CMS Releases Proposed Rule Governing Accountable Care Organizations

Health Care Organizations Face Complex Strategic Decisions

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On March 31, 2011, the Centers for Medicare and Medicaid Services ("CMS") released a long-awaited Proposed Rule governing accountable care organizations ("ACOs"). The Proposed Rule will be formally published in the Federal Register on April 7, 2011. Comments are due by June 6, 2011. Three other related documents were released simultaneously with the Proposed Rule:

- CMS and the Department of Health and Human Services Office of Inspector General ("OIG") issued a regulation waiving the application of fraud and abuse laws to certain ACO arrangements.
- The Federal Trade Commission ("FTC") and the Department of Justice ("DOJ") issued a statement of antitrust policy governing ACOs (the "Policy Statement").
- The Internal Revenue Service ("IRS") issued a notice addressing the application of the tax laws to ACOs in which tax-exempt health care providers participate.

The Proposed Rule was issued under Section 3022 of the Patient Protection and Affordable Care Act (the "ACA"), which establishes the Medicare Shared Savings Program under which ACOs may operate. The Shared Savings Program is designed to create a new framework for hospitals, physicians and other health care providers to work together to improve the quality and reduce the cost of health care services covered by Medicare.

Who Is Eligible to Form an ACO?
The Proposed Rule defines an ACO as a legal entity recognized under state law that consists of Medicare-enrolled providers or suppliers ("ACO participants") that work together to manage and coordinate care for Medicare fee for service ("FFS") beneficiaries. Under the ACA, the following groups of providers and suppliers are eligible to form an ACO:

- ACO professionals in group practice arrangements.
- Networks of individual practices of ACO professionals.
- Partnerships or joint venture arrangements between hospitals and ACO professionals.
- Hospitals employing ACO professionals.

CMS also proposes that certain critical access hospitals be eligible to form an ACO. Other Medicare-enrolled entities such as federally qualified health centers ("FQHCs") and rural health clinics ("RHCs") may participate in an ACO, but may not independently form their own ACO.

How Do Organizations Apply for ACO Status?
CMS proposes that for the "first round" of the ACO program, ACOs enter into a three-year participation agreement with CMS. Organizations must apply to participate in the Shared Savings Program; CMS is not obligated to accept all applicants.

The Proposed Rule describes various types of information, documentation and certifications that prospective ACOs would have to provide in their applications, and proposes to approve or deny ACO applications prior to the end of the calendar year in which they are submitted. The term of an ACO's participation agreement would then start on the January 1 following CMS's approval of the ACO's application. CMS would have authority, with limited exceptions, to

change program standards for ACOs unilaterally during the three-year term. The ACA requires CMS to establish the Shared Savings Program by January 1, 2012.

What Type of Legal Structure Is Required for an ACO?
The Proposed Rule requires an ACO to:

- Be recognized and authorized to conduct its business under applicable state law;
- Have a taxpayer identification number; and
- Be capable of receiving and distributing shared savings, repaying shared losses, ensuring and reporting compliance with program requirements, and performing other ACO functions.

CMS clarifies that it is not proposing to require existing legal entities that meet ACO eligibility requirements to form a new entity for the purpose of forming an ACO. However, if an existing entity were to include ACO participants that are not already part of its existing legal structure, it would have to establish a separate entity to provide all ACO participants a mechanism for shared governance.

How Must ACOs Be Governed?
An ACO must demonstrate a mechanism of shared governance that provides *all* ACO participants with appropriate "proportionate control" over the ACO's decision-making process. The governing body must have broad responsibility for the ACO's administrative, fiduciary and clinical operations, and must consist of ACO participants or their designated representatives. It must also include Medicare beneficiary representative(s) served by the ACO. At least 75% control of the ACO's governing body must be held by ACO participants.

CMS proposes to require that ACOs meet specified leadership and management criteria, including that the ACO's operations be managed by an executive, officer, manager, or general partner who is appointed and removed by the ACO's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice; that clinical management and oversight be managed by a senior-level, full-time medical director who is a board-certified physician in the state in which the ACO resides; and that ACO participants have a "meaningful commitment" to the ACO, which could include a meaningful financial or human investment in the ongoing operations of the ACO.

