



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: February 23, 2016

Posted: March 1, 2016

[Name and address redacted]

Re: OIG Advisory Opinion No. 16-02

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a state academic medical center that in certain circumstances offers pregnant women: (1) transportation aid to and from the campus hospital for delivery; and (2) short-term lodging near the campus hospital (collectively, the “Arrangement”). Specifically, you have inquired whether the Arrangement constitutes 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 the 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 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 Arrangement. This opinion is limited to the 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] (the “Requestor”) is an academic medical center and a component of a public university system of the State of [name redacted] (the “State”). The Requestor’s main campus, located on [name redacted] (the “Island”), is home to a large acute care hospital (the “Hospital”) that includes the Requestor’s Department of Obstetrics and Gynecology and Department of Pediatrics. The Department of Obstetrics and Gynecology operates the Hospital’s labor and delivery facilities. The Department of Pediatrics operates the Hospital’s Neonatal Intensive Care Unit (the “NICU”), which provides specialty care for seriously ill or premature newborns.

The Requestor operates 12 hospital-based clinics that provide prenatal care in certain State counties. One of these clinics is located on the Island; the remainder are located between 14 and 103 miles from the Hospital. The transportation and lodging assistance programs discussed in this opinion are only open to patients of the 11 clinics that are not located on the Island (the “Clinics”). The Clinics’ patients primarily are low-income women,¹ and the Clinics provide care without regard to a patient’s resources or means of payment. A Clinic

¹ Because of their low incomes, the great majority of Clinic patients qualify for aid from State or Federal health care programs, including Medicaid and the State Children’s Health Insurance Program (“CHIP”).

patient typically begins her prenatal care at a Clinic within her local community and continues to receive prenatal care at that Clinic for the duration of her pregnancy, until labor and delivery.

The Requestor certified that the Clinics are considered based at the Hospital and meet the requirements at 42 C.F.R. § 413.65 for facilities that have provider-based status. The Hospital maintains each Clinic patient's electronic medical record and serves as the practice location of all physicians and other health care providers who treat patients through the Clinics. Treatment is provided either in person, at the Clinics, or remotely, via telemedicine systems that link the Clinic with the Hospital and the Requestor's other facilities. Hospital staff, including all physicians and other health care providers who treat patients through the Clinics, are either the Requestor's employees or are temporary contracted personnel retained by the Hospital on an as-needed basis.

Some patients of the Clinics experience high-risk pregnancies. A determination of whether a patient's pregnancy is high-risk is made by the patient's physician or nurse practitioner, applying the Requestor's written guidelines. These guidelines are based on national standards set by the American Congress of Obstetricians and Gynecologists. When clinically appropriate, the Clinics provide their patients with access to maternal-fetal medicine specialists, who are experts in the medical and surgical management of high-risk pregnancies.

During the course of her pregnancy, a Clinic patient typically collaborates on her individual birth plan with Clinic staff. During this process, the Hospital is identified as a potential delivery location. The Requestor certified that Clinic staff are required to explain to the patient that she may choose to deliver at a hospital unaffiliated with the Requestor, where usually neither Clinic staff nor other health care providers based at the Hospital have privileges. The Requestor certified that the patient's selection of a delivery location in her birth plan does not commit her to giving birth at that location and does not influence the course of her subsequent treatment at the Clinic. In practice, the great majority of Clinic patients who elect to use the Hospital for their deliveries are experiencing high-risk pregnancies.²

Because of the distances between the Clinics and the Hospital, Clinic patients may express concern about the costs and difficulty of travel to the Hospital for delivery. When a patient who is experiencing a high-risk pregnancy expresses such concern, the Requestor offers aid

² In 2014, for example, 97 percent of Clinic patients who delivered at the Hospital had high-risk pregnancies.

in the form of mileage reimbursement or fare reimbursement for public transportation. The Requestor does not offer luxury or ambulance conveyance or airline tickets, nor does it reimburse any of the costs of these forms of travel.

In addition, in certain circumstances, the Requestor may offer a Clinic patient free lodging at a perinatal residence (the “Residence”) located about four blocks away from the Hospital campus. Lodging at the Residence is made available only if a Clinic patient has a physician’s order justifying the stay, issued under the terms of a written protocol. The Requestor certified that the great majority of pregnant women who stay at the Residence are patients whose high-risk pregnancies require frequent maternal and fetal monitoring. Non-high-risk patients may be offered lodging in the Residence if they are experiencing contractions but not yet in active labor, or if they are scheduled for induction of labor or delivery by caesarean section the following day.

The Residence consists of 12 rooms leased by the Requestor in an apartment building for use by Clinic patients under the Arrangement. The rooms are staffed by an on-call nurse and offer simple living accommodations for patients and any companions who escort them. A patient typically enters the Residence as her due date approaches and leaves when she is admitted to the Hospital for delivery. Patients are transported the four blocks from the Residence to the Hospital without charge.

