

POSTED ON: September 8, 1998

[Issued August 31, 1998]

[name and address redacted]

Re: Advisory Request No. 98-10

Dear [name redacted]:

We are writing in response to your request for an advisory opinion, in which you asked whether the payment of a sales commission to an independent manufacturers' representative (the "Arrangement") constitutes grounds for sanctions under the anti-kickback statute, section 1128B(b) of the Social Security Act (the "Act"), the exclusion authority for kickbacks, section 1128(b)(7) of the Act, or the civil monetary penalty provision for kickbacks, section 1128A(a)(7) of the Act.

You have certified that all of the information you provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the material facts regarding the Arrangement. In issuing this opinion, we have relied solely on the facts and information you presented to us. We have not undertaken any independent investigation of such information.

Based on the facts certified in your request for an advisory opinion, we conclude that the Arrangement could constitute prohibited remuneration under the anti-kickback statute if the requisite intent to induce referrals were present, but that the OIG will not subject the Arrangement, as described in the request and supplemental submissions, to sanctions arising under the anti-kickback statute pursuant to sections 1128(b)(7) or 1128A(a)(7) of the Act.

This opinion may not be relied on by any person other than the requestor and is further qualified as set out in Part IV below and in 42 C.F.R. § 1008.

I. Factual Background

A. The Parties

Requestor is the sole shareholder and employee of Sales Agent A ("Sales Agent A"), an independent manufacturers' representative. Sales Agent A markets itself as a service providing "negotiation of national hospital agreements." Manufacturer B ("Manufacturer B") is a manufacturer of, among other things, disposable medical supplies.

B. The Arrangement

In April 1997, Sales Agent A entered into a sales agency contract (the "Contract") with Manufacturer B.⁽¹⁾ Under the Contract, Sales Agent A agreed to submit bids and negotiate contracts on behalf of Manufacturer B for the sale and distribution of disposable medical supplies, including adult diapers and disposable underpads, to six potential purchasers (the "Purchasers").⁽²⁾ Each Purchaser was either a multi-hospital health care system or a

group purchasing organization representing primarily hospitals and hospital systems. As compensation for Sales Agent A's efforts, Manufacturer B agreed to pay Sales Agent A a monthly commission of between 1% and 1.25% of invoiced amounts, the specific percentage being set in advance for each Purchaser.⁽³⁾ Sales Agent A has certified that this compensation represents fair market value. Sales Agent A performed services under the Contract for which it has not yet been paid. The Contract was subsequently canceled as to future Sales Agent A services.

The Contract was the only financial arrangement between Sales Agent A and Manufacturer B, and Sales Agent A had no arrangements with any of the Purchasers for or involving Manufacturer B products. To Sales Agent A's knowledge, Manufacturer B had no financial arrangements with any of the Purchasers involving Manufacturer B products covered by the Contract, other than those arrangements set forth in the contracts negotiated by Sales Agent A. Sales Agent A has certified that the group purchasing organization fees paid by Manufacturer B to the Purchasers that are group purchasing organizations were 2% or less of sales volume, and that, to Sales Agent A's knowledge, rebates offered to multi-hospital systems were allocated down to each purchasing hospital and properly disclosed to the Federal health care programs. Neither Sales Agent A nor Manufacturer B billed or received any payment from a Federal health care program for the goods sold under the contracts Sales Agent A negotiated.

Sales Agent A's representation of Manufacturer B was limited to submitting bids to and negotiating contracts with the Purchasers and making routine follow-up calls to the Purchasers to resolve questions and to report and reconcile group purchasing organization fees and discounts⁽⁴⁾

earned by the Purchasers. Specific orders for goods under the Purchasers' contracts were placed by the Purchasers' purchasing agents directly with Manufacturer B or one of its authorized distributors. Sales Agent A interacted exclusively with centralized purchasing departments of multi-hospital systems and group purchasing organizations; it had no contact with individual hospitals, physicians, or beneficiaries and did not contact or market to anyone in a professional position to make referrals or order goods or services on behalf of individual patients.

