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ACO LEGAL ISSUES

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The Patient Protection and Affordable Care of Act of 2010 (the "Act") provides for shared savings between the Medicare program and healthcare providers organized as Accountable Care Organizations ("ACOs"). In late March, 2011 CMS issued a Proposed Rule covering 429 pages and addressing a variety of issues relating to the formation and operation of these ACOs. In a companion paper by this author entitled **To ACO or Not...That Is the Question** I address the pertinent portions of the Rule impacting ACO implementation. In this paper I shall address some of the more important legal ramifications surrounding ACOs and their participants.

Legal Structure:

An ACO must employ a legal structure approved by the laws of the state in which it operates. In most cases that would include a corporation, partnership (general or limited), limited liability company (LLC), foundation or similar entity. Regardless of the form chosen, the entity must be organized under state law and have its own Tax Identification Number. The Rule also requires the entity to have a comprehensive plan in place to address how the ACO will comply with all legal requirements.

Specifically the proposed Rule says:

> "...we are proposing to require an ACO to be an organization that is recognized and authorized to conduct its business under applicable State law *and is capable of -- (1) receiving and distributing shared savings; (2) repaying shared losses; (3) establishing, reporting, and ensuring ACO participant and ACO provider/supplier compliance with program requirements, including the quality performance standards; and (4) performing the other ACO functions identified in the statute."* (Emphasis added.)

Corporate governance:

The governing body of an ACO must include the following: participating providers and suppliers (collectively "ACO participants") or their representatives as well as Medicare beneficiaries or their representatives. The Rule provides that at least 75% of

the governing body seats be held by ACO participants. The reason for this requirement is to decrease outside influence on the decisions of the ACO.

To meet the requirements of the Act, the Rule sets forth some important requirements:

- The ACO must be operated by persons who have demonstrated the ability to oversee clinical practice in order to improve both processes and outcomes.
- All clinical management must be overseen by a medical director who is (1) a board-certified physician, (2) licensed in the State in which the ACO operates, (3) and physically present in that State. In short, the medical director must be hands-on in his/her relationship with the ACO.
- Both ACO participants and providers/suppliers would have a meaningful commitment to the ACO's clinical integration program to ensure its likely success. To borrow a phase, they must have “skin in the game”. This commitment may include a significant financial and/or human (time and effort) investment in the ACO, or a meaningful human investment (for example, time and effort) in the ACO. Also, this investment must be at risk of loss.
- Quality assurance and process improvement are at the heart of the ACO model. Therefore, the ACO would implement a quality assurance program that establishes internal performance standards for quality of care and services, cost effectiveness, and process and outcome improvements, and hold ACO providers/suppliers accountable for meeting the performance standards. When necessary the program should be able to identify and correct poor compliance with such standards.
- Utilizing evidence-based medicine is one of the themes of the ACO model. The ACO should embrace clinical guidelines and processes for delivering care consistent with the three primary goals of the ACO program: better care for individuals, better health for populations, and lower growth in expenditures. ACO participants and ACO providers/suppliers would have to agree to comply with these guidelines and processes and to be subject to performance evaluations and potential remedial actions where appropriate.

Don Berwick, M.D. and CMS Administrator, has said, “IT is a core competency of any ACO”. Thus, investing in electronic health record technology will be part of the development and operation of each ACO. This technology should enable the ACO to collect and evaluate data and provide feedback to the ACO managers, participants, providers/suppliers across the entire organization. Furthermore, CMS is requiring that each ACO be able to demonstrate “meaningful use” of such technology.

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These are serious performance requirements that when fully implemented have the potential to change the way much of U.S. healthcare is delivered.

Antitrust:

In order for hospitals and healthcare providers to negotiate agreements at the heart of development of an ACO it will be necessary for the principals to share data (pricing and otherwise) that could be deemed a violation of the antitrust laws. Recognizing the chilling effect that this would have on negotiations, the Antitrust Division of the Department of Justice and the Federal Trade Commission released a Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program. That Statement does not apply to merger transactions, which will be reviewed as they always have been. The Statement applies solely to "collaborations among otherwise independent providers" formed after March 23, 2010.

The statement identifies its purpose as follows:

> "The Policy Statement is intended to ensure that healthcare providers have the antitrust clarity and guidance needed to form procompetitive ACOs that participate in both the Medicare and commercial markets."

The statement addresses three separate situations and provides guidance as to when participants will trigger an expedited review:

Safety Zone: ACOs with 2 or more independent participants with less than 30% market share for any common service fall in the "safety zone" and will not have to seek review. The safety zone will remain in effect for the duration of an ACO's agreement with CMS unless there is some significant change in circumstances.

Mandatory Review: ACOs with 2 or more independent participants with greater than 50% market share for any common service must request an expedited antitrust review from the FTC or DOJ before applying to be certified as an ACO. The reviewer will notify CMS as to whether the proposed ACO will or will not be anticompetitive.

Market Shares Between 30 and 50%: ACOs with 2 or more independent participants with a market share between 30% and 50% for any common service share may use an expedited review process but will not be required to obtain "clearance" before applying to CMS for ACO recognition. The Statement provides guidance to these potential ACOs as to activities to be avoided in order to avoid being deemed anticompetitive.

Fraud & Abuse:

Since no healthcare provider or hospital wants to run afoul of any Medicare fraud and abuse provisions, CMS has suggested that waivers will be available to ACOs so they can create combinations without fear of prosecution. CMS proposes to waive Stark Law and Anti-Kickback Statue for shared savings distributions that are paid to ACO participants, providers or suppliers for the year that shared savings are earned. Furthermore, they suggest that waivers should also apply to civil monetary penalties if both the hospital and physician are ACO participants and the payments aren't made to induce referrals.

This is an area where more guidance from CMS or the OIG for those setting up ACOs would be helpful and welcome.

Exempt Organization Tax Laws:

According to IRS guidance, arrangements between a 501(c)(3) and an ACO will be unlikely to result in an impermissible private inurement or private benefit if:

- The terms of participation are negotiated at arm's length;
- The ACO has been accepted into the Medicare shared savings program by CMS and has not been terminated from the program;
- The 501(c)(3) receives benefits from the ACO that are proportional to the benefits or contributions the ACO receives from the entity;
- The entity's ownership share (if any) is proportionate to its capital contribution;
- The entity's share of ACO losses does not exceed the share of economic benefits it is entitled to (gains and losses are shared among the ACOs owners according to the same proportions); and
- The ACO transacts business at fair market value.

If the above conditions are met then the tax-exempt ACO participant should not endanger its tax-exempt status.

Conclusion:

This analysis of legal issues confronting ACO participants is not intended to be exhaustive or all encompassing. It is intended to introduce some of the key issues inherent in establishing an ACO and report on the current state of guidance provided in the Proposed Rule published by CMS as well as guidance from other government agencies involved in various aspects of the process. Since the Rule is not final, changes can (and likely will) occur as comments are received. Therefore, anyone interested in this topic would be wise to stay tuned for changes prior to implementation of the final regulations.

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