Ropes & Gray Analysis of CMS Proposed ACO Rule and Related Agency Issuances

Introduction

On March 31, 2011, the Centers for Medicare & Medicaid Services ("CMS") released the long-awaited Medicare Shared Savings Program proposed regulations establishing Medicare Accountable Care Organizations ("ACOs") (the "Proposed Rule"). The Shared Savings Program, which is authorized under section 3022 of the Affordable Care Act (the "Act"), represents another step in a long line of efforts to move Medicare towards a program that pays for the value, not the quantity, of care furnished to its beneficiaries. The proposed ACO program would reward ACOs for delivering integrated care at lower costs while meeting quality standards. According to CMS Administrator Donald Berwick, "ACOs are not just a new way to pay for care but a new model for the organization and delivery of care." ACOs are also intended to help achieve the triple aim of "better care for individuals," "better health for populations," and "lower growth in expenditures."

The Proposed Rule is part of a multi-agency collaboration to launch the program. In conjunction with the Proposed Rule, CMS and the Department of Health & Human Services Office of Inspector General ("OIG") issued a waiver statement, the Federal Trade Commission ("FTC") and Department of Justice ("DOJ") released an antitrust policy statement, and the Internal Revenue Service ("IRS") promulgated a notice regarding tax-exempt organizations. Ropes & Gray has assembled a team of health care, antitrust, and tax attorneys to review these various issuances. Additional Ropes & Gray ACO analyses, including materials from our ongoing ACO webinar series, can be found at the ACO page of the Ropes & Gray Health Reform Resource Center.

The Proposed Rule and related issuances were published in the Federal Register today. CMS will be accepting comments on the proposed rule until June 6, 2011 and plans to release a final rule by the end of the calendar year. The Shared Savings Program is expected to begin in January of 2012.

The detailed analysis below of the Proposed Rule and the related agency issuances discusses the following topics:

I. Eligibility and Governance

ACOs and ACO Participants. Under the Proposed Rule, "an ACO means a legal entity that is recognized and authorized under applicable State law, as identified by a Taxpayer Identification Number ("TIN"), and comprised of an eligible group ... of ACO participants." These eligible groups of ACO participants are: (1) ACO professionals in a group practice arrangement; (2) networks of individual practices of ACO professionals; (3) partnerships or joint venture arrangements between hospitals and ACO professionals; and (4) hospitals employing ACO professionals. CMS proposes to expand this list to include critical access hospitals that bill under "method II" (*i.e.*, an optional method for billing outpatient services). "ACO professionals" include an ACO provider or supplier that is either a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist.

Participation Requirements. An otherwise eligible ACO also must satisfy participation requirements. While an ACO is not required to enroll in Medicare, each ACO participant must be a Medicare-enrolled provider of services and/or a supplier. An ACO provider/supplier means a provider of services and/or a supplier that bills for items and services it furnishes to Medicare beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant.

In addition, the ACO must have a mechanism for shared governance and must satisfy program integrity and patient-centeredness criteria while maintaining adequate numbers of primary care physicians and beneficiaries. The ACO also must meet certain antitrust requirements; execute a 3-year agreement with CMS; and be legally permitted to receive and distribute savings and repay any shared losses. These eligibility requirements, summarized below, must be verified by providing supporting materials as part of the application process.

Shared Governance. Shared governance is a statutory requirement for ACOs seeking to participate in the Shared Savings Program. CMS proposes that the governing body of the ACO must be comprised of ACO participants and Medicare beneficiary representatives. At least 75% of the governing body must be controlled by the ACO participants, and each ACO participant must have undefined "appropriate proportional control" over decision-making. Additionally, the Proposed Rule effectively prohibits the board of one ACO participant from serving as the board of the ACO itself unless the ACO is composed of a single participant that is financially and clinically integrated and 75% of such participant's governing body is comprised of representatives of the participant.

CMS also proposes that the ACO "partner" with community stakeholders — a partnership CMS suggests may be achieved by having a community stakeholder organization represented on the governing body. CMS does not specify the level of Medicare beneficiary involvement in governance and seeks comment on whether a minimum standard for beneficiary participation is appropriate.

Leadership and Management. CMS proposes that ACO operations be managed by an individual whose appointment and removal is subject to the governing body and that ACO participants, as well as ACO providers and suppliers, must demonstrate a meaningful commitment to the ACO's clinical integration program, including, for example, through a meaningful financial investment in the ACO or a meaningful investment of time and effort in ACO operations.

Clinical management and oversight are to be provided by a full-time senior level director who is a board-certified physician and licensed by the state. The ACO's quality assurance and improvement program is to be directed by a committee of physicians. The ACO is required to develop and implement evidence-based

medical practices or clinical guidelines and processes for the provision of care. The ACO is also required to have an infrastructure that enables the ACO to collect and evaluate data and provide feedback to ACO participants, providers and suppliers. This infrastructure may include information technology, such as electronic health record ("EHR") technology certified to meet the standards adopted for meaningful use EHR incentive programs.

The ACO also must establish and demonstrate its authority and ability to execute the statutory functions of an ACO, including defining processes to promote evidence-based medicine and patient engagement; reporting on quality and cost measures; and coordinating care.

