



[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 8, 2011

Posted: November 15, 2011

[Name and address redacted]

Re: OIG Advisory Opinion No. 11-16

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a hospital's domiciliary services program that provides transportation, lodging, and meal assistance to certain patients and their family members (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: (i) the Arrangement does not constitute grounds for the

imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while 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. 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

A. The Requestor’s Mission and Billing Policy

[Name redacted] (the “Requestor”) is an internationally known, not-for-profit institution dedicated to finding cures for catastrophic diseases in children through research and treatment. It is focused primarily on infectious diseases, pediatric cancers, non-malignant hematologies (such as sickle cell disease), and certain other genetic disorders. The Requestor certified that the vast majority of its patients are on clinical research protocols.

The Requestor treats children from across the United States and around the world. To receive services at the Requestor’s facility, a child must be referred by a physician or an independent licensed clinician. Families that contact the Requestor seeking medical care are advised to consult their pediatrician or other physician. Acceptance at the Requestor’s facility is primarily based on protocol eligibility, and the Requestor states that more patients are referred to its facility than it is able to accept under its admissions policy.

The Requestor certified that it offers unique and cutting-edge research and therapy options. The Requestor states that the highly complex nature of many of the clinical and translational trials that it designs and conducts requires greater patient participation, and more time at the Requestor’s campus, than the clinical trials conducted by most cooperative groups or single institutions. According to the Requestor, the success of the therapies and the pace by which new therapies can be identified rests, in part, on the willingness of patients to comply with the rigors and requirements of the protocols and the number of patients enrolling in the Requestor’s treatment and research activities. For these reasons, many of the patients who

seek to avail themselves of these options must travel or temporarily relocate to the Requestor's metropolitan area.

In furtherance of its commitment to cutting-edge research and therapy options, and to ease the burdens associated with participation in its programs, the Requestor maintains contractual arrangements with a network of six pediatric hematology-oncology clinics, hospitals, and universities (collectively, the "Affiliates"), which allow children to receive some of their therapy closer to home. The physicians and staff at the Affiliates work in collaboration with the Requestor's staff to deliver protocol-related care to pediatric hematology and oncology patients.

The Requestor does not bill children or their families for any part of the cost of their medical care, including copayments or deductibles, a practice that has been in place since the Requestor's inception and which extends to patients at the Affiliates.¹ To support its charitable mission, the Requestor relies heavily on donations raised by [charity name redacted] (the "Charity"), which, historically, account for approximately 70 percent of the Requestor's operating revenue. The remainder of the Requestor's operating revenues comes from third party payors, including Federal health care programs, and research grants. Third party payments, however, are insufficient to cover the patient care costs incurred by the Requestor for insured children. For example, in fiscal year 2011, the Requestor recovered only about 23 cents for every dollar that it incurred in patient costs for Federal health care program beneficiaries. The Requestor certified that it does not: (i) claim any unbilled amounts as bad debt on its Federal program cost reports, or (ii) shift any costs to other third-party payors in the form of higher rates or charges.

B. The Arrangement

Under the Arrangement, the Requestor offers an extensive domiciliary services program that provides transportation, lodging, and meal assistance for patients and their families depending on criteria such as anticipated length of stay and distance from the Requestor (the "Domiciliary Services" or the "Domiciliary Services Program").² The Requestor states that the Domiciliary Services are intended to improve access to care, enhance infection control to reduce the risk of infection in the Requestor's immune-suppressed patients, help ensure clinical research protocol compliance, enhance quality of life, and reduce the stress for patients and families receiving therapies at the Requestor's facility.

¹ We do not address the Requestor's billing policy in this opinion.

² The Arrangement does not apply to Affiliates.

The Domiciliary Services Program is not advertised or marketed to prospective patients, their families, or referring physicians; however, the Requestor states that many pediatricians and oncologists who refer patients to the Requestor likely are aware of the Domiciliary Services Program, either from prior experience with the Requestor or as a result of the Charity's fundraising efforts for the Requestor. Patients generally are informed of the availability of Domiciliary Services only after they have been accepted to the Requestor's facility. The Requestor certified that the Domiciliary Services Program is funded by philanthropic sources through the Charity and that none of the costs of items and services provided under the Domiciliary Services Program are claimed or have their costs shifted—either directly or indirectly—to the Federal health care programs or other third party payors.

