Accountable Care Organization (“ACO”) - The Real Journey Begins

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On March 30, 2011, the Centers for Medicare & Medicaid Services (“CMS”), placed on public display a notice of proposed rulemaking (“Proposed Rule”) to implement the Accountable Care Organization (“ACO”) provisions of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the “ACA”). According to CMS, an ACO is intended to assist doctors, hospitals, and other health care providers better coordinate care for Medicare beneficiaries. ACOs would be eligible to receive a portion of any savings if they meet certain criteria. The full text of this Proposed Rule is currently available at www.ofr.gov/inspection.aspx and is expected to be published in the Federal Register on April 7, 2011. Comments must be submitted on or before 5:00 PM EDT on June 6, 2011. This Alert summarizes some key provisions of the Proposed Rule. It is not intended to provide a detailed description of the proposal.

I. In General

An ACO is a legal entity of eligible providers and suppliers working together to coordinate care for Medicare beneficiaries. Under the Proposed Rule, the ACO will be jointly governed by its members. Providers and suppliers participating in an ACO would continue to be reimbursed by Medicare under existing law, but would also be eligible to receive a portion of money that it saves Medicare through better care and better health. In general, to be eligible for shared savings, ACOs must reduce spending below a minimum savings rate target set by CMS, and meet or exceed quality performance standards.

The Proposed Rule offers ACOs the option of participating in a one-sided or a two-sided model of sharing risk, and offers two tracks for ACO participation. Under the one-sided model, an ACO shares savings, but is not at risk for any negative savings, i.e., aggregate payment increases. In contrast, under the two-sided model, the ACO is eligible to receive shared savings, but is also liable for spending above the benchmark.

Under the first track, an ACO operates through the one-sided model for the first two years, but is then required to operate under the two-sided model for the third and subsequent years. Under the second track, an ACO would participate in the two-sided model from the beginning. ACOs that select this second track would be eligible to receive a higher percentage of savings generated. Except as otherwise stated below, CMS has proposed that the majority of the requirements for ACOs participating in the one-sided model will also apply to those ACOs participating in the two-sided model.

II. Eligibility and Governance

The following types of health care entities are authorized to form ACOs under the Proposed Rule:
(1) certain health care providers in group practices;
(2) networks of individual practices;
(3) partnerships or joint venture arrangements between hospitals and certain health care providers;
(4) hospitals employing ACO professionals; and
(5) certain Critical Access Hospitals ("CAHs").

In addition, these entities may establish ACOs with broader collaborations. Those collaborations may include additional Medicare-enrolled entities such as Federally Qualified Health Centers ("FQHCs"), Rural Health Centers ("RHCs"), and other Medicare-enrolled providers and suppliers as defined in the ACA as ACO participants. ACOs may incorporate other groups of Medicare enrolled providers and suppliers, many of whom would not be able to form ACOs and participate in the program independently.

A. Legal Structure and Governance

An ACO may be structured as a corporation, partnership, limited liability company, foundation, or other entity permitted by state law that is capable of: (1) receiving and distributing shared savings; (2) repaying shared losses; (3) establishing, reporting, and ensuring that its members (i.e., ACO participants) comply with program requirements, including the quality performance standards; and (4) performing the other ACO functions identified in the statute.

Under the Proposed Rule, ACOs shall satisfy the following operational elements, among others: (1) at least 75% of control of the ACO’s governing body must be held by the ACO participants; (2) the ACO’s overall operations must be managed by an executive, officer, manager, or general partner, whose appointment and removal are under control of the organization's governing body; (3) the clinical aspects of an ACO must be managed by a medical director who is a board-certified physician licensed in the state in which the ACO operates and who is physically present in that state; (4) there must be a quality assurance and improvement program which is physician-directed; (5) the ACO must implement evidence-based medical practice or clinical guidelines and processes for delivering care consistent with the goals of better care for individuals, better health for populations, and lower growth in expenditures; and (6) the ACO must have an information technology infrastructure that enables it to collect and evaluate data and provide feedback to ACO providers and suppliers across the entire organization.

B. Accountability for Beneficiaries, Distribution of Savings and Patient Threshold.

The ACO participants must certify that they will become accountable for and report to CMS on the quality, cost, and overall care of the Medicare beneficiaries assigned to the ACO during the three-year agreement period. The number of Medicare patients assigned to the ACO over the three-year period must exceed 5,000 for each year the ACO participates in the Shared Savings Program. Shared savings distributions will be provided directly to the ACO, not to providers directly.

