent diagnosis (for example, newly diagnosed cancer) that is expected to result in an increased cost.[27]

CMS would use the monitoring measures previously outlined to identify patterns suggestive of the avoidance of at-risk beneficiaries. If CMS finds anything to suggest that an ACO and its suppliers/ providers are avoiding at-risk beneficiaries, CMS may follow up with the beneficiary. If CMS determines that an ACO, its ACO participants, or any ACO providers/ suppliers, or any contracted entities performing functions or services on behalf of the ACO, avoids at-risk beneficiaries, the ACO would be required to submit a corrective action plan ("CAP") and implement the CAP as approved by CMS. An ACO would not be eligible to receive shared savings during the probation period, for the performance period attributable to the time the ACO was under the CAP, and the ACO would not be

eligible to receive shared savings for the performance period attributable to the time the ACO was under the CAP. CMS would re-evaluate the ACO during and after CAP implementation to ensure it is not still avoiding at-risk beneficiaries. If an ACO continues to avoid at-risk beneficiaries during or after the CAP, it may be terminated.

Actions Prior to Termination

CMS could take several actions prior to terminating an ACO. If, through the monitoring measures discussed above in Part VI.A, CMS discovers that an ACO may be subject to termination, CMS, in its sole discretion, may take an action prior to termination of the ACO. CMS could: (1) provide a warning to the ACO regarding the specific performance at issue; (2) request a corrective action plan from the ACO; or (3) place the ACO on a special monitoring plan. CMS would not have the ability to take the aforementioned actions prior to termination for violations of the Sherman Antitrust Act, the Clayton Act, or the Federal Trade Commission Act.

Termination

Under the proposed rule, CMS could terminate an agreement with an ACO if the ACO, the ACO participants, the ACO providers/suppliers or contracted entities performing services or functions on behalf of the ACO: (1) avoid at-risk beneficiaries; (2) fail to meet quality performance standards; (3) fail to completely and accurately report information or fail to make timely corrections to reported information; (4) are not in compliance with eligibility requirements or have fallen out of compliance with the requirements; (5) are unable to effectuate any required regulatory changes; (6) are not in compliance with requirements to notify beneficiaries of ACO provider/supplier participation in an ACO; (7) engage in material noncompliance or show a pattern of noncompliance with respect to public reporting and other CMS reporting requirements; (8) fail to submit or implement a CAP or fail to demonstrate improved performance after implementation of CAP; (9) violate the physician self-referral prohibition, civil monetary penalties, anti-kickback statute, or other applicable antitrust and antifraud laws; (10) submit to CMS false, inaccurate, or incomplete data or information; (11) use marketing materials that are not approved by CMS; (12) fail to maintain at least 5,000 beneficiaries; (13) fail to offer beneficiaries the option to opt-out of sharing claims information; (14) limit or restrict beneficiary's medical records or summaries of care from other providers/ suppliers within and outside of the Shared Savings Program; (15) improperly use or disclose claims information received from CMS in violation of the HIPAA Privacy Rule, Medicare Part D Data Rule, Privacy Act, or the data use agreement; or (16) fail to demonstrate that the ACO has adequate resources in place to repay losses and maintain those resources for the agreement period.

CMS proposes that if an ACO is terminated, it may not re-apply to the Shared Savings Program until the end of its original three-year agreement period. In addition, if CMS terminates an agreement with an ACO prior to the end of the three-year agreement period, CMS would not return the 25 percent withhold of shared savings.

If an ACO chooses to terminate its participation in the Shared Savings Program, it must notify CMS, its ACO participants, and other organizations of its decision 60 days prior to the date of termination, and must notify beneficiaries of its termination in a "timely manner."

Reconsideration Review Process

The proposed rule would severely limit reconsideration, appeals, or other administrative or judicial review. In fact, the proposed rule stipulates that there is no reconsideration, appeals, or other administrative or judicial review of the following determinations: (1) specification of quality and performance standards; (2) the assessment of the quality of care furnished by an ACO; (3) the assignment of Medicare beneficiaries; (4) the determination of whether an ACO is eligible for shared savings; (5) the percent of shared savings specified by the Secretary and the limit on the total amount of shared savings; (6) the termination of an ACO for failure to meet the quality performance standards; and (7) a determination made by the reviewing antitrust agency that is likely to challenge or recommend challenging the ACO.

