Medicare Shared Savings Program Final ACO Fraud and Abuse Waivers:
Issues of Interest for Pharmaceutical and Medical Device Manufacturers

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On October 29, 2015, the Department of Health and Human Services Office of Inspector General (OIG) and the Centers for Medicare & Medicaid Services (CMS) released a final rule\(^1\) that, effective immediately, waives the anti-kickback statute (AKS), the beneficiary inducement statute, and the Stark Law with respect to certain arrangements involving Medicare Shared Savings Program (MSSP) accountable care organizations (ACOs). While the final rule’s waivers primarily protect the healthcare providers that participate (or are planning to participate) in MSSP ACOs, these waivers may also affect other U.S. healthcare system stakeholders, including pharmaceutical and medical device manufacturers. This advisory briefly summarizes these waivers and highlights certain issues of interest for pharmaceutical and device manufacturers.

Under the statute establishing the MSSP, the Secretary of Health and Human Services may waive provisions of the Medicare statute, as well as the healthcare fraud and abuse provisions in Social Security Act §§ 1128A and 1128B, “as may be necessary to carry out the [MSSP statute].”\(^2\) On November 2, 2011, concurrent with CMS issuing a final rule implementing the MSSP, CMS and OIG jointly issued an interim final rule with comment period (IFC)\(^3\) setting forth five waivers of otherwise applicable healthcare fraud and abuse laws for certain arrangements related to MSSP ACOs.\(^4\) (For more information on the IFC, please see our advisory, Medicare Shared Savings Program: Issues of Interest for Pharmaceutical and Medical Device Manufacturers.) The final rule largely finalizes the waivers issued in the IFC, making only the following limited changes:

- The final rule does not finalize the IFC’s waivers of the gainsharing statute, due to recent changes to the gainsharing statute enacted as part of the Medicare Access and CHIP Reauthorization Act of 2015

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\(^1\) Medicare Program; Final Waivers in Connection With the Shared Savings Program; Final Rule, 80 Fed. Reg. 66726 (Oct. 29, 2015) (Waiver Final Rule).

\(^2\) Social Security Act § 1899(f).

\(^3\) Medicare Program; Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67992 (Nov. 2, 2011) (Interim Final Rule with Comment Period or “IFC”).

\(^4\) CMS uses Social Security Act § 1115A, and its waiver authority, for ACO models other than the MSSP. The final ACO waiver rule just released by CMS and the OIG only applies to MSSP ACOs.
(MACRA). MACRA limited the gainsharing statute to certain incentives to reduce or limit “medically necessary” services (not services generally). Given this change, payments by hospitals to induce physicians to reduce or limit medically unnecessary services no longer implicate the gainsharing statute. Therefore, the arrangements covered by the interim gainsharing waiver no longer could violate the law and the waiver is unnecessary.

- In the Pre-Participation and the Participation Waivers, the ACO governing body is now required, rather than encouraged, to make a meaningful determination that an arrangement is reasonably related to the purposes of the MSSP.

- A “home health supplier” is now defined for purposes of the Pre-Participation waiver (specifically, “a provider, supplier or other entity that is primarily engaged in furnishing home health services”).

I. ACO Pre-Participation Waiver

The ACO Pre-Participation Waiver waives the AKS and the Stark Law with respect to certain “start-up” arrangements - arrangements under which ACOs, ACO participants or ACO providers / suppliers would provide items, services, facilities or goods used to create or develop an ACO and that predate an ACO’s participation agreement with CMS. These entities do not include pharmaceutical or medical device manufacturers, and start-up arrangements involving drug and device manufacturers are explicitly excluded from the Pre-Participation Waiver. The final rule reiterated, word-for-word, the IFC’s statements that the “pre-participation waiver does not cover arrangements involving drug and device manufacturers, distributors, DME suppliers, or home health suppliers,” and that “drug and device manufacturers and distributors are not Medicare enrolled suppliers and providers.” In the final rule, CMS and OIG defend the exclusion of drug and device manufacturers based on “continuing program integrity risks, the heightened risks inherent in the pre-participation waiver, and an assessment based on four years of program experience that the pre-participation waiver is sufficiently broad for the purposes of the Shared

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6 Id.
7 Id.
8 Waiver Final Rule, 80 Fed. Reg. at 66727.
9 See Waiver Final Rule, 80 Fed. Reg. at 66726. ACO provider/supplier means “an individual or entity that -- (1) Is a provider (as defined in [42 C.F.R. § 400.202]) or a supplier (as defined at 42 C.F.R. § 400.202)); (2) Is enrolled in Medicare; (3) Bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations; and (4) Is included on the list of ACO providers/suppliers that is required under § 425.204(c)(5).” See 42 C.F.R. § 425.20.
Savings Program” as well as their belief that “this policy is consistent with the goals of the Shared Savings Program and has not created barriers to the participation or development of ACOs.”

Therefore, the Pre-Participation Waiver does not protect any arrangements between drug and device manufacturers and providers that are seeking to form an ACO. The final rule notes, however, that failure to qualify for a waiver would “not, in and of itself, entail a violation of the law” because an arrangement might not implicate fraud and abuse laws to begin with, or may comply with these laws.