How Are Medicare Beneficiaries Assigned to ACOs?
CMS proposes to assign beneficiaries to an ACO based on their utilization of primary care services, which CMS defines as a set of specified HCPCS codes provided by a primary care physician who was an ACO participant during the performance year. Therefore, beneficiary assignment would be carried out on a retrospective basis. CMS proposes to assign a beneficiary to an ACO if the beneficiary received a plurality of his or her primary care services from primary care physicians who are participants in the ACO. Under the ACA, an ACO must be assigned at least 5,000 Medicare beneficiaries.

Primary care physicians may participate in only one ACO. Other providers and suppliers may participate in more than one ACO.

During a performance year, if an ACO's assigned beneficiary population falls below 5,000, CMS would issue a warning to the ACO and place it under a corrective action plan ("CAP"). If the ACO's assigned population does not return to at least 5,000 beneficiaries by the end of the next performance year, however, CMS would terminate the ACO's participation agreement and the ACO would be ineligible to share in savings for that year.

The Proposed Rule requires ACO participants to post signs in each of their facilities and provide written notification to beneficiaries about their participation in the Shared Savings Program.

What Type of Care Management Programs Must ACOs Have in Place?
The ACA requires an ACO to "define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies." Rather than identifying specific criteria that ACOs must meet, the Proposed Rule simply requires an ACO to document, as part of its application, its plans to meet each of these requirements. The ACA further requires an ACO to "demonstrate to the Secretary that it meets patient-centeredness criteria specified by the Secretary, such as the use of patient and caregiver assessments or the use of individualized care

plans." CMS proposes a number of criteria that an ACO would have to meet to demonstrate patient-centeredness, including having a beneficiary experience of care survey in place. The Proposed Rule prohibits ACOs from developing any policies that would restrict a beneficiary's freedom to seek care from providers and suppliers outside of the ACO.

What Type of Health Information Technology Requirements Are Imposed on ACOs?
The Proposed Rule includes a number of health information technology-related requirements. For example, there is a requirement that at least 50% of an ACO's primary care physicians be meaningful users of electronic health records by the ACO's second performance year. Further, ACOs would have to meet specified performance thresholds on a number of health-related measures, including the percentage of primary care physicians using clinical decision support.

How Will CMS Share Data With ACOs?
CMS proposes to provide ACOs with de-identified, aggregated beneficiary utilization data, a list of names and other information about historically assigned beneficiaries derived from the benchmark calculation, and patient-identifiable claims data from Medicare Parts A, B and D. Patient-identifiable information would be provided pursuant to a Data Use Agreement with each ACO. Although CMS notes that patient-identifiable data may be shared without patient authorization under HIPAA, CMS nonetheless proposes to allow beneficiaries to opt-out of having Medicare share their claims data with ACOs.

How Will ACOs Participate in Shared Savings?
Two Models. CMS offers two models of risk sharing. First, there is the one-sided model, where the ACO shares only in savings compared to what Medicare would have spent without the ACO. Second, there is the two-sided model, in which the ACO also shares in losses if the ACO spends more compared to what Medicare would have spent without the ACO. In Track One, the savings only model applies for years one and two; for the third year of the three year contract, ACOs must transition to the two-sided model. Under Track Two, the two-sided model applies for all three years of the ACO's agreement.

Determining The Benchmark. To determine whether an ACO saved the Medicare program money, CMS must estimate what Medicare would have paid for the care of the beneficiaries attributed to the providers in the ACO (the "benchmark"). The benchmark spending data includes all Part A and Part B expenditures, as well as indirect medical education and disproportionate share payments. Catastrophic claims (above the 99th percentile and approximately $100,000 per patient per year) are capped at the 99th percentile. The expected claims costs will be risk adjusted based on health status (under the same method as utilized by Medicare Advantage). CMS will then apply trend factors to adjust for growth in health care expenditures during the three years of the contract.

The ACO's Share of Savings. CMS will compare actual expenditures to the benchmark after applying a "minimum savings rate," which reflects fluctuations so small they likely are not due to the ACO's efforts. Under the one-sided model, the minimum savings rate ranges from 2% for large ACOs to 3.9% for small ACOs. Under the two-sided model, the minimum savings rate is 2% for all ACOs. All ACOs are entitled to receive 50% of the savings under the one-sided model. As an incentive to include FQHCs or RHCs, an additional 0.5% to 2.5% is available based on beneficiaries' use of those facilities, for a total maximum sharing rate of 52.5%. Payments of savings are contingent upon meeting the quality scores set forth in the ACO's contract. For example, if the ACO attains an 80% quality score, the ACO then is entitled to 80% of the 50% shared savings that are available. An ACO's sharing rate in all contracts with downside risk will be 60%, with an additional 1% to 5% available based on beneficiaries' use of FQHCs or RHCs, for a total maximum sharing rate of 65%. Under the two-sided model, all ACOs, regardless of size, will be eligible to share in the first dollar of savings. Under the one-sided model, there is a maximum shared savings payment to the ACO of 7.5% of the benchmark. Under the two-sided model, the cap is 10%.

