

CMS and OIG Propose Waivers of Fraud and Abuse Laws for ACOs

April 12, 2011

On April 7, 2011, the Centers for Medicare & Medicaid Services and the Office of Inspector General published proposed waivers of federal fraud and abuse laws—specifically the Stark law, the federal anti-kickback statute and the CMP law—as they apply to certain financial arrangements between and among ACOs and their constituent providers and suppliers. Comments on the proposals and on specifically identified outstanding issues and areas of concern will be accepted until June 6, 2011.

Concurrent with the release of the proposed accountable care organization (ACO) regulations on March 31, 2011, the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) released a notice with comment period (the Waivers Notice), which then was published in the [Federal Register](#) on April 7, 2011. The Waivers Notice proposes waivers of the federal fraud and abuse laws as they apply to certain financial arrangements between and among ACOs and their constituent providers and suppliers. Section 3022 of the Patient Protection and Affordable Care Act, codified at Section 1899(f) of the Social Security Act, grants the Secretary of the U.S. Department of Health and Human Services (Secretary) the authority for such waivers as necessary to carry out the Medicare Shared Savings Program. Specifically, the Waivers Notice outlines proposals for waiving application of the Stark law, the federal anti-kickback statute and the CMP law's prohibition on hospital payments to induce physicians to reduce or limit services to Medicare or Medicaid patients. The notice requests comments on these proposals and on specifically identified outstanding issues and areas of concern by 5 p.m. ET, June 6, 2011. This newsletter summarizes the Waivers Notice; a more detailed discussion of the Waivers Notice will be published as a *White Paper* in the coming weeks.

Threshold Qualification for Proposed Waivers

To qualify for a waiver, an ACO would have to enter into an agreement with CMS to participate in the Shared Savings Program. Further, the ACO and its participants and providers/suppliers would have to maintain compliance with the agreement and Section 1899 of the Social Security Act and its implementing regulations.

Scope of the Proposed Waivers

The Stark Law

Under this proposal, the Secretary would waive application of the Stark law's prohibitions to an ACO's distributions of shared savings received from CMS under the Shared Savings Program to or among ACO participants and ACO

providers/suppliers, including individuals and entities that were ACO participants and ACO providers/suppliers during the year in which the shared savings were earned by the ACO; or to other individuals or entities for activities “*necessary for and directly related to*” the ACO’s participation in and operations under the Shared Savings Program. Notably, the waiver is limited to the ACO’s distribution of shared savings earned under the Shared Savings Program. No other financial relationships between or among an ACO and its participants and providers/suppliers would be protected by the waiver.

The Anti-Kickback Statute

The Secretary’s waiver of application of the anti-kickback statute would, like the Secretary’s waiver of the Stark law, extend to an ACO’s distributions of shared savings received from CMS under the Shared Savings Program to or among ACO participants and ACO providers/suppliers, or to other individuals or entities for activities “*necessary for and directly related to*” the ACO’s participation in and operations under the Shared Savings Program.

In addition, this waiver of application of the anti-kickback statute would extend to any financial relationship between or among the ACO, its participants and providers/suppliers that implicates the Stark law, meets a Stark law exception and is “*necessary for and directly related to*” the ACO’s participation in and operations under the Shared Savings Program.

The CMP Law Prohibition on Hospital Payments to Induce Physicians to Reduce or Limit Services (the Gainsharing CMP)

The proposed waiver of the Gainsharing CMP would apply to an ACO’s distributions of shared savings received by the ACO in circumstances where the distributions are made by a hospital to a physician, provided, that such payments are not made knowingly to induce a physician to reduce or limit *medically necessary* items or services and the applicable hospital and physician are ACO participants or providers/suppliers, or, if applicable, were ACO participants or providers/suppliers during the year in which the shared savings were earned by the ACO.

In addition, the Gainsharing CMP waiver would protect any financial relationship between or among the ACO, its participants and providers/suppliers that implicates the Stark law, meets a Stark law exception and is “*necessary for and directly related to*” the ACO’s participation in and operations under the Shared Savings Program.

Request for Comments

Recognizing that the proposed waivers do not cover all of the possible financial arrangements that may arise in the development and operation of every ACO that chooses to participate in the Shared Savings Program, CMS and the

OIG request comments from stakeholders regarding additional waivers or modifications to the scope of the proposed waivers. Commenters should explain why the additional waiver or modification is necessary to carry out the Shared Savings Program and why the financial arrangements at issue would not qualify for existing safe harbors or exceptions. Comments are specifically requested regarding:

- ACO development costs
- ACO operating costs
- Financial arrangements between the ACO, ACO participants, ACO providers/suppliers and outside individuals or entities
- Distributions of shared savings and similar incentive payments from private payors
- Duration of the waivers
- Additional safeguards
- Special issues raised by the two-sided risk model
- Use of existing EHR exception and safe harbor after the 2013 sunset
- The need for a waiver of the CMP's prohibition on patient inducements
- The timing of the final waivers relative to the timing of the final shared savings rule

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