Thus, any manufacturers evaluating potential arrangements with entities seeking to form an ACO should analyze the arrangements on a case-by-case basis under existing compliance rules and guidance. The reference by CMS and the OIG to unspecified “continuing program integrity risks” may have the effect of chilling manufacturer activities in this area, or encouraging manufacturers to seek advisory opinions from the OIG (under which the OIG may issue an opinion that it will not seek administrative sanctions with respect to a specified arrangement).

II. ACO Participation Waiver

Under the Participation Waiver, the AKS and Stark Law are waived with respect to any arrangement in which an ACO, one or more of its ACO participants or its ACO providers/suppliers, or a combination of these parties, funds or otherwise supports an ACO’s operations during the term of the ACO’s participation agreement.

A threshold issue exists under the final rule as to whether arrangements involving entities that do not fall within these categories -- “outside parties” -- are protected under the Participation Waiver. The language of the ACO Participation Waiver does not explicitly address this issue, but the final rule preamble suggests that OIG and CMS intend to protect relationships with at least certain outside parties:

“We agree with the commenters who advocated that arrangements with outside parties should be protected under these waivers so long as all requirements for the applicable waiver are met. We believe that these arrangements are important in furthering the quality and patient care goals of the Shared Savings Program. We recognize that, for example, some individuals and entities furnishing care to beneficiaries in an ACO will not be an ACO participant or ACO provider/supplier. ACOs may want to enter into arrangements with these outside individuals or

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entities, however, to promote care coordination for their patients or to encourage quality improvement.”

Because it appears that an ACO, ACO participant, or ACO provider/supplier could satisfy the deliberation, documentation, and disclosure requirements of the Participation Waiver with respect to an arrangement with an “outside party,” such an arrangement apparently “should be protected under these waivers.”

However, because OIG and CMS did not explicitly state that the Participation Waiver applies to protect arrangements with outside parties, some uncertainty remains.

CMS and OIG also do not explicitly address in the final rule whether drug manufacturers may qualify as “outside parties.” The final rule preamble provides: “An outside party arrangement is an arrangement with an individual or entity that does not meet the definition of an ACO, an ACO participant, or an ACO provider/supplier, as those terms are defined in section IV of this final rule, but has a role in coordinating and managing care for ACO patients.” CMS and OIG do not state whether in their view a manufacturer could serve such a role. Finally, the final rule preamble uses both the terms “outside providers and suppliers” and “outside parties,” without drawing any distinction between the two, and gives as examples of the former “hospitals, specialists, or post-acute care facilities that might not be part of the ACO but have a role in coordinating and managing care for ACO patients,” a list that omits manufacturers.

In sum, it is unclear whether CMS and OIG intend for drug and device manufacturers to qualify as “outside parties.” In addition, CMS and OIG do not address in the final rule whether “outside parties” themselves could be protected by the Participation Waiver. In light of this uncertainty, manufacturers wishing to avail themselves of this waiver may wish to consider seeking clarity from CMS and the OIG on these issues.

III. Shared Savings Distribution Waiver

Under the Shared Savings Distribution Waiver, the AKS and the Stark Law are waived with respect to distributions of shared savings earned by an ACO (1) to ACO participants and providers/suppliers, and (2) to “outside parties” if conveyed as compensation for activities reasonably related to the purposes of the MSSP. The final rule provides: “Payments from hospitals to physicians to reduce or limit medically necessary treatments.”

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15 Id.
16 Waiver Final Rule, 80 Fed. Reg. at 66735 (emphasis added).
necessary services are not, and never have been, consistent with the purposes of the Shared Savings Program, were not protected by the waivers in the IFC, and are not permitted by the amended Gainsharing CMP, and are not protected by the waivers in this final rule.”

However, CMS and OIG notably reiterated the IFC’s statements that the distribution of shared savings by an ACO that incentivize the provision of “alternate and appropriate” medically necessary care are protected.19 This could be interpreted to protect payments to physicians that induce them to substitute one medically necessary drug or device product for another, which raises concerns about whether this would lead to physicians stinting on more costly products. Allowing ACOs to provide physicians with financial incentives to substitute one medically necessary item or service for another could interfere with clinical decision-making, potentially compromising patient quality of care and undermining the goals of the MSSP. In fact, CMS and OIG have themselves expressed concern about the risk that physicians will “limit[] their use of quality-improving but most costly devices, tests, or treatments (‘stinting’)” as a result of shared savings distributions.20

In response to comments requesting that CMS and OIG “incorporate additional safeguards to prevent stinting . . . or reducing or limiting medically necessary items or services,” CMS and OIG rejected the idea that safeguards such as “ensuring the availability of the same range of items and services” were needed.21 CMS and OIG responded that while “it is critical to protect patients from . . . stinting on care, and the withholding of medically necessary items or services,” the final rule “preserves the protections contained in the Gainsharing CMP and reflects our commitment to the quality and safety of patient care.”22 CMS and OIG also stated that the MSSP already has "extensive quality requirements"; that CMS “has monitoring authorities to prevent ACOs from engaging” in stinting;23 and that the risk of stinting on care is further reduced because Medicare’s shared savings payments to ACOs are conditioned on meeting certain quality metrics.24

