



[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: September 17, 2010

Posted: September 27, 2010

[Name and address redacted]

Re: OIG Advisory Opinion No. 10-18

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding your proposal to extend one night of free post-surgical accommodations to pediatric tonsillectomy patients insured by Federal health care programs (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for 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 Proposed Arrangement would not constitute grounds

for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while 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 [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 letter 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 “Health System”) is an integrated health services organization that offers a wide range of health care services to residents of a largely rural area of [state redacted]. Part of the Health System’s mission is to serve as a proponent for the needs of a rural population and to identify resources for such communities.

Tonsillectomies may be performed on an inpatient basis or, when medically appropriate, on an outpatient basis. Four facilities owned by the Health System offer tonsillectomy services: [name redacted] (the “Hospital”); [name redacted] (the “Outpatient Surgery Center”); and two other hospitals, [names redacted] (the “Affiliated Hospitals”). These four facilities all operate under the Health System’s global budget. [Name redacted] (the “Clinic”), also owned by and operated under global budget of the Health System, employs ear, nose, and throat specialists (the “Clinic ENTs”) who have privileges to perform tonsillectomies at these facilities. These Clinic ENTs do not have privileges at hospitals outside the Health System and do not perform tonsillectomies at hospitals outside the Health System.

The Outpatient Surgery Center, which is a free-standing, provider-based department of the Hospital, is located approximately three miles from the Hospital campus. All tonsillectomies performed at the Outpatient Surgery Center are performed by Clinic ENTs. For post-surgical pediatric tonsillectomy patients who undergo outpatient surgery at the Outpatient Surgery Center and who are not Federal health care program beneficiaries, the Hospital has a program to provide these patients and their parents or guardians the option to stay at a local hotel adjacent to the Hospital at no cost for the night after the tonsillectomy (the “Program”). The Program targets patients who live further away from the Hospital.

However, any patient is eligible to participate in the Program, regardless of where he or she lives in proximity to the Hospital, if: (1) the patient is three years of age and older¹; (2) the patient's Clinic ENT has determined, in his or her professional judgment, that the Outpatient Surgery Center is a medically appropriate site to perform the surgery; and (3) the patient is not a Federal health care program beneficiary. This service is provided in close proximity to the Hospital so that, in the unlikely event complications develop, participating patients can quickly access post-surgical care.² Patients who participate in the Program and need post-surgical care for complications are not required, however, to select the Hospital for such services.

Under the Program, the Hospital pays for one-night's stay at the adjacent [name redacted]. The cost of the room is approximately [amount redacted]. The Hospital also stocks the hotel room with post-surgical snacks routinely utilized for a pediatric patient recovering from a tonsillectomy procedure (e.g., ice cream, popsicles, and fruit beverages). The Hospital pays for all costs of the Program; no insurance plan or third-party payor is charged. The Program is unique to post-surgical, non-Federal payor pediatric tonsillectomy patients.

The Program is not generally advertised to the public. Information about the Program is provided to patients and their parents or guardians during the pre-surgical visit, a stage at which the selection of a physician to perform the tonsillectomy has already occurred. If a Clinic ENT has been selected, then the patient's choice of site of service is among the four sites within the Health System where the tonsillectomy may be performed and where the Clinic ENT has privileges to perform the surgery. It is at this time that a Clinic ENT informs an eligible patient's family of the Program, and the patient's family may elect to participate.³ The Program is not offered to patients receiving inpatient tonsillectomies at the Hospital or Affiliated Hospitals. It is only available to patients receiving outpatient surgery at the Outpatient Surgery Center to give patients and their families the assurance of

¹ Patients under three years of age are generally observed in the hospital setting and do not receive the procedure on an outpatient basis.

² To date, no patients electing the Program have had complications. According to several studies cited by the Hospital, the average complication rate of tonsillectomies in children older than three years old, where there is no known increased risk of post-surgical complications prior to surgery, is between 3-10%. The Health System's experienced complication rates are approximately 1-3%.

³ If on the day of surgery, however, the patient determines that he or she does not wish to participate in the Program, the patient is not required to stay at the hotel, and there is no penalty of any kind.

proximate hospital services should complications develop. Participation in the Program is not conditioned on the use of any other goods or services from the Hospital or any other particular practitioner or provider. The Clinic ENT's salaries are unaffected by the volume or value of surgeries performed at the Outpatient Surgery Center. In connection with the Program, the Clinic ENTs do not have any improper incentives to steer patients to the Outpatient Surgery Center within the Health System or to order unnecessary surgeries.

