[*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: January 29, 2008

Posted: February 5, 2008

[Name and address redacted]

Re: OIG Advisory Opinion No. 08-02

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a marketing and research company's proposal to encourage physicians and other health care professionals to complete online surveys by offering them the opportunity to designate a public charity to which the company or one of its clients would make a monetary charitable contribution (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 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 Arrangement would not generate prohibited remuneration under the anti-kickback statute, and thus the OIG would not impose administrative sanctions on [name 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 [name redacted], 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

[Name redacted], (the "Requestor") is a company that serves pharmaceutical and medical products manufacturers and entities that distribute and market their products. The Requestor assists these entities in developing clinical, marketing, and other data about how physicians diagnose and treat certain illnesses relevant to the entities' areas of research, or for which their products would be useful. The Requestor is not a health care provider or supplier and, thus, does not participate in any Federal health care programs. The Requestor is not owned or controlled directly or indirectly by any company that manufactures health care items or provides health care services that are reimbursed in whole or part by Federal health care programs.

The Requestor owns and operates a web-based platform that provides a means of surveying physicians. The platform is interactive: it can be used to collect information from, and transmit information to, physicians. This capability permits it to perform various tasks as a research, educational, and promotional tool.

The Requestor has developed a web-based program offering clients electronic consultations with practicing physicians and other health care professionals (the "Program"). The Program will be used to deliver specific on-label clinical and product information to targeted clinicians for the specific purpose of extracting real-time market research data that can benchmark educational needs, current product usage by indication, brand awareness and effectiveness, clinician attitudes, effectiveness of detailing programs, current best practices, and competitive product analysis. The Program is primarily designed to develop research data to be used by the clinical, scientific, and marketing divisions of drug and medical products companies. The Requestor expects that some of the communications will, in whole or part, promote or market particular drugs or other products. All information related

to particular drugs or products will comply with approved product labeling.[1] The Requestor's compensation from its clients for use of the Program and access to the survey results will be fair market value based on arms length negotiations and will be documented in writing.[2]

Under the Proposed Arrangement, the Requestor would encourage physicians and other health care professionals to participate in Program consultations by offering them the opportunity to designate a public charity to which the Requestor or one of its clients would make a monetary charitable contribution "in the name of" the health care professional. The designated charity would have to be organized under section 501(c)(3) of the Internal Revenue Code ("IRC"), qualify as a public charity under section 509(a) of the IRC, and meet the public support test under section 509(a) of the IRC.[3] Contributions would not be made to private foundations. The contributions would be made directly to the charity by the Requestor or its client, and use of the donated funds would be solely in the discretion of the recipient charity. While donations would be made in recognition of the health care professional, the health care professional would not be entitled to a tax deduction or otherwise receive any monetary benefit from the contribution. All contributions would clearly state that they are from the Requestor or its client.

The Proposed Arrangement would operate as follows. The health care professional would receive an email from Requestor with a link to an online survey that is part of a multi-media presentation. The health care professional would review the presentation and respond to survey questions.[4] Upon completing the survey, the health care professional would be able

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[1]The Requestor has certified that all content transmitted to physicians or other health care professionals would comply with all relevant Food and Drug Administration (FDA) requirements and would pertain only to indications permitted under FDA-approved labeling.

[2] We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). Further, we have not been asked, and express no opinion, about the application of the fraud and abuse laws to the fee arrangements between the Requestor and its clients. This opinion is limited to the monetary contributions made to public charities under the Proposed Arrangement.

[3] The Requestor would implement a compliance system to confirm, via publicly available records or otherwise, that designated charities meet these IRC requirements. The Requestor may provide participating health care professionals with a drop-down list of major public charities that meet these IRC criteria, but the health care professionals would not be limited to this list.

[4] The Requestor would maintain the presentation content transmitted to the physicians and the survey responses for at least three years and would make such information available to the Secretary or the OIG upon request.

to designate a public charity to receive a monetary contribution.[5] The amount of the contribution might vary depending on the survey, but the anticipated range is [dollar amounts redacted] per completed survey; the contribution amount would be uniform for all participants in a given survey. The aggregate donation in the name of any one health care professional to any one charity would be capped at [dollar amount redacted] per year.

Health care professionals wishing to designate a charity would be required to meet only two criteria. First, they would complete a survey. Second, they would certify to the Requestor that neither they, nor any immediate family member, holds a position on the board of the designated charity, is employed by the charity, or has any other financial relationship with the charity (including any financial relationship through their medical practices).

The Requestor has certified that neither the availability, nor the amount, of the charitable contribution would be determined in any manner that relates to a health care professional's prescribing choices. The Requestor has further certified that surveys under the Proposed Arrangement would not be provided to health care professionals as part of any electronic prescribing transaction.

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.), 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

[5]Requestor's clients would not be informed of the identity of the public charity selected by any particular health care professional.

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

We have long recognized the important role that charitable contributions from health care providers and suppliers play in strengthening the health care system, and we are mindful that the majority of donors who make contributions to charitable organizations involved in health care – and the majority of organizations who accept them – are motivated by *bona fide* charitable purposes. To avoid chilling bona fide charitable activities, the OIG has also long recognized the need to exercise caution in undertaking any enforcement action in this area.

