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HEALTH REFORM IMPACT
Alert

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The Mythical Creature Takes Shape: CMS Issues Final Accountable Care Organization Rule

Ever since they were created by the Patient Protection and Affordable Care Act,[1] Accountable Care Organizations ("ACOs") have seemed to many in the healthcare industry like a unicorn – a mythical creature that is often depicted in fantasy, but that no one has ever actually seen. On October 20, 2011, the industry got perhaps its first real glimpse of ACOs as the Centers for Medicare & Medicaid Services ("CMS") released the final rule ("Final Rule") establishing ACOs under the Medicare Shared Savings Program ("MSSP").

As discussed in previous issues of *Health Reform IMPACT*, [2] the MSSP proposed rule was the subject of much debate and criticism in the healthcare industry. Perhaps in response to provider wariness, including the 1,300 comments received in response to the proposed rule, CMS has made a number of important changes in its Final Rule. Providers interested in establishing an ACO under the MSSP should submit an ACO Notice of Intent to Apply Memo ("NOI") by January 6, 2012.[3] Likewise, applications to participate in the first round of the MSSP are due on or before January 20, 2012.[4]

Organization Overview

ACO Structure. Providers interested in participating as an ACO under the MSSP must apply as: (1) a new MSSP ACO, (2) a re-applicant,[5] or (3) a Physician Group Practice ("PGP") Transition Demo.[6] Similar to the proposed rule, the Final Rule lists the following groups as eligible to participate as an ACO entity: (1) ACO professionals[7] in a group practice arrangement, (2) networks of individual practices of ACO professionals, (3) partnerships or joint venture arrangements between hospitals and ACO professionals, (4) hospitals employing ACO professionals, (5) Critical Access Hospitals ("CAH") billing under Method II, (6) Rural Health Clinics ("RHC"), and (7) Federally Qualified Health Centers ("FQHC").

Also like the proposed rule, ACOs must choose whether to participate under Track 1 (one-sided model: shared savings) or Track 2 (two-sided model: shared savings/losses) of the MSSP. However, in response to "the most commonly made recommendation," the Final Rule allows ACOs enrolling in a "one-sided" model to avoid the mandatory risk-sharing that would have occurred in year three under the proposed rule. Thus, ACOs participating under Track 1 can remain in the program for all three years of the contract term without sharing in the risk of loss if the ACO does not

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[1] Pub. L. 111-148, Section 3022 of the Health Reform Legislation.
[2] Read past *Health Reform IMPACT* alerts on our website.
[3] To participate as an ACO in the MSSP with a start date of April 1, 2012, the NOI is due no later than January 6, 2012. To participate as an ACO in the MSSP with a start date of July 1, 2012, the NOI must be submitted no later than February 17, 2012.
[4] Applications must be submitted by 5:00 pm EST January 20, 2012, for the April 1, 2012 start date, and by 5:00 pm EST March 30, 2012 for the July 1, 2012 start date.
[5] ACOs that are terminated from the program will be afforded the opportunity to re-apply to participate in the shared savings again only after the date on which the term of the original participation agreement would have expired if the ACO had not been terminated. 42 C.F.R. § 425.222(a).
[6] PGP Transition Demonstration Participants have the opportunity to complete a condensed application.
[7] Like the proposed rule, the Final Rule, defines "ACO professional" as an ACO provider/supplier who is either of the following: (1) a physician legally authorized to practice medicine and surgery by the State in which he performs such function or action, or (2) a practitioner who is one of the following: (i) a physician assistant, (ii) a nurse practitioner, (iii) a clinical nurse specialist. 42 C.F.R. § 425.20.

produce adequate savings.[8] Nevertheless, ACOs may still elect to participate in Track 2 – a two-sided risk model whereby the ACO will share in potential losses in order to receive a greater proportion of savings. If an ACO selects Track 2, it must select a repayment mechanism it will use to repay any money owed to CMS (e.g., reinsurance, funds placed in escrow, surety bonds, line of credit).

In addition, the Organization Overview section of the application requires the applicant to provide the legal entity name, entity type, d/b/a name, date of formation, mailing address and ACO Taxpayer Identification Number ("TIN") for the ACO.[9] The TIN must be established for the ACO as a legal entity. The shared savings payments will be made to the TIN provided on the application, and beneficiary assignment is dependent upon the TIN being exclusive to one MSSP ACO.[10]

Finally, the ACO applicant must disclose whether it has signed or jointly negotiated any contracts with private payer(s), on or before March 23, 2010.[11] If the applicant has not, CMS will share the application with the Antitrust Agencies, including the Federal Trade Commission ("FTC") and the Department of Justice ("DOJ"). In fact, by submitting the application, the applicant ACO agrees to permit CMS to share a copy of its application, including all information and documents submitted with the application, with the FTC and DOJ.

Organization Contacts. The Application also must designate: (1) the ACO Executive, (2) the CMS Liaison, (3) the Application Contact, and (4) the IT Contact. The ACO Executive has the authority to bind the ACO and must certify that its participants are willing to become accountable for, and to report to CMS on, the quality, cost, and overall care of the Medicare Fee-for-Service beneficiaries assigned to the ACO.

