On December 7, 2016, the Office of Inspector General of the US Department of Health and Human Services (OIG) published a final rule containing revisions to both the federal Anti-Kickback Statute (AKS) safe harbors and the beneficiary inducement prohibition in the civil monetary penalty rules (CMP Law) (Final Rule). The Final Rule follows the proposed rule that was published on October 2, 2014. The Final Rule is effective January 6, 2017.

Anti-Kickback Statute

The Final Rule modifies certain existing safe harbors to the AKS and added additional safe harbors that provide new protections or codify certain existing protections. Overall, the Final Rule adopts all of the AKS safe harbors previously proposed, with certain modifications suggested by commenters. Following is a brief summary of each safe harbor and change.

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.

Cost-Sharing Waivers by Pharmacies: A new subsection to the safe harbor relating to waiver of beneficiary coinsurance/deductible amounts (42 C.F.R. § 1001.952(k)) implements Section 1128B(b)(3)(G) of the Social Security Act (Act)—as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)—to protect waivers or reductions by pharmacies of Medicare Part D cost-sharing obligations. To meet the safe harbor, pharmacies are required to satisfy 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 is made on behalf of a “subsidy-eligible” individual, 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.

Cost-Sharing Waivers for Emergency Ambulance Services: The Final Rule finalized the OIG’s proposal to create another new section of the safe harbor relating to waiver of beneficiary coinsurance/deductible amounts to protect waivers 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 uniform basis, and the waivers should not be based on patient-specific factors, which include anything other than residency in the

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municipality or other government unit providing ambulance services. Further, providers are prohibited from claiming the reduction or waiver amount as bad debt. The OIG had previously proposed including an additional requirement that the reduction or waiver not be considered the furnishing of free services paid for directly or indirectly by a government entity. However, the OIG removed this requirement, stating that the Centers for Medicare & Medicaid Services (CMS) policy adequately addresses the issue. 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 adds a new safe harbor to implement Section 237 of the MMA, which created a statutory exception to the AKS for any remuneration between a federally qualified health center and a Medicare Advantage organization (MAO) pursuant to a written agreement.

**Medicare Coverage Gap Discount Program:** Section 3301(d) of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (ACA) amended the AKS to create 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 those terms are defined in the Medicare Coverage Gap Discount Program statute.

**Local Transportation:** The most highly anticipated AKS provision in the Final Rule is the new safe harbor to protect free or discounted local transportation services provided to Federal health care program beneficiaries in order to obtain medically necessary items or services. In finalizing the rule, the OIG addressed multiple issues raised by commenters, including 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.

The final safe harbor includes numerous elements, requiring that services be provided by “eligible entities” (which excludes entities that primarily supply health care items such as durable medical equipment and pharmaceutical companies), and otherwise meet various safeguards, including prohibitions on air, luxury or ambulance transportation, marketing the services, and transports in excess of 25 miles or 50 miles if the patient resides in a rural area. The OIG believes that signage designating the source of the transportation on vehicles used to transport patients is an important safety feature and would not be “marketing,” for purposes of the safe harbor. However, providers that give patients pamphlets or other marketing or informational materials during transport would not be protected by the safe harbor.

The Final Rule also permits shuttle service (a vehicle that runs on a set route, on a set schedule and that may include stops at locations that do not relate to a particular patient's medical care). Non-shuttle local transportation services must be provided pursuant to a policy which the eligible entity applies uniformly and consistently (individualized documentation for each patient whom transportation is provided is not required), and the services may be provided only to “established patients.”

The proposed rule defined “established patients” to include only patients who had selected a provider or supplier and had attended an appointment with the provider or supplier. However, in the Final Rule, the OIG acknowledged that due to the marketing restriction, providing services to new patients who contact the provider or supplier on their own initiative is sufficiently low risk to also warrant safe harbor protection. As a result, under the Final Rule, a patient is considered “established” once he or she selects and initiates contact with a provider or supplier to schedule an appointment.

**Civil Monetary Penalty Law**

Under the beneficiary inducement provisions of the CMP Law, a person who offers or provides any remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services may be liable for civil money penalties, subject to a limited number of exceptions. The Final Rule excepts certain practices from the definition of “remuneration” for purposes of the CMP rules in an effort to establish a balance between preserving restrictions against fraud and abuse and facilitating activities that incentivize beneficiaries to comply with their wellness or treatment regimens and seek coordinated care.

