[*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 17, 2010

Posted: September 27, 2010

To: The Attached Distribution List

Re: OIG Advisory Opinion No. 10-19

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a proposed arrangement for a non-profit charitable organization to receive donations of cash and durable medical equipment ("DME") from pharmaceutical manufacturers, DME suppliers and others, to provide funding grants and DME to entities that serve individuals suffering from coagulation disorders, and to provide DME directly to certain financially needy individuals (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 [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 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 letter or supplemental submissions.

This opinion may not be relied on by any persons other than [names redacted], 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 "Council") is a non-profit public benefit corporation organized to provide education, information, and psychological services and advocacy to individuals with hemophilia in [state redacted] (the "State"). The members of the Council are: [names redacted], each of which serves similar purposes to the Council in different regions of the State (the "Member Organizations"). Collectively, the Council and its Member Organizations will be designated in this opinion as the "Requestors." The Requestors propose to form the [name redacted], an independent, non-profit, tax-exempt charitable organization (the "Foundation") that would provide: (i) financial grants to entities that provide services to individuals suffering from coagulation disorders; and (ii) DME to such entities as well as directly to individuals suffering from coagulation disorders.

The entities that would receive financial grants would include the Member Organizations and other non-profit, tax-exempt organizations serving the needs of persons with coagulation disorders, as well as Hemophilia Treatment Centers ("HTCs"). HTCs are Federally designated centers housed in university-based tertiary care hospitals that provide comprehensive care to patients with hemophilia. HTCs are organized by region, and the Foundation would provide assistance to HTCs within the region that includes the State. The Requestors estimate that only approximately 10% of grants would be allocated to HTCs.

The Requestors anticipate that Foundation donors would include pharmaceutical manufacturers that make drugs for the treatment of coagulation disorders, pharmacies dispensing such drugs, and providers that furnish items and services to individuals who have coagulation disorders (collectively, the "Coagulation Disorder Industry"). Donors would also include the general public.

Donors would not be permitted to impose any restrictions on use of their contributions, except that donors would be permitted to earmark contributions to be used for a specific coagulation disorder. Donors would not be able to direct to whom such contributions should be awarded. Donors would not be told the specific use to which their contributions were or would be put, but they would have access to quarterly reports disclosing the recipients of awards granted by the Foundation. Similarly, recipients of funding grants would not be told the identity of the particular donor that contributed to an award, but quarterly reports issued by the Foundation would disclose the names of donors; the amounts contributed to the Foundation; and for donors that make public filings, the percentage that identifies the relation such contribution has to the operations of the donor.

The Requestors have certified that the Foundation would not be subject to control, whether directly or indirectly, by any donor. The Foundation would be governed by a Board of Directors (the "Board"). The bylaws will provide that individuals who derive any financial benefit, directly or indirectly, from the Coagulation Disorder Industry would not be permitted to serve on the Board. Donors to the Foundation and any individual affiliated with a donor in any way, including as an employee, agent, officer, shareholder, or contractor of a donor, would be barred from serving on its Board. Similarly, no Board member would be affiliated in any way, including as an employee, agent, officer, shareholder, or contractor, with a manufacturer of pharmaceutical drugs, particularly those used in the treatment of coagulation disorders; wholesalers of such drugs; pharmacies dispensing such drugs; and providers furnishing services and products that are reimbursable by Federal health care programs to individuals suffering from coagulation disorders.

Four of the members of the Board would be non-voting ex officio members who would be appointed by the governing bodies of the four Member Organizations. These non-voting ex officio Board members could be any officer or member of the Member Organizations or a member of the public so long as they are not donors to the Foundation or affiliated with a donor. The elected members of the Board who are permitted to vote would be nominated by a nominating committee consisting of the members of the boards of directors of the Member Organizations. The individuals that participate in the nominating committee would not be affiliated in any way, including as an employee, agent, officer, shareholder, or contractor, with a manufacturer of pharmaceutical drugs, particularly those used in the treatment of coagulation disorders; wholesalers of such drugs; pharmacies dispensing such drugs; and health care providers furnishing services and products that are reimbursable by Federal health care programs to individuals suffering from coagulation disorders. The voting members of the Board would elect the subsequent class of voting directors.

Board members, officers, and other staff of the Foundation would not make any referrals to physicians, suppliers, or other health care providers and would not provide any recommendations with regard to any particular drug, supply, or item of DME used to treat

coagulation disorders. Moreover, neither the Foundation nor the Member Organizations provide health care services or bill Federal health care programs.

