ALERT
APRIL 1, 2011

HEALTH CARE
ANTITRUST UPDATE
News Concerning Recent Antitrust Developments
Affecting the Health Care Industry

COZEN
O'CONNOR
www.cozen.com

Proposed Rules For Accountable Care Organizations Released March 31, 2011 By The Federal Trade Commission, Department Of Justice, And The Center For Medicare & Medicaid Services

John R. Washlick • 215.665.2134 • *jwashlick@cozen.com*
Melissa H. Maxman • 202.912.4873 • *mmaxman@cozen.com*
Jonathan M. Grossman • 202.912.4866 • *jgrossman@cozen.com*
Elizabeth L. Holdefer • 202.912.4814 • *eholdefer@cozen.com*
Melanie K. Martin • 215.665.2724 • *mmartin@cozen.com*

After a two month delay, the Federal Trade Commission (FTC) and Department of Justice (DOJ), acting jointly, and the Center for Medicare & Medicaid Services (CMS) released proposed regulations for Accountable Care Organizations (ACOs) participating in the Medicare Shared Savings Program (the Program). The Program was created pursuant to the Affordable Care Act and was intended to encourage health care providers to better work together to lower costs and improve patient outcomes.

Joint FTC/DOJ Proposed Statement of Antitrust Enforcement Policy

The highlight of the joint FTC/DOJ Proposed Statement of Antitrust Enforcement Policy is a three-tiered categorization of ACOs based on participating members' market shares and a 90-day antitrust review process that can be either voluntary or mandatory, depending on the tier into which an ACO falls.

For antitrust purposes, the FTC and DOJ will consider a number of factors to determine the appropriate tier for a proposed ACO. The most important factor is the combined market share of the ACO participants in each of more than 50 categories of common services (*e.g.*, physician specialties, outpatient categories, and inpatient major diagnostic categories) in each provider's primary service area (PSA). The PSA is defined as the lowest number of contiguous zip codes from which a provider draws at least 75 percent of its patients.

There are a number of additional criteria and exceptions, but the basic qualifications for each tier are as follows:

- Barring "extraordinary circumstances," the Agencies will not challenge ACOs that fall into a new antitrust "safety zone." As such, these ACOs have no obligation to notify the Agencies prior to formation.
- An ACO qualifies for the safety zone if: (1) it does not combine providers of any common service such that the participant's combined share exceeds 30 percent in that service; (2) it does not include a physician practice with greater than a 50 percent share in any common service that is exclusive to the ACO; and (3) all of the ACO's hospital and ambulatory service center participants are nonexclusive to the ACO.
- If the ACO combines providers of any common service such that a participant's combined share of that service exceeds 50 percent, the ACO is subject to mandatory review by either the FTC or DOJ. Such review must be completed within 90 days of the ACO providing to the agencies certain enumerated documents and information. Importantly, the ACO may not file its application with CMS unless and until this review is complete and the reviewing agency has provided a letter to the ACO stating that it does not intend to challenge the ACO under the antitrust laws.
- If the ACO does not fall within the safety zone, but also does not qualify for mandatory review, it has the option of availing itself of the agencies' 90-day review process. If it chooses the review process, however, it is then bound by the result.

Center for Medicare & Medicaid Services Proposed Regulations for ACOs

As to the CMS rule, ACOs — teams of physicians, hospitals, and other health care providers — would coordinate and

improve care for patients with original Medicare, and Medicare Parts A and B. To share in savings, ACOs would have to meet quality standards in five key areas: patient/caregiver care experiences, care coordination, patient safety, preventive health, and at-risk population/frail elderly health. The Program would begin January 1, 2012.

Proposed Eligibility Requirements and Termination

Under the proposed rule, an ACO refers to a group of providers and suppliers of services that will coordinate care for their Medicare beneficiaries. An ACO may consist of ACO professionals (physicians and hospitals meeting the statutory definition) in group practice arrangements, networks of individual practices of ACO professionals, partnerships or joint venture arrangements between hospitals and ACO professionals, and hospitals employing ACO professionals, as well as certain critical access hospitals.

While patient and provider participation in an ACO is purely voluntary, providers must apply to participate in the Program; participation is not automatic. To apply, the ACO must explain how it plans to deliver high-quality care at lower costs and agree to accept responsibility for at least 5,000 beneficiaries. If approved, the ACO must sign an agreement with CMS to participate in the Program for three years. Once enrolled in the Program, CMS will monitor ACO performance by analyzing specific financial and quality data, conducting site visits and audits, and assessing and investigating beneficiary and provider complaints. CMS may terminate an ACO agreement if the ACO fails to meet the established quality performance standards or inappropriately avoids at-risk or high-cost patients. Termination of an ACO from the Program for any reason will result in loss of the mandatory 25 percent withhold of shared savings.