The Domiciliary Services provided by the Requestor can be grouped into four categories: transportation assistance, lodging assistance, meal assistance, and miscellaneous items and services. We describe the assistance provided within each category more fully, below.

1. Transportation Assistance

The Requestor certified that more than 70 percent of its patients live more than 35 miles away from its facility. In an effort to remove barriers to access to care and participation in research, the Requestor offers assistance with plans and costs associated with travel for planned treatments and check-ups to its patients and one parent or guardian who express a need for transportation assistance. Transportation assistance is also provided to transplant donors.

The Requestor determines the mode and schedule of transportation by selecting the most economical and appropriate means of transportation at the time of the request.³ For patients traveling more than 35 miles, but less than 300 miles, the Requestor typically arranges for bus or rail travel, or will reimburse for automobile mileage driven in personal vehicles. Patients traveling more than 300 miles are eligible to receive air transportation assistance, as well as bus, rail, or automobile mileage reimbursement. For airline, train, and bus tickets, the Requestor covers the cost of the lowest economy fare. Although patients who live within 35 miles of the Requestor's facility are not eligible for these forms of transportation assistance, they may receive shuttle van service to and from treatments and study appointments scheduled by their attending physicians if they have no other means of transport.

³ The Requestor certified that assistance is not provided for luxury or specialized transportation.

2. Lodging Assistance

The Requestor provides complimentary lodging to patients and their core caregivers who live more than 35 miles away from the Requestor when: (i) the patient's treatment requires an overnight stay, and (ii) the patient or his or her parent or guardian expresses a need for lodging assistance. Patients and their families requesting lodging assistance must sign a written lodging assistance agreement and must agree to be photographed for identification purposes. The Requestor typically arranges for lodging for patients and their families at one of three Requestor-sponsored lodging facilities. The specific facility to which a patient is assigned typically depends on the patient's anticipated length of stay. All of the lodging facilities meet the Requestor's standards for infection control, including HEPA filtration systems, no carpet, and pressurized buildings. To minimize infection risk, the Requestor caps the occupancy of the rooms or suites at four people.

3. Meal Assistance

To address the basic nutritional requirements of the patient and one family member, the Requestor offers assistance with the cost of meals by issuing either: (i) a meal card that may be used at the cafeteria at Requestor's hospital, at Requestor's lodging facilities, or to buy coupons for certain restaurant chains, or (ii) a grocery store gift card. Meal cards are available for patients and caregivers for the period during which the patient is in the Requestor's metropolitan area for scheduled treatment at the Requestor's facility. The Requestor allots \$8.00 for breakfast, \$10.00 for lunch, and \$12.00 for dinner. Dollar amounts do not carry over from one meal period to another. The Requestor provides grocery store gift cards in lieu of meal cards only to patients who are expected to stay in the Requestor's metropolitan area for eight or more days for treatment. The value of the grocery store gift cards is between \$80.00–\$100.00 per week. For inpatients, in-room meal service is provided in lieu of meal cards. The caregiver of an inpatient may receive a meal card as long as the family has not received a grocery store gift card. The Requestor's policy limits the use of meal cards and grocery store gift cards to food purchases only, and specifically prohibits the purchase of tobacco or alcohol products with the cards.

4. Miscellaneous Items and Services

The Requestor provides certain other items and services to help patients and their families maintain their well-being and quality of life, including: child restraint devices for automobiles; handling of patient mail; developmental items such as bouncy seats and strollers; and special events and dinners, such as prom, graduation, and Halloween events, and "no more chemo" parties.

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.” 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 value to be no more than \$10 per item, or \$50 in the aggregate on an annual basis.” 65 Fed. Reg. 24,400, 24,410–24,411 (April 26, 2000) (preamble to the final rule on the CMP).

Section 6402(d)(2)(B) of the Patient Protection and Affordable Care Act (P.L. 111–148, 124 Stat. 119), as amended by the Health Care and Education Reconciliation Act of 2010

(P.L. 111–152, 124 Stat. 1029), amends the Act’s statutory definition of “remuneration” by adding a new exception as subsection (F) for “any other remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in section 1128B(f) and designated by the Secretary under regulations).” No regulations relating to this provision have been promulgated.

