Accountable Care Organizations – The FTC, CMS and OIG Perspective

By: Donald R. Moy, Esq., Michael J. Schoppmann, Esq. & Mathew J. Levy, Esq.
Kern Augustine Conroy & Schoppmann, P.C.

On October 5, 2010, the FTC, CMS, and OIG hosted a public workshop on ACOs at the offices of CMS in Baltimore, MD. The purpose of the workshop was to obtain information from industry stakeholders who have an interest in, or experience with, the development and operation of ACOs. One key focus of the workshop was to assess how the variety of possible ACO structures in different health care markets could affect the prices and the quality of health care delivered to privately insured patients, as well as to Medicare and Medicaid beneficiaries. Another key focus was to address how the requirements of the law could or should be addressed in regulations that CMS is currently developing. Finally, the workshop also focused on whether, and if so, to what extent any safe harbors, exceptions, exemptions or waivers from the laws may be warranted.

Background

The Affordable Care Act seeks to improve the quality of health care services and to lower health care costs by encouraging physicians and other health care providers to create integrated delivery systems. These integrated delivery systems are designed to test new reimbursement methods intended to incentivize providers to enhance health care quality and lower costs. One important delivery system reform is the Shared Savings Program §3022 of the Affordable Care Act, which promotes the formation and operation of ACOs. Under this provision, "groups of providers… meeting the criteria specified by the Secretary may work together to manage and coordinate care for Medicare… beneficiaries through an (ACO)." An ACO may receive payments for shared savings if the ACO meets certain quality performance standards established by the Secretary. In addition, under §3021 of the Affordable Care Act, the Secretary is authorized to test whether ACOs improve the quality of care for Medicare beneficiaries and reduce unnecessary costs for the Medicare program.

Legal Issues

A variety of legal issues – such as the antitrust laws, the physician self-referral prohibition (§1877 of the Social Security Act), the Federal Anti-Kickback statute (§1128B(b) of the Social Security Act), and the civil monetary penalty (CMP) law (§§1128A(b)(1) and (2) of the Social Security Act) – will apply to ACOs, including those participating in the Medicare Shared Savings Program pursuant to §3022 of the Affordable Care Act. The FTC, together with the Department of Justice Antitrust enforce the Federal antitrust laws. CMS has the primary enforcement authority for the physician self-referral prohibition. The OIG enforces the anti-kickback statute and CMP law and imposes civil money penalties for knowing violations of the physician self-referral prohibition.

Each of these agencies has stated that it recognizes the importance of evaluating how to apply these laws to the creation and operation of ACOs. These laws are also a critical consideration in CMS's developing regulations to implement the Medicare Shared Savings Program.

In addition, these agencies recognize that an ACO may wish to contract with payers in the private health care market, as well as with CMS. CMS states that experience has shown that the integration of health care delivery among independent providers is a complex process that requires a substantial, commitment of health care providers' resources and time. CMS further opines that as a result of the resources and time required to integrate independent provider practices, health care providers are more likely to integrate their care delivery for Medicare and Medicaid beneficiaries if they also use the same delivery system for patients covered by health insurance in the private market. The potential for ACOs to operate in both public and private insurance markets further supports the need to explore the application of these laws enforced by the FTC, CMS and OIG to ACOs.

Exercise of §3022 Affordable Care Act Waiver Authority

§3022 of the Affordable Care Act gives the Secretary the authority to waive such requirements of Title XVIII as well as §§1128A and 1128B of the Social Security Act as may be necessary to carry out the provisions of §3022 of the Affordable Care Act. HHS has stated that it is interested in hearing from the public whether a waiver, to the extent granted, should apply only to the incentive payments distributed to the ACOs and participating physicians and providers, or whether it is necessary to create a broader waiver to apply to other financial relationships created by ACOs that participate in the Shared Savings Program. For example, if the commentator recommends that a waiver should apply to all contractual service relationships between ACOs and ACO professionals, the HHS has stated that the commentator should explain why this broad waiver is necessary.

Creations of a New Stark Exception and Anti-Kickback Safe Harbor

An alternative to the use of the Secretary's waiver authority under §3022 of the Affordable Care Act would be for the Secretary to use her authority under §1877(b)(4) of the Social Security Act to create a new shared savings/incentive payment exception to the physician self-referral prohibition. Similarly, the OIG could consider a new safe harbor under §1128B(b)(3) of the Act. The Agencies stated that they are interested in the public's recommendations for how a meaningful exception and safe harbor for the incentive payments related to ACOs could be crafted. In particular, the Agencies stated that they are interested in how a physician self-referral exception could be designed.

For more information regarding the ACO Public Workshop to the FTC website:

http://www.ftc.gov/opp/workshops/aco/index.shtml[1]

The AMA Statement

A. Antitrust

- The Administration should do everything possible to facilitate participation by all types of provider structures authorized under the Accountable Care Act, and not inadvertently bias participation in favor of large health systems and hospital-dominated networks.

- The AMA strongly recommends that the Agencies explicitly recognize that ACOs should be protected by the antitrust laws and their fee negotiations should not be subject to the per-se rule.

- Financial risk sharing arrangements were common in the 1990s. Since then, the market has turned against risk sharing models of integration. It is thus unclear whether many physicians creating ACOs will pursue a risk sharing model. For those physicians and those markets where financial risk sharing arrangements are still viable, the Agencies should clarify the requirements for adequate financial risk sharing within the context of ACOs. Accordingly the Agencies should acknowledge sufficient financial integration in the care of any contract employing: (1) capitation; (2) substantial withholds (15%-20% range); (3) a percentage of premium; (4) global fees for or all-inclusive case rates; (5) cost and utilization targets; (6) or any other pay-for-performance reimbursement models that involve risk.

