Health Care Reform ALERT
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CMS and OIG Issue Joint Notice, Solicit Comments Related to Waivers of Fraud and Abuse Provisions for Accountable Care Organizations

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On March 31, 2011, the Centers for Medicare & Medicaid Services (CMS) and the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) issued the long-awaited joint notice proposing regulatory waivers to encourage arrangements involving accountable care organizations (ACOs) formed in connection with the Medicare Shared Savings Program authorized by the Patient Protection and Affordable Care Act (ACA).

The formation of ACOs, including any corresponding waivers of fraud and abuse provisions, is an area that will receive considerable attention between now and when comments are due (currently expected to be May 30, 2011), as well as when CMS issues the ACO final rule.

The proposed waivers (the "Waiver Proposal")[1] involve the physician self-referral (or "Stark") law,[2] the federal anti-kickback statute (the "AKS"),[3] and the prohibition on hospital payments to physicians to induce reduction or limitation of services (the "Gainsharing CMP").[4] CMS and OIG also solicited comments "on different, potentially broader waivers, as well as additional waiver design considerations." The Waiver Proposal was published the same day CMS issued a proposed rule outlining the requirements for ACOs to participate in the Medicare Shared Savings Program (the "ACO Proposed Rule").[5]

Background

The ACA[6] authorized the Medicare Shared Savings Program (the "Program"),[7] which will permit groups of health care providers and suppliers to receive additional Medicare payments for shared savings if the parties coordinating care through ACOs meet performance standards the Secretary of HHS establishes. Most health care industry observers expect that ACOs will have larger purposes than the narrow goals set forth in the Program, but our focus here is a discussion of ACOs as they will function under the Program.

The ACO Proposed Rule requires ACOs to participate in the Program for at least three years and enter into one of two tracks. Track one permits the ACO to share in actual savings to the Medicare program during the first two years of the agreement, but requires the ACO to enter into a "two-sided risk model" during the third year, thereby permitting a higher rate of savings but also requiring the ACO to repay the Medicare program if certain benchmarks are not met. Track two requires ACOs to enter into the "two-sided risk model" at the beginning of the agreement. Both tracks require ACOs to meet quality and savings requirements established by the Secretary of HHS.

Although the Program is intended to encourage integrated delivery models designed, as CMS states, to achieve "better health, better care, and lower cost," sharing in Medicare savings and entering into arrangements structured like the two-sided risk model mentioned above would normally implicate

many of the fraud and abuse statutes designed to address overutilization, underutilization, waste, and health care decision-making based on a physician's financial incentives. Accordingly, the Program permits the Secretary of HHS to waive various fraud and abuse laws, including the Stark law, the AKS, and the Gainsharing CMP, that would otherwise be implicated for those providers and suppliers that form ACOs and meet the Program's requirements.[8]

Proposed Waivers

The Waiver Proposal states that in order to qualify for any of the waivers, the following two conditions must be met: (1) ACOs must enter into an agreement with CMS to participate in the Program; and (2) ACOs, ACO participants, and ACO providers/suppliers must comply with the agreements required under the Program (section 1899 of the Social Security Act and its implementing regulations).

Under the Waiver Proposal, the Secretary would waive the Stark law and the AKS for distributions of shared savings received by an ACO from Medicare to ACO participants and providers/suppliers during the year the ACO earned shared savings or for activities necessary and directly related to the ACO's participation in and operations under the Program. The waiver would not apply to a physician's referrals outside an ACO unless the ACO is compensating the physician for activities necessary for and directly related to the ACO's participation and operations under the Program. The Waiver Proposal further states that the OIG would waive application of the AKS if there is a financial relationship between or among the parties to an ACO necessary for and directly related to the ACO's participation in and operations under the Program that implicates the Stark law but complies with a Stark exception.

CMS and OIG highlight how tying the AKS to the Stark law is inconsistent with existing guidance:

> Ordinarily, compliance with an exception to the Physician Self-Referral Law does not operate to immunize conduct under the anti-kickback statute, and arrangements that comply with the Physician Self-Referral Law are still subject to scrutiny under the anti-kickback statute. Here, however, in light of the specific safeguards proposed to be incorporated in the Medicare Shared Savings Program, the authority under section 1899(f) of the Act for the Secretary to waive the anti-kickback statute as necessary to carry out section 1899 of the Act, and our desire to minimize burdens on entities establishing ACOs under section 1899 of the Act, we are proposing a limited exception to the general rule.

