

Ober|Kaler ACO Update



Julie E. Kass | jekass@ober.com

This is part of Ober|Kaler's comprehensive overview of federal agencies' implementation of the Accountable Care Act's ACO and Shared Savings Program provisions: [CMS Proposed ACO Implementing Regulations](#); [Antitrust](#); [Fraud and Abuse](#); [Privacy](#); [Tax-Exempt Organizations](#).

Proposed ACO Fraud and Abuse Waivers Narrower than Expected

Recently issued regulations and other notices for comments have given health care providers guidance on how to organize and operate accountable care organizations (ACOs) in order to be eligible to receive payments under Medicare's Shared Savings Program. The Affordable Care Act (ACA), signed into law in March 2010, included incentives for the creation of ACOs. Congress established the ACO Shared Savings Program in the ACA to promote accountability of providers to patient populations and to coordinate services under Medicare as well as to encourage providers to make investments in infrastructure and to design care processes for high-quality, efficient service delivery. Almost a year later on March 31, 2011, several federal agencies (CMS, OIG, DOJ, FTC and IRS) jointly announced the release of proposed rule making and guidance regarding the ACO program. The proposed rule and related guidance is expected to remove the existing legal impediments in the areas of fraud and abuse, antitrust, tax and privacy to allow for the development of ACOs, and provide guidance on such issues as eligibility to participate, governance, legal structure, quality and privacy.

The ACA authorizes the Department of Health and Human Services to waive certain fraud and abuse laws as necessary to carry out the provisions of the Shared Savings Program. CMS and OIG jointly issued a notice with comment period (Notice) describing how the agencies intend to exercise their waiver authority. The Notice does not include specific regulatory language. Rather, it describes the scope of the potential waivers being considered and seeks public input on additional or different waivers. Further, it clarifies that the OIG and CMS will base the final regulations on the outcome of the final CMS regulations implementing the Shared Savings Program.

The OIG and CMS clearly intend to exercise their waiver authority in light of the competing goals of encouraging the development of ACOs under the Shared Savings Program while ensuring that ACO arrangements do not abuse federal program patients or funds. The OIG and CMS are concerned the existence of continued fee-for-service payments could create incentives for inappropriate arrangements among providers. Further, some ACOs will be under an agreement with CMS under which there is only upside potential until year three of the agreement. Accordingly, CMS and the OIG are concerned that ACOs could structure and implement arrangements intended to pay remuneration in return for referrals that could negatively affect patients or the Medicare program without any positive impact on the shared savings.

CMS and the OIG specify that the waivers address the distribution of the shared savings funds under the Stark self-referral law, the anti-kickback statute and the civil money penalty provision for hospital payments to physicians to reduce or limit services (CMP). Waivers under the various fraud and abuse laws are intended to be as consistent as possible and to be applied uniformly to all qualified ACOs, ACO participants and ACO providers/suppliers. In order to qualify under the proposed waivers, CMS and the OIG require two threshold qualifications:

- ACOs must have an agreement with CMS to participate in the Shared Savings Program
- The ACO, ACO participants and ACO providers/suppliers must comply with all provisions of the ACO agreement with CMS, section 1899 of the ACA and all implementing regulations

Under the specific waiver for each of the three laws, CMS and OIG state their intent to protect financial arrangements to distribute the shared savings among those individuals or entities within the ACO, as well as those individuals or entities that are not within the ACO but that assist the ACO in meeting the quality and savings goals of the Shared Savings Plan. The agencies specifically exclude from the waivers distributions of shared savings to physicians and other individuals and entities that are outside of the ACO and are not being compensated for activities that are necessary and related to the ACO's participation in the Shared Savings

Program. Any other financial relationships with physicians or other individuals or entities would need to meet an exception under Stark, an anti-kickback safe harbor or not implicate those statutes.

Stark Waiver

The Notice states that the Stark law would be waived with respect to distributions of shared savings under the Shared Savings Program received by an ACO from CMS:

- to or among ACO participants, ACO providers/suppliers, and individuals and entities that were ACO participants or ACO providers/suppliers during the year that the shared savings was earned or
- for activities necessary for and directly related to the ACO's participation in and operations under the Shared Savings Program

The Stark waiver applies to the distribution of the savings earned by the ACO while it was under contract with CMS, even if the distribution occurred after the end of the term of the agreement.

