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Limited Modifications in Final ACO Fraud and Abuse Waivers Most Notably Include Cut of Gainsharing CMP Waiver [Ober|Kaler]

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Nearly four years after publishing their joint interim final rule with comment period [PDF], effective November 2, 2011 (IFC), the OIG and CMS (Agencies) have finalized the waivers of various fraud and abuse laws in the context of accountable care organizations (ACOs) operating within the Medicare Shared Savings Program (MSSP) in their final rule [PDF] effective October 29, 2015 (Final Rule).

As explained in detail within the IFC and further echoed in the Final Rule, the purposes of the MSSP are (1) promoting accountability for the quality, cost and overall care of the Medicare population; (2) managing and coordinating care for Medicare fee-for-service beneficiaries through an accountable care organization (ACO); and (3) encouraging investment in infrastructure to support and facilitate high quality and efficient service delivery for patients including Medicare beneficiaries. CMS noted that it continues to interpret the purpose of "efficient service delivery" as including the appropriate reduction of costs/growth of expenditures which is consistent with quality of care, physician medical judgment and patient freedom of choice.

To fulfill the triple aim, providers must integrate in ways that ordinarily could implicate the health care fraud and abuse laws. These laws encourage separation between sources of health care program referrals and those who receive such referrals for the purpose of protecting beneficiaries, reducing overutilization and preventing fraudulent practices. However, the MSSP ultimately encourages *increased* coordination between these groups. Accordingly the Secretary of the Department of Health and Human Services (HHS), the department in which both Agencies reside, waives certain laws for MSSP arrangements that meet specific requirements. Specifically, the waivers apply to the physician self-referral "Stark" law,[1] the Anti-Kickback Statute,[2] and the Beneficiary Inducements civil monetary penalty (CMP) law,[3] collectively referred to herein as the "Fraud and Abuse Laws." In the IFC, the Agencies proposed five circumstantial waivers of these laws and elicited comment from stakeholders, noting that the purpose of the waivers was to foster innovative ACO arrangements that further quality and efficiency goals of the MSSP but also protect beneficiaries. In this Final Rule, the Agencies set forth those waivers in their final form, with few changes from the IFC.

In discussing the final waivers, the Agencies remind stakeholders that waivers are not needed when an arrangement either does not implicate the laws and/or fits within an applicable safe harbor or exception. The Agencies believe that many MSSP can fit within an existing exception or safe harbor. They also take effort to emphasize that the waivers will not protect arrangements that blatantly violate or run afoul of the purpose of the Fraud and Abuse laws, examples of which are provided below.

Overarching Safeguard

One safeguard inherent in several of the waivers is that an arrangement be "reasonably related to the purposes of the Shared Savings Program." The Agencies discuss how some commenters felt this standard is too broad or vague, but that they continue to believe the standard achieves the right mix of allowing ACOs while requiring a connection to the MSSP. The Agencies maintain that the standard is not broad enough to encompass all arrangements, as many will clearly never meet this standard. To illustrate the point, the Agencies give the examples of: (1) "pay-to-play" arrangements under which a physician is required to pay a

fee to the ACO to receive ACO referrals; (2) a medical director or personal services arrangement pursuant to which payment is made but no services are actually rendered; (3) free gifts to referral sources; and (4) payments to induce reduction of medically necessary services. As an example of an arrangement on the other side of the coin, the Agencies note how compensation to a physician for achieving certain quality metrics for patient care set by the ACO *could be* reasonably related to the purposes of the MSSP, although such arrangement may result in the physician being more likely to refer to or within the ACO. The Agencies' commentary provides support for waiver protection of this common type of ACO arrangement.

Gainsharing CMP Waiver Eliminated

The most significant change in the IFC waivers is the removal of the Gainsharing CMP waiver. When the IFC was issued, the Gainsharing CMP[4] prohibited a hospital from providing a physician with anything of value that could induce that physician to reduce or limit services to Medicare or state health care program beneficiaries. Accordingly, MSSP arrangements that in any way incentive such a practice, which could reasonably occur for the purpose of incentivizing efficiency, quality and cost reduction, would require a waiver from the Gainsharing CMP. However, since the Medicare Access and CHIP Reauthorization Act revised the Gainsharing CMP in April 2015 to limit the prohibition to the reduction or limitation of *medically necessary services*, payments to induce the reduction of *medically unnecessary services* do not run afoul of the CMP and do not need a waiver. Payments to induce the reduction of medically necessary services continue to implicate the Fraud and Abuse laws and, potentially, state licensing laws. The Agencies note, however, that the withdrawal of the Gainsharing CMP waiver will not prevent parties from entering into arrangements that previously fit into that waiver under the IFC.

Final MSSP Waivers

Prior to setting forth the final waivers, the Agencies remind the industry that the waivers are self-implementing. Each waiver is summarized below, with any specific changes from the IFC highlighted.

