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Accountable Care Organizations: The Devil is in the Details

By Virginia Alverson and Dan Hayes

The Centers for Medicare and Medicaid Services ("***CMS***") recently sent the proposed regulations regarding Accountable Care Organizations ("***ACOs***") to the Office of Management and Budget for final review, which means that the regulations will be released any day. In anticipation of their arrival, it is time to revisit some key facts you should know about ACOs and explore some of the lingering questions that the regulations may answer. Although providers are anxious to get an ACO up and running, it has been impossible to know what an ACO should look like or how it should operate without further guidance from CMS addressing the multitude of unresolved administrative and legal issues. Many are hopeful that the soon-to-be released regulations will provide answers and clarity on these issues and as a result, allow the process of forming ACOs to begin.

Background:

The Patient Protection and Affordable Care Act ("***the PPACA***") mandates the establishment by CMS of a mechanism for the establishment of a shared savings program which: (i) promotes accountability for a defined patient population and coordinates items and services under Medicare Parts A and B; (ii) encourages investment in infrastructure; and (iii) redesigns care processes for high quality and efficient service delivery. Under this plan, groups of providers and suppliers meeting certain criteria will be allowed to work together, through an ACO, to manage and coordinate care for Medicare fee-for-service beneficiaries. ACOs that meet certain quality performance standards will be eligible to receive additional Medicare payments for the "shared savings" generated by the ACO.

While some claim ACOs could revolutionize the way healthcare is delivered in America, there are regulatory hurdles that must be overcome and many questions to be answered before ACOs become a reality. Outlined below are key facts about ACOs and some of the significant unanswered questions they raise.

Facts and Questions:

1) **Eligibility**. The PPACA states that the following groups of providers and suppliers which have established a mechanism for "shared governance" are eligible to participate as ACOs: (a) physicians and certain allied health professionals ("***ACO Professionals***") in group practices; (b) ACO Professionals in a network of practices; (c) partnerships or joint ventures between hospitals and ACO Professionals; (d) hospitals employing ACO Professionals; and (e) other forms that the Secretary of Health and Human Services ("***Secretary***") may deem appropriate.

Unanswered Questions: What is meant by "shared governance"? Will there be rules on the structure of these entities and the types of individuals who can serve on their governing boards? Will the prospect of shared savings be enough to justify hospitals and

physicians relinquishing some of the autonomy they currently enjoy?

2) **Qualifying to be an ACO**. The PPACA also outlines basic criteria that an ACO must meet to qualify for participation in the shared savings plan. Pursuant to these statutory criteria, an ACO must:

(a) Have, at a minimum, at least 5,000 beneficiaries and a sufficient number of primary care professionals to take care of those beneficiaries;

(b) Agree to participate in the program for three (3) years;

(c) Have sufficient information regarding the participating ACO Professionals, as the Secretary determines necessary, to support beneficiary assignment and for the determination of payments for shared savings;

(d) Have a leadership and management structure that includes clinical and administrative systems;

(e) Have defined processes to: (i) promote evidenced-based medicine; (ii) report the necessary data to evaluate quality and cost measures (this could incorporate requirements of other programs, such as the Physician Quality Reporting Initiative, Electronic Prescribing, and Electronic Health Records); and (iii) coordinate care;

(f) Be able to demonstrate that it meets patient-centeredness criteria, as determined by the Secretary, such as the use of individualized care plans.

Unanswered Questions: What is a "sufficient number" of primary care professionals: will CMS require specific ratios? What information must an ACO disclose concerning its participating ACO Professionals? What is meant by a leadership and management structure that includes clinical and administrative systems? What constitutes "evidence-based medicine", and how will an ACO prove it is promoting evidence-based medicine? What will patient-centered criteria look like? What processes must the applicant follow to prove that it meets the above criteria and be certified as an ACO?

3) **Assigning Beneficiaries**. The PPACA requires the Secretary to determine an appropriate method to assign Medicare beneficiaries to ACOs.

Unanswered Questions: Will beneficiaries voluntarily enroll with a selected ACO? Will they be assigned before or after the fact of treatment? May a beneficiary "disenroll" from an ACO? Will CMS make the decision on establishing a physician/patient relationship? What if an existing ACO drops below 5,000 enrollment?

4) **Qualifying for Shared Savings**. The shared saving program will work as follows: ACOs will be paid the usual Medicare payments for care delivered to ACO participants. Then, for each 12-month period, participating ACOs that meet specified quality performance standards will be eligible to receive a share of any savings if the actual per capita expenditures of its assigned Medicare population are a sufficient percentage below a specified benchmark amount. The benchmark for each ACO will be based on the most recent available three years of per-beneficiary expenditures for Medicare Parts A and B services, adjusted for beneficiary characteristics and other factors deemed appropriate by the Secretary, and updated by the projected absolute growth in national per capita expenditures for Parts A and B.

Unanswered Questions: Will the regulations give additional guidance on beneficiary characteristics and other factors determined appropriate by the Secretary in establishing the benchmark that each ACO must meet to qualify to participate in shared savings? How will the "sufficient percentage below its specified benchmark amount" that an ACO must achieve before sharing in savings be determined?

5) **Quality Performance Standards**. As mentioned above, in order to receive money in connection with a shared savings plan, an

ACO must not only save a certain percentage below its specific benchmark, but it also must meet certain quality performance standards. Moreover, the Secretary may terminate an agreement with an ACO if it does not meet the quality performance standards.

Unanswered Question: Will the regulations establish or give further guidance on these quality performance standards? Will standards vary by region or patient demographics?

6) **Existing Law Hurdles**. The implementation of ACOs could violate the fraud and abuse and anti-trust laws. To facilitate the establishment of ACOs, the PPACA grants the Secretary the authority to waive certain provisions of the fraud and abuse laws under the Social Security Act or other provisions of the Medicare law. Further, the FTC has announced that it will develop antitrust safe harbors for ACOs and an expedited review process for ACOs that do not qualify for those safe harbors. For more information on this topic, please see our e-alert entitled "*AHLA Releases Option Paper to Waive Medicare Fraud and Abuse Provisions to Establish ACOs*."

Unanswered Questions: When and how will existing regulatory barriers to ACOs be removed? Must ACOs request exemption, or will it be automatic? Will CMS attempt to preempt conflicting state laws such as Insurance laws?

As soon as the ACO regulations are published, Jackson Walker will distribute an E-Brief summarizing the key aspects of the regulations. For more information on ACOs, contact **Virginia Alverson** at **valverson@jw.com** or 214.953.5875 or **Daniel J. Hayes** at **dhayes@jw.com** or 713.752.4334.

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