Accountable Care Organizations – Multiple Comment Periods

Proposed Waivers – CMS and OIG

CMS and HHS Office of Inspector General (OIG) jointly issued a notice with comment period outlining proposals for waivers of certain Federal laws-the physician self-referral law, the anti-kickback statute, and certain provisions of the civil monetary penalty law-in connection with the Shared Savings Program. CMS and OIG are also asking for comments on further waiver design considerations for the Shared Savings Program and for the separate waiver authority for the Center for Medicare and Medicaid Innovation under section 1115A of the Social Security Act. Comments will be due 60 days after they are formally published in the Federal Register.

Three year agreement, Two track process. As proposed in the Medicare Shared Savings Program proposed rule, ACOs will enter into an agreement with the Secretary to participate in the Medicare Shared Savings Program for not less than a 3-year period under one of two tracks. Under the first track, an ACO would have the opportunity to share in actual savings during the first 2 years of the agreement. During the third year, the ACOs would be in a "two-sided risk" model in which they would be eligible to receive a higher potential shared savings, but also would be required to repay the Medicare program if costs for the ACO's aligned beneficiaries exceed certain thresholds. Under the second track, ACOs would operate under the two-sided risk model from the beginning of their agreement period. Under either model, in order to share a percentage of achieved savings with the Medicare program, ACOs must successfully meet quality and savings requirements and certain other conditions under the Medicare Shared Savings Program.

Proposed waivers. Pursuant to the authority granted under section 1899(f) of the Act, the Secretary would waive sections 1128A(b)(1) and (2), 1128B(b)(1) and (2), and 1877(a) of the Act in the specific circumstances. The waivers would not apply to any other provisions of Federal or State law. All financial arrangements not covered by a waiver would be required to comply with existing laws. The waivers related to the distribution of shared savings would apply to the distributions of shared savings earned by the ACO during the term of agreement with CMS to participate in the Medicare Shared Savings Program, even if the actual distributions occur after the expiration of the agreement. In contrast, the anti-kickback and the reduction or limitations of services waivers would only apply during the term of the ACO's agreement with CMS to participate in the Medicare Shared Savings Program.

- *Physician Self-Referral Law (Section 1877(a) of the Act)* --Under this proposal, the Secretary would waive application of the provisions of section 1877(a) of the Act (42 U.S.C. 1395nn(a)) to distributions of shared savings received by an ACO from CMS under the Medicare Shared Savings Program: (1) to or among ACO participants, ACO providers/suppliers, and individuals and entities that were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO; or (2) for activities necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program. This proposed waiver would be limited to distributions of shared savings; all other financial relationships involving physicians (or their immediate family members) or entities participating in the Medicare Shared Savings Program that implicate the Physician Self-Referral Law would still need to satisfy an existing exception.

- *The Anti-Kickback Statute (Sections 1128B(b)(1) and (2) of the Act)* -- Under this proposal, the Secretary would waive application of the provisions of sections 1128B(b)(1) and (2) of the Act (42 U.S.C. 1320a-7b(b)(1)–(2)) with respect to the following two scenarios:
    - Distributions of shared savings received by an ACO from CMS under the Medicare Shared Savings Program: (1) to or among ACO participants, ACO providers/suppliers, and individuals and entities that were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO; or (2) for activities necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program.
    - Any financial relationship between or among the ACO, ACO participants, and ACO providers/suppliers necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program that implicates the Physician Self-Referral Law and fully complies with an exception at 42 CFR 411.355 through 411.357.
- *Prohibition on Hospital Payments to Physicians to Induce Reduction or Limitation of Services (Sections 1128A(b)(1) and (2) of the Act)*--Under this proposal, the Secretary would waive application of the provisions of sections 1128A(b)(1) and (2) of the Act (42 U.S.C. 1320a-7a(b)(1) and (2)) with respect to the following two scenarios:
    - Distributions of shared savings received by an ACO from CMS under the Medicare Shared Savings Program in circumstances where the distributions are made from a hospital to a physician, provided that (1)the payments are not made knowingly to induce the physician to reduce or limit medically necessary items or services; and (2) the hospital and physician are ACO participants or ACO providers/suppliers, or were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO.
    - Any financial relationship between or among the ACO, its ACO participants, and its ACO providers/suppliers necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program that implicates the Physician Self-Referral Law and fully complies with an exception at 42 CFR 411.355 through 411.357.

Commenting on additional waivers. HHS is soliciting comments regarding waivers for financial arrangements that would be necessary to carry out the provisions of the Medicare Shared Savings Program. When commenting in response to this notice with comment period, please explain how any favored waivers, modifications, or additions would be necessary to carry out the provisions of the Medicare Shared Savings Program and why the financial arrangements at issue would not qualify for existing safe harbors or exceptions.

