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Health Law Alert: CMS Issues Final Rule for Accountable Care Organizations

November 4, 2011

On November 2, the Centers for Medicare and Medicaid Services (CMS) published in the Federal Register final regulations (the Final Rule) implementing the Accountable Care Organizations (ACO) initiative under the Medicare Shared Savings Program (SSP). On balance, the Final Rule represents a marked improvement over proposed regulations issued this past April (the Proposed Rule). However, the initiative, which is slated to begin as early as April 2012, remains subject to a litany of hyper-technical reporting requirements and compliance obligations. With financial benefits from ACO participation unclear, providers will need to carefully evaluate the Final Rule to make decisions about whether involvement in the SSP is worthwhile. CMS has indicated that it will begin accepting applications as early as January 1, so providers will need to make up their minds quickly.

The Gray Plant Mooty Health Law team will be holding a roundtable breakfast on the Final Rule on Wednesday, November 30. Registration information for this free event can be found at the bottom of this Alert. The following summary is a brief overview of key elements of the Final Rule.

Eligibility, Participation, and Governance

A range of participants are eligible to form ACOs, including hospitals with employed physicians, group practices, and joint ventures involving certain providers. The ACO itself must be a legal entity (in any form authorized under state law) and is required to have a governing body with participants holding at least 75 percent control. CMS had initially proposed that ACO participants must have "proportionate" control; the Final Rule relaxes this standard, however, instead requiring that participants have "meaningful" participation on the governing body, a much more flexible standard. CMS retained the requirement from the Proposed Rule that a Medicare beneficiary (served by the ACO) be included on the governing board.

ACOs are required to have a CEO or other executive leader, the appointment and removal of which is controlled by the governing body. The ACO must have a compliance officer (separate from any ACO legal counsel) who reports to the governing body, along with a compliance plan and conflicts of interest policy. In an improvement over the Proposed Rule, CMS abandoned the requirement that the ACO be managed by a "full time senior level" physician leader, instead permitting clinical management to be provided on less than a full-time basis.

Beneficiary Alignment and Reporting Burdens

To participate in the SSP, ACOs will be required to file an application and range of supporting materials with CMS. Among other things, applicants must provide a description of the ACO's quality assurance and improvement program and documentation showing how the ACO will implement processes that promote evidence-based medicine and beneficiary engagement, and report on quality and cost-metrics and coordinate care.

If CMS grants an application to participate, the ACO will need to select one of two starting dates: April 1, 2012 (with an initial term of three years, nine months, and an initial performance year of 21 months), or July 1, 2012 (with an initial term of three years, six months, and an initial performance year of 18 months). In a departure from the Proposed Rule, ACOs are permitted to add new providers as ACO participants even after CMS approves participation, so long as the agency is notified in advance of these changes.

An ACO must have a minimum of 5,000 beneficiaries assigned to it during each reporting year. Beneficiaries will be assigned prospectively by CMS based on utilization of primary care services (defined based on HCPCS codes). This will occur through a two-step process:

- Beneficiaries who received at least one primary care service from a primary care physician (PCP) in an ACO will be assigned to that ACO so long as the allowed charges for primary care services furnished by ACO PCPs are greater than charges furnished by PCPs outside of the ACO.
- For beneficiaries who have not received any primary care services from a PCP, the beneficiary is assigned to the ACO only if they received at least one primary care service from an ACO physician (regardless of specialty) during the performance year and the allowed charges for primary care provided by all ACO professionals exceed allowed charges for primary care services by professionals outside the ACO.

CMS goes to great pains to stress that this "assignment" is only for purposes of measuring shared savings, and in no way restricts a beneficiary's choice about where to receive care.

The Final Rule greatly simplifies ACO reporting obligations, reducing the number of measures for which reporting to CMS is required from 65 to 33. ACOs will be required to report on a range of measures in four separate domains: patient/caregiver experience (7 measures); care coordination and patient safety (6 measures); preventive health (8 measures); and at-risk populations (12 measures). The SSP will initially require only a "pay-for-reporting" standard, but will shift gradually towards "pay-for-performance" (with 32 of the 33 measures requiring performance-based reporting by year three of the ACO's participation).

