



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



[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: November 1, 2018

Posted: November 6, 2018

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 18-13

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding proposed donations from the [trust name redacted] and [name redacted], in your individual capacity, to the [name redacted] (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, although 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 the

[trust name redacted] or [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 for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than the [trust name redacted] and [name redacted], the requestors of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

The [trust name redacted] (the “Trust”) is a charitable trust that [name redacted] (“Grantor”) established in 1989 and funded primarily out of his estate interests. The Trust instrument describes Grantor’s preference that distributions from the Trust be used to support: (a) institutions of higher learning, such as [name redacted] (the “University”) through the [name redacted] (the “University Foundation”), and (b) local charitable endeavors in and around the [location redacted] (the “Community”). Grantor, who passed away in 1993, was heavily involved in civic activities in the Community during his lifetime, including serving on various boards for the University.

[Name redacted] (the “Health Care System”), based in the Community, is a comprehensive network of hospitals and physician practices located throughout the western portion of [location redacted] (the “State”). In 2008, the University and the Health Care System entered into a public-private partnership to create a medical research institute called the [name redacted] (the “Research Institute”).¹ The Research Institute’s mission is to:

- make transformative scientific advances in understanding and addressing the fundamental processes of human health and disease;
- train the next generation of leading biomedical scientists;
- facilitate discovery-based medical education; and
- sustain and strengthen the University-Health Care System partnership in order to develop one of the nation’s premier biomedical research environments in the Community.

¹ This public-private partnership also produced the [name redacted], which is a private, accredited, four-year medical school that was granted tax-exempt status as a public charity by the Internal Revenue Service on July 21, 2009. The medical school became part of the University effective July 1, 2018. Neither the medical school nor the University runs any residency or fellowship training programs.

A central focus of the Research Institute is to integrate new technologies and foster multidisciplinary collaboration to understand how the brain develops, makes choices, and responds to disease and injury. Although the scientific research performed at the Research Institute is geared toward future clinical application, the faculty's and researchers' roles at the Research Institute do not involve the practice of clinical medicine. The Research Institute is not enrolled in Medicare or Medicaid and does not provide items or services reimbursable by Federal health care programs.

Under the Proposed Arrangement, the Trust would make a donation of \$42-50 million² to the Research Institute through the University Foundation, which is the vehicle for all private donations for University programs. The donation would be in the form of the use of Trust principal over a 12-year period. The Trust is directed by certain members of Grantor's family (the "Trustees"), each of whom have ownership and financial interests in long-term care facilities throughout the State. The Trust has no ownership or other financial interests in the long-term care facilities. The donation would be earmarked for the purposes of promoting and conducting biomedical research.

In addition to the transfer by the Trust, one of the Trustees, [name redacted], individually and not in his capacity as a Trustee ("the Individual Trustee Donor"), would make a separate donation to the Research Institute, through the University Foundation, under substantially identical terms and earmarked for the same purpose as the donation by the Trust. The Individual Trustee Donor would contribute any amount necessary to bring the total aggregate donation from both the Trust and the Individual Trustee Donor to the Research Institute up to a value of \$50 million at the time of donation.

The long-term care facilities in which all of the Trustees, including the Individual Trustee Donor, have ownership and financial interests have long-standing, ongoing business relationships with the Health Care System. These include, for example, transfer agreements³ and arrangements involving medical director services, professional medical and dental services, educational services, laboratory services, hospice services, transportation services, and clinical research. In some such arrangements, the Health Care System provides items and services to the Trustees' long-term care facilities, while the reverse occurs in others.

² Due to current investments, the value of the principal of the Trust varies.

³ To participate in the Medicare program, a skilled nursing facility must have a written transfer agreement with one or more participating hospitals providing for the transfer of patients between the hospital and the skilled nursing facility, and for the interchange of medical and other information. See 42 C.F.R. § 483.70(j); see also Centers for Medicare & Medicaid Services, *Medicare General Information, Eligibility, and Entitlement Manual*, Ch. 5, Sec. 30.2, available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ge101c05.pdf> (last visited October 19, 2018).

The Trust has certified that none of the arrangements between the Trustees' long-term care facilities and the Health Care System are exclusive; the Health Care System may enter into similar agreements with any other long-term care facility and vice versa.⁴ The Research Institute's discretion regarding how to use the donation would be absolute, independent, and autonomous; the Trust certified that it would not restrict or place conditions on the donation other than to earmark it to promote and conduct biomedical research. The Trust also certified that the proposed donation would not be explicitly or implicitly tied to, or conditioned on, the generation of any referrals to the Trustees' long-term care facilities. Further, the amount of the proposed donation would not be determined in a manner that varies with, or otherwise takes into account, the volume or value of any referrals or any other business that the Health Care System might generate for the Trustees' long-term care facilities. The Individual Trustee Donor has also certified to each of the above statements in his individual capacity.

The Health Care System, as the private partner in the public-private partnership that created the Research Institute, made an initial financial contribution to establish the Research Institute and remains affiliated with the Research Institute in its mission to develop one of the nation's premier biomedical research environments in the Community. Since its establishment, however, the Research Institute has operated on a budget controlled solely by the University and, as part of a State entity, is subject to State budgetary oversight. The Trust certified that the Health Care System has no role in developing the Research Institute's budget, nor any oversight or control over expenditures made by or on behalf of the Research Institute.⁵ In addition, the Research Institute, as part of the University, and the Health Care System, as a private, not-for-profit entity, operate under separate and distinct governance structures. Members of the University's board are appointed by the State governor and confirmed by the State senate, whereas the Health Care System's board is determined by that entity's governance documents.⁶

⁴ We rely on this certification regarding the non-exclusivity of these agreements. If it is incorrect, this opinion is without force and effect.

