ROPES & GRAY

ALERT

Health Care

January 4, 2017

HHS OIG Expands Anti-Kickback Safe Harbors and Civil Monetary Penalties Law Exceptions; Issues Guidance on Gifts of Nominal Value

On December 7, 2016, the Office of Inspector General (the "OIG") of the U.S. Department of Health and Human Services ("HHS") issued a final rule modifying the safe harbors to the anti-kickback statute[1] and the civil monetary penalties ("CMP") rules[2], as well as a policy statement adjusting the monetary value of nominal gifts not subject to the CMP prohibition against beneficiary inducements. The new rules become effective January 6, 2017. We previously issued an alert discussing the proposed rulemaking, available here.[3]

The final rule revises existing safe harbors and adds new safe harbors to codify existing protections in an effort, generally, to facilitate certain arrangements that both increase access to care and present low risk of abuse. These include:

- Protections for free and discounted local transportation for established patients of certain providers;
- Protections for pharmacy cost-sharing waivers for financially needy beneficiaries;
- Protections for manufacturer drug discounts on drugs furnished to beneficiaries under the Medicare Coverage Gap Program;
- Protections for payments between Medicare Advantage plans and federally qualified health centers;
- Protections for cost-sharing waivers for emergency ambulance services furnished by state- or municipality-owned ambulance companies; and
- A technical correction to the existing safe harbor for referral services.

The OIG also revised the definition of "remuneration" in the CMP regulations at 42 C.F.R. part 1003 to implement CMP statutory provisions that except from the definition of "remuneration" certain patient payment discounts and waivers. Under the final rule, the following arrangements are not considered "remuneration" subject to the CMP law:

- Copayment reductions for certain hospital outpatient services;
- Arrangements that pose a low risk of harm and promote access to care;
- Coupons, rebates, and other reward programs that meet specified requirements;
- Certain payments to financially needy individuals; and
- Copayment waivers for the first fill of generic drugs.

[1] 42 U.S.C. § 1320a-7b.
[2] 42 U.S.C. § 1320a-7a.
[3] PDF copy of the proposed rule.

ANTI-KICKBACK STATUTE SAFE HARBORS

Local Transportation

The OIG added a new safe harbor that permits eligible entities to provide free or discounted local transportation to established patients in order to access medically necessary services. Transportation cannot take the form of air, luxury, or ambulance-level service. The OIG went further in the final rule than it did in the proposed rule by (i) broadening its interpretation of "established patient" to encompass any patient who has made an appointment with the provider or supplier, (ii) expanding its interpretation of "local" to include different distances for rural and non-rural areas, and (iii) adding guidance applicable to shuttle services.

In the final rule, for example, the OIG defined an "eligible entity" to be any individual or entity other than those that primarily supply and sell health care items (*e.g.*, durable medical equipment suppliers or pharmaceutical companies). It determined a patient to be "established" within the meaning of the safe harbor once the patient makes an initial appointment with a provider/supplier. And it defined "local" as an area within a 25-mile distance for patients in an urban area and within a 50-mile distance for patients in a rural area.

The final rule also protects shuttle services. The OIG interpreted "shuttle" to be a vehicle (not air, luxury vehicle, or ambulance) that operates on a set route pursuant to a set schedule. The safe harbor for shuttle services does not require that users of the shuttle service be established patients, as otherwise required by the safe harbor for local transportation.

In the final rule, the OIG offered examples of situations that can fall within the "local transportation" safe harbor:

- Transporting patients to another provider or supplier, such as a hospital's transporting a patient to affiliated post-acute sites;
- Transporting patients to another provider or supplier that is a referral source, as long as the transportation offer is not contingent on the patient's choosing a referral source;
- Transporting a patient to a provider and back to the patient's home;
- Offering transportation either in advance for services or in connection with ad hoc services that arise unexpectedly; and
- Offering transportation provided either directly by the eligible entity or through vouchers.

