Medicare Accountable Care Organizations: CMS Announces Final Rule

On November 2, 2011, the Centers for Medicare & Medicaid Services ("CMS") issued the final rule establishing Accountable Care Organizations ("ACOs") under the Medicare Shared Savings Program ("Final Rule").

This alert highlights the differences between the Final Rule and the proposed rule ("Proposed Rule") released in April 2011, and includes an analysis of complementary rules and statements issued by other federal enforcement agencies.

CMS intends the Final Rule to address the concerns expressed in the more than 1,300 public comments it received in response to the Proposed Rule. Among other things, in the Final Rule, CMS (1) changed the beneficiary assignment methodology; (2) reduced the number of quality measures providers are required to report and satisfy; (3) established a more flexible admissions process; (4) modified the risk and reward calculations to eliminate risk for some participants; (5) adjusted the measures for calculating shared savings; and (6) eliminated mandatory antitrust review.

CMS did not modify the data collection and reporting requirements through the Final Rule. Nor did CMS make significant changes to the organizational requirements, including the requirement that an ACO be identifiable as a separate legal entity capable of accepting Medicare payments.

Stakeholders have been slow to respond to the Final Rule but initial reactions are positive. Providers are pleased with the changes and believe that CMS responded thoughtfully to industry concerns and has made substantial progress toward making the program more attractive to hospitals and other providers.

More mature health systems may, however, be disappointed with CMS's failure to make more than minimal changes to the organizational requirements and its decision to leave the separate legal entity requirement intact. Such organizational requirements may create significant administrative barriers to participation by such systems.

Beneficiary Assignment

To be eligible to participate in the Shared Savings Program, an ACO must realize savings for a population of assigned beneficiaries. Beneficiary assignment is a function of a beneficiary's utilization of primary care services. Under the Proposed Rule, CMS proposed a retrospective assignment method according to which beneficiaries would have been assigned to an ACO at the end of the performance year based on primary care services utilized by those beneficiaries during that year. According to the CMS preamble to the Final Rule, however, commenters were "overwhelmingly in favor of prospective assignment" on the ground that prior knowledge of patients for whom the ACO would be responsible is critical to the ACO's ability to effectively coordinate care and implement a care management program.

In the Final Rule, CMS adopted an assignment method that is primarily prospective with a retrospective reconciliation. Beneficiaries will be preliminarily assigned to ACOs at the beginning of a performance year based on the beneficiaries' most recent historical utilization data available. Thereafter, beneficiary assignment will be updated quarterly based on the most recent 12-month utilization data and then ultimately finalized after the end of each performance year based on data from that year.

Quality Measures

A participating ACO must also meet established quality performance standards before sharing in any savings realized. Under the Proposed Rule, CMS proposed to use 65 measures in five domains (e.g., patient/caregiver experience and preventive health) to establish these quality performance standards. As proposed, an ACO would have had to meet the quality performance thresholds for *all* measures in *each* domain; and, if the ACO failed to do so, the ACO would have been *in*eligible for shared savings regardless of how much its per capita costs were reduced.

In response to concerns that this all-or-nothing requirement was overly, even prohibitively, burdensome, CMS reduced the measures in the Final Rule to 33 measures in four domains. In addition, because CMS recognized that achieving the quality performance standard on 33 out of 33 measures may be difficult, especially in the early years, the Final Rule requires ACOs to achieve the quality performance standard on 70 percent of the measures in each domain.

Admission Dates and First Performance Term

Under the Proposed Rule, providers would have been required to enter into a three-year agreement with CMS no later than January 1, 2012. Under the Final Rule, the agreement term is still three years but now approved providers can enroll in the Shared Savings Program in 2012 on one of two dates. The first start date will be April 1, 2012; providers starting on this date will have a first performance year of 21 months that terminates on December 31, 2013. The second start date will be July 1, 2012; providers starting on this date will have a first performance year of 18 months that also terminates on December 31, 2013. All providers enrolling in 2012 will, therefore, have a three-year agreement that expires on December 31, 2015.

Options to Share Benefits and Losses

In the Proposed Rule, CMS proposed two options (or "Tracks") for determining the nature and degree of risk assumed by the ACO.

Under the Proposed Rule, ACOs selecting the first option ("Track 1") would, in years one and two, have shared in the savings while bearing no risk of losses above the expenditure target (the "one-sided model"). Then, in year three under the Proposed Rule, Track 1 ACOs would have been obligated to shift into the "two-sided model" under which the ACO would have also assumed the risk of losses. By contrast, under the Proposed Rule, ACOs selecting the second option ("Track 2") would have shared in both savings and losses during all three years of the agreement period. In exchange for this greater risk assumed, Track 2 ACOs would have been eligible to realize a greater level of savings than Track 1 ACOs.

