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: May 25, 2012

Posted: June 1, 2012

[Name and address redacted]

Re: OIG Advisory Opinion No. 12-06

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding two proposals by an anesthesia services provider to enter into contracts with physician-owned professional corporations or limited liability companies to provide anesthesia services ("Proposed Arrangement A" and "Proposed Arrangement B," respectively, and, together, the "Proposed Arrangements"). Specifically, you have inquired whether the Proposed Arrangements 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 Arrangements 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 Arrangements. 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

A. Background and Medicare Billing Rules Applicable to ASC Services

[Name redacted] (the "Requestor") is an anesthesia services provider comprised of 31 physician members, 10 physician employees, and 3 administrative employees. The Requestor provides anesthesia services on an exclusive basis at several outpatient surgery/endoscopy centers (the "Centers") that are owned and operated by physician-owned professional corporations ("PCs") or limited liability companies ("LLCs").[1] The Centers are certified as ambulatory surgical centers ("ASCs") for Medicare reimbursement purposes, and the Requestor believes that they were formed and operate in compliance with the safe harbor for ASCs, 42 C.F.R. § 1001.952(r).

Participating ASCs receive payment under Medicare Part B for ASC services furnished to Medicare beneficiaries in connection with covered surgical procedures. ASC services include ASC facility services for which payment is packaged into the ASC payment for a covered surgical procedure, and ancillary items and services that are integral to a covered surgical procedure and for which separate payment is allowed. See 42 C.F.R. §§ 416.163 and 416.164. The Centers for Medicare & Medicaid Services ("CMS") Medicare Claims Processing Manual ("CPM"), Pub. No. 100-04, Chapter 14, section 10, provides that ASCs must accept the Medicare payment as payment in full with respect to those services defined as ASC services. ASC facility services for which payment is packaged in the ASC payment for a covered surgical procedure include, but are not limited to:

- nursing, technician, and related services;
- use of the facility where the surgical procedures are performed;
- administrative, recordkeeping, and housekeeping items and services;

[1] None of the Requestor's members or employees has any ownership or investment interest in the Centers, and none of the Centers' physician-owners has any ownership or investment interest in the Requestor.

- materials, including supplies and equipment for the administration and monitoring of anesthesia; and
- supervision of the services of an anesthetist by the operating surgeon.

See 42 C.F.R. § 416.164(a). Services not included in this ASC facility payment, such as physician services and anesthesia services (whether provided by a physician or nurse anesthetist), may be covered and separately billable under other provisions of Medicare Part B. See 42 C.F.R. § 416.163(b) and (c); Pub. No. 100-04 CPM, Chap. 14, section 10.2 at: http://www.cms.gov/manuals/downloads/clm104c14.pdf.

Under the Requestor's current agreements with the Centers, the Requestor assumes responsibility for employing personnel to staff the Centers' anesthesia needs and independently bills patients and third party payors, including Medicare, for the professional fees associated with these services. The Requestor states that its financial risk lies in balancing the expense of hiring anesthesia personnel against the revenue it receives from the anesthesia services, the volume of which is controlled by the Centers' physician-owners. The Requestor further states that the Centers' owners bill for their own professional services, and that the Centers charge Medicare, other third party payors, and patients a facility fee for the materials and ancillary staff required to operate the Centers.

The Requestor states that it is under pressure to enter into the Proposed Arrangements to compete with other anesthesia groups in its area that are engaging in similar practices and to stem the loss of its business.

B. Proposed Arrangement A

Under Proposed Arrangement A, the Requestor would continue to serve as the Centers' exclusive provider of anesthesia services and to bill and retain all collections from patients and third party payors, including Medicare, for its services. In a departure from current practice, however, the Requestor would begin paying the Centers for "Management Services." The Management Services would include:

- pre-operative nursing assessments;
- adequate space for all of the Requestor's physicians, including their personal effects;
- adequate space for the Requestor's physicians' materials, including documentation and records; and
- assistance with transferring billing documentation to the Requestor's billing office.

