DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of Inspector General
Washington, D.C. 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 requestors.*]

Issued: May 7, 2002

Posted: May 14, 2002

[names and addresses redacted]

Re: OIG Advisory Opinion No. 02-5

Gentlemen:

We are writing in response to your request for an advisory opinion regarding the proposed reorganization of an existing radiation oncology group practice (the "Proposed Reorganization"). Specifically, you have inquired whether the Proposed Reorganization 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.

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 Reorganization 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, but that the Office of Inspector General ("OIG") would not impose administrative sanctions on [Company A], [Physician X], or [Physician Y] 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 Reorganization. We express no opinion regarding the application of the physician self-referral law, section 1877 of the Act, to the Proposed Reorganization.

This opinion may not be relied on by any persons other than [Company A], [Physician X], and [Physician Y], the requestors of this opinion (the "Requestors"), and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

1. FACTUAL BACKGROUND

[Company A] (the "Company") is a radiation oncology group practice providing both professional and technical radiation therapy services. The Company has had a certificate of need ("CON") to own and operate radiation therapy equipment since 1992 and, currently, it provides both professional and technical services at three sites where the Company either owns or leases radiation therapy equipment. At a fourth site, the Company provides professional services only.

The Company proposes to restructure its existing business into two separate legal entities. The existing Company will continue to hold the CON, own or lease the radiation therapy equipment, provide technical radiation therapy services, and bill the technical component. The second, newly-formed entity will be a professional organization that will provide and bill the professional component of the radiation therapy services.

Ownership of both the reorganized Company and the new professional organization will be identical to the Company's current ownership. In other words, [Physician X] and [Physician Y] (the "Physician Investors"), each of whom currently owns one-half of the Company, will each own one-half of both the reorganized Company and the newly-formed professional organization.

II. LEGAL ANALYSIS

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 mere reorganization of an existing, unified radiation oncology group practice into two separate legal entities -- one providing professional services and the other providing technical services -- does not create a substantial risk of fraud or abuse under the anti-kickback statute where both reorganized entities will have ownership that is identical in all respects to the original entity and where the ongoing operations of the reorganized entities will be substantially the same as the original entity. Therefore, based upon all of the facts presented, we conclude that we will not impose administrative sanctions on the Requestors in connection with the Proposed Reorganization. We caution, however, that any difference in the facts, including any difference in any aspect of the ownership or operations of the original entity and the two reorganized entities, might lead to a different result. We express no opinion regarding any remuneration to or from the Company, the new professional organization, any Physician Investor, or any other individual or entity.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Reorganization 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, but that the OIG would not impose administrative sanctions on [Company A], [Physician X], or [Physician Y] 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 Reorganization. We express no opinion regarding the application of the physician self-referral law, section 1877 of the Act, to the Proposed Reorganization.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [Company A], [Physician X], and [Physician Y], 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 Reorganization, 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 Reorganization 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 Reorganization 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,

/s/

D. McCarty Thornton
Chief Counsel to the Inspector General