



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: December 13, 2016

Posted: December 20, 2016

[Name and address redacted]

Re: OIG Advisory Opinion No. 16-13

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding: (i) a proposal to waive cost-sharing obligations incurred by individuals for health care services required for participation in a government-funded clinical research study (the “Proposed Arrangement”); and (ii) the payment of a stipend to study participants for the time and effort required to participate in study visits (the “Current Arrangement”). Specifically, you have inquired whether the Proposed Arrangement or the Current Arrangement 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, although both the Proposed Arrangement and the Current 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”) 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 Proposed Arrangement or the Current 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 Proposed Arrangement or the Current Arrangement. This opinion is limited to the Proposed Arrangement and the Current 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 [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] (“Requestor”) operates ten campuses of [name redacted] (the “University”), including [name redacted] (“Campus A”), which exclusively focuses on education, care, and research in the health sciences. Requestor employs [name redacted] (“Dr. X”), an infectious disease specialist who serves on the faculty of Campus A’s School of Medicine. Dr. X developed a clinical research study (the “Study”) that seeks to determine whether treating anal high-grade squamous intraepithelial lesions (“HSIL”) is effective in reducing the incidence of anal cancer in HIV-infected persons, who data indicate are disproportionately affected by anal cancer. The Study is a strategy trial in which the strategy of treating anal HSIL is being tested for its ability to reduce the incidence of anal cancer; it is not a treatment trial of any specific treatment modality. Dr. X developed the Study without the input or support of any commercial enterprise.

The Study focuses on treatment of anal HSIL in HIV-infected persons who are 35 years or older. Under the Study, HIV-infected persons are screened for anal HSIL; individuals with confirmed anal HSIL are enrolled in the Study and randomly assigned to either a proactive treatment arm or a standard of care active monitoring arm. Study participants will be tracked either for five years or until the last enrolled participant completes five years of follow-up, whichever is longer. Requestor states that it is essential to the successful completion of the Study that participants maintain compliance with the protocol-required schedule of visits and services.

The National Cancer Institute (“NCI”) awarded the AIDS Malignancy Consortium (the “AMC”)¹ a supplement of approximately \$89 million under Public Health Service funding to fund the Study with Dr. X as protocol chair. The recipient of the award is [name redacted] (“Campus B”), another University campus that Requestor operates. Campus B manages the principal award, and Campus A (along with many other institutions) participates in the AMC, through which many research projects are funded. The Study is being performed as an AMC protocol and is funded exclusively via the Public Health Service grant awarded by NCI to the AMC.

The Study is monitored by [name redacted] (the “Monitor”). The Monitor has served as the contract research organization (“CRO”) for the AMC since the AMC’s formation; because the Study is funded through the AMC, NCI selected the Monitor to serve as the Study’s CRO. As the Study’s CRO, the Monitor will, among other duties, monitor compliance with the Study’s protocol, perform site visits, and frequently report data to NCI. Requestor certified that the Monitor serves as an independent monitor with no financial interest in the outcome of the Study.

A. The Proposed Arrangement

Participants who are enrolled in the Study normally would be liable for applicable out-of-pocket cost-sharing obligations for medically necessary items and services they receive in connection with Study participation. According to Requestor, these out-of-pocket obligations could be significant, particularly for those who are randomized to the treatment arm. Under the Proposed Arrangement, Study participants would be relieved of all out-of-pocket cost-sharing obligations² for Study-related health care services. The trial sites would waive any cost-sharing obligations Study participants owe, and then submit an invoice to Campus A for reimbursement of the waived amounts.³ The trial sites would continue to bill, and collect reimbursement from, third-party payors, including Federal health care programs, for the services the trial sites render to Study

¹ The AMC is an NCI-supported clinical trials group founded in 1995 to support innovative trials for HIV-associated malignancies.

² Out-of-pocket cost-sharing obligations include copayments, coinsurance, and deductibles.