Program Integrity. To protect the Shared Saving Program from fraud and abuse, CMS proposes program integrity criteria. An ACO must have a compliance plan that includes: a designated compliance official who reports directly to the ACO's governing body and is not legal counsel to the ACO; mechanisms for identifying and addressing compliance problems; a method for reporting suspected problems related to the ACO; compliance training; and a requirement to report suspected violations of law to an appropriate law enforcement agency. The ACO will be responsible for its activities as well as those of its participants, providers and suppliers. In addition, CMS proposes to require the following certifications by an executive with authority to bind the ACO, which could serve as the basis for an action under the False Claims Act:

- Certification that the Shared Savings Program application, three-year agreement and submissions of quality data and other information are accurate, complete and truthful.
- Certification in a request for shared savings payments that the ACO is in compliance with program requirements and that all quality data and other information submitted are accurate, complete and truthful.

CMS has solicited comments on whether to subject ACOs to some form of screening process with regard to their program integrity history. Notably, the existing Medicare program screen would not apply to ACOs since ACOs would not be required to enroll in Medicare.

Primary Care Physicians and Beneficiaries. The Act requires ACOs to "include primary care ACO professionals that are sufficient for the number of Medicare FFS beneficiaries assigned to the ACO …" and, "the ACO shall have at least 5,000 such beneficiaries assigned to it …." Under the Proposed Rule, CMS will deem an ACO to have a sufficient number of primary care physicians and beneficiaries if the number of beneficiaries historically assigned to the ACO participants is 5,000 or more. CMS further proposes that if, at the end of a performance period an ACO's assigned population falls below 5,000, the ACO will be issued a warning and placed on a corrective action plan. Beneficiary assignment is discussed in Section III below.

Patient-Centeredness. Under the Act, an ACO must demonstrate that it meets patient-centeredness criteria specified by the Secretary of the Department of Health & Human Services (the "Secretary"). CMS has interpreted this to require that the governing body promote and achieve patient-centeredness by ensuring that ACO leadership and ACO management work together with the ACO's health care teams. The Proposed Rule requires an ACO to demonstrate patient-centeredness by addressing each of nine concerns, including: (1) implementing a beneficiary experience of care survey and a plan to use the results to improve care; (2) adopting a process for evaluating the health needs of the ACO's assigned population and developing and implementing a plan to address those needs; (3) implementing systems to identify and update high-risk individuals and a process to develop individualized care plans to care for those individuals; and (4)

establishing a process for beneficiary engagement and shared decision-making that takes into account the beneficiaries' needs, preferences, values and priorities.

II. The ACO Agreement

The Act requires ACOs to enter into an agreement with the Secretary to participate in the Shared Savings Program. In the Proposed Rule, CMS sets forth detailed requirements for the content and execution of participation agreements and data exchange between the ACO and CMS.

Term and Related Requirements. Under the Act, an ACO's agreement with the Secretary must be for a term of at least 3 years. The ACO agreement must be signed by an authorized executive of the ACO and submitted to CMS for review and approval. The agreement must include representations that the ACO will comply with Shared Savings Program requirements. In addition, all contracts or arrangements between or among the ACO, ACO participants, ACO providers and suppliers, and other entities furnishing services related to ACO activities will be required to comply with the terms of the 3-year agreement. The ACO could terminate the agreement at any time during its term by providing 60 days' written notice to CMS; and, in the event of early termination by the ACO, the ACO would forfeit any portion of shared savings withheld for the purpose of offsetting future losses. The Shared Savings Program withhold is discussed in Section V below.

Start Date and Performance Periods. Under the Proposed Rule, the agreement would begin on January 1 of the year following the year in which CMS approves the ACO application and would have three 12-month performance periods. Recognizing that a single annual start date may not provide sufficient flexibility for all interested ACOs to complete applications, CMS has asked whether it should allow an additional start date of July 1 for the first year (*i.e.*, 2012) of the Shared Savings Program.

Distribution of Savings. Under the Proposed Rule, an ACO must specify in its application how it proposes to use potential shared savings payments to meet the goals of the Shared Savings Program, including criteria for distributing shared savings among ACO participants and ACO providers and suppliers.

Effect of New Program Initiatives and Other Significant Changes. CMS proposes that the ACO would be subject to all statutory changes that occur during the term of its 3-year agreement. The ACO also would be subject to regulatory changes that occur during the term, except regulatory changes that affect: (1) eligibility requirements concerning ACO structure and governance, (2) calculation of sharing rate, and (3) beneficiary assignment. The ACO may be required to supplement its original application to explain how it will address statutory or regulatory changes and the ACO may be terminated from the program if it cannot effect needed modifications.

The ACO would be required to notify CMS within 30 days of "significant changes" to the ACO, such as changes in structure, governance, provider/supplier composition, or other elements of its application. CMS also proposes that the ACO lack the unilateral authority to add ACO participants over the course of the 3-year agreement. To maintain a measure of flexibility, the ACO may remove ACO participants, or add or remove ACO providers and suppliers over the course of the 3-year agreement, but such an event may require notification to CMS.

Program Participation of Terminated Participants. CMS would retain the right to terminate the 3-year agreement if the ACO, ACO participants, ACO providers and suppliers or contracted entities performing services or functions on behalf of the ACO engage in proscribed activities (*e.g.*, avoid at-risk beneficiaries, fail

to comply with eligibility requirements, or violate the Civil Monetary Penalties statute ("CMP"), the Stark law, the Anti-Kickback Statute ("AKS"), HIPAA or other applicable laws). If CMS terminates its agreement with an ACO, under the Proposed Rule, ACO participants and ACO providers and suppliers of the terminated ACO may be eligible to re-enroll in the Shared Savings Program. The new ACO or ACO that takes in the participant, provider or supplier would be required to specify in its application whether the ACO or any participants, providers or suppliers previously participated in the program, whether participation was terminated or voluntarily withdrawn, and the reasons for any termination. Commentary to the proposed rule suggests that CMS would not approve applications if the previously-terminated ACO experienced a net loss during its first 3-year agreement and would not consider applications until the term of the first participation agreement had expired.

