



## CMS and OIG Issue Final Fraud and Abuse Waivers in Connection with the Medicare Shared Savings Program

On October 29, 2015, the Centers for Medicare & Medicaid Services (“CMS”) and the U.S. Department of Health and Human Services’ Office of Inspector General (“OIG”) [published a final rule](#) (“Final Rule”) finalizing the waivers of the application of various fraud and abuse laws, including the physician self-referral law (“Stark Law”), the federal anti-kickback statute (“Anti-Kickback Statute”), and certain provisions of the civil monetary penalties law (“CMP Law”), to arrangements pursued by accountable care organizations (“ACOs”) participating in the Medicare Shared Savings Program (“Shared Savings Program”).

The publication of the Final Rule comes approximately three years after CMS and OIG’s joint publication in November 2011 of the [Interim Final Rule](#) (“Interim Rule”), which established the waivers, a year after CMS and OIG [extended](#) the timeline for publication of the Final Rule, and some months after CMS and OIG issued [additional related waiver guidance](#). The Final Rule predominantly adopts the provisions of the Interim Rule and the related guidance with little variation, as explained in more detail below, and provides additional explanation and clarification with respect to the various waiver requirements.

### Available Waivers

Since the publication of the Interim Rule, CMS and OIG have monitored the use of the waivers in connection with the purposes of the Shared Savings Program and determined that “the waivers are adequately protecting beneficiaries and Federal health care programs while promoting innovative structures within the Shared Savings Program.” Accordingly, the Final Rule finalizes the five waivers identified in the Interim Rule: (i) an ACO pre-participation waiver; (ii) an ACO participation waiver; (iii) a shared savings distribution waiver; (iv) a compliance with the Stark Law waiver; and (v) a patient incentive waiver. However, CMS and OIG remind stakeholders that they will continue to monitor application of the waivers to protect beneficiaries and the Medicare program from fraudulent and abusive conduct and “may propose to revise these waivers or take other appropriate action” in the future, if needed.

### Elimination of the Gainsharing CMP Waiver

The primary difference between the Interim Rule and the Final Rule is the elimination of the waiver of the CMP Law’s prohibition of payments made by hospitals to physicians to reduce or limit services

("Gainsharing CMP") due to recent legislative changes. At the time the Interim Rule was published in 2011, a Gainsharing CMP could be imposed whenever hospitals made payments to physicians for reducing or limiting services, regardless of whether those services were medically necessary. However, the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA") narrowed the Gainsharing CMP to prohibit hospitals from knowingly paying physicians to induce them to reduce or limit medically *necessary* services. Because of this change, payments by hospitals to physicians to reduce or limit medically *unnecessary* services no longer implicates the Gainsharing CMP. As stated in the Final Rule, "arrangements between hospitals and physicians that incentivize greater efficiency and reduction of waste, which previously may have run afoul of the Gainsharing CMP, would no longer implicate the provision, provided those arrangements do not involve reductions or limitations in medically necessary care. Thus, a waiver of the Gainsharing CMP is no longer necessary to carry out the Shared Savings Program, which, by its terms, promotes quality and patient care goals like fostering efficient medically necessary care, but not stinting on medically necessary care."

## Reasonably Related to the Purposes of the Shared Savings Program

Many of the waivers include a requirement that an arrangement be "reasonably related to the purposes of the Shared Savings Program." Although certain commenters argued that the "reasonably related" standard was overly broad and vague, CMS and OIG believe that this standard "best achieves our goal of providing flexibility to ACOs to develop the innovative 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."

The Final Rule lists a number of examples of arrangements that are not reasonably related to the purposes of the Shared Savings Program, including:

- An arrangement whereby a provider is required to pay a sum to receive ACO-related referrals (e.g., "pay-to-play" arrangements);

- Medical directorships or personal services arrangements where referring physicians receive payments for no actual services performed;
- Payments to induce a physician or other provider to stint on medically necessary care for beneficiaries; or
- Free gifts (e.g., sporting tickets) to ACO providers/suppliers or ACO participants.

## Home Health Suppliers

Of the available waivers, CMS and OIG are most concerned with abuse of the pre-participation waiver because it applies to arrangements that occur prior to an ACO's participation in the Shared Savings Program and its attendant regulation and oversight. As such, the Final Rule adopts many of the safeguards identified in the Interim Rule for the pre-participation waiver, including the exclusion of certain entities from using the pre-participation waiver (e.g., drug and device manufacturers, distributors, DME suppliers, and home health suppliers).

While commenters were concerned with the exclusion of home health suppliers from the pre-participation waiver, CMS and OIG clarified the intended meaning of such exclusion. For purposes of the Final Rule, "home health supplier" means a provider, supplier, or other entity that is "primarily engaged" in the furnishing of "home health services." Medicare-enrolled providers or suppliers (e.g., hospitals, skilled nursing facilities, physician practices) are eligible to take advantage of the pre-participation waiver as long as such entities are not "primarily engaged" in providing home health services.