³ Requestor stated that it also would reimburse participants who had enrolled in the Study prior to implementation of the Proposed Arrangement for any Study-related out-of-pocket cost-sharing obligations they incurred.

participants, when applicable.⁴ Requestor certified that the reimbursements for cost-sharing obligations would come from NCI funds, with NCI's approval.

Requestor stated that the Proposed Arrangement is intended both to encourage eligible individuals to enroll in the Study⁵ and to encourage Study participants to remain compliant with the schedule of visits and services required under the protocol for the duration of the Study. Requestor also certified that enrolling participants who are historically under-represented in clinical research studies is widely seen as an important matter of equity, and that Campus A is strongly committed to ensuring that its clinical research studies are accessible to individuals who meet a study's inclusion criteria, regardless of their health insurance coverage status. To reflect the emerging demographics of the HIV-infected population, the Study aims to enroll a widely diverse group of participants, including men and women, under-represented minorities, and individuals of varying socioeconomic backgrounds.

Requestor certified that enrollment and retention in the Study will require multiple visits, a substantial time commitment on the part of Study participants, and dedication to addressing the issues that are the focus of the Study. Participants will need to undergo multiple uncomfortable diagnostic procedures⁶ and, for those in the treatment arm, potentially uncomfortable treatments. Study participants will be asked to attend Study visits at least every six months for five years or more.

Requestor certified that the Study team leadership believes that the cost-sharing obligations could be a substantial burden to Study participants given the level of commitment required, the uncertain benefit to them, and the possibility of up to several thousand dollars of out-of-pocket costs per year. Requestor stated that, because the Study is a cancer prevention research study and not a cancer treatment trial in which participants feel an urgent need to maintain compliance with their treatment plan, it is particularly important to minimize the disincentive for Study participants to attend their visits. Requestor further stated that, if out-of-pocket cost-sharing obligations are not waived for Study participants, there is a risk that Study participation would be skewed

⁴ Requestor certified that AMC research funding assumes that all standard of care procedures performed during the course of funded studies will be billed to insurance, if available.

⁵ Requestor certified that, to achieve sufficient statistical analysis for the research, the Study has a recruitment goal of 5,058 individuals. The Study will be conducted at 15 sites in 13 cities across the United States.

⁶ For example, at each six-month visit, Study participants will have three anal swabs and a digital anal/rectal exam and high resolution anoscopy, and may have one or more anal biopsies.

towards individuals for whom the out-of-pocket costs are negligible or not unduly burdensome and, consequently, the diversity of Study enrollment that Campus A, the investigators, and NCI desire would be negatively impacted.

Requestor certified that NCI has approved the expenditure of grant funds in connection with the Proposed Arrangement.

B. The Current Arrangement

Once enrolled, many Study participants incur expenses they otherwise would not incur if they sought care from their usual health care providers, including expenses related to travel to Study sites and time off from work. Requestor stated that Study-related visits typically require approximately twice as much time as standard clinical care visits.

Under the Current Arrangement, Study participants are reimbursed for their time and expenses at every Study visit, including both visits that involve only research services that are not billed to any third-party payor and visits that involve a mix of Study-scheduled clinical care billed to third-party payors and extra time for non-billable, research-only activities. Study participants receive \$100 for every scheduled visit where high-resolution anoscopy is performed, and \$25 for Study visits where only anorectal swabs are collected (collectively, the “Stipends”).

To arrive at the Stipend amounts, Study leadership considered the overall inconvenience Study participation may cause, any potential lost wages and expenses participants may incur, the need to encourage continuous Study participation, and the nature of the procedures the participants would undergo. Study leadership also consulted with the Study’s Community Advisory Board (“CAB”).⁷ After considering these factors, Study leadership and the CAB concluded that the amounts were in accordance with accepted reimbursement practices in other HIV studies and were neither excessive nor coercive.

Requestor certified that NCI has approved the expenditure of grant funds in connection with the Current Arrangement.

⁷ The CAB is composed of at least one community representative from each Study trial site. Requestor certified that the CAB’s purpose is, among other tasks, to provide feedback on ethical, practical, and community concerns in the conduct and implementation of the Study, and to provide feedback and assistance to the Study protocol team in overcoming obstacles and impediments to enrolling participants in the Study.