Data Sharing. CMS proposes to share "aggregate" data with respect to the assigned or potentially assigned population (*i.e.*, data that does not include patient identifiers, as defined by HIPAA) with an ACO at the start of a 3-year agreement and each quarter thereafter during the term of the agreement. Aggregate data reports would include information similar to aggregate data provided to participants in the Physician Group Practice ("PGP") demonstration, such as financial performance data, quality performance scores, aggregated metrics on the assigned beneficiary population, and utilization data.

In addition to aggregate data reports, CMS would share beneficiary identifiable data with an ACO in limited circumstances. CMS proposes sharing two types of beneficiary identifiable data: (1) the name, date of birth and Health Insurance Claim Number of each beneficiary used to generate the ACO's expenditure benchmark, which would be available at the beginning of the 3-year agreement and at the end of each performance period; and (2) monthly claims data for potentially assigned beneficiaries (including Medicare Parts A, B and D claims data), which would be provided each month on an ongoing basis.

Unlike aggregate data reports, beneficiary-identifiable data would be provided only if the ACO requests the data from CMS and certifies that it is a covered entity or business associate under HIPAA and that the request is for the minimum data necessary to conduct its health care operations. Additionally, prior to receiving any beneficiary identifiable data, the ACO would be required to enter into data use agreements with CMS specifying that misuse of beneficiary identifiable data could result in termination from the Shared Savings Program, subject to additional sanctions and penalties available under law. With respect to monthly claims data, beneficiaries would be given an opportunity to opt out of having their claims data shared with the ACO. The Proposed Rule lists data elements that may be included in a minimum necessary data set with respect to Medicare Part A, B and D claims.

III. Assignment of Medicare FFS Beneficiaries to an ACO

Assignment as an Alignment of Beneficiaries. CMS has proposed a detailed process for the assignment of Medicare FFS beneficiaries to ACOs. CMS believes that assignment should be more appropriately viewed as an "alignment" of beneficiaries with ACOs, a term that reflects the free choice that "assigned" beneficiaries continue to exercise in selecting their health care providers and suppliers. In its commentary, CMS takes pains to clarify that assignment to an ACO does not limit, restrict or diminish the right of Medicare FFS beneficiaries to exercise complete freedom of choice of the physicians and other health care practitioners and suppliers from whom they receive services.

Retrospective Assignment. CMS will retrospectively assign a beneficiary to an ACO by determining whether a beneficiary has chosen to receive primary care services from physicians associated with a specific ACO to a sufficient degree that the ACO may be designated as exercising responsibility for that beneficiary's

care. Specifically, CMS will determine where beneficiaries receive a plurality of allowed charges for primary care services and will assign beneficiaries accordingly. CMS proposes a defined set of services that would qualify as primary care services if furnished by specified primary care physicians (*i.e.*, internal medicine, general practice, family practice and geriatric medicine providers). Primary care services provided by specialists are excluded. Assignment will occur retrospectively, at the end of the performance year, based on primary care utilization data collected during the performance year. CMS believes that the retrospective method of assignment will: (1) ensure that ACOs are held accountable only for the population they actually treat during the performance year; (2) encourage ACOs to change the care experience of all beneficiaries; and (3) protect against cost-shifting. CMS requests comments on alternative assignment approaches and the use of a plurality rule for beneficiary assignment, including whether a minimum threshold should be set for the number of primary care services that a beneficiary should receive from physicians in the ACO in order to be assigned to the ACO. CMS also requests comments on the scope of primary care services and the treatment of delivery of primary care services by specialists. Importantly, the Act expressly forecloses either administrative or judicial review of beneficiary assignment determinations.

Use of TINs. For beneficiary assignment purposes, CMS proposes that ACOs will be identified as a collection of Medicare-enrolled TINs practicing as a "group practice arrangement" or in a "network." Beneficiaries will then be assigned to an ACO based on the TIN used to bill for primary care services received. CMS further proposes that all primary ACO professionals within a TIN be exclusive to one ACO agreement in the Shared Savings Program. ACO participant TINs upon which beneficiary assignment is not dependent (*e.g.*, acute care hospitals and Federally Qualified Health Centers/rural health clinics (FQHCs/RHCs)) would not be restricted to participation in a single ACO. CMS is also proposing that organizations applying to be an ACO must provide a list of associated National Provider Identifiers for all ACO professionals as well as TINs, including a list that separately identifies physicians that provide primary care.

IV. Quality Measurement and Reporting Requirements

Proposed Measures to Assess Quality. Under the Proposed Rule, an ACO must meet the so-called "quality performance standard" in order to qualify for shared savings. CMS has proposed the use of 65 measures to calculate whether an ACO has met the quality performance standard. The proposed measures fall within the following five domains:

- Patient/Caregiver Experience, which includes seven measures;
- Care Coordination, Transitions, and Information Systems, which includes 16 measures;
- Patient Safety, which includes two measures;
- Preventive Health, which includes nine measures; and
- At-Risk Population/Frail Elderly Health, which is further subdivided into six categories (Diabetes, Heart Failure, Coronary Artery Disease, Hypertension, Chronic Obstructive Pulmonary Disorder, and Frail Elderly) and includes 31 measures.