The Requestor certified that the Centers currently do not charge it for the Management Services, and that payment for the expenses associated with the Management Services is

included in the facility fees paid by private payors and the ASC payment paid by Medicare. Under Proposed Arrangement A, the Centers would begin charging the Requestor for the Management Services in the form of a per-patient fee. According to the Requestor, the Management Services fees it would pay would be in addition to, and not in lieu of, the facility fees that the Centers would continue to bill Medicare and private payors in the same amounts as currently billed. Federal health care program patients would be excluded from the Management Services fee calculation. The Requestor certified that the Management Services fee would be set at fair market value[2] and would not take into account the volume or value of referrals or any other business conducted between the parties.

C. Proposed Arrangement B

Under Proposed Arrangement B, the Centers' physician-owners would establish separate companies for the purpose of providing anesthesia-related services to outpatients undergoing surgery at the Centers ("Subsidiaries"). The Subsidiaries would be wholly owned either directly by the PCs and LLCs, or by the Centers. The Subsidiaries would exclusively furnish and bill for all anesthesia-related services provided at the Centers. The Subsidiaries would, in turn, engage the Requestor as an independent contractor to provide the following anesthesia-related services (collectively, the "Services") to the Subsidiaries on an exclusive basis:

- recruiting, credentialing, and scheduling anesthesia personnel;
- ordering and maintaining supplies and equipment;
- assisting the Subsidiaries in selecting and working with a reputable anesthesia billing company;
- monitoring and overseeing regulatory compliance;
- providing financial reports;
- implementing quality assurance programs; and
- providing logistics (including, if necessary, assisting the Subsidiaries in structuring independent contractor or employment relationships with anesthesia personnel[3] and assisting in establishing a separate anesthesia corporation).

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[2] We are precluded by statute from opining on whether fair market value shall be, or was, paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A).

[3] The Requestor certified that the Subsidiaries would either: (i) employ anesthesia personnel, including anesthesia personnel who also work as employees or members of the Requestor, or (ii) engage the Requestor's employees or members to provide anesthesia services on an independent contractor basis.

The Subsidiaries would pay the Requestor a negotiated rate for the Services. The fees for the Services would be paid out of the collections made by the Subsidiaries for anesthesia-related services, with the Subsidiaries retaining any profits.

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.

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.

According to the Requestor, the Centers are Medicare-certified ASCs that were formed and operate in compliance with the ASC safe harbor, 42 C.F.R. § 1001.952(r). This safe harbor excludes from the definition of "remuneration," for purposes of the anti-kickback

statute, any payment that is a return on an investment interest made to an investor, as long as the investment entity is a Medicare-certified ASC and satisfies certain additional conditions.

The employee safe harbor, which was created by statute and interpreted by regulation, potentially applies to Proposed Arrangement B. That safe harbor excludes from the definition of "remuneration," for purposes of the anti-kickback statute, any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program. See 42 C.F.R. § 1001.952(i). The safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), also potentially applies to Proposed Arrangement B. 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

1. Proposed Arrangement A

Under Proposed Arrangement A, the Requestor would serve as the Centers' exclusive provider of anesthesia services and pay the Centers a per-patient fee, excluding Federal health care program patients, for the Management Services. As a threshold matter, we must address whether the "carve out" of Federal health care program patients is dispositive of the question of whether Proposed Arrangement A implicates the anti-kickback statute. We conclude it is not.

The OIG has a long-standing concern about arrangements under which parties "carve out" Federal health care program beneficiaries or business generated by Federal health care programs from otherwise questionable financial arrangements. Such arrangements implicate, and may violate, the anti-kickback statute by disguising remuneration for Federal health care program business through the payment of amounts purportedly related to non-Federal health care program business. Here, although the Centers would charge the Requestor Management Services fees only with respect to non-Federal health care program patients, the Requestor would serve as the exclusive provider of anesthesia services for all of the Centers' patients, including Federal health care program beneficiaries. Thus, carving out Federally insured patients under Proposed Arrangement A does not reduce the risk that the Requestor's payments to the Centers for Management Services would be paid to induce referrals to the Requestor of Federally insured patients.

The anti-kickback statute seeks to ensure that referrals will be based on sound medical judgment, and that health care professionals will compete for business based on quality and convenience, instead of paying for referrals. Under Proposed Arrangement A, the Centers would continue their current practice of billing for and collecting facility fees with respect to both Federal and non-Federal health care program patients, and also would begin charging the Requestor for services that those facility fees are intended to cover for non-Federal health care program patients. In short, the Centers would be paid twice for the same services, and the additional remuneration paid by the Requestor in the form of the Management Services fees could unduly influence the Centers to select the Requestor as the Centers' exclusive provider of anesthesia services.

