HONIGMAN ALERT

Health Care and Insurance Departments

April 15, 2011

Proposed ACO Regulations: What You Need to Know

On March 31, 2011, the Centers for Medicare & Medicaid Services (CMS) issued the long-awaited proposed regulations implementing the section of the Patient Protection and Affordable Care Act relating to the Medicare Shared Savings Program and Accountable Care Organizations (ACOs) - a new delivery and payment model aimed at better care for individuals, better health for populations and lower growth in health care spending. Other administrative agencies also issued notices on the same day to address related legal issues raised by ACOs. While only in proposed form, the regulations and notices provide valuable insight into the key structural and operational issues confronting ACOs, fraud and abuse considerations, tax and antitrust concerns, as well as considerations related to CMS' implementation and ongoing administration of the Medicare Shared Savings Program.

The proposed regulations are lengthy and impose extensive conditions and requirements on parties desiring to form ACOs. To assist our clients in digesting the proposed regulations, we have briefly summarized below some of the significant provisions. The full text of the proposed regulations can be found by clicking here. We thought this Alert might be of interest to you or someone else in your organization involved with ACO development. Please feel free to pass it along.

Organization and Structure

The proposed regulations establish a comprehensive framework for the formation and operation of an ACO. An ACO may be formed by groups of health care providers and suppliers, separately or in combination, who are expected to work together to manage and coordinate care for Medicare fee-for-service beneficiaries, including the following:

- Physicians organized in a group practice
- Networks of individual physician practices
- Partnerships or joint ventures between hospitals and physicians
- Hospitals employing physicians
- Critical Access Hospitals using Method II billing

An ACO can be structured in various ways, including as a corporation, partnership, limited liability company or foundation, but the proposed regulations require that an ACO be a legal entity "recognized and authorized" under applicable state law with its own tax identification number. An ACO's legal structure must allow it to receive and distribute shared savings from CMS and provide the basis for shared

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governance. Existing legal entities organized under state law are not required to form a separate legal entity to qualify as an ACO but may need to substantially change the composition of their governing body to meet CMS' shared governance requirements.[1] The proposed regulations require that ACO participants in the aggregate have at least 75% control of the ACO's governing body, with each ACO participant having a representative on the governing body. In addition, to ensure that a patient-centered approach is adopted by the ACO, the proposed regulations mandate that ACOs "demonstrate a partnership with Medicare beneficiaries by having representation by a Medicare beneficiary serviced by the ACO on the ACO's governing body."

The ACO legal entity itself need not be enrolled in Medicare; but, each ACO participant must be a Medicare provider or supplier. Significantly, primary care physicians may only participate in one ACO, unlike other ACO participants, including hospitals, which may participate in more than one ACO.

Participation

Participation in the Medicare Shared Savings Program is voluntary. To enroll, an ACO must successfully complete an extensive enrollment application and enter into a three-year agreement with Medicare. Although it initially was expected that an ACO participating in the Medicare Shared Savings Program would only share in the savings it generated, the proposed regulations require that ACOs enrolled in the program ultimately must share in the risk of loss as well. The requirement to share risk may deter participation in the program.

During its initial three-year agreement period only, an ACO may elect one of two tracks:

- On Track 1, an ACO is entitled to receive a certain percentage of its shared savings, subject to a 52.5% maximum sharing rate, but is not required to share in any losses for the first two years of the three-year agreement. CMS refers to this as the "one-sided" approach. The ACO must transition to the "two-sided" approach (described below) for the third year of its initial agreement period and will not be able to return to the "one-sided" approach for subsequent agreement periods. It is anticipated that ACOs with less experience managing care and accepting financial risk (*i.e.,* smaller ACOs) will opt for Track 1.
- On Track 2, ACOs directly enter into the "two-sided" approach and are entitled to a greater share of any savings as compared to Track 1, but must also share in a percentage of any losses for all three years. Specifically, under Track 2, ACOs are eligible to share in up to 65% of the savings generated but must also share in up to 10% of any losses. It is anticipated that ACOs that include providers or suppliers experienced in managing risk will opt for Track 2.

As part of its three-year agreement, an ACO must agree to be subject to CMS audits and to comply with public reporting requirements. Each ACO must serve at least 5,000 Medicare beneficiaries who will be assigned to the ACO based on the source of a plurality of their primary care services. ACO beneficiaries are to be assigned retrospectively, at the end of the performance year on the basis of services actually rendered by the ACO during the performance year. CMS will then review the cost of

1 CMS recognized that not requiring an ACO to be a separate legal entity could make it more difficult to audit the ACO's performance. Accordingly, CMS is seeking comments on whether all ACOs should be formed as separate legal entities.

the services rendered to the assigned beneficiaries during the performance year in making its shared savings determination for the ACO.

Shared Savings Determination

To receive payment of shared savings, an ACO must meet annual quality measures and achieve annual cost-savings targets. The proposed regulations contain sixty-five quality measures in five standard areas: Patient/Caregiver Experience; Care Coordination; Patient Safety; Preventative Health; and At-Risk Population/Frail Elderly Health. CMS indicates it has attempted to align these quality measures with other Medicare incentive programs such as the Medicare EHR Incentive Program. To measure cost-savings, CMS will establish a benchmark for Medicare expenditures for each three-year period, based on a claims review of historic spending for beneficiaries assigned to the ACO. The amount of the shared savings that CMS distributes to an ACO will be a percentage of the difference between the estimated benchmark for Medicare expenditures and the actual costs expended by the ACO, assuming the ACO has also met its annual quality measures.

