The ACO-Man Cometh

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On March 31, 2011, the federal government released the long-awaited details on how it proposes to implement the only substantial cost–containment provision contained within last year's massive federal health care reform law. Proposed regulations were issued to implement the Accountable Care Organization ("ACO") component of the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act (collectively referred to as the "Affordable Care Act"). Perhaps second only to the constitutional challenge mounted against certain aspects of the Affordable Care Act, discussion and supposition about ACOs have consumed the health care provider community since the reform initiative was passed just over a year ago. While the Affordable Care Act was widely criticized as containing nothing to stem the tide of rising health care costs, proponents of the law pointed to the development of ACOs as providing the groundwork to address the serious underlying issue of uncontrolled costs.
The Centers for Medicare and Medicaid Services (CMS) issued a pre-release draft of the proposed regulations following a full year of meetings, discussion sessions, letters and public lobbying efforts. Perhaps just as importantly, the Federal Trade Commission (FTC), Department of Justice (DOJ), Internal Revenue Service (IRS) and Office of the Inspector General (OIG) for the federal Department of Health and Human Services (HHS) added to the fanfare by issuing related notices, describing how their agencies would address compliance issues with regard to the operation of ACOs. All of these governmental pronouncements and proposed regulations solicit comments and one can expect that the health care trade press will be full of reports as those comments roll in.

CMS released over 400 pages of discussion and proposed regulatory language, far too massive for detailed coverage in an article of this length. However, there are general touchstones which providers may wish to consider as they attempt to wade through the onslaught of excruciating detail and technical analysis that is forthcoming.

ACOs may be thought of as the vehicles through which health care providers can participate in the Medicare Shared Savings Program that was part of the Affordable Care Act. The purpose of the Shared Savings Program is to promote, "accountability for patient populations … [coordinate] items and services under Parts A and B [of the Medicare program] and [encourage] investment in infrastructure and redesigned care processes for high quality and efficient service delivery". In other words, the Shared Savings program provides financial incentives to coordinated groups of health care providers (hospitals, physicians and other kinds of health care services professionals and suppliers), to provide high quality, cost effective care, by permitting them to share in the overall savings that result from coordinated delivery systems. However, in order to assure that savings to the Medicare program are not simply the result of ACOs denying necessary care and/or selecting only the healthiest of Medicare patients, the proposed regulations impose significant quality analysis and reporting obligations on ACOs and establish strenuous governmental oversight, with the ability to impose significant penalties if patient "cherry-picking" behavior occurs.

The proposed regulations permit ACOs to be any combination of health care providers, so long as they include a sufficient number of primary care "ACO professionals" (presumably physicians and mid-levels) to serve the population of Medicare enrollees who are assigned to the ACO. Each ACO will be required to serve at least 5,000 Medicare enrollees in order to be eligible for

shared savings payments. In order to successfully apply for participation in the Shared Savings Program, an ACO must:

* become accountable for quality, cost and overall care of all Medicare enrollees who are assigned to it;
* enter into a three-year agreement with HHS;
* have a formal legal structure that allows it to receive and distribute shared savings payments to its participating providers;
* provide the Secretary with all the information he/she deems necessary to support the assignment of Medicare enrollees to the ACO, the implementation of quality and other reporting requirements and the calculation of shared savings payments;
* have a leadership and management structure that includes clinical and administrative systems;
* have processes to promote evidence-based medicine, report on quality and cost measures and coordinate care through the use of telehealth, e-remote monitoring and other enabling technologies; and
* demonstrate that it meets "patient-centeredness" criteria, through such evaluators as patient and caregiver assessments and individualized care plans.

Once accepted into the program, ACOs are eligible for shared savings payments if they (i) meet the quality and performance standards set by the Secretary, and (ii) realize a requisite amount of savings. Savings are measured by the difference between the estimated average per capita Medicare expenditures for the Medicare enrollees assigned to the ACO and a benchmark of savings to be determined by the Secretary. If the ACO performs such that its estimated average expenditures fall a requisite percentage below the benchmark, it will be paid a percentage of the savings between the estimate and the benchmark. In addition, the ACO may select between two tracks, one which offers a higher potential return. If the ACO agrees to shoulder the downside financial risk (i.e. agrees to repay the Medicare program for costs which exceed the estimate), it can receive a higher percentage of the savings. Alternatively, an ACO may, for its first two years, insulate itself from the downside risk and be eligible for a smaller percentage of the savings (if any) than under the "full-risk" option.

In addition to the HHS-issued regulations, the Federal Trade Commission and the Department of Justice issued a joint notice on how they will analyze proposed ACOs for compliance with federal antitrust laws. Many critics over the last year noted that ACO arrangements would be highly constrained — some might even say impossible — without major accommodations under antitrust laws. In the joint notice, the FTC and DOJ said that while they are still cognizant of potential anti-competitive behavior that could injure consumers by reason of providers who are otherwise competitors participating in the same ACO, they have proposed not only an expedited program to review compliance by ACOs with antitrust laws, but also "antitrust safety zones" that would insulate ACOs meeting certain criteria from further review, absent extraordinary circumstances. Generally, so long as an ACO (1) meets the criteria for participation set by HHS, (2) has a low enough combined market share in separate service lines and (3) does not require any hospital participant to be "exclusive" to the ACO, they will not challenge the arrangement. The expedited review process will be available to ACOs with participants that are

"dominant providers" (i.e. have a 50% or higher market share in a service line) or where the combined market shares of the participants exceed the threshold.

Similarly, the OIG gave notice that within the context of an approved ACO, it will consider requests for waivers of its enforcement authority with respect to ACO activities that might otherwise cause concern under the physician self-referral or Stark laws, the federal anti-kickback statutes and prohibitions on payments to induce the limitation or reduction of services provided to Medicare patients.

Finally the IRS issued guidance on how it will view and analyze the participation of tax-exempt entities in ACOs and how to structure such participation so that it does not give rise to tax-exemption compliance issues or unrelated business income tax. While still a bit restrictive, this guidance clearly addresses another significant hurdle that would otherwise stand in the way of certain ACOs.

The regulations and notices issued on March 31 are still only proposals. They are subject to further review and revision. Moreover, as with so much in the health care regulatory world, the devil is in the detail. It appears, however, at least on the surface, that the federal government, in an uncharacteristic show of cooperation and coordination between agencies, is attempting to present a coordinated approach to realistically implementing ACOs and establish an avenue to begin to address health care cost control.

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