DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

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 requester*.]

Issued: July 19, 2001

Posted: July 26, 2001

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 01-9

Dear [Names redacted]:

We are writing in response to your request for an advisory opinion regarding a proposed grant from [name redacted] to [name redacted] (the "Proposed Grant") to defray the costs of providing services to uninsured patients. Specifically, you have inquired whether the Proposed Grant 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 to us, 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 Grant could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward

referrals were present, but that the Office of Inspector General ("OIG") would not impose administrative sanctions on [names redacted], 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 Grant.

This opinion may not be relied on by any persons other than [names redacted], the requestors 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

A. The Parties

[Name redacted] is a non-profit community health center in [city and state redacted] (the "CHC"). For eighteen years, the CHC has received grant funding under section 330 of the Public Health Service Act, 42 U.S.C. § 254(b). As a section 330 grantee, the CHC is located in a medically underserved area ("MUA"),[1] has a community-based board of directors (a majority of whom are health center users), provides a broad array of preventive and primary health care and related services, and serves all persons within its community regardless of ability to pay. Also as a section 330 grantee, the CHC qualifies and operates as a Federally qualified health center ("FQHC") under Medicare and Medicaid. The CHC employs five primary care practitioners to treat patients at its center and contracts with three practitioners to provide certain specialty services. The CHC's physicians have admitting privileges at [name redacted] (the "Hospital").

The Hospital is a public teaching hospital located in [city and state redacted]. Wholly owned by the City of [name redacted], the Hospital receives no tax dollars and is entirely self-supporting (including funding from its associated charitable foundation). The Hospital currently provides approximately 70% of the uncompensated health care in its community for patients with little or no health insurance, at an estimated annual cost of over $18 million, all of which is uncompensated. The Hospital is located approximately

[1]The area has been designated by the Department of Health and Human Services as a MUA based on geographic area, rather than specific population, and is also designated as a Health Professional Shortage Area ("HPSA"), based on a shortage of health care professionals within the area.

four miles from the CHC and is the closest accessible facility in the area that routinely accepts Medicaid and uncompensated care cases.[2]

B. The Proposed Arrangement

The Hospital provides services in several off-site locations, including the [name redacted] (the "Clinic"). The Clinic, also located in a MUA, provides primary care and related support services, such as transportation and translation services. The Clinic also has a senior center that provides enhanced and specialty services to seniors and an urgent care center and is a site for graduate medical education activities in conjunction with the Hospital's teaching function. The Clinic logs approximately 20,000 patient visits per year. In addition to Federally insured and uninsured patients, the Clinic's patient mix includes a significant volume of commercially insured patients, virtually all of whom are managed care enrollees.

The Clinic operates at a substantial loss, and the Hospital is considering several options, including closing the Clinic or curtailing services. The preferred option is for the Clinic to become a CHC site (and therefore a FQHC site). To accomplish this, the CHC, in consideration of ongoing financial support from the Hospital, would assume operation of, and financial liability for, the Clinic's primary health care and urgent health care services. The Hospital would continue to operate the Clinic's senior center and medical education activities. The CHC is seeking (and expects) approval from the Bureau of Public Health Care to expand the scope of its current section 330 grant to include the Clinic site (although, under the expansion, the CHC would not receive additional section 330 funds).

To effectuate the arrangement, the Hospital would lease the portion of the Clinic used to provide primary and urgent care services (i.e., all of the Clinic other than the senior

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[2]The CHC's only financial relationship with the Hospital involves a physician-hospital organization ("PHO") partially owned and controlled by the Hospital. The PHO contracts with managed care organizations ("MCOs") on behalf of its "network" of providers. Among those providers are the CHC's physicians, who contract with the PHO to provide services to the CHC's Medicaid patients who are enrollees of the MCOs. The MCOs make payment for the services directly to the CHC. The requesting parties have certified that all payments under this contract are at fair market value. Apart from this contract, the CHC and the Hospital have no other direct or indirect financial relationships between them.

center) to the CHC under a fair market value lease that would fit in the space and equipment rental safe harbors at 42 C.F.R. §§ 1001.952(b) and (c), respectively. The CHC would provide primary and urgent care services, including support services, to the Clinic's existing patients. In addition, because of the CHC's reputation in the community as a safety net provider and the outreach, education, and transportation activities required of it as a FQHC, the CHC projects approximately 2,500 added visits each year, primarily by uninsured and partial-pay patients.

Besides providing services itself, the CHC would purchase certain clinical services from the Hospital at fair market value. The Hospital would purchase from the CHC, also at fair market value, certain support services for the Hospital's medical education activities.[3]

To defray the CHC's cost of providing uncompensated care to needy patients at the Clinic and in furtherance of its own charitable mission, the Hospital will make the Proposed Grant to the CHC on an annual basis for a period of three years. The grant agreement will designate the maximum funds available for each of the three years. The annual amount of the grant will approximate the CHC's expected cost of providing uncompensated services for uninsured patients at the Clinic. Grant funds will be used solely to support the otherwise uncompensated costs of providing preventive and primary care services, support services (e.g., translation, outreach, and eligibility assistance), and other services currently provided at the Clinic.