Audits and Record Retention

Under the proposed rule, an ACO participating in the Shared Savings Program must agree, and must require its ACO participants, ACO providers and suppliers, and any contracted entities to agree, that HHS has the right to audit, inspect, and evaluate any books, contracts, records, and other documents. Further, the ACO, its participants, its providers and suppliers, and any contracted entities, must agree to maintain and give HHS particular records.

Areas Where CMS Solicits Comments

- Additional actions that might be appropriate prior to termination of an ACO
- Whether lesser sanctions may be appropriate when an ACO avoids at-risk beneficiaries, such as the cessation of, or a reduction in, the assignment of new beneficiaries to the ACO, a reduction in the amount of the shared savings payment, or a fine for each instance of at-risk beneficiary avoidance
- The definition of "at-risk beneficiary," and whether other beneficiary characteristics should be considered when determining if a beneficiary is "at-risk"
- Whether any additional situations might merit the termination of an ACO agreement
- The structures and procedure of an appropriate review process for ACOs terminated for avoidance of at-risk beneficiaries and other reasons not exempted for review by the statute

Data Sharing

Data Sharing With ACOs

Data Sharing Generally

CMS proposes to make certain beneficiary-identifiable data available to an ACO at the beginning of the first performance year of the Shared Savings Program, and again on an annual basis during the ACO's agreement. Specifically, CMS would provide each ACO with the name, date of birth, sex, and health insurance claim number of beneficiaries that would have been historically assigned to that ACO. In addition, ACOs would have the opportunity to request certain beneficiary-identifiable claims data on a monthly basis, in compliance with applicable laws. These data sets would be limited to the content necessary for the ACO to effectively coordinate care of its patient population. If an ACO chooses to request beneficiary-identifiable claims data as part of the application process, CMS would require the ACO to explain in its application how it would use the data to evaluate the performance of ACO participants, suppliers, and providers, conduct quality assessment and improvement activities, and conduct population-based activities to improve the health of the assigned beneficiary population. If an ACO does not initially request beneficiary-identifiable claims data in its application, it must submit a written request to CMS explaining how it would use the data to evaluate the performance of ACO participants, suppliers, and providers, conduct quality assessment and improvement activities, and conduct population-based activities to improve the health of the assigned beneficiary population. CMS hopes that allowing an ACO to identify beneficiaries that would have been assigned in the past will help an ACO develop improved care coordination strategies.

Further, CMS proposes to provide ACOs with aggregate data reports that would include aggregated metrics on the assigned beneficiary population at the start of the agreement period and on a quarterly basis, based upon the most recent 12 months of data from assigned beneficiaries. This data would include the following: (1) financial performance; (2) quality performance scores; (3) aggregated metrics on the assigned beneficiary population; and (4) utilization data at the start of the agreement period based on historical beneficiaries used to calculate the benchmark.

Under the proposed rule, and consistent with statutory and regulatory restrictions, CMS would not disclose data related to patient records by federally conducted or assisted substance abuse programs, except as expressly authorized.

Data Use Agreement

CMS proposes to require that an ACO enter a Data Use Agreement ("DUA") with it prior to the receipt of any beneficiary-identifiable claims data. Under the DUA, an ACO would be prohibited from sharing the Medicare claims data provided to it with any entity outside of the ACO, and would also be prohibited from using or disclosing data in a manner in which a HIPAA-covered entity could not without violating the HIPAA Privacy Rule. CMS proposes that if an ACO does not comply with the Data Use Agreement, it would result in the ACO no longer being eligible to receive data, and could also lead to the termination from the Shared Savings Program, or additional sanctions and penalties available under law.

