



[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: April 7, 2011

Posted: April 14, 2011

[Name and address redacted]

Re: OIG Advisory Opinion No. 11-03

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding the formation of a new long-term care pharmacy with which you would enter into an agreement to manage all of its day-to-day operations and provide all personnel and related services necessary for its operation (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 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 Arrangement 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 Arrangement. 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

[Name redacted] (the “Requestor”) is a long-term care pharmacy that provides pharmaceutical products and services primarily to skilled nursing facilities, intermediate care facilities, assisted living facilities, and residential care facilities in [State redacted] (collectively, “LTC Facilities”). The Requestor provides support and services to LTC Facilities, including the acquisition and delivery of medications, medication distribution systems, consultant pharmacist services, and formulary management services. The Requestor also provides ancillary services including: nursing support and education, such as IV training/certification; state and Federal regulatory assistance; and management of medical records (*e.g.*, physician order sheets, medical administration records, treatment records, and other various tracking reports).

[Name redacted], one of the Requestor’s employees (“Requestor’s Employee”), is a pharmacist currently serving as the Requestor’s director of business integration. His duties include participating in Medicare Part D analyses, automation, and joint venture development. He also serves as a consultant pharmacist to LTC Facilities and is the director of the Requestor’s consultant pharmacist division.

Under the Proposed Arrangement, Requestor’s Employee would form a new long-term care pharmacy (“Newco”) that he would own along with one or more LTC Facility owners in the Requestor’s market area. Newco shares would be issued to the LTC Facility owners in proportion to the amount of capital they invest. Requestor’s Employee would be awarded the initial shares in Newco at a nominal price as an incentive for future services he would provide, namely, bringing in new investors and contracting with additional LTC Facilities on behalf of Newco. Any dividends or distributions would be paid in proportion to share ownership.

The Requestor estimates that Newco would require an initial equity investment of [amount redacted] to cover startup costs and provide beginning working capital. Startup costs would include both the legal and accounting costs associated with forming a new entity, and the costs related to procuring the initial pharmaceutical inventory and medication carts to be used at LTC Facility customer sites. The Requestor's [amount redacted] estimate is based on the assumption that Newco initially would service approximately [number redacted] LTC Facility beds.

Newco would engage in the exact same business as the Requestor. Under the Proposed Arrangement, Newco and the Requestor would enter into a management agreement under which the Requestor would provide all personnel and day-to-day services necessary for Newco to serve its LTC Facility customers. The Requestor would make all decisions associated with Newco's operations and Newco's agreements with LTC Facility customers. The Requestor would provide Newco with any office space it might need. The Requestor would direct the purchase of supplies and non-capital equipment Newco would need to operate and anticipates that Newco would purchase most of its non-controlled substances directly from the Requestor.¹ Newco would not have any employees, and would store its entire inventory either with its LTC Facility customers or at the Requestor's facility. Any Newco inventory stored at the Requestor's facility would be segregated from the Requestor's inventory. The Requestor would provide billing services to Newco, but all bills for services and items provided by Newco to its customers would be issued in Newco's name.

The Requestor asserts that, in exchange for these services, Newco would pay a management fee based on fair market value.² Under the parties' initial agreement, Newco would pay the Requestor a management fee of \$1.25 per script. In addition, Newco would pay direct costs for pharmacy operations, billing services, consultant pharmacist services, clinical education, medical record management, internal pharmacist services, customer care, delivery/driver services, order entry, up-front processing, purchasing, pharmacy management software maintenance, and overhead expenses (e.g., rent, real estate taxes, and utilities). Newco would also pay the Requestor for all non-controlled drugs dispensed to Newco customers by the Requestor.

¹ Newco would have its own DEA number and would pay applicable vendors directly for controlled drugs purchased under that number.

² We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A).

The pharmaceutical products and services that Newco would provide to its LTC Facility customers would include items and services covered and reimbursed by Federal health care programs.

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

The OIG has longstanding concerns about certain problematic joint venture arrangements between those in a position to refer business, such as the LTC Facilities here, and those furnishing items or services for which Medicare or Medicaid pays, especially when all or most of the business of the joint venture is derived from one or more of the joint venturers. See, e.g., OIG’s 1989 Special Fraud Alert on Joint Venture Arrangements, reprinted in the Federal Register in 1994 (59 Fed. Reg. 65372, 65373 (Dec. 19, 1994)).

The OIG issued additional guidance on suspect contractual joint venture arrangements in its Special Advisory Bulletin titled “Contractual Joint Ventures.” See 68 Fed. Reg. 23148 (April 30, 2003) (the “Special Advisory Bulletin”). As set forth in the Special Advisory

Bulletin, suspect joint venture arrangements typically exhibit certain common elements, several of which are present in the Proposed Arrangement. In fact, the Special Advisory Bulletin describes an arrangement very similar to the Proposed Arrangement:

[A] health care provider in one line of business (hereafter referred to as the “Owner”) expands into a related health care business by contracting with an existing provider of a related item or service (hereafter referred to as the “Manager/Supplier”) to provide the new item or service to the Owner’s existing patient population, including federal health care program patients. The Manager/Supplier not only manages the new line of business, but may also supply it with inventory, employees, space, billing, and other services. In other words, the Owner contracts out substantially the entire operation of the related line of business to the Manager/Supplier—otherwise a potential competitor—receiving in return the profits of the business as remuneration for its federal program referrals.

68 Fed. Reg. at 23148. We believe that the LTC Facility owners and the Requestor are in the same position as the Owner and Manager/Supplier described in the Special Advisory Bulletin.

Like the Owner in the arrangement described in the Special Advisory Bulletin, the LTC Facility owners in the Proposed Arrangement would be expanding into a related line of business—long-term care pharmaceutical products and services—that would be dependent on referrals from the LTC Facilities. The LTC Facility owners would not actually participate in the operation of Newco but rather would contract out substantially all Newco operations, including the professional services necessary to provide the pharmaceutical products and services, to the Requestor. Moreover, Requestor’s Employee would participate as an owner and organizer of Newco.

Like the “Owner” in the Special Advisory Bulletin, the LTC Facility owners’ actual financial and business risk would be minimal or nonexistent, because they would control the amount of business they would refer to Newco.

Other elements described in the Special Advisory Bulletin that are present in the Proposed Arrangement include:

- the Requestor is an established provider of the same services that Newco would provide and is in a position to directly provide the pharmaceutical products and

services in its own right, to bill insurers and patients in its own name, and to retain all available reimbursement;

- the aggregate payment to the Requestor would vary with the volume of referrals from the LTC Facilities, as would the LTC Facility owners' income (which is based on net profits and positive cash flow generated by Newco's operations); and
- the Requestor and the LTC Facility owners would share in the economic benefit of Newco.

Accordingly, based on the facts presented here, we are unable to exclude the possibility that the Proposed Arrangement is designed to permit the Requestor to do indirectly what it cannot do directly; that is, to pay the LTC Facility owners a share of the profits from their pharmaceutical products and services referrals. Indeed, there is a significant risk that the Proposed Arrangement would be an improper joint venture that would be used as a vehicle to reward the LTC Facility owners for their referrals.

III. CONCLUSION

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