Health Law Alert: CMS Issues Proposed ACO Regulations

April 13, 2011

On March 31, 2011, the Centers for Medicare & Medicaid Services (CMS) issued proposed regulations to guide the development of Accountable Care Organizations (ACOs)—a key part of the Medicare Shared Savings Program (SSP) enacted in the 2010 Affordable Care Act (ACA). In addition, CMS and a host of other agencies released guidance that day explaining how a range of key laws governing ACOs, such as the Stark Law and Anti-kickback Statute, will apply. The ACO program is scheduled to go into effect on January 1, 2012. CMS will be accepting comments on the proposed regulations through June 6, 2011.

Background on Accountable Care Organizations

ACOs are intended to encourage hospitals, physicians, and other providers to improve the quality of care they provide and reduce unnecessary costs through a collaborative approach to care delivery. ACOs will be patient-centered organizations that hold providers accountable for delivering quality care, measuring provider performance against benchmarks adopted by CMS. ACO providers will continue to be paid as they are currently under Medicare Parts A and B, but will have the opportunity to share in savings made possible through efficiencies in care delivery.

Participation in an ACO

ACO participation is voluntary, both for providers and patients. To participate, an ACO must apply and be accepted into the SSP under a 3-year agreement with a performance period of 12 months. ACOs must have at least 5,000 beneficiaries, and must include a sufficient number of primary care physicians to treat the ACO beneficiary population. Beneficiaries will be assigned to ACOs based on their utilization of primary care services. ACO assignment will not restrict beneficiary choice in receiving services, but rather act as a way to measure utilization. CMS will measure utilization by establishing a fixed benchmark and update the benchmark annually based on the growth in Medicare expenditures.

Payment under the Shared Savings Program: Two ACO Models

ACOs that meet quality and savings requirements may qualify for a percentage of the savings accrued by the Medicare program. To calculate this, CMS will develop a performance benchmark for each ACO that will assess whether it is qualified to receive shared savings or be held accountable for losses. This benchmark will be updated for each performance year within the 3-year performance period.

CMS has proposed two ACO models—termed the "one-sided" and "two-sided" risk models. The one-sided model will share only in savings for the first two years and, in the third year, share both savings and losses. The two-sided model will share savings (in greater amounts than the one-sided model) and losses for all three years. ACOs may choose whether to operate under the one-sided or two-sided model during the first three years of operation. However, after the 3-year mark, all ACOs must operate under the two-sided model and share both gains and losses with Medicare. CMS believes use of the one-sided model will give smaller providers, which might have less experience with patient management, a chance to wade gently into the shared savings/shared risk model on which the ACO program is based.

Monitoring Quality Performance

CMS will use quality of care measures in five areas: patient experience, care coordination, patient safety, preventive health, and at-risk population/frail elderly health. ACOs will be required to monitor and report claims, review financial and quality data, and evaluate quality care by conducting site visits, administering patient surveys, and performing quarterly and annual reports. ACOs will be held accountable for monitoring quality internally through a physician-directed committee. This committee will oversee a quality assurance and improvement program that monitors internal performance standards for quality of care and cost-effectiveness. The committee must hold the ACO providers accountable for meeting these standards and must have processes in place to identify and correct compliance issues.

Stark Law, Anti-kickback Statute, and Civil Monetary Penalties Statute

Since the SSP was first announced in 2010, providers have wondered how ACOs would comply with the Stark Law, Anti-kickback Statute, and Civil Monetary Penalties (CMP) prohibition on financial incentives to reduce care. All of these laws seemed to prohibit the very activities that ACOs were intended to encourage. To address this, CMS and the Office of Inspector General (OIG) proposed certain waivers of these laws:

- The Stark Law and Anti-kickback Statute will not apply to distributions of shared savings to or among qualified ACO participants, as well as to other parties for activities necessary for and directly related to the ACO's participation in the SSP.
- The CMP will not apply to ACO distributions from a hospital to a physician, provided that payments were not made knowingly to induce the physician to reduce or limit medically necessary services.
- The Anti-kickback Statute and CMP will also be waived for certain financial relationships that are necessary for and directly related to the ACO's participation in the SSP and fully comply with a Stark Law exception.

CMS and OIG made clear that these waivers would only apply to ACOs that have an agreement with CMS to participate in the SSP and only while ACO participants remain in compliance with the SSP's requirements. No guidance was given as to how the Stark Law and Anti-kickback Statute apply to payment for start-up costs in developing the ACO, and the waivers do not explicitly apply to such costs. However, the

agencies asked for comments about whether ACOs need broader waivers to participate in the SSP.

Application of Antitrust Laws and IRS Guidance

The Federal Trade Commission (FTC) and Department of Justice (DOJ) issued a Policy Statement to address how ACOs will be analyzed under the antitrust laws. The Statement explains when the agencies will apply rule-of-reason analysis to ACOs; creates a new "safety zone" for ACOs that hold shares of under 30% (as measured by specialty) and meet certain other conditions; creates a "rural exception" that allows rural ACOs to qualify for the safety zone even if their share exceeds the 30% figure; and establishes a 90-day timeframe for the FTC/DOJ to respond to advisory opinion requests. ACOs with shares in excess of 50% (that cannot meet the rural exception) cannot participate absent receipt of a letter approving the arrangement from FTC or DOJ.

Meanwhile, the IRS published a notice indicating that it intends to apply its traditional analysis as to tax-exempt organizations' participation in ACOs. The IRS asked for comments regarding whether existing guidance is sufficient for ACOs or whether it should publish specific guidelines.

Upcoming Gray Plant Mooty Roundtable

Gray Plant Mooty's Health Law group will be hosting "The New Accountable Care Organization Regulations: A Mystery Partially Revealed," a roundtable event to discuss the new ACO regulations on May 4, 2011. You are welcome to attend this free event. If you have any questions about the new regulations or the upcoming roundtable, please do not hesitate to contact Jesse Berg (612.632.3374 or jesse.berg@lathropgpm.com).