

Washington, D.C. 20201

[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: December 22, 2004

Posted: December 29, 2004

[Name and address redacted]

Re: OIG Advisory Opinion No. 04-18

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a series of cash donations to a nonprofit hospice from a charitable foundation affiliated with a health system (the "Proposed Donations"). Specifically, you have inquired whether the Proposed Donations would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (the "Act") or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act.

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 facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Donations could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the Office of Inspector General ("OIG") would not impose administrative sanctions on [Entity X] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Donations.

This opinion may not be relied on by any persons other than [Entity X], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[Entity Y] (the "Health System") is a health system that, among other things, operates [Entity Z] (the "Hospital"). The Hospital is the only hospital in [city and state redacted] (the "City"), a city within northern [state redacted] (the "Region"). The Health System formed, and provided the initial capital for, [Entity X] (the "Foundation"). The Foundation was formed to assist hospitals and other nonprofit providers of health services within the Region and to provide grants and scholarships to ensure the continuation and improvement of quality health care offered to the residents of the Region and contiguous areas. The Foundation, the Health System, and the Hospital are nonprofit corporations exempt from Federal taxation. Many of the Foundation's directors are also directors of the Health System and the Hospital. In addition, two of the Foundation's officers are officers of the Health System and the Hospital.

[Entity A] (the "Hospice"), a nonprofit corporation exempt from Federal taxation, was formed to establish a Medicare-certified inpatient hospice facility in the City. The Hospice will provide general inpatient and outpatient hospice care, as well as

¹The Health System includes six acute care hospitals; nursing homes; a home care service; a behavioral health center; a cancer center; and an in-home hospice program operated by the Hospital. For purposes of convenience in this advisory opinion, we consider the Health System and all of its subsidiaries, including the Hospital, to be sufficiently related that they will be referred to individually and collectively as the "Health System."

respite care.² The Hospice's patients will include individuals insured by Medicare and Medicaid, as well as privately-insured patients; no patient will be denied care based upon his or her inability to pay. The Hospice has received a grant of approximately [amount redacted] from the U.S. Department of Housing and Urban Development for construction of its hospice and for care of the homeless, and has received donations from hundreds of businesses and community residents. According to the Foundation, no facility in the Region specializes in inpatient hospice services, and there is a need for inpatient hospice care because many of the Region's patients who need hospice care are homeless.

Under the Proposed Donations and consistent with its charitable mission, the Foundation would make unrestricted donations of up to [amount redacted] per year over a consecutive five-year period to the Hospice. The Foundation has certified that neither the Foundation, nor the Health System, will exert any influence over the Hospice's use of the donated funds.

The Hospice may, but will not be required to, purchase various items and services from the Health System.³ The Foundation has certified that neither the offer nor the amount of the Proposed Donations will be determined in a manner that varies with, or otherwise takes into account in any way, the volume or value of any referrals or other business that the Hospice might generate for the Health System.

Medicare's hospice benefit provides palliative care to individuals who are terminally ill. Palliative care focuses on pain control, symptom management, and counseling for both the patient and family. In order to elect the hospice benefit, a Medicare beneficiary must be entitled to Medicare Part A services and certified as terminally ill, which is defined (for Medicare purposes) as a medical prognosis of six months or less to live, if the illness runs its normal course. A beneficiary who elects to enroll in a hospice program waives all rights to Medicare payments for curative care related to his or her terminal illness, as well as for any care that is related to the terminal illness and related conditions which is not provided, or arranged for, by the hospice, during the period of election of hospice

²The total number of inpatient care days for a hospice's Medicare beneficiaries may not exceed 20% of the total days for which these patients had elected hospice care. See 42 C.F.R. § 418.98(c). According to the Foundation, the Hospice intends to participate in the Rural Hospice Demonstration Project, which allows hospice patients in rural areas who do not have caregivers to receive hospice care in a facility of twenty or fewer beds instead of in their homes. The demonstration waives the inpatient cap, but patients still must meet the coverage requirements for a general inpatient day. See section 409 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173.

