



[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: June 10, 2010

Posted: June 17, 2010

[Name and address redacted]

Re: OIG Advisory Opinion No. 10-08

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a proposal whereby two affiliated corporate entities that each own and operate a freestanding radiation oncology center would provide the services of a dietitian¹ and social worker at no additional charge to each center's Medicare cancer patients as part of the patients' treatment at the centers (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Social Security Act (the "Act"), or under the exclusion authority at section 1128(b)(7) of 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

¹ We note that the request refers to "a dietitian or licensed nutritionist." For purposes of this opinion, we will refer to both collectively using the term "dietitian."

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 [names 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. In addition, the OIG would not impose administrative sanctions on [names redacted] under section 1128A(a)(5) 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 for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than [names redacted], 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

[Names redacted] (collectively, the “Requestors”)² each own and operate a freestanding radiation oncology center (each a “Center,” and collectively, the “Centers”) in the State of [state name redacted] that is devoted to the treatment of cancer. The Centers provide a variety of different radiation therapy services for their cancer patients, including Medicare beneficiaries. Under the Proposed Arrangement, the Requestors would offer the services of a dietitian and a social worker to each Center’s Medicare patients at no additional charge.³ Specifically, the Requestors would offer the patients the opportunity to consult with a dietitian at the commencement of treatment. The patients identified as being at risk of nutritional complications would visit with the dietitian during the course of their treatment and for a limited⁴ period of time thereafter. With respect to the social worker’s services, at commencement of, and periodically through the course of treatment, the social worker

² The Requestors are affiliated corporate entities.

³ We note that, while the Requestors would offer the same free services to all Center patients, this opinion is limited to the offer and provision of free services to Medicare beneficiaries.

⁴ The Requestors have certified that the dietitian services would be provided within the same plan of care as the radiation oncology services at the Centers.

would assess the patient to determine whether the patient had any financial and/or emotional needs with which the social worker could assist the patient. The Requestors have certified that their websites and promotional materials would indicate that the Centers offer the dietitian and social worker services, but would not advertise that the services would be “free” or “at no charge.” In addition, the Requestors have further certified that they would not separately bill for the dietitian and social worker services and would not routinely waive otherwise applicable cost-sharing obligations for Medicare beneficiaries.

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. 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.

Section 1128A(a)(5) of the Act provides for the imposition of civil monetary penalties against any person who gives something of value to a Medicare or state health care program (including Medicaid) beneficiary that the benefactor knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a state health care program (including Medicaid). The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs. Section 1128A(i)(6) of the Act defines “remuneration” for purposes of section 1128A(a)(5) as

including “transfers of items or services for free or for other than fair market value.” The OIG has previously taken the position that “incentives that are only nominal in value are not prohibited by the statute,” and has interpreted “nominal value to be no more than \$10 per item, or \$50 in the aggregate on an annual basis.” 65 F.R. 24400, 24410 – 24411 (April 26, 2000) (preamble to the final rule on the CMP).

B. Analysis

Standing alone, free dietitian and social worker services offered or provided to Medicare beneficiaries would implicate section 1128A(a)(5) of the Act and the anti-kickback statute. However, in this instance, we have been advised by the Centers for Medicare and Medicaid Services (“CMS”) that, if dietitian and social worker services are provided in the freestanding radiation oncology center setting, the expenses of such services are included in the Medicare payment for radiation oncology services. Accordingly, the Medicare patients’ applicable cost-sharing obligations include a portion attributable to the costs of the dietitian and social worker services. Because the costs of the services would be reimbursed by Medicare and because the Requestors would not waive otherwise applicable cost-sharing obligations, the Requestors would not be providing free goods or services to Medicare beneficiaries under the Proposed Arrangement. We therefore conclude that the Proposed Arrangement would not, under these specific facts, be an impermissible inducement under section 1128A(a)(5) of the Act and would not generate prohibited remuneration from the Requestors to Medicare beneficiaries under the anti-kickback statute.⁵

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 [names 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. In addition, the OIG would not impose administrative sanctions on [names redacted] under section 1128A(a)(5) 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

⁵ Providing dietitian and social worker services at no additional charge in settings and situations in which the costs of such services are not included in the Federal reimbursement and/or routinely waiving otherwise applicable cost-sharing obligations could change our analysis.

arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], 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 [names redacted] 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

[names redacted] 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