



[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: September 13, 2010

Posted: September 20, 2010

[Name and address redacted]

Re: OIG Advisory Opinion No. 10-17

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding two potential donations to support programs that provide services to children and families, which were included as part of a private settlement of an administrative dispute (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement 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, the Federal anti-kickback statute.

You have certified that all of the information provided in your request, including all supplemental submissions, 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 while the Proposed Arrangement 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, the Office of Inspector General (“OIG”) would not impose administrative sanctions on [name redacted] or [name redacted] (collectively, the “Requestors”) 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 Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than 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

[Name redacted] (the “Health System”) and [name redacted] (the “Children’s Health System”), the Requestors of this opinion, are both non-profit entities that are headquartered in [state redacted]. The Health System and the Children’s Health System are not related entities, but have been providing physician and ancillary services to each other since February 2000 under various agreements. The Requestors have certified that these agreements meet applicable safe harbor requirements.¹

The Health System owns and operates hospitals and other health care facilities in central [state redacted], including a children’s hospital and a hospital for women and babies. The Health System also owns and operates the [name redacted] (the “Center”), which has provided a number of programs for children and their families dealing with issues such as child abuse, sexual trauma, developmental disabilities, and HIV/AIDS. Two such programs are [Program A], which is a mobile health unit that provides free medical care and counseling to uninsured and at-risk teens; and [Program B], which provides medical care, counseling, support, education and outreach for children, women, and families affected by HIV/AIDS.

Another relevant entity, the [name redacted] (the “Health System Foundation”), is a wholly owned subsidiary of the Health System. The Health System Foundation is an Internal Revenue Code section 501(c)(3), tax-exempt organization that raises funds for the Health System, its subsidiaries, affiliates, and programs, but it does not provide any healthcare services or make or receive any referrals.

The Children’s Health System provides health care services to children in [states redacted]. In [state redacted], the Children’s Health System currently owns and operates children’s

¹ We have not been asked about, and we express no opinion regarding, these agreements.

specialty clinics and, as described more fully below, is in the process of constructing a full-service children's hospital.

Both Requestors provide health care services that are reimbursable by Federal health care programs, and both employ and contract with physicians and other providers who are in a position to refer patients to each other. Although the Health System owns and operates hospitals, clinics, and other programs for children and would not be a significant referral source for the Children's Health System, the Health System occasionally refers patients to the Children's Health System for certain specialty services that the Health System does not offer.

In 2007, the Children's Health System applied through the [state agency redacted]'s Certificate of Need ("CON") process to establish a full-service children's hospital and two neonatal intensive care units in [county and state redacted]. When the Children's Health System received preliminary approval of the CONs, the Health System timely filed a Petition for Administrative Hearing to challenge each CON. The Requestors have certified that this administrative (and potentially judicial) process could take months or even years to complete and would be expensive for both parties. To avoid the significant time and costs associated with pursuing the formal appeal process, the Requestors resolved their dispute by negotiating and entering into a settlement agreement that they believe will also benefit the central [state redacted] community by supporting specific programs that operate at the Health System's Center. Certain aspects of the settlement agreement have already been implemented, and the Requestors have certified that the terms of the agreement are not subject to renegotiation.²

In fulfillment of one requirement of the settlement agreement, the Health System withdrew its challenge to the CONs. In exchange, subject to receiving a favorable advisory opinion, the Children's Health System agreed to donate the following to the Health System Foundation: (1) \$150,000 per year for five years, commencing January 1, 2008, to be used to support [Program A], and (2) \$105,000 per year, commencing January 1, 2008, to be used for services offered through the [Program B] to [Program B] patients until either: (a) the Health System employs a pediatric infectious disease physician, or (b) two years of payments are made, whichever happens first. The Health System Foundation must provide the donations to the Health System to be used solely for [Program A] and [Program B] and for no other purpose, but the donations are otherwise unrestricted. The settlement agreement provides that these funds will accrue, but will not be paid, unless and until a

² The [state agency redacted] reviewed the terms of the settlement agreement in connection with closing the CON dispute and submitted no objections. We express no opinion with respect to whether the settlement agreement and the Proposed Arrangement comply with state law.

favorable advisory opinion is issued.³ Since the time the parties executed their settlement agreement, the Health System transferred [Program B] to the [county redacted] Health Department.⁴ The Requestors have certified that the Children’s Health System would donate the accrued amounts, and all future contributions due under the settlement agreement, to a mutually agreeable alternative organization that is not owned or operated by the Health System if this office were to issue an unfavorable advisory opinion. The Requestors also certified that the donations constitute only a small percentage of the funding for the Health System and the Center.

No provision of the settlement agreement requires or encourages the Health System, the Health System Foundation, the Center, or individuals associated with those entities to refer patients to the Children’s Health System or any person or entities affiliated with the Children’s Health System.

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 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. 1985), 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. Where a party commits an act described in section

³ Nonpayment of amounts owed pursuant to a contractual agreement does not, by itself, absolve parties from liability under the fraud and abuse laws.

⁴ The transfer was effective as of October 1, 2009. Therefore, the portion of the donation accruing from October 1, 2009 through December 31, 2009 would go to the [county redacted] Health Department to be used for [Program B].

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. A business relationship between a donor and a recipient does not make the donation automatically suspect, but here it warrants further scrutiny because the parties are in a position to refer to one another. We further note that the negotiated resolution of the Requestors' CON dispute under which the Health System agreed to withdraw its challenge to the Children's Health System's CONs in exchange for these charitable donations may implicate other state or Federal concerns that fall outside the scope of this advisory opinion. Therefore, the analysis and conclusions below relate solely to risk of the Proposed Arrangement under sections 1128A(a)(7) and 1128(b)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act. With that said, and for the following reasons, we conclude that the Proposed Arrangement poses a limited risk of fraud and abuse arising under those provisions.

First, both Requestors are non-profit, tax-exempt, charitable organizations that operate hospitals and programs to improve the health of children. They provide many of the same services in the same geographic area. Although the Health System occasionally refers patients to the Children's Health System for certain specialty services not offered by the Health System, neither party is, or has an incentive to be, a significant referral source for the other.

Second, under the Requestors' settlement agreement, the Children's Health System is obligated to pay the agreed-upon sums regardless of whether the funds go to the Health System or to an unrelated party without potential referrals. For example, the Health System transferred [Program B] to [county redacted] effective October 1, 2009, so [county redacted] would receive the funds accruing after the transfer rather than the Health System.

Third, other safeguards are in place to ensure further that the donations are not connected to, or contingent on, referrals. The donations are for a fixed amount and duration. The parties have certified that the terms of their settlement agreement, including the proposed donations, are not subject to renegotiation, increases, or decreases. The donations are not

expressly contingent on any referrals. The donations are earmarked for two specific programs, but the donations are otherwise unrestricted. Moreover, the donations are only a small part of the funding of the Health System and the Center.

Finally, the donations would go towards programs that serve children and their families in central [state redacted], many of whom are uninsured, and therefore would provide a benefit to that community.

Based on the totality of facts and circumstances and for all of the reasons stated above, it appears that the risk that the proposed donations would induce referrals is low, and we conclude that the OIG would not subject the Requestors to administrative sanctions in connection with the anti-kickback statute for the Proposed Arrangement.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that while the Proposed Arrangement 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, the OIG would not impose administrative sanctions on the Requestors 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 Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted] and [name 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 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

Arrangement, 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 Requestors with respect to any action that is part of the Proposed 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 Proposed 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, 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,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General