MD LAWALERT
APRIL 6, 2011

KATHLEEN L. DEBRUHL & ASSOCIATES, L.L.C.
614 TCHOUPITOULAS STREET
NEW ORLEANS, LOUISIANA 70130
504.522.4054 (OFFICE) 504.522.9049 (FAX)
WWW.MD-LAW.COM

CMS RELEASES PROPOSED ACCOUNTABLE CARE ORGANIZATION REGULATIONS

By: Kathleen L. DeBruhl, Esq. and Lindsey E. Surratt, Esq.

On March 31, 2011, the Centers for Medicare and Medicaid Services ("CMS") issued proposed rules for the participation of physicians and hospitals in the "Medicare Shared Savings Program" for accountable care organizations ("ACOs"). These regulations implement the provisions of Section 3022 of the Patient Protection and Affordable Care Act ("PPACA") and provide proposed standards for the creation of, and participation in, ACOs by Medicare providers and suppliers. At this time, these regulations are not final. However, the proposed rule will allow providers to begin taking the steps necessary to form, or participate in the Medicare Shared Savings Program as, an ACO.

The proposed rule provides details regarding eligibility and participation criteria, governance and operational structure requirements, the application process, assignment of beneficiaries, shared savings payment models, and quality control and reporting requirements. This article provides a brief summary of certain key provisions found in the proposed rule.

ABOUT US:

Kathleen L. DeBruhl & Associates, LLC *is a regional healthcare law firm with a national client base which offers its physician and other healthcare provider clients sophisticated and substantial expertise on their corporate business needs including organization, joint ventures, mergers and acquisitions, and contractual and financial arrangements.*

The Firm counsels and defends clients on highly complicated regulatory matters involving reimbursement, fraud and abuse, and compliance with the myriad of laws and regulations imposed upon the healthcare industry by both federal and state governments.

WHAT IS AN ACO?

An ACO is a legal entity recognized under state law which can be identified by a Taxpayer Identification Number. An ACO must be comprised of an eligible group of ACO participants that work together to manage and coordinate care for Medicare fee-for-service beneficiaries. Participation in an ACO is entirely voluntary. Healthcare providers and suppliers are not required by the regulations to participate in an ACO or in the Medicare Shared Savings Program.

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WHO MAY FORM AN ACO?

PPACA lists certain groups of healthcare providers and suppliers which are eligible to form an ACO. These groups are: (1) ACO professionals in a group practice arrangement; (2) Networks of individual practices of ACO professionals; (2) Partnerships or joint venture arrangements between hospitals and ACO professionals; and (4) Hospitals employing ACO professionals. "ACO professionals" include physicians (doctors of medicine or of osteopathy), and practitioners, such as nurse practitioners and physician assistants. The Secretary of the U.S. Department of Health and Human Services may designate other groups eligible to form an ACO at a later date. An ACO participant must be a Medicare-enrolled provider or supplier of healthcare services. Such provider or supplier must bill for the items and services it furnishes to Medicare beneficiaries under a Medicare billing number which is assigned to the Taxpayer Identification Number of the ACO participant.

There are some providers and suppliers which cannot form an ACO without the participation of one of the providers or suppliers listed above. They may, however, participate in an ACO. For example, federally qualified health centers, rural health clinics, and critical access hospitals may not form an ACO without the participation of another eligible provider or supplier. Some providers, like primary care physicians, will participate exclusively with one ACO, while others may participate in one or more ACOs. Each ACO participant must make a meaningful financial investment in the ACO or provide meaningful services to the ACO.

GOVERNANCE AND ORGANIZATIONAL REQUIREMENTS

An ACO may be formed as a corporation, limited liability company, partnership, or any other legal entity allowed by state law. Although each ACO participant must be enrolled in the Medicare program, the proposed rule does not require that the ACO itself be enrolled in Medicare. An ACO must also employ a "shared governance" system, giving each ACO participant proportionate control in the ACO decision making process. A board of directors, board of managers, or other governing body comprised of representatives of the ACO participants and Medicare beneficiary representatives will govern the ACO. The proposed rule would require Medicare-enrolled ACO participants to maintain at least seventy-five percent (75%) control of the ACO's governing body. This provision allows certain non-provider groups, like management companies and health plans, and small provider groups to participate in an ACO on a limited basis.

The proposed rule also details certain organizational criteria for ACO leadership and management which emphasizes clinical involvement in ACO operations. Operations will be managed by an executive, officer, or manager who serves at the discretion of the governing body. The proposed rule also requires management of clinical operations by a senior-level medical director who is a board-certified physician, licensed and physically present in the state in which the ACO operates. An ACO must form a physician-directed committee to oversee ongoing quality assurance and improvement programs. An ACO must also implement evidence-based clinical guidelines which promote quality, cost-efficient care and utilize information technology sufficient to gather certain types of data and distribute it across the organization.

