



February 1, 2017

Transportation, Co-Pays and Patient Inducements: New Anti-Kickback Safe Harbors and Civil Monetary Penalty Exceptions

I. New OIG Anti-Kickback safe harbors allowing patient transportation and certain copay waivers

New safe harbors to the federal Anti-Kickback law, including allowing hospitals and other “eligible entities” to provide local transportation for Medicare patients, became effective January 6, 2017. These changes affect hospitals, physicians, pharmacies, FQHCs and other providers, as well as Medicare Advantage organizations.

Under the Anti-Kickback law, it is illegal to offer, pay, solicit or receive anything of value in order to induce or reward the referral of business reimbursable under Medicare, Medicaid or other federal health care programs. This includes not only remuneration intended to induce or reward referrals of patients, but also remuneration intended to induce or reward purchasing, leasing or ordering of any item reimbursable by a federal health care program. Because of the broad reach of the Anti-Kickback law, the OIG has published safe harbors in various areas, so that compliance with a safe harbor insulates a person from liability under the anti-kickback law.

The new safe harbors, effective January 6, 2017, are as follows:

1. Local transportation

Hospitals, doctors and others have long struggled with whether they can provide taxis, metro cards or other transportation to patients to come to appointments or receive care, or whether transportation can be considered to be a “kickback” to use that provider, as well as a violation of the Civil Monetary Penalty (CMP) law, which prohibits giving patients inducements to receive care. The OIG has now allowed providers to give free or discounted transportation to patients if the following conditions are met, and to provide a shuttle that goes to various sites (including non-hospital sites) to transport patients.

Under the new safe harbors, a health care provider or other eligible entity (i.e., any individual or entity, except those who primarily supply health care items) can provide free or discounted local transportation to Medicare patients and other federal health care program beneficiaries if all of the following conditions are met:

- the provider has a policy that is applied consistently;
- the transportation's availability is not related to volume or value of federal business;
- the transportation is not air, luxury or ambulance level transportation;
- the transportation is not publicly advertised or marketed, and persons involved in transportation are not paid on a per-beneficiary-transported basis;
- the transportation is available only to established patients (i.e., a patient who has scheduled an appointment, or previously attended an appointment), within 25 miles of the provider/supplier to or from which the patient is being transported (50 miles in a rural area), for purpose of obtaining medically necessary items and services; and
- the eligible entity bears the cost of the transportation.

In addition, an eligible entity can provide a "shuttle service" (a vehicle that runs on a set route, on a set schedule) if it:

- is not air, luxury or ambulance transport,
- is not marketed or advertised (other than posting necessary route and schedule details), and persons involved are not paid on a per-beneficiary transported basis; and
- there is no more than 25 miles from any stop on the shuttle to any stop at a location where items/services are provided (50 miles in a rural area).

There are several important factors to keep in mind with the new local transportation safe harbor:

- A. It protects transportation both to a provider or supplier of services and back to a patient's home, as long as all conditions are met.
- B. The transportation need not be planned in advance, and patients may use vouchers rather than having transportation provided directly by the eligible entity.
- C. "Eligible entities" are any providers or suppliers of **services**, but suppliers of **items** are excluded, e.g., DME suppliers or pharmaceutical companies. ACOs, health plans and health systems that do not directly provide health care are also "eligible entities."
- D. Free or discounted local transportation is available only to "established patients." (This does not apply to entities that do not provide services such as health plans or ACOs). A patient is "established" after the patient schedules an appointment or receives services. However, shuttles protected under the safe harbor are not subject to the established patient requirement (i.e., a health system could offer a shuttle service to the public that makes stops at

its own facilities but no facilities outside the system).

E. If an eligible entity chooses to make transportation available for services provided by others, it must provide the transportation to the provider or supplier of the patient's choice, but cannot determine transportation based upon referrals, e.g., cannot limit transportation only to physicians affiliated with the hospital providing the transportation. However, the hospital can set limits on the transportation provided, such as providing transportation only within a certain geographic range, or only to primary care providers, or only for visits included in a discharge plan.

2. Waiver of beneficiary co-pays and deductibles.

Providers have long struggled with when they can waive co-pays or deductibles. Medicare has taken the position that routine waiver of copayments constitutes an illegal kickback (see the OIG's 1994 Special Fraud Alert), and commercial insurers have taken the position that routine waivers of co-pays are financial fraud, because the billed charge is not the actual charge if the patient is not expected to pay a portion (the co-pay) of the billed charge. Waiver of copays in cases of financial hardship have been allowed, but the financial hardship must be documented.

Health care providers may now reduce or waive co-pays and deductibles for Medicare patients and other federal health care program beneficiaries as long as the following conditions are met:

- if for inpatient hospital services, the offer to reduce or waive co-pays cannot be tied to reason for admission, length of stay or the DRG; the waiver cannot be part of a price reduction agreement with a third party payer (unless part of a Medicare supplemental policy), and the hospital can't claim the amount as bad debt.
- an FQHC may waive co-pays for patients who qualify for subsidized services,
- pharmacies may waive co-pays if (A) the waiver or reduction is not advertised or part of a solicitation, (B) the pharmacy does not routinely waive co-pays and waives the copay only after determining that the patient is in financial need or making reasonable collection efforts (except for subsidy-eligible individuals);
- ambulances may waive co-pays if owned and operated by the State or a subdivision, is engaged in an emergency response, and offers such to all individuals transported.

