HHS Office of Inspector General Proposes Expansions of Anti-Kickback Safe Harbors and Civil Monetary Penalties Law Exceptions

On October 3, 2014, the Office of the Inspector General (the "OIG") of the U.S. Department of Health and Human Services ("HHS") issued a proposed rule[1] that would amend regulations implementing the federal anti-kickback statute[2] and the federal civil monetary penalties law.[3]

- The proposed rule would expand the "safe harbors" that protect certain activities from the broad scope of federal anti-kickback prohibition. The expansion would add new safe harbors responsive to requests from the health care industry that the OIG believes would present minimal risk to federal health care programs if appropriately structured. These would include:
  - Part D cost-sharing waivers by pharmacies;
  - Cost-sharing waivers for government owned and operated emergency ambulance services;
  - Payments between Medicare Advantage plans and federally qualified health centers;
  - Drug discounts under the Medicare Coverage Gap Program; and
  - Free and discounted local transportation for established patients of certain providers.

- The proposed rule also would codify in regulation existing statutory provisions, including:
  - exceptions to both the federal anti-kickback statute and the civil monetary penalties law that would protect against liability for certain inducements to beneficiaries; and
  - the long-standing statutory prohibition on gainsharing, for which OIG solicits comments on how to interpret in a way more accepting of such arrangements than the agency's historic position.
  - The OIG is soliciting comments on the proposed rule, including particular proposals as noted below. Comments are due by December 2, 2014.

Anti-Kickback Statute Safe Harbors

Cost-Sharing Waivers

The OIG proposes two new safe harbors for certain waivers of cost-sharing obligations. The OIG is also seeking comments on whether these safe harbors should be expanded to apply to all federal health care programs.

Part D Cost-Sharing Waivers by Pharmacies. The OIG proposes to codify in regulation the statutory exception under the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA") for a pharmacy that waives cost-sharing obligations for Medicare Part D beneficiaries. The safe harbor would require that:

- the waiver or reduction is not advertised or part of a solicitation;
- the pharmacy does not routinely waive the cost-sharing; and

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

- before waiving the cost-sharing, the pharmacy either determines in good faith that the beneficiary has financial need or makes a reasonable effort to collect the cost-sharing amount.

Cost-Sharing Waivers for Governmentally Owned and Operated Emergency Ambulance Services. The OIG notes that it frequently receives, and has ruled favorably on, advisory opinion requests for arrangements involving government agencies' waiver of cost-sharing obligations in connection with their provision of emergency ambulance services. Consistent with that history, the OIG proposes a new safe harbor that would permit the reduction or waiver of coinsurance or deductible amounts owed for emergency ambulance services if the ambulance provider is owned and operated by a state or local government authority and other conditions are satisfied.

- The ambulance provider must be owned and operated by a state, a political subdivision of a state, or a federally recognized Indian tribe. The proposed safe harbor would not apply to private ambulance providers, even if contracted by a local government.
- The ambulance service provider would be required to offer the reduction or waiver on a uniform basis, without regard to patient-specific factors.
- Reductions or waivers would apply only to *emergency* ambulance services (*i.e.*, initiated as a result of a 911 call or other emergency access number or a call from another acute care facility unable to provide the higher level care required by the patient).
- Providers could not claim the amount of the reduction or waiver as bad debt for payment purposes under federal health care programs or otherwise shift the burden of the reduction or waiver onto federal health care programs, other payers, or individuals.

Federally Qualified Health Centers and Medicare Advantage Organizations

The OIG proposes to codify in regulation the statutory exception under the MMA that permits remuneration between a federally qualified health center ("FQHC") and a Medicare Advantage ("MA") organization if:

- the remuneration is provided under 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.

Medicare Coverage Gap Discount Program

The OIG proposes to codify 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 when such beneficiaries 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 would require the manufacturer's compliance with the terms of the Medicare Coverage Gap Discount Program and would apply to "applicable drugs" and "applicable beneficiaries" under that program.

Local Transportation

The OIG proposes a new safe harbor that would permit "eligible entities" to provide free or discounted local transportation to established patients who are beneficiaries of federal health care programs in order to access medically necessary services. Although the OIG solicited comments on a local transportation safe harbor in a 2002 proposed rule, no safe harbor was finalized at that time. However, the OIG has evaluated transportation programs through its advisory opinion process, using a set of common factors to consider programs that could not satisfy the nominal value safe harbor (*i.e.*, services that exceed $10 per trip per patient or $50 in the aggregate, annually).[4] The current proposed safe harbor generally follows the factors set forth in the OIG advisory opinions, but adds definition to the factors, for example proposing to define the geographic area that constitutes "local" and clearly limiting the application to "established patients." The current proposed safe harbor would require that:

- the availability of the free or discounted local transportation services is not determined in a manner related to past or anticipated volume or value of federal health care program business (*e.g.*, providers cannot tie provision of transportation to receipt of certain services or require a certain number of trips to qualify);
- luxury services (*e.g.*, limousine transportation), air and ambulance level transportation not be used;
- the free and discounted transportation services are not marketed to patients; no marketing occurs during transportation; and payment to transportation providers is not based on the number of patients transported;
- free and discounted services could be provided (i) only to an *established patient* (and, if needed, a companion to assist the patient) to obtain *medically necessary services* and (ii) only within a local area (which the OIG proposes would be no further than a 25-mile distance) to and from the premises of the health care provider or supplier; and
- the eligible entity must bear the cost of the free or discounted transportation services and cannot shift such cost to any federal health care program, other payers, or individuals.