Drug and device manufacturers should continue to watch closely to see whether CMS is using its monitoring authorities set forth in 42 C.F.R. 425.316(b) to ensure that ACOs, ACO participants, and ACO

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22 Id.
23 Id.
24 Id.
providers/suppliers do not stint on medically necessary care, including drugs and devices.\textsuperscript{25} Manufacturers should also watch as CMS periodically revises the package of quality metrics used to evaluate ACOs to see if those metrics are in fact likely to discourage stinting.

IV. Waiver for Patient Incentives

Under the Patient Incentives Waiver, the AKS and the beneficiary inducements statute are waived with respect to "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 preventive care, adherence to treatment, drug, or follow-up care regimens, or management of a chronic disease or condition."\textsuperscript{26} The final rule provides that drug and device manufacturers may not seek protection under the Patient Incentive Waiver, even if they are performing services or functions related to ACO activities.\textsuperscript{27} Thus, although the waiver could protect ACOs and ACO providers/suppliers in connection with arrangements in which they "give beneficiaries items or services that they have received from manufacturers at discounted rates," it does not protect drug and device manufacturers when providing these very same items to ACOs or ACO providers/suppliers to provide to patients.\textsuperscript{28}

One commenter "opposed the exclusion of pharmaceutical manufacturers from protection under the patient incentives waiver," and emphasized that "these entities are particularly well situated to develop effective programs to educate and support patients."\textsuperscript{29} In response, CMS and OIG reiterated that the waiver applies to incentives "furnished by an ACO, its ACO participants, or its ACO providers/suppliers" and that they "are not extending protection under this waiver to incentives provided by any other parties, including pharmaceutical manufacturers."\textsuperscript{30} CMS and OIG failed to explain the rationale behind the exclusion of manufacturers from the Patient Incentive Waiver, stating only that "based on CMS' program experience to date, we continue to believe that such waivers are not necessary to carry out the Shared Savings Program."\textsuperscript{31}

\begin{footnotesize}
\begin{itemize}
\item[^27] Waiver Final Rule, 80 Fed. Reg. at 66740.
\item[^28] Id.
\item[^29] Id.
\item[^30] Id. (emphasis added).
\item[^31] Id.
\end{itemize}
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However, the exclusion of drug and device manufacturers from the waiver is inconsistent with the goal of the waiver, which is to promote “broad improvement in care coordination and quality” for beneficiaries and to “improve[] quality and lower[] costs for the Medicare program and its beneficiaries.” The waiver specifically recognizes that the distribution of items promoting adherence or disease management should be encouraged to improve quality of care and lower costs. However, the decision by CMS and OIG to exclude manufacturers from this waiver could limit an important source of these materials (for no apparent reason) and thus limit the utility of the waiver. Drug and device manufacturers have unique knowledge and experience with issues related to adherence to their products and to management of the diseases in their therapeutic areas, and therefore are well-positioned to develop and distribute the same educational materials that ACO providers/suppliers will be allowed and encouraged to distribute to beneficiaries. Why CMS and OIG would exclude manufacturers from this waiver -- which could restrict the flow of disease and adherence-related materials from manufacturers -- while also acknowledging that these materials are beneficial and worth protecting under the waiver -- is unclear.

Nevertheless, the fact that manufacturers are excluded from the Patient Incentive waiver does not mean that items distributed by manufacturers that promote adherence or disease management necessarily violate (or are “suspect” under) the fraud and abuse laws. The final rule emphasizes that “a waiver of a fraud and abuse law is not needed for an arrangement to the extent that the arrangement: (1) does not implicate the specific fraud and abuse law; or (2) implicates the law, but either fits within an existing exception or safe harbor, as applicable, or does not otherwise violate the law.” Thus, CMS and OIG may believe that no waiver is necessary to allow pharmaceutical manufacturers to provide the sorts of unbranded disease state and compliance educational materials that OIG has previously advised do not implicate the AKS. Because CMS and OIG did not specify why they believe waivers for drug and device manufacturers are unnecessary, however, manufacturers must still structure these arrangements with care.

V. Compliance with Stark Law Waiver

Under the Compliance with Stark Law Waiver, the AKS is waived with respect to any financial relationship between or among the ACO, its ACO participants, and its ACO providers/suppliers that implicates the Stark Law, provided that the financial relationship complies with a Stark Law exception. The Stark Law

only prohibits a physician from making a “referral” for certain designated health services to an “entity” with
which the physician has a financial relationship, and CMS has interpreted the Stark Law to include only
referrals to entities that directly provide items or services to patients. Therefore drug and device
manufacturers’ arrangements ordinarily would not implicate the Stark Law to begin with.

If you have any questions about any of the topics discussed in this advisory, please contact your Arnold & Porter
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