3. FQHCs arrangements with Medicare Advantage Organizations.

The OIG incorporated in the safe harbors the statutory exception in the anti-kickback statute for "any remuneration between a federally qualified health center (or an entity controlled by such) and a Medicare Advantage organization pursuant to a written agreement." The law specifies that agreements must provide for a level and amount of payment to the FQHC that is not less than the MA organization would make for such services if they were furnished by other than a FQHC.

4. Medicare coverage gap discount program.

Under the Medicare Coverage Gap Discount Program, prescription drug manufacturers may enter into an agreement with HHS to provide certain beneficiaries with access to discounts on drugs at the point of sale.

Hospitals, doctors and other providers, as well as ACOs and health plans, may find the above safe harbors very helpful in coordination of care and assisting patients to obtain health care services. As more payment becomes “value based,” and providers take more responsibility for the overall care of their patients, these safe harbors can be used to design a program that helps patients receive needed services within the provider’s system of care.

II. Changes to the Civil Monetary Penalties Law

OIG has increased what is “de minimis” under Civil Monetary Penalties Law, and published additional CMP exceptions as to what are not “patient inducements”

Under the Civil Monetary Penalties Law (CMP), a person who offers or transfers to a Medicare or Medicaid patient any remuneration that the person knows or should know is likely to influence the selection of a particular provider or supplier of Medicare or Medicaid items or services may be liable for civil monetary penalties (CMPs) of up to \$10,000 for each act. “Remuneration” includes waivers of copays and deductibles, and transfer of items and services for free or for less than fair market value. There are a limited number of exceptions, including “inexpensive” gifts of nominal value. The threshold for “nominal value” has been \$10 per item or \$50 per patient in the aggregate annually (which may not be cash or cash equivalents). The OIG in a Policy Statement published December 7, 2016, raised the “nominal value” to \$15 per item and \$75 in the aggregate per patient annually.

In addition, the OIG, in the same federal register as the anti-kickback safe harbors, published regulatory exceptions under the CMP law, effective January 6, 2017, allowing providers and suppliers to give patients certain items or services without violating the CMP law. (This is in addition to the above safe harbors, as safe harbors to the anti-kickback statute are incorporated by reference as exceptions to the beneficiary inducements CMP.)

In keeping with the CMP’s law exception that protects “any other remuneration which promotes access to care and poses a low risk of harm to patients and federal health care programs,” the OIG identified the following as permissible to provide to patients without being considered to be an “inducement”:

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 the Medicare/caid programs by

- being unlikely to interfere with clinical decision making

- being unlikely to increase costs through overutilization or inappropriate utilization, &
- not raising patient safety or quality of care concerns.

The above exception is not limited to items that are medically necessary, as long as the items increase the patient's ability to obtain care and pose a low risk of harm. Protected items or services may also be given before seeing a doctor if to facilitate a patient's obtaining care, e.g., a physician practice may send a patient a monitoring device to collect health data before the appointment. As with all exceptions, the remuneration cannot be cash or a cash equivalent, or copay waivers, but can be any other form that complies with this exception.

Retailer rewards programs (e.g., coupons or rebates) that are (i) offered on equal terms to the public, regardless of insurance (e.g. if a reward can be obtained only by Medicare beneficiaries, it does not fit into the exception), and (ii) not tied to the provision of other items or services reimbursed by Medicare or Medicaid (e.g., not be conditioned on the purchase of goods or services paid for by Medicare).

Discounted or free items to patients determined to be in financial need if: (i) the items or services are not advertised, or tied to the provision of other items or services reimbursed by Medicare or Medicaid, and (ii) there is a reasonable connection between the items or services and the medical care of the patient. The OIG states that although they are not requiring any specific documentation of financial need, they expect that entities offering these items would have a set "financial assistance" policy.

Any hospital, doctor, pharmacy or other provider or supplier that is considering giving items or services to patients for less than fair market value should examine the changes in the CMP regulations and determine whether a proposed program may fit under the new exceptions.

If you have any questions or would like to discuss, please contact Margaret Davino at mdavino@foxrothschild.com or 646.601.7615; Eric Bixler at ebixler@foxrothschild.com or 646.601.7616; or David Sokolow at dsokolow@foxrothschild.com or 215.299.2712, or any member of Fox Rothschild's **Health Law Group**.



www.foxrothschild.com   

California | Colorado | Connecticut | Delaware | District of Columbia | Florida
Illinois | Minnesota | Nevada | New Jersey | New York | Pennsylvania | Texas

Copyright © 2017 Fox Rothschild LLP. Fox Rothschild LLP is a Pennsylvania Limited Liability Partnership. The material contained in this document has been authored or gathered by Fox Rothschild for informational purposes only. This document is not intended to be and is not considered to be legal advice. Transmission of this document is not intended to create, and receipt does not establish, an attorney-client relationship. Legal advice of any nature should be sought from legal counsel.

Attorney Advertising

[Click here](#) to manage your profile or unsubscribe from mailings.