# Health Law Alert: Changes to Anti-Kickback Statute Safe Harbors and Civil Monetary Penalty Rules Now Effective

February 28, 2017

As of January 6, 2017, new changes are in effect to the federal Anti-Kickback Statute (AKS) and Civil Monetary Penalty (CMP) rules. The Department of Health and Human Services Office of Inspector General (OIG) issued a long-awaited final rule in December that creates new AKS safe harbors, modifies existing AKS safe harbors, and amends the definition of "remuneration" under CMP guidelines.

A second rule published on the same day implements several provisions of the Affordable Care Act (ACA) that allow for the expanded imposition of CMPs for conduct such as failing to give the OIG quick access to documents and ordering or prescribing medication while excluded from Medicare or Medicaid.

With these rules now in effect, providers should consider how the new safe harbors and exceptions to the definition of "remuneration" can be utilized to permit additional business relationships and practices, while remaining mindful of the OIG's continued focus on fraud and abuse enforcement.

**Changes to Anti-Kickback Statute Safe Harbors**

The AKS imposes criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce or reward the referral of business reimbursable under federal health care programs. Congress and the OIG have carved out certain AKS safe harbors to describe various payment and business practices that, although they potentially implicate the AKS, are not treated as fraudulent kickbacks or violations under the statute. The first Final Rule created new safe harbors and revised several existing ones:

- ***Referral Services***. The OIG finalized a technical correction to the safe harbor for referral services. The OIG explained there was an inadvertent error in a 2002 revision, such that the regulation prohibited basing a participant's fee on the volume or value of any referrals or business otherwise generated by either party for the referral service. The final rule returns the safe harbor to the prior language stating that any payment to the referral service by participants must not be based on the volume or value of any

referrals to or business otherwise generated by either party for the other party.

- ***Cost-Sharing Waivers by Pharmacies***. The final rule created a new protection for certain cost-sharing waivers by pharmacies to beneficiaries who demonstrate financial need. To meet this safe harbor, pharmacies are required to meet the following criteria: (1) the waiver/reduction is not advertised or part of a solicitation; (2) the pharmacy does not routinely waive cost-sharing; and (3) before waiving a cost-sharing obligation, the pharmacy determines in good faith that either the beneficiary has a financial need or the pharmacy fails to collect cost-sharing amounts after making a reasonable effort to do so. Only the first criterion would apply if the reduction/waiver were made on behalf of "subsidy-eligible" individuals since such individuals would have already been deemed to satisfy financial need criteria for purposes of subsidy of their Part D premiums. In response to public comment, the OIG also extended the entire safe harbor (not just the section on Part D cost-sharing waivers) to all federal health care programs, as the safe harbor had applied only to Medicare and state health care programs. However, the OIG cautioned that the waiver is still only applicable to pharmacies and does not protect, for example, waivers by physicians for copayments for Part B drugs.

- ***Cost-Sharing Waivers for Emergency Ambulance Services***. The final rule created another new safe harbor relating to waiver of beneficiary coinsurance/deductible amounts to protect exemptions and reductions for "emergency ambulance services" furnished by a Medicare Part B ambulance provider or supplier owned or operated by a state, a political subdivision of a state or a tribal health program. Under the final rule, ambulance providers are required to offer the reduction/waiver on a consistent basis, and the waivers should not be based on patient-specific factors, which include anything other than residency in the municipality or other government unit providing ambulance services. Further, providers are prohibited from claiming the reduction or waiver amount as bad debt. The OIG also expanded the cost sharing under this part of the safe harbor to all federal health care programs.

- ***Federally Qualified Health Centers and Medicare Advantage Organizations***. The final rule added a new safe harbor for any remuneration between a federally qualified health center and a Medicare Advantage organization (MAO) under a written agreement.

- ***Medicare Coverage Gap Discount Program***. The final rule also created a statutory exception for discounts under the Medicare Coverage Gap Discount Program, which provides beneficiaries with discounts on covered Part D drugs while they are in the coverage gap or "donut hole." The new safe harbor protects discounts for "applicable drugs" furnished to an "applicable beneficiary," as defined in the Medicare Coverage Gap Discount Program statute.

- ***Local Transportation***. The last new safe harbor protects free or discounted local transportation services provided to federal health care program beneficiaries to obtain medically necessary items or services. In

finalizing the rule, the OIG addressed multiple issues raised by commenters, including (but not limited to) clarifying that the safe harbor protects transportation to a provider or supplier of services and back to a patient's home, as long as all conditions of the safe harbor are met, and that the transportation does not need to be planned in advance and can be accessed through use of vouchers rather than directly by the eligible provider or supplier.

**Civil Monetary Penalty Rules—Beneficiary Inducement Amendments**

In addition to modifying AKS safe harbors, the OIG also created several exceptions to the definition of "remuneration" that allow providers to give free services to beneficiaries without triggering a CMP. Typically, the beneficiary inducement provisions prohibit any person from offering remuneration to Medicare or Medicaid beneficiaries that the offeror knows or should know are likely to influence the selection of particular providers, practitioners, or suppliers. However, the new rule amended the definition of "remuneration" by codifying statutory exceptions added by the Balanced Budget Act of 1997 (BBA) and the ACA:

- ***Copayment Reductions for Certain Hospital Outpatient Department Services***. The OIG codified an existing statutory exception that allows hospitals to reduce copayment amounts for certain outpatient department services. Congress added this exception as part of the BBA, and the OIG adopted regulatory language identical to the BBA.

