

[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.]

Issued: November 17, 2000

Posted: November 24, 2000

[Name and Address Redacted]

Re: OIG Advisory Opinion No. 00-7

Dear [Name Redacted]:

We are writing in response to your request for an advisory opinion regarding free transportation services that Hospital X ("Hospital X" or the "Requestor") offers to certain patients who have been referred to Hospital X for extended courses of treatment involving chemotherapy, dialysis, radiation therapy, cardio/pulmonary rehabilitation treatment, or certain similar services (the "Arrangement"). Specifically, the question raised by your request is whether the Arrangement constitutes grounds for sanctions under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Social Security Act (the "Act"), or the anti-kickback statute, section 1128B(b) of the Act, in the circumstances presented.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided, we conclude that: (i) the Office of Inspector General ("OIG") will not impose a civil monetary penalty under section 1128A(a)(5) of the Act on Hospital X in connection with the Arrangement, as described and certified in your request letter and supplemental submissions; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent were present, but that the OIG will not subject Hospital X to sanctions for violations of the anti-kickback statute under sections 1128(b)(7) or 1128A(a)(7) of the Act in connection with the Arrangement, as described and certified in your request letter and supplemental submissions.

This opinion may not be relied on by any persons other than Hospital X, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

Hospital X is a not-for-profit health care system located in City A, State B. Hospital X has three City A locations at which medical services are provided:

- the West Campus, where acute care services, emergency services, cancer care, cardiac care, cardiac and pulmonary rehabilitation services, diagnostic services, and other services are provided. Hospital X's [number redacted]-bed acute care hospital, the only acute care hospital in City A, and its [name redacted] Cancer Center are located on this campus;
- the East Campus, where outpatient clinic services and medical rehabilitation services are provided for patients who suffer from spinal cord injury, stroke, amputation, brain trauma, and musculoskeletal diseases; and

- the [name redacted] Dialysis Center.

Hospital X's primary service area encompasses not only City A, but a ten-county rural area in [area redacted] State B covering [over 8,000] square miles. Many of the counties within Hospital X's primary service area are rural or contain medically underserved areas and populations. Hospital X is the only provider of radiation oncology within its primary service area. Moreover, within Hospital X's primary service area, there is only one other provider of dialysis services, and there are only two other providers of cardiac rehabilitation services.

Public transportation within Hospital X's primary service area is very limited. Within the City A city limits, there is one taxi service, which has five or fewer vehicles, and a single "Handibus," which runs on a set schedule and provides transportation to handicapped individuals. No public transportation is available outside the City A city limits.

The Arrangement is set forth in a written policy which describes in detail Hospital X's free transportation policy and procedures. Under the Arrangement, Hospital X uses two of its own vehicles to provide free one-way or round-trip general transportation services between Hospital X and each eligible patient's residence. Transportation is only provided to patients who reside within Hospital X's primary service area or for whom Hospital X is the nearest provider of the prescribed treatments. The transportation services are not ambulance-level services, and no state license is required. Notwithstanding, most drivers have a current state emergency medical technician ("EMT") license, which allows them to respond appropriately if a medical emergency arises en route. To be eligible for the free transportation services, a patient must: (i) have been referred to Hospital X for an extended course of treatment involving chemotherapy, dialysis, radiation therapy, cardio/pulmonary rehabilitation treatment, or certain similar services; (ii) be unable to provide his or her own transportation and have no other regular and reliable means of transportation (public or private); and (iii) be at significant medical risk if treatment is not provided.

Hospital X does not charge the patient or any third party payor for the transportation services. General transportation, such as the type offered by Hospital X under the Arrangement, is not reimbursable under any Federal health care program. Hospital X has certified that the costs of the free transportation services will not be claimed directly or indirectly on any Federal health care program cost report or claim or otherwise shifted to any Federal health care program.

Hospital X has not, and will not, market or advertise the availability of its free transportation services. Under the Arrangement, Hospital X's hospital staff are instructed that, in the course of arranging for extended courses of treatment, they should be alert for those patients who indicate an inability to obtain regular and reliable transportation to and from Hospital X, obtain information from the patients about their particular circumstances, and recommend such patients to the appropriate department director for review. If the department director determines that the patient meets the eligibility requirements described above, the department director offers free transportation services to the patient, and upon acceptance of the offer, refers the patient to the Patient Transportation Department. The Patient Transportation Department prioritizes the referred patients' requests based upon medical need, travel distance, the number of other patients needing transportation, and the time of treatment. Hospital X has certified that neither referrals made by Hospital X's hospital staff, decisions made by department directors, nor decisions made by the Patient Transportation Department will be based, directly or indirectly, upon the patient's ability to pay for the underlying medical services or the existence, nature, or extent of the patient's insurance coverage.

