

Health Reform Alert

CMS and OIG Propose ACO Fraud and Abuse Waivers

April 3, 2011

On March 31, 2011, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule establishing accountable care organizations (ACOs) under the Medicare Shared Savings Program pursuant to provisions of the Patient Protection and Affordable Care Act (PPACA). CMS and the Department of Health and Human Services (HHS) Office of Inspector General (OIG) also jointly released a notice and solicitation of public comments (the Notice) regarding the waiver of certain federal fraud and abuse laws in connection with the Medicare Shared Savings Program.

Anticipating that the Medicare Shared Savings Program would potentially implicate fraud and abuse laws, Congress included a provision in the PPACA that grants the Secretary of HHS the authority to waive the application of certain fraud and abuse laws “as may be necessary” to implement the program.¹ The fraud and abuse laws addressed by the proposed waivers are the Physician Self-Referral Law (the “Stark Law”),² the federal Anti-Kickback Statute,³ and a provision of the Civil Monetary Penalties law (CMP Law), the so-called Gainsharing CMP, that prohibits a hospital from making a payment directly or indirectly to induce a physician to reduce or limit services to Medicare and Medicaid beneficiaries.⁴ Industry stakeholders have expressed concerns that without such waivers the establishment and operation of ACOs would necessarily involve the creation of financial relationships between physicians and hospitals and other individuals and entities that would otherwise be restricted or prohibited by these laws.

The Notice sets forth three proposed waivers and solicits comments on a number of related issues. To be eligible for waivers from the fraud and abuse laws, an ACO must enter into a formal agreement with CMS to participate in the Medicare Shared Savings Program and the ACO, ACO participants and ACO providers/suppliers would be required to comply with the various ACO requirements found in Section 1899 of the Social Security Act⁵ (as promulgated by the PPACA) and the ACO implementing regulations, including the requirements regarding transparency, reporting and monitoring.

The requirements for the proposed waivers are set forth below—

- Stark Law waiver: The proposed waiver would waive application of the Stark Law to distributions of shared savings received by an ACO from CMS as follows—
 - Within the ACO: To or among ACO participants, ACO providers/suppliers or 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

¹ Pub. L. No. 111-148, § 3022(f).

² 42 U.S.C. § 1395nn.

³ 42 U.S.C. § 1320a-7b(b).

⁴ 42 U.S.C. § 1320a-7a(b)(1)-(2).

⁵ 42 U.S.C. § 1395jjj.



- Outside of the ACO: For activities necessary for and directly related to the ACO’s participation in and operations under the Medicare Shared Savings Program.
- Anti-Kickback Statute waiver: The proposed waiver would waive application of the Anti-Kickback Statute with respect to the following two scenarios—
 - Distributions of shared savings received by an ACO from CMS under the Medicare Shared Savings Program—
 - Within the ACO: To or among ACO participants, ACO providers/suppliers or 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
 - Outside of the ACO: 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 Stark Law and fully complies with a Stark Law regulatory exception. Because, ordinarily, compliance with an exception to the Stark Law does not necessarily immunize an arrangement under the Anti-Kickback Statute, OIG and CMS included this language in the waiver in order to minimize the burden on entities establishing ACOs in a manner consistent with the Stark Law regulatory exceptions (e.g., the exception for certain physician incentive plans⁶).
- CMP Law waiver: The proposed waiver would waive the CMP Law with respect to the following two scenarios—
 - Distributions of shared savings by a hospital to a physician, provided that:
 - payments are not made knowingly to induce the physician to reduce or limit medically necessary services; and
 - 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, 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 Stark Law and fully complies with a Stark Law regulatory exception.

CMS anticipates that the proposed waivers would be somewhat limited in duration. Waivers related to the distribution of shared savings would apply to the distribution of such savings earned by the ACO during the term of its agreement with CMS, even if the actual distributions occur after the agreement expires. In other words, an ACO’s distribution of shared savings after an agreement with CMS has terminated would still be immunized from liability under these fraud and abuse laws as long as such savings were *earned* during the term of the agreement. The Anti-Kickback Statute and CMP Law waivers for arrangements in compliance with a Stark Law exception would apply during the term of the ACO’s agreement with CMS.

Notably, the proposed waivers do not apply to protect conduct that occurs before the ACO has entered into a formal agreement with CMS. For example, financial arrangements that may occur in the process of setting up the ACO would not be protected under the waivers. However, CMS is specifically soliciting comments on whether it is necessary to waive the fraud and abuse laws with respect to activities or conduct undertaken during the process of forming an ACO. CMS is also seeking comments regarding whether transfers of value other than the above-described distributions of shared savings should be protected.

⁶ 42 C.F.R. § 411.357(d)(2).

Additional topics for which CMS is seeking comments include: whether there are any other financial arrangements necessary for and directly related to the operations of ACOs that should receive waiver protection; whether protection should be extended to distribution of shared savings from private payors to the ACO; whether additional waivers are necessary to protect the risk-sharing aspects of the two-sided risk ACO payment model under the proposed rule; and the necessity of waiving the provision of the CMP law prohibiting inappropriate inducements provided to Medicare and Medicaid beneficiaries.⁷ CMS also posed general questions regarding stakeholders' opinions on the scope and duration of the proposed waivers, additional safeguards that could be implemented and the timing of the release of the final waivers as it relates to the release of the final ACO regulation.

Finally, CMS requested comments regarding the Secretary's separate waiver authority granted by Section 1115A of the Social Security Act,⁸ enacted under the PPACA, which creates the Center for Medicare and Medicaid Innovation and grants the Secretary broad waiver authority with respect to creating and testing payment and service delivery models.

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⁷ 42 U.S.C. § 1320a-7a(a)(5).

⁸ 42 U.S.C. § 1315a.