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Office of Inspector General Enacts New Safe Harbors and Policy Statement under the Anti-Kickback Statute

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On December 7, 2016, the United States Department of Health and Human Services, Office of Inspector General (“OIG”) issued a final rule pursuant to its authority under the Federal Anti-Kickback Statute adding several new “safe harbors” and expanding the scope of certain existing safe harbors (the “Final Rule”). The Anti-Kickback Statute, codified at Section 1128B(b) of the Social Security Act, provides for the imposition of criminal and civil penalties on individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce or reward the referral of business reimbursable under Federal health care programs. Violation of the Anti-Kickback Statute is classified as a felony and punishable by fines of up to \$25,000 and imprisonment of up to five years. Violations may also result in the imposition of civil monetary penalties, exclusion from participation in Federal health care programs, and civil and/or criminal liability under the False Claims Act.

“Remuneration” under the Anti-Kickback Statute is defined very broadly and includes outright kickbacks, bribes, and rebates (whether made directly or indirectly, overtly or covertly) in cash or in kind, to induce the leasing or ordering of, or arrangement for or recommending, the purchasing, leasing or ordering of any good, facility, services or items reimbursable by any Federal health care program. Case law has made it clear that a violation occurs whenever one of the purposes of remuneration is the inducement of such referrals, even where there are also legitimate business reasons supporting the arrangement.

The OIG is mindful that the Anti-Kickback Statute, taken literally, is broad enough to encompass many reasonable commercial arrangements. For example, compensation paid to an employee for work performed could be considered a kickback to induce the employee to refer patients to his or her employer. In order to help protect against the risk of criminal prosecution or civil liability for such matters, the OIG has promulgated “safe harbors,” which specify various business arrangements that will not be treated as violations of the Anti-Kickback Statute even though the arrangements are capable of inducing referrals. Each safe harbor includes a list of requirements which must be met in order for a particular arrangement to qualify for protection under the applicable safe harbor. Failure of a business arrangement to fully comply with a safe harbor does not mean that the arrangement is automatically in violation of the Anti-Kickback Statute because the prohibitions of the Anti-Kickback Statute include an element of intent. However, without safe harbor protection, the arrangement is subject to scrutiny by applicable regulatory authorities to determine whether at least one purpose of the arrangement was to induce referrals.

The Final Rule includes the following additional safe harbor protections:

Cost-Sharing Waivers- Pharmacies

The Final Rule added safe harbor protection to pharmacies that provide waivers of cost-sharing amounts otherwise payable by the beneficiaries when the following criteria are met:

1. the waiver is not advertised or part of a solicitation;

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2. the pharmacy does not routinely waive cost-sharing (except for waivers or reductions offered to subsidy-eligible individuals); and
3. the pharmacy reasonably determines that the beneficiary is in financial need or the pharmacy fails to collect cost-sharing after making a reasonable effort to collect the cost-sharing amount owed.

If a patient qualifies as a subsidy eligible individual (an individual qualifying for an insurance subsidy under the Patient Protection and Affordable Care Act), the pharmacy does not need to satisfy requirements 2 and 3. The preamble to the Final Rule also makes clear that this safe harbor does not apply to waivers by physicians of copayments for Part B drugs. The Final Rule includes similar protection for State owned and operated emergency ambulance services for certain waivers of costsharing covered under a Medicare fee-for-service payment system.

Local Transportation

The local transportation safe harbor protects certain free or discounted local transportation services provided by an eligible entity to Federal health care program beneficiaries. "Eligible entities" are defined as any individuals or entities, except for individuals or entities (or family members or others acting on their behalf) that primarily supply health care items such as pharmacies or durable medical equipment suppliers.

The following criteria must be met for protection under the local transportation safe harbor:

1. The transportation must be provided pursuant to a policy which is applied uniformly and under which the decision to provide transportation services is not made in a manner related to the past or anticipated volume or value of Federal health care program business;
2. The transportation may not be air, luxury or ambulance-level transportation;
3. The availability of transportation may not be marketed or advertised;
4. The drivers may not be paid on a per patient basis;
5. The transportation must only be made available to established patients, to and from the eligible entity, for the provision of medically necessary services;
6. The transportation must be provided within 25 miles of the eligible entity (50 miles in rural areas); and
7. The eligible entity must bear the cost of the transportation.

The eligible entity may also provide a shuttle services if the following conditions are met:

1. The shuttle services may not be air, luxury or ambulance level transportation;
2. The shuttle service may not be marketed or advertised;
3. The drivers may not be paid on a per patient basis;
4. Each stop of the shuttle service must be within 25 miles of the eligible entity (50 miles in rural areas); and
5. The eligible entity must bear the cost of the transportation.

Despite its name, an "established patient" is not required to have been treated by a provider prior to receiving free or discounted transportation. An "established patient" under the safe harbor is defined as a person who has selected and initiated contact with a provider or supplier to schedule an appointment or who has previously attended an appointment with the provider or supplier.

Policy Statement on Gifts of Nominal Value

Concurrently with the issuance of the Final Rule, the OIG released a new policy statement regarding gifts of nominal value to Medicare and Medicaid Beneficiaries. With the passage of the Anti-Kickback Statute, Congress expressed its intent that inexpensive gifts of nominal value would not be prohibited. In 2002, the OIG issued a policy defining "nominal value" as a retail value of no more than \$10 per item or \$50 in the aggregate per patient on an annual basis. The OIG has now increased this amount to account for inflation. As of December 7, 2016, "nominal value" mean a retail value of no more than \$15 per item or \$75 in the aggregate per patient on an annual basis. The items may not be cash or cash equivalents. If a gift has a value at or below these thresholds, then the gift need not fit into a safe harbor.

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