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OIG Issues New Safe Harbor on Free or Discounted Local Transportation Services



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Arrangements involving free or discounted transportation can benefit patient care by providing access to treatment that patients may otherwise forgo because of inadequate or lack of transportation. If patients cannot obtain transportation to get to health care providers where care is available, they defer care, and deferred care leads to human suffering, poor health care outcomes, and higher costs to federal and state health care programs. Notwithstanding the benefits of free local transportation programs, such arrangements are sometimes subject to fraudulent or abusive schemes which lead to inappropriate steering of patients, overutilization, and the provision of medically unnecessary services.

Health care providers that offer free or discounted transportation services to Federal health care program beneficiaries may be subject to civil monetary penalties (see 42 U.S.C. 1320-7a(a)(5)). In the Social Security Act, Congress specifically addressed the issue of providers offering remuneration to Medicare and Medicaid beneficiaries in order to influence their selection of a particular provider by authorizing the imposition of Civil Monetary Penalties (“CMP”) against such providers.

The CMP law provides for a penalty against any person who “offers or transfers remuneration to any indi-

vidual . . . to influence such individual to order or receive from a particular provider . . . any item or service for which payment may be made, in whole or in part, under [Medicare or Medicaid].”

“Remuneration” for the purposes of the CMP law is defined as “transfers of items or services for free or for other than fair market value.

A violation of the CMP law may result in a penalty of up to \$10,000 for each item or service, an assessment of up to three times the amount claimed for each such item or service, and exclusion from participation in Medicare and Medicaid.

Free or discounted transportation services may also implicate the criminal anti-kickback statute, which makes it a criminal offense to knowingly and willfully offer, pay, solicit or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program (see 42 U.S.C. 1320a-7b(b)).

Notwithstanding the applicability of the CMP law and anti-kickback statute, the Office of Inspector General (“OIG”) has recognized that many arrangements involving free or discounted transportation have important and beneficial effects on patient care, especially where such arrangements are narrowly tailored to address issues of financial need, limited transportation resources, treatment compliance, or safety (see OIG Advisory Opinion No. 00-7). Moreover, the anti-kickback law’s legislative history indicates that Congress did not intend to “preclude the provision of complimentary local transportation of nominal value” (see 79 Fed. Reg. 59717, October 3, 2014).

The New Local Transportation Safe Harbor

On December 7, 2016, the HHS Office of Inspector General (OIG) finalized a new safe harbor (see 81 Fed. Reg. 88368, December 7, 2016), modifying the safe harbors to the anti-kickback statute (see 42 U.S.C. § 1320a-7b) and the civil monetary penalties (“CMP”) rules (see 42 U.S.C. § 1320a-7a), that protects certain free or discounted local transportation arrangements provided to federal health care program beneficiaries (e.g., Medicare and Medicaid beneficiaries) from enforcement under the anti-kickback law. The new safe harbor reinforces prior OIG Advisory Opinion guidance and permits free or discounted local transportation made available by an “eligible entity” to federal health care program beneficiaries if certain criteria are met, including providing free transportation to “established

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patients” for medically necessary services within a local service area.

Prior OIG Advisory Opinions on Free or Discounted Local Transportation Programs

No. 00-7, Nov. 24, 2000, patient referral to hospitals for extended treatment

No. 09-01, March 13, 2009, transportation for friends and family of skilled nursing facility residents; advertising

No. 11-01, Jan. 10, 2011, pediatric charity hospital networks

No. 11-02, March 24, 2011, hospital transport from physician offices located on, or contiguous to, the hospital campus

No. 11-16, Nov. 15, 2011, hospital provision of transportation, lodging, and meal assistance

No. 13-04, June 14, 2013, provision of non-emergency ambulance transportation services by the county health district

No. 15-13, Oct. 21, 2015, free van shuttle service to certain medical facilities in an integrated health system; posting of the availability of that service in facility waiting areas

No. 16-02, March 1, 2016, temporary lodging and perinatal residence

No. 16-10, Oct. 11, 2016, joint funding of transportation coordinator to educate patients about local options and subsidize transportation for patients with financial need

No. 11-16, May 20, 2011, online referral services; transport over 35 miles

The local transportation safe harbor is available for transportation of a patient both to multiple providers or suppliers of services and back to a patient’s home if the conditions of the safe harbor are met. Additionally, the OIG does not require that the transportation be planned in advance. A local transportation program can apply its own terms for patient eligibility for free or discounted transportation services as long as such eligibility is not based on the source of payments for health care or whether or not the patient is a federal health care program beneficiary. Health care providers should review the local transportation safe harbor criteria and apply to guidelines to existing or future free or discounted local transportation programs.

