[*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 19, 2008

Posted: September 26, 2008

[Name and address redacted]

Re: OIG Advisory Opinion No. 08-12

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposed arrangement under which your newly formed legal entity would provide purely administrative insurance preauthorization processing and submission services for various radiology and imaging centers (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 the Proposed Arrangement would not generate prohibited

remuneration under the anti-kickback statute. Accordingly, the Office of Inspector General ("OIG") would not impose administrative sanctions on you 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 you, 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

Under the Proposed Arrangement, you (the "Requestor"), would form and wholly own and manage a new legal entity ("Newco"). Newco would contract with various radiology and imaging centers across the nation (each a "Center," and collectively, the "Centers") and provide purely administrative services consisting solely of the processing and submission of insurance preauthorizations for certain radiology and imaging procedures whenever a Center's patient's insurer[1] required such a preauthorization (the "Services").[2]

The Centers would provide Newco with the pertinent patient information required for Newco to process and submit the preauthorizations.[3] In return for performance of the Services, the Centers would pay Newco a "per service" fee for each preauthorization processed and submitted, regardless of whether or not the patient's insurer ultimately grants the preauthorization for the subject radiology or imaging procedure. The Requestor has certified that the fee would be the same for all Centers, and would represent fair market value in an arm's-length transaction for the Services. Neither the Requestor nor Newco (nor their affiliates) would have any other direct or indirect financial relationship with the

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[1] The vast majority of preauthorizations would be submitted with respect to patients insured by private payors; however, it is possible that the Services could be provided under the Proposed Arrangement in connection with Federal health care program beneficiaries (e.g., a Center's patient could be a Medicare beneficiary enrolled in a Medicare Advantage plan that has preauthorization requirements).

[2] The Services would not include any marketing services or any management services other than the administrative preauthorization services described in the Proposed Arrangement.

[3] The Centers would be Newco's only source of patient information; if Newco needed additional information to perform the Services, the additional information would be obtained by the Centers and provided to Newco. The Requestor has certified that the parties would comply with applicable state and Federal laws, rules, and regulations related to the privacy of such patient information.

Centers or their affiliates. Further, the Requestor has certified that neither the Requestor nor Newco (nor their affiliates) is making, has made, or would make assurances to the Centers or any patient with respect to obtaining a preauthorization from any insurer.

The Requestor has also certified that neither the Requestor nor Newco (nor their affiliates) is, was, or would be: (i) a health care provider, practitioner, or supplier; (ii) in any way affiliated with the health care industry (other than through the performance of the Services under the Proposed Arrangement); (iii) in a position to receive or influence referrals of items or services covered under a Federal health care program; or (iv) in contact with private payor or Federal health care program beneficiaries in the performance of their businesses.

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 personal services and management contracts, 42 C.F.R. § 1001.952(d), is potentially applicable to the Proposed Arrangement. In relevant part for purposes of this advisory opinion, the personal services and management contracts safe harbor requires that the aggregate compensation paid over the term of the agreement be set in advance. See 42 C.F.R. § 1001.952(d)(5). The Proposed Arrangement would not fit in the safe harbor because Newco would be paid on a per service basis, and, thus, the aggregate compensation would not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Proposed Arrangement must be subject to case-by-case evaluation.

B. Analysis

It is axiomatic that there can be no violation of the anti-kickback statute absent potential referrals of Federal health care program business. Notwithstanding the possibility that Newco could provide the Services[4] in connection with a Federal health care program beneficiary, on the facts presented here,[5] the Proposed Arrangement would not result in referrals of Federal health care program business.

First, neither the Requestor nor Newco (nor their affiliates) is, was, or would be a health care provider, practitioner, or supplier or in any way affiliated with the health care industry (other than through the performance of the Services under the Proposed Arrangement). Further, the Requestor proposes to furnish, through Newco, purely administrative services at an arm's-length fair market rate to health care providers and suppliers and has certified that neither the Requestor nor Newco (nor their affiliates) would have the ability to receive or influence referrals.

Second, the Proposed Arrangement is distinguishable from arrangements involving marketing services, which by their nature are intended to promote a particular item or service, because the Services are purely administrative and do not involve such promotion. Neither the Requestor nor Newco (nor their affiliates) would have contact with patients or with anyone other than the Centers. All patient information would be supplied by the

[4] We iterate that the Services provided pursuant to the Proposed Arrangement would be purely administrative services consisting solely of the processing and submission of insurance preauthorizations.

[5] Any change in the facts, including, but not limited to, the scope of the Services or the Requestor's, Newco's, or their affiliates' ability to receive or influence referrals could change our analysis and could result in an unfavorable opinion.

Centers, without any independent development of information by the Requestor or Newco (or their affiliates) through contacts with Center referral sources (e.g., patients or physicians). The Services, therefore, do not rise to the level of arranging for or recommending purchasing, leasing, or ordering items or services payable under a Federal health care program. Moreover, Newco's Services do not involve coding, billing, or claims processing or review, which are activities that can, in some circumstances, generate Federal health care program business.

Third, the Proposed Arrangement is distinguishable from potentially problematic arrangements where administrative services are provided by, or on behalf of, a supplier, such as an imaging company or a manufacturer, to an existing or potential referral source. In those situations, there is a significant risk that at least one purpose of providing the services is to influence referrals to the party providing the services. As discussed above, however, the Requestor, Newco, and their affiliates are not, have not been, and would not be health care providers, practitioners, or suppliers, or affiliated with the health care industry (other than through the performance of the Services under the Proposed Arrangement).[6] Further, the Requestor, Newco, and their affiliates do not have, have not had, and would not have contact with private payor or Federal health care program beneficiaries in the performance of their businesses. The limitations inherent in these facts support the Requestor's certifications that the Requestor, Newco, and their affiliates are not in a position to receive or influence referrals of Federal health care program business and the conclusion that the Proposed Arrangement does not share the same significant risk of fraud and abuse present in the aforementioned potentially problematic arrangements.

In light of the foregoing, the Proposed Arrangement would not result in referrals of Federal health care program business. We express no opinion about any relationships between the Centers and their referral sources. We note, however, that if a Center or other third party (such as a manufacturer) paid Newco to provide the Services for or on behalf of a referral source (such as a physician), and thus relieved the referral source of the costs of processing and submitting preauthorizations, then the Center or other third party could be providing prohibited remuneration to the referral source, in violation of 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 would not generate prohibited remuneration under the anti-kickback statute. Accordingly, the OIG would not impose administrative sanctions on you under sections 1128(b)(7) or 1128A(a)(7) of the Act (as

[6] Neither the Requestor nor Newco (nor their affiliates) would have any other direct or indirect financial relationship with the Centers or their affiliates.

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.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to you, 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 the Requestor 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 Requestor 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