A full list of the proposed domains and measures is available here. The regulations propose using these 65 measures for the first performance year (which will require reporting only) and indicate that measures to be used during later performance years will be proposed in future rulemaking.

In deciding which measures to use, CMS prioritized measures addressing the two central aims of better care for individuals and better health for populations. CMS notes that most of the proposed measures can be derived from other existing CMS programs and resources such as the Physician Quality Reporting System ("PQRS"), E-Prescribing, HITECH, Hospital Compare, and the Centers for Disease Control and Prevention National Healthcare Safety Network. To the extent possible, CMS plans to align the Medicare Shared Savings Program measures specifications with the measures specifications for other Medicare and Medicaid programs, including the EHR Incentive Programs.

Data Submission Requirements. Under the Proposed Rule, results for the 65 measures would be calculated through claims data, survey data and a new data collection tool called the ACO Group Practice Reporting Option ("GPRO"), to be made available by CMS. For the measures that will be reported through the GPRO, ACOs would be required to submit data for a sample of assigned beneficiaries. CMS would retain the right to validate the reported data through an audit process detailed in the proposed regulations and to terminate or impose sanctions on an ACO that does not timely report complete and accurate quality measures data.

Calculation of Quality Performance Score. The Proposed Rule outlines a sliding scale quality performance measurement methodology that rewards ACOs that achieve higher scores on the quality performance measures with higher percentages of shared savings. The program would operate as a "pay for reporting" program during its first year: ACOs would achieve the maximum score, and the maximum percentage of shared savings, by submitting quality data for all 65 quality measures. After the first year, CMS proposes to use a "performance scoring" approach to measuring quality, incorporating both a minimum attainment level and a benchmark level for most measures; these levels would be made available prior to the start of each year. CMS also seeks comment on an alternative approach using only achievement of minimum quality thresholds to earn full shared savings. The "performance scoring" approach would operate as follows:

- **Calculation of the Quality Performance Score for a Single Measure.** An ACO can earn up to two points on each of the 65 measures. Scores for most of the measures are awarded on a sliding scale: an ACO receives 1.10 points for achieving the "minimum attainment level" for a measure and up to two points for achieving the higher "performance benchmark" for that measure. Points for the diabetes composite measure and coronary artery disease composite measure are awarded on an "all or nothing" basis.
- **Calculation of the Quality Performance Score across All Domains and Measures.** The scores for the individual measures are converted into a quality performance score percentage for a domain, comparing points earned to total possible points that could be earned. The quality performance score percentages on the five domains are then combined, giving equal weight to each, to determine the total quality performance score percentage across all domains and measures.
- **Conversion of the Quality Performance Score into Shared Savings Payments.** The quality performance score percentage across all domains is used to calculate the percentage of shared savings earned. For example, an ACO would be eligible for the maximum percentage of shared savings (*i.e.*, 50% for ACOs participating under the one-sided model and 60% for ACOs participating under the two-sided model) only if it achieves a 100% quality performance score across all domains. The shared savings would be reduced on a pro rata basis for a performance score of less than 100%. The one-sided and two-sided Shared Savings Program models are discussed in Section V below.

Under the Proposed Rule, an ACO's failure to meet the minimum attainment level for one or more of the five domains would result in the issuance of a warning in the first year and termination in a subsequent year. Notably, as set forth in the Act, the specification of criteria for meeting quality performance standards and CMS' assessment of quality of care furnished by an ACO are exempt from administrative and judicial review.

Physician Quality Reporting System Incentive. The Proposed Rule offers ACO professionals that are eligible to receive a Physician Quality Reporting System incentive payment the opportunity to receive the payment as a group practice rather than as individuals, based on their submission of the required ACO quality data.

Requirements for Use of Electronic Health Records Technology. In order for an ACO to continue participating in the Shared Savings Program during the program's second performance year, at least 50% of the ACO's primary care physicians must be meaningful users of certified EHR technology.

Public Reporting and Transparency. In the interest of improving quality and efficiency of care through increased transparency, the Proposed Rule requires ACOs to report directly to the public certain information relating to participation in the Shared Savings Program, including organizational information, quality performance scores, information on shared savings or losses and the proportion of shared savings distributed to ACO participants and used to support quality performance, better care for individuals, better health for populations, and lower growth in expenditures.

V. Shared Savings Models and Methodology

As stipulated in the law, providers and suppliers participating in an ACO will continue to be paid on an FFS basis. In addition, an ACO will be eligible to share in savings achieved at the end of each year as long as the ACO achieves a minimum amount of savings against a benchmark of expected average per capita Medicare FFS expenditures and satisfies the quality performance requirements described above.

Two Shared Savings Program Models: One-Sided Risk and Two-Sided Risk. The Proposed Rule describes two Shared Savings Program models: (1) a one-sided model under which an ACO is eligible to share in savings but is not required to share in any losses and (2) a two-sided model under which an ACO shares in both savings and losses. Although the Act is silent with respect to risk sharing, CMS has determined that, to achieve systematic changes in behavior and ensure program accountability, all ACOs must participate in the two-sided model for at least a portion of the agreement period. CMS' proposal not to include a purely one-sided savings model could chill participation by potential applicants with either a small number of providers/suppliers and/or little capacity, experience or track record in managing full risk.