Historically, Hospital X has offered free transportation services to a limited number of patients, averaging approximately 6% of all radiation oncology, dialysis, and cardio/pulmonary patients. The average age of individuals receiving transportation under the Arrangement is sixty-six, and the average distance of the transportation is twenty-eight miles.

II. LEGAL ANALYSIS

A. Fraud and Abuse Implications of Free Transportation Services

Health care providers that offer free goods or services, such as free transportation services, to Federal health care beneficiaries may be subject to civil monetary penalties. In section 1128A(a)(5) of the 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 against such providers. Moreover, free transportation services may implicate the criminal anti-kickback statute which prohibits offering anything of value to any "person" (including a Federal health care beneficiary) to reward or induce referrals (including self-referrals) for items or services reimbursable under any Federal health care program.⁽¹⁾ Given the overlap between the two statutes, we will begin with some general observations about free transportation services.⁽²⁾

First, we recognize that many arrangements involving free 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.

Second, we also recognize that free transportation services are sometimes an integral part of fraudulent or abusive schemes which lead to inappropriate steering of patients, overutilization, and the provision of medically unnecessary services. Examples of abusive arrangements involving free transportation services include:

- Psychiatric facilities offering out-of-state patients free round-trip airline tickets to Florida in order to receive services at their facilities;
- Van drivers soliciting, and offering free transportation services to, Medicaid patients for health care providers who compensate the drivers on a per patient or per service basis;
- Unscrupulous health care providers offering residents of nursing facilities and other congregate care facilities free transportation services to and from their offices for services that are frequently of questionable necessity;
- Hospitals offering patients free limousine services; and
- Hospitals offering patients free ambulance services without making individual determinations of financial need.

Third, given their potential for abuse, we evaluate arrangements involving free transportation services on a case-by-case basis. We have identified several risk factors including, but not limited to, the following:

- **The population to whom free transportation services are offered.** While free transportation services offered to "all comers" can implicate section 1128A(a)(5) of the Act and the anti-kickback statute, so can free transportation services offered to select patients or populations. To the extent the services are offered selectively, we evaluate the basis on which the selection is made. For example, an offeror of free transportation services might select individuals based upon one or more of the following criteria: relationship with the offeror (including physician-patient relationships); relationship with other providers (including nursing facility-resident relationships); diagnosis; insurance coverage; geographic location; financial need; or concerns regarding safety or treatment compliance.
- **The nature or type of free transportation services offered.** Expensive transportation services such as limousines, airline tickets, or ambulance transports raise greater concerns.
- **The geographic area in which free transportation services are offered.** Services offered within a provider's historic service area are less suspect than services offered outside its historic service area.
- **The availability and affordability of alternate means of transportation.**
- **Whether free transportation services are marketed or advertised and, if so, how.**

- **The type of provider offering the free transportation services.** Free transportation services offered by individual or small groups of providers, including physicians, or by freestanding clinics are subject to greater scrutiny. Historically, unscrupulous providers and clinics have offered free transportation services in conjunction with Medicare and Medicaid mills.
- **Whether the costs of the free transportation services will be claimed directly or indirectly on any Federal health care program cost report or claim or otherwise shifted to any Federal health care program.**

These factors are not exclusive, and the presence or absence of any one factor is not determinative of whether the OIG would subject parties to sanctions for providing free transportation services to patients.

Fourth, we weigh these factors, as well as other relevant concerns, in assessing the level of risk presented by an arrangement. They are not necessarily determinative or probative of whether an arrangement violates the applicable statutes. The elements required for a violation of the statutes are discussed below.

B. Application of Section 1128A(a)(5) of the Act

Section 1128A(a)(5) of the Act provides for the imposition of civil monetary penalties against any person who:

offers or transfers remuneration to any individual eligible for benefits under [Medicare or a State health care program] that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under [Medicare or a State health care program].

See also 65 Fed. Reg. 24400, 24416 (April 26, 2000) (to be codified at 42 C.F.R. § 1003.102(b)(13)). Section 1128A(i)(6) of the Act defines "remuneration" for purposes of section 1128A(a)(5) of the Act as including, among other things, "transfers of items or services for free or for other than fair market value." Unlike the anti-kickback statute, section 1128A(a)(5) of the Act is solely concerned with remuneration offered or transferred to Medicare or State health care program beneficiaries.

