Armstrong Teasdale

Regulatory Update

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ACO REGULATORY SUMMARY

This is the first in a series of summaries prepared by Armstrong Teasdale attorneys analyzing the proposed rule for Accountable Care Organizations. Our Health Care practice group lawyers will focus on specific sections of the rule in the following weeks and throughout the 60-day comment period. The summaries will examine the potential impact on providers and patients and discuss participation requirements, the development of an ACO, fraud and abuse concerns, the economic impact of the Shared Savings Program, tax implications, quality of care issues, and data submission.

Introduction
On March 31, 2011, the Centers for Medicare & Medicaid Services ("CMS") released its proposed rule and guidance for Accountable Care Organizations ("ACOs"), including the implementation of the Shared Savings Program (the "ACO Proposed Rule"). In addition to CMS releasing the ACO Proposed Rule, the OIG and CMS jointly released a notice and request for comments relating to fraud and abuse waiver authorities; the DOJ and FTC issued joint guidance related to anti-trust issues; and the IRS released a notice and request for comments related to tax-exempt organizations. The ACO Proposed Rule will be published in the Federal Register on April 7, 2011 and comments will be accepted through June 6, 2011.
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Background
Section 3022 of the Patient Protection and Affordable Care Act ("PPACA") requires CMS to establish a shared savings program to facilitate coordination and cooperation among providers to improve the quality of care for Medicare fee-for-service beneficiaries and to reduce unnecessary costs (the "Shared Savings Program"). CMS intends for ACOs to be the vehicle for the Shared Savings Program by:

- Promoting accountability for the care of Medicare fee-for-service beneficiaries;
- Requiring coordinated care for all services provided under Medicare fee-for-service; and
- Encouraging investment in infrastructure and redesigned care processes.

Structure and Management
Under the ACO Proposed Rule, CMS defines an ACO as a recognized legal entity under state law compromised of a group of ACO participants (Medicare enrolled providers or suppliers) that have established a mechanism for shared governance and will work to coordinate care for Medicare fee-for-service beneficiaries. The following is a list of eligible ACO participants:

- ACO professionals (physicians and other professionals recognized under the Medicare program) 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; and
- Such other groups of providers of services and suppliers as the Secretary determines appropriate.

Pursuant to the ACO Proposed Rule, an eligible ACO must "have in place a leadership and management structure that includes clinical and administrative systems." CMS proposes that an ACO establish and maintain a governing body authorized to execute statutory functions, which may be in the form of a board of directors, a board of managers, or another decision-making body allowing for shared governance by the ACO participants. As currently drafted, for an ACO to be eligible for the Shared Savings Program, the ACO participants must control 75 percent of the ACO's governing body. Finally, management of the ACO must satisfy the following criteria:

- The ACO's 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 and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency processes and outcomes.
- Clinical management and oversight must be managed by a senior-level medical director who is a board-certified physician, licensed in the state in which the ACO operates, and physically present in that state.
- ACO participants and ACO providers/suppliers must have a meaningful commitment (e.g., financial or human capital) to the ACO's clinical integration program to ensure its likely success.
- The ACO must have a physician-directed quality assurance and process improvement committee that would oversee an ongoing quality assurance and improvement program.
- The ACO must develop and 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.
- The ACO must have an infrastructure, such as information technology, that enables the ACO to collect and evaluate data and provide feedback to the ACO providers/suppliers across the entire organization, including providing information to influence care at the point of care.

The ACO Proposed Rule requires that an ACO submit numerous documents/reports demonstrating its compliance with the above requirements and criteria. CMS remains open to innovative management styles, but will wait for comments before expressly permitting alternative structures and/or exceptions.

Participation Agreement
PPACA requires that an ACO "be willing to become accountable for the quality, cost, and overall care of Medicare fee-for-service beneficiaries assigned to it." Therefore, an ACO will be required to certify that its participants are willing to become accountable for, and to report to CMS on, such quality, cost and overall care. This certification would be included in the ACO's application and three-year participation agreement.