Cost-Sharing Waivers by Pharmacies

The OIG added a new safe harbor that expands the protections for pharmacy cost-sharing waivers and reductions for financially needy beneficiaries to all federal health care program beneficiaries, not just those enrolled in Medicare Part D. This addition codified in regulation the statutory exception under the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA") for a pharmacy's waiver or reduction of cost-sharing obligations for Medicare Part D beneficiaries, and, as noted above, expanded this protection to include waivers by pharmacies under all federal health care programs (not just Medicare Part D plans), as long as:

- The waiver or reduction is not advertised or part of a solicitation;
- The pharmacy does not routinely waive or reduce the cost-sharing obligation; and
- Before waiving or reducing the cost-sharing obligation, the pharmacy either determines in good faith that the beneficiary has financial need or makes a reasonable effort to collect the cost-sharing amount.

Medicare Coverage Gap Discount Program

The final rule codifies in regulation the statutory exception under the Affordable Care Act ("ACA") that permits pharmaceutical manufacturers to provide discounts to beneficiaries of Medicare Part D prescription drug plans who are in the so-called "coverage gap" or "doughnut hole" (*i.e.*, the beneficiary is responsible for the full cost of his or her drugs because annual drug costs have exceeded an established threshold but have not yet reached the threshold at which catastrophic coverage begins). The safe harbor requires the manufacturer's compliance with the terms of the Medicare Coverage Gap Discount Program and applies only to "applicable drugs" and "applicable beneficiaries"; namely, to beneficiaries enrolled in, and drugs that are covered by, prescription drug plans and MA-PD plans. The exception would not encompass, for example, Medicare reasonable cost contractors that offer a Part D supplemental benefit.

Federally Qualified Health Centers and Medicare Advantage Organizations

The final rule also codifies in regulation the statutory exception under the MMA that permits remuneration between a federally qualified health center ("FQHC") and a Medicare Advantage ("MA") organization under certain circumstances if:

- The remuneration is provided pursuant to a written agreement between the FQHC and MA organization; and
- The written agreement specifically provides that the MA organization will pay the FQHC no less than the level and amount of payment that the plan would make for the same services if the services were furnished by another type of entity.

CIVIL MONETARY PENALTIES LAW

The OIG also amended the CMP rules to broaden the categories of "remuneration" that may be given to beneficiaries, even if potentially likely to influence the beneficiaries to order or receive covered services from a particular provider, practitioner, or supplier—which otherwise would be prohibited. The amendments codify five revisions to the definition of "remuneration," broadly supporting organizations' ability to provide support for beneficiaries' access to care.[4] Separately, the OIG also increased the dollar caps on nominal-value gifts.

The OIG's only substantive change from its earlier proposed rulemaking was to the exception relating to copayment waivers for the first fill of a generic drug, discussed below. (Another difference from the proposed rulemaking is that the final rule does not address the CMP's gainsharing prohibitions. That is not, however, a substantive change, because the issue was superseded by the Medicare and CHIP Reauthorization Act of 2015 ("MACRA"), passed in April 2015, which amended the language of the statute such that only payments to reduce or limit medically necessary services are prohibited by law. Accordingly, the OIG did not need to address the issue in regulation.)

Exceptions to Prohibition on Beneficiary Inducements

Copayment Reductions for Certain Hospital Outpatient Department Services. The OIG codified a statutory exception that permits hospitals to reduce copayment amounts for certain covered hospital outpatient department ("HOPD") services pursuant to sections 1833(t)(8)(B) and 1128A of the Social Security Act ("the Act"). Section 1128 permits hospitals to reduce copayment amounts for some or all covered HOPD services to 20 percent of the Medicare HOPD fee schedule amount, and section 1833(t)(8)(B) defines these covered HOPD services.[5] The final rule codifies this exception.

[4] 42 U.S.C. §1320a-7a(a)(5).
[5] Section 1833(t)(8)(B) of the Act includes under "covered services" certain hospital outpatient and inpatient services "designated by the Secretary," as well as some implantable items; it also excludes certain therapy and ambulance services, as well as mammography and personalized prevention plan services.

Promotes Access with Low Risk of Harm. Under the final rule, the OIG exempts items or services that "improve a particular beneficiary's ability to obtain items and services that are payable by Medicare or a State health care program" and pose a low risk of harm to patients and Federal health care programs. Remuneration is considered to pose a "low risk of harm" if the remuneration (i) is unlikely to interfere with, or skew, clinical decision-making; (ii) is unlikely to increase costs to federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) does not raise patient-safety or quality-of-care concerns.

