



[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: April 26, 2006

Posted: May 3, 2006

[Name and address redacted]

Re: OIG Advisory Opinion No. 06-05

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding the practice of [name redacted] of providing drugs and supplies to its affiliated entities for administration to [name redacted] patients receiving outpatient treatment at the affiliated entities, and, in very limited circumstances, to its patients receiving inpatient treatment at the affiliated entities (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes 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.

You have certified that all of the information provided in your request, including all supplementary letters, 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 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 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 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.

1. FACTUAL BACKGROUND

A. [Name redacted]

[Name redacted] (“Requestor”) is a non-profit, pediatric institution in [city and state redacted], dedicated to finding cures for catastrophic diseases through research and treatment, focusing primarily on pediatric cancers, immuno-deficiencies, and genetic disorders.

Children come to Requestor from all over the country and the world, and typically are accepted for treatment based solely on their eligibility for, and willingness to participate in, Requestor’s research protocols or other clinical trials. Requestor’s admission policy provides that children are eligible for admission if there is an open research protocol (and in limited other circumstances), but children who have been previously treated are generally not accepted except for highly experimental or investigative procedures. Requestor does not bill children or their families for any portion of the cost of their medical care, including copayments or deductible amounts (“Billing Policy”).¹ In order to support its charitable mission, Requestor relies in large part on voluntary contributions raised by the [charity name redacted]; in 2004, for example, [charity name redacted] contributed more than 68% of Requestor’s operating revenue. The remainder of Requestor’s operating funds come from third party payors (including Medicaid), research grants, and other sources. Third party payments, however, are insufficient to cover the patient care costs incurred by Requestor for insured children. With respect to Federal program beneficiaries, for example, Requestor expects to recover only about 30 cents for every dollar it incurred in 2005 in patient care costs. Consistent with its research mission, Requestor also provides substantial experimental care that generally is not covered by Federal or private health insurance programs.

¹We approved Requestor’s Billing Policy, and its extension to certain of Requestor’s affiliate entities, in Advisory Opinion 99-06. See OIG Advisory Opinion No. 99-06.

B. Requestor's Affiliated Entities

Many of Requestor's patients and their families must travel or temporarily relocate to [city redacted] in order to avail themselves of Requestor's treatment. Approximately one-third of Requestor's patients are treated in clinical trials that involve frequent clinic visits and medication for at least two and one half to three years. Such clinical trials can impose substantial financial, logistical, and other burdens on patients and their families.

Patients' willingness to comply with research protocols, and the rate at which patients enroll in Requestor's studies, greatly influence the success of Requestor's research activities and the speed at which significant results can be achieved. Therefore, in order to ease the burdens associated with participating in research sponsored by Requestor, and to expand the number of children participating in research protocols, Requestor maintains contractual relationships with six entities that comprise four regional affiliates ("Affiliates"), which allow children to receive some of their therapy closer to home. The Affiliates are:

- [Affiliate name redacted];
- [Affiliate name redacted];
- [Affiliate name redacted]; and
- [Affiliate name redacted].

Each of the Affiliates operates a distinct pediatric oncology clinic for Requestor's patients being treated at the Affiliates. The majority of the care provided at the Affiliates is on an outpatient basis, although inpatient care may be required on occasion. The Affiliates agree to follow Requestor's Billing Policy with respect to Requestor's patients.²

C. The Arrangement

Under the Arrangement, Requestor provides selected elements of monitoring and treatment of Requestor's patients, including the provision of protocol medications and related supplies ("Protocol Related Therapy") for administration during the course of care provided at the Affiliates. Protocol Related Therapy includes all scheduled medications and related pharmaceutical supplies defined by the Requestor-approved clinical study protocols, as necessary to meet the study aims. According to Requestor, the Arrangement helps to ensure that Protocol Related Therapy and other medications and supplies are available for Requestor's patients receiving outpatient care at the Affiliates.

Requestor's Pharmaceutical Department dispenses all Protocol Related Therapy. With respect to individual patient courses of Protocol Related Therapy that will be administered at an Affiliate, Requestor's Pharmaceutical Department directly mails the Protocol Related Therapy to the designated physician, pharmacy, or clinic at the

²Under Requestor's Billing Policy, [charity name redacted] pays all deductible and coinsurance amounts for Requestor's patients enrolled at the Affiliates.

Affiliate.³ The Requestor accepts financial responsibility for the acquisition costs of all Protocol Related Therapy for patients enrolled in Requestor's protocols, and for billing and recovery of the acquisition costs.⁴ Consistent with its Billing Policy, Requestor waives all copayments and deductibles, and the patients and their families are not billed for any of the costs of care, including the Protocol Related Therapy provided at the Affiliate. Any billing and reimbursement associated with the costs incurred by the Affiliates for mixing and administration of the Protocol Related Therapy that takes place in the Affiliates' facilities, exclusive of the acquisition costs of the medications themselves, is the sole responsibility of the Affiliates.⁵ Requestor has certified that the mixing and administrative services that could be provided and/or billed by the Affiliates will not duplicate the services provided and/or billed by Requestor.

