CMS/OIG, FTC/DOJ and IRS Weigh In on ACOs

Apr 06 2011

Posted By: Jeffrey E. Mark

Practice Area: Health Law & Health Intellectual Property

"The Administration has led an unprecedented, collaborative effort among all of the agencies responsible for developing guidance for ACOs," said FTC Chairman Jon Leibowitz. "*This guidance will help ensure that ACOs meet their goals of improving quality and lowering costs while minimizing the regulatory burden on healthcare providers."*

As the Chairman notes, the agencies responsible for development and oversight of Accountable Care Organizations ("ACOs") issued on March 31, 2011 guidance regarding qualification and implementation of Medicare Shared Savings Programs. This *Update* provides summaries of the proposed rules offered by the Centers for Medicare & Medicaid Services ("CMS")/Department of Health and Human Services Office of Inspector General ("OIG") and Federal Trade Commission ("FTC")/Antitrust Division of the Department of Justice ("DOJ") and the notice issued by the Internal Revenue Service ("IRS") all of which address ACOs. The agencies will accept public comments until May 31, 2011.

Waivers of Fraud and Abuse Laws
As hospitals, physicians and other providers establish the infrastructure and ultimately develop methodologies for sharing the savings and risks of ACOs, new financial and referral relationships will arise that are not contemplated – or protected – under the existing statutory and regulatory framework of fraud and abuse laws. In particular, these relationships raise liability concerns under the civil monetary penalties ("CMP") law, the federal anti-kickback statute ("AKS"), and the federal physician self-referral law ("Stark"). For example, hospitals may contribute up-front human and financial capital in establishing the legal and corporate framework through which ACOs operate; those contributions could constitute "remuneration" to referring physicians who then participate in or otherwise refer to those entities, remuneration that does not neatly fit into existing Stark exceptions or AKS safe harbors. Shared savings methodologies pose similar issues, as well as the potential that such methodologies might be construed as a gainsharing program involving hospital payments to physicians in order to reduce or limit services to Medicare or Medicaid beneficiaries in the physicians' care, in potential violation of the CMP law.

Section 1899(f) of the Affordable Care Act ("ACA") authorized the Secretary of DHHS to waive certain fraud and abuse laws as necessary to carry out the provisions of the Shared Savings Programs. This waiver authority only applies to the ACA Shared Savings Program; the statute does not specifically address waivers for ACOs or other integrated care models that fall outside of the ACA program. In a joint document released on the same day as the proposed ACO regulations, CMS and OIG have solicited comments on a waiver program addressing these fraud and abuse considerations.

The common elements for all of these proposed waivers include the following:

- The ACO would be required to enter into an agreement with CMS under the Shared Savings Program.
- The ACO, all ACO participants, and ACO providers would be required to comply with the agreement, the pertinent provisions of the ACA, and all implementing regulations, including but not limited to requirements pertaining to transparency, reporting and monitoring.

Stark and AKS Waivers.
Waivers under Stark and the AKS would apply to distributions of shared savings received by an ACO from CMS (1) to or among ACO participants and ACO providers/suppliers; and (2) for other activities necessary for and directly related to the ACO's participation in the Shared Savings Program. In addition, OIG would create what amounts to a new AKS safe harbor for financial relationships between or among the ACO, ACO participants and ACO providers/suppliers that are necessary for and directly related to the ACO's participation in the Shared Savings Program where those financial relationships would implicate Stark and meet a Stark exception. Compliance with a Stark exception ordinarily does not insulate the involved parties from potential AKS liability, but in this instance OIG believes that compliance with both Stark and ACO program requirements will provide sufficient safeguards to warrant a waiver of AKS liability.

CMP Waivers.
The waiver as to the CMP would apply to payments by a hospital to a physician where the hospital and physician were ACO participants or providers/suppliers, so long as the payments were not made knowingly to induce the physician to reduce or limit medically necessary items or services. This is a key distinction, as the CMP law as currently interpreted and enforced applies even to payments that are only intended to limit or reduce medically unnecessary items or services. Under the proposed waiver, such payments would now be exempt from the CMP so long as the other waiver requirements are met. As with the AKS waivers, OIG also proposes to waive the CMP as to financial relationships between or among the ACO, ACO participants and ACO providers/suppliers that are necessary for and directly related to the ACO's participation in the Shared Savings Program where those financial relationships would implicate Stark and meet a Stark exception.