Beneficiary Opt-Out

CMS proposes to allow Medicare beneficiaries to opt-out of sharing their protected health information with an ACO. In fact, CMS proposes that ACOs would only have access to beneficiary-identifiable claims data for beneficiaries who have (1) visited a primary care provider participating

in the ACO during the performance year; (2) been informed about how the ACO intends to use beneficiary claims data; and (3) not chosen to opt-out of claims data sharing. However, even if a beneficiary eventually chooses to opt-out of sharing his or her data, CMS would provide each ACO with the name, date of birth, sex, and health insurance claim number of beneficiaries that would have been historically assigned to that ACO. In the preamble, CMS discusses an example of the opt-out approach:

When a beneficiary has a visit with their primary care physician, their physician would inform them at this visit that he or she is an ACO participant or ACO provider/supplier and that the ACO would like to be able to request claims information from [CMS] in order to better coordinate the beneficiary's care. If the beneficiary objects, [CMS] proposes that the beneficiary would be given a form stating that they have been informed of the physician's participation in the ACO and explaining how to opt-out of having their personal data shared. The form could include a phone number and/or email address for beneficiaries to call and request their data not be shared.

Public Reporting and Transparency

CMS proposes that several aspects of an ACO's operation and performance must be publicly reported: (1) providers and suppliers participating in the ACO; (2) parties sharing in the governance of the ACO; (3) quality performance standard scores; (4) general information on how an ACO shares savings with its members; (5) the name and location of the ACO; (6) the primary contact of the ACO; and (7) ACO's organizational information. Each ACO would be responsible for making this information available to the public in a standardized format that CMS will publish through subregulatory guidance.

Areas Where CMS Solicits Comments

CMS solicits comments on almost every aspect of the proposed rule. With respect to data sharing, CMS seeks comments in the following areas:

- Its proposal to provide aggregate data reports to ACOs, and the kinds of aggregate data and frequency of data reports that would be most helpful to the ACO's efforts in coordinating care, improving health, and producing efficiencies
- Whether providing data on historically assigned beneficiaries at the beginning of the agreement period would be helpful to ACOs and how this information would be beneficial to the goals of improved care coordination and improving care delivery for the ACO's assigned beneficiary population
- Its proposal to require an ACO to explain in its application how it would use the data to evaluate the performance of ACO participants, suppliers, and providers, conduct quality assessment and improvement activities, and conduct population-based activities to improve the health of the assigned beneficiary population; and CMS' proposal that if an ACO did not request the data in its application, an ACO must submit a formal request for data during the agreement period
- Its proposals related to the provision of both aggregate and beneficiary-identifiable data to ACOs, particularly the kinds and frequency of data that would be useful to ACOs, potential privacy and security issues, and the implications for sharing protected health information with ACOs
- Its proposal to require that an ACO publicly report certain information, including whether the proposed list includes elements that should not be required or excludes elements that are important for achieving transparency or meaningful public disclosure
- Whether CMS should standardize the format of what is required for public disclosure, or allow ACOs the flexibility to try different and innovative approaches for providing this information to beneficiaries
- Whether ACOs themselves should be required to make the information publicly available, or whether ACOs should report the information to CMS and then CMS would make the information publicly available

Miscellaneous

Managing Significant Changes to the ACO

During the three-year agreement period with CMS, an ACO may remove, but not add, ACO participants, but it may remove or add ACO providers/suppliers. Further, if the ACO undergoes a significant change, such as a reorganization of its legal structure or a government-required

reorganization as a result of fraud or antitrust concerns, the ACO must notify CMS at least 30 days prior to the significant change. CMS will review the ACO's notification and make a determination as to whether or not the ACO can continue with the Shared Savings Program based on the previously approved ACO's application.

Future Participation

The proposed rule would require that an ACO disclose to CMS if the ACO or any ACO participant is related to or had an affiliation with another Shared Savings Program ACO. Further, if the ACO were previously terminated from the program, the ACO must identify the cause of termination and what changes the ACO has made that will allow it to participate in a full, three-year agreement period.

Overlap with Other CMS Shared Savings Initiatives

The proposed rule stipulates that providers and suppliers may not participate in the Shared Savings Program as ACO participants if they participate in the independence-at-home medical practice pilot or any other Medicare initiative that involves shared savings. The other shared savings programs that preclude ACO participation include the Medicare Health Care Quality Demonstration Programs and the medical home demonstrations with a shared savings element. While Physician Group Practice Demonstration participants cannot participate in both the Physician Group Practice Demonstration and the Shared Savings Program, any Physician Group Practice participants applying for participation in the Shared Savings Program would be required to complete only a condensed application form.