ACOs may choose to participate in one of two tracks, each of which incorporates both the one-sided and two-sided model:

- ACOs participating in **Track 1** will share in savings all three years but will be required to automatically assume risk for losses in the third contract year.
- ACOs participating in **Track 2** will share in savings all three years and will be required to assume risk for losses in all three contract years.

After their first agreement period, all ACOs will be required to participate in Track 2. As further incentive for ACOs to assume risk, ACOs will be eligible for a greater percentage of shared savings in years in which they operate under the two-sided model.

CMS also plans to test a partial capitation Shared Savings Program model, under which an ACO would be at risk for some but not all Part A and B services, through the Center for Medicare and Medicaid Innovation.

Eligibility for Savings. To be eligible for shared savings, an ACO must (1) meet the quality requirements described in Section IV and (2) achieve savings in excess of a certain percentage of the ACO's benchmark expenditures, defined as a minimum savings rate ("MSR"). The purpose of the MSR threshold is to account for normal variations in spending that are unrelated to efficiency and quality gains. In those years in which an ACO is not at risk for loss, the MSR is set according to a sliding scale and decreases as the number of assigned beneficiaries increases (from 2% for ACOs with 50,000 or more beneficiaries to 3.9% for ACOs with only 5,000 beneficiaries). In those years in which an ACO is at risk, the MSR will be set at a flat 2% regardless of size, to incentivize ACOs to take on risk by making it easier for them to qualify for shared savings.

Calculation of Shared Savings and Losses. ACOs will be eligible for a portion of shared savings, subject to a cap, and liable for a portion of shared losses, likewise subject to a cap, on an annual basis as compared to a CMS-calculated benchmark. In the Proposed Rule, CMS outlines the elements required to perform these calculations and expresses willingness to revisit the technical details of these calculations based on public comment.

- *Expenditure Benchmark*. CMS will calculate an expenditure benchmark for each ACO based on the most recent three years of Medicare Part A and B expenditure data available for the beneficiaries that would have been assigned to the ACO in those years. CMS considered, but decided against, calculating the benchmark based on past data for the beneficiaries actually assigned to the ACO. The agency solicits comments on this alternative.
    - CMS will risk-adjust this data to address demographic factors as well as relative health status, employing the CMS-Hierarchal Condition Category ("CMS-HCC") risk adjuster used by the Medicare Advantage program. In addition to demographic variables, the CMS-HCC prospective risk adjustment model uses beneficiaries' prior year diagnoses to develop risk scores that are then applied to their current year expenditures. CMS will update the benchmark annually by the projected absolute amount of growth in national per capita expenditures for Medicare Part A and B by applying the same update across low and high Medicare cost growth areas. This methodology is being used to ameliorate the impact on costs resulting from changes in coding intensity and the mix of specialists and providers performing services rather than from improved methods of delivering care.

- *Annual Assigned Beneficiary Expenditures*. To determine an ACO's savings (or losses) each year, CMS will calculate the average per capita Medicare FFS Part A and B expenditures for the ACO's assigned beneficiaries in the ACO for each performance year.
    - Because CMS expects ACO's average population risk scores to be stable over time, it will apply the same historical risk adjustment score calculated for the benchmark to expenditures in each year, rather than adjusting the risk adjustment during the period for the health status of the beneficiaries actually assigned to the ACO.

Notably, CMS has proposed to exclude from the benchmark and actual expenditure calculations any Medicare payments from the Physician Quality Reporting System, E-Prescribing, and EHR Incentive Payment programs. However, CMS states that it does not have the authority to exclude Hospital Value-Based Purchasing Program or EHR Incentive Program payments, nor Medicare disproportionate share hospital or indirect medical education supplemental payments, from these calculations.

Calculation of Shared Savings

- *Net Savings.* Net savings are determined by comparing the ACO's average per capita benchmark to the ACO's actual average per capita expenditures in a year. For years in which an ACO participates in the one-sided model, if the ACO has achieved the above eligibility criteria, the ACO can share in savings in excess of a threshold of 2% of its benchmark. ACOs participating in the two-sided model, and certain exempt ACOs, are not subject to this threshold and can receive first-dollar savings.

- *Sharing rate.* The percentage of the savings that an ACO can receive is based primarily on quality measure performance. As described in more detail in Section IV above, ACOs in the one-sided model will have their savings rate increased by up to 10 percentage points for each quality measure domain that is achieved for a maximum of 50%; ACOs in the two-sided model will be eligible for up to 12 percentage points for each quality measure domain for a maximum of 60%. In addition, ACOs with strong FQHC/RHC participation will be eligible for a sliding scale bonus of up to 2.5 percentage points in the one-sided model and 5 percentage points in the two-sided model.

- *Maximum shared savings cap.* An ACO cannot receive shared savings in each agreement year of more than 7.5% under the one-sided model or 10% under the two-sided model.

Calculation of Shared Losses

To calculate losses, CMS proposes to apply the same benchmark and expenditure calculations described above. Under the two-sided model, if an ACO's expenditures are greater than the benchmark, the ACO will share in losses that exceed a minimum loss rate, which is calculated as 2% of benchmark.

