



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: November 5, 2013

Posted: November 12, 2013

[Name and address redacted]

Re: OIG Advisory Opinion No. 13-15

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding an anesthesia services provider's proposal to contract with a psychiatry practice group to provide anesthesia services in connection with electroconvulsive therapy procedures at a hospital (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute 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, 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 the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the Office of Inspector

General (“OIG”) could potentially 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. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties’ intent, which determination is beyond the scope of the advisory opinion process.

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”) is an anesthesia services provider comprised of 17 physician owners and several non-owner physicians and administrative employees. From 1993 until early 2011, Requestor contracted with [name redacted] (the “Hospital”) to provide all anesthesia services, other than chronic pain management procedures, on an exclusive basis.

Requestor certified that, in or around December 2010, [name redacted] (the “Psychiatry Group”), an existing medical practice dedicated to the care and treatment of complicated and treatment-resistant psychiatric patients, relocated its practice to the Hospital.¹ The Psychiatry Group’s practice centers on performing electroconvulsive therapy (“ECT”) procedures. Requestor certified that, among the ECT patients the Psychiatry Group refers to the Hospital are patients whose care is paid for in whole or in part by a Federal health care program.

According to Requestor, [name redacted] (“Dr. X”) is a co-owner of the Psychiatry Group who is board certified in both psychiatry and anesthesiology but who no longer accepts new psychiatry patients. Requestor certified that, before the Psychiatry Group relocated to the Hospital, Requestor provided all of the anesthesia services for ECT procedures performed at the Hospital.² Shortly after the Psychiatry Group relocated to the Hospital, Requestor began negotiating the 2011 renewal of its exclusive anesthesia service contract (the “2011 Contract”) with the Hospital. Requestor certified that, in the course of negotiating the 2011 Contract, the Hospital negotiated for Dr. X’s right to

¹ Requestor states that, prior to its relocation to the Hospital, the Psychiatry Group was located at another hospital in the same state.

² The ECT procedures for which Requestor provided anesthesia services prior to the Psychiatry Group’s relocation to the Hospital were performed by psychiatrists who were not affiliated with the Psychiatry Group.

provide anesthesia services to ECT patients independent of any relationship with Requestor. The final 2011 Contract included a provision permitting Dr. X to provide anesthesia services to ECT patients in the Hospital's ECT program and requiring Requestor to provide up to six weeks of coverage for Dr. X (i.e., provide anesthesia services for ECT procedures that otherwise would have been performed by Dr. X in his role as an anesthesiologist).³ Requestor certified that it attempted to preserve its exclusivity during the 2011 Contract negotiations but that the Hospital refused to remove the "carve-out" provision to Requestor's exclusivity allowing Dr. X to provide anesthesia services to the Hospital's ECT patients.

The 2011 Contract had a one-year term. Requestor certified that, in the course of negotiating the 2012 renewal of Requestor's anesthesia services contract (the "2012 Contract"), the Hospital negotiated for further amendments to the 2011 Contract's carve-out provision. Ultimately, the 2012 Contract allowed Dr. X to provide anesthesia services to ECT patients in the Hospital's ECT program and required Requestor "to provide coverage for [Dr. X] with prior notice as agreed to between [Requestor] and [Dr. X]." The 2012 Contract also included the following provision (the "Additional Anesthesiologist Provision"):

In the event [the Psychiatry Group] or the Hospital determines that an additional anesthesiologist is needed to provide ECT, [Requestor] shall negotiate in good faith with [the Psychiatry Group] to contract with [Requestor] to provide those services. If, after good faith negotiations, [Requestor] and [the Psychiatry Group] are not successful in negotiating the terms of an agreement for [Requestor] to provide anesthesia services to [the Psychiatry Group], then, so long as the last offer from [the Psychiatry Group] was at a fair market value rate, as reasonably determined by the Hospital, [the Psychiatry Group] or [Dr. X] may contract with an additional anesthesiologist to provide anesthesia services for ECT, and the provision of anesthesia services by that additional anesthesiologist shall not constitute a violation of [Requestor's right to provide anesthesia services on an exclusive basis].