Marketing Materials Requirements

The proposed rule would require any ACO marketing materials, communications, and activities that are used to educate, solicit, notify, or contact Medicare beneficiaries or providers/ suppliers regarding the ACO be approved by CMS before use. Further, any changes to CMS-approved marketing materials must be approved before use. Finally, CMS proposes that an ACO that fails to adhere to these requirements may be placed under corrective action or terminated.

Summary of Jointly Issued CMS/OIG Proposed Waiver

Introduction

In a companion rulemaking to CMS' Shared Savings Program proposed rule, CMS and the OIG propose certain waivers of federal fraud and abuse laws.

The rulemaking takes the form of a notice with comment period as CMS and OIG acknowledge that the waivers proposals are very much a work in progress and necessarily tied to developments in the larger rulemaking. Like the proposed Shared Savings Program rule issued by only CMS, stakeholders who wish to provide comment on the proposed waiver must do so ***no later than 5 p.m. ET June 6, 2011***.

Purpose

The stated purpose of the jointly issued CMS/OIG rulemaking is to "address application of these fraud and abuse laws [to ACOs] so that the laws do not unduly impede development of beneficial ACOs, while also ensuring that ACO arrangements are not misused for fraudulent or abusive purposes that harm patients or Federal health care programs."[29] Specifically, the proposed waivers are intended to address concerns that the restrictions that the fraud and abuse laws would impose on financial relationships would "impede developments of some of the innovative integrated-care models envisioned by [the ACO rulemaking]."[30] The PPACA authorizes the Secretary to waive, *inter alia*, the fraud and abuse laws, in order to carry out the purposes of the ACO rulemaking.[31]

Implicated Fraud and Abuse Laws

The proposed waivers directly implicate three different federal fraud and abuse laws: (1) the Anti-Kickback Statute ("AKS"); (2) the Stark Law, which prohibits certain physician self-referrals; and (3) the Civil Monetary Penalty Law ("CMPL") – specifically the "gainsharing" prohibitions.

Proposed Waivers

The proposed waivers are limited to ACOs that are enrolled in the Shared Savings Program. With regard to duration, the shared savings waivers would apply to the distribution of shared savings earned by the ACO during the term of its agreement with CMS to participate in the Shared Savings Program, even if the distributions occur after the expiration of the agreement. For the AKS and CMPL waivers applicable to financial relationships that also comply with a Stark Law exception, the duration of the waiver is concurrent with the term of the ACO's agreement to participate in the Shared Savings Program.

A **first proposal** would waive application of both the AKS and the Stark Law to:

- Distributions of such "shared savings" received by an ACO from CMS: (1) to or among ACO participants, ACO providers/suppliers, and individuals and entities that had such status during the year when such savings were earned by the ACO; and (2) for activities necessary for and directly related to the ACO's participation in and operation under the Shared Savings Program.

A **second proposal** would waive application of the CMPL gainsharing prohibitions to

- Such "shared savings" received by an ACO from CMS and made from a hospital to a physician provided that: (1) the payments are not made knowingly to induce the physician to reduce or limit *medically necessary* items or services; and (2) the hospital and physician are ACO participants (or were participants during the year that the shared savings were earned).

A **third proposal** would waive application of the AKS or the CMPL's gainsharing prohibitions to any "necessary" financial relationships between or among ACO participants that meet a Stark Law exception.