Payment of Shared Savings and Responsibility for Shared Losses

CMS retained its proposal for a "two track" approach to sharing savings, while implementing improvements designed to make participation more likely. Under the "one-sided" model, ACOs can elect to share in up to

50 percent of any savings (without being responsible for losses) during the initial term. Under the "two-sided" model, ACOs can agree to share savings and losses during the initial term (with the incentive of obtaining up to 60 percent of savings). All ACOs are required to use the "two-sided" model after their initial term. Any savings that an ACO earns are paid to the ACO itself, which is then responsible for distributions to participants. The manner in which this will occur is another item that the ACO must describe in its application with CMS to participate.

The Final Rule outlines a complex process by which benchmark costs—of beneficiaries' care under Medicare Parts A and B—are calculated, and against which the ACO's performance can be measured. To receive savings payments, the ACO's performance under either model must reach a minimum savings rate under the benchmark. In another improvement over the Proposed Rule, CMS will permit sharing in first dollar savings under either model and will not require a withhold of shared savings (as a means of ensuring the ACO can repay future losses). In addition, CMS raised the caps on available savings under both the one and two-sided models, so that potential recoveries are higher than under the Proposed Rule, while also capping the potential losses for which the ACO is responsible.

New Fraud and Abuse Waivers, Improved Antitrust Guidance

When the SSP was initially created, one of the first questions raised was how the ACO concept would comply with the laws regulating financial relationships among referral sources. In yet another effort to encourage participation, CMS and the HHS Office of Inspector General (OIG) expanded the waivers proposed earlier this year of the Stark Law, Anti-kickback Statute, and Civil Monetary Penalties (CMP) "gainsharing" prohibition.

CMS and OIG took a number of steps to make the waivers more useful. For example, they created a new waiver for ACO "pre-participation" intended to protect arrangements among referral sources leading up to ACO formation, such as infrastructure creation, capital investments and acquisition of technology. Parties using the "pre-participation" waiver will have to post certain information about how they are using it on an ACO Web site. There are also waivers for ACO "participation" (which seems to cover all aspects of arrangements among ACOs and its providers/suppliers) and for the distribution of shared savings to ACO participants. In addition, the agencies adopted a waiver under which arrangements that meet Stark Law exceptions will be deemed to comply with the Anti-kickback Statute and gainsharing CMP, and created a new waiver for limited "incentives" that can be provided by the ACO to beneficiaries. CMS remains concerned that beneficiaries receive accurate information about ACOs and not be misled, for instance, into thinking that they cannot receive care outside of the ACO. Thus, parties considering applying to the SSP will need to pay careful attention to the Final Rule's restrictions on marketing to beneficiaries.

Because ACOs at their core are collaborations among providers that might normally compete with one another, compliance with antitrust laws is essential. Guidance proposed this past April by the Department of Justice (DOJ) and Federal Trade Commission (FTC) on ACO development was quite proscriptive. For example, the agencies would have required mandatory antitrust review for ACOs with primary service area market shares of above 50 percent. Fortunately, DOJ/FTC abandoned this proposal and there is no longer a requirement that any ACO obtain advance blessing from the agencies.

Gray Plant Mooty ACO Roundtable

The Federal Register version of the Final Rule runs to about 190 pages and raises a host of additional issues including data sharing obligations, HIPAA compliance, guidance from the IRS on the participation of tax exempt organizations, and a number of program integrity requirements. The Gray Plant Mooty Health Law team will be holding a free roundtable breakfast on ACOs on Wednesday, November 30. Please look for an electronic invitation and overview of the event in the next few days. In the meantime, to register in advance, please email to events@lathropgpm.com or call 612.632.3170.

If you have any questions about the Final Rule, please contact Jesse Berg at jesse.berg@lathropgpm.com or 612.632.3374.

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