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Health Care ADVISORY ■

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Proposed OIG Rules Would Expand Anti-Kickback Statute Safe Harbors

On October 2, 2014, the Department of Health and Human Services Office of Inspector General (OIG) published proposed rules to add new safe harbors to the federal Anti-Kickback Statute (AKS). The OIG's proposed rules would also codify certain revisions made to the federal Civil Monetary Penalty Law ("CMP Law") by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and the Patient Protection and Affordable Care Act (ACA), as amended by the Health Care and Education Reconciliation Act of 2010.

Overview

The proposed rule makes a technical correction to the AKS's referral services safe harbor and also proposes five new AKS safe harbors that would protect:

- Pharmacy cost-sharing waivers for financially needy Medicare Part D participants;
- Emergency ambulance service cost-sharing waivers when the services are furnished by state- or municipality-owned providers;
- Certain remuneration between federally qualified health centers and Medicare Advantage organizations;
- Discounts by manufacturers on drugs provided under the Medicare Covered Gap Discount Program; and
- Certain free or discounted local transportation.

The OIG also proposed adding four new exceptions to the CMP Law's definition of remuneration, allowing for certain:

- Remuneration that promotes access to care while posing a low risk of harm;
- Coupons, rebates or other retailer reward programs;
- Remuneration to financially needy individuals; and
- Copayment waivers for the first prescription fill of generic drugs.

Finally, the OIG would change regulatory definitions as they apply to gainsharing arrangements under the CMP Law to narrow the statute's application.

The OIG will accept comments on these proposed changes until December 2, 2014.

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Anti-Kickback Statute

Part D Cost-Sharing Waivers by Pharmacies: The OIG would protect certain cost-sharing waivers, including pharmacy waivers for financially needy Medicare Part D participants and emergency ambulance services furnished by providers owned by states or municipalities. Cost-sharing waivers are generally not allowed under the AKS. The OIG has stated its concern that such waivers present the opportunity for abuse and overutilization of health care resources. To meet the safe harbor, pharmacies would be required to satisfy three 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. The OIG specifically requests comment on whether the safe harbor should be extended to all federal payors, as the current safe harbor applies only to Medicare and state health care programs.

Cost-Sharing Waivers for Emergency Ambulance Services: The proposed rule would protect cost-sharing waivers for emergency ambulance services furnished by providers owned by states or municipalities. This new safe harbor would codify the favorable advisory opinions the OIG has issued regarding these waivers in the past. Ambulance providers would be required to offer the reduction/waiver on a uniform basis, without regard to patient-specific factors. Though generally items and services provided free of charge by a government entity are not reimbursable, the OIG and CMS have confirmed that they do not interpret such a reduction/waiver to mean that the government entity is providing free services. Thus, providers would be prohibited from claiming the reduction/waiver amount as bad debt.

Federally Qualified Health Centers and Medicare Advantage Organizations: The OIG's proposed rule would protect certain remuneration between federally qualified health centers (FQHCs) and Medicare Advantage organizations. Certain remuneration between the two is already protected under an AKS statutory exception created by the MMA. The OIG's proposed rule would add a similar regulatory safe harbor, providing protection for discounts on "applicable drugs" for "applicable beneficiaries" (i.e., Medicare Part D) while they are in the Medicare coverage gap or "donut hole."

Local Transportation: The OIG would protect free or discounted local transportation provided to federal health care program beneficiaries, stating its belief that previous policies have been overly restrictive in the context of complimentary local transportation. Among other terms, the OIG is seeking comments on how to define "local." The OIG has proposed definitions based on mileage, time travelled and/or provider location, but recognizes a one-size-fits-all approach may not be appropriate. The OIG also seeks comments on what types of providers should be eligible for this safe harbor.

Technical Correction: The proposed rule would make a technical correction to the AKS's referral services safe harbor, reverting back to language finalized in the 1999 rule that was inadvertently changed in a 2002 revision. Thus, it will again be clear that the referral services safe harbor precludes protection for payments from participants to referral services that are based on the volume or value of referrals to, or business otherwise generated by, either party for the other party.