- ***Remuneration that Promotes Access to Care and Poses a Low Risk of Harm***. This exception protects remuneration that "promotes access to care and poses a low risk of harm to patients and federal health care programs." Importantly, there is no maximum amount of remuneration that qualifies for this safe harbor. However, as at least one commentator suggests, the trick will be defining these terms, and providers should be aware that avoiding a CMP might hinge on how they document and present their program.

    - *What Is "Care"?* When considering whether an item or service offered to a beneficiary will "promote access to care," the OIG stated that the relevant "care" means any items or services provided to a Medicare or Medicaid beneficiary and that are payable by Medicare or Medicaid. In response to the many comments received, the OIG rejected its proposal to limit the definition of "care" to "medically necessary care" because some states cover care that is not medical in nature (e.g., Medicaid coverage of personal care services). As such, providers should be aware that this particular term is likely to be interpreted broadly.

- *What Does it Mean to "Promote Access" to Care?* The regulations provide that an arrangement promotes access to care only if it "improves a particular beneficiary's ability to obtain" care. The OIG's discussion on this point focused on remuneration that removes obstacles or provides tools and resources that will help a beneficiary access care, but any remuneration that incentivizes or rewards a patient's adherence to treatment is not reimbursable. Remuneration that may entice a recipient to receive care (e.g., movie tickets in return for attending a counseling session) would not qualify for the exception, but items that make it possible for the beneficiary to access care (e.g., child care assistance during the time of the counseling session) will be reimbursable under this safe harbor. Providers should know that it will be important to structure any offerings or programs in a way that facilitates or promotes access to health services, as opposed to rewarding treatment adherence, even if adherence might prove beneficial to a patient's health and save Medicare and Medicaid money.

- *What Type of Remuneration Poses a "Low Risk of Harm"?* The OIG proposed a three-part test for determining whether remuneration offered to a beneficiary poses a "low risk of harm." Specifically, remuneration poses a low risk of harm if the items or services: (1) are unlikely to interfere with or bias clinical decision-making; (2) are unlikely to increase costs to federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (3) do not raise patient safety or quality of care concerns. The OIG stressed that they are concerned with increased costs relating to "overutilization" and "inappropriate utilization"—not increased utilization so long as it is appropriate.

- ***Coupons, Rebates, and Other Retailer Reward Programs****.* The final rule codified the ACA exception permitting retailers to offer or transfer coupons, rebates, or other rewards for free or less than fair market value if the items or services are available on equal terms to the general public and are not tied to the provision of other items or services reimbursed in whole or in part by Medicare or Medicaid. For more information, the OIG's responses to the comments provided some clarifications on what arrangements would be covered by this exception.

- ***Financial Need-Based Exception****.* The final rule also codified the ACA exception that permits individuals or entities to offer or transfer items or services (excluding cash or cash equivalents such as checks or debit cards) for free or less than fair market value to Medicare and Medicaid beneficiaries if: (1) there is a good faith determination of the individual's financial need, (2) the items or services are not advertised, (3) the offer is not tied to the provision of other items or services reimbursed by Medicare or Medicaid, and (4) there is a "reasonable connection" between the items or services being offered and the medical needs of the individual. In the final rule, the OIG indicated that it would interpret "reasonable connection to medical care of the individual" broadly and rely on the patient's medical professional to determine what is reasonably connected to his or her patient's medical care.

- ***Waivers of Cost-Sharing for the First Fill of a Generic Drug***. The last exception codified in the final rule permits Part D and MA-PD plan sponsors to waive enrollee copayments for the first fill of a generic drug covered by Part D. In the final rule, the OIG relies on the definition of "generic drug" outlined in the Part D regulations. Additionally, the final rule requires plan sponsors to disclose this incentive program in their benefit plan package submissions to CMS for coverage years beginning on or after January 1, 2018.

**Expanding Civil Monetary Penalties**

On the same day it released the rule discussed above, OIG issued a second Final Rule that also affects CMP regulations. This final rule mainly implements statutory provisions of the ACA providing for CMPs, assessments, and exclusions for: failure to grant OIG timely access to records; ordering or prescribing while excluded; making false statements, omissions, or misrepresentations in an enrollment application; failure to report and return an overpayment; and making or using a false record or statement that is material to a false or fraudulent claim. This final rule also reorganized the regulations regarding CMPs, assessments, and exclusions to "improve readability and clarity."

*If you have questions about the federal Anti-Kickback Statute or civil monetary penalty rules, please contact Catie Bitzan Amundsen at catherine.amundsen@lathropgpm.com (612-632-3277) or Julia Reiland at julia.reiland@lathropgpm.com (612-632-3280).*