⁵ The Trust and the Individual Trustee Donor make this certification in consultation with, and having received confirmation from, the University. We rely on these certifications regarding the Health Care System's absence of influence and control over the Research Institute. If these certifications are incorrect, this opinion is without force and effect.

⁶ The CEO of the Health Care System currently serves on the Board of Directors for the University Foundation, whose members are appointed by current Directors. The University Foundation is a 501(c)(3) charitable organization distinct from the University itself. The Foundation's purpose is to manage private funds given to support the University and to foster and promote the University's growth, progress, and general welfare.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense to knowingly and willfully 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. See, e.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); 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 \$100,000, imprisonment up to ten 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

Substantial charitable donations to an institution of higher learning to promote and conduct biomedical research are at the crux of the Proposed Arrangement. We recognize the proposed donations’ importance to the Research Institute’s advancement of biomedical research and appreciate their significance to the Research Institute’s mission. The Proposed Arrangement nevertheless warrants analysis under the anti-kickback statute because of the relationships between various entities that provide federally reimbursable items and services, on the one hand, and the Trust, the Individual Trustee Donor, and the Research Institute, on the other. The Trustees, including the Individual Trustee Donor, each have ownership and financial interests in long-term care facilities. By directing a substantial proposed donation from the Trust, the Trustees would pay remuneration to the Research Institute, which is part of the University and affiliated with the Health Care System; the Individual Trustee Donor would pay remuneration directly to the same. Although the Research Institute does not itself provide items or services that may be

reimbursable by a Federal health care program, its affiliated Health Care System may generate Federal health care program business for the Trustees' long-term care facilities. In short, the Proposed Arrangement involves remuneration that implicates the anti-kickback statute. For purposes of this advisory opinion, the core issue is whether the donation would likely constitute improper payments to generate Federal health care program business for the Trustees' long-term care providers.

We conclude that that the risk of fraud and abuse posed by the Proposed Arrangement under the anti-kickback statute is sufficiently low for the combination of the following reasons.

First, the Trust and the Individual Trustee Donor certified that their respective proposed donations would not be explicitly or implicitly conditioned on referrals to the Trustees' long-term care facilities, nor would they be subject to any restrictions other than using the funds to promote and conduct biomedical research. The Research Institute's discretion regarding how to use the donations would be absolute, independent, and autonomous. Further, the amount of the proposed donations would not be determined in a manner that varies with, or otherwise takes into account in any way, the volume or value of any referrals or any other business that the Health Care System might generate for the Trustees' long-term care facilities.

Second, although the Health Care System is a partner in the Research Institute's mission and endeavors, the Health Care System would not control how the Research Institute, which is part of the University, uses the proposed donation. The Health Care System and the University are separate entities that operate under separate and distinct budgets and governance structures. The Health Care System is not involved in developing the Research Institute's budget or making decisions about its expenditures. Accordingly, the Research Institute is positioned to make decisions about the use of the proposed donation in an independent manner, reducing the risk of improper ties between the remuneration and the source of referrals, the Health Care System, in the Proposed Arrangement.

Third, the existence of outside business relationships between entities affiliated with donors and a recipient does not make the charitable donations automatically suspect under the anti-kickback statute. The Health Care System and the Trustees' long-term care facilities have various long-standing, ongoing contractual arrangements involving Federal health care program business. The substantial amount of business that already existed between these entities before the proposed donations, particularly in combination with the unique factors described in the next paragraph, lessens the likelihood that the proposed donations are motivated by the prospect of increased referrals to the Trustees' long-term care facilities.

Lastly, several factors distinguish the Proposed Arrangement from arrangements involving donors motivated to provide improper payment for referrals as opposed to donations for *bona fide* charitable purposes or a desire to benefit their communities.

When Grantor established the Trust almost 30 years ago, he stated his preferences that the Trust be used to support higher learning institutions and local charitable endeavors. Consistent with Grantor's stated preferences, the proposed donations would support the Research Institute, which is part of the University, in advancing important scientific research; because the Research Institute is based in the Community, the proposed donations would also support a local charitable endeavor.⁷

On the basis of all these factors, in combination, we conclude that that the risk of fraud and abuse posed by the Proposed Arrangement under the anti-kickback statute is sufficiently low, and we would not impose administrative sanctions in connection with the proposed donation.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG would not impose administrative sanctions on the [trust name redacted] or [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 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 the [trust name redacted] and [name redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.
- This advisory opinion may not be introduced into evidence by a person or entities other than the [trust name redacted] and [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

⁷ This advisory opinion relates only to the application of the anti-kickback statute. We have no authority and do not express any opinion as to whether the Proposed Arrangement complies with other Federal laws and regulations, including those administered by the Internal Revenue Service.

- 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 (or that provision's application to the Medicaid program at section 1903(s) 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 [trust name redacted] or [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 the [trust name redacted] or [name redacted] with respect to any action that is part of the Proposed Arrangement 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,

/Robert K. DeConti/

Robert K. DeConti
Assistant Inspector General for Legal Affairs