C. Processes, Marketing and Program Integrity Requirements.

ACOs must develop and report to CMS its processes and plans to promote evidence-based medicine, patient engagement, reporting, and coordination of care. Additionally, all ACO marketing materials, both those used by the ACO and the ACO participants, must be approved in advance. The ACO must also have in place criteria for program integrity, including compliance plans with program requirements, a conflict of interests’ policy, screening methods for ACO applicants, and policies to prohibit conditioning participation in the ACO on referrals of Federal health care program business provided to beneficiaries who are not assigned to the ACO.

D. Two-Sided Model Requirements.

Under the Proposed Rule, ACOs participating in the two-sided model would be required to establish a repayment mechanism that is sufficient to ensure repayment of at least 1% of the ACO’s per capita expenditures for a particular performance year. While CMS is proposing that the ACO have some freedom in what type of repayment mechanism it implements (e.g., capitalization, reinsurance, recoupment from the ACO’s participants), the ACO will be required to maintain such mechanism for the duration of the
III. 3-Year Agreement for Participation in Shared Savings Program

The minimum duration of an ACO-CMS contract is three years, under the Proposed Rule, beginning January 1 of a given year. The rule proposes a 6-month “claims run-out period” the time between when a Medicare-covered service has been furnished to a beneficiary and final payment has been issued for determining shared savings.

The Proposed Rule permits CMS to provide substantial data to ACOs about their assigned beneficiaries’ use of health care services to help the ACO improve the quality of care, health, and efficiency of the delivery of services. Specifically, CMS would provide aggregate data reports that include historical utilization, some limited identification information (including name and date of birth), frequency of the beneficiary’s use of certain services such as emergency department visits, and Part D data for Medicare patients who have primary care visits with an ACO primary care physician. The ACO will be required to execute a Data Use Agreement with CMS (“DUA”) to receive this information.

IV. Assignment of Medicare Beneficiaries to ACOs

The Proposed Rule assigns beneficiaries to ACOs based solely on their utilization of primary care services provided by physician ACO participants. Thus, primary care physicians would be required to belong exclusively to one ACO, whereas other provider types could belong to multiple ACOs. CMS will develop a set of educational materials for beneficiaries about ACOs, and ACOs would be required to provide notification to beneficiaries when they seek services from ACO providers and suppliers. This notified must be provided through written information and through signs posted in the facilities of participating ACO providers and suppliers, of the organization's status and the implications for the beneficiary. Beneficiaries must also be notified if an ACO is terminated or withdraws from the program.

V. Quality and Other Reporting Requirements

In an effort to reward providers for high quality care, the Proposed Rule sets forth certain quality measures and reporting requirements, including: (1) measures to assess quality; (2) instructions on how to report data; (3) performance standards; and (4) reporting requirements to CMS and the public.

A. Measures and data reporting.

The Proposed Rule proposes 65 measures relating to outcome, process and patient experience that are designed to promote better care to individuals and better health for certain populations. These measures are designed to assess: (1) improved patient/caregiver experience; (2) care coordination; (3) patient safety; (4) preventive health; and (5) the health of at-risk populations, such as those with diabetes, heart failure, coronary artery disease, hypertension and the frailty. The specific measures for each of these categories can be found on pages 174-194 of the public display version of the Proposed Rule’s preamble. Additionally, ACOs must report certain data to CMS and the agency will establish collection tools to assist with that requirement.

B. Standards.

The Proposed Rule proposes two alternatives for rewarding quality. The first option is Performance Scoring under which CMS would use quality performance standards to arrive at a total performance score for an ACO. That score would determine its shared savings percentage.

The second option is to establish a minimum Quality Threshold for participating ACOs using the same set of quality measures and benchmarks as the first option. If an ACO meets these thresholds, it would be eligible for a percentage of shared savings attributable to quality. If an ACO fails to meet this threshold, it would not be eligible for shared savings. CMS invites comments on these options, as well as on alternatives that would blend the two approaches.

C. PQRS/EHR.

CMS has incorporated some existing Medicare Physician Quality Reporting System (“PQRS”) and EHR reporting requirements into the Shared Savings Program. Specifically, the Proposed Rule would require eligible professionals (i.e. physicians, physical therapists, and certain other providers) to use the PQRS group practice reporting option to provide data through the ACO, upon which an incentive payment would be conditioned. The
Proposed Rule would also require that at least 50 percent of an ACO’s primary care physicians to be “meaningful EHR users” by the start of the ACO’s second performance year. CMS has invited comments on these proposals.