Civil Monetary Penalties Authorities

The OIG also proposed amending the CMP Law's definitions of remuneration. The ACA expanded the definition of remuneration, and the OIG seeks to codify the changes as well as establish other exceptions. The new exceptions "are intended to protect certain arrangements that offer beneficiaries incentives to engage in their wellness or treatment regimens or that improve or increase beneficiary access to care, including better care coordination." The OIG has attempted to strike a balance between these potential benefits and the potential for abuses of the exceptions that could lead to unnecessary, expensive or poor quality services being billed to Medicare or Medicaid.

Beneficiary Inducements: The OIG proposes codifying the exception to the definition of "remuneration" added by the Balanced Budget Act of 1997 concerning reductions in copayment amounts for covered hospital outpatient department services.

Promotes Access to Care: The new rule would exclude certain remuneration that promotes access to care. The OIG is seeking comment on how broadly the definition of "access to care" should be interpreted. For example, the OIG has proposed crafting the definition to accommodate the growing rise of coordinated or integrated care arrangements that depend, in part, on patient engagement. The OIG also seeks comments on whether access to care should include nonclinical care that is reasonably related to the patient's medical care. The OIG believes "giving items that are necessary to patients to record and report health data" can also promote access to care. The OIG also seeks comment on which providers should be eligible for this exception.

Retailer Rewards Program: The OIG seeks to establish an exception allowing for certain retailer rewards programs that are offered on equal terms, regardless of health insurance status. Generally, these rewards programs must consist of coupons, rebates or other rewards, including a discount on merchandise or services. While excluding individuals or entities that primarily provide services (e.g., hospitals, physicians) from the definition of "retailer," the OIG is soliciting comments on whether entities that primarily sell items that require a prescription (e.g., medical equipment stores) should be considered retailers. The OIG also explained that the reward itself must not be conditioned on the purchase of goods or services reimbursed in whole or in part by a federal health care program, nor should a reward itself be an item or service reimbursed in whole or in part by a federal health care program.

Financially Needy Recipient: Under the proposed rule, the OIG would allow for the offer or transfer of items or services for less than fair market value after the provider has made a good faith effort to determine whether the recipient is financially needy. The OIG set forth numerous conditions, including: the protected items or services may not be offered as part of any advertisement or solicitation, there is a reasonable connection between the items or services and the medical care of the individual, and the items or services are not tied to the provision of other services reimbursed by a federal or state health care program. The OIG proposed a broad definition of "medical care" to include "the treatment and management of illness or injury and the preservation of health through services offered by the medical, dental, pharmacy, nursing, and allied health professions." The OIG is seeking comments on whether it can (and should) identify specific conditions under which remuneration would be deemed to be "reasonably connected" to a patient's medical care.

Waivers of Cost-Sharing for the First Fill of a Generic Drug: The OIG proposes including an exception for waivers of the cost for the first time a Medicare Part D or Medicare Advantage recipient fills a prescription for a generic drug. The OIG believes this exception could minimize drug costs for both private and federal insurers. Sponsors seeking this exception would have to register with CMS and disclose this incentive program in their benefit plan package submissions to CMS. The OIG noted that it will not exercise its enforcement authority against plans complying with the CMS requirements for these waivers prior to finalization of the proposed rule.

Gainsharing Civil Monetary Penatlies

The OIG has repeatedly "recognized gainsharing can be beneficial" and has approved 16 gainsharing arrangements through advisory opinions. The OIG has expressed a desire to accommodate health care industry developments toward coordinated or integrated care arrangements and efforts by insurers to lower costs and improve care.

The gainsharing provision of the CMP Law prohibits a hospital from knowingly making a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided to Medicare or Medicaid beneficiaries who are under the direct care of the physician. Believing it could not read a "medically necessary" element in the

prohibition without a statutory change, the OIG instead narrowed its interpretation of "reduce or limit services." The OIG states, "as hospitals move towards using objective quality metrics, we recognize that a change in practice does not necessarily constitute a limitation or reduction of services, but may in fact constitute an improvement in patient care or a reduction in cost without reducing patient care or diminishing its quality." Note that the OIG interprets "reduce or limit services" to include payments to limit *items* used in providing services.

The OIG also proposed adding a definition of hospital and is soliciting comments on whether to include a definition of the term "reduce or limit services." The OIG listed several other specific areas of concern for which it is soliciting comments.

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