Many of the pediatric diseases that Requestor investigates are relatively rare; thus, while the Protocol Related Therapy used for Requestor's patients may be commercially available, it is often not FDA-approved for use in children with these conditions. Accordingly, the Arrangement centralizes the dispensing of Protocol Related Therapy, which facilitates uniformity in the initial preparations dispensed and ensures that all patients on each research protocol receive the same formulations and quality of medications. This process ensures that the data generated from these studies are consistent whether the care is provided at Requestor or one of the Affiliates. The Arrangement also provides an effective mechanism for monitoring therapy related problems and drug interactions by maintaining comprehensive, single site pharmacy records at Requestor.

³Requestor has certified that its Pharmaceutical Department is licensed in all appropriate states and meets all regulatory requirements for dispensing medications to patients at Requestor and the Affiliates.

⁴In extremely rare cases, Requestor will also provide drugs to the Affiliate for Requestor's patients who are inpatients at the Affiliate (e.g., where the drug is not readily available to the Affiliate). Under such circumstances, the cost of the drugs would be included in the Affiliate's reimbursement under an inpatient prospective payment system. Requestor will not bill any Federal health care program for drugs that Requestor provides to an Affiliate for Requestor's patients who are inpatients at an Affiliate.

⁵Requestor and the Affiliates will continue to waive copayments and deductibles pursuant to the policy that we approved in OIG Advisory Opinion No. 99-06.

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.), 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.

B. Analysis

The Arrangement, by which Requestor provides Protocol Related Therapy without charge to the Affiliates for administration to Requestor’s patients receiving outpatient treatment at the Affiliates, and, in very limited circumstances, to its patients receiving inpatient treatment at the Affiliates, potentially implicates the anti-kickback statute. Requestor potentially confers a benefit on the Affiliates that, if the requisite intent were present, could potentially violate the anti-kickback statute. However, for the reasons set forth below, we conclude that, in the particular circumstances presented here, the Arrangement is unlikely to result in fraud or abuse under the anti-kickback statute, and we will not seek to impose administrative sanctions.

First, the Arrangement confers little, if any, benefit on the Affiliates. The Affiliates do not bill for the cost of the Protocol Related Therapy. Accordingly, the Protocol Related Therapy does not inure to the economic value of Affiliates.⁶ Moreover, while the

⁶Requestor has certified that in extremely rare cases it provides drugs to an Affiliate for Requestor’s patients who are inpatients at the Affiliate, such as when the drug is not readily available to the Affiliate. Whereas we recognize that in some cases

Arrangement may result in some avoided administrative costs for the Affiliates (e.g., a reduction in administrative burden associated with procuring and billing for Protocol Related Therapy), such a benefit is likely to be relatively small and speculative in the particular circumstances presented here. To the extent the Affiliates incur costs for mixing and/or administering Protocol Related Therapy in their own facilities, the Affiliates will be responsible for any billing and reimbursement associated therewith, and there will be no overlap with services that are potentially billed by Requestor.

Second, while we cannot determine a party's intent, we think it is implausible that Requestor entered into the Arrangement in order to generate referrals of Federal program business from the Affiliates. The agreements between Requestor and the Affiliates are expressly intended to minimize referrals to Requestor by making it easier for patients to receive treatment at facilities other than Requestor's campus in [city redacted]. Moreover, the size of the patient universe that the Affiliates could potentially refer to Requestor is substantially limited by Requestor's admission policy, which generally limits admissions to children eligible for an open research protocol. Perhaps more pertinent, the low, 30% rate at which Requestor estimates it is able to recoup the cost of treating Federal program beneficiaries suggests it is unlikely that the Arrangement is designed to generate referrals of Federal program business in particular.

Third, there is little risk that referrals from the Affiliates, if any, would result in inappropriate utilization or increased program costs at Requestor. Much of Requestor's treatment is dictated by peer-reviewed clinical protocols, which afford some protection against overutilization. Of those referred, many typically will need experimental interventions not generally covered by Federal or private insurance. Moreover, Requestor's policy of not billing its patients for copayments or deductible amounts, and its corresponding policy of paying for the copayments of its patients being treated at the Affiliates through [charity name redacted], creates a significant financial incentive for Requestor to monitor utilization so as to keep its copayment expenses to a minimum.

Finally, we note that there is a substantial public benefit from expanded research into childhood diseases. Requestor is a non-profit institution whose primary mission is the research and treatment of childhood diseases, and the Arrangement furthers that mission by promoting uniformity in the preparations dispensed to Requestor's patients, assuring consistent access to Protocol Related Therapy, and being consistent with good clinical research practices.

this practice could create an opportunity for an Affiliate to be reimbursed for such drugs under a prospective payment system without having incurred costs for them, here, the inpatient aspect of the Arrangement is sufficiently small, and any remunerative value so speculative, that we believe this aspect of the Arrangement would not constitute an inducement by the Requestor to the Affiliates for referrals.

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.

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,

/s/

Lewis Morris
Chief Counsel to the Inspector General