This exception also applies to remuneration that generally promotes access to care for a defined beneficiary population. Specific guidance from the OIG indicates that such access to care could include participation in smoking cessation, nutritional counseling or other disease-specific support groups. It does not, however, reach to arrangements that apply to all beneficiaries or inducements and rewards for compliance with treatment. The final rule does not specify particular arrangements that would fall under the exception, leaving evaluation of arrangements subject to a facts-and-circumstances analysis. However, the lack of specific guidance indicates that the exception may reach to a broader scope of arrangements than do other exceptions.

Retailer Rewards Programs. The final rule codifies a statutory exception that protects coupons, rebates, and other rewards from a retailer (interpreted as an entity that sells items directly to consumers, not including entities that primarily provide services) that (i) are made available to the general public regardless of health insurance status and (ii) are not tied to the provision of other items or services reimbursable by a state or federal health care program. The final rule does not require "a complete severance of the offer from the medical care of the individual," but requires that the reward program must treat reimbursable and non-reimbursable items equally for purposes of earning or redeeming rewards.

Financial-Need-Based Exception. The OIG codified a statutory exception that protects the offer or transfer of items (other than cash or cash equivalents) or services for free or less than fair market value after a good-faith determination that the recipient is in financial need, and provided that the items or services (i) are not offered as part of any advertisement or solicitation; (ii) are not tied to the provision of other reimbursable items or services; and (iii) are "reasonably connected to the medical care of the individual."

The OIG noted that this exception "is not designed to induce the patient to seek additional care," but rather to help financially needy individuals to access items or services related to medical care. "Medical care" refers to "the treatment and management of illness or injury and the preservation of health." Assessment of whether a "reasonable connection" exists between the remuneration and the patient's medical care is based on (i) whether the items or services would "benefit or advance identifiable medical care or treatment that the individual patient is receiving" and (ii) whether the monetary value of the remuneration is "disproportionately large compared with the medical benefits conferred on the individual patient." The OIG gave an example of remuneration protected under this exception: a physician's offer to a financially needy patient of a tool or service to assist a patient in remembering when to take medication upon the physician's learning that the patient lives alone and has trouble remembering which medication to take at what time. In another example, the OIG recognized that the exception would apply to a pharmacist's provision of a free extra package of diabetic test strips to a financially needy diabetic patient who had run out of test strips and needed an immediate supply before a refill could be authorized.

Co-Payment Waiver for First Fill of a Generic Drug. The final rule codifies a statutory exception, effective January 1, 2018, that permits a Part D Plan sponsor to waive any copayment that otherwise would be owed by its enrollees for the first fill of a generic drug or authorized generic covered by Part D if the sponsor discloses such waivers in its benefit plan package submitted to the Centers for Medicare & Medicaid Services. The final rule modifies the proposed rule by including "authorized generic drugs" in the exception and specifying when the exception becomes effective.

Gifts of Nominal Value. In tandem with the final rule, the OIG also issued a policy statement revising the monetary value of gifts considered "inexpensive" or of "nominal value" under the statutory exception for nominal gifts. In the Conference Committee report accompanying the enactment of section 1128A(a)(5) of the Act, enacted as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Congress expressed its intent that inexpensive gifts of nominal value be permitted.[6] In 2000, the OIG last interpreted "inexpensive" or "nominal value" to mean a retail value of no more than $10 per item or $50 in the aggregate per patient on an annual basis and noted that it would periodically review these limits and adjust them according to inflation, if appropriate.[7]

In this policy statement, the OIG adjusts these figures to interpret "nominal value" as having a retail value of no more than $15 per item or $75 in the aggregate per patient on an annual basis. If a gift has a value at or below these thresholds, then the gift need not fit into a statutory exception to the remuneration prohibition.

[6] See Joint Explanatory Statement of the Committee of Conference, section 231 of HIPAA, Public Law 104-191.
[7] See, e.g., 65 FR 24400, 24411 (Apr. 26, 2000), available here, and Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries, August 2002, available here (Special Advisory Bulletin).