Under the Proposed Arrangement, the Hospital would extend the Program to eligible pediatric tonsillectomy patients who are insured by Federal health care programs. The Hospital believes that, of the entire payor mix of potential patients in the Program, approximately 28% to 30% would be Federal health care program beneficiaries, and the overwhelming majority of these patients would be Medicaid patients. Based on historical experience with non-Federal payor patients, the Hospital expects that approximately 18% of patients undergoing a tonsillectomy at the Outpatient Surgery Center would participate in the Program under the Proposed Arrangement. The Hospital would pay for all costs of the Program; neither the Federal health care programs nor private insurers would be billed directly or indirectly by the Hospital for these costs, and the costs would not be on the Hospital's or Outpatient Surgery Center's cost reports.

II. LEGAL ANALYSIS

A. Law

Section 1128A(a)(5) of the Act (the "CMP") provides for the imposition of civil monetary penalties against any person who gives something of value to a Medicare or Medicaid program 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 Medicaid. 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 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.

B. Analysis

The Proposed Arrangement, under which the Hospital would extend its hotel accommodation program to Federal health care program beneficiaries, could potentially implicate both the CMP prohibiting beneficiary inducements and the anti-kickback statute. However, for the reasons set forth below, we conclude that the Proposed Arrangement presents a minimal risk of Federal health care program abuse, while providing the prospects of improved access to post-surgical services and improved quality of care to pediatric tonsillectomy patients located in the mostly rural geographical area served by the Health System. Accordingly, we would not seek to impose administrative sanctions in connection with the Proposed Arrangement under the statutes discussed above.

Importantly, we believe the Proposed Arrangement presents minimal anti-competitive effects because of the unique structure of the Health System. The Health System is a fully integrated care model with respect to tonsillectomies performed by Clinic ENTs. When a patient's parent or guardian chooses a Clinic ENT to perform the tonsillectomy, which occurs before the patient's parent or guardian is informed of the Program,⁴ he or she also effectively chooses to have the surgery performed at a facility within the Health System. Clinic ENTs do not have privileges at hospitals outside the Health System and do not perform tonsillectomies at hospitals outside the Health System. Only Clinic ENTs perform tonsillectomies at the Outpatient Surgery Center, which is the only facility where the Program is available.

The Program may impact the choice of facility within the Health System, but the four facilities that offer tonsillectomy services all operate under the Health System's global

⁴ Under the Proposed Arrangement, the Program would not be advertised generally to the public.

budget. In these circumstances, a decision by the Health System to encourage patients for whom the patient's Clinic ENT has determined that an outpatient procedure is medically appropriate to use its Outpatient Surgery Center instead of its inpatient facilities for tonsillectomies does not disadvantage competing providers, and would be a reasonable business decision unrelated to generating referrals. Moreover, Clinic ENTs are employed by the Clinic, which is owned by the Health System, and their salaries are unaffected by the volume or value of surgeries performed at the Outpatient Surgery Center. In connection with the Program, the Clinic ENTs do not have any improper incentives to steer patients to the Outpatient Surgery Center within the Health System or to order unnecessary surgeries.

Participation in the Program will not be conditioned on the use of any other goods or services from the Hospital or any other particular practitioner or provider. In addition, the Proposed Arrangement is distinct from other arrangements where a provider or supplier provides free items or services to patients with Medicare or Medicaid coverage, with the knowledge and expectation that the patients are likely to continue to utilize its items or services. It is only in the unlikely event of complications arising from the surgery that a patient would be likely to utilize additional Hospital items or services related to the tonsillectomy. As noted above, the Health System's experienced complication rates are approximately 1-3%.

While we recognize that a free night's stay at a local hotel post-surgery could give some pediatric tonsillectomy patients and their families a generalized feeling of goodwill toward the Hospital, which could potentially influence them to choose the Hospital and/or its Outpatient Surgery Center for services unrelated to the tonsillectomy in the future, we believe any such influence under these particular set of facts would be speculative and attenuated by circumstances beyond the Hospital's control.

Lastly, the Health System services a geographic location in [state redacted] that consists of mostly rural counties. The Program is designed to help overcome access barriers to tonsillectomy procedures for those families who must travel out of their immediate area to obtain them. Accordingly, the Proposed Arrangement would potentially improve access to post-surgical services and improve quality of care for Federal health care program pediatric patients receiving tonsillectomies on an outpatient basis.

For this combination of reasons, we conclude that the Proposed Arrangement presents a minimal risk of Federal health care program abuse, and we would not impose administrative sanctions arising in connection with the anti-kickback statute on the Hospital in connection with the Proposed Arrangement. Similarly, we conclude that the Proposed Arrangement does not constitute a prohibited inducement under the CMP.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while 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 [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, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter 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 Proposed 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 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 [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