

November 17, 2015

CMS and OIG Issue Final Rule on Fraud and Abuse Waivers for ACOs

On October 29, 2015, the Centers for Medicare & Medicaid Services (CMS) and the Office of the Inspector General (OIG) of the Department of Health and Human Services published a [final rule](#) related to fraud and abuse law waivers in connection with the Shared Savings Program (the Final Rule).

The Final Rule finalizes waivers available to Accountable Care Organizations (ACOs) operating under the Shared Savings Program of provisions of the physician self-referral law (the Stark Law),¹ the Federal anti-kickback statute (the AKS)² and provisions of the civil monetary penalties law (Beneficiary Inducements CMP).³ For the past few years, ACOs have operated under waivers set forth in an Interim Final Rule issued November 2, 2011 (the IFR).⁴ With the exception of the few changes discussed below, the Final Rule largely preserves the waivers as set forth in the IFR. CMS and OIG continue to believe that the waivers are necessary to carry out the Shared Savings Program and feel that the waivers are “adequately protecting beneficiaries and Federal health care programs while promoting innovative structures within the Shared Savings Program.”⁵

I. The Five Shared Savings Program Waivers

The Final Rule finalizes five waivers to the Shared Savings Program: (1) the ACO Pre-Participation Waiver; (2) the ACO Participation Waiver; (3) the Shared Savings Distributions Waiver; (4) the Compliance with the Stark Law Waiver; and (5) the Patient Incentive Waiver. CMS and OIG note that any given arrangement related to the Shared Savings Program may and can qualify for more than one waiver.

1. The ACO Pre-Participation Waiver

The ACO Pre-Participation Waiver waives the requirements of the Stark Law and the AKS with respect to start-up arrangements that pre-date an ACO’s participation agreement. A number of elements must be satisfied for this waiver to apply. Notably:⁶

- The arrangement must be undertaken with a good-faith attempt to develop an ACO and the parties must take diligent steps to develop the ACO.
- The parties to the arrangement may not include drug or device manufacturers, distributors, durable medical equipment suppliers or home health suppliers.
- The ACO’s governing body must have made and duly authorized a *bona fide* determination that the arrangement is reasonably related to the purposes of the Shared Savings Program, which include promoting accountability for a Medicare patient population, managing and coordinating care for Medicare fee-for-service beneficiaries, and encouraging redesigned care processes to improve quality.
- The arrangement, its authorization by the ACO’s governing body, and the diligent steps to develop the ACO must be documented.

¹ 42 U.S.C. § 1395nn.

² 42 U.S.C. § 1320a-7b(b).

³ 42 U.S.C. § 1320a-7a(a)(5).

⁴ 76 Fed. Reg. 67,802 (Nov. 2, 2011).

⁵ 80 Fed. Reg. 66,726, 66,727 (Oct. 29, 2015).

⁶ For the full text of the ACO Pre-Participation Waiver, *see* 80 Fed. Reg. 66,726, 66,742–66,743 (Oct. 29, 2015).

- The description of the arrangement must be publically disclosed, typically on a public website.
- If the ACO does not submit an application, it must submit a statement detailing why it was unable to do so.

2. The ACO Participation Waiver

The ACO Participation Waiver waives the requirements of the Stark Law and the AKS with respect to any arrangement that is reasonably related to the purposes of the Shared Savings Program of an ACO, one or more of its ACO participants or its ACO providers/suppliers, or a combination thereof, provided that certain conditions are met. Notable conditions include:⁷

- The ACO must have entered into a participation agreement and must be in good standing thereunder.
- The ACO meets requirements concerning its governance, leadership, and management.
- The ACO's governing body must have made and duly authorized a *bona fide* determination that the arrangement is reasonably related to the purposes of the Shared Savings Program.
- Both the arrangement and its authorization by the ACO's governing body must be documented.
- The description of the arrangement must be publically disclosed, typically on a public website.

3. The Shared Savings Distribution Waiver

The Shared Savings Distribution Waiver waives the requirements of the Stark Law and the AKS with respect to distributions or use of shared savings earned by an ACO. This waiver permits shared savings to be used within the ACO in any form or manner, including downstream distributions or uses between or among the ACO, its participants and its providers/suppliers. The waiver also protects arrangements that involve the use of shared savings to pay parties outside an ACO, provided that all waiver conditions are met. Conditions include:⁸

- The ACO must have entered into a participation agreement and must be in good standing thereunder.
- The shared savings must be earned by the ACO pursuant to the Shared Savings Program.
- The shared savings must be earned during the term of the participation agreement.
- The shared savings must be timely distributed to ACO participants or used for activities that are reasonably related to the purposes of the Shared Savings Program.

