



[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: December 29, 2008

Posted: January 7, 2009

To: Attached Distribution List

Re: OIG Advisory Opinion No. 08-24

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding investments in a shared medical practice by 23 physicians and podiatrists (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 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 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 the Inspector General ("OIG") would not impose administrative sanctions on [facility name

redacted] or its members [practitioner names redacted] (referred to collectively herein as the “Requestors”) 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 the Requestors 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

[Facility name redacted] (the “Practice”) is a limited liability company that was formed under [state name redacted] law by 23 investor physicians and podiatrists. The Practice is located in [county and state names redacted] in a rural Health Professional Shortage Area. It offers various medical care, consultation, diagnosis, and treatment services by means of shared office space, facilities, equipment, and personnel. The Practice’s operations include physician consultation on a walk-in urgent care basis, and various clinical laboratory and diagnostic radiology services.

With one exception,¹ all equity interests in the Practice are held by licensed physicians and podiatrists who treat patients at the Practice. None of the investors works at the Practice full-time, however. Each investor in the Practice also sees patients separately at different office locations not affiliated with the Practice. Each investor owns a fixed percentage investment stake in the entire Practice. Each shares in the Practice’s profits or losses in direct proportion to his or her individual investment stake.

The Practice is organized as a limited liability company with a central governing Board of Managers (the “Board”) comprised of managing Practice members. The Board meets regularly and has sole authority to make decisions for the Practice.² It maintains control over Practice assets and liabilities. It develops, drafts, and approves the company budget, compensation rates, and staff salaries. Significant expenses undertaken by the Practice must

¹A one percent (1%) interest in the entire Practice is held by [Stakeholder name redacted], who is licensed to practice medicine in [state name redacted], but whose duties at the Practice are administrative. [Stakeholder name redacted] incurs profits and losses in direct proportion to his investment interest.

²Nearly all major business decisions made by the Practice require consent of the majority of the Board.

receive formal Board approval. The Board also formulates and approves Practice policies and procedures regarding both clinical matters (e.g., how walk-in patients who appear at the Practice are evaluated and treated) and business matters (e.g., how and when debts to the Practice are collected or written-off).

The Practice maintains a single consolidated accounting system for managing billing and finances. All expenses and revenues are pooled across the Practice and not separated in relation to individual Practice members.

The Requestors have certified that revenues generated by the Practice from ancillary services are derived from “in-office ancillary services” as defined in section 1877(b)(2) of the Act and implementing regulations. The Requestors have certified that the Practice has achieved or will shortly achieve compliance with the definition of “group practice” in section 1877(h)(4) of the Act and corresponding regulations.³ As described in section II.A below, these certifications related to the physician self-referral statute at section 1877 of the Act are relevant to the inquiry under the anti-kickback statute. It is beyond the scope of this advisory opinion to assess whether the Proposed Arrangement, in fact, meets the terms of section 1877 of the Act (also known as the “physician self-referral law”) and the corresponding regulations.⁴

³Specifically, it may be necessary, in order to meet the minimum percentage of physician-patient encounters conducted by practice members under 42 C.F.R. § 411.352(h), for the Practice to bring onboard as members a number of urgent care physicians who are not among the Requestors and who are currently working as independent contractors. The Requestors have certified that they will shortly do so. It is for this reason that we describe the facts on which this opinion is based as a Proposed Arrangement. No opinion is expressed on the existing arrangement. Nor is any opinion expressed with respect to any employment or independent contractor arrangements with these physicians.

⁴Questions pertaining to compliance with the physician-self referral law and regulations come within the jurisdiction of the Centers for Medicare & Medicaid Services (“CMS”). See 42 C.F.R. §§ 411.370 –.389. The Practice has been the subject of a favorable advisory opinion from CMS in connection with issues under the physician self-referral law. See CMS Advisory Opinion 2008-02 (June 2008). That opinion addressed the Practice’s compliance with the rural provider exception in section 1877(d)(2) of the Act and 42 C.F.R. § 411.356(c)(1). It did not address whether the revenues generated by the Practice from ancillary services will be derived from “in-office ancillary services” as defined in section 1877(b)(2) of the Act and corresponding regulations or whether the Practice complies with the definition of “group practice” in section 1877(h)(4) of the Act and corresponding regulations. We rely on the certifications of the Requestors with respect to these issues. If the certifications are not accurate, this opinion is without force and effect.