- *Shared Loss Rate.* CMS proposes to calculate the shared loss rate as 1 minus the shared savings rate described above. For example, a Track 2 ACO with the maximum shared savings rate of 65% will have a shared loss rate of 1 minus 65%, or 35%; in contrast, a Track 2 ACO with a maximum shared savings rate of 60% will have a shared loss rate of 1 minus 60%, or 40%. Thus, an ACO with a higher shared savings rate will have a correspondingly lower loss rate, thereby limiting losses for ACOs that do well on quality performance and qualify for the FQHCs/RHC bonus.

- *Maximum Shared Loss Cap.* Losses are capped at 5% in the first year in which an ACO bears risk, 7.5% in the second year, and 10% in the third year. For the third year of Track 1, the first year in which the ACO is at risk, the 5% cap will apply.

Shared Savings Withhold and Recoupment of Losses. To enable ACOs to repay losses and to encourage ACOs to participate for the full 3-year term, CMS will withhold 25% of an ACO's annual savings—the same amount withheld under the PGP demonstration—until the end of the agreement period. In addition to this withhold, prior to each year in which it will assume risk, an ACO must demonstrate that it is capable of repaying losses equal to at least 1% of per capita expenditures for its assigned beneficiaries. Among other

mechanisms allowed by CMS, an ACO may demonstrate this ability by opting to have more savings withheld or by obtaining a line of credit or reinsurance.

No Appeals of Shared Savings Determinations. As set forth in the Act, there is no administrative or judicial review for the amount of shared savings awarded to an ACO. Although neither the Act nor the Proposed Rule explicitly states that shared loss determinations may also not be appealed, the calculation of an ACO's expenditure benchmark and the calculation of its annual assigned beneficiary expenditures, each of which is integral to the calculation of both shared losses and shared savings, are not appealable.

Summary of Shared Savings Methodology

Design Element	One-Sided Model (Track 1, yrs 1 & 2)	Two-Sided Model (Track 2, Track 1 yr 3)
Minimum Savings Rate ("MSR")	Varies from 2% to 3.9% based on size of ACO population	Flat 2% regardless of size
Shared Savings	-Eligible once exceed MSR -Amount is net of 2% of benchmark, unless eligible for first dollar savings (*e.g.*, ACOs with less than 10,000 beneficiaries and comprised only of professionals in group practice arrangements)	-Eligible once exceed MSR -No threshold; eligible for first dollar savings
Sharing Rate	Maximum 52.5%	Maximum 65%
- Quality Scoring	Sharing rate up to 50% based on quality performance (up to 10% for each domain)	Sharing rate up to 60% based on quality performance (up to 12% for each domain)
- FQHC/RHC Participating Incentives	Up to 2.5 percentage points	Up to 5 percentage points
Maximum Shared Savings Cap	7.5% of ACO's benchmark	10% of ACO's benchmark
Minimum Loss Rate	N/A	2% of benchmark
Shared Losses	N/A	-First dollar shared losses once the MLR is exceeded -Calculated as 1 minus the Sharing Rate
Maximum Shared Losses Cap	N/A	Track 1: 5% in 3rd year Track 2: 1st year 5%; 2nd year 7.5%; 3rd year 10%
Shared Savings Withhold	25% in each agreement year	25% in each agreement year

VI. Monitoring and Termination of ACOs

Monitoring. CMS will continually monitor ACOs and may terminate agreements with ACOs under certain circumstances. ACOs, ACO participants, ACO providers and suppliers and contracted entities performing services and functions on behalf of an ACO must comply with various notice, record inspection and retention requirements. This includes a requirement that records be maintained for 10 years from the end of

the ACO agreement period, or the completion of any audit, evaluation or inspection, whichever is later. Additionally, if CMS determines that there is a reasonable possibility of fraud or similar fault, it may inspect, evaluate and audit the ACO entity at any time. Provisions for CMS monitoring must be included in ACO contracts.

Avoidance of At-Risk Beneficiaries. CMS also will monitor ACOs to ensure that they do not take steps to avoid at-risk beneficiaries in order to reduce the likelihood of increasing ACO costs. CMS proposes that beneficiaries be considered at-risk if they are dually eligible for Medicare and Medicaid, have a high utilization pattern, or have multiple chronic conditions, among other factors. CMS proposes to analyze claims and other beneficiary-level documentation, such as medical record audits or beneficiary complaints, and, if a trend is identified suggesting avoidance of at-risk beneficiaries, to initiate an investigation. ACOs that have engaged in such risk-avoidance would be required to submit a corrective action plan. If the ACO continues to avoid at-risk beneficiaries, CMS may terminate an ACO's participation in the Shared Savings Program.

Termination. In addition to terminating ACOs that continue to avoid at-risk beneficiaries, CMS may terminate an ACO for a variety of other reasons. These include, but are not limited to: (1) failing to meet quality performance standards; (2) failing to meet the eligibility requirements for participation in the Shared Savings Program; (3) failing to make required regulatory changes; (4) failing to demonstrate that the ACO has or can maintain adequate resources to repay losses; (5) failing to meet beneficiary notification requirements; (6) failing to report completely and accurately; and (7) limiting access to records. If CMS terminates an ACO from the Shared Savings Program, or if an ACO voluntarily leaves the program, CMS would retain indefinitely any portion of shared savings withheld for the purpose of offsetting future losses. CMS has proposed an administrative process by which ACOs can request review of eligibility and termination decisions.