Duration of Waivers.
Under these proposals, waivers applicable to the distribution of shared savings will apply to the distribution of shared savings earned during the term of an ACO agreement even if the actual distribution takes place after the expiration of the agreement. Waivers under the AKS and CMP that are premised upon meeting a Stark exception would only be available during the term of the ACO's agreement with CMS, however.

Open Questions.
While helpful, the proposed waiver program leaves many unanswered questions, a point acknowledged by CMS and OIG in their joint document. For example, the waiver program as currently proposed would only apply to distributions of shared savings, but would not protect remuneration or other financial relationships relating to the initial formation of the ACO, implementation of governance or administrative requirements relating to the ACO or the building of the technological or administrative capacity needed to achieve cost and quality goals under the program. The capital investment required to establish and operate an ACO are huge, and the absence of waiver protection may create substantial uncertainty and disincentives among hospitals, physicians and other providers as they sort through various funding methodologies.

Similarly, the proposed waivers would not protect other financial relationships between or among the ACO, ACO participants, and ACO suppliers/providers that might be directly related to and necessary for the operation of the ACO, including relationships that are designed to achieve integrated care, cost savings, and quality goals.

A third area not covered by the proposed waiver program involves ACOs and their participants who have entered into innovative savings arrangements with commercial payers. The proposed program only covers the distribution of shared payments received from CMS under the Shared Savings Program. Many providers are already engaged with private payers in establishing accountable care strategies that may involve incentive payments relating to quality and cost-savings initiatives, where those payments could be shared with physicians who refer to other participants in the organization. Even though these referrals may involve services that are not paid for by Medicare/Medicaid, fraud and abuse laws may still be implicated in situations involving potential "swapping" of referrals or (in the case of Stark) "other business generated" between the parties.

As noted above, CMS and OIG recognize that there may be a need to expand the waiver program to address these situations as well as other circumstances where Stark exceptions or AKS safe harbors might otherwise be unavailable. The agencies have solicited comments on how waivers might be crafted to address these concerns, and what safeguards would be necessary in order to qualify for those protections.

Timeline for Finalizing Waiver Program.
CMS and OIG have solicited comments on the proposed waiver programs during the next sixty days. Due to the close interrelationship between the waivers and the underlying Shared Savings Programs, the agencies will also consider comments relating to ACO requirements when they craft final rules on the waivers. The agencies therefore anticipate that the fraud and abuse waivers will be issued at the same time that CMS releases the final ACO regulations.

Antitrust: FTC/DOJ Proposed Policy Statement
In a joint statement the FTC and DOJ (jointly the "Antitrust Agencies") issued on March 31, 2011, the Antitrust Agencies state how they propose to analyze and enforce the antitrust laws in relation to ACOs. The Antitrust Agencies recognize the opportunities that ACOs present, but remain focused on ensuring that the collaborative efforts of ACO participants do not diminish competition. The Policy Statement proposes to create an antitrust "safety zone" for ACOs satisfying certain criteria, establishes an expedited antitrust review for ACOs not fitting within the safety zone and describes CMS' mandatory antitrust review process for certain ACOs.

The Antitrust Agencies state affirmatively that CMS' criteria for ACOs is consistent with the Antitrust Agencies' expectations for clinical integration. Further, the Antitrust Agencies believe that ACOs satisfying CMS' criteria are likely to improve quality and reduce cost through joint efforts. These assumptions and CMS' monitoring of various metrics, provide the basis for the Antitrust Agencies' decision to apply rule of reason treatment to ACOs whose operations and governance are the same for their Shared Savings Program and commercial market participation. The rule of reason standard balances anticompetitive harm against beneficial aspects of an arrangement.