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.

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 investments in group practices, 42 C.F.R. § 1001.952(p), is potentially applicable to the Proposed Arrangement. The safe harbor applies if the following four standards are met:

- (1) The equity interests in the . . . group must be held by licensed health care professionals who practice in the . . . group.
- (2) The equity interests must be in the . . . group itself, and not some subdivision of the . . . group.

- (3) [A group practice] must: (i) [m]eet the definition of “group practice” in section 1877(h)(4) of the . . . Act and implementing regulations; and (ii) [b]e a unified business with centralized decision-making, pooling of expenses and revenues, and a compensation/profit distribution system that is not based on satellite offices operating substantially as if they were separate enterprises or profit centers.
- (4) Revenues from ancillary services, if any, must be derived from “in-office ancillary services” that meet the definition of such term in section 1877(b)(2) of the Act and implementing regulations.

42 C.F.R. § 1001.952(p). If all of the conditions of the safe harbor are met, it protects “any payment that is a return on investment interest, such as a dividend or interest income, made to an investor” in the group practice.

B. Analysis

Our opinion is based on the facts presented, including, but not limited to, the Requestors’ certifications that they have or will shortly achieve compliance with the group practice definition of the physician self-referral law.

The Proposed Arrangement cannot fit in the investments in group practices safe harbor because [Stakeholder name redacted], who holds one percent of equity, does not treat patients at the Practice. However, the absence of safe harbor protection is not fatal. Instead, the Proposed Arrangement must be evaluated based on the totality of its facts.

Under the Proposed Arrangement, the Practice will comply with the requirements of the safe harbor for investments in group practices in nearly all respects. First, all equity interests except [Stakeholder name redacted]’s one percent stake are held by health care professionals who practice in the Practice. Second, all equity interests are held in the Practice and not some subdivision thereof. Each investor (including [Stakeholder name redacted]) holds a fixed percentage stake in the entire Practice, rather than in particular specialty groups or other subdivisions. To a degree directly proportionate to their individual stake in the Practice, each investor shares in the entire enterprise’s risks and returns. Third, the Requestors have certified that the Proposed Arrangement will comply fully in all respects with the requirements of the “group practice” definition under the physician self-referral law. As described in the facts, the Practice is structured and operated as a unified business. For example, central decision-making authority rests with the Board, which determines both clinical and financial policies. Expenses and revenues are pooled across the enterprise and are not separated in relation to satellite offices maintained by individual

Practice members. Fourth, the Practice has certified that revenues from ancillary services are derived from “in-office ancillary services” that meet the definition of that term under the physician self-referral law.

Given the totality of facts and circumstances described above, [Stakeholder name redacted]’s one percent stake in the Practice does not pose any appreciable additional risks to Federal programs or beneficiaries. His returns are directly proportional to his investment interest, and he provides substantial services integral to the Practice’s operation and administration, thus minimizing the risk that his small equity interest reflects referrals.

For a combination of the above reasons, we conclude that the Proposed Arrangement presents a minimal risk of Federal health care program abuse, and we would not seek to seek to impose administrative sanctions in connection with the statutes discussed above. This favorable opinion is conditioned on the Practice’s full compliance with relevant provisions under the physician self-referral law regulations. (See infra note 4.) This opinion only applies to returns on investment interests made to the current investors in the Practice. It does not apply to any other remuneration arising out of this venture, including compensatory income paid physicians for services.

III. CONCLUSION

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

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to the Requestors 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 the Requestors 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 the Requestors 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

[Distribution List redacted]