The OIG would waive provisions related to the Gainsharing CMP, which are similar to the Stark law and the AKS waivers but that are tailored more narrowly to the requirements of this civil money penalty, in the following two scenarios:

1. Distributions of shared savings received by an ACO from Medicare in circumstances where the distributions are made from a hospital to a physician, provided that: (a) the payments are not made knowingly to induce the physician to reduce or limit medically necessary items or services; and (b) the hospital and physician are parties to the ACO during the year in which the shared savings were earned; and
2. Any financial relationship between or among the parties to the ACO necessary for and directly related to the ACO's participating in and operations under the Program that implicates the Stark law and fully complies with a Stark exception.

CMS and OIG plan to issue waivers for ACOs participating in the Program concurrently with CMS's publication of the ACO final rule. The agencies further note that the waiver authority is specific to the Program and does not address other integrated-care delivery models. The agencies state, however, that waivers of exceptions and/or safe harbors for other integrated delivery models may be considered at a later date. It is important to note that CMS and OIG are not proceeding here under their respective authorities to promulgate new Stark law exceptions or AKS safe harbors.[9] The proposed waivers do not apply to any other provisions of federal or state law.

Solicitation of Comments

Perhaps based on the observation that "no clear consensus has emerged on the scope of the waivers necessary to carry out the Medicare Shared Savings Program," CMS and OIG are soliciting comments on a range of topics. They include:

- Whether the Stark law, the AKS, and the Gainsharing CMP should be waived for remuneration received directly related to: (1) the ACO's formation; (2) the implementation of the governance and administrative requirements required under the Program's final rule; and (3) the construction of the technological or administrative capacity to achieve the Program's cost and quality goals.
- Whether the Stark law, the AKS, and the Gainsharing CMP should be waived for financial arrangements that are necessary for or directly related to operating the ACO or achieving the integrated care, cost savings, and quality goals of the Program.
- Whether the Stark law, the AKS, and the Gainsharing CMP should be waived between the ACO, its ACO participants, and/or its ACO providers/suppliers and outside individuals or entities.
- Whether a waiver is necessary to address distributions of shared savings payments received by the ACO from a private payer.
- Whether there are financial arrangements that are not addressed in the Waiver Proposal for which waivers of the Stark law, the AKS, or the Gainsharing CMP should apply.
- The duration of the length of waivers.
- Whether additional safeguards are needed to protect patients and Federal health care programs.
- Whether the waivers CMS and OIG proposed are too broad or too narrow, and, if so, how this should be addressed.
- Whether additional or different fraud and abuse waivers are appropriate for ACOs participating in the two-sided risk model.
- Whether the Stark law and AKS should be waived for arrangements that meet the electronic health records exception/safe harbor, which are scheduled to sunset on December 31, 2013.
- Whether, and under what circumstances, it would be necessary to waive the provisions of the CMP law related to the prohibition on inducements offered to Medicare and Medicaid beneficiaries.
- Whether final waivers should be published at the same time, before, or after the final rule regarding the Program is published.
- How waiver authority can be best exercised relating to a different section of the ACA,[10] which establishes the Center for Medicare and Medicaid Innovation within CMS and provides additional waiver authority.

The many comments CMS and OIG solicit illustrate the uncertainty surrounding the technical requirements, the breadth, and the shape that waivers of the Stark law, the AKS, and the Gainsharing CMP will take for ACOs meeting the Program's standards. Questions will continue to arise, at least until CMS and the OIG issue the ACO final rule. Nevertheless, CMS and OIG deserve credit for planning to issue waivers concurrently with CMS's publication of the ACO final rule, thereby enabling providers and suppliers to enter the Program with assurances that they will not be out of compliance with fraud and abuse laws. Although the Waiver Proposal is very narrow in scope (and applies only to ACOs in the Program), we are confident the agencies will receive, and consider carefully, many

comments suggesting broader waivers (including requests that CMS and the OIG use their authorities to either create exceptions/safe harbors or promulgate regulations related to waivers set forth in other sections of the ACA) to providers and suppliers forming integrated-delivery models not meeting the Program's requirements. Clients should review carefully the Waiver Proposal and determine if it is adequate to protect the financial relationships they plan for the future, and consider submitting comments for agency consideration of broader protections for ACOs.

If you have any questions about this alert, please contact the authors or your Mintz Levin attorney.

Endnotes

1 Medicare Program: Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center. The Notice is expected to be published in the *Federal Register* on April 7, 2011.

2 42 U.S.C. § 1395nn.

3 42 U.S.C. § 1320a-7b(b).

4 42 U.S.C. § 1320a-7a(b).

5 The ACO Proposed Rule is expected to be published in the *Federal Register* on April 7, 2011.

6 Pub. L. No. 111-148.

7 ACA § 3022 (establishing section 1899 of the Social Security Act).

8 42 U.S.C. § 1395jjj(f).

9 42 U.S.C. §§ 1320a-7b(b)(3), 1395nn(b)(4).

10 42 U.S.C. § 1315a.

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