The chart below summarizes the proposed waivers:

Implicated F&A Law	Context of Waiver
Stark and AKS	*Distribution of earned shared savings* among ACO participants, providers, and suppliers
CMPL ("Gainsharing" only)	*Distribution of earned shared savings* among ACO participants, providers, and suppliers when the payments are not made knowingly to induce the physician to reduce or limit *medically necessary* items or services
AKS and CMPL ("Gainsharing" only)	Any necessary financial relationship among ACO participants, providers and suppliers that meets a Stark Law exception

Areas Where CMS/OIG Solicit Comments

CMS and OIG acknowledge in the rulemaking that the proposed waivers are fairly narrow in nature. The agencies solicit public comment on a number of different topics:

- Arrangements related to the establishment of the ACO
- Arrangements between or among ACO participants and/or ACO providers/ suppliers related to ongoing operations of the ACO and achieving ACO goals
- Arrangements between the ACO, its ACO participants, and/or its ACO providers/suppliers and outside individuals or entities
- Distributions of shared savings or similar payments received from private payers
- Other financial arrangements for which a waiver would be necessary
- Duration of waivers
- Additional safeguards
- The scope of proposed waivers
- The two-sided risk model
- The use of the existing exception and safe harbor for electronic health records arrangements
- Beneficiary inducements
- The timing of waivers

Analysis and Potential Issues for Comments

The *sine qua non* of the ACO model is to create financial incentives to reduce Medicare costs by sharing the resulting savings between CMS, physicians, suppliers, and provider entities. Therefore, it is unsurprising that the proposed waivers are narrowly tailored to achieve this goal.

The proposed waivers are potentially limited in scope and likely reflect OIG and CMS' unease over the unforeseen effects of such forbearance. Only financial savings that directly result from the Shared Savings Program would be available for protection—so the shared savings waiver protection is arguably limited to a redistribution of identifiable monies paid by CMS. In addition, the waivers that provide a shield to AKS or CMPL prosecution if the arrangement meets a Stark exception, are similarly narrow and low-risk. The government now has years of experience with these regulatory concepts and there is already substantive overlap with many of the AKS safe harbors.

The CMPL gainsharing prohibition authorizes the OIG to impose financial penalties upon a hospital whenever it "knowingly makes a payment, directly or indirectly, to a physician as an inducement to *reduce* or *limit* services provided with respect to individuals who are entitled to benefits under the Medicare or Medicaid programs and who are under the direct care of the physician." The prohibition contains three key elements: (1) the payments are made knowingly; (2) they are an inducement to *reduce* or *limit* services; and (3) they are paid with respect to patients under the *direct* care of the physician receiving the payment.

The OIG has previously interpreted the gainsharing prohibition very broadly, stating that it prohibits any payment that may influence a physician to reduce or limit services to his or her patients. "There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. In short, any hospital incentive plan that encourages physicians through payments to reduce or limit clinical services directly or indirectly violates the statute."[32]

In contrast, the proposed waiver does challenge this previously held OIG perspective by limiting prohibited payments to reductions or limitations in *medically necessary* care. While this change is significant, it is unsurprising given that the ACO model would not be able to otherwise operate; hospitals and physicians are financially incentivized to reduce services to beneficiaries in order to reduce overall Medicare costs.

While it will be interesting to see whether CMS and OIG expand on the proposed waivers in the final rule, it is unlikely that they will do so absent an obvious oversight. As with the AKS safe harbors and Stark Law exceptions, the waivers will likely develop over time along with the ACO program (if it is successful). OIG and CMS may also choose to incorporate the ACO provisions in later rulemakings under the Stark and AKS regulations.

Conclusion

The Medicare Shared Savings Program, and similar efforts to establish alternative payment models at the state level, in partnerships with commercial insurance, or through the Center for Medicare and Medicaid Innovation, present both challenges and opportunities for the health care/life sciences industry in the coming years. Reed Smith will be closely monitoring the regulatory guidance issued as a result of the Patient Protection and Affordable Care Act, and we will be reporting on major developments on our policy blog, www.healthindustrywashingtonwatch.com. We also look forward to working together with our clients to develop and implement strategies to respond to alternative payment models, including proposals related to ACOs. Please feel free to contact us if you have questions or if you need additional information.

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1 *See* 42 U.S.C. § 1395jjj.

2 76 Fed. Reg. 19528 (Apr. 7, 2011).

3 76 Fed. Reg. 19655 (Apr. 7, 2011).