B. Analysis

Under its Domiciliary Services Program, the Requestor provides lodging, transportation, and meal assistance, and certain other miscellaneous items and services to the Requestor’s patients and their families, including Federal health care program beneficiaries, without regard to financial need. The Domiciliary Services Program thus implicates the anti-kickback statute’s proscription against offering or paying something of value as an inducement to generate business payable by a Federal health care program, as well as the proscription against beneficiary inducements under section 1128A(a)(5) of the Act.

Based on the facts presented, we find that the following factors adequately protect the Arrangement against the risk of fraud and abuse and, for the reasons elaborated below, we will not subject the Requestor to sanctions under section 1128A(a)(5) of the Act or the anti-kickback statute.

First, the Requestor is a not-for-profit institution that is reimbursed for less than a quarter of the costs it expends to care for the Federal health care program beneficiaries it treats. Most of the remaining costs for care not reimbursed by the Federal health care programs, and all of the costs of providing the Domiciliary Services, are funded by philanthropic sources through the Charity. Although we cannot determine a party’s intent, we think it is implausible that the Requestor, already faced with more qualified patient applicants than it can accommodate, provides the Domiciliary Services to generate additional referrals of business for which it receives less than a quarter of the cost of providing care.

Second, the unique nature of the services the Requestor provides makes it unlikely that the Domiciliary Services will induce patients to self-refer to the Requestor’s facilities for unnecessary services. The Requestor focuses on the treatment and cure of catastrophic diseases in children; such services typically are not susceptible to overutilization. Furthermore, the fact that the vast majority of the Requestor’s patients are on clinical research protocols not offered elsewhere makes it unlikely that the Requestor’s provision of Domiciliary Services would cause a patient to seek services at the Requestor’s facility at the expense of another facility.

Third, the Domiciliary Services help ensure that the Requestor’s patients can take advantage of, and remain compliant with, the research and treatment protocols that the Requestor

offers. Because the Requestor draws its pediatric patient base from across the United States and around the world, many of the Requestor's patients and their families must travel or temporarily relocate to the Requestor's metropolitan area. The Domiciliary Services help ease the hardships associated with this displacement, and also permit the Requestor to closely monitor its patients and their compliance with the research protocols and prescribed treatment regimens.

Fourth, many of the Requestor's patients have compromised immune systems and, therefore, have special hygiene needs. The Requestor's lodging facilities have been designed with infection control in mind, and offer a clean, safe environment that promotes healing.

Fifth, the Requestor's provision of meal assistance ensures that its patients and their families are able to satisfy their basic nutritional requirements. Its provision of miscellaneous items and services such as child restraint devices, developmental items, and special events, allows its patients and their families to focus on their treatment regimens and to celebrate treatment milestones. The meal assistance and the miscellaneous items and services are small in value compared to the other Domiciliary Services and the care itself, are not advertised, and are funded exclusively by philanthropic sources. We therefore conclude that these types of assistance are unlikely to influence a beneficiary to seek unnecessary services or to seek services from the Requestor's facility at the expense of another facility, and therefore pose a low risk of harm to the Federal health care programs.

Sixth, because the Domiciliary Services are not advertised or marketed to prospective patients, their families, or referring physicians, and because patients generally are informed of the availability of the Domiciliary Services only after they have been accepted for treatment, the Domiciliary Services are unlikely to serve as an inducement to select the Requestor's facility.

Seventh, none of the costs of the items and services provided under the Domiciliary Services Program are claimed or have their costs shifted—either directly or indirectly—to the Federal health care programs or other third party payors. The Arrangement therefore is unlikely to lead to increased costs to the Federal health care programs.

Finally, we also take into account the substantial public benefits obtained from the specialized care provided, and the research conducted, by the Requestor in its mission to find cures for catastrophic diseases in children. Although we have not investigated the matter, based on the Requestor's statements, it appears that the Domiciliary Services Program permits the fullest possible preservation of those benefits.

For the combination of reasons listed above, we conclude that we would not subject the Requestor to administrative sanctions under section 1128A(a)(5) of the Act or the anti-kickback statute in connection with the 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: (i) the Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while 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 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. 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 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 Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.
- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.
- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against [name redacted] 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 [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