To obtain grant funds, the CHC will submit a proposal and budget each year to the Hospital for expenditure of the grant funds. The amount of the grant for each year will be fixed at the beginning of the grant year, and the CHC will return to the Hospital at the end of the year any funds in excess of the actual costs attributable to the uncompensated care services. Except for the requirement that grant funds be expended for uncompensated services to the community served by the Clinic, the grant will be without restrictions or conditions of any kind. The parties have certified that neither the

[3]The Hospital and CHC will each have representatives on the others' board of directors (or committees of the boards), and the parties have agreed to explore additional ways to provide high quality, cost-effective medical care for the communities they serve through future affiliations that might integrate and coordinate certain medical, operational, and administrative functions. These future arrangements are speculative, and we neither address, nor opine on, them here.

aggregate nor annual grant amounts will vary with, or otherwise take into account in any way, the volume or
value of any referrals or other Federal health care program business generated between the parties, and that the grant funds will not include any discount, rebate, or reduction in charge.

Under the grant agreement, any future increase in available grant funds will be in the Hospital's sole discretion. The Hospital can increase the grant only if the CHC proposes an increase in the scope of its uncompensated care services at the Clinic. The grant agreement will require each party to use its best efforts to serve all patients referred by the other party, regardless of the patients' ability to pay. All patients will be advised in writing that they may request a referral to any provider they choose (subject to valid restrictions imposed by the patient's managed care plan, if any).

II. LAW AND ANALYSIS

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 Federal health care programs. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services paid for 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 is to obtain money for 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 (3rd Cir.), cert. denied, 476 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.

Charitable donations play an essential role in sustaining and strengthening the health care safety net for the uninsured and underinsured. 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 help their communities. Substantial numbers of health care providers are not-for-profit organizations, many of which -- like the CHC -- 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.

In this case, however, the business relationship between the Hospital and the CHC raises concerns that must be addressed. The proposed arrangement could have benefits for the Hospital and the CHC beyond those strictly attributable to the Proposed Grant itself. For example, the Clinic has significantly more commercially insured patients than are in the CHC's current patient mix. Thus, through the proposed arrangement, the Hospital could potentially provide a substantial economic benefit to the CHC, a health care provider that sends a substantial volume of patients to the Hospital. Moreover, the Proposed Grant will be coupled with other ties between the parties, including certain rental and services agreements. Taken as a whole, these ties could serve to reward past referrals and cement a longstanding relationship between the parties to the detriment of other existing or potential competition in the marketplace.

Notwithstanding, given the singular set of facts presented, we conclude that the Proposed Grant would not warrant imposition of administrative sanctions. We reach this conclusion for a number of reasons. First, the Proposed Grant will ensure continuity of care for the Hospital's patients who currently use the Clinic. If the Clinic were to close or significantly curtail its primary care services, many patients would have to find care elsewhere; some might forgo care altogether. Second, the Proposed Grant furthers the shared charitable mission of the CHC and the Hospital to ensure the availability of health care services for underserved persons, who will be the primary beneficiaries of the Proposed Grant. In addition to the Clinic's current patients, the CHC anticipates a substantial increase in underserved patients at the Clinic once it converts to a CHC site. This is likely to result in increased admissions of uninsured patients to the Hospital, given its mission, proximity, and accessibility, as well as its agreement to accept CHC referrals without regard to patients' insurance status. These additional uninsured referrals from the CHC may offset any potential benefit from insured referrals.

Third, the CHC is willing to assume operation of the Clinic only if the Hospital provides some subsidy to cover the CHC's anticipated costs for uncompensated care. Since these costs would otherwise have to be covered by CHC funds, including section 330 grant dollars, the Proposed Grant indirectly relieves the burden on the Federal fisc. The Proposed Grant is narrowly tailored to cover no more than the actual costs of uncompensated care.

Finally, the Proposed Grant contains the following features that further minimize the risk of fraud and abuse:

- Except for the requirement that grant funds be expended for the actual costs of uncompensated services to the community served by the Clinic, the Proposed Grant will be without restrictions or conditions of any kind. The parties have certified that neither the aggregate nor annual grant amounts 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 Federal health care program business generated between the parties, and that the grant funds will not include any discount, rebate, or reduction in charge.

- The ancillary agreements for leasing space, equipment, and furnishings and for purchasing clinical services will be at fair market value, and the leases will fit in the space and equipment rental safe harbors at 42 C.F.R. §§ 1001.952(b) and (c), respectively.

- Patients will be advised in writing of their freedom to choose providers.

In sum, based on the totality of facts and circumstances and for the reasons stated above, we conclude that the Proposed Grant poses a minimal risk of fraud and abuse under the anti-kickback statute. Given the low risk and clear public benefit in this particular situation, the OIG would not impose administrative sanctions related to the anti-kickback statute in connection with the Proposed Grant.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Grant could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward

referrals were present, but that the OIG would not impose administrative sanctions on [names redacted], 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 Grant.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors 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 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 Proposed Grant.

- 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 that 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 requestors with respect to any action that is part of the Proposed Grant 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 Grant 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, 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 requestors 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