



[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: July 23, 2010

Posted: July 30, 2010

[Name and address redacted]

Re: OIG Advisory Opinion No. 10-11

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a company's proposal to encourage health care providers to use its online program for scheduling meetings with manufacturer representatives by offering the provider an opportunity to select a public charity to which the company would make a monetary, charitable contribution in the provider's name (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 the Proposed Arrangement would not generate prohibited remuneration under the anti-kickback statute. Accordingly, the Office of Inspector General (“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 other 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 [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 corporation that provides marketing services to pharmaceutical, medical, and diagnostic product manufacturers. The Requestor is not a health care provider or supplier and does not participate in or bill Federal health care programs. Except as set forth below, the Requestor is not owned or controlled directly or indirectly by any individual or entity that manufactures health care items or provides health care services that are reimbursed in whole or in part by Federal health care programs.¹

Requestor has developed an online scheduling website, which pharmaceutical, medical, and diagnostic product manufacturers would use to schedule time with health care providers (including physicians) to educate them about new products (the “Program”). The Program would not be used for delivering specific clinical or product information to providers, nor would the Requestor or any party to the Proposed Arrangement use the Program to provide any marketing or clinical data to any other party to the Proposed Arrangement. The website would provide manufacturers and providers with an online scheduling interface that allows manufacturers to schedule time intervals to meet in-person with health care providers. Health care providers would enroll in the Program and provide a schedule for timeslots when the provider would be available to meet in-person with manufacturer representatives.

Under the Proposed Arrangement, the manufacturers would pay the Requestor an enrollment fee and a fee per five minute interval of time scheduled with each health care provider. The

¹ Five of the Requestor’s shareholders are physicians; three have retired from practicing medicine, and two currently practice as hospital-based physicians, one of whom will retire in 2010. The Requestor certified that none of its physician owners will use its online scheduling program under the Proposed Arrangement.

Requestor has certified that these fees would be fair market value based on an arm's-length transaction.² Manufacturers would schedule appointments online with providers on a first-come, first-served basis. Each manufacturer's representative would be permitted to schedule only one appointment per month with an individual health care provider, equaling up to twelve, five-minute appointments annually for each manufacturer representative with an individual health care provider.³ Health care providers would not pay to participate in the Proposed Arrangement, nor would they be paid anything in connection with it.⁴

Under the Proposed Arrangement, the Requestor would encourage health care providers to participate in its scheduling Program by offering them the opportunity to designate a public charity to which the Requestor would make a monetary, charitable contribution "in the name of" the health care provider. The designated charity would be organized under section 501(c)(3) of the Internal Revenue Code ("IRC"), would qualify as a public charity under section 509(a) of the IRC, and would meet the public support test under section 509(a) of the IRC. Contributions would not be made to private foundations. The contributions would be made directly to the charity by the Requestor and use of the donated funds would be solely in the discretion of the recipient charity.⁵

The provider may choose a charity from a list of public charities selected by the Requestor. Additionally, a health care provider may choose a bona fide charity not pre-selected by the Requestor to receive the contribution, provided that the recipient charity meets all of the criteria set forth herein. The Requestor certified that providers would not be permitted to select charities affiliated with trade associations or medical societies to which providers may belong.

The amount of the contribution per scheduled visit would be [amount redacted] for each health care provider. The aggregate donation from the Requestor in the name of any one health care provider to any one charity under the Proposed Arrangement would be capped at

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

³ Manufacturer representatives could meet with multiple individuals who may practice within the same group practice or practice entity.

⁴ Providers participating in the Proposed Arrangement would interact with manufacturers participating in the Proposed Arrangement through means other than the Program. We have not been asked about, and we express no opinion regarding, these ancillary arrangements.

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

[amount redacted] per year. While donations would be made in recognition of the health care provider, the provider 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.