Notwithstanding the lawful purposes of most charitable donations, in some circumstances, payments characterized as "charitable donations" are nothing more than disguised kickbacks intended to induce referrals, directly or indirectly. For example, we are aware that some pharmaceutical or other health care companies may be engaging in schemes that use donations to charities (including private foundations) affiliated with, or controlled by, physicians or health care professionals to channel unlawful remuneration to those health care professionals. In some cases, the contributions may be solicited by a health care professional in return for referrals; in others, the contributions may be offered by companies to induce referrals. Examples of potentially problematic contributions include, without limitation:

- contributions to private foundations or other charitable organizations directed or controlled by referral sources (or family members);

- contributions to organizations that employ or otherwise compensate referral sources (or family members);

- contributions "earmarked" (explicitly or implicitly) to benefit a referral source, a family member, or the referral source's medical practice (by way of example only, it would be problematic if a pharmaceutical company earmarked donated funds for uses that benefited a particular physician's medical practice, such as through research grants or the provision of staffing by "fellows");

- contributions to charities that provide free or below market rate office space, equipment, or staff to a referral source, a family member, or the referral source's medical practice;

- restricted contributions to charities that provide educational or research grants or other funding to referral sources or their medical practices; and

- contributions determined in any manner that takes into account past or expected prescriptions, orders, or purchases of items or services payable by any Federal health care program.

These examples of potentially problematic arrangements under the anti-kickback statute are illustrative, not exhaustive. These and other potentially abusive arrangements must be scrutinized to ensure that they are not kickback schemes to induce referrals.

We review the Proposed Arrangement in light of these concerns. Under the Proposed Arrangement, the Requestor would encourage health care professionals to complete Program surveys by offering to make monetary contributions to public charities selected by the health care professionals. The donations would be funded by the Requestor and its clients, including pharmaceutical and medical products companies. The health care professionals selecting the charities would be in a position to prescribe or order products manufactured by these companies and payable by Federal health care programs. Thus, the Proposed Arrangement would potentially implicate the anti-kickback statute, if the charitable contributions result in any actual or expected economic or other actionable benefit, whether direct or indirect, for the health care professionals.

Having examined the totality of facts and circumstances of the Proposed Arrangement, we conclude that the Proposed Arrangement would be structured to prevent health care professionals from receiving any actual or expected economic or other actionable benefit from the charitable contributions. All donations would be made directly to the charities. No funds would be transmitted to the health care professionals, and the health care professionals would not be entitled to any tax deduction or other monetary benefit from the donation. All designated charities would be 501(c)(3) organizations, would be public charities, and would meet the public support test under section 509(a) of the IRC. These IRC restrictions minimize the risk that the donations would be made to private foundations or other organizations subject to the direction or control of the designating health care professionals. Donations would not be restricted or "earmarked"; the charity would have sole discretion in the use of the donated funds. In addition, prior to making any contributions, the Requestor would obtain certifications from the health care professionals that neither they, nor any immediate family member, holds a position on the board of the designated charity, is employed by the charity, or has any other financial relationships with the charity (including any financial relationship through the health care professional's medical practice).

Given the facts and circumstances of the Proposed Arrangement, the actual or expected benefits to the health care professionals who complete a survey and designate a charity would be wholly intangible in the form of potential personal satisfaction. We discern no actual or expected economic or other actionable benefit that would inure to health care professionals as a result of the contributions. Accordingly, we conclude that charitable contributions provided under the Proposed Arrangement would not constitute prohibited "remuneration . . . directly or indirectly… in cash or in kind" to the health care professionals within the meaning of the anti-kickback statute. See section 1128B(b) of the Act.

Notwithstanding the absence of discernable remuneration to health care professionals within the meaning of the anti-kickback statute, we note that the Requestor included in the Proposed Arrangement certain additional safeguards against potential abuse. The Requestor has certified that the charitable donations would not be determined in any manner that relates to a health care professional's prescribing choices, thus precluding any potential link between the opportunity to designate a charity and a health care professional's referrals. The Requestor's pharmaceutical and medical device clients would not be apprised of any individual health care professional's charity of choice, minimizing any opportunity for the clients to use the Proposed Arrangement to identify charities favored by particular health care professionals. Moreover, the surveys and the corresponding offer to make a charitable contribution would not be provided to the health care professional as part of any electronic prescribing transaction, thus eliminating any explicit link between the opportunity to direct a donation to a charity and a prescription or order of a product. The Requestor has also certified that all information transmitted under the Proposed Arrangement would be FDA compliant, and the Proposed Arrangement would not be used for any off-label marketing.

Finally, the Requestor would impose dollar limits on the donation per completed survey (which would be a uniform amount for all respondents to a given survey), and on the annual aggregate donation to any one charity on behalf of any one health care professional. In other contexts, dollar caps would be ineffective as a safeguard against abuse, and in many contexts the particular dollar amounts involved in the Proposed Arrangement would clearly implicate the fraud and abuse laws. Here, however, where there is no discernable prohibited remuneration to the health care professionals, the limits would serve as backstop protection, minimizing any incentive an unscrupulous party might have to attempt to subvert the Proposed Arrangement in order to generate payments for referrals.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement would not generate prohibited remuneration under the anti-kickback statute, and thus the OIG would not impose

administrative sanctions on [name 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 [name redacted], 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 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 [name 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 [name 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,

/s/

Lewis Morris
Chief Counsel to the Inspector General