4. The Compliance with the Stark Law Waiver

The Compliance with the Stark Law Waiver waives the requirements of the AKS with respect to any financial relationship between or among the ACO, its participants or its provider/suppliers that implicates the Stark Law. The purpose of this waiver is to avoid requiring parties involved in the Shared Savings Program to undertake a separate legal review under the AKS once they have determined that a Stark Law exception has been met. Elements of this waiver include:⁹

- The ACO must have entered into a participation agreement and must be in good standing thereunder.
- The financial relationship must be reasonably related to the purposes of the Shared Savings Program.
- The financial relationship must fully comply with a Stark Law exception.

⁷ For the full text of the ACO Participation Waiver, *see* 80 Fed. Reg. 66,726, 66,743 (Oct. 29, 2015).

⁸ For the full text of the Shared Savings Distribution Waiver, *see id.*

⁹ For the full text of the Compliance with the Stark Law Waiver, *see id.*

5. The Patient Incentives Waiver

The Patient Incentives Waiver waives the requirements of the AKS and the Beneficiary Inducements CMP with respect to items or services provided by an ACO, its participants or its providers/suppliers to beneficiaries for free or below market value. Elements necessary to satisfy this waiver include:¹⁰

- The ACO must have entered into a participation agreement and must be in good standing thereunder.
- There must be a reasonable connection between the items or services and the medical care for the beneficiary.
- The items or services must be in-kind.
- The items or services must be for preventive care or advance one or more of the following clinical goals: (1) adherence to a treatment regime; (2) adherence to a drug regime; (3) adherence to a follow-up care plan; or (4) management of a chronic disease or condition.

II. Differences Between the IFR and the Final Rule

The most significant difference between the IFR and the Final Rule is that, unlike the IFR, none of the waivers in the Final Rule apply to the civil monetary penalties law relating to gainsharing arrangements (the Gainsharing CMP).¹¹ At the time of the IFR's publication, a hospital was prohibited from knowingly making a payment, directly or indirectly, to induce a physician to reduce or limit services to Medicare or state health care program beneficiaries under the physician's direct care. The IFR provided a waiver of the Gainsharing CMP for arrangements that reduced or limited *medically unnecessary services*. It did not, however, provide a waiver for arrangements that reduced or limited *medically necessary services*.

Earlier this year, Congress enacted the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA),¹² which revised the Gainsharing CMP to prohibit hospitals from making a payment to induce a physician to reduce or limit only *medically necessary* services to certain beneficiaries. With MACRA's addition of the medically necessary standard into the Gainsharing CMP, the need for a waiver is no longer necessary. CMS and OIG stress that the exclusion of the Gainsharing CMP from the Shared Savings Program waivers is not a substantive change to the waivers, but rather a reflection of the fact that MACRA's revision of the Gainsharing CMP obviates the need for a waiver that achieves the same end result.

Other differences between the IFR and the Final Rule include (1) changing language in the ACO Pre-Participation Waiver and the ACO Participation Waiver to reflect that the ACO's governing body "must" maintain certain documentation, instead of the more permissive "should" that was included in the IFR, and (2) defining "home health supplier" to mean an entity that is primarily engaged in furnishing home health services.

III. Significance of the Final Rule

While the Final Rule largely mirrors the IFR, this is, in and of itself, fairly significant. It shows that CMS and OIG did not feel the need to walk-back any of the fraud and abuse law waivers that were applicable to ACOs in the Shared Savings Program. This recognition of the need for ACO flexibility was demonstrated throughout the Final Rule. For instance, several waivers contain language indicating that an arrangement must be "reasonably related" to the purpose of the Shared Savings Program. Some commenters felt that this standard was overly broad and should instead be narrowed to a "necessary" standard. In response to these comments, CMS and OIG stated: "We believe the 'reasonably related' standard best achieves our goal of providing flexibility to ACOs to develop the innovative

¹⁰ For the full text of the Patient Incentives Waiver, *see id.*

¹¹ 42 U.S.C. § 1320a-7a(b)(1)–(2).

¹² Public Law No. 114-10.

arrangements envisioned by CMS, while still requiring a verifiable connection with the Shared Savings Program so as to minimize the risk of allowing fraudulent or abusive arrangements.”¹³

While the fraud and abuse law waivers for ACOs in connection with the Shared Savings Program are significant, they apply only to ACOs, ACO participants and ACO providers/suppliers in the Shared Savings Program context. Providers who desire to implement innovative and collaborative approaches to providing efficient, quality care outside of the ACO model are not, in those contexts, eligible for waiver protection.

Ropes & Gray will continue to monitor regulatory developments in this area. If you have any questions, please contact any member of Ropes & Gray’s [health care practice](#) or your usual Ropes & Gray advisor.

¹³ 80 Fed. Reg. 66,726, 66,731 (Oct. 29, 2015).