VII. Overlap with Other CMS Shared Savings Initiatives

Participation in Multiple Medicare Programs. CMS has clarified that Medicare providers and suppliers that participate in other shared saving programs, such as the Independence at Home Medical Practice Demonstration program, the Medicare Health Care Quality Demonstration programs, medical home demonstrations with a shared savings element (currently only the Multi-payer Advanced Primary Care Initiative), and the PGP demonstration, may not also participate in the Shared Savings Program. This restriction does not apply to non-Medicare shared savings programs, such as participation in the Medicaid health home and community health team initiatives that are authorized under the Act. This restriction also does not apply to individual providers and suppliers who submit claims under multiple Medicare-enrolled TINs. Further, sites participating in the PGP demonstration, which would be barred from participating in the Shared Savings Program, may choose to transition to the Shared Savings Program using a condensed application process. Finally, CMS states that it will coordinate efforts to ensure that there is no duplication of participation in the Shared Savings Programs and future shared savings models tested by the Center for Medicare and Medicaid Innovation.

VIII. CMS and OIG ACO Fraud and Abuse Waivers

Stark, AKS and CMP. In a companion release, CMS and the OIG issued a notice proposing clear—but limited—waivers from the Stark law's prohibition on referrals, the AKS's prohibition on remuneration intended to induce referrals, and the CMP's prohibition of payments intended to reduce or limit services. Specifically, CMS and OIG proposed the following waivers to promote the formation of ACOs:

- **Stark law:** Waiver of the Stark law's referral prohibition for the distribution of shared savings received by an ACO to ACO participants, ACO providers and suppliers, and parties outside the ACO for activities necessary for and directly related to the ACO's participation in and operations under the Shared Savings Program.

- **AKS:** Protection from enforcement under the AKS for (1) the distribution of shared savings covered by the Stark law waiver and (2) other financial relationships among ACO participants that implicate the Stark law and fully comply with an existing Stark law exception. Under current law, compliance with a Stark law exception does not immunize an arrangement from scrutiny under the AKS. Given the absence of AKS safe harbors that parallel the Stark law exceptions that shield certain percentage- and unit-based compensation arrangements, the latter waiver proposal would help protect certain physician compensation arrangements that, although intended to promote care coordination, are not funded with shared savings.

- **CMP statute:** Protection from enforcement under the CMP statute for the distribution of shared savings by a hospital participating in an ACO to a physician participating in the ACO if the payments are not made knowingly to induce the physician to reduce or limit medically necessary items or services. Under current law, payments to reduce even non-medically necessary items or services implicate the CMP statute. Other financial relationships among ACO participants would be protected to the extent they implicate the Stark law and fully comply with an existing Stark law exception.

Proposed Waivers May Need to Be Expanded to Encourage Widespread Participation in the Shared Savings Program. On one hand, the decision by CMS and OIG to propose blanket waivers rather than a process for seeking individualized waivers suggests that the agencies intend to support widespread participation in the Shared Savings Program. On the other hand, the proposed waivers lack key features that may be necessary to encourage the formation of ACOs, especially if, as proposed, Shared Savings Program participants are at risk for losses in one or more years of the program. First, the proposed waivers would be available only to participants in the Shared Savings Program and only during the term of their agreement with CMS, limiting the ability of providers to expand the shared savings model to other patient populations. Second, the waivers would protect only shared savings payments distributed by an ACO, not other financial arrangements among ACO participants, such as capital investments in ACO infrastructure, that do not satisfy an existing Stark law exception or AKS safe harbor. Third, the waivers would protect the distribution of shared savings to non-participating physicians and other parties outside the ACO only to the extent such distributions are integral to the operation of the ACO, potentially limiting the ability of the ACO to coordinate care and manage costs. Finally, the more limited proposed CMP statute waiver is likely to invite subjective debate over the meaning of medical necessity and may not give providers the certainty and predictability needed to encourage participation in the Shared Savings Program.

Open Questions. CMS and OIG, recognizing that the scope of their proposed waivers is relatively narrow, are seeking comments on whether broader waivers should be adopted to protect, among other things, remuneration related to ACO formation, ongoing operations of the ACO, achieving ACO goals, and distribution of shared savings payments received from private payers. Industry stakeholders generally have agreed that waivers are needed to protect capital investments in ACOs, both initial investments needed to develop an ACO's infrastructure and investments made after formation to improve ACO operations (*e.g.*, investment in EHRs). Even if CMS and OIG expand the scope of the proposed waivers to protect capital expenditures related to ACO formation and operations, IRS rules still may impede investment in ACOs as

explained below. Thus, changes to both the proposed fraud and abuse waivers and IRS guidance will be needed to allow a tax-exempt hospital to fund the costs of forming an ACO if physicians participating in the ACO will receive a disproportionate portion of the ACO's shared savings or will have a disproportionate ownership interest in the ACO. Comments on the joint CMS/OIG notice are due by June 6, 2011.

IX. FTC/DOJ Joint Statement Regarding Antitrust Scrutiny of ACOs

In a companion release, the FTC and the DOJ issued a joint proposed enforcement policy (the "Joint Statement") regarding antitrust regulation of ACOs under the ACA.

The Three Categories. The Joint Statement classifies ACOs into three enforcement categories: (1) a "safety zone"; (2) a "mandatory review" category; and (3) a third category, where a proposed ACO neither meets the safety zone requirements nor requires mandatory FTC/DOJ review. The enforcement category for a proposed ACO is determined on the basis of the ACO's share of services in each participant's Primary Service Area ("PSA"). The PSA is defined as the "lowest number of contiguous postal zip codes from which the ACO participant draws at least 75% of its patients for that service."

