



[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: May 13, 2011

Posted: May 20, 2011

[Name and address redacted]

Re: OIG Advisory Opinion No. 11-05

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a tax-exempt charitable organization's: (1) proposal to provide financial assistance with cost-sharing obligations for certain genetic tests to financially needy individuals, including but not limited to Medicare and Medicaid beneficiaries (the "Cost-Sharing Arrangement"), and (2) current practice of providing vouchers for free genetic tests to individuals who are uninsured or whose insurance does not cover genetic tests (the "Voucher Arrangement" and, together with the Cost-Sharing Arrangement, the "Arrangements"). Specifically, you have inquired whether the Arrangements would constitute grounds for the imposition of sanctions under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Social Security Act (the "Act"), or under the exclusion authority at section 1128(b)(7) of 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 Voucher Arrangement does not generate prohibited remuneration under the anti-kickback statute. Accordingly, the Office of Inspector General (“OIG”) will 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 Voucher Arrangement. In addition, the OIG will not impose administrative sanctions on [name redacted] under section 1128A(a)(5) of the Act in connection with the Voucher Arrangement. We further conclude that: (i) the Cost-Sharing Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while the Cost-Sharing 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 [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 Cost-Sharing Arrangement. This opinion is limited to the Arrangements 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 [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 “Foundation”) is a non-profit, tax-exempt charitable organization dedicated to the creation and dissemination of information and resources for the assistance of people who have cancer, their loved ones, and their providers. Under the Cost-Sharing Arrangement, the Foundation will provide copayment assistance to financially needy individuals for use in connection with genetic testing services to screen for and assist with the diagnosis of cancer. Under the Voucher Arrangement, the Foundation operates a voucher program for individuals who are uninsured or whose insurance does not cover this type of genetic testing. We address each Arrangement in turn.

A. The Cost-Sharing Arrangement

Under the Cost-Sharing Arrangement, the Foundation will establish a copayment assistance program to help insured, financially needy patients, including but not limited

to Medicare and Medicaid beneficiaries, obtain access to genetic testing services that are intended to screen for and assist with the diagnosis of cancer.

Patients will have access to a variety of genetic tests under the Cost-Sharing Arrangement. The Foundation will determine the tests for which it will provide copayment assistance based on each test's potential to impact care and the number of requests it receives for assistance for that test.¹ Although some of the tests have been patented and may be available from only a single source or a limited number of sources,² the Foundation does not anticipate that any one test will account for more than 25% of program disbursements.

The Foundation will solicit and receive cash donations for the copayment assistance program from a variety of sources, including but not limited to genetic testing facilities, and through a variety of means, including fundraising activities and its website. The Foundation will have absolute, independent, and autonomous discretion as to the use of donor contributions. Donations will be unrestricted; donors will not be permitted to earmark their contributions for specific genetic tests, specific types of cancer, or tests from specific facilities. The Foundation will reserve the right to use donated funds for other charitable assistance it provides, including patient travel and other expenses to assist patients in their care.³

The Foundation is governed by an independent board of directors (the "Board"). The Foundation's conflict of interest policy (the "Policy") prohibits Board members from influencing matters where they have a conflict of interest. Although the Policy currently does not specifically address relationships between Board members and genetic testing facilities, the Foundation intends to update the Policy to clarify that Board members may neither serve, nor have spouses who serve, as agents, officers, or directors of a genetic testing facility. Currently, none of the Foundation's Board members or their spouses is

¹ The Foundation initially will cover the twelve most common tests currently available for cancer predisposition genetic testing. The Foundation intends to provide assistance for additional tests that satisfy the Foundation's criteria for coverage to the extent that funding is available and as such tests become available.

² In some cases, patent holders may license other laboratories to provide the patented genetic test.

³ This opinion is limited to the Arrangements. No opinion has been sought, and we express no opinion, regarding the Foundation's use of donated funds other than for copayment assistance.

affiliated with any genetic testing facility. The Policy does not prohibit Board members from making donations to the Foundation.

