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Legal Review

Cms Releases Long Awaited Proposed Regulations On Accountable Care Organizations

On March 31, 2011, the Department of Health and Human Services (“HHS”) released the long awaited proposed regulations on Accountable Care Organizations (“ACOs”). The regulations provide details on the Center for Medicare and Medicaid Services (“CMS”) insight on, as dictated by the Patient Protection Affordable Care Act’s (“PPACA”), ACOs in general including: ACO structure, eligibility, IT requirements, antitrust issues (which can be found at www.ftc.gov/opp/aco/), marketing, tax implications (which can be found at <http://www.irs.gov/pub/irs-drop/n-11-20.pdf>), waivers relating to Stark law and Anti-Kickback (“AKS”), and finally a tree-top overview of how ACOs relate to the Medicare Shared Savings Program (“Program”). This article will focus simply on a broad overview of the proposed regulations. For more details, readers can locate the proposed regulations at <http://www.cms.gov/sharedsavingsprogram>.

A review of the proposed regulations details the structure required for approval of an ACO by CMS. To be eligible as an ACO and participate in the Program, an ACO must meet a basic physician and minimum patient population requirement, certain financial rewards and possible loss responsibilities that ACOs must undertake, as well as dozens of patient care protocols and standards that each ACO must adopt. Each ACO, after it is organized, must apply to CMS for approval prior to participating in the Program.

According to CMS/DHH, one of the most basic requirements for ACO structure calls for at least five thousand (5,000) primary care patients of ACO primary care physicians (PCPs). To clarify whether a patient can be counted as part of the ACO, CMS defined stated that a patient under the care of a specialist who is not “signed on” with one of the ACO’s PCPs will not be included as an ACO patient to meet the minimum 5,000 patient requirement for qualification. If at the end

of a calendar year the ACO does not have enough patients to meet the 5,000 minimum, the regulations provide for a one year grace period to allow the ACO to increase its patient base to attain the 5,000 minimum threshold. However, if at the end of the grace period year, the ACO’s population has not reached at least 5,000, CMS will terminate the agreement and the ACO will be prohibited from participating in the Program.

According to the proposed regulations, 5,000 patients is the minimum threshold in order to be approved in the Program; however, a review of the minimum savings rate provided in the regulations establishes that ACOs should desire to increase their number of patients because the minimum savings rate that an ACO must achieve in order to receive payments under the program trends lower as an ACO increases the number of patients.

It appears possible that an ACO can consist solely of primary care physicians having at least 5,000 patients admitted to the ACO program. The ACO’s financial reward calculation and eligibility for payment of shared savings will be based on what Medicare pays for all care given to these primary care ACO patients, as Medicare fee-for-service (“FFS”) beneficiaries, for Parts A and B services, and whether or not these expenditures fall below a specified benchmark established by the Secretary of Health and Human Services (“Secretary”).

Patients will have the option to not participate in an ACO. The proposed regulations state that each patient will have to be informed of his or her participation in the ACO, and will have the right to “opt out” of claims data sharing. The regulations request that the PCPs provide each patient with a form to “opt out,” after being informed of their physician’s participation in an ACO, from having their personal data shared.

In addition to patient minimum eligibility requirements, the proposed regulations

provide guidance on legal entity formation for ACOs. Specifically, the regulations state that an ACO should be a separately formed legal entity, which can be a limited liability company, a professional corporation, foundation or other entity permitted by Louisiana law. This separate legal entity will have a separate taxpayer identification number (“TIN”) that will be linked to CMS records with the identification numbers of all ACO participants. The regulations further provide that an ACO organization will have to have bylaws or equivalent documentation to show appropriate ownership and governance. Lastly, ACOs will be required to have sufficient leadership and clinical/administrative systems in place and meet the criteria outlined by CMS.

To assist in determining who can form ACOs, CMS provided a list of the following ACO participants are eligible, separately or in combination, to form ACOs:

1. ACO professionals, including physicians and nurse practitioners, 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.
5. Providers or suppliers as defined under § 425.4 – found in 42 C.F.R. 400.202.
6. Critical Access Hospitals (“CAH”) as described in §42 C.F.R. 413.70(b)(3).

CMS further issued regulations dictating control requirements for participation in the Program. According to the regulations, at least 75 percent (75%) of control of an ACO’s governing body must be held by ACO participants. ACO participants are described in the six categories outlined above. Further, the regulations provide that at least one Medicare ACO system patient must also sit on the governing board. Of note, the regulations did

not address ownership limitations, as such, one could assume that any combination of ownership will be acceptable if appropriately registered and legal in Louisiana.

By way of example, hospitals and specialist groups may fund ACOs in exchange for rights of participation and percentages of profits. PCPs may be given ownership and rights to a percentage of profit in exchange for being willing and able to participate in the ACO as well as bringing significant portions of their patient bases into the ACO. Profits may be allocated amongst PCPs and specialists in recognition of how their ACO patient expenses compare to those of others in the ACO.

As evidence of its commitment to the success of the Program, CMS has united in an unprecedented inter-agency collaboration with Office of Inspector General (“OIG”), the Federal Trade Commission (“FTC”), the Department of Justice (“DOJ”) and the IRS to propose additional rules toward addressing issues related to the Program.

Make no mistake, the proposed rules on the Program are very detailed and provide an insight on the future of the delivery of care to Medicare beneficiaries. Interested ACO participants who wish to form an ACO should read and familiarize themselves with the proposed regulations which can be found at the links provided above. Whether couched as an ACO or other shared savings system, CMS has showed the healthcare sector that the Medicare Shared Savings Program is here to stay.



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