

HEALTH REFORM **IMPACT**

What you need to know NOW

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

ACOs Part I: Assembly Instructions

April 15, 2011

Section 3022 of the Patient Protection and Affordable Care Act (“PPACA”) spans a mere five pages, yet this brief provision has generated tremendous anticipation and speculation within the healthcare industry ever since PPACA’s passage in March 2010. Section 3022 mandates the creation of the Medicare “Shared Savings Program,” which allows qualified groups of providers and suppliers to earn a share of the savings generated for the Medicare program as a result of coordinating and managing care for Medicare fee-for-service beneficiaries through collaborative organizations called Accountable Care Organizations (“ACOs”).¹

Now, after a year of numerous open door forums, “unprecedented” interagency coordination,² ongoing solicitations for public comments, and escalating industry buzz, the proposed ACO regulations are finally here. On March 31, 2011, the Centers for Medicare & Medicaid Services (“CMS”) released the proposed rule and commentary (the “Proposed Rule”)³ with a stated goal of achieving better care for individuals, achieving better health for populations, and lowering cost without limiting access to necessary care. While the Proposed Rule builds on the statutory requirements of Section 3022 of PPACA, many details of the Proposed Rule have surprised the healthcare industry. This issue of *Health Reform IMPACT* will be the first in a series dedicated to analyzing and explaining the Proposed Rule and the related guidance.⁴

Structure and Governance

Under the Proposed Rule, an ACO is a legal entity (e.g., corporation, partnership, LLC) “that is recognized and authorized under applicable State law,⁵ as identified by a Taxpayer Identification Number (TIN), and comprised of an eligible group . . . of ACO participants.” Under Section 3022, eligible ACO participants include: (1) ACO professionals (defined as doctors of medicine or osteopathy, physician assistants, nurse

¹ For additional information regarding Section 3022 of the Patient Protection and Affordable Care Act, please [click here](#).

² In a March 31, 2011, press release, FTC Chairman Jon Leibowitz stated that “[t]he Administration has led an unprecedented, collaborative effort among all of the agencies responsible for developing guidance for ACOs.” Press Release available at <http://www.ftc.gov/opa/2011/03/aco.shtm> (last visited Apr. 11, 2011).

³ 76 F.R. 19528 et. seq (Apr. 7, 2011).

⁴ Four documents were released on March 31, 2011: (1) CMS Proposed Rule for the Medicare Shared Savings Program; (2) Joint CMS and OIG Proposed Rule on waiver designs addressing proposed waivers of the Civil Monetary Penalties (“CMP”) law, Federal Anti-Kickback Statute, and the Physician Self-Referral law; (3) Internal Revenue Service (“IRS”) notice soliciting comments regarding the need for additional tax guidance for tax-exempt organizations, including tax-exempt hospitals participating in the Medicare Shared Savings Program; and (4) Proposed Antitrust Policy Statement issued by the Federal Trade Commission (“FTC”) and the Department of Justice (“DOJ”).

⁵ The Proposed Rule would require each ACO to certify that it is recognized as a legal entity under State law and authorized by the State to conduct its business. 76 F.R. at 19540.

practitioners, and clinical nurse specialists) in group practice arrangements; (2) networks of individual practices of ACO professionals; (3) partnerships or joint venture arrangements between hospitals and ACO professionals; (4) hospitals employing ACO professionals; and (5) other groups of providers and suppliers as the Secretary of Health and Human Services (the "Secretary") deems appropriate. While each ACO participant must be enrolled in the Medicare program in order for the ACO to participate in the Shared Savings Program, the ACO itself is not required to be enrolled in Medicare.

Despite having Secretarial discretion to expand the statutory list of eligible ACO participants, CMS in the Proposed Rule adds only one provider type to the list -- critical access hospitals ("CAHs") billing under "Method II."⁶ However, even though the list of eligible ACO participants is relatively narrow, all eligible ACO participants are permitted to establish an ACO with "broader collaborations" by including additional Medicare entities such as Federally Qualified Health Centers ("FQHCs"), Rural Health Clinics ("RHCs"), and "other Medicare-enrolled providers and suppliers as defined in the [Social Security] Act" (a phrase that presumably encompasses *all* other types of Medicare-enrolled providers and suppliers). These other types of Medicare providers and suppliers cannot independently form an ACO, but they can apparently participate in an ACO that is formed by one of the statutorily identified groups (as well as CAHs billing under Method II). Note that an ACO must have a "sufficient number" of primary care physicians and beneficiaries, a requirement that CMS will deem to have been met if the number of beneficiaries assigned to the ACO participants using the assignment methodology is 5,000 or more.

Prior to acceptance into the Shared Savings Program, each ACO must submit a lengthy and detailed application with supporting documentation to CMS. The governance, leadership, and management participation requirements are numerous and are potentially onerous from a business perspective. For example, in order to ensure that ACOs remain "provider driven," rather than being controlled by "entrepreneurial management companies and health plans," ACO participants in the aggregate must control at least 75 percent of the ACO's governing body, with each such ACO participant having "appropriate proportional control," a term that is undefined. Additionally, under the Proposed Rule, the governing body must include Medicare beneficiaries serviced by the ACO.⁷ These provisions may be viewed by would-be ACOs as an impediment to procuring the management talent that will be critical to navigating the risk that, as will be discussed next, ACOs will be required to assume under the Proposed Rule.

