[*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: July 28, 2011

Posted: August 4, 2011

[Name and address redacted]

Re: OIG Advisory Opinion No. 11-11

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding two proposals by a supplier that furnishes medical supplies, equipment, and related services to enter into a contract with a skilled nursing facility to provide such items and services (individually, "Proposed Arrangement A" and "Proposed Arrangement B," 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. The Parties

[Name redacted] (the "Requestor") is a supplier that furnishes medical supplies and equipment to skilled nursing facilities. In connection with furnishing the medical supplies and equipment, the Requestor also provides certain related services to the skilled nursing facilities, including emergency delivery of the medical supplies and equipment, inventory control, frequent visits by customer service representatives to check on existing orders and determine whether other patients require supplies, customized resident-specific packaging, and simple returns of products for credit.

[Name redacted] (the "SNF") is a county-operated skilled nursing facility. The SNF is located in the State of [state redacted].

B. Billing Procedures

When the medical supplies and equipment that the Requestor furnishes to a skilled nursing facility are covered by Medicare Part B (the "Covered Items"), the Requestor bills the Medicare program directly. When they are not (the "Non-Covered Items"), the Requestor bills the skilled nursing facility directly. Under normal circumstances, for Non-Covered Items, the Requestor charges a skilled nursing facility a markup, which covers the cost of providing the related services described above, as well as the Requestor's overhead and profit. The Requestor has certified that the amount paid by Medicare Part B for the Covered Items is sufficient to also cover the costs of the related services provided in connection with the Covered Items, as well as related overhead and profit.

C. The Request for Proposals

The SNF has issued a request for proposals (the "RFP") soliciting bids to be the exclusive supplier of Covered Items and related services to the SNF. Suppliers that submit bids in response to the RFP are also required to submit pricing for the Non-Covered Items and related services, which the SNF may purchase at its option.

D. Proposed Arrangement A

Under Proposed Arrangement A, the Requestor would submit a bid in connection with the RFP and, if selected, enter into a contract with the SNF to: (1) serve as the SNF's exclusive supplier of Covered Items, (2) furnish Non-Covered Items at the pricing listed in its bid if the SNF chose to purchase those items from the Requestor, and (3) furnish the related services in connection with all Covered Items and Non-Covered Items it would furnish under the contract. The Requestor has stated that the pricing it would offer in its bid for the Non-Covered Items would be such that the total package of Non-Covered Items and related services would be offered below the Requestor's costs. According to the Requestor, if it does not offer this below-cost pricing on the Non-Covered Items and related services, the SNF would be unlikely to select it as the SNF's exclusive supplier of the Covered Items. While the pricing that the Requestor would offer on the Non-Covered Items and related services would not be conditioned expressly on becoming the exclusive supplier of the Covered Items, the Requestor has noted that a losing bidder would not be bound by the pricing included in its bid and that it is unlikely that the Requestor would offer that pricing if the SNF selected another supplier for the Covered Items. The Requestor has stated that the Medicare Part B payments that it would receive as the supplier of the Covered Items under Proposed Arrangement A would more than offset any losses the Requestor would incur in furnishing the Non-Covered Items and related services at the below-cost pricing.

E. Proposed Arrangement B

Under Proposed Arrangement B, the Requestor's owners would form a new company ("Newco"). The Requestor and Newco would submit a joint bid in response to the RFP and, if selected, enter into a contract with the SNF whereby the Requestor would be the exclusive supplier of the Covered Items and related services and Newco would furnish the Non-Covered Items and related services. Proposed Arrangement B would be identical to Proposed Arrangement A in all other respects.

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.

B. Analysis

1. Proposed Arrangement A

As we stated in the OIG Supplemental Compliance Program Guidance for Nursing Facilities, "if any direct or indirect link exists between a price offered by a supplier or provider to a nursing facility for items or services that the nursing facility pays for out-of-pocket and referrals of Federal business for which the supplier or provider can bill a Federal health care program, the anti-kickback statute is implicated." 73 Fed. Reg. 56832, 56844 (Sept. 30, 2008).

Under Proposed Arrangement A, the Requestor would charge the SNF an amount that would be below the Requestor's costs for Non-Covered Items and related services. Thus, the circumstances surrounding Proposed Arrangement A suggest that a nexus may exist between the below-cost payment rates offered to the SNF for Non-Covered Items and related services and referrals of other Federal health care program business. First, the SNF

is in a position to direct business to the Requestor that is not paid by the SNF under Proposed Arrangement A, i.e., Covered Items. Second, the single RFP solicits pricing information for the Non-Covered Items, together with service information related to the provision of both Covered Items and Non-Covered Items, suggesting a link between the two. Third, both parties have obvious motives for agreeing to trade below-cost payment rates for the Non-Covered Items and related services for referrals of other Federal health care program business: the SNF to minimize out-of-pocket payments for medical supplies and equipment, and the Requestor to secure business as an exclusive supplier of the Covered Items in a highly competitive market.

In evaluating whether an improper nexus exists between the rates offered for items and services and referrals of Federal business in a particular arrangement, we look for indicia that the rate is not commercially reasonable in the absence of other, non-discounted business. Prices offered to a skilled nursing facility that are below the supplier's total costs of providing the items and services—as in the facts presented here—give rise to an inference that the supplier and the skilled nursing facility may be "swapping" the below-cost rates on business for which the skilled nursing facility bears the business risk (i.e., the Non-Covered Items) in exchange for other profitable non-discounted Federal business (i.e., the Covered Items), from which the supplier can recoup losses incurred on the below-cost business, potentially through overutilization or abusive billing practices. In fact, the Requestor has acknowledged that the Medicare Part B payments that it would receive as the supplier of the Covered Items under Proposed Arrangement A would more than offset any losses it would incur in providing the Non-Covered Items and related services at the below-cost pricing.

Based on the facts presented here, we are unable to exclude the possibility that the Requestor may be offering improper discounts to the SNF for the Non-Covered Items and related services with the intent to induce referrals of more lucrative Federal business. Nor are we able to exclude the possibility that the SNF may be soliciting improper discounts on business for which it bears risk in exchange for referrals of business for which it bears no risk. Indeed, Proposed Arrangement A poses a substantial risk of such improper "swapping" of business that may run afoul of the anti-kickback statute.

2. Proposed Arrangement B

Proposed Arrangement B reflects the same substantial risk of improper "swapping" as Proposed Arrangement A. The fact that the Covered Items and related services would be provided by the Requestor and the Non-Covered Items and related services would be provided by Newco—a separate, but commonly-owned, company—does not mitigate that risk. It is the substance, not the form, of an arrangement that governs under the anti-kickback statute. Superficial appearances are not controlling. At the core of Proposed

Arrangement B, just like in Proposed Arrangement A, we find the Requestor's owners in a position to: (1) offer below-cost pricing on the Non-Covered Items and related services, and (2) benefit from referrals of the more lucrative Federal business. Further, nothing about Proposed Arrangement B diminishes the possibility that the SNF may be soliciting improper discounts on business for which it bears risk in exchange for referrals of business for which it bears no risk. Thus, under these particular facts, the interjection of a separate, but commonly-owned, company to provide the Non-Covered Items and related services at below-cost prices does not change our analysis.

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 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 Arrangements, 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 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,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General