D. Public Reporting.

Finally, the Proposed Rule compels ACOs to publish a variety of information related to their operations and performance, including: (1) the identities of the ACO’s participating providers; (2) shared savings or losses; (3) the manner in which the ACO has used shared savings payments; and (4) quality performance standard scores.

VI. Determining Shared Savings

To be eligible for shared savings, an ACO must achieve a minimum threshold of savings above a benchmark amount in a given year. This minimum threshold is the “minimum savings rate” ("MSR"). The percentage of the savings that the ACO is eligible to receive is referred to as the “sharing rate” which is capped under the Proposed Rule.

The shared savings methodology requires three components to be determined. First, CMS sets an expenditure benchmark which is a projection of what expenditures would have been for the ACO population if the ACO did not exist. Second, CMS will compare the benchmark to the actual per capita Medicare spending for the ACO population. Third, CMS will calculate the MSR to ensure that savings are due to the ACO’s efforts and not merely due to other factors.

Under the Proposed Rule, the MSR for the one-sided model ranges from 3.9 percent for an ACO with the minimum 5,000 beneficiaries to 2 percent for ACOs with 60,000 or more beneficiaries assigned. The proposed MSR for all ACOs in the two-sided model would be 2 percent across the board.

Certain rural ACOs and those serving underserved populations may be exempt from the MSR and therefore, share in all the savings below the benchmark if they meet specified characteristics. In addition, ACOs in the one-side model that include a strong FQHC/RHC presence would be eligible for up to a 2.5 percentage point increase it its shared savings rate for the first two years of its agreement.

ACOs in the one-sided model may be eligible for up to 50 percent of the total savings generated by the ACO above the MSR, and those under the two-sided model would be eligible for up to 60 percent of the savings above the MSR. In addition, there is a cap on the amount of savings that can be paid to any one ACO. Under the Proposed Rule, the cap for one-sided ACOs would be set at 7.5 percent of the ACO’s benchmark for the first two years of the agreement. For an ACO in the two-sided model, the proposed cap would be set at 10 percent of the ACO’s benchmark. CMS is soliciting comments on the payment caps and whether higher limits or different limits for different ACOs would be more appropriate.

For the benchmark calculation, CMS considered two approaches and requests comments on both. Under Option 1, the benchmark would be based on the FFS spending in Parts A and B for beneficiaries who would have been assigned during the previous three years prior to the start of the ACO’s agreement period. In Option 2, the benchmark would be based on the FFS spending in Parts A and B for beneficiaries who are actually assigned to the ACO in the performance year. In the proposed rule, CMS is proposing to use Option 1 for calculating the benchmark.

Both the benchmark and the calculation of the actual average per capita beneficiary spending would be risk adjusted, and CMS specially requests comments in this area. This risk adjustment is to ensure that ACOs that realize savings do so because of the effectiveness of the delivery model and interventions and not due to treating a more favorable patient mix.

The ACO will also be required to submit a certification to CMS at the time it submits payment for such losses (as well as when it receives payment for a shared savings) that states that it has complied with all ACO program requirements and that all relevant information submitted by it and its ACO participants and providers and suppliers is accurate, complete, and truthful. This is significant because such certification could potentially make any shared payments or losses (and other ACO activity) subject to claims under the Federal False Claims Act.

CMS has also requested comments on the two-sided model in regard to whether any of its proposals would trigger the application of any State insurance laws and ways that it can work with ACOs and States to
minimize the burden of any additional regulation.

**VIII. Monitoring and Termination of ACOs**

Section 1899(d) of the Social Security Act, as amended by ACA, authorizes the Secretary to impose “appropriate sanctions,” including termination from the Shared Savings Program, if the ACO has not met established quality performance standards or “has taken steps to avoid patients at risk in order to reduce the likelihood of increasing costs to the ACO.” Consequently, CMS has proposed that ACOs, ACO participants, and ACO providers and suppliers retain (and make available for audit and inspection) records of its activities for a period of ten (10) years from the end of the agreement period.

Significantly, CMS has also proposed that voluntary or involuntary of an ACO agreement would result in the loss of the ACO’s mandatory 25% withholding of shared savings. Further, CMS retains the ability to terminate an ACO for avoiding “patients at-risk.” CMS has also requested comments on its definition of “patients at-risk” and whether additional characteristics should be considered.