The ACO's Share of Losses. There is a similar 2% corridor from the benchmark where the ACO will not be responsible for losses. The shared loss rate for an ACO is 1 minus the ACO's shared savings rate. For example, an ACO with a shared savings rate of 65% is responsible for 35% of the losses. An ACO's shared losses may not exceed 5% of the benchmark in its first year in the two-sided model, 7.5% of the benchmark in its second year, and 10% of the benchmark in its third year.

Financial Security. All applicants will be required to demonstrate financial resources to absorb possible losses. ACOs may demonstrate their ability to repay losses in many ways, including by demonstrating sufficient cash reserves, arrangements with insurers, or assurances from providers within the ACO. Additionally, CMS will withhold 25% of any shared savings payments as an offset to future repayment of potential losses.

Summary: What Are the Differences Between the One-Sided and Two-Sided Models?

Design Element	One-Sided Model	Two-Sided Model
Maximum Sharing Rate	52.5%	65%
Quality Scoring	50%	60%
FQHC/RHC Participation Incentives	2.5%	5%
Minimum Savings Rate	Between 2% and 3.9%, based on the number of assigned beneficiaries	2% regardless of ACO size
Savings Eligible for Sharing	All savings exceeding the minimum savings rate. For ACOs with fewer than 10,000 beneficiaries who meet certain requirements, sharing begins at first dollar of savings.	First dollar of savings
Maximum Sharing Cap	7.5% of benchmark	10% of benchmark
Losses Eligible for Sharing	N/A	First dollar of losses
Minimum Loss Rate	N/A	2%, regardless of ACO size
Maximum Losses	N/A	Year 1: 5% Year 2: 7.5% Year 3: 10%

What Type of Quality Standards Will Be Applied to ACOs?
CMS has proposed 65 quality measures falling into five domains. The domains are patient experience of care, care coordination, patient safety, preventive health and at-risk population/frail elderly health. In the first performance year, an ACO will be deemed to meet the quality standards by simply reporting the required data. Thereafter, performance will be measured at the level of an individual measure, an aggregate of all measures within each of five domains and a single performance score across all measures and domains.

A single performance score will be developed for each ACO in the form of a percentage and will be applied to determine the quality sharing rate for which the ACO is eligible. The quality sharing rate is 50% under the one-sided model and 60% under the two-sided model. For example, a 90% quality performance score will result in a shared savings rate of 45% for the one-sided model.

CMS has proposed the establishment of benchmarks for each measure based on Medicare FFS claims data, Medicare Advantage quality performance rates, or where appropriate, the corresponding recent performance rates that an ACO will be required to demonstrate. In addition, a minimum attainment level has been proposed and is set at 30% or the 30th percentile of Medicare FFS or the Medicare Advantage rate, depending on what performance data are available.

A quality standard will be developed for each of the five domains. The percentage score will be based on the number of points earned by the ACO across all measures in the domain divided by the total points available in the domain. Each domain will be worth a pre-defined number of points.

For one-third of the proposed ACO quality measures, a metric can be derived from CMS systems and calculated for the assigned patient population served by the ACO. However, for the majority of measures, the ACO will need to use the CMS-specified data collection tool, referred to as the Group Practice Reporting Option ("GPRO"). The 44 GPRO-based measures would need to be reported starting with the second year of the agreement. CMS proposes to incorporate certain requirements and payments related to a Physician Quality Reporting System for ACO professionals.

How Will the Fraud and Abuse Laws Be Applied to ACOs?
CMS and OIG have proposed a framework for granting waivers of the Stark Law, the Anti-Kickback Statute and the "gainsharing" provision of the Civil Monetary Penalties Law that prohibits a hospital from making payments to induce a physician to limit services to federal health care program beneficiaries under the physician's direct care. To qualify for any of the proposed waivers, the ACO must enter into an agreement with CMS to participate in the Shared Savings Program.

Application of the Anti-Kickback Statute and the Stark Law would be waived with respect to the distributions of shared savings received by an ACO from CMS under the Shared Savings Program:

- To or among ACO participants and other ACO providers or suppliers, and
- For activities necessary for and directly related to the ACO's participation in and operations under the Shared Savings Program.