Potential grant recipients typically will learn about the Foundation's copayment assistance program from their physicians or certified genetic counselors. The Foundation will not market the copayment assistance program directly to patients; however, general information about genetic testing and the copayment assistance program will be available on the Foundation's website.

All prospective grant recipients will be required to complete a copayment assistance application. The application will request patient identifying information, including the patient's name, social security number, date of birth, source of insurance and nature of policy, and deductible. The patient also will be required to certify his or her gross annual household income and the number of persons in his or her family. Applicants will also be required to submit supporting income documentation, such as an IRS Form 1040.

The Foundation will award financial assistance based solely on financial and medical criteria. The financial criteria will be determined with reference to the Federal poverty level and will be the same for all applicants. The Foundation will use the medical criteria established by the National Comprehensive Cancer Network; where medical criteria do not exist, the Foundation will ask the patient's physician or certified genetic counselor to confirm the institutional or medical guidelines for testing. The patient's physician or genetic counselor must certify that he or she has verified that the patient meets the applicable medical and financial criteria.

Applications for copayment assistance will be considered on a first-come, first-served basis, to the extent of available funding. The Foundation will assess patient applications and make copayment assistance awards without regard to: (i) the interests of any donor or donor affiliate; (ii) the applicant's choice of provider, practitioner, supplier, product, service, or insurance plan; (iii) the identity of any referring person or organization; or (iv) the amount of contributions made by any donor whose services or products are used or may be used by the patient.

The Foundation has certified that it will not influence or advise patients or their health care providers on the choice of a testing facility. Patients will have complete freedom of choice regarding their providers, practitioners, suppliers, products, services, and insurance plans, and typically will already have selected a genetic testing facility prior to contacting the Foundation. The Foundation will provide written notification to all grant recipients that they may switch providers, practitioners, suppliers, products, services, or insurance plans without affecting their continued eligibility for financial assistance from the Foundation.

When possible, the Foundation will provide the financial assistance directly to the testing facility or other third party that bills the patient for the genetic testing services; otherwise, financial assistance will be paid to the patient, subject to proof that the patient incurred the cost-sharing expense. The Foundation intends to impose an annual cap, which it currently estimates will be [amount redacted], on the amount of financial assistance awarded. The amount of the cap is likely to be reviewed from time to time. The Foundation has not yet instituted policies addressing applicants' requests for assistance in multiple years; however, it has certified that such individuals will be permitted to reapply for assistance if additional tests either become available or become medically necessary.

The Foundation will make certain data about the Cost-Sharing Arrangement publicly available, including the aggregate number of patient applications, the amount of money distributed, and the number of patients assisted per year. No individual patient information will be conveyed to any donor. Patients will not be informed of the identity of specific donors; however, the names of donors will be listed on the Foundation's website and may be publicly available through the Foundation's IRS tax forms.

B. The Voucher Arrangement

Under the Voucher Arrangement, the Foundation operates a voucher program for individuals who are uninsured or whose insurance does not cover genetic testing services intended to screen for and assist with the diagnosis of cancer. The vouchers entitle eligible individuals to receive the requested genetic tests from a participating genetic testing laboratory. Participating laboratories do not bill the patient or any payor for any portion of the testing obtained through a voucher. Individuals who are eligible for Medicare, Medicaid, or any other Federal health care program may not participate in the Voucher Arrangement.

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.

Section 1128A(a)(5) of the Act provides for the imposition of civil monetary penalties against any person who gives something of value to a Medicare or state health care program (including Medicaid) beneficiary that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a state health care program (including Medicaid). The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of section 1128A(a)(5) as including "transfers of items or services for free or for other than fair market value."

B. Analysis

We analyze each Arrangement separately, below.