Additional areas of comments. HHS is also soliciting comments regarding –

- *Arrangements related to establishing the ACO.* Provide comments addressing whether it is necessary to waive certain requirements directly related to: (1) forming the ACO; (2) implementing the governance and administrative requirements applicable to the ACO under the final regulations for the Medicare Shared Savings Program; or (3) building technological or administrative capacity (including providing training) needed to achieve the Medicare Shared Savings Program cost and quality goals.
- *Ongoing operations of the ACO and achieving ACO goals.* Provide comments on whether the proposed waivers should include other financial arrangements.
- *Outside entities.* Provide comments on whether additional entities should be subject to the waivers.
- *Private payers.* Provide comments on whether a waiver is necessary to address distributions of shared savings payments received by the ACO from a private payer.

- *Other financial arrangements.* Comment on whether there are financial arrangements not addressed in the proposed waivers that should apply.
- *Duration of the waivers.* Comment on whether the currently proposed duration is sufficient.
- *Additional safeguards.* Comment on whether additional safeguards are warranted.
- *Scope of the proposed waivers.* Comment on whether the scope is too broad or too narrow.
- *Two-sided risk model.* Comment on whether different waivers are required for the proposed two-sided risk model.
- *Electronic health records.* Comment on whether HHS should waive the Physician Self-Referral Law and anti-kickback statute for ACO arrangements that satisfy the existing exception and safe harbor for electronic health records arrangements (42 CFR 411.357(w) and 42 CFR 1001.952(y)), but that are expected to occur after the sunset date of 2013 currently applicable to that exception and safe harbor.
- *Beneficiary inducements.* Comment on whether and under what circumstances it would be necessary for the Secretary to waive, in whole or in part, the provisions of section 1128A(a)(5) of the Act (the prohibition on inducements offered to Medicare and Medicaid beneficiaries) in connection with the Medicare Shared Savings Program.
- *Timing of waivers.* Comment on whether final waivers should be published contemporaneously with, in advance of, or soon after final rule regarding the Medicare Shared Savings Program.

Antitrust Policy Statement – FTC and DoJ

The Federal Trade Commission and the Department of Justice jointly issued a "Proposed Statement of Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program" (Antitrust Policy Statement). Comments are due May 31, 2011.

Primary Service Area and Safety Zones. As an initial step in determining whether an ACO is likely to raise competitive concerns, the Agencies will use a streamlined analysis that evaluates the ACO's share of services in each ACO participant's Primary Service Area ("PSA"). The higher the PSA share, the greater the risk the ACO will be anticompetitive. Therefore, the Agencies will treat ACO applicants that meet CMS eligibility criteria for the Shared Savings Program based on how they fit in the different ranges of PSA shares. Depending on an ACO's range of PSA shares, CMS may mandate, or an ACO may choose to seek, an expedited antitrust review. For ACOs that meet the CMS eligibility criteria to participate in the Shared Savings Program and are highly unlikely to raise significant competitive concerns, the Agencies will not challenge ACOs that fall within the safety zone, absent extraordinary circumstances. ACOs in the safety zone, therefore, have no obligation to contact the Agencies.

Definition of safety zone.

- *30 percent or less.* Independent ACO participants (e.g., physician group practices) that provide the same service (a "common service") must have a combined share of 30 percent 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 PSA for each service is defined as "the lowest number of contiguous postal zip codes from which the [ACO participant] draws at least 75 percent of its [patients]" for that service.
- *Non-exclusive hospitals and ASCs.* Any hospital or ambulatory surgery center ("ASC") participating in an ACO must be non-exclusive to the ACO to fall within the safety zone, regardless of its PSA share. In a non-exclusive ACO, a hospital or ASC is allowed to contract individually or affiliate with other ACOs or commercial payers.

- *Rural exception.* An ACO may include one physician per specialty from each rural county (as defined by the U.S. Census Bureau) *on a non-exclusive basis* and qualify for the safety zone, even if the inclusion of these physicians causes the ACO's share of any common service to exceed 30 percent in any ACO participant's PSA for that service. Likewise, an ACO may include Rural Hospitals *on a non-exclusive basis* and qualify for the safety zone, even if the inclusion of a Rural Hospital causes the ACO's share of any common service to exceed 30 percent in any ACO participant's PSA for that service.
- *Dominant provider limitation.* This limitation applies to any ACO that includes a participant with a greater than 50 percent share in its PSA of any service that no other ACO participant provides to patients in that PSA. Under these conditions, the ACO participant (a "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.