Legal Requirements

Each ACO applicant must confirm that it is a recognized legal entity formed under applicable State, Federal or Tribal law and is authorized to conduct business in each State in which it operates. Additionally, although not required to submit the documents along with the application, an applicant ACO must indicate that it has available all documents effectuating the formation and operation of the ACO (i.e., charters, by-laws, articles of information, financial statements and records, resumes and other documentation required for leaders of the ACO).

Governance/Leadership

Each ACO applicant must submit a leadership and organizational chart for the ACO, a list of committee members and job descriptions for the ACO's senior administrative and clinical leaders. In contrast to the proposed rule, the Final Rule allows ACOs greater flexibility and innovation in the organization and governance requirements. For example, there is no longer a "bright-line" requirement that at least 75 percent of the governing body consist of ACO participants; instead, the ACO applicant has the opportunity to describe how the ACO will involve ACO participants in ACO governance in an innovative way if the governing body will not be controlled by at least 75 percent of ACO participants. Likewise, there is

[8] 76 Fed. Reg. 67802, 67906 (Nov. 2, 2011).
[9] The ACO must be a legal entity formed under applicable State, Federal, or Tribal law and authorized to conduct business in each State in which it operates for purposes of the following: (1) receiving and distributing shared savings, (2) repaying shared losses or other monies owed to CMS, (3) establishing, reporting, and ensuring compliance with healthcare quality criteria, including quality performance standards, (4) fulfilling other ACO functions identified by this part. 42 C.F.R. § 425.104(a)(1)-(4).
[10] 42 C.F.R. § 425.306(a)-(b).
[11] Specifically, the application asks: "Has the ACO signed or jointly negotiated any contracts with private payor(s) or does the ACO comprise only the same; or a subset of the same providers that signed or jointly negotiated any contracts with a private payor(s), on or before March 23, 2010?"

no longer a “bright-line” requirement that the governing body include Medicare beneficiaries; instead, the application gives ACO applicants an opportunity to describe how the ACO will ensure meaningful participation in the ACO governance by Medicare beneficiaries if the governing body proposes not to include one or more Medicare beneficiaries.

From a leadership standpoint, each ACO must demonstrate how it intends to manage the operations of the ACO and how its leadership and management structure will accomplish the ACO’s mission. The ACO must also indicate how the ACO’s clinical management and oversight structure will accomplish the ACO’s mission. Finally, each ACO must have a compliance plan that includes, at a minimum, the following five elements: (1) a designated compliance official or individual who is not legal counsel to the ACO and reports directly to the ACO’s governing body; (2) mechanisms for identifying and addressing compliance problems related to the ACO’s operations and performance; (3) a method for employees or contractors of the ACO, ACO participants, ACO providers/suppliers or other entities performing functions or services related to ACO activities to anonymously report suspected problems to the compliance officer; (4) compliance training for the ACO, ACO participants and ACO providers/suppliers; and (5) a requirement for the ACO to report probable violations of the law to an appropriate law enforcement agency.

Participation in Other Medicare Initiatives Involving Shared Savings

As required by the implementing statute, the Final Rule requires ACO applicants to certify that neither the ACO nor any of the ACO participants are participating or will participate in another Medicare initiative involving shared savings during the term of the ACO Agreement.

Financial

The MSSP application requires the ACO applicant to describe in a narrative how the ACO plans to use the shared savings payments, including whether the shared savings will be shared with ACO participants, providers and suppliers or will be re-invested in the ACO’s infrastructure. Further, the ACO applicant must include the percentage of savings that it intends to distribute to each category, and how such criteria are determined.

Provider Information

Notably, ACO participants are not required to submit copies of executed agreements between the ACO and the ACO participants and the other entities furnishing services related to ACO activities. However, the ACO applicant must submit sample participation agreements which include a number of details regarding the participation agreements.

Data Sharing, Required Clinical Processes and Patient Centeredness

One of the biggest differences between the proposed and Final Rule is the fact that the Final Rule changed the beneficiary assignment process from retrospective to prospective. In other words, under the Final Rule, the ACO will generally know what beneficiaries are included in its ACO from the outset. In addition, the number of quality measures that providers are required to report was reduced from 65 measures in five domains to 33 measures in four domains.

If the ACO intends to (1) request from CMS the name, DOB, gender and Health Insurance Claim Number of beneficiaries used to generate the ACO’s benchmark, or (2) request from CMS beneficiary-identifiable Part

A, B and/or D claims data, the ACO must certify that it is requesting this information as a HIPAA-covered entity or as a business associate of a HIPAA covered entity. In addition, the ACO must describe how it will ensure the privacy and security of data and how the data will be used.

Likewise, an ACO applicant should indicate that it has qualified healthcare professionals who are responsible for the ACO's quality assurance and improvements program. Such a program must: (1) promote evidence-based medicine; (2) propose beneficiary engagement; (3) report internally on quality and cost metrics; and (4) coordinate care.

Although the Final Regulations address many of the major concerns voiced by the healthcare industry, the detail and the volume of information requested by CMS, as well as the not inconsiderable capital and infrastructure requirements, could still be viewed as a barrier to providers interested in becoming an ACO during the first two MSSP application periods. Stay tuned for future *Health Reform IMPACT* alerts discussing the requirements and implications of the MSSP.

If you have any questions about this issue of *Health Reform IMPACT*, please contact any of the attorneys in our Healthcare Practice Group listed below.

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