*Copayment Reductions for Outpatient Department Services as an Exception to the Definition of “Remuneration”:* The Final Rule codifies the exception to the definition of “remuneration” added by Section 4523 of the Balanced Budget Act of 1997 concerning reductions in copayment amounts for covered hospital outpatient department services pursuant to Section 1833(t)(8)(b) to the Act.

*ACA-Mandated Exceptions to the Definition of “Remuneration” into the CMP Laws:* The Final Rule incorporates ACA-
mandated exceptions into the definition of “remuneration” by including the following:

- **Promotes Access to Care and Low Risk of Harm.** The Final Rule exempts “items or services that improve a beneficiary’s ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs” from the definition of remuneration. The OIG maintained its interpretation of “low risk of harm,” categorizing such items or services as those that are: “(i) unlikely to interfere with, or skew, clinical decision making; (ii) unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) not raising patient safety or quality-of-care concerns.” While “items or services that support or help patients to access care, or make access to care more convenient than it otherwise would be” would often fall under this exception, “inducements to comply with treatment or rewards for compliance with treatment” would not fall under this exception.

This section of the Final Rule was a highly anticipated regulatory implementation of one of the ACA’s CMP exceptions. While other exceptions require a determination of financial need or are narrowly tailored to specific circumstances (e.g., the retailer rewards programs described below), this exception potentially covers a broader array of programs, which is very helpful. However, this flexibility also means that the exception does not include explicit guidelines for specific arrangements, so evaluation of arrangements under the Final Rule still requires a facts and circumstances analysis. The preamble to the Final Rule includes a fairly lengthy discussion of this section that should be reviewed when evaluating the facts and circumstances of a particular program or practice under the exception.

- **Retailer Rewards Program.** The Final Rule retains language and interpretation of the proposed exception, exempting “items or services for free or less than fair market value by a person if: (i) the items or services consist of coupons, rebates, or other rewards from a retailer; (ii) the items or services are offered or transferred on equal terms available to the general public, regardless of health insurance status; and (iii) the offer or transfer of the items is not tied to the provision of other items or services reimbursed in whole or in part by the program under” Medicare or a State health care program. The term “retailer” is interpreted to exclude entities that primarily provide services, such as hospitals and physicians. As a result, this exception is primarily of use to pharmacies and other retailers that also include a pharmacy, as opposed to most health care providers.

- **Financial-Need-Based Exemption.** The Final Rule maintains the language and interpretation of this proposed exception, exempting offers or transfers of items or services (excluding cash or instruments that can be converted into cash) for free or less than fair market value if: (i) the items or services are not offered through advertising or solicitation; (ii) the offer or transfer is not tied to other reimbursable services and (iii) are “reasonably connected” to the individual’s medical care from both medical and financial perspectives; and (iv) the offeror or transferor of the items or services “determines in good faith” that the individual has financial need.

- **Waivers of Cost-Sharing for the First Fill of a Generic Drug.** The Final Rule retains the text of the proposed exception, allowing Part D Plan sponsors or Medicare Advantage (MA) organizations to waive copayments for the first fill of a covered Part D “generic drug,” as defined in Part D regulations. Sponsors aiming to offer these waivers to enrollees must disclose such waivers in the benefit design packets that they are required to submit to CMS. As a result, this exception will not be available until January 1, 2018.

The OIG notes in the Final Rule that non-cash or cash equivalent payments that are nominal in value are not inducements and therefore do not require an exception to the beneficiary inducement prohibition. Concurrently with issuance of the Final Rule, the OIG announced an increase in its guidelines for “nominal value” from $10 to $15 for an individual gift and from $50 to $75 in value in the aggregate annually per patient.

Finally, the OIG previously proposed to adopt a regulation implementing the gainsharing CMP, which prohibits a hospital from knowingly paying a physician to induce the physician to reduce or limit the services provided to Medicare or Medicaid beneficiaries under the physician’s direct care. Approximately six months after the proposed rule was published, Congress passed the Medicare and CHIP Reauthorization Act of 2015 (MACRA) in April 2015, which amended the language so that only payments to reduce or limit medically necessary services are prohibited by the law. Because of the amendment to the statute, OIG did not finalize the regulation.

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