Category of Antitrust Review
The potential for anticompetitive impact will largely depend on an ACO's share of services in each ACO participant's primary service area ("PSA"). The larger an ACO's share in a PSA, the greater the risk for anticompetitive harm. The Antitrust Agencies' treatment of ACO applicants will fall into three categories determined by an ACO's PSA share.

The categories are:

1. safety zone – absent extraordinary circumstances, ACOs falling within the safety zone (criteria below) will not be challenged and do not need not the Antitrust Agencies' review;
2. mandatory review prior to participating in the Shared Savings Program – ACOs whose share exceeds 50% (unless the rural exception applies) for any common service that two or more ACO participants provide to patients in the same PSA; and
3. voluntary review – ACOs with shares between 30% and 50% may elect to have an optional antitrust review by the Antitrust Agencies.

ACO Safety Zone
The ACO safety zone requires that ACO participants (*e.g.,* physician group practices) that provide the same service (a "common service") must have a combined share of 30% or less of each common service in each participant's PSA, wherever two or more ACO participants provide that service to patients from that PSA. The Antitrust Agencies use Medicare's definition of PSA: "the lowest number of contiguous postal zip codes from which the [ACO participant] draws at least 75 percent of its [patients]" for that service. Further, any hospital or ambulatory surgery center ("ASC") participating in an ACO must be non-exclusive to the ACO, regardless of its PSA share. In this context, non-exclusive means that a hospital or ASC is able to contract directly with payers (outside of the ACO) or affiliate with other ACOs or commercial payers. Finally, the Dominant Provider Limitation applies to any ACO that has a participant with a greater than 50% share in its PSA of any service that no other ACO participant provides to patients in that PSA. If an ACO has a dominant provider, the dominant provider must be non-exclusive to the ACO to fall within the safety zone. In addition, to fall within the safety zone, an ACO with a dominant provider cannot require a commercial payer to contract exclusively with the ACO or otherwise restrict a commercial payer's ability to contract or deal with other ACOs or provider networks.

Expedited Review
ACOs that are required or elect to have an expedited review must submit a request to both Antitrust Agencies who will determine which of them will conduct the review. The ACO must submit information and documentation specified in the Policy Statement to the reviewing Agency for consideration and analysis. Within 90 days of receiving all of the necessary documents and information, the reviewing Agency will complete the review and notify the ACO regarding the outcome.

Conduct to Be Avoided
ACOs that are in the voluntary review category may conduct their ACO activities without Agency review. To provide additional guidance to these ACOs, the Antitrust Agencies identify five types of conduct that reduce significantly the likelihood of an antitrust investigation. The Antitrust Agencies note that avoiding the first four types of conduct is important to facilitate payers' ability to offer insurance products that differentiate among providers based on cost and quality. Avoiding the final type of conduct ensures that the ACO does not facilitate collusion involving ACO participants that contract with payers outside the ACO.

1. Preventing or discouraging commercial payers from directing or incentivizing patients to choose certain providers, including providers that do not participate in the ACO, through "anti-steering," "guaranteed inclusion," "product participation," "price parity," or similar contractual clauses or provisions
2. Tying sales (either explicitly or implicitly through pricing policies) of the ACO's services to the commercial payer's purchase of other services from providers outside the ACO (and vice versa), including providers affiliated with an ACO participant (*e.g.,* an ACO may not require a purchaser to contract with all the hospitals in the same network as the hospital that belongs to the ACO)
3. With an exception for primary care physicians, contracting with other ACO physician specialists, hospitals, ASCs or other providers on an exclusive basis, thus preventing or discouraging them from contracting outside the ACO, either individually or through other ACOs or provider networks
4. Restricting a commercial payer's ability to make available to its health plan enrollees cost, quality, efficiency and performance information to aid enrollees in evaluating and selecting providers in the health plan, if that information is similar to the cost, quality, efficiency and performance measures used in the Shared Savings Program
5. Sharing among the ACO's provider participants competitively sensitive pricing or other data that they could use to set prices or other terms for services they provide outside the ACO

The Appendix to the Policy Statement sets forth in detail the method of calculating shares.