Duration of the safety zone. The safety zone will remain in effect for the duration of an ACO's agreement with CMS, unless there is a significant change to the ACO's provider composition. An ACO that is not within the rural exception and later exceeds the 30 percent share limitation solely because it attracts more patients will not lose its safety zone status.

Mandatory review of PSA above 50. As described in the CMS regulations, an ACO that does not qualify for the rural exception cannot participate in the Shared Savings Program if its share exceeds 50 percent for any common service that two or more independent ACO participants provide to patients in the same PSA, unless, as part of the CMS application process, the ACO provides CMS with a letter from one of the Agencies stating that the reviewing Agency has no present intention to challenge or recommend challenging the ACO under the antitrust laws.

Potential review of PSA below 50 but not in the Safety zone. ACOs that are outside the safety zone and below the 50 percent mandatory review threshold frequently may be procompetitive. As is current practice, however, if it appears that an ACO's formation or conduct may be anticompetitive, one of the Agencies may investigate the ACO and, if appropriate, take enforcement action at any time during the ACO's participation in the Shared Savings Program. To provide additional antitrust guidance for ACOs that fall below the mandatory review threshold and outside the safety zone, the Agencies identify five types of conduct that an ACO can avoid to reduce significantly the likelihood of an antitrust investigation.

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

Tax-exempt organizations -- IRS

The Internal Revenue Service (IRS) issued a notice requesting comments regarding the need for guidance on participation by tax-exempt organizations in the Shared Savings Program through ACOs.

Tax-exempt participation. The IRS anticipates that tax-exempt organizations typically will be participating in the Medicare Shared Savings Program (MSSP) through an ACO along with private parties, including some that might be considered insiders with respect to the tax-exempt organization. The IRS further anticipates that a tax-exempt organization's participation may take a variety of forms, including membership in a nonprofit membership corporation, ownership of shares in a corporation, ownership of a partnership interest in a partnership (or a membership interest in an LLC), and contractual arrangements with the ACO and/or its other participants.

Issue of net earnings. To avoid adverse tax consequences, the tax-exempt organization must ensure that its participation in the MSSP through an ACO is structured so as not to result in its net earnings inuring to the benefit of its insiders or in its being operated for the benefit of private parties participating in the ACO. The IRS must determine whether prohibited inurement or impermissible private benefit has occurred on a case-by-case basis, based on all the facts and circumstances. Because of CMS regulation and oversight of the MSSP, as a general matter, the IRS expects that it will not consider a tax-exempt organization's participation in the MSSP through an ACO to result in inurement or impermissible private benefit to the private party ACO participants where:

- The terms of the tax-exempt organization's participation in the MSSP through the ACO (including its share of MSSP payments or losses and expenses) are set forth in advance in a written agreement negotiated at arm's length.
- CMS has accepted the ACO into, and has not terminated the ACO from, the MSSP.
- The tax-exempt organization's share of economic benefits derived from the ACO (including its share of MSSP payments) is proportional to the benefits or contributions the tax-exempt organization provides to the ACO. If the tax-exempt organization receives an ownership interest in the ACO, the ownership interest received is proportional and equal in value to its capital contributions to the ACO and all ACO returns of capital, allocations and distributions are made in proportion to ownership interests.
- The tax-exempt organization's share of the ACO's losses (including its share of MSSP losses) does not exceed the share of ACO economic benefits to which the tax-exempt organization is entitled.
- All contracts and transactions entered into by the tax-exempt organization with the ACO and the ACO's participants, and by the ACO with the ACO's participants and any other parties, are at fair market value.

Unrelated Business Income Tax (UBIT). An additional issue raised by the participation of tax exempt organizations in ACOs is whether the share of the MSSP payments received by a tax-exempt organization will be subject to unrelated business income tax (UBIT) under § 511. Whether the MSSP payments will be subject to UBIT depends on whether the activities generating the MSSP payments are

substantially related to the exercise or performance of the tax-exempt organization's charitable purposes constituting the basis for its exemption under § 501. The IRS expects that, absent inurement or impermissible private benefit, any MSSP payments received by a tax-exempt organization from an ACO would derive from activities that are substantially related to the performance of the charitable purpose of lessening the burdens of government within the meaning of Treas. Reg. § 1.501(c)(3)-1(d)(2), as long as the ACO meets all of the eligibility requirements established by CMS for participation in the MSSP.

Conduct of activities unrelated to MSSP. The IRS seeks comments regarding how a tax-exempt organization's participation in particular non-MSSP activities through an ACO further or are substantially related to an exempt purpose.