- To qualify for the ***safety zone***, any participants in the ACO that provide the same service must have a combined share of less than 30% of each such service in each participant's PSA. In addition, any hospital or ambulatory surgery center participating in an ACO must be non-exclusive to the ACO to fall within the safety zone, regardless of its PSA share. The non-exclusivity rule also applies to any "dominant provider"—a participant with greater than 50% share in its PSA of any service that no other ACO participant provides to patients in that PSA. (There are also allowances made for ACOs in rural counties, which are narrowly defined.)
- The ***mandatory review*** category is triggered if the ACO's share is over 50% for any common service that two or more independent participants provide to patients in the same PSA. Proposed ACOs in this category must submit various documents and information to the FTC/DOJ for assessment of competitive impact. ACOs will have an opportunity at that time to offer procompetitive justifications for the ACO and to provide data to suggest that the PSA shares are not reflective of the ACO's likely market power. The FTC/DOJ will provide a response within 90 days of receipt of all required materials.
- If the proposed ACO is in the third category, it may voluntarily request review pursuant to the same 90-day period provided for proposed ACOs in the mandatory-review category, and thereby obtain greater clarity to move forward under CMS regulations.

The Joint Statement offers the following example to illustrate the concept of "common services," which can place a proposed ACO in either the *safety zone* or the *mandatory review* category: "If two physician group practices form an ACO and each includes cardiologists and oncologists, cardiology and oncology would be *common services*. If, on the other hand, one physician group practice consists only of cardiologists and the other only of oncologists, then there are no common services . . . ."

In an effort to provide additional guidance, the Joint Statement identifies five types of conduct that should be *avoided* in order to reduce the likelihood of an investigation and challenge:

(1) Preventing commercial payers from directing patients to providers outside the ACO (referred to as "anti-steering" provisions);

(2) Requiring commercial payers to contract with providers outside the ACO as a condition of contracting within the ACO ("tying sales");
(3) Requiring provider exclusivity (except for primary care physicians);
(4) Prohibiting commercial payers from sharing certain cost, quality, efficiency, and other information with enrollees; and
(5) Sharing among participants of pricing information for services provided outside the ACO.

Finally, the Joint Statement makes clear that hospital mergers and affiliations (as opposed to ACOs) will be reviewed pursuant to the *Horizontal Merger Guidelines* and remain subject to the Hart-Scott-Rodino Act, if applicable. Comments on the Joint Statement are due May 31, 2011.

X. IRS Guidance on ACOs

In a companion release, the IRS issued Notice 2011-20 (the "Notice"), which offers guidance to tax-exempt organizations seeking to participate in the Shared Savings Program. The Notice is primarily a restatement of current law, with a request for comments on whether additional guidance is necessary regarding ACO participation by exempt organizations. Those comments are due by May 31, 2011.

The Notice speculates that exempt organizations may participate in ACOs with private parties. The Notice explains that the IRS does not generally expect that an exempt organization's participation in the Shared Savings Program through an ACO will result in impermissible private inurement or private benefit, provided the following five factors are present: (1) a written agreement negotiated at arm's length sets out the terms of the exempt organization's participation it the ACO; (2) CMS has accepted the ACO into the Shared Savings Program; (3) the exempt organization's share of economic benefits derived from the ACO is proportional to the benefits it provides to the ACO; (4) the exempt organization's share of the ACO's losses does not exceed the share of ACO benefits to which it is entitled; and (5) all contracts and transactions entered into by the exempt organization with the ACO and the other ACO participants and any other parties are at fair market value. The Notice also states that because an ACO's activities that generate Shared Savings Program payments lessen the burdens of government, these activities would be considered substantially related to the performance of a charitable purpose.

The Notice acknowledges that ACOs also may engage in activities unrelated to the Shared Savings Program, such as entering into shared savings arrangements with private health insurance payers or with Medicaid. The Notice states that the former activity would not generally be considered charitable, while the latter activity might be considered charitable, but does not address when other non-Shared Savings Program activities might jeopardize tax-exempt status or generate unrelated business taxable income ("UBTI"). The Notice requests comments on how an exempt organization's participation in non-Shared Savings Program activities through an ACO may further or be substantially related to an exempt purpose.

The Notice is perhaps most notable for what it does not address. Importantly, the Notice does not comment directly on whether an ACO could itself qualify as a tax-exempt organization, and focuses instead on implications for existing exempt organizations that choose to participate in ACOs. It therefore remains unclear whether there are particular requirements the IRS might impose on ACOs that apply for tax-exempt status. In addition, with respect to UBTI, although the Notice indicates that an ACO's activities that generate Shared Savings Program payments are substantially related to the charitable purpose of lessening the burdens of government, the IRS does not address whether UBTI would result for an exempt ACO participant with stated purposes that do not include lessening the burdens of government.

Final Thoughts

Please remember that comments are due on the Proposed Rule by June 6, 2011, CMS's New Program Integrity Requirements by June 6, 2011, the FTC/DOJ Joint Statement by May 31, 2011, and the IRS Notice by May 31, 2011.

Ropes & Gray will be hosting a webinar on April 27th to present an overview of these many interesting and exciting initiatives. We will send out reminders of this upcoming webinar and continue to notify you of our ongoing webinar series focused on ACO regulatory developments and how they may affect your organization.