Mandatory Risk-Sharing

If accepted into the Shared Savings Program, the ACO must agree to participate for three years, and the applicable ACO executive must certify that the ACO participants are willing to become accountable for, and report on the quality, cost and overall care of, the Medicare fee-for-service beneficiaries "assigned" to the ACO. Perhaps most surprisingly, and as a new requirement not appearing in PPACA, the Proposed Rule requires that any participating ACO accepted into the Shared Savings Program share in the downside risk, i.e., be liable to pay back a share of losses sustained by the Medicare program on a beneficiary's course of care, in addition to being eligible to share in the upside, i.e., the savings sustained

⁶ Under Method II, a CAH submits bills for both the facility and the professional services to its Medicare fiscal intermediary or its Medicare Part A/B MAC. If a CAH chooses this method for outpatient services, the physician or other practitioner must reassign his or her right to bill the Medicare program for those services to the CAH. Under Method II, the CAH receives – (1) 101 percent of the reasonable cost payment for its facility costs; and (2) 115 percent of the amount otherwise paid under the MPFS for professional services under Medicare. 76 F.R. 19539 (Apr. 12, 2011).

⁷ The ACO may also, but is not required to, include "community stakeholders" on the board, although even if the ACO does not include "community stakeholders" on the board, it must still "partner with" at least one community stakeholder. The term "community stakeholders" is not defined. The partnership between the ACO and community stakeholders must advance the three-part aim of better care for individuals, better health for populations, and lower growth in expenditures. 76 F.R. 19642, 19601 (Apr. 7, 2011).

by the Medicare program. Furthermore, ACOs must reach a certain threshold of savings before they can share in the upside.⁸

As the vehicle for assuming risk, a participating ACO must choose between two “Tracks.” Under “Track 1,” or the “One-Sided” approach, a participating ACO will share in the savings for all three years, but will be required to assume risk for losses only in the third year under the ACO Agreement. Under “Track 2,” or the “Two-Sided” approach, a participating ACO will share in the savings for all three years and will also be required to assume risk for losses for all three years under the ACO Agreement. ACO participants choosing Track 2 will be eligible for a higher percentage of savings than the ACO participants choosing the more conservative one-sided approach.

Potential Drawbacks

Providers considering ACOs should be aware of several potential drawbacks in the Proposed Rule in addition to the mandatory risk-sharing feature discussed above:

- Notably, to facilitate ACOs repayment of losses and encourage ACOs to participate for the full three-year term, CMS will withhold 25 percent of an ACO's annual savings until the end of the agreement. If the agreement is terminated for any reason prior to the end of the three-year term, the ACO will forfeit the full amount of the 25 percent withholding.
- For an ACO to remain part of the Shared Savings Program during the second year, at least 50 percent of the ACO's primary care physicians must be “meaningful users” of certified electronic health record technology.⁹
- Another potential issue for ACO participants is the process of beneficiary assignment to ACOs or, as CMS calls it, “alignment.” CMS proposes to assign beneficiaries to an ACO retrospectively, i.e., at the end of the year based on where they received the most primary care. While CMS cites certain benefits to retrospective assignment, many would-be ACOs may wonder how they will accurately create budgets and quality improvement strategies at the beginning of a year for an unknown population. In addition, CMS places a high priority on freedom of choice for Medicare fee-for-service beneficiaries. Patients are free to seek care from any provider, even one outside the ACO (yet the ACO will still be responsible for that patient if he or she is “assigned” to the ACO at the end of the year). Each beneficiary is also free to opt out of data sharing under the ACO, which could further impede an ACO's ability on the front end to manage risks of a patient population. All of the foregoing could potentially lead to higher start-up costs for ACOs.

Looking Forward

Throughout the materials, CMS makes it abundantly clear that the Proposed Rule is just that . . . proposed. Comments on the Proposed Rule are due June 6, 2011. Meanwhile, CMS continues to hold open door forums to discuss the Proposed Rule.

Under Section 3022 of PPACA, the Shared Savings Program must be established by January 1, 2012, which is a very short time frame given that the final version of the Proposed Rule likely will not be released until late summer or early fall. Meanwhile, providers who still have many questions about the efficacy of an ACO may feel compelled to go ahead and “just build it” so as not to fall behind the curve, or alternatively, may be compelled to “wait and see.”

As mentioned earlier, this alert is the first in a series dedicated to ACOs. Future issues of *Health Reform IMPACT* will discuss the antitrust, quality, fraud and abuse and data sharing issues contained in the

⁸ This threshold savings rate is lower for ACOs with higher numbers of beneficiaries than it is for ACOs with relatively small numbers of beneficiaries.

⁹ The “meaningful use” regulations adopted pursuant to the HITECH Act appear at 75 F.R. 44314 et. seq. (July 28, 2010).

Proposed Rule. If you have questions, please contact any of the attorneys in our Healthcare Practice Group listed below.

Also, please [click here](#) to visit our special webpage on Health Reform IMPACT.

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