ACO Pre-Participation Waiver

The Stark and anti-kickback laws are waived for start-up arrangements related to an ACO participating in the MSSP. Examples include, without limitation: infrastructure and creation; network development and management; mechanisms for care coordination, clinical management or quality improvement; hiring of new staff; information technology; training costs; and capital investments. The following requirements must be met:

The arrangement involves those acting with the good faith intent to develop an ACO that will participate in the MSSP. The parties to the arrangement must include, at a minimum, the ACO or at least one ACO participant of the type eligible to form an ACO. The parties may not include drug and device manufacturers, distributors, durable medical equipment (DME) suppliers, or home health suppliers.

Clarification: Despite requests to include home health providers within this waiver, the Agencies finalized their exclusion based on the continued belief that the waiver has a heightened potential for misuse, given its application to situations that predate an ACO's commitment to the MSSP. Add to this the fact that home health providers have historically posed a heightened risk of fraud. Notwithstanding, the Agencies clarify that the definition of a home health provider includes only those primarily engaged in providing home health services. The Agencies note it was never their intent to include in this definition, and thereby exclude from the waiver, hospitals, skilled nursing facilities or physician practices, even if they provide *some* home health services and provided they do not *primarily* engage in the home health business.

The ACO's governing body has made and duly authorized a bona fide determination that the arrangement is reasonably related to the purposes of the Shared Savings Program.

The arrangement, its authorization by the governing body, and the diligent steps to develop the ACO are contemporaneously documented. All such documentation must be retained for at least 10 years. Documentation must identify the following:

A description of the arrangement (i.e., parties, dates, purpose, items, services, facilities, goods, financial terms, etc.).

The date and manner of the governing body's authorization of the arrangement, which must include the basis for its determination that the arrangement is reasonably related to the purposes of the Shared Savings Program (see discussion above).

Clarification: The Agencies changed the *should include* in the IFC to *must include*, which mirrors the discussion and intent of the IFC. In the Final Rule, the Agencies emphasize that the documentation requirements are mandatory.

A description of the diligent steps taken to develop an ACO, including the timing of actions undertaken and the manner in which the actions relate to the development of an MSSP-eligible ACO.

The description of the arrangement (excluding the financial terms) is publicly disclosed at a time and in a place and manner established in guidance issued by HHS.

If an ACO does not submit an application for a participation agreement by the last available application due date for the target year, the ACO must submit a statement on or before the last available application due date for the target year, in a form and manner to be determined by HHS, describing the reasons it was unable to submit an application.

The time frame for the waiver begins one year before the application due date or the date of the IFC and ends on the start date of the ACO's participation agreement. However if an ACO application is denied, the waiver ends six months after that denial. If an ACO fails to submit the application, the waiver terminates on the earlier of the application due date or the date the ACO submits a statement of reasons for failing to submit. Also of note is that an ACO may use this pre-participation waiver only once.

ACO Participation Waiver

The Stark law and Anti-Kickback Statute are waived with respect to a wide variety of arrangements entered into by and among ACOs, their participants and ACO providers and suppliers, such as investment, start-up, operating and other arrangements that carry out the MSSP, provided:

Commentary/Extension: The Agencies declined to adopt a 6-month tail period to the participation waiver for an ACO that CMS terminates.

Commentary/Outside Parties: The Agencies received comments requesting that additional safeguards be placed on ACO arrangements with outside parties, i.e., parties who are not an ACO, ACO participant or ACO provider supplier. As in the IFC, the Agencies believe arrangements with these parties can further goals of the MSSP. Despite requests from commenters, the Agencies do not see the need for additional requirements such as fair market value or commercial reasonableness or any certification requirements for these outside party arrangements.

The ACO has entered into and remains in good standing under a participation agreement.

The ACO meets the MSSP requirements related to governance, leadership, and management.

The ACO's governing body has made and duly authorized a bona fide determination that the arrangement is reasonably related to the purposes of the Shared Savings Program.

The contemporaneous documentation of the arrangement, its establishment and authorization must be retained for at least 10 years. Documentation must identify the following:

A description of the arrangement (i.e., parties, dates, purpose, items, services, facilities, goods, financial terms, etc.).

The date and manner of the governing body's authorization of the arrangement, which must include the basis for its determination that the arrangement is reasonably related to the purposes of the Shared Savings Program (see discussion above).

Clarification: Same clarification related to governing board documentation made in the Pre-Participation waiver.

The description of the arrangement (excluding the financial terms) is publicly disclosed at a time and in a place and manner established in guidance issued by HHS.

The term of the waiver ordinarily begins on the start date of the participation agreement and ends six months following the earlier of the expiration of the participation agreement, including any renewals thereof, or the date on which the ACO has voluntarily terminated the participation agreement. However, if CMS terminates the participation agreement, the waiver period will end on the date of the termination notice.

Shared Savings Distributions Waiver

The Stark law and Anti-Kickback Statute are waived with respect to distributions of shared savings earned by an ACO. The intent of this waiver is to protect both arrangements created by the distribution of shared savings within an ACO and arrangements for the payment of shared savings to parties outside of the ACO, provided the arrangement satisfies the following waiver requirements.