What Types of Health Care Providers Are Eligible Entities? An *eligible entity* for purposes of the safe harbor includes any individual or entity, except for individuals or entities (or family members or others acting on their behalf) that primarily supply health care items. (The OIG specifically discussed DME suppliers and pharmacies as examples of health care providers that primarily provide items rather than services and, as such, would not qualify for this safe harbor. Other entities that do not directly render health care services to patients (e.g. Medicare Advantage Plans, Accountable Care Organizations, Clinically Integrated Networks and Charitable Organizations) are excluded from the definition of eligible entity.) Eligible entities would include, for example, hospitals, home health agencies, laboratories, skilled nursing facilities, health plans, accountable

care organizations and a variety of others. If an eligible entity is transporting a patient to another provider or supplier and the transporting entity is itself a provider or supplier of federal health care program services, the patient must have an established relationship with both the transporting entity and the provider to which he/she is being transported.

Who Is an Established Patient? An eligible entity may make free or discounted local transportation services available only to individuals who are: (1) established patients of the eligible entity providing the free or discounted local transportation; or (2) an established patient of the provider or supplier to or from which the individual is being transported. An *established patient* is a person who has selected and initiated contact to schedule an appointment with a provider or supplier, or who previously attended an appointment with the provider or supplier. Another person, such as a family member, a case manager, or a provider or supplier where a patient is attending an appointment, who has been given permission to do so, can schedule an appointment on behalf of the patient to meet this criterion of the safe harbor.

What Are Permissible Transportation Purposes? The local transportation safe harbor is available only for transportation to obtain medically necessary items or services. An eligible entity that is a health care provider or supplier can choose to provide its established patients with transportation services to its own location without extending this service to patients of other providers. However, because the availability of transportation cannot be determined in a manner related to past or anticipated volume or value of referrals of federal health care program business, if an eligible entity chooses to make transportation available to health care services provided by others, the eligible entity must provide transportation to the patient’s provider of choice. The local transportation safe harbor makes it clear that the following transportation purposes are permissible:

- Transporting patients from the patient’s home to and from a health care provider site;
- Transporting patients to another provider or supplier that is not a referral source, and
- 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.

What Are Permissible Modes of Transportation? The local transportation safe harbor is applicable to individual and shuttle transportation services, and excludes air, luxury and ambulance-level transportation. Transportation via provider owned or sponsored automobiles, vans, or vehicles equipped for wheelchairs, other than ambulances, as well as third-party transportation such as public transportation (including buses, taxicabs, and Uber or Lyft), are each eligible for safe harbor protection if the other criteria of the safe harbor are met. Situations that require airplane, train, or ambulance transportation would need to be considered on a case-by case basis.

Shuttle services are included as permissible modes of local transportation. The OIG interprets “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 us-

ers of the shuttle service be established patients, as otherwise required by the local transportation. Shuttle safe harbor services are subject to the same marketing prohibitions to receive safe harbor protection with a clarification that the schedule and stops can be posted.

Local Transportation Distance Limits. A distance limitation is included in the regulations, with separate distance limitations for urban and rural areas. In urban areas, the patient may be transported within 25 miles of the health care provider or supplier to or from which the patient would be transported. An *urban area* is defined as a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget; or certain New England counties specified in the regulations. In rural areas, the patient may be transported within 50 miles of the health care provider or supplier to or from which the patient would be transported. *Rural area* is an area that is not an urban area. Distance limits can be measured “as the crow flies” and would include any route within the specified radius, even if the chosen route is more than the mileage limitation when driven.

Payment Methodologies for Local Transportation Providers. The safe harbor protects arrangements in which drivers or others involved in arranging the transportation are not paid on a per-beneficiary transported basis or based on the volume or value of services obtained by the transported patients. Hourly based compensation and mileage-based compensation for drivers are two acceptable payment methodologies.