Anti-Kickback Waiver

The anti-kickback waiver contains the same language as the Stark waiver, but adds an additional waiver for:

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 operation under the Shared Savings Program that implicates the Physician Self-Referral Law and fully complies with an exception at 42 CFR 411.355 through 411.357.

This additional waiver broadens the waiver under the anti-kickback statute by creating consistency between the Stark and anti-kickback statutes in a way that the Notice acknowledges has not been permitted with respect to other arrangements. In previous anti-kickback safe harbor preambles, the OIG has been very clear on its position that the Stark self-referral law and the anti-kickback statute are two different laws and that simply because a financial arrangement meets a Stark exception does not preclude the arrangement violating the anti-kickback statute. In the case of the Shared Savings Program however, the agencies have determined that the safeguards incorporated into the Shared Savings Program, and a desire to minimize burdens on entities establishing ACOs, warrants a deviation from the general rule. The anti-kickback waiver for distribution of shared savings applies to the distribution of the savings earned by the ACO while it was under contract with CMS, even if the distribution occurred after the end of the term of the agreement. The waiver for financial arrangements that comply with a Stark exception applies during the term of the ACO's agreement with CMS to participate in the Shared Savings Program.

The Notice also clarifies that failure to meet one of the proposed waivers under the anti-kickback statute does not mean that the arrangement is necessarily illegal. In addition, the agencies note that other Stark exceptions and anti-kickback safe harbors may protect certain aspects of ACO arrangements.

Civil Monetary Penalty (CMP) Waiver

The CMP waiver applies to two scenarios:

- Distributions of shared savings from a hospital to a physician provided that the payments are not made knowingly to induce the physician to reduce or limit medically necessary items or services; and the hospital and physician were ACO participants or ACO providers/suppliers during the year the shared savings were earned by the ACO
- Any financial relationship that meets a Stark exception (similar to the anti-kickback waiver)

Similar to the anti-kickback waiver, the CMP waiver for distribution of shared savings applies to the distribution of the savings earned by the ACO while it was under contract with CMS, even if the distribution occurred after the end of the term of the agreement. The waiver for financial arrangements that comply with a Stark exception applies during the term of the ACO's agreement with CMS to participate in the Shared Savings Program.

Recognizing that the various waivers encompass only a small part of an ACO's arrangements, the Notice solicits comments on whether those waivers are too narrow, as well as whether to create separate additional waivers. The agencies have asked that comments submitted include an explanation of how any new or modified waivers would be necessary to carry out the provisions of the Shared Savings Program and why another exception or safe harbor would not already apply. The Notice specifically requests comments on arrangements in the following areas:

- Establishment of the ACO, such as start-up expenses or initial investments needed for the formation of an ACO, governance, and building technological or administrative capacity (including training)
- Arrangements among or between ACO participants and/or ACO providers/suppliers in the ongoing operations of the ACO
- Arrangements between the ACO, ACO participants and/or ACO providers/suppliers and outside individuals or entities
- Distribution of shared savings or similar payments from private payers
- Separate waivers where ACO participants and/or ACO providers/suppliers bear risk under the Shared Savings Program two-sided risk model

- Arrangements that currently meet the EHR exception or safe harbor that are expected to continue after the 2013 sunset date
- Arrangements under the Shared Savings Program that might require a waiver of the beneficiary inducement CMP

The Notice requests comments on the duration of the waivers and other safeguards that might be necessary to protect the Medicare program and its beneficiaries. Finally, the Notice requests comments as to whether the waivers should be published before, after or contemporaneously with the Shared Savings Program regulations.

About Ober|Kaler

Ober|Kaler is a national law firm that provides integrated regulatory, transaction and litigation services to financial, health care, construction and other business organizations. The firm has more than 130 attorneys in offices in Baltimore, MD, Washington, DC and Falls Church, VA. For more information, visit www.ober.com.

This publication contains only a general overview of the matters discussed herein and should not be construed as providing legal advice.

Copyright© 2011, Ober, Kaler, Grimes & Shriver