Health care providers wishing to select a charity to receive a donation would be required to meet only two criteria. First, they would use the Program to schedule appointments with the Requestor's clients. Second, the health care providers would certify to the Requestor that neither they, nor any immediate family members, hold a position on the board of the recipient charity, are employed by the charity, or have any other financial relationship or affiliation with the charity (including any employment, affiliation, or other financial relationship through the health care providers' clinical practices).

The Requestor certified that neither the availability, nor the amount, of the charitable contribution would be determined in any manner that relates to a health care provider's prescribing or ordering choices. The Requestor has further certified that the Program and the online scheduling services it provides would not be provided to health care providers 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. 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

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. Our law enforcement activities have detected situations in which pharmaceutical or other health care companies use donations to charities (including private foundations) affiliated with, or controlled by, physicians or other health care providers to channel unlawful remuneration to those health care providers. In some cases, the contributions may be solicited by a health care provider 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 their family members);
- contributions to organizations that employ or otherwise compensate referral sources (or their family members);
- contributions “earmarked” (explicitly or implicitly) to benefit a referral source, its 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 referral source’s 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.

In addition, payment to physicians or other providers in connection with sales representative activities (“detailing”) may also implicate the anti-kickback statute. Examples of suspect payment arrangements involving detailing include, but are not limited to, compensating physicians for time spent listening to sales representatives and compensating physicians for time spent accessing web sites to view or listen to marketing information or perform “research.” See, e.g., OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23738 (May 5, 2003) (“CPG”).⁶

We review the Proposed Arrangement in light of these concerns. Under the Proposed Arrangement, the Requestor would encourage health care providers to schedule detailing appointments using its online scheduling website by offering to make monetary contributions to public charities selected by the health care providers. The donations would be funded through fees paid by the Requestor’s clients, including pharmaceutical, medical, and diagnostic product companies. The health care providers 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 would result in any actual or expected economic or other actionable benefit, whether direct or indirect, for the health care providers.

Having examined the totality of the facts and circumstances of the Proposed Arrangement, we conclude that the Proposed Arrangement would be structured to prevent health care providers from receiving any actual or expected economic or other actionable benefit from the charitable donations. All donations would be made directly to the public charities by the Requestor. No funds would be transmitted to any health care provider, and no provider would be entitled to any tax deduction or other monetary benefit from the donation. All charities designated by the Requestor under the Proposed Arrangement would be 501(c)(3)

⁶ In addition, we have long-standing concerns about abusive detailing arrangements involving off-label marketing.

organizations that are 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 providers. Furthermore, providers would not be permitted to select charities affiliated with trade associations or medical societies to which the providers may belong. 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 providers that neither they, nor any immediate family member, hold a position on the board of the recipient charity, are employed by the charity, or have any other financial relationship or affiliation with the charity (including any employment, affiliation or other financial relationship through the health care providers’ clinical practices).

Given the facts and circumstances, the actual or expected benefits to the health care providers who would use the online scheduling service and select a charity to receive a contribution would be wholly intangible, in the form of personal satisfaction. We discern no actual or expected economic or other actionable benefit that would inure to health care providers 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 providers within the meaning of the anti-kickback statute. Section 1128B(b) of the Act.

Notwithstanding the absence of discernable remuneration to health care providers 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 contributions would not be determined in any manner that relates to a health care provider’s prescribing choices, thus precluding any potential link between the opportunity to select a charity and a health care provider’s referrals. The Requestor’s clients would not be apprised of any individual health care provider’s charity of choice, minimizing any opportunity for the manufacturers to use the Proposed Arrangement to identify charities favored by particular health care providers. Moreover, the use of the scheduling website and the corresponding offer to make a charitable contribution would not be provided to the health care provider 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.

Finally, the Requestor would impose a dollar cap on the donation per health care provider (which would be a uniform amount for each provider per scheduled appointment), and on the annual aggregate donation to any one charity on behalf of any one health care provider. 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 providers, the limits would serve as a 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. Accordingly, 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 other 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 the Requestor 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 Requestor 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