Based on the facts presented here, we think there is risk that the Requestor would be paying the Management Services fees with regard to non-Federal health care program patients to induce the Centers' referral of all of its patients, including Federal health care program beneficiaries.

2. Proposed Arrangement B

The OIG has long been concerned about the potential for investments in ASCs to serve as vehicles to reward referrals. As explained in the preamble to the final rule providing safe harbor protection for returns on investment interests in ASCs, the decision to extend this protection derives in large measure from the Department of Health and Human Services' long-standing policy of promoting greater utilization of ASCs, where appropriate, because of the substantial cost savings the Federal health care programs may achieve when procedures are performed in ASCs rather than in more costly hospital inpatient or outpatient facilities. See 64 Fed. Reg. 63,518, 63,537 (Nov. 19, 1999). When promulgating the ASC safe harbor, the OIG stated that its chief concern was that "a return on investment in an ASC might be a disguised payment for referrals." Id. at 63,536. However, recognizing that some physician-owned ASCs may be beneficial to the Federal health care programs and their beneficiaries, the OIG stated:

> [w]here the ASC is functionally an extension of a physician's office, so that the physician personally performs services at the ASC on his or her own patients as a substantial part of his or her medical practice, we believe that the ASC serves a bona fide business purpose and that the risk of improper payments for referrals is relatively low.

Id.

The OIG has also stated on numerous occasions its view that the opportunity for a referring physician to earn a profit, including through an investment in an entity for

which he or she generates business, could constitute an illegal inducement under the anti-kickback statute.

The remuneration generated for the Centers' physician-owners by Proposed Arrangement B would be the difference between: (i) the amounts the Subsidiaries would bill and collect from Medicare, Medicaid, other third party payors, and patients for anesthesia services, and (ii) the amounts the Subsidiaries would pay to the Requestor for the Services, plus any amounts the Subsidiaries might directly pay any employed or independent contractor anesthesia personnel.

Several safe harbors potentially apply to the PCs' or LLCs' various arrangements; however, no safe harbor would protect the remuneration the Subsidiaries would distribute to the Centers' physician-owners under Proposed Arrangement B.

The Requestor believes that the Centers were formed and operate in compliance with the ASC safe harbor. Assuming for purposes of this opinion that the Requestor's assertion is true, the remuneration generated by surgical services performed in the Centers would qualify for protection under the ASC safe harbor. However, the remuneration generated by Proposed Arrangement B could not qualify for protection under the ASC safe harbor, regardless of the Centers' safe harbor status. The ASC safe harbor protects returns on investments only in circumstances where the investment entity itself is a Medicare-certified ASC under 42 C.F.R. Part 416. Part 416 of title 42 defines the term "ASC" as "any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization…." See 42 C.F.R. § 416.2 (emphasis added). Anesthesia services are not surgical services. See 42 C.F.R. §§ 416.2 and 416.164(c).

Under Proposed Arrangement B, the Subsidiaries would be established for the sole purpose of providing anesthesia services to the Centers' patients. Because the Subsidiaries would not provide surgical services, they could not qualify as Medicare-certified ASCs for purposes of the ASC safe harbor and, thus, the Subsidiaries' income would not be protected by the ASC safe harbor.

Furthermore, neither the employment safe harbor nor the personal services and management contracts safe harbor would protect the remuneration the Subsidiaries would distribute to the Centers' physician-owners under Proposed Arrangement B. To the extent any anesthesia personnel were bona fide employees of the Subsidiaries,[4] the Subsidiaries' payments to such employees could be protected by the employee safe harbor, if all of the other requirements of the safe harbor were satisfied. Likewise, the

[4] Whether an employee is a bona fide employee for purposes of the employee safe harbor is a matter that is outside the scope of the advisory opinion process. See section 1128D(b)(3)(B) of the Act.