Requirement for Written Local Transportation Policies and Procedures. In order to qualify for the local transportation safe harbor, eligible entities must have written policies and procedures regarding the availability of transportation assistance, and must apply those policies and procedures uniformly and consistently. In addition, the availability of free or discounted local transportation cannot be determined in a manner related to the past or anticipated volume or value of federal health care program business. The OIG comments note that eligible entities can choose to provide transportation in a variety of permissible ways, including: only for primary care visits; for visits included in a discharge plan; or for a limited geographic radius.

Local Transportation Policy Marketing Prohibitions. The OIG does not want the marketing of free transportation to be used as a means to generate referrals. Transportation assistance cannot be publicly advertised or marketed to patients or others who are potential referral sources. Signage designating the source of the transportation on the vehicles used to transport patients is considered a permissible safety feature and not marketing. Donors of transportation services or vehicles can be acknowledged only if the donor is not a health care provider or supplier, and does not make, market, or sell health care items or supplies. The marketing prohibition includes marketing on websites, in printed materials, social media, and the marketing of health care items or services during the course of the transportation.

Prohibition on Shifting the Local Transportation Costs to Governmental or Private Payors. The eligible entity must bear the cost of free or local transportation services. The eligible entity cannot write off local transportation program costs as bad debt, or otherwise shift the cost to Medicare, a state health care program, other

payors or individuals. An entity is not precluded from entering arrangements to partner with other parties to provide the transportation services as long as these arrangements are voluntary and not related to any explicit or implicit threat of withholding future referrals.

What About Local Transportation Program Features That Do Not Fit Within The Safe Harbor? Some of the local transportation programs approved by the OIG in previous advisory opinions extended the programs to friends and family of patients; transportation over more than 50 miles; airline, bus or train transportation or automobile mileage reimbursement, temporary lodging and meal assistance; and/or permitted limited advertising and marketing, however, such arrangements are not included within the parameters of the local transportation safe harbor and will continue to be evaluated on a case-by-case basis going forward. Before implementing a local transportation program that does not fit within the safe harbor, health care providers should consult a health care law attorney concerning their situation and have that attorney evaluate the legal and compliance risks of the proposed local transportation program.

Compliance Best Practices

The local transportation safe harbor provides health care providers with compliance certainty that has not previously been available for such arrangements. Under the Local Transportation Safe Harbor, any arrangements protected by the safe harbor would be excluded from the definition of “remuneration” under the beneficiary inducement prohibition. By complying with each prong of the local transportation safe harbor and the recommendations below, health care providers can rest assured that their local transportation program will not be subject to legal enforcement actions.

Transportation Offered In A Manner Related to Referrals: Do not offer the free transportation services in a manner related to past or anticipated patient referrals. Do not condition the receipt of local transportation services on the use of any other goods or services of the health care provider, or the specific selection of any affiliated provider or practitioner.

Patient Source of Payment: Do not selectively limit the free transportation services based on the patient’s source of payment for health care services (e.g., Medicare or Medicaid patients);

Marketing or Advertising: Health care providers should not advertise the free transportation services; and transportation drivers should not market health care items or services during the transport;

Eligible Patients: Provide service only to patients who have an appointment for care with you (and their caregiver, if applicable), and offer it to all similarly situated patients who may need it. Do not target patients based upon a diagnosis, condition, or treatment that could increase provider revenues. Patient eligibility should be determined in accordance with the health care provider’s written policies and procedures setting forth the operational requirements for the local transportation program;

Geographic Area For Local Transportation: Limit the geographic area within which you offer transportation;

Mode of Transportation: Make sure the form of transportation you offer is reasonable and does not in-

clude expensive transports such as airline tickets, ambulance transports, limousines or specialized transportation;

Transportation Destination: Only transport patients to health care provider or supplier eligible entity locations to obtain medically necessary services or supplies or home.

Treatment of the Costs of the Free or Discounted Local Transportation: Don't bill Medicare, Medicaid, or any other third-party payor for the transportation, and do not claim such costs as bad debt, or otherwise include the costs of such transportation in cost reports, or shift the transportation costs to any Federal health care program.

Compensation of Local Transportation Providers: Compensation of local transportation providers should not be based on a per-patient or per-service basis.

Documentation of Local Transportation Services: Providers should keep logs of transportation provided, as well as cost records to prove that related costs have not directly or indirectly been shifted to a federal health care program.

Health care providers and their compliance officers should review existing free or discounted local transportation programs and modify such as necessary to obtain safe harbor protection.