Although the percentage may be higher or lower depending on factors such as the number of Medicare beneficiaries served and the geographic location of the ACO, generally there will not be any cost savings shared unless expenditures are at least 2% below the benchmark. CMS will remit shared savings directly to the ACO. To offset any future losses, under both Tracks CMS will withhold 25% of any shared saving payment until completion of an ACO's three-year agreement with CMS.

Operational Conditions

The proposed regulations describe numerous procedural, administrative and operational conditions applicable to ACOs. While not an exhaustive list, some of the more notable requirements include:

- ACOs must develop a process to promote evidence-based medicine, patient engagement and coordination of care;
- ACOs must have a patient survey/quality feedback tool in place;
- ACOs must have a process for evaluating the health needs of the populations served;
- ACOs must have systems to identify high-risk beneficiaries and develop individual care plans for target populations;
- ACOs must maintain a database of all ACO participants and their National Provider Identifiers;
- ACOs must have a compliance plan, conflict of interest policies and the means to screen ACO participants;
- ACOs must obtain CMS approval for any changes in ACO participants (i.e., providers and suppliers) during the three-year agreement period;
- At least 50% of an ACO's primary care physicians must be meaningful EHR users as defined by the HITECH Act and subsequent Medicare regulations;
- ACOs must have a data-use agreement with CMS; and

- CMS must approve all marketing materials or other communications, and changes thereto, promoting the ACO.

Timing of Implementation

With a statutory mandate to establish the Medicare Shared Savings Program before January 1, 2012, CMS faces an abbreviated time frame to finalize the proposed regulations, process ACO applications, enroll ACOs and execute participation agreements. The proposed regulations include the following time frames:

- Comments on the proposed regulations will be accepted for sixty days after the proposed regulations were published in the Federal Register on April 7, 2011.
- CMS will issue a deadline for the submission of enrollment applications and will review and approve applications by December 31, 2011.
- The ACO program has a once-a-year start date of January 1 (*i.e.*, no rolling application process). Accordingly, the initial ACO program is scheduled to go into effect on January 1, 2012 and, thereafter, all ACOs approved will start on the January 1 following the calendar year in which approval is received.

Other Government Agencies Weigh In

On the same day that the proposed regulations were released, other administrative agencies issued notices addressing related legal issues affecting ACOs.

- CMS and the OIG issued a joint notice titled, "Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and Innovation Center," which proposes limited waivers with regard to the Stark Law, the Anti-Kickback Statute and the gainsharing and civil monetary penalty laws for ACOs participating in the Medicare Shared Savings Program. For the Stark Law and Anti-Kickback Statute, the waiver applies to the distribution of shared savings received by the ACO from CMS to or among the ACO participants and providers/suppliers, or for activities necessary for and directly related to the ACO's participation in the Medicare Shared Savings Program. Additionally, application of the Anti-Kickback Statute will be waived for any financial relationship between or among the ACO, ACO participants and providers/suppliers that directly relates to the ACO's participation in the Medicare Shared Savings Program, if the financial relationship meets a Stark Law exception. CMS will accept comments on this notice until June 6, 2011. The notice is available by clicking here.
- The FTC and DOJ issued a joint notice titled, "Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program" to discuss how antitrust laws will be applied and enforced for ACOs. This proposed antitrust enforcement policy proposes an "antitrust safety zone" and provides that ACOs will not be challenged if independent ACO participants (*e.g.*, physician group practices) have a combined share of 30% or less of each common service in each participant's service area wherever two or more ACO participants provide that same service to patients from that area. ACOs with a greater than 50% share in their service area will be required to seek

approval as an ACO through a 90-day expedited review process before proceeding with enrollment for the Medicare Shared Savings Program. Comments must be submitted to the FTC by May 31, 2011. The FTC and DOJ's notice is available by clicking here.

- The IRS issued Notice 2011-20 requesting comments regarding whether a need exists for guidance on participation of tax-exempt organizations in the Medicare Shared Savings Program through ACOs. Comments must be submitted to the IRS on or before May 31, 2011. The IRS notice is available by clicking here.

Conclusion

Many observers view these proposed regulations as reflecting CMS' ideal concept of ACOs and the role they should serve in promoting effective, efficient and patient-centered healthcare services. Given the scope of the proposed regulations and the number of actions and approvals necessary to qualify and participate as an ACO, these proposed regulations foreshadow the establishment of a complex and complicated system. In fact, some commentators have already questioned the value of participating in the Medicare Shared Savings Program. While the proposed regulations offer some guidance and insight regarding the ultimate structure and operation of ACOs, it is important to remember that they currently are only in proposed form and significant outstanding issues and questions remain. Some of these questions and issues may best be addressed by submitting comments to CMS for consideration in issuing the final regulations. Accordingly, we encourage clients to submit questions or suggestions to CMS or one of the other relevant government agencies. For assistance in this process or if you have questions about the proposed regulations, contact any of the insurance or health care attorneys listed on the front page of this Alert.