**IX. Coordination with Other Agencies and Overlap with Other CMS Shared Savings Initiatives**

Due to the scope of the Proposed Rule and its potential implication on other federal laws and policies, CMS coordinated with the HHS Office of Inspector General (“OIG”), the Federal Trade Commission, and the Department of Justice when issuing this Proposed Rule. The results of this coordination are further described below.

Additionally, the ACA prohibits providers and suppliers who participate in other CMS shared savings programs from also participating as an ACO. However, CMS has proposed that this prohibition only apply to the ACO itself and not individual providers and suppliers acting as ACO participants or ACO providers or suppliers.

**X. Waivers of CMP, Anti Kickback, and Physician Self Referral Laws**

**A. General.**

Section 1899(f) of the Social Security Act authorizes the Secretary to waive application of certain federal healthcare regulatory provisions – specifically, Civil Monetary Penalty Act (“CMP”), the Anti-Kickback Statute (“AKS”), and the Physician Self-Referral Law (the “Stark Law”) – in connection with operations of ACOs.

**B. Stark Law.**

Section 1877 of the Act, or the Stark Law, is a civil statute prohibiting physicians from making referrals for so-called “designated health services” to other physicians or entities with which the referring physicians have a financial relationship. Distributions of shared savings would be considered a financial arrangement, and to the extent that ACO providers refer to one another, the Stark Law would be implicated.

However, under the proposed waivers, an ACO will receive waivers from application of the Stark Law application for distributions of shared savings received by the ACO from CMS if: a) the distribution is to or among ACO participants; or b) the distribution is for activity “necessary for and directly related to” the operation of the ACO, whether or not the recipient is participating in the ACO.

Financial relationships between the ACO and outside referring physicians will not be protected unless the physicians are being compensated for activities “necessary for and directly related to” the ACO’s operations and participation in the Shared Savings Program. This proposed waiver is limited to distributions of shared savings received from CMS; other financial relationships must still fit an exception within Stark.

**C. Anti-Kickback Statute.**

Section 1128B(b) of the Act, or the AKS, provides criminal penalties for individuals and entities who knowingly give or receive remuneration to induce referrals of services payable by federal healthcare programs. Similar to the Stark Law, the AKS could be implicated by an ACO’s distributions of shared savings as between healthcare providers who refer to one another, if the distributions are intended to induce referrals. However, under the Proposed Rule, applicability of the AKS would be waived in the following two scenarios.
The first scenario addresses distribution of shared savings is to or among ACO participants, or the distribution is for activities “necessary for and directly related to” the operation of the ACO, whether or not the recipient is participating in the ACO. The second scenario addresses any financial relationship between or among the ACO participants supplliers “necessary for and directly related to” the ACO’s operations in the Shared Savings Program that both a) implicates the Stark Law and b) fully complies with an existing Stark Law exception.

The Proposed Rule clarifies that the first scenario above is meant to protect financial arrangements created by the distribution of shared savings within the ACO and outside the ACO if the outside activities are “necessary for and directly related to” the operation of the ACO.

The second scenario above, however, protects those financial relationships that implicate the Stark Law, but fit squarely within one of the Stark Law’s statutory exemptions. (Note that under the second scenario, any financial relationship compliant with Stark is safe. Only those financial relationships created by distribution of shared savings, are eligible for waiver under the first bullet point.)

Rarely does compliance with the Stark Law immunize conduct under the AKS or CMP. But in this case, for administrative and regulatory simplicity, the Secretary attempted to minimize the regulatory burden on ACOs and allow Stark Law compliance to act as a surrogate safety net in the AKS and CMP contexts as well.

Also notable is that failure to comply with the AKS waiver provisions does not mean the ACO is necessarily noncompliant with AKS. Indeed, the financial arrangement between referring entities within the ACO may implicate the AKS and remain compliant with the statute in another way – perhaps by fitting within a safe harbor or by lacking the requisite intent to induce referrals.

D. Civil Monetary Penalties.

Section 1128A(b)(1) and (2) of the Act, or CMP, prohibits payments from hospitals to physicians to induce reduction or limitation of services to federal program beneficiaries. ACOs invite scrutiny under CMP to the extent that hospitals share distributions of shared savings with physicians who, given improper motive, could be incentivized to reduce or limit services to Medicare beneficiaries to artificially increase the ACO’s savings to Medicare and thus its remuneration under the Shared Savings Program.