³We express no opinion on the legality of any specific purchase or any other agreement or arrangement between the Hospice and the Health System.

care. However, Medicare will continue to pay for services furnished by the patient's non-hospice attending physician and for the treatment of conditions unrelated to the terminal illness.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable 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, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where <u>one</u> purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. <u>United States v. Kats</u>, 871 F.2d 105 (9th Cir. 1989); <u>United States v. Greber</u>, 760 F.2d 68 (3d Cir.), <u>cert. denied</u>, 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. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

B. Analysis

Charitable donations play an essential role in sustaining and strengthening the health care safety net. We accept that the majority of donors who make contributions to tax-exempt organizations and the majority of tax-exempt donees who solicit or accept donations -- including donors and donees with ongoing business relationships with one another -- are

motivated by *bona fide* charitable purposes and a desire to benefit their communities. Substantial numbers of health care providers are nonprofit organizations, many of which - like the Hospice -- are community-based service providers and depend on tax-deductible charitable donations to fund all or part of their operations. A business relationship between a donor and a donee does not make a tax-deductible donation automatically suspect under the anti-kickback statute.

Although the crux of the Proposed Donations is an unrestricted donation from a charitable foundation to a nonprofit hospice, the Proposed Donations warrant closer scrutiny because of the donor-foundation's affiliation with the Health System through its origins and common officers and directors, in combination with the prospect that the Hospice may generate Federal health care program business for the Health System. In most arrangements between hospices and other health care providers, such as nursing homes or hospitals, we are concerned about remuneration flowing from the hospice to the other health care providers in exchange for the other providers' referrals of hospice business payable by a Federal health care program. However, in the instant case, the remuneration (i.e., the donation) will flow to the Hospice. Therefore, to assess the risk of fraud and abuse, we must consider whether there is any nexus between the Proposed Donations and the generation of Federal health care program business by the Hospice for the Health System.

For the following reasons, we conclude that the Proposed Donations are unlikely to result in fraud or abuse under the anti-kickback statute. In particular, the facts make it unlikely that any purpose of the Proposed Donations would be to generate business for the Health System. <u>First</u>, referrals of patients from the Hospice to the Health System will necessarily be limited, because patients electing Medicare hospice services are required to relinquish their rights to curative care for their terminal illnesses.

<u>Second</u>, the Proposed Donations will be unrestricted as to the use of funds, and neither the Foundation, nor the Health System, will exert any influence over the Hospice's use of the donated funds. The Proposed Donations will be made as part of a broad solicitation of funding by the Hospice; funding sources include the Federal government and hundreds of businesses and community residents.

<u>Third</u>, the Proposed Donations will be subject to an annual cap and a fixed duration. The Foundation has certified that neither the offer nor the amount of the Proposed Donations will be determined in a manner that varies with, or otherwise takes into account in any way, the volume or value of any referrals or other business that the Hospice might generate for the Health System. The Hospice will not be required to purchase items or services from the Health System. Because inpatient hospice services are reimbursed on a per diem basis, the Hospice will have an incentive to act as a prudent purchaser when deciding on a source for items and services.

In addition to the above factors, the Foundation is a charitable entity formed to assist health care providers within the Region and improve the quality of health care services within the Region. The uses to which the Proposed Donations will be put -- establishment of an inpatient hospice that accepts patients without regard to their ability to pay -- clearly further this mission. The Hospice will substantially increase the availability of inpatient hospice services in the Region, including the availability of such services for homeless and uninsured patients.

Accordingly, based on the totality of facts and circumstances and for all of the reasons stated above, we conclude that the OIG would not subject the Foundation to administrative sanctions under the anti-kickback statute in connection with the Proposed Donations.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Donations could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on [Entity X] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Donations.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [Entity X], the requestor of this opinion. This advisory opinion has no application to, 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 of this opinion.
- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein 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 Proposed Donations, including, without limitation, the physician self-referral law, section 1877 of the Act.
- 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 Foundation with respect to any action that is part of the Proposed Donations 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 Proposed Donations in practice comport 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, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Foundation 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/

Lewis Morris Chief Counsel to the Inspector General