The OIG proposes that only *established patients* would be eligible for free or discounted local transportation to mitigate the concern that a provider could use the offer of transportation to drive provider selection. The OIG further proposes to exclude from the definition of "eligible entities" permitted to provide free or discounted local transportation those individuals and entities (or family members or others acting on their behalf) that primarily supply health care products (*e.g.*, durable medical equipment suppliers and pharmaceutical companies) as well as laboratory service providers and home care providers for certain types of transportation. These individuals and entities are heavily dependent on practitioner prescriptions and referrals; could use transportation arrangements to generate business by steering transported patients to those providers who order their products; and do not have broader roles in patient care that may generate general needs for patient transportation.

The OIG seeks comments on various aspects of the proposed safe harbor, including categories of providers that should be outside the scope of the safe harbor and whether an eligible entity could provide transportation only to providers and suppliers only within the eligible entity's system.

[4] *See, e.g.*, Advisory Opinion No. 11-02 (March 24, 2011); Advisory Opinion No. 09-01 (March 13, 2009); Advisory Opinion No. 00-7 (November 24, 2000).

Civil Monetary Penalties Law

The OIG would codify in regulation four statutory exceptions to the civil monetary penalties law prohibition on paying or offering "remuneration" to any federal health care program beneficiaries that the provider knows or should know is likely to influence the selection of particular providers or suppliers.[5] The proposed rule also would codify in regulation the civil monetary penalties law prohibition on hospitals paying incentives to physicians to induce the physicians to "reduce or limit services" provided to beneficiaries.[6]

Exceptions to Prohibition on Beneficiary Inducements

Promotes Access with Low Risk of Harm. The OIG would codify in regulation the statutory exception that protects remuneration that "promotes access to care and poses a low risk of harm to patients and federal health care programs." Under the proposed rule, the phrase "promotes access to care" would be interpreted to mean that the remuneration "improves a particular beneficiary's ability to obtain medically necessary health care items and services." The OIG is soliciting comments on whether the phrase should be more broadly interpreted, to include encouraging or supporting patients to access care or making access to care more convenient for patients than it would otherwise be. The OIG is also considering whether the exception should apply to remuneration that promotes access to care for a defined beneficiary population generally (*e.g.*, patients being treated under a designated care protocol). Consistent with considerations historically identified by the OIG, remuneration would be 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.

Retailer Rewards Programs. The OIG would codify in regulation the statutory exception that protects the offer or transfer of items or services for free or less than fair market value through coupons, rebates, or other rewards from a retailer that are: (i) made available to the general public regardless of health insurance status; and (ii) not tied to the provision of other items or services reimbursable by a federal health care program. Regarding the second requirement, the proposed rule would not require "a complete severance of the offer from the medical care of the individual," but only 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 would codify in regulation the 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 determination that the recipient is in financial need, 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 notes 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 their care. "Medical care" would therefore refer to "the treatment and management of illness or injury and the preservation of health" and would not typically include standard preventive care. The question of whether a "reasonable connection" exists between the remuneration and the patient's medical care would be based on: (i) whether the items or services would "benefit or advance identifiable medical care or treatment that the individual patient is

[5] 42 U.S.C. § 1320a-7a(a)(5).
[6] 42 U.S.C. § 1320a-7a(b).

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 further provides examples of various transfers that might qualify as reasonably connected to the recipient's medical care: distribution of protective helmets to hemophiliac children; distribution of pagers to alert patients with chronic medical conditions to take their drugs; provision of free blood pressure checks to hypertensive patients; distribution of nutritional supplements to malnourished patients with end-stage renal disease; and provision of air conditioners to asthmatic patients.

Co-Payment Waiver for First Fill of a Generic Drug. The OIG would codify in regulation the statutory exception that permits a prescription drug plan sponsor of a Part D plan or an MA organization offering an MA-PD plan to waive any copayment that would otherwise be owed by its enrollees for the first fill of a generic drug covered by Part D if the sponsors disclose such waivers in their benefit plan package submitted to the Centers for Medicare & Medicaid Services.

Gainsharing Prohibition

The OIG has historically interpreted the gainsharing prohibition broadly to encompass "any hospital incentive plan that encourages physicians through payments to reduce or limit clinical services directly or indirectly."[7] The proposed rule attempts to respond to long-running criticisms that the prohibition disallows many hospital initiatives that may control costs but do not diminish—and may even improve—the quality of patient care. The OIG solicits comments on how to narrow its interpretation of the phrase "reduce or limit services" and seeks proposals that would permit incentive plans "that further the goal of delivering high quality health care at a lower cost" while including adequate safeguards.

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We continue to monitor developments in federal fraud and abuse laws. Should you have questions regarding this alert or the proposed rule, please contact your usual Ropes & Gray advisor.

[7] OIG Special Advisory Bulletin: Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries (July 1999), available here.