After the 2012 Contract went into effect, the Psychiatry Group informed Requestor that it had determined that an additional part-time physician was needed to provide ECT anesthesia services and asked Requestor to enter into the Proposed Arrangement. Under the Proposed Arrangement, Requestor and the Psychiatry Group would enter into a contract pursuant to which Requestor would fulfill the Psychiatry Group's need for an

³ Requestor certified that, in all instances when its anesthesiologists provided anesthesia services for ECT procedures, including cases in which its anesthesiologists provided coverage for Dr. X, Requestor billed and collected for its own account; Requestor did not reassign any rights to Dr. X or to the Psychiatry Group.

additional part-time physician to provide ECT anesthesia services: (i) every Monday, (ii) as necessary to provide vacation coverage for Dr. X, and (iii) as necessary when emergent coverage is required. The Psychiatry Group estimated that such coverage would require between 6 and 12 hours of the anesthesiologists' time during each day of service. Requestor would reassign its right to bill for the services rendered by its anesthesiologists to the Psychiatry Group on coverage days. The Psychiatry Group would bill and collect for those services and, in turn, would pay Requestor a fixed, per diem rate of [amount redacted] for the anesthesiologists' services, which Requestor asserts is below fair market value⁴ and below what it would receive if it billed for the services directly. The Psychiatry Group would retain the difference between the amount collected and the per diem rate.

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.

⁴ We are not authorized to opine on whether fair market value shall be, or was paid or received for any goods, services, or property. See section 1128D(b)(3) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), which protects certain payments made by a principal to an agent as compensation for the agents' services, potentially applies to the Proposed Arrangement. Among the conditions of the personal services and management contracts safe harbor is that the aggregate compensation to be paid to the agent over the term of the agreement must be set in advance, consistent with fair market value in an arms-length transaction, and not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made, in whole or in part, by a Federal health care program. See 42 C.F.R. § 1001.952(d)(5).

B. Analysis

The OIG has stated on numerous occasions its view that the opportunity to generate a fee could constitute illegal remuneration under the anti-kickback statute, even if no payment is made for a referral. Under the Proposed Arrangement, Requestor would provide the Psychiatry Group the opportunity to generate a fee equal to the difference between the amounts the Psychiatry Group would bill and collect from Medicare, Medicaid, other third party payors, and patients for Requestor's anesthesia services, and the per diem amounts the Psychiatry Group would pay to Requestor.

The per diem amounts the Psychiatry Group would pay Requestor under the Proposed Arrangement would not qualify for protection under the safe harbor for personal services and management contracts for a number of reasons, including that the aggregate compensation to be paid over the term of the agreement would be neither set in advance nor, according to Requestor, consistent with fair market value. Furthermore, the safe harbor protects only those payments made by a principal (here, the Psychiatry Group) to an agent (here, Requestor); no safe harbor would protect the remuneration Requestor would provide to the Psychiatry Group. Because no safe harbor would protect the Proposed Arrangement, we must determine whether, given all of the relevant facts, the Proposed Arrangement would pose no more than a minimal risk under the anti-kickback statute. For the following reasons, we conclude that it would not.

The Proposed Arrangement appears to be designed to permit the Psychiatry Group to do indirectly what it cannot do directly; that is, to receive compensation, in the form of a

portion of Requestor's anesthesia services revenues, in return for the Psychiatry Group's referrals of ECT patients to Requestor for anesthesia services. The Additional Anesthesiologist Provision gave the Psychiatry Group the ability to solicit this remuneration for its ECT patient referrals by allowing the Psychiatry Group to contract with an anesthesiologist other than Requestor if Requestor and the Psychiatry Group were not successful in negotiating the terms of an agreement for Requestor to provide ECT anesthesia services.⁵ The Proposed Arrangement therefore presents the significant risk that the remuneration Requestor would provide to the Psychiatry Group—i.e., the opportunity to generate a fee equal to the difference between the amounts the Psychiatry Group would bill and collect for Requestor's anesthesia services, and the per diem amounts the Psychiatry Group would pay to Requestor—would be in return for the Psychiatry Group's anesthesia referrals to Requestor. We discern no safeguards in the Proposed Arrangement that would minimize this risk. Therefore, for the combination of reasons stated herein, we cannot conclude that the Proposed Arrangement would pose no more than a minimal risk of fraud and abuse under the anti-kickback statute.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the OIG could potentially 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. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

⁵ The Additional Anesthesiologist Provision is the vehicle that makes the Proposed Arrangement possible; if the Additional Anesthesiologist Provision had not been included in the 2012 Contract, Requestor's exclusivity rights would have precluded the Psychiatry Group from billing for any anesthesia services provided at the Hospital other than those provided by Dr. X. Although we have not been asked to opine on, and express no opinion regarding, any aspect of Requestor's relationship with the Hospital, including the 2012 Contract or the Additional Anesthesiologist Provision, we cannot exclude the possibility that: (i) the Hospital agreed to negotiate for the Additional Anesthesiologist Provision in exchange for, or to reward, the Psychiatry Group's continued referral of patients to the Hospital for ECT procedures; (ii) the Hospital leveraged its control over its large base of anesthesia referrals to induce Requestor to agree to the Additional Anesthesiologist Provision; and (iii) Requestor agreed to the Additional Anesthesiologist Provision in exchange for access to the Hospital's stream of anesthesia referrals.

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, 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 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.

Sincerely,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General