The ACO has entered into and remains in good standing under a participation agreement.

The shared savings are earned by the ACO pursuant to the MSSP.

The shared savings are earned by the ACO during the term of its participation agreement, even if the actual distribution or use of the shared savings occurs after the expiration of that agreement.

The shared savings are

Distributed to or among the ACO's ACO participants, its ACO providers/suppliers, or individuals and entities that were its ACO participants or its ACO providers/suppliers during the year in which the shared savings were earned by the ACO; or

Used for activities that are reasonably related to the purposes of the Shared Savings Program.

Changes to remove reference to medically necessary services: Considering the modification to the Gainsharing CMP, the Agencies feel it is no longer necessary to require that the distributions do not reduce medically necessary services, and therefore removed that requirement.

Commentary/Documentation: Though not required by the waiver, the Agencies recommend that an ACO maintain documentation explaining how payments would be and are being used for activities reasonably related to the purpose of the MSSP.

Commentary/Application of Waiver: Similar to their discussion on what is "reasonably related to the purpose of the MSSP" the Agencies note arrangements to which this waiver would not apply, such as distributions to physician providers or other parties in return for referrals to the ACO.

Commentary/Commercial Programs: As in the ACO Final Rule issued on June 9, 2015,[5] the Agencies address the application of the waivers and ACO models in general within the commercial setting. They acknowledge comments requesting the expansion of waivers to programs sponsored by commercial health plans, but note only that they will continue to monitor the situation and may consider addressing it in the future.

Compliance with Physician Self-Referral Law Waiver

The Anti-Kickback Statute is waived for arrangements that qualify under an existing Stark exception. The intent is to alleviate the need for parties to undertake a separate legal review under the Anti-Kickback Statute. To qualify for the waiver the following requirements must be met:

The ACO has entered into and remains in good standing under a participation agreement.

The financial relationship is reasonably related to the purposes of the Shared Savings Program.

The financial relationship fully complies with an exception at 42 C.F.R. §§ 411.355 – 411.357.

The waiver starts on the start date of the participating agreement and ends on the earlier of the expiration of the participation agreement or the date on which the participation agreement is terminated.

Commentary/Extension: The Agencies declined to adopt a 6-month tail period to the waiver for an ACO that CMS terminates.

Patient Incentive Waiver

The Anti-Kickback Statute and Beneficiary Inducements CMP are waived for arrangements pursuant to which ACOs, ACO participants and ACO providers/suppliers provide beneficiaries with free or below-fair-market-value items and services that advance the goals of preventative care, adherence to treatment, drug or follow-up care regimens or management of a chronic disease or condition. The Agencies note that the availability of the waiver is strictly limited to the identified parties. To fall within the waiver the arrangement must meet the following requirements:

The ACO has entered into and remains in good standing under a participation agreement.

There is a reasonable connection between the items or services and the medical care of the beneficiary.

Commentary/"reasonable relation": The Agencies note that hypertensive beneficiaries may be offered a blood pressure cuff for their chronic disease management. The Agencies emphasize the need for a reasonable connection between the items or services and the medical care of the beneficiaries. They comment that incentives noted by commenters such as gym memberships, massages, skin creams should be carefully

scrutinized. The Agencies also note that free items or services provided to beneficiaries as inducements for receiving services from the ACO are not covered by the waiver.

The items or services are in-kind.

The items or services—

Are preventive care items or services; or

Commentary: The Agencies declined to define preventative care.

Advance one or more of the following clinical goals:

Adherence to a treatment regime.

Adherence to a drug regime.

Adherence to a follow-up care plan.

Management of a chronic disease or condition.

Commentary/Transportation: Taking the opportunity to address local transportation, the Agencies note that nothing precludes it from being an in-kind item or service under this waiver. However, the agencies note that the transportation must relate to medical care and cannot relate to entertainment, recreation or errands. Further, beneficiaries may not be given cash; rather, they must be given a voucher redeemable only for transportation when money is required for the transport.

The waiver period will start as of the start date of the participation agreement and will end on the earlier of the expiration of the term of the participation agreement or the date on which the participation agreement has been terminated, provided that a beneficiary may keep items received before the participation agreement expired or terminated, and receive the remainder of any service initiated before the participation agreement expired or terminated.

Notable Remarks

In closing, the Agencies remind stakeholders that these waivers in no way diminish their commitment to detecting and protecting the federal health programs and beneficiaries against fraud. Stakeholders should still expect the agencies to continually monitor ACOs and the MSSP for potential fraud and abuse, as well as the application of the waivers with specific attention to whether they have any unintended effect. The waivers will not be codified in regulation; rather they are published in the *Federal Register*.

The Final Rule is effective October 29, 2015.

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1 42 U.S.C. § 1395nn.
2 42 U.S.C. § 1320a-7b.
3 42 U.S.C. § 1320a-7a(a)(5).

4 42 U.S.C. § 1320a-7a(b)(1).
5 80 Fed. Reg. 32,692 (June 9, 2015).