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THE APPLICATION PROCESS

During an annual application period, ACOs may apply to participate in the Medicare Shared Savings Program under the terms of a three (3) year agreement, which may be terminated earlier by the ACO or by CMS under certain circumstances. The proposed rule lists the documentation an ACO is required to submit with its application. These materials will include employment contracts, corporate operational documents, and participation agreements demonstrating the obligations of each ACO participant within the organization, documents showing the makeup of committees and job descriptions of senior administrative and clinical leaders, a description of the quality assurance and clinical integration programs, and other evidence showing the ACO complies with the "shared governance" and organizational requirements referenced above. An ACO would also be required to demonstrate in its application how any shared savings distributed to the ACO would be used to promote quality of care and accountability to the Medicare population.

ASSIGNMENT OF BENEFICIARIES

The proposed rule assigns beneficiaries to an ACO on the basis of primary care services received by the beneficiary which are provided by a physician. Generally, ACOs will be required to serve a population of at least 5,000 Medicare beneficiaries. The proposed rule contains guidelines for an ACO whose assigned population falls below 5,000 beneficiaries while participating in the Medicare Shared Savings Program. The proposed rule also prohibits ACOs from developing policies which restrict a beneficiary's freedom to seek care from providers and suppliers outside of the ACO.

SHARED SAVINGS MODELS

CMS has developed two shared savings risk models for ACOs. The shared savings risk model chosen by the ACO in its application will determine the percentage of Medicare shared savings the ACO is eligible to receive based on expenditure benchmarks determined by CMS. If an ACO elects to continue participating in the Medicare Shared Savings Program after the expiration of its first three year agreement with CMS, it must participate under the Two-Sided Risk Model. Each risk model is described below.

ONE-SIDED RISK MODEL: This model provides that savings will be shared in the first two years of the three year agreement. In the third year of the agreement, the ACO will share both savings and losses. If the ACO exceeds its "minimum savings rate," it will be eligible to receive up to fifty percent (50%) of shared savings. The actual percentage will be based on the ACO meeting certain quality performance standards.

TWO-SIDED RISK MODEL: In this model, both savings and losses are shared for all three years of the agreement. Although the risk is greater under this model, ACOs participating under the Two-Sided Risk Model which exceed the "minimum savings rate" are eligible to share up to sixty percent (60%) of the savings. The actual percentage shared will be based on the ACO meeting certain quality performance standards.

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QUALITY CONTROL AND REPORTING REQUIREMENTS

In order to be eligible for shared savings benefits, the proposed rule identifies five areas of quality control which will measure ACO performance. These five areas are:

- Patient/caregiver care experiences
- Care coordination
- Patient safety
- Preventative health
- At-risk population/frail elderly health

ACOs will be required to report certain data in these five categories to CMS. CMS will evaluate the ACO's compliance with quality of care standards under these criteria. The proposed rule also subjects certain ACO information to public reporting requirements. The type of information subject to this public reporting requirement includes the name, location, and primary contact for the ACO, a list of the ACO participants, any shared savings payments received by the ACO or shared losses paid to CMS by the ACO, and quality performance standard scores.

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OUR ATTORNEYS:

KATHLEEN L. DEBRUHL
kdebruhl@md-law.com

GILBERT F. GANUCHEAU, JR.
gganucheau@md-law.com

LINDSEY E. SURRATT
lsurratt@md-law.com

KATHLEEN L. DEBRUHL & ASSOCIATES, L.L.C.
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CONCLUSION

CMS is soliciting public comments on the proposed rule until June 6, 2011. Other federal agencies have issued notices and proposed policies addressing participating in ACOs. The Federal Trade Commission and Department of Justice issued a Policy Statement describing the antitrust issues created by ACOs and how those agencies will deal with such issues. CMS and the Office of Inspector General ("OIG") also issued a joint notice addressing proposed waivers of the Physician Self-Referral regulations, the Anti-Kickback Statute, and the Civil Money Penalties law for the distribution of shared savings payments to physicians and other healthcare providers. The Internal Revenue Service published a notice soliciting comments as to whether additional guidance is necessary regarding the tax implications of participation in ACOs by tax-exempt hospitals and other tax-exempt healthcare organizations. It is important that providers interested in forming or participating in an ACO be aware of the proposed rules issued by CMS and guidance issued by other federal agencies addressing the various issues involved in the creation of an ACO and participation in the Medicare Shared Savings Program.

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IMPORTANT NOTICE

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