Per the proposed rule, ACO participation agreements would have a uniform start date, beginning on January 1 of the year following CMS approval, to minimize potential problems with beneficiary assignments and comparison of ACO savings. The deadlines for submission of ACO applications will be established by CMS. CMS acknowledged the difficulty with getting applications submitted and evaluated in time for the initial participation agreements to begin January 1, 2012, and is soliciting suggestions for alternative approaches for timing with the initial applications.

The participation agreement between an ACO and CMS would be executed by an executive of the ACO and, at a minimum, include the following:

- An acknowledgement that the ACO agrees to comply with all requirements of the Shared Savings Program;
- A notice provision requiring the ACO to provide 60-days prior written notice if the ACO desires to terminate its participation in the Shared Savings Program;
- A refund clause whereby if the ACO successfully completes its three-year participation agreement, CMS will refund any savings withheld during such period so long as this money is not needed to offset losses;
- A retention clause whereby CMS shall have the right to retain any withheld savings should the ACO not complete the three-year participation agreement; and
- An acknowledgement that all ACOs, ACO participants and ACO providers/suppliers with direct or indirect obligations under the Shared Savings Plan are subject to the requirements of the participation agreement.

Each ACO will be required to have a Taxpayer Identification Number ("TIN"), and as a result, Medicare will distribute any shared savings directly to the ACO. The participation agreement will not include distribution requirements; however, as part of the application process, CMS may require an ACO to disclose how its shared saving distributions would be allocated to foster the purposes of the program.

Medicare Beneficiaries
PPACA requires participating ACOs to "include primary care ACO professionals that are sufficient for the number of Medicare fee-for-service beneficiaries assigned to the ACO;" and at a minimum, "the ACO shall have at least 5,000 such beneficiaries assigned to it."

Under the ACO Proposed Rule, CMS proposes to assign beneficiaries on the basis of primary care services rendered by physicians with primary care specializations. This algorithm will be used to assign beneficiaries during the baseline years in order to establish a historical per capita cost benchmark against which the ACO would be evaluated during each year of the agreement period. An ACO would be considered to have a sufficient number of primary care ACO professionals to serve the number of Medicare beneficiaries assigned to it if the number of beneficiaries historically assigned over the three-year benchmarking period, using the ACO participants' TINs, exceeds the 5,000 threshold for each year.

If an ACO falls below 5,000 beneficiaries, CMS will issue a warning to the ACO and place it on a corrective plan. However, the ACO will remain eligible for shared savings for the performance year in which the warning was issued. Failure to obtain 5,000 beneficiaries by the end of the second performance year will result in the termination of the ACO's participation agreement.

Shared Savings Determination
Pursuant to PPACA, ACO participants will continue to receive payment "under the original Medicare fee-for-service program under Parts A and B in the same manner as they would otherwise be made." However, in addition, PPACA also provides for shared savings should an ACO achieve (i) the quality performance standards established by the Secretary and (ii) those savings against a benchmark of expected average per capita Medicare fee-for-service expenditures.

Under the ACO Proposed Rule, CMS will adopt a hybrid approach for awarding shared savings. This hybrid approach should benefit those organizations with less experience with risk models, while at the same time, allowing more experienced ACOs to enter into sharing arrangements that provide for greater reward for the their increased responsibility. Below is a brief description of the different tracks:

- Track 1: Shared savings are shared on an annual basis for the first two years using a one-sided shared savings approach. For the third year, the ACO must agree to share both the losses and savings.
- Track 2: Under this track, the ACO would enter into a risk-based model for the entire three-year period. This track provides for higher sharing rates.

Please be advised that both the ACO Proposed Rule and Health Care Reform remain in flux as the courts and political parties continue to weigh in. In addition to issuing summaries, Armstrong Teasdale is planning a half-day seminar on ACOs near the end of the 60-day comment period. We will forward details once they become available. If you have questions or are interested in submitting a comment on the ACO Proposed Rule, please contact one of the Health Care attorneys at Armstrong Teasdale LLP listed below:

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