## Authorization from ACO's Governing Body

To be eligible for the pre-participation or participation waivers, an ACO's governing body must make and authorize a "bona fide determination that an arrangement is reasonably related to the purposes of the Shared Savings Program." Like the Interim Rule, the Final Rule does not "prescribe[re] particular methods for this determination" but expects members of the ACO governing body to employ a "thoughtful, deliberative process" for making such a determination that "articulate[s] clearly the basis for their determinations and authorizations." For example, one factor that CMS and OIG evaluate in

determining whether such an authorization is bona fide is the proximity of time between the establishment of the arrangement and the ACO governing body's corresponding determination and authorization. A significant passage of time between establishment of the arrangement and the ACO governing body's determination might indicate that the ACO governing body was acting for other purposes.

The Final Rule continues to require that the ACO governing body's determination be "contemporaneously documented" in order to clearly demonstrate the nexus between the arrangement and the purposes of the Shared Savings Program. While nothing specific is required for documentation purposes, best practices would include a duly authorized written resolution showing the basis for the ACO governing body's determination. Additionally, although none of the waivers require an agreement signed by the parties, such an agreement would be a best documentation practice as well as one way to satisfy the Stark Law's writing requirement if a waiver does not apply to the arrangement, or if waiver protection were to be lost in the future.

The Final Rule also adopts the Interim Rule's requirements for public disclosure of arrangements for which waiver protection under the pre-participation waiver or participation waiver is invoked. Although several commenters wanted to impose additional disclosure requirements on ACOs, CMS and OIG refer to their [additional waiver guidance issued in February 2015](#) as adequately responding to the commenters' concerns.

## Shared Savings Distribution Arrangements for Commercial Health Plans

The Interim Rule requested comments regarding a potential waiver for shared savings derived from arrangements sponsored by commercial health plans. CMS and OIG decided not to expand the shared savings distribution waiver beyond the Shared Savings Program but would "consider addressing shared savings derived from commercial plans in future rule-making." In support of their decision, CMS and OIG remarked that such commercial shared savings arrangements do not necessarily implicate the fraud and abuse laws, and they provided examples of ways in which private payer arrangements may not need a specific waiver. For example, an arrangement

might qualify for the participation waiver if there is a sufficient nexus to the Shared Savings Program. Additionally, many commercial shared savings arrangements can be structured to fit within an exception to the Stark Law and a safe harbor under the Anti-Kickback Statute.

## Patient Incentive Waiver

The Final Rule formalizes the patient incentive waiver, which waives application of the Anti-Kickback Statute and the CMP Law's prohibition on beneficiary inducements. As stated in the Interim Rule, in order to take advantage of the patient incentive waiver, there must be a "reasonable connection" between the item or service provided to the beneficiary and the beneficiary's medical care. While incentives permitted under the patient incentive waiver largely depend upon specific facts and circumstances, the Final Rule provides some guidance in this area. Appropriate incentives could include local transportation to medical appointments or a blood pressure cuff given to a hypertensive patient in an ACO's chronic disease management program. Inappropriate incentives would include items like beauty products or theater tickets. The Final Rule does not offer much clarity for more ambiguous items and services (e.g., gym memberships, personal training sessions, massages, skin creams) but advises ACOs to scrutinize such incentives carefully on a case-by-case basis.

## Conclusion

The Final Rule provides comfort to many ACOs participating in the Shared Savings Program that have taken advantage of the fraud and abuse waivers outlined in the Interim Rule to protect a wide variety of arrangements. CMS and OIG regard the waivers as a way to promote all the benefits of the ACO model—innovation, quality, and efficiency—while still protecting patients from potential fraud and abuse. However, CMS and OIG will continue to monitor arrangements protected under the waivers to ensure that the waivers are not raising concerns of overutilization, increased costs, and poor quality of care, among others, and may make modifications to the waivers in the future as needed. Accordingly, ACOs taking advantage of one of the waivers should have a fall-back strategy in place to deal with the loss or restriction of a waiver should it no longer be available.

In August 2015, Jones Day reviewed the publicly available websites of approximately 425 ACOs participating in the Shared Savings Program to determine the scope and use of the various fraud and abuse waivers. Despite the breadth and power of the waivers, particularly the participation waiver, we found only 66 ACOs utilizing waivers to protect approximately 90 different types of arrangements. ACOs participating in the Shared Savings Program should strongly consider taking advantage of the waivers given the issuance of the Final Rule, which signals CMS and OIG's approval of the benefits of the waivers.

## Lawyer Contacts

Jones Day attorneys have substantial knowledge of the Shared Savings Program and significant experience advising clients on many aspects of the Shared Savings Program, including developing and structuring arrangements under the fraud and abuse waivers and ensuring ongoing regulatory compliance. For further information, please contact your principal Firm representative or one of the lawyers listed below. General email messages may be sent using our "Contact Us" form, which can be found at [www.jonesday.com/contactus/](http://www.jonesday.com/contactus/).

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