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Understanding the Implications of Proposed Legal Structure Requirements of Accountable Care Organizations

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On March 31, 2011, a little over a year after the Patient Protection and Affordable Care Act (PPACA) became law, the Centers for Medicare & Medicaid Services (CMS) released proposed regulations on the operation and structure of Accountable Care Organizations (ACOs).[1] The proposed regulations create the Medicare Shared Savings Program (MSSP), which CMS will implement no later than January 1, 2012, in line with section 3022 of PPACA. The deadline for submitting comments on the proposed rule is June 6, 2011. These proposed regulations have far-reaching implications for new and existing health care organizations that want to participate in the MSSP as ACOs. CMS is seeking comments to determine which legal entities should qualify as ACOs, what the MSSP should require of its participants, and how the final MSSP should function. Click here for the full text of the rule.

Overview of Eligibility Criteria to Participate in the Medicare Shared Savings Program

CMS defines an ACO as a legal entity that is recognized and authorized under applicable state law, identified by a Taxpayer Identification Number (TIN), and comprised of an eligible group of Medicare-enrolled providers and/or suppliers[2] (ACO participants) that work together to manage and coordinate care for Medicare fee-for-service beneficiaries. CMS also proposes that ACOs must establish a mechanism for shared governance, which will provide all ACO participants with appropriate "proportionate control"[3] over the ACO's decision-making process.

Under the proposed rule, the following entities are eligible to participate in the MSSP:

- ACO professionals[4] in a group practice;
- Networks of individual practices of ACO professionals;
- Partnerships or joint venture arrangements between hospitals and ACO professionals;
- Hospitals[5] that employ ACO professionals;
- Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) that join as ACO participants in an ACO formed as one of the above types of eligible entities (FQHCs and RHCs are not eligible to form their own ACOs to participate in the MSSP); and
- A critical access hospital (CAH) that utilizes method II to submit bills for the facility and professional services.

Proposed Legal Structure Requirements for Participation

Under the proposed regulations, an ACO may be structured as a corporation, partnership, limited

liability company, foundation, or other entity permitted by state law. An ACO is not required to be enrolled in the Medicare program to receive its shared savings payments from CMS. The ACO legal entity must be able to perform the following functions:

- Receive and distribute shared savings payments;
- Repay shared losses;
- Establish, report, and ensure ACO participant and ACO provider/supplier compliance with the MSSP program requirements, including the quality performance standards; and
- Perform other ACO functions indentified in the statute, including having a mechanism for shared governance.

If an existing legal entity meets the above eligibility requirements and is recognized as a legal entity by the state law applicable to where it is established, then it may operate as an ACO under the proposed rule without forming a separate entity for the purpose of participating in the MSSP. But if an existing entity wants to include new ACO participants not already part of its existing legal structure, a new separate legal entity must be formed to ensure that all ACO participants share in the ACO's governance and decision making.

The above requirements may change between now and the publication of the final rule because CMS is soliciting comments on the following issues relating to the legal structure of ACOs:

- Whether the proposed legal structure requirements are sufficient;
- Whether other suitable legal structures should qualify for participation in the MSSP;
- Whether mandating existing legal entities to create a separate legal entity to operate an ACO would create disincentives and whether there is an alternative that will achieve the aim of shared governance and decision making; and
- How to encourage not-for-profit, community-based organizations to participate in the MSSP, and specifically, whether the requirements for creating a separate legal entity may deter these organizations from applying for the MSSP and if there are other viable alternatives to requiring a separate legal entity.

Important Implications of Legal Structure Requirements for Potential ACO Participants

An organization interested in participating in the MSSP will need to determine whether its existing legal entity will meet the statutory and proposed regulatory requirements. For example, if an organization decides to form a new ACO legal entity, it will need to decide upon the corporate structure that will best serve the ACO, taking into account factors such as the financial and tax implications of risk-sharing, the potential profits and losses, and the considerations germane to newly forming entities, generally. Even if an existing legal entity does meet the applicable requirements, it should nonetheless examine whether forming a new legal entity to participate in the MSSP would be an opportunity to realize any additional benefits, such as separation of financial assets, insulation of participants from legal challenges, or tax advantages.

Also, CMS has noted that not having a separate legal entity to operate the ACO may make it harder to audit and assess performance of the ACO. Accordingly, existing legal entities should consider using the comment process to offer suggestions regarding how CMS could measure performance of currently existing legal entities that have decided to participate in the MSSP.

Note that all MSSP participants must comply with the antitrust and program integrity-related requirements proposed by the other agencies, such as the Federal Trade Commission, the Department of Justice, and the Office of Inspector General for the Department of Health and Human Services. Ultimately, health care organizations must determine whether participation in the MSSP will result in benefits to the providers and the community that will outweigh the cost of forming an ACO.

Mintz Levin will be publishing additional advisories on other relevant portions of the proposed regulations in the coming weeks. Mintz Levin is ready to assist potential MSSP participants in drafting and submitting comments to CMS before the June 6th deadline. Additionally, Mintz Levin can also assist with a cost-benefit analysis of participating in the MSSP, and help potential ACOs to comply with the necessary prerequisites to participation.

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Endnotes

1 76 Fed. Reg. 19537 (April 7, 2011).

2 ACO provider/suppliers are providers of services and/or suppliers that bill for items and services they furnish to Medicare beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant.

3 Although proposed 42 C.F.R. § 425.5(8)(iv) places this requirement for "proportionate control" in a sentence immediately following the requirement that "[a]t least 75 percent control of the ACO's governing body must be held by ACO," CMS otherwise fails to specifically define acceptable methods and governing structures that achieve proportionate control.

4 ACO Professionals are physicians (M.D. or D.O.) or practitioners (a physician assistant, a nurse practitioner, or a clinical nurse specialist).

5 Under the proposed rule, only acute care hospitals paid under the Inpatient Prospective Payment System may participate in the MSSP.

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