The Policy Statement solicits feedback regarding changes to the guidance offered, suggestions for other data sources that could be used to determine relevant PSA shares and whether the Policy Statement is an overly burdensome process for ACOs. The Antitrust Agencies are accepting comments to the Policy Statement until May 31, 2011.

IRS Notice

The IRS has posted a notice and request for comments regarding issues for tax exempt organizations participating in various activities through an ACO. Tax exempt organizations must be mindful of private inurement and unrelated business income tax ("UBIT") issues. The IRS's notice and request pertains to both activities related to and unrelated to the Shared Savings Program, including any shared savings arrangements with other payers (*e.g.,* commercial payers).

Shared Savings Program

• Shared Savings Program – Private Inurement and Impermissible Private Benefit. Tax exempt organizations must operate exclusively for charitable and/or certain other tax exempt purposes. Organizations are not operating exclusively for tax exempt purposes if part of the organization's income inures to the benefit of "insiders" or the organization operates for the benefit of private parties. Some of the participants in an ACO may be "insiders." The IRS determines on a case-by-case basis whether private inurement or impermissible private benefit has occurred. The IRS, however, expects that private inurement or impermissible private benefit will not occur if all of the following circumstances are satisfied:

o The terms of the tax-exempt organization's participation in the Shared Savings program through the ACO are set forth in advance in a written agreement, negotiated at arm's length. The written agreement must include the tax-exempt organization's share of Shared Savings Program payments or losses and expenses.

o CMS has accepted the ACO into the Shared Savings Program. Additionally, CMS must not have terminated the ACO's participation in the Shared Savings Program.

o The tax-exempt organization's share of economic benefits (including its share of the Shared Savings Program payments)derived from the ACO is proportional to the benefits and contributions the tax-exempt organization provides to the ACO. Any ownership interest the tax exempt organization receives in the ACO is proportional and equal in value to the organization's capital contributions to the ACO and all returns of capital, allocations and distributions are made in proportion to ownership interests.

o The tax exempt organization's share of the ACO's losses does not exceed the share of the ACO's economic benefits to which the tax-exempt organization is entitled.

o All contracts and transactions entered into by the tax-exempt organization with the ACO and its participants are at fair market value. Additionally, all contracts and transactions entered into by ACO with its participants and any other parties are at fair market value. Note that establishing fair market value may pose challenges due to the innovative nature of the financial relationships attendant to the ACO Shared Savings Program, where market comparables may not be readily available.

• Shared Savings Program – UBIT. UBIT is a tax on income derived by tax exempt organizations from any unrelated trade or business. An unrelated trade or business is generally any trade or business that is not substantially related to the performance of the organization's tax exempt purpose. The IRS expects that any Shared Savings Program payments received by the tax exempt organization from an ACO would not result in UBIT, absent private inurement or impermissible private benefit. This is because the IRS expects that any Shared Savings Program payments received by the tax exempt organization would derive from activities substantially related to the performance of the charitable purpose of lessening the burdens of government. The organization, however, would have to meet all eligibility requirements established by CMS for participation in the Shared savings Program.

The IRS requests comments on whether tax exempt organizations require any additional guidance relating to the Shared Savings Program. If additional guidance is requested, the IRS seeks comments on the criteria and requirements for determining whether: (1) an organization's participation in the Shared Savings Program through an ACO is consistent with tax exempt status; and (2) whether the organization is receiving any unrelated business income.

Activities Unrelated to the Shared Savings Program
The IRS anticipates that an ACO may engage in activities unrelated to the Shared Savings Program through an ACO, such as shared savings arrangements with other payers. The IRS indicates that many activities unrelated to the Shared Savings Program may be substantially unrelated to an exempt purpose. According to the IRS, many such activities are unlikely to lessen the burdens of the government. And while the promotion of health is often a tax exempt purpose, the IRS points out that not every activity that promotes health supports tax exemption. The IRS ultimately declines in its notice to address the circumstances under which a tax-exempt organization's participation in activities unrelated to the Shared Savings Program through an ACO would be consistent with the organization's tax exemption and not result in UBIT. The IRS instead requests comments on what guidance is necessary for such unrelated activities.