However, under this proposed waiver, an ACO would be waived from liability under the CMP under two different scenarios. The first scenario addresses distribution of share savings under the Shared Savings Program from a hospital to a physician, if the payments are not made knowingly to induce the physician to reduce or limit medically necessary services; and the hospital and physician are ACO participants. The second scenario addresses any financial relationship between or among the ACO participants suppllers “necessary for and directly related to” the ACO’s operations in the Shared Savings Program that both a) implicates the Stark Law; and b) fully complies with an existing Stark Law exception.

These waivers from application of the Stark Law, the AKS, and the CMP will last as long as the ACO participates in the Shared Savings Program, even if the actual distributions of share savings come after the agreement between CMS and the ACO ends.

XI. IRS Guidance Relating to Tax Treatment of Shared Savings

The IRS has published a notice seeking comment on the issues presented by the Medicare Shared Savings Program’s Proposed Rule. The IRS anticipates that tax exempt organizations, such as hospitals and other health care organizations, will be participating in ACOs. The notice solicits comments on what, if any, additional exempt organization guidance is warranted in light of the Proposed Rule.

It is not clear that the IRS will issue formal guidance. Nevertheless, its notice is instructive. In the notice, the IRS stated that its guiding principal is that, to avoid adverse tax consequences, a tax exempt organization participating in an ACO must ensure that its participation is structured so as not to result in its net earnings inuring to the benefit of insiders or in its being operated for the benefit of private parties participating in the ACO.

The key requirements noted by the IRS are as follows: (i) a written agreement negotiated at arms length setting forth the terms of the tax exempt organization’s participation in the ACO; (ii) CMS has accepted the ACO into and has not terminated the ACO; (iii) the tax exempt organization’s share of benefits is proportional to the benefits it provides; (iv) the tax exempt organization’s share of losses does not exceed the share of economic benefits to which it is entitled; and (v) all contracts and transactions between the
ACO and the tax exempt organization are at fair market value. However, the IRS anticipates that, in general, where a tax exempt organization participates in an ACO, it likely would be determined to be substantially related to the organization’s exempt purpose, as long as the ACO meets all of the CMS requirements.

The IRS also noted that some ACOs are likely to participate in non-Medicare programs, as well as in Medicare. These might include Medicaid or commercial insurance. In the case of Medicaid, it is likely that the participation would not raise tax exemption or private benefit issues. In the case of commercial insurance, the IRS intends to apply the above principles. Comments to the IRS’s solicitation of comments are due May 31, 2011.

XII. Antitrust Policy Statement

Along with CMS’s Proposed Rule on ACOs, the Federal Trade Commission (“FTC”) and the Antitrust Division of the Department of Justice (“DOJ”) published for notice and comment their “ACO Antitrust Policy Statement”, which applies to collaborations among otherwise independent providers and provider groups formed after the date of enactment of the ACA (March 23, 2010). FTC/DOJ stated that the ACO Antitrust Policy Statement was proposed (1) to clarify the antitrust analysis of newly formed collaborations among independent providers that seek to become ACOs in the Shared Savings Program; and, (2) to coordinate the antitrust analysis with the CMS review of ACO applications to participate.

For antitrust review purposes, ACOs will essentially be divided into three categories: (1) A “safety zone” or exemption for which no Antitrust Agency review is required; (2) a “Mandatory Review” category, for which pre-application review by the Antitrust Agencies is mandatory to securing Shared Savings Program participation; and (3) an intermediate category for which is no “safety zone” exemption, but no mandatory review. These ACOs would be entitled to an expedited review process.

ACOs must analyze market share based on the respective “common services” rendered by independent ACO participants performed within their respective “Primary Service Areas” or “PSAs”. Each ACO must perform and submit an analysis of collective market shares relevant to the primary service area of each independent provider of common services, using zip code.

The results of the PSA market share analyses will indicate to an ACO whether they are subject to mandatory review, qualify for a safety zone, or land in the middle ground. ACOs may not participate in the Shared Savings Program without performing the comprehensive market share analysis, which in turn will determine if review by the Antitrust Agencies under the proposed ACO Antitrust Policy Statement is required, optional, or unnecessary.

The requirements of the ACO Antitrust Policy Statement could turn out to be very burdensome on some ACO’s. The PSA market share analyses, along with a complete copy of the materials to be submitted to CMS for the Shared Savings Program application must be submitted to one of the Antitrust Agencies at least 90 days prior to the CMS deadline for submission of applications. ACOs must be ready to accelerate their formation process to complete its application to CMS with sufficient time for the Antitrust Agencies to complete their review.

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