1. The Cost-Sharing Arrangement

Two remunerative aspects of the Cost-Sharing Arrangement require scrutiny under section 1128A(a)(5) of the Act and the anti-kickback statute: the donor contributions to the Foundation and the Foundation's grants to patients. We address them in turn.

a. Donor Contributions to the Foundation

Long-standing OIG guidance makes clear that industry stakeholders can effectively contribute to the health care safety net for financially needy patients, including beneficiaries of Federal health care programs, by contributing to independent, *bona fide* charitable assistance programs. Under a properly structured program, such donations should raise few, if any, concerns about improper beneficiary inducements.

In the instant case, the Foundation's particular design and administration of the Cost-Sharing Arrangement will interpose an independent, *bona fide* charitable organization between donors and patients in a manner that effectively insulates beneficiary decision-making from information attributing the funding of their benefit to any donor. Thus, it appears unlikely that donor contributions would influence any Federal health care program beneficiary's selection of a particular provider, practitioner, supplier, product, or service. Similarly, there would appear to be a minimal risk that donor contributions would improperly influence referrals by the Foundation. We reach this conclusion based on the combination of the following factors.

First, no donor or affiliate of any donor will exert direct or indirect control over the Foundation or the copayment assistance program. The Foundation will continue to operate as an independent, non-profit, tax-exempt charitable organization with an independent Board that will have absolute, independent, and autonomous discretion as to the use of donor contributions. Although the Foundation's conflict of interest policy does not prohibit Board members from making donations to the copayment assistance program, it prohibits Board members from influencing matters where they have a conflict of interest. In addition, no Board member, nor any spouse of any Board member, is or will be affiliated with any genetic testing facility.

Second, the Foundation will award assistance in a truly independent manner that severs any link between donors and beneficiaries. The Foundation will make all financial eligibility determinations using its own objective criteria. Applications will be considered on a first-come, first-served basis, to the extent of available funding. Before applying for financial assistance, each patient will have selected his or her physician or genetic counselor, and that physician or genetic counselor will have ordered the necessary genetic tests. In most cases, patients will have selected a testing facility prior to contacting the Foundation. While receiving the Foundation's financial assistance, all patients will remain free to change their providers, practitioners, suppliers, products, services, and insurance plans. Under the Cost-Sharing Arrangement, the Foundation will not refer any patient to any donor or to any provider, practitioner, supplier, product, service, or plan.

Third, the Foundation will award assistance without regard to any donor's interests and without regard to the applicant's choice of provider, practitioner, supplier, product, service, or insurance plan. When determining an applicant's eligibility for copayment assistance, the Foundation will not take into account: (i) the identity of any provider, practitioner, supplier, product, or service the patient may use; (ii) the identity of any referring person or organization; or (iii) the amount of any contributions made by a donor whose services or products are used or may be used by the patient. The Foundation also

will not take into account the identity of the insurer or insurance plan selected by the patient.

Fourth, based on the Foundation's certifications, the Foundation will provide assistance based upon a reasonable, verifiable, and uniform measure of financial need that will be applied in a consistent manner.

Fifth, the Foundation will not provide donors with any data that would facilitate the donor in correlating the amount or frequency of its donations with the amount or frequency of the use of its products or services. Neither individual patient information, nor any data related to the identity, amount, or nature of services subsidized under the Cost-Sharing Arrangement, will be conveyed to any donor. The Foundation may make some aggregate data publicly available, but such data will be limited to aggregate numbers of applicants; aggregate funds disbursed during that reporting period; and the number of patients assisted per year. The Foundation will not disclose any information to patients about donors, or any information to donors about other donors, except that the Foundation will list the names of donors on its website and make such other information publicly available as required by the IRS. In the instant case, we believe these safeguards appropriately minimize the potential risk otherwise presented by reporting donor and patient data to donors and patients.