The Arrangement is not advertised, and participation in the Arrangement is available only to patients who are already receiving prenatal care at a Clinic. A Clinic patient’s receipt of aid under the Arrangement is not conditioned on her use of any other goods or services from the Hospital or the Clinics, or the selection of any other particular provider or practitioner. The Requestor does not consider whether the patient is a Federal health care program beneficiary or the source of her payments for health care when it distributes aid under the Arrangement. The Requestor has certified that none of the costs of the Arrangement are or will be claimed as bad debt, nor is the burden otherwise shifted to the Medicare or Medicaid program or other payors.

The Requestor states that the forms of aid available under the Arrangement remove obstacles that otherwise would prevent Clinic patients from benefiting from the specialty care and continuity of care available at the Hospital as the patient’s due date nears. For example, a maternal-fetal medicine specialist is able to coordinate with the Hospital for any special care an infant may require after birth, including, when needed, admission to the NICU.

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 the CMP as including “transfers of items or services for free or for other than fair market value.” The OIG has previously taken the position that “incentives that are only nominal in value are not prohibited by the statute,” and has interpreted “nominal in value” to mean “no more than \$10 per item, or \$50 in the aggregate on an annual basis.” 65 Fed. Reg. 24,400, 24,410–11 (Apr. 26, 2000) (preamble to the final rule on Civil Money Penalties).

B. Analysis

The aid the Requestor provides to Clinic patients under the Arrangement, which includes free transportation and short-term lodging, could influence the patients' selection of the Hospital as their provider for labor and delivery and postpartum care. Some recipients of this aid are Medicaid beneficiaries. Thus, the Arrangement implicates both the CMP and the anti-kickback statute. However, for the combination of reasons described below, we conclude that, in an exercise of our discretion, we will not pursue administrative sanctions under the CMP or the anti-kickback statute in connection with the Arrangement.

First, we conclude that the Arrangement is beneficial to Clinic patients. The transportation and lodging aid provided under the Arrangement provide Clinic patients who lack sufficient financial means the option of delivering at the Hospital. The Requestor's physicians, who are familiar with Clinic patients' individual pregnancies and medical histories, are based at the Hospital, and the patients' medical records are readily available there. Labor and delivery at the Hospital thus provides the patients with continuity of care, which is particularly important for high-risk patients. These patients' special needs identified during the course of treatment at a Clinic can be anticipated and prepared for at the Hospital, including preparation for rapid admission of a newborn with complications to the NICU, when appropriate. At the Hospital, moreover, the patient benefits from the special expertise and other treatment resources available from an academic medical center.

Second, the aid that patients receive under the Arrangement is modest in nature and made available only in limited circumstances. Clinic patients are informed of transportation aid only if they are determined to be experiencing high-risk pregnancies, and only when they express concern about their ability to afford the costs of travel for delivery at the Hospital. Free lodging at the Residence is made available only when medically necessary. Further, the transportation aid does not cover air, ambulance, or any kind of luxury transportation, and the Residence accommodations are basic. These factors reduce the risk that patients choose to deliver at the Hospital because of the aid offered under the Arrangement, as opposed to other reasons related to continuity and quality of care.

Third, the aid offered under the Arrangement is not advertised and is offered only to existing Clinic patients who, because the Clinics are hospital-based, are also patients of the Hospital. Thus the Arrangement does not appear to be designed to serve as an inducement for patients to select a Clinic over other local competing prenatal care facilities.

Fourth, the Requestor does not consider whether the patient is a Federal health care program beneficiary or the source of payments for her health care when it distributes aid under the

Arrangement. Eligibility is not limited to a group of patients targeted on the basis of their health insurance coverage.

Fifth, the Requestor certified that none of the costs of the Arrangement are or will be claimed as bad debt, nor is the burden otherwise shifted to the Medicare or Medicaid program or other payors.

Finally, the Arrangement is part of a program of care established and operated by a State academic medical center for the benefit of a specific patient population served by Federal health care programs (including Medicaid and CHIP) operated and partially funded by the State. We rely, in part, upon the State's own responsibility, in carrying out the Arrangement, to promote both the well-being of these patients and the integrity of these programs.

The unique combination of all of these factors leads us to conclude that we will not subject the Requestor to administrative sanctions under the CMP. We stress that no individual factor set forth above, nor any subset of them, would justify this conclusion.

In an exercise of our discretion, and for the same reasons set forth above, we conclude that we also will not subject the Requestor to administrative sanctions under the anti-kickback statute in connection with remuneration provided to patients under the Arrangement.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the 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, but that 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 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 Arrangement. This opinion is limited to the 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 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 Requestor with respect to any action that is part of the 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 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 that is part of the 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