B. ACOs and Clinical Integration

Clinical integration is an important model for physician collaboration. The FTC/DOJ should clarify the clinical requirements an ACO should meet in order to avoid application of the per se rule. It is essential, however, that the FTC/DOJ not put forward ACO clinical integration requirements that will themselves pose an unreasonable barrier to ACO development. The current clinical integration standards published in the FTC/DOJ Joint Standards and FTC advisory opinions to date will deter the formation of ACOs. Both Med South and GRIPA made significant

[1] The website includes a recording and transcripts of the sessions of the workshop, and includes public comments submitted by various organizations, including the American Medical Association.

investments in capital and resources, using a cadre of consultants and technology experts to assist in the effort. The evidence to date suggests that few, if any, clinical integration programs will soon recover their initial investment. For example, GRIPA has not come close to recovering its investment in its efforts to comply with the FTC's standards.

C. Clinical Integration Programs

ACOs need the ability to negotiate with insurers on an exclusive basis. If health insurers want to benefit from the ACOs clinical integration program, they must deal with the ACO directly. Non-exclusive clinical integration programs have not done well commercially. Structuring a clinical integration program on a non-exclusive basis invites "free riding". Developing a clinical integration program is expensive and requires both a substantial start up investment and then continuing investments to maintain the program. The ACO must (a) create treatment protocols that improve outcomes and lower costs, (b) teach these protocols to physicians, (c) make sure these protocols are being followed, and (d) create the infrastructure needed to support the clinical integration efforts such as HIT systems and interoperability to enable physicians to securely exchange health information about their patients. An individual health insurer has significantly less incentive to purchase this enhanced service from the ACO program, if it can sign contracts with individual network physicians (whose practices have been advantaged by, for example, HIT training) and get some of the benefits created by the clinical integration program at no additional cost. This practice is called a "free ride". If enough insurers take a "free ride", then the clinical integration programs will fail as it will discourage physicians from setting up ACO networks. Exclusive dealing arrangements are a critical tool that ACOs will need to use, and antitrust enforcement agencies need to recognize this in the case of ACOs. Also noted:

- The 20 percent market share threshold for exclusive arrangements is extremely low.

- The agencies should adopt the principle that joint negotiation at the request of the health insurer cannot constitute an antitrust conspiracy.

- Physicians will be discouraged from investing and taking part in new delivery and payment models if the legal protections from civil penalties and criminal sanctions afforded to them suddenly expire. Therefore, any safe harbors exceptions, exemptions, or waivers allowed under the Shared Savings Program should continue beyond the expiration date of the program so that the organizational structure

participating as an ACO does not become illegal overnight simply because the program does not continue.

D. Waivers, Safe Harbors, and/or Exceptions under §§1128A, 1128B and Title XVIII of the Social Security Act

The AMA supports the establishment of a full range of waivers and/or the establishment of safe harbors or exceptions that will enable independent physicians to effectively participate in ACOs.

- Gainsharing – Under §1128(b)(1) of the Social Security Act, a hospital is prohibited from making payment directly or indirectly to a physician as an inducement to reduce or limit services to Medicare or Medicaid beneficiaries. Hospitals that make such payments are subject to CMPs up to $2,000.00 per patient. The AMA supports a safe harbor for gainsharing arrangements that meet certain criteria to be established by the OIG including transparency, requested disclosure to patients, and patient care safeguards.

- Antikickback Statute (AKS) - §1128B of the Social Security Act contains the AKS which prohibits an entity or person (the payor) from paying, or even offering to pay remuneration, i.e., anything of value, to a person or entity (payee) in exchange for the payee making referrals to, or otherwise generating business for, the payor. The AKS contains a number of safe harbors, which if satisfied, protect the parties to an arrangement from AKS exposure. A violation of the AKS can result in civil penalties, program exclusion, and even possible imprisonment. The AMA has urged the OIG to establish a safe harbor for physician organizations that are integrating in an effort to become ACOs. ACOs that involve integration of physicians practice must have safe harbor protection since these organizations will need to exercise a degree of control over the physician's referrals.

- The Stark Law – Title XVIII of the Social Security Act contains the Stark statute and its implementing regulations. The Stark Law prohibits a physician from referring a Medicare beneficiary to an entity for the furnishing of designated health service (DHS) if the physician (or the physician's immediate family member) has a financial relationship with the entity, unless a Stark Law exception applies. A financial relationship can take the form of an ownership/investment interest. A financial arrangement may be a compensation arrangement. A violation of the Stark Law, even a technical violation, can result in substantial civil penalties and program exclusion. The AMA urges the OIG to waive current Stark Law restrictions or create a new exception for physician led ACOs.

> Accordingly, if a physician organization is integrating as a means of becoming an ACO, that organization's payment to its constituent members should be excepted from the Stark Law if the remuneration is consistent with fair market value of members' services and not determined in a manner that takes into account the volume or value of any members' referrals.

It is impossible to know, at this time, exactly how a physician network should be structured to seek approval as an ACO. As specific regulations governing the required structure and activities of ACOs have not yet been created, nonetheless published, the future course and/or potential viability of any contemplated ACO will require careful scrutiny and detailed analysis.

Kern Augustine Conroy & Schoppmann, P.C., Attorneys to Health Professionals, www.drlaw.com has offices in New York, New Jersey, Pennsylvania and Illinois. The firm's practice is solely devoted to the representation of health care professionals. The authors may be contacted at 1-800-445-0954 or via email at dmoy@drlaw.com, mschoppmann@drlaw.com ormlevy@drlaw.com.