Commenters suggested that the absence of an entirely risk-free option would deter participants, especially given the uncertainty over whether savings can be realized and the significant start-up costs required to establish and maintain participation in the program. In response, CMS finalized the two Tracks but eliminated the risk-sharing year three requirement for Track 1, thus creating a wholly risk-free, shared-savings only option in the Final Rule. Track 2 remains a two-sided shared savings and losses model and Track 2 ACOs remain eligible to realize a greater level of savings than Track 1 ACOs.

Note that in periods subsequent to the initial three-year period, all ACOs entering into the Shared Savings agreement must participate in the two-sided model.

Minimum Savings Requirement, Cap and Withhold

In response to comments that the Shared Savings Program as proposed did not create sufficient opportunities for meaningful "up-side," the Final Rule made several changes to the methods outlined in the Proposed Rule for determining how ACOs would share in savings.

In the Proposed Rule, CMS proposed a minimum saving requirement ("MSR") of 2 percent of the ACO's benchmark expenditure. As proposed, Track 1 ACOs would have been entitled to share in savings once the MSR was achieved but would have been able to share only in those savings that exceeded the 2 percent MSR. By contrast, Track 2 ACOs under the Proposed Rule would have been able to share in first dollar savings once the MSR was achieved.

The Proposed Rule also sought to cap the total savings an ACO could earn at 7.5 percent for Track 1 ACOs and at 10 percent for Track 2 ACOs. In addition, the Proposed Rule sought to impose on all ACOs, regardless of Track, a 25 percent withhold of any shared savings realized to offset any future losses (or to be forfeited if an ACO's agreement were subject to early termination).

The Final Rule eliminated the 2 percent MSR for Track 1 ACOs, thus allowing Track 1 ACOs, like Track 2 ACOs, to share in first dollar savings once the MSR is met. The Final Rule also raised the cap on the total savings an ACO can earn to 10 percent for Track 1 ACOs, and to 15 percent for Track 2 ACOs, but marginally lowered the share of savings that ACOs can keep. In addition, the performance payment withhold requirement of 25 percent has been eliminated in the Final Rule for both Track 1 and 2 ACOs.

Antitrust Review

In the Proposed Rule, CMS proposed to require that certain ACOs be subject to mandatory review by antitrust agencies as a condition to their participation in the Shared Savings Program. Specifically, CMS proposed that mandatory antitrust review would be required for any newly formed ACO (a) with a Primary Service Area ("PSA") share above 50 percent for any service that two or more ACO participants provide within the same PSA, and (b) that did not qualify for an exception articulated in the proposed Antitrust Policy Statement (discussed below). Under the Proposed Rule, such ACOs would have been required to submit a letter to CMS from the reviewing antitrust agency confirming that the agency had no present intent to challenge or recommend challenging the proposed ACO as a condition to participation.

In the Final Rule, CMS deleted this requirement in favor of an expedited, *voluntary* review process.

Statements From Other Federal Agencies

In addition to the Final Rule, several federal agencies simultaneously issued documents addressing legal issues regarding ACOs participating in the Shared Savings Program.

CMS/OIG: Interim Final Rule on Fraud and Abuse Waivers

CMS and the HHS Office of Inspector General ("OIG") jointly issued an interim final rule with comment period ("IFR") establishing waivers of certain federal fraud and abuse laws; specifically, the physician self-referral (or "Stark") law, the anti-kickback statute ("AKS"), and certain provisions of the civil monetary penalty ("CMP") law (i.e., relating to hospital payments to physicians to reduce savings (gainsharing) and to the prohibition of inducements to beneficiaries). These waivers apply only to the Shared Savings Program and to ACOs participating in the Shared Savings Program. There is no waiver, even for the Shared Savings Program, for analogous state fraud and abuse laws.

The IFR went into effect, and was published in the Federal Register, on November 2, 2011. Comments to the IFR are due by January 3, 2012.

The IFR includes the following five fraud and abuse waivers for ACOs participating in the Shared Savings Program, of which two are modifications to those originally proposed and three are new. Each waiver addresses different circumstances across the ACO lifecycle. Even though an arrangement that would or may otherwise violate a particular fraud and abuse law must satisfy only one waiver, in some cases an arrangement may meet the criteria of more than one waiver.

