

## *CMS Provides Additional Guidance for Medicare Shared Savings Program Accountable Care Organization Applicants*

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On March 16, 2012, the Centers for Medicare and Medicaid Services (“CMS”) released additional guidance (the “CMS Memo”) regarding the formation of accountable care organizations (“ACOs”) and participation in the Medicare Shared Savings Program (the “Program”). Based on questions and comments received by CMS after release of the ACO final rule which was published in the November 2, 2011 Federal Register (the “Final Rule”), the CMS Memo seeks to clarify aspects of the Final Rule for ACO applicants. The CMS Memo provides valuable information not only for potential ACO applicants, but also for those who have already applied and may have to modify previously submitted applications.

### **ACOs and The Program: The Basics**

Born out of the Patient Protection and Affordable Care Act of 2010 (commonly referred to as the Healthcare Reform Law), ACOs are intended to bring together Medicare-enrolled providers and/or suppliers to work together to manage and coordinate care for Medicare beneficiaries. In doing so, ACOs are meant to serve as a mechanism to provide better health and better care to individuals at lower costs. Participation in the Program will incentivize ACOs to reduce costs and increase quality of care by allowing ACOs to share in generated savings (and in some instances, losses as well) if certain quality standards are satisfied.

### **The CMS Memo**

In response to questions and comments which conveyed uncertainty with respect to how aspects of the Final Rule should be interpreted, CMS released the CMS Memo on March 16, 2012. The CMS Memo seeks to clarify several pieces of the Final Rule, including the following:

1. Definitions of ACO Participant and ACO Provider/Supplier. In an effort to quash the confusion surrounding these terms, the CMS Memo provides very specific definitions for each and also provides some useful examples. An ACO participant is an individual or group of ACO providers/suppliers, identified by a Medicare-enrolled taxpayer identification number (“TIN”), which alone or together with other ACO participants comprises an ACO. As an example, the CMS Memo points out that an ACO participant can be, among other things, a solo practice, a group practice, a hospital, or a federally qualified health center. An ACO provider/supplier, on

the other hand, is a provider or supplier enrolled in Medicare that bills Medicare under a number assigned to the TIN of an ACO participant.

2. All ACO Participants and ACO Providers/Suppliers Must Agree to Participate. By virtue of their relationship to an ACO, all ACO participants are included in an ACO and, likewise, by virtue of their relationship to an ACO participant, all ACO providers/suppliers are included in an ACO. This means, in order for an ACO to participate in the Program, each ACO participant, and each ACO provider/supplier billing through an ACO participant, must agree to participate in the Program and to comply with the Program requirements. Consequently, if any providers/suppliers billing under the TIN of an ACO participant refuse to participate in the Program, the ACO participant is also prohibited from participating. This feature may limit the ability and/or willingness of certain entities to participate in the Program. For example, if a California medical foundation clinic wants to act as an ACO participant, all physicians billing for services under the foundation's TIN would arguably be required to participate in the ACO as well.
3. Agreements Related to Participation in the Program. As part of the application process, CMS requires an applicant to submit a list of ACO participants that have agreed to participate in the Program. The CMS Memo clarifies that this means all of the ACO participants must have signed the agreement(s) amongst the parties related to participation in the Program before the application is submitted, and all ACO providers/suppliers must have agreed to participate in advance as well. Moreover, for an ACO that is accepted into the Program and, after being accepted, wants to add a new ACO participant, the ACO would likely have to provide notice and gain approval from CMS in advance of adding the new ACO participant. An applicant is also required to submit a sample agreement between the ACO and its ACO participants as part of the application process. At a minimum, the agreement must contain an explicit requirement that the ACO participant agrees to participate in and comply with the requirements of the Program, and also a description of how the arrangement will encourage the ACO participant and the individual ACO providers/suppliers to satisfy quality metrics established by the Program. The CMS Memo points out that general language in the agreement about compliance with federal law or Medicare regulations is insufficient, and each agreement should give the ACO the authority to remove an ACO participant for non-compliance.
4. ACO Legal Entity and Governing Body Requirements. An ACO's governing body must have responsibility for oversight and strategic direction of the ACO, and members of the governing body must have and act in accordance with a fiduciary duty to the ACO. The CMS Memo explains that the governing body must be separate and unique to the ACO (and cannot be a governing body of one of the ACO participants) in situations where the ACO is comprised of multiple independent ACO participants, and also that the members of the governing body cannot meet the fiduciary duty requirement if the governing body is also responsible for individuals and entities that are not part of the ACO. In cases like this, where an ACO applicant is comprised of multiple independent ACO participants, the ACO itself must be a separate legal entity, distinct from each individual ACO participant. On the other hand, as the CMS Memo explains, if an already existing entity applies to the Program as an ACO, or if an individual ACO participant applies as an ACO without other ACO participants, the governing body of the applicant entity may serve as the governing body of the ACO, as long as all other requirements (including the fiduciary duty requirement) are met.

## Take Away

While the CMS Memo does not make any significant changes to the ACO concept or the Program, it does provide clarity on certain issues, including those outlined above, many of which were sources of confusion after the release of the Final Rule. For those considering applying to participate in the Program as an ACO, the CMS Memo should serve as a useful guide for preparing for the Program and submitting an application. For those who have already submitted an application, you should consider what changes, if any, should be made to your application in light of the explanations provided in the CMS Memo. Any appropriate changes should be submitted to CMS via written request. We encourage anyone interested in participating in the Program to read the CMS Memo carefully and consider how it impacts the Program application process.



*If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings Los Angeles lawyers:*

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