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. Borrasi, 639 F.3d 774 (7th Cir. 2011); 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 \$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 (the “CMP”) provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration 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.” The OIG has taken the position that incentives that are only nominal in value are not prohibited by the statute, and currently interprets “nominal in value” to mean no more than \$15 per item, or \$75 in the aggregate on an annual basis. See, e.g., 81 Fed. Reg. 88,368, 88,394 (Dec. 7, 2016) and “Office of Inspector General Policy Statement Regarding Gifts of Nominal Value To Medicare and Medicaid

Beneficiaries,” available at: <https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf>.

B. Analysis

Under the Proposed Arrangement, Study participants, including those who are Federal health care program beneficiaries, would be relieved of all out-of-pocket cost-sharing obligations for Study-related health care services. Requestor certified that the Proposed Arrangement is intended to encourage eligible individuals to enroll in, and remain compliant with protocol-required services for, the Study. Because the Study sites would continue to bill and collect reimbursement from third-party payors (including Federal health care programs) in connection with the Study, the Proposed Arrangement implicates both the anti-kickback statute and the CMP. The Current Arrangement, under which Study participants receive Stipends, likewise implicates both the anti-kickback statute and the CMP.

For the combination of the following reasons, we conclude that both the Proposed Arrangement and the Current Arrangement present a minimal risk of fraud and abuse under the anti-kickback statute.

First, the Study is being performed as an AMC protocol and is funded exclusively via the Public Health Service grant awarded by NCI to the AMC. NCI approved the expenditure of grant funds in connection with the Proposed Arrangement and the Current Arrangement and appointed the Monitor, an independent entity with no financial interest in the outcome of the Study, to, among other duties, monitor compliance with the Study’s protocol, perform site visits, and frequently report data to NCI. The Proposed Arrangement and Current Arrangement therefore are consistent with NCI policy objectives and subject to government oversight.

Second, according to Requestor, waiving out-of-pocket cost-sharing obligations and paying Stipends are necessary to encourage eligible individuals to enroll in, and remain compliant with protocol-required services for the duration of, the Study. Requestor certified that the Study aims to enroll a widely diverse group of participants, including under-represented minorities and individuals of varying socioeconomic backgrounds. Requestor also certified that compliance with the protocol-required schedule of visits and services will be essential to the successful completion of the Study. Requestor faces several hurdles to meeting these objectives, including that the protocol-required services may be uncomfortable and time consuming, that the Study is a cancer prevention research study rather than a cancer treatment trial in which participants feel an urgent need to maintain compliance with their treatment plan, and that the cost-sharing obligations could be a substantial burden to Study participants. The Proposed Arrangement and the Current Arrangement appropriately address these hurdles and therefore are reasonable means of achieving Requestor’s goals.

Finally, the Study is neither a commercial study nor a product-oriented or product-specific study. Rather, the Study is a strategy trial in which the strategy of treating anal HSIL is being tested for its ability to reduce the incidence of anal cancer. The Study therefore is not intended to develop, study, or benefit any specific commercial product or entity. Furthermore, the unique nature of the services offered by the Study makes it unlikely that the out-of-pocket cost-sharing waivers and Stipends will induce Study participants to self-refer to the Study sites for unnecessary services.

For the combination of reasons described above, we conclude that both the Proposed Arrangement and the Current Arrangement present a minimal risk of fraud and abuse under the anti-kickback statute. For the same reasons, in an exercise of our discretion, we choose not to impose sanctions under the CMP in connection with the Proposed Arrangement and the Current Arrangement.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although both the Proposed Arrangement and the Current 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 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 Proposed Arrangement or the Current 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 Proposed Arrangement or the Current Arrangement. This opinion is limited to the Proposed Arrangement and the Current 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 [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 by a person or entity other than [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.

- 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 or Current 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 [name redacted] with respect to any action that is part of the Proposed Arrangement or the Current 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 and the Current Arrangement 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 that is part of the Proposed Arrangement or the Current 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,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General