The Requestors have certified that the Foundation would operate with absolute, independent and autonomous discretion as to the award of assistance, and that it would award assistance without regard to any donor's financial interest and without regard to whether the recipient refers patients for a donor's products, services, or supplies. The Requestors have certified that neither the Foundation nor any of its Board members (whether voting or non-voting) or Member Organizations would provide donors with any information that would facilitate the donor in correlating the amount or frequency of its donations with the amount or frequency of referrals of or use of its products, services, or supplies.

A. Financial Grants to Entities

The Foundation would distribute financial assistance to: (1) non-profit organizations serving the needs of persons with coagulation disorders that meet the criteria to be designated as an Internal Revenue Code Section 501(c)(3) public charity, including Member Organizations; and (2) Federally funded HTCs in the Foundation's region, as long as the HTC does not have a 340B program. (Together, these two types of entities will be designated in this opinion as "Qualified Entities.") Individuals would not be eligible to apply to the Foundation for financial grants. Qualified Entities (including the Member Organizations) could apply to the Foundation to receive funding grants for the provision of services that support individuals and families affected by coagulation disorders. Specifically, grants would be awarded only for operational purposes, such as capital support for construction of facilities used to provide services to individuals and families affected by coagulation disorders; general and operating expenses of the recipient; program development, which may include funding for staff positions or fellowships at an HTC (but not for salaries for treating physicians); technical assistance to improve recipient organizational and internal program operations; and to fund ancillary services needed by hemophilia patients such as transportation expenses for treatment and housing during treatment. Grants would not be available to fund health care items or services or to subsidize cost-sharing obligations of beneficiaries.

The Foundation would disseminate information about the availability of grants through various mediums, including fliers, pamphlets, relationships with the Requestors, and through health care facilities. Qualified Entities would apply for grants by participating in a formal Request for Assistance ("RFA") process. Qualified Entities would submit a RFA to the Foundation's Board, and the Board would award financial grants based on objective criteria unrelated to the use of any donor's products or services. The Board would designate a panel comprised of individuals with professional expertise or personal knowledge of coagulation disorders to make non-binding recommendations to the Board with regard to an

RFA. No employee, agent, officer, shareholder, or contractor of an applicant or donor would be permitted to serve on the advisory panel. The Foundation would maintain a conflict of interest policy to assist the Board in determining whether a conflict exists with respect to a person's consideration of a particular RFA. If a conflict existed, the Board would exclude such person from considering that application. After receiving the panel's recommendation, the Board would determine which entities would be awarded a grant and the amount of such grant by a two-thirds vote in favor of the award by voting Board members.

The Foundation would develop a contribution acceptance policy to ensure that the decision-making of any ultimate recipient is insulated from information that could influence their choices. The policy would indicate that receipt of the grant is not dependent on use of any particular product or service of a donor and would reiterate that recipients would not be permitted to use the funds for health care items or services; to subsidize Federal health care program beneficiary cost-sharing; or to pass the funds on to other affiliated entities. This policy would require that the recipient use the grant funds only for the operational and administrative purposes for which the grant was awarded. To ensure compliance with this requirement, the Foundation would require the recipient to provide quarterly reports and supporting documentation detailing how the funds are being used. The funds would be distributed in parts on a quarterly basis, and the Foundation would not distribute the next quarter's funds until the quarterly report is received and the recipient confirms that the funds were used only as authorized.

B. In-Kind Donations to the Foundation Distributed to Individuals

The Foundation would solicit donations of DME and would also purchase such equipment. The Foundation would distribute this equipment to Qualified Entities as well as directly to hemophilia patients.[1] The Foundation would not, however, provide equipment to a Federal health care program beneficiary if the beneficiary were enrolled in a Federal program that covered such equipment. Types of equipment to be distributed include helmets, sharps disposal containers, walkers, and wheelchairs. The Foundation would not accept or distribute equipment requiring ongoing maintenance. The Foundation would only distribute such items to financially needy persons who have no insurance or whose insurance does not cover these items. None of the donated items would be reimbursable to the recipient by Federal health care programs.

[1] The Requestors certified that the distribution of DME by the Foundation would be a very minor aspect of the Proposed Arrangement. Requests for DME would be considered on a rolling basis rather than through a formal RFA process.