II. Legal Analysis

The anti-kickback statute makes it a criminal offense knowingly and wilfully to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by Federal health care programs. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce referrals of items or services paid for by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes 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, in cash or in-kind, directly or indirectly, covertly or overtly.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to obtain money for 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 (3rd Cir.), cert. denied, 476 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. This Office may also initiate administrative proceedings to exclude persons from Federal health care programs or to impose civil monetary penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.⁽⁵⁾

Sales agents are in the business of recommending or arranging for the purchase of the items or services they offer for sale on behalf of their principals, typically manufacturers, or other sellers (collectively, "Sellers"). Accordingly, any compensation arrangement between a Seller and an independent sales agent for the purpose of selling health care items or services that are directly or indirectly reimbursable by a Federal health care program

potentially implicates the anti-kickback statute, irrespective of the methodology used to compensate the agent. Moreover, because such agents are independent contractors, they are less accountable to the Seller than an employee. See 56 Fed. Reg. 35952, 35981 (July 29, 1991); 54 Fed. Reg. 3088, 3093 (Jan. 23, 1989). For these reasons, this Office has a longstanding concern with independent sales agency arrangements.

In some circumstances, our concerns can be addressed by structuring a sales agency arrangement to fit in a safe harbor. See, e.g., 56 Fed. Reg. at 35974. The Department of Health and Human Services has published safe harbor regulations that protect certain arrangements that might otherwise technically violate the anti-kickback statute from prosecution. See section 1128B(b)(3) of the Act; 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 only afforded to those arrangements that precisely meet all of the conditions set forth in the safe harbor. The regulatory safe harbor potentially applicable to the Arrangement is the personal services and management contracts safe harbor. See 42 C.F.R. §1001.952(d). The Arrangement could not qualify under this safe harbor, however, since the nature of the services provided under the Contract precluded an exact specification of the schedule for the performance of Sales Agent A's services and a determination of Sales Agent A's total aggregate compensation in advance, as required by the regulation.

In reviewing sales arrangements that do not fit in the personal services and management contracts safe harbor, this Office has identified several characteristics of arrangements among Sellers, sales agents, and purchasers that appear to be associated with an increased potential for program abuse, particularly overutilization and excessive program costs. These suspect characteristics include, but are not limited to:

- compensation based on percentage of sales;
- direct billing of a Federal health care program by the Seller for the item or service sold by the sales agent;
- direct contact between the sales agent and physicians in a position to order items or services that are then paid for by a Federal health care program;
- direct contact between the sales agent and Federal health care program beneficiaries;
- use of sales agents who are health care professionals or persons in a similar position to exert undue influence on purchasers or patients; or
- marketing of items or services that are separately reimbursable by a Federal health care program (e.g., items or services not bundled with other items or services covered by a DRG payment), whether on the basis of charges or costs.

This list is illustrative, not exhaustive, and the absence of any of these factors certainly does not mean that a sales arrangement is permissible under the anti-kickback statute. However, the more factors that are present, the greater the scrutiny we ordinarily will give an arrangement. Of course, in all cases the statute is not violated unless the parties have the requisite intent to induce referrals.

While Sales Agent A's compensation was established as a percentage of the sales made to specified accounts, none of the other factors triggering increased scrutiny was present. Neither Manufacturer B nor Subsidiary B billed any payer for the items being sold. There was no contact between Sales Agent A and patients or physicians. Sales Agent A was not in a position to exert undue influence on medical decision-making. Sales Agent A's direct contacts were with sophisticated purchasers, either group purchasing organizations or the purchasing units of multi-hospital systems, none of whom were in a position to order specific products for individual patients. Disposable medical supplies, including adult diapers and disposable underpads, are not, as a general matter, separately reimbursed to hospitals by Federal health care programs.