Application of the gainsharing provision of the Civil Monetary Penalties Law would be waived with respect to distributions of shared savings received by an ACO under the Shared Savings Program, so long as 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 ACO providers or suppliers, or were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO. CMS and OIG expect to issue waivers for participating ACOs concurrently with CMS's publication of final regulations for the Shared Savings Program.

The proposed waivers would not cover the distribution of shared savings received by an ACO from payers other than Medicare. In addition, the waivers would not apply to financial arrangements relating to the establishment or ongoing financing of an ACO. Recognizing the limited scope of the proposed waivers, CMS and OIG have solicited public comment on the need for waivers to cover these and other ACO-related arrangements.

How Will the Antitrust Laws Be Applied to ACOs?
The Policy Statement issued by FTC and DOJ eliminates much of the uncertainty related to what constitutes "clinical integration" under the antitrust laws by establishing a bright line test that ACOs approved to participate in the Shared Savings Program will be deemed clinically integrated. As a result, ACOs that follow Shared Savings Program requirements will be subject to a "rule of reason" test under the antitrust laws.

The way in which the rule of reason analysis is carried out will depend on the market share of the ACO's participants. The Policy Statement requires ACOs to calculate their Primary Service Area ("PSA") share for each service provided by ACO participants. A PSA is the lowest number of contiguous zip codes from which a provider draws at least 75% of its patients for a particular service. To calculate the PSA share for each service, the ACO must determine (1) which services are provided by two or more unaffiliated providers (or groups of providers) that are ACO participants and (2) for each service, the share of such service provided by all ACO participants within each participant's PSA. PSA shares would be calculated for hospitals by using all payor discharge data for the relevant Major Diagnostic Categories.

Depending on the PSA share, there are three categories of possible antitrust review:

ACO PSA Share	Review Process
≤30 percent (with a rural exception)	*Safety Zone* – No antitrust review necessary by the Antitrust Agencies
>30 percent and ≤50 percent	*Optional review, comply with list of conduct restrictions or proceed without antitrust assurances.*
>50 percent	*Mandatory review* – ACO must seek review by the Antitrust Agencies to assess likelihood of anticompetitive effects and submit approval of Antitrust Agencies to CMS.

FTC and DOJ will decide between them which agency will respond to requests for review. The Policy Statement promises an expedited review within 90 days.

How Will the Tax Exemption Laws Be Applied to ACOs?
The IRS Notice states that the IRS will not consider a tax-exempt organization's participation in an ACO under the Shared Savings Program to result in inurement or impermissible private benefit to other ACO participants where:

- The terms of the tax-exempt organization's participation in the Shared Savings Program are set forth in advance in a written agreement negotiated at arm's length.
- CMS has not terminated the ACO from the Shared Savings Program.
- The tax-exempt organization's share of economic benefits derived from the ACO (including its share of payments) is proportional to the benefits or contributions the tax-exempt organization provides to the ACO. If the tax-exempt organization receives an ownership interest in the ACO, the ownership interest received is proportional and equal in value to its capital contributions to the ACO and all ACO returns of capital, allocations and distributions are made in proportion to ownership interests.
- The tax-exempt organization's share of the ACO's losses does not exceed the share of ACO economic benefits to which the tax-exempt organization is entitled.
- All contracts and transactions entered into by the tax-exempt organization with the ACO and the ACO's participants, and by the ACO with the ACO's participants and any other parties, are at fair market value.

The IRS expects that, absent inurement or impermissible private benefit, as long as the ACO meets all of the eligibility requirements established by CMS for participation in the Shared Savings Program, any shared savings payments received by a tax-exempt organization from an ACO would derive from activities that are substantially related to the performance of the charitable purpose of lessening the burdens of government. This should shield such payments from unrelated business income tax.

How Does the Shared Savings Program Relate to Other CMS Initiatives?
The ACO program is being run out of the CMS Center for Medicare, which houses the "permanent" Medicare programs—the original Medicare Fee-for-Service program, Medicare Advantage, and Part D—which may be a way of CMS signaling its commitment to the ACO program. A number of other shared savings models will also be evaluated by the Center for Medicare & Medicaid Innovation ("CMI"), which is a new CMS component that was created by the ACA. Under the Proposed Rule, providers would not be allowed to participate at the same time in both the ACO program and another shared savings program run by CMI.