Although free transportation services clearly fall within the ambit of the prohibition, legislative history indicates that, in enacting section 1128A(a)(5), Congress did not intend to impose civil monetary penalties against persons offering complimentary local transportation of nominal value. H.R. Conf. Rep. No. 104-736, at 255 (1996). In the preamble to 42 C.F.R. § 1003.102(b)(13), the final rule addressing section 1128A(a)(5) of the Act, we interpreted nominal value for purposes of section 1128A(a)(5) to be no more than \$10 per item, or \$50 in the aggregate on an annual basis. 65 Fed. Reg. 24400, 24411 (April 26, 2000). Moreover, we theorized that "frequent rendering of items or services to any individual may preclude such items and services from being classified as nominal in value." Id. at 24407. However, many free transports, including many of those provided under the Arrangement, exceed the nominal value and local service limits.

Notwithstanding, for all of the following reasons, we will not subject Hospital X to civil monetary penalties under section 1128A(a)(5) of the Act in connection with the Arrangement:

- There is either limited or no economical means of public transportation in the geographic area where Hospital X provides the free transportation services.
- The free transportation services are not advertised and are available only to individuals who have already been referred to, or are being treated at, Hospital X.
- The free transportation services are available only if there has been an individualized determination of need (i.e., the patient has no other regular and reliable means of transportation).

- The free transportation services are available to all qualified patients who require a course of multiple treatments, subject to available resources. The Arrangement is not limited to, or targeted at, particular profitable treatments or patient populations.
- The costs of the free transportation services will not be claimed directly or indirectly on any Federal health care program cost report or claim or otherwise shifted to any Federal health care program.
- The geographic area within which the free transportation services are offered is limited to Hospital X's historic primary service area, the size of which is determined in part by its rural location, and other areas that include patients for whom Hospital X is the nearest provider of the prescribed treatments.
- Consistent with Hospital X's not-for-profit mission, the Arrangement provides a benefit to the community by giving elderly and low-income Hospital X patients access to medically necessary, life-prolonging treatments that they may otherwise forego, in whole or in part, because of inadequate transportation.

C. Application of the Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by any Federal health care program. See section 1128B(b) of the Act. Specifically, the statute provides that:

Whoever knowingly and willfully offers or pays [or solicits or receives] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person -- to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony.

Id. Thus, where remuneration is paid purposefully to induce referrals of items or services for which payment may be made by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, in cash or in-kind, directly or indirectly, covertly or overtly.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. The OIG may also initiate administrative proceedings to exclude persons from Federal and State health care programs or to impose civil monetary penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.

Remuneration from a hospital to a patient that is intended to induce the patient to obtain hospital services implicates the anti-kickback statute. For example, the routine waiver of Medicare Part B coinsurance -- a payment obligation required by Federal law -- implicates the anti-kickback statute, as would offers of cash or other valuable gifts that are intended to induce patients to order services paid for in whole or in part by a Federal health care program. Free transportation services offered by a hospital to Federal health care program beneficiaries may have monetary value and implicate the anti-kickback statute, if the requisite intent to induce self-referrals is present. Notwithstanding, in the instant case, for all of the reasons set forth above in the analysis of section 1128A(a)(5) of the Act, we will not subject Hospital X to sanctions for violations arising under the Federal anti-kickback statute in connection with the Arrangement.

III. CONCLUSION

For all of the above reasons, and based on the information provided, we conclude that: (i) the OIG will not impose a civil monetary penalty under section 1128A(a)(5) of the Act on Hospital X in connection with the Arrangement, as described and certified in your request letter and supplemental submissions; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent were present, but that the OIG will not subject Hospital X to sanctions for violations of the anti-kickback statute under sections 1128(b)(7) or 1128A(a)(7) of the Act in connection with the Arrangement, as described and certified in your request letter and supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to Hospital X, who is the requestor of this opinion. This advisory opinion has no application, and cannot be relied upon, by any other individual or entity.
- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.
- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is herein expressed or implied with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement.
- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.
- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestor with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, rescind, modify or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestor with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely and accurately disclosed to the OIG.

Sincerely,

/s/

D. McCarty Thornton
Chief Counsel to the Inspector General

FOOTNOTES:

1. Because both the criminal and administrative sanctions related to the anti-kickback implications of the Arrangement are based on violations of the anti-kickback statute, the analysis for purposes of this advisory opinion is the same under both.
2. Providers offering transportation services to beneficiaries at a price that is below fair market value would be subject to the same concerns, analysis, and, if applicable, sanctions as offerors of free transportation services.