Shared Savings

Medicare providers who join a participating ACO would continue to receive payment under original Medicare fee-for-service (FFS) rules. CMS will develop a benchmark for each ACO against which its performance is to be measured to determine whether the ACO will share in savings or be held accountable for losses. The benchmark is an estimate of what the total Medicare FFS costs for ACO beneficiaries would have been absent the ACO, even if all those services would not have been provided by providers in the ACO. The benchmark will reflect beneficiary characteristics and other factors that affect the need for services, and will be updated for each performance year within the three-year period.

Under the proposed rule, CMS will implement two models: (1) a one-sided risk model under which the ACO will share only in savings for the first two years and savings and losses in the third year and (2) a two-sided risk model under which the ACO will share in savings and losses for all three years. The ACO may select the model under which it will operate. CMS believes the one-sided model, with shared savings in years one and two without the risk of loss if actual expenditures exceed the benchmark, will serve as an entry point for organizations with less experience, while the two-sided model will provide an opportunity for more experienced ACOs to receive greater shared savings for all three years but at the risk of loss.

CMS is also proposing to establish a minimum savings rate (MSR) that would account for normal variations in health care expenditure. The MSR is a percentage of the benchmark that ACO savings must exceed for an ACO to qualify for shared savings and would be based upon the number of Medicare beneficiaries participating in an ACO. Once the savings realized by the ACO exceed the MSR, the difference between the actual expenditures of the ACO's beneficiaries during each year of its agreement and the ACO's benchmark should reflect how well the ACO is coordinating and improving the overall efficiency of care. ACOs in the one-sided model with smaller populations (and thus, more variation in spending) would have a larger MSR; ACOs with larger populations (and thus, less variation in spending) would have a smaller MSR. CMS proposes a flat, 2 percent MSR for ACOs in the two-sided model. If an ACO meets quality standards and achieves savings greater than the MSR, the ACO would share in savings based on its quality score.

To encourage providers to participate in the Program in 2012, CMS is setting the quality performance standard to reporting only. Thus, ACOs would be eligible for the maximum sharing rate — 60 percent for the two-sided model and 50 percent for the one-sided model — if the ACO generates sufficient savings and reports the required quality measures. This will provide newly created ACOs with a grace period while they start up.

ACOs and the Medicare Beneficiary

Beneficiaries would not enroll in a specific ACO. Rather, Medicare would retrospectively review a beneficiary's use of services to determine whether an ACO should be credited with improving care and reducing costs. Thus, ACOs will have an incentive to improve care for all patients treated by its member providers.

Under the proposed rule, participating providers must notify a beneficiary that they are participating in an ACO, and that the provider will be eligible to share in savings for improving quality of care while reducing overall costs and liability for losses when expenditures exceed a benchmark. The beneficiary may then elect to receive services from that participating provider or seek services elsewhere. The participating provider must also notify the beneficiary that the beneficiary's claims data may be shared with the ACO to facilitate coordination of care, and provide the beneficiary with the right to opt-out of these data sharing arrangements.

Fraud and Abuse Laws

Lastly, CMS and the OIG have issued a joint notice outlining proposals for waivers of the Stark Law, the Anti-Kickback Statute (AKS), and the Civil Monetary Penalties Law (CMP) necessary to carry out the provisions of the Program and to facilitate the operations of ACOs. CMS and OIG have proposed to waive these laws in three circumstances:

- The distribution of shared savings payments received by an ACO to or among ACO participants;
- An ACO's distribution of shared saving payments to other individuals or entities for activities necessary for and directly related to the ACO's participating in the Program; and
- For the AKS and CMP only, certain financial relationships that are necessary for and directly related to the ACO's participation in the Program and fully comply with a Stark Law exception.

These waivers would cover savings earned and financial relationships existing during the ACO agreement period. All financial arrangements not covered by a waiver would be required to comply with existing laws. Importantly, CMS does not intend to protect distributions of shared savings to referring physicians outside the ACO, unless those referring physicians are being compensated — using shared savings — for activities necessary for and directly related to the ACO's participation under the Program. Other financial relationships with referring physicians would need to comply with an existing Stark Law exception. CMS has requested comments regarding waivers for other financial arrangements and, for example, distributions received from private payers, the scope and duration of waivers, and safeguards necessary to protect federal health care programs and patients.

For more information regarding accountable care organizations, the Medicare Shared Savings Program, or any antitrust developments affecting the health care industry please contact:

John R. Washlick • 215.665.2134 • *jwashlick@cozen.com*
Melissa H. Maxman • 202.912.4873 • *mmaxman@cozen.com*
Jonathan M. Grossman • 202.912.4866 • *jgrossman@cozen.com*
Elizabeth L. Holdefer • 202.912.4814 • *eholdefer@cozen.com*
Melanie K. Martin • 215.665.2724 • *mmartin@cozen.com*