Finally, the Foundation has certified that the copayment assistance program will cover the twelve most common tests currently available for cancer predisposition genetic testing and that it does not anticipate that any one test will account for more than 25% of the financial assistance awarded. Because the program is not narrowly defined in such a way that it would effectively result in patients being steered to particular tests based on the availability of the subsidy, it is unlikely that the program would serve as an improper conduit for donors to provide funds to patients who use their specific tests.

In sum, the Foundation's interposition as an independent charitable organization between donors and patients and the design and administration of the Cost-Sharing Arrangement will provide sufficient insulation so that the Foundation's proposed subsidies should not be attributed to any of its donors. Donors will not be assured that the amount of financial assistance their patients, clients, or customers receive will bear any relationship to the amount of their donations. Indeed, donors will not be guaranteed that any of their patients, clients, or customers will receive any financial assistance whatsoever from the Foundation. In these circumstances, we do not believe that the contributions made by donors to the Foundation can reasonably be construed as payments to beneficiaries of Federal health care programs or to the Foundation to arrange for referrals.

b. The Foundation's Grants to Federal Health Care Program Beneficiaries

In the circumstances presented by the Cost-Sharing Arrangement, the Foundation's subsidy, in whole or in part, of cost-sharing obligations for certain eligible, financially needy Federal health care program beneficiaries is not likely to improperly influence any beneficiary's selection of a particular provider, practitioner, supplier, product, or service.

First, the Foundation will assist all eligible, financially needy patients on a first-come, first-served basis, to the extent that funding is available. Patients will not be eligible for assistance unless they meet the Foundation's financial need eligibility criteria. At the time of application, a patient will already be under the care of a physician or genetic counselor who will have ordered the necessary genetic tests and, in most cases, the patient will already have selected a genetic testing facility. The Foundation will make no referrals or recommendations regarding specific providers, practitioners, suppliers, products, or services. Although patients may generally learn the identities of donors to the Foundation by visiting a page on the Foundation's website, the Foundation will not otherwise inform or seek to inform patients of the donors' identities.

Second, the Foundation's determination of an applicant's financial qualification for assistance will be based solely on his or her financial need, without considering the identity of any of his or her health care providers, practitioners, suppliers, products, services, or insurance plans; the identity of any referring party; the identity of any donor that may have contributed to support the Foundation; or the amount of any donation. The Foundation will provide assistance based upon a reasonable, verifiable, and uniform measure of financial need that will be applied in a consistent manner. The Foundation will notify all patients that they are free at any time to switch providers, practitioners, suppliers, products, services, or insurance plans without affecting their continued eligibility for financial assistance.

Third, for the reasons noted above, the Foundation's assistance will in no way limit beneficiaries' freedom of choice.

Finally, the Foundation's own interest as a charitable, tax-exempt entity that must maximize use of its scarce resources to fulfill its charitable mission ensures that the Foundation will have a significant incentive to monitor utilization so as to keep subsidies to a minimum.

2. The Voucher Arrangement

Under the Voucher Arrangement, the Foundation does not provide remuneration to Federal health care program beneficiaries, physicians, or genetic counselors. Because Federal health care program beneficiaries are not eligible to receive vouchers, and because physicians and genetic counselors receive no actual or expected economic or other actionable benefit as a result of alerting or referring patients to the Voucher Arrangement, the Voucher Arrangement does not implicate the anti-kickback statute or section 1128A(a)(5) of the Social Security Act.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Voucher Arrangement does not generate prohibited remuneration under the anti-kickback statute. Accordingly, the OIG will 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 Voucher Arrangement. In addition, the OIG will not impose administrative sanctions on [name redacted] under section 1128A(a)(5) of the Act in connection with the Voucher Arrangement. We further conclude that: (i) the Cost-Sharing Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while the Cost-Sharing 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 [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 Cost-Sharing Arrangement. This opinion is limited to the Arrangements 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], 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 Arrangements, 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 Arrangements 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 Arrangements in practice comport 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,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General