Sales Agent A has certified that most of the ultimate purchasers of the products were acute care hospitals. Because the particular products being sold, i.e., adult diapers and disposable underpads, are generally not separately reimbursable by Federal health care programs, the cost of the items furnished to inpatients represents an expense to the hospitals that must be covered by the fixed DRG payment. Such costs necessarily reduce the amount of profit for the hospital; thus, there is little, if any, incentive to overutilize the products or to pay more

than necessary for the items, unless there are side agreements that confer additional benefits on the hospitals.⁽⁶⁾ This conclusion is consistent with Sales Agent A's certification that in 1997 its sales commission from Subsidiary B was renegotiated and reduced in part because Sales Agent A's customers were demanding price reductions. In such circumstances, the risk of overutilization and excessive costs is largely offset by the inability of the purchaser to pass on the costs of the items purchased to the Federal health care programs.⁽⁷⁾

Finally, this opinion is premised on Sales Agent A's certifications that: (i) Sales Agent A had no commission-splitting or other arrangements with any Purchaser; (ii) Sales Agent A had no arrangement with Manufacturer B other than the Contract; (iii) to Sales Agent A's knowledge, Manufacturer B had no arrangements with the Purchasers with respect to the products sold in connection with the Contract, other than the rebates and group purchasing fees disclosed in the request for an advisory opinion; (iv) the group purchasing fees paid by Manufacturer B were 2% or less of sales volume; and (v) to Sales Agent A's knowledge, discounts from Manufacturer B to the Purchasers for products sold in connection with the Contract were allocated down to the purchasing hospital and properly disclosed to the Federal health care programs.

III. Conclusion

For the above reasons, we conclude that, although the Arrangement would technically fall within the prohibition of the anti-kickback statute if the requisite intent were present, we would not seek to impose sanctions under sections 1128(b)(7) (as it relates to kickbacks) or 1128A(a)(7) of the Act for payments made under the Contract, provided the compensation is fair market value as Sales Agent A has certified.⁽⁸⁾

IV. Limitations

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to Sales Agent A, the requestor of this opinion. This advisory opinion has no application, 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 to this opinion.
- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is herein expressed or implied 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 Arrangement.
- 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 that appear similar in nature or scope.

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 requester with respect to any action that is part of the 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, the compensation under the Contract represented fair market value, and the 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, rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the requester 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, where the compensation under the Contract represented fair market value, 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

1. Specifically, the Contract is between Sales Agent A and Subsidiary B, a division of Manufacturer B.
2. Sales Agent A successfully negotiated contracts with three of the six potential purchasers identified in the Contract.
3. In 1997, Sales Agent A's sales commission from Subsidiary B was renegotiated and reduced, in part because Sales Agent A's customers were demanding price reductions.
4. Manufacturer B gave hospital systems discounts in the form of rebates based on sales volume. Nothing in this advisory opinion should be construed as expressing an opinion as to the legality of such rebates.
5. Because both the criminal and administrative sanctions related to the anti-kickback implications of the Arrangement are based on violations of the anti-kickback statute, the analysis for the purposes of this advisory opinion is the same under both.
6. The fact that some small number of ultimate purchasers may have been skilled nursing facilities or other providers receiving cost-based reimbursement would not have reduced the incentive of the group purchasing organization or hospital system that negotiated with Sales Agent A to obtain the best deal and lowest prices for their clients as a whole.
7. We express no opinion regarding the liability of the Purchasers or any other party under the False Claims Act or other legal authorities for any improper billing, claims submission, or other conduct in connection with products purchased pursuant to the Arrangement.
8. While we are not authorized to opine on "fair market value," see section 1128D(b)(3) of the Act, we note that Sales Agent A's percentage commission under the Contract was less than one-half of the 3% amount established in the safe harbor for group purchasing organizations, see 42 C.F.R. § 1001.952(j), and that the amount of the sales price paid as a commission to Sales Agent A and the group purchasing organizations together either equaled or only slightly exceeded the 3% amount.