4 Judy Feder & David Cutler, *Achieving Accountable and Affordable Care*, Center for American Progress, Dec. 20, 2010, 7, *available at* http://www.americanprogress.org/issues/2010/12/aco_report.html.

5 *See* Mark Merlis, *Health Policy Brief, Health Affairs*, July 27, 2010, *available at* http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=23.

6 Engelberg Center for Health Care Reform at Brookings and The Dartmouth Institute for Health Policy & Clinical Practice, *Reforming Provider Payment: Moving Toward Accountability for Quality and Value*, Mar. 2009, *available at* http://www.brookings.edu/events/2009/0311_aco.aspx.

7 Judy Feder & David Cutler, *Achieving Accountable and Affordable Care*, Center for American Progress, Dec. 20, 2010, 7, *available at* http://www.americanprogress.org/issues/2010/12/aco_report.html.

[8] *See* Letter from Kathleen Sebelius, Secretary, Department of Health & Human Services, to Governors, *available at* http://www.hhs.gov/news/press/2011pres/01/20110203c.html. Note that § 2706 of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, authorizes a pediatric accountable care organization demonstration project.

[9] 42 U.S.C. 1396a note.

[10] *See*, *e.g.*, Cigna, CIGNA's Collaborative Accountable Care Programs Improving Quality and Reducing Costs, http://newsroom.cigna.com/NewsReleases/CIGNA-s-Collaborative-Accountable-Care-Programs-Improving-Quality-and-Reducing-Costs.htm?view_id=3897; S. Bill 807, 88th Leg., Reg. Sess. (Ark. 2011).

[11] *See* Pauline Chen, *The Missing Ingredient in Accountable Care*, N.Y.Times, Jan. 27, 2011, available at http://www.nytimes.com/2011/01/27/health/views/27chen.html.

[12] 76 Fed. Reg. 19528, 19536 (Apr. 7, 2011).

[13] 76 Fed. Reg. 19528, 19537, 19641 (Apr. 7, 2011).

[14] 76 Fed. Reg. 19528, 19539 (Apr. 7, 2011).

[15] The Federal Trade Commission ("FTC") and the Department of Justice ("DOJ") jointly issued an Antitrust Policy Statement titled, "Proposed Statement of Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program," *available at* http://www.ftc.gov/os/fedreg/2011/03/110331acofrn.pdf.

[16] 76 Fed. Reg. 19528, 19541 (Apr. 7, 2011).

[17] Section 5501 of the PPACA states the following: "The term 'primary care services' means services identified, as of January 1, 2009, by the following HCPCS codes (and as subsequently modified by the Secretary): (i) 99201 through 99215; (ii) 99304 through 99340; (iii) 99341 through 99350."

[18] 76 Fed. Reg. 19528, 19603 (Apr. 7, 2011).

[19] The claims run-out period is the time between when a Medicare-covered service has been furnished to a beneficiary and when the final payment is actually issued for the respective services. A six-month run-out of claims data results in a completion percentage of approximately 99.5 percent for physician services and 99 percent for Part A services.

[20] 76 Fed. Reg. 19528, 19608 (Apr. 7, 2011).

[21] 76 Fed. Reg. 19528, 19608 (Apr. 7, 2011).

[22] 76 Fed. Reg. 19528, 19646 (Apr. 7, 2011).

[23] 76 Fed. Reg. 19528, 19611 (Apr. 7, 2011).

[24] 76 Fed. Reg. 19528, 19615 (Apr. 7, 2011).

[25] 76 Fed. Reg. 19528, 19621 (Apr. 7, 2011).

[26] 76 Fed. Reg. 19528, 19621 (Apr. 7, 2011).

[27] 76 Fed. Reg. 19528, 19625 (Apr. 7, 2011).

[28] 76 Fed. Reg. 19528, 19560 (Apr. 7, 2011).

[29] 76 Fed. Reg. 19655 (Apr. 7, 2011).

[30] 76 Fed. Reg. 19655 (Apr. 7, 2011).

[31] 42 U.S.C. § 1395jjj(f).

[32] Department of Health & Human Services Office of Inspector General, Special Advisory Bulletin, *Gainsharing Arrangements*, July 1999, *available at* http://oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm.

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