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 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

In the Proposed Arrangement, providers or suppliers of services or items paid for by Federal health care programs would make contributions to a non-profit entity that would, in turn, make grants to other entities that have the ability to refer patients or otherwise direct business to the original donors. The non-profit entity (the Foundation) would also distribute DME, which might be donated or purchased with donated funds, to entities and individual patients.

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 entities that solicit or accept donations—including donors and recipients 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 non-profit organizations, many of which depend on tax-deductible charitable donations to fund all or part of their operations. A

business relationship between a donor and a recipient does not make a tax-deductible donation automatically suspect under the anti-kickback statute. On the other hand, a donation made for the purpose of inducing the recipient to refer Federally-payable business to the donor would violate the anti-kickback statute, regardless of whether the donation was direct or passed through an intermediary. Thus, the Proposed Arrangement requires scrutiny under the anti-kickback statute.

1. Donors' Cash Contributions to the Foundation

The Proposed Arrangement involves a mechanism by which donors to the Foundation are insulated from decisions about the use of their contributions and the recipients of the Foundation's financial grants. Under the circumstances described in the request for an advisory opinion and supplemental submissions, the risk that donations to the Foundation would serve as remuneration for referrals of Federal health care program business is minimal for the following reasons.

First, no donor or affiliate of any donor would exert direct or indirect control over the Foundation or its programs. The Foundation would be an independent, nonprofit, tax-exempt charitable organization that would have absolute, independent, and autonomous discretion as to the use of donor contributions. Donors or affiliated individuals would not serve on the Board in a voting or non-voting capacity, nor would donors or affiliated individuals serve on panels that make recommendations on grant applications.

Second, the Foundation would award financial grants in a truly independent manner that severs any connection between donors and recipients of grants.

Third, the Foundation would make financial grants without regard to any donor's financial interest and without regard to whether the recipient refers patients for a donor's products, services, or supplies. Donors would not be permitted to impose any restrictions on use of their contributions, except that donors could earmark contributions to be used for a specific coagulation disorder. Donors would not be told the specific use to which their donations were put, nor would recipients of grants be told the identity of the particular donor that contributed to an award.

Fourth, neither the Foundation nor any of the Requestors would provide donors with any information that would enable a donor to correlate the amount or frequency of its donations with the amount or frequency of referrals or use of its products, services, or supplies.

Fifth, grants would only be awarded for operational and administrative purposes and not for health care items, services, cost-sharing support, or the salaries of physicians. Further,

recipients would be required to document how the funds were used, and confirm that they were used for purposes approved in the RFA.

Sixth, the Foundation itself would not make any referrals to physicians or other service providers and would not provide any recommendations with regard to any particular drug, supply, or DME item used to treat coagulation disorders. The governing documents of the Foundation would prohibit Board members, officers, and other staff from making any referrals to physicians, suppliers or other health care providers and would not provide any recommendations with regard to any particular drug, supply, or item of DME used to treat coagulation disorders. Moreover, the Member Organizations, which have representatives on the Board in a non-voting capacity and may also apply for grant funds, do not provide health care services or bill Federal health care programs.

For a combination of the foregoing reasons, we conclude that there is minimal risk that the cash contributions made by donors to the Foundation would be remuneration to the Foundation or to grant recipients to arrange for referrals.

2. Donors' In-Kind Donations to Foundation and Foundation's In-Kind Donations to Entities and Individuals

In addition to soliciting and distributing financial assistance to certain entities that serve individuals with coagulation disorders, the Foundation would purchase and solicit donations of DME that does not require ongoing maintenance and make it available, without cost, to Qualified Entities and individuals. The Foundation would not, however, provide such equipment to Federal health care program beneficiaries if the item or equipment would be reimbursable by the applicable Federal health care program. For the reasons set forth above with respect to cash donations, we conclude that, in these unique circumstances, the donations of equipment to the Foundation and the Foundation's donation of equipment to Qualified Entities pose a low risk of abuse. As to the Foundation's donation of equipment to individuals, because the Foundation would not provide reimbursable equipment to Federal health care program beneficiaries, this aspect of the Proposed Arrangement does not implicate the anti-kickback statute.[2]

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

[2] For the same reason, the Proposed Arrangement does not implicate the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act.

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 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 letter or supplemental submissions.

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 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 [names redacted] 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 [names redacted] 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

DISTRIBUTION LIST FOR
OIG ADVISORY OPINION NO. 10-19

[Names and addresses redacted]