- The ACO pre-participation waiver: Applies to ACO-related start-up arrangements in anticipation of participation in the Shared Savings Program, subject to certain limitations, including limits on the duration of the waiver and types of parties covered. According to the IFR, the following items, services, facilities and goods would be considered among the start-up arrangements: infrastructure creation and provision; network development and management; care coordination mechanisms; information technology; consultant and other professional support; incentives to attract primary care physicians; and capital investments (e.g., loans, capital contributions, grants and withholds).

- The ACO participation waiver: Applies broadly to ACO-related arrangements during the term of the ACO's participation agreement and for a specified time thereafter.

- The shared savings distributions waiver: Applies to distributions and uses of shared savings payments earned under the Shared Savings Program within the ACO.

- The compliance with the Physician Self-Referral Law waiver: Applies to ACO arrangements that implicate Stark but also meet an existing Stark exception.

- The patient incentive waiver: Applies to in-kind, medically related incentives offered by ACOs under the Shared Savings Program for free or below-market value to encourage preventive care and compliance with treatment regimens among beneficiaries (e.g., blood pressure cuffs for hypertensive patients). The waiver would not protect any financial incentives, such as covering a beneficiary's copayment or deductible.

In addition, CMS/OIG adopted the recommendation of the American Medical Association that the waivers begin sooner than an ACO's enrollment in the Shared Savings Program so that the waivers will apply to providers as they plan and establish Medicare ACOs. Pre-participation waivers, therefore, began on November 2, 2011 for ACOs enrolling in the Shared Savings Program in 2012 and will begin one year prior to an application due date for ACOs enrolling in 2013 or later years.

As with the Final Rule, the fraud and abuse waivers have been positively received by providers and industry analysts who note that the waivers are not overly prescriptive and afford greater flexibility than the two originally proposed. It is generally believed that most ACOs will be covered by one or more of these waivers.

FTC/DOJ: Antitrust Policy Statement

The Federal Trade Commission ("FTC") and the Department of Justice ("DOJ") jointly issued a "Statement of Antitrust Enforcement Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program" ("Antitrust Policy Statement") which details how the agencies will enforce U.S. antitrust laws with respect to ACOs.

According to the Antitrust Policy Statement, the agencies will not challenge as *per se* illegal an ACO that jointly negotiates with private insurers to serve patients in commercial markets if the ACO satisfies certain conditions, including compliance with CMS's eligibility criteria and use of the same governance and leadership structures and clinical and administrative processes to serve patients in both Medicare and commercial markets. For ACOs that meet applicable criteria, the agencies will apply a "rule of reason" analysis in analyzing a potential antitrust violation.

In addition, the Antitrust Policy Statement provides for an antitrust "safety zone" for certain ACOs. With some exceptions, safety zone eligibility is based on the combined PSA shares of ACO participants that provide a common service (e.g., the same physician specialty or the same inpatient service) to patients from the same PSA. To fall within the safety zone, an ACO's independent participants that provide a common service must have a combined share of 30 percent or less of each common service in each participant's PSA, where two or more participants provide that service to patients in that PSA.

The Antitrust Policy Statement also provides examples of conduct that, under certain circumstances, may raise competitive concerns. For example, all ACOs should, among other things, refrain from, and implement safeguards against, conduct that may facilitate collusion among ACO participants in the sale of competing services outside of the ACO.

Finally, the FTC and DOJ will, consistent with the Final Rule's elimination of mandatory antitrust review, offer voluntary expedited 90-day reviews for newly formed ACOs that are seeking additional antitrust guidance.

As with the other agency statements, the response to date has generally been positive, especially with regard to the removal of mandatory antitrust review in favor of voluntary review. The expectation is that proposed ACOs will likely not file with the FTC/DOJ for review, following the adage "ask for forgiveness, not permission."

IRS: Fact Sheet

The Internal Revenue Service ("IRS") has posted a Fact Sheet with questions and answers titled "Tax-Exempt Organizations Participating in the Medicare Shared Savings Program through Accountable Care Organizations" ("IRS Fact Sheet").

The IRS Fact Sheet responds to key questions, especially those relating to the consequences of ACO participation and shared savings distributions by and among one or more tax-exempt organizations. Industry response has been positive but cautious. Providers are seeking more guidance from the IRS regarding permissible shared savings allocations as well as organizations composed of ACO participants with substantially different levels of resources to contribute to the ACO.

Notably, the IRS Fact Sheet does not reflect any substantive changes or shifts in the IRS's position regarding ACOs since its publication of Notice 2011-20 on April 18, 2011.

If you have questions about these initiatives or other questions related to ACOs, please contact the Ropes & Gray attorney who normally advises you. 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.