Subsidiaries' payments to the Requestor or independent contractor anesthesia personnel might be protected by the personal services and management contracts safe harbor, if all of the requirements of that safe harbor were satisfied. However, neither of these safe harbors would protect the Subsidiaries' profits that would be distributed to the Centers' physician-owners under Proposed Arrangement B, and such remuneration would be prohibited under the anti-kickback statute if one purpose of the remuneration is to generate or reward referrals for anesthesia services.

The absence of safe harbor protection is not fatal. Instead, we must determine whether Proposed Arrangement B would pose no more than a minimal risk of fraud and abuse under the anti-kickback statute. For the following reasons, we conclude that Proposed Arrangement B would pose more than a minimal risk of fraud and abuse.

The OIG has long-standing concerns about arrangements, such as joint ventures, between those in a position to refer business, such as the Centers' physician-owners here, and those furnishing items or services for which Medicare or Medicaid pays, especially when all or most of the business of the joint venture is derived from one or more of the joint venturers. See, e.g., OIG's 1989 Special Fraud Alert on Joint Venture Arrangements, reprinted in the Federal Register in 1994 (59 Fed. Reg. 65,372, 65,373 (Dec. 19, 1994)).

The OIG issued additional guidance on suspect contractual joint venture arrangements in its Special Advisory Bulletin titled "Contractual Joint Ventures." See 68 Fed. Reg. 23,148 (Apr. 30, 2003) (the "Special Advisory Bulletin"). As set forth in the Special Advisory Bulletin, suspect joint venture arrangements typically exhibit certain common elements, several of which are present in Proposed Arrangement B. In fact, the Special Advisory Bulletin describes an arrangement very similar to Proposed Arrangement B:

> [A] health care provider in one line of business (hereafter referred to as the "Owner") expands into a related health care business by contracting with an existing provider of a related item or service (hereafter referred to as the "Manager/Supplier") to provide the new item or service to the Owner's existing patient population, including [F]ederal health care program patients. The Manager/Supplier not only manages the new line of business, but may also supply it with inventory, employees, space, billing, and other services. In other words, the Owner contracts out substantially the entire operation of the related line of business to the Manager/Supplier—otherwise a potential competitor—receiving in return the profits of the business as remuneration for its [F]ederal program referrals.

68 Fed. Reg. at 23,148. We believe that the Centers' physician-owners and the Requestor are in the same position as the Owner and Manager/Supplier described in the Special Advisory Bulletin.

Like the Owner in the arrangement described in the Special Advisory Bulletin, the Centers' physician-owners would be expanding into a related line of business—anesthesia services—that would be wholly dependent on the Centers' referrals. The Centers' physician-owners would not actually participate in the operation of the Subsidiaries but rather would contract out substantially all of the operations exclusively to the Requestor. And, like the Owner in the Special Advisory Bulletin, the Centers' physician-owners' actual business risk would be minimal because they would control the amount of business they would refer to the Subsidiaries.[5]

Other elements described in the Special Advisory Bulletin that are present in Proposed Arrangement B include:

- the Requestor is an established provider of the same services that the Subsidiaries would provide, and otherwise would be a competitor providing the services in its own right, billing insurers and patients in its own name, and collecting and retaining all available reimbursement; and
- the Requestor and the Centers' physician-owners would share in the economic benefit of the Centers' new business, with the Requestor receiving its share in the form of a negotiated rate and the Centers' physician-owners receiving their share in the form of the residual profits from the new business.

Based on the facts presented here, it appears that Proposed Arrangement B is designed to permit the Centers' physician-owners to do indirectly what they cannot do directly; that is, to receive compensation, in the form of a portion of the Requestor's anesthesia services revenues, in return for their referrals to the Requestor. This conclusion is consistent with, and supported by, the Requestor's representation that it is under competitive pressures to enter into the Proposed Arrangements to stem the loss of its business.

[5] The Special Advisory Bulletin also cites an Owner's failure to commit substantial financial, capital, or human resources to a venture as an element that is typically exhibited by problematic joint venture arrangements. Although the extent of the Centers' physician-owners' commitment to provide financial, capital, and human resources under Proposed Arrangement B is unclear, Proposed Arrangement B would present more than a minimal risk of fraud and abuse regardless of the level of the Centers' physician-owners' contributions.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangements 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 Arrangements. 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.

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 Arrangements, 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