

[We have redacted specific information regarding the requestor and certain potentially privileged, confidential or financial information associated with the individual or entity, unless otherwise specified by the requester.]

Dated: March 16, 1999

Posted: March 23, 1999

[name and address redacted]

Re: [name redacted]

Advisory Opinion No. 99-3

Dear [name redacted]:

We are writing in response to your request on behalf of Company A, for an advisory opinion concerning whether a proposed pricing arrangement for a package of therapeutic mattresses for skilled nursing facility patients to be marketed by Company A, and certain commissioned agents (the "Proposed Arrangement") would result in prohibited remuneration under the anti-kickback statute, section 1128B(b) of the Social Security Act (the "Act") or would constitute grounds for the imposition of sanctions under the anti-kickback statute, section 1128B(b) of the Act, the exclusion authority related to kickbacks, section 1128(b)(7) of the Act, or the civil monetary penalty provision for kickbacks, section 1128A(a)(7) of the Act.

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, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion, we conclude that the Proposed Arrangement, as described in your advisory opinion request and supplemental submissions, might constitute prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals of Federal health care program business were present, but that the Office of Inspector General ("OIG") will not subject it 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 addressee and is further qualified as set out in Part III below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

Company A ("Company A"), a wholly-owned subsidiary of Company B, is a distributor of therapeutic mattresses used for the treatment and prevention of pressure ulcers. The Proposed Arrangement involves two types of mattresses (also known as support surfaces): (i) a powered support surface, the Company A therapeutic mattress system; and (ii) a non-powered support surface, the Company A pressure relieving mattress. Typically, a powered mattress is used as part of a treatment protocol for aggressive wound healing, while a non-powered mattress may be used to complete the course of treatment by facilitating continued healing and preventing the recurrence of pressure ulcers. Company A has certified that the Company A powered mattress has a fair market rental value of \$x per month.⁽¹⁾ Company A has certified that \$y is the fair market value of a single non-powered mattress purchased by an institution.

Company A proposes offering Medicare-certified skilled nursing facilities ("SNFs") special pricing for these therapeutic mattresses for patients undergoing treatment for pressure ulcers. Under the Proposed Arrangement, Company A will rent a SNF a powered mattress for thirty days for a fixed amount (\$x) set in advance by Company A and applicable to all similarly-situated SNF customers. The rental price includes the provision of a

non-powered mattress at no additional charge, to be used when the patient's condition improves such that he or she no longer requires the powered mattress. If the patient continues to require a powered mattress after the initial thirty days, Company A will provide the powered mattress for additional thirty-day periods at half of the original thirty day rental amount ($\$(1/2)(x)/\text{month}$). The total amount charged for the powered/non-powered mattress combination ($\$x$) will be substantially lower than the price Company A currently charges for these mattresses when rented and sold separately ($\$x + \$y = \$(x+y)$). The price charged for successive months' rental of the powered mattress will also be lower than the price charged for the same number of months rented separately. For example, a package of two months' rental of the powered mattress will cost $\$(x+1/2x)$, whereas two months rented separately costs $\$2x [(\$x + \$x)]$.

While Company A will market the Proposed Arrangement directly to its major customers, it will also contract with durable medical equipment ("DME") suppliers to serve as sales agents to market the Proposed Arrangement to some SNFs. As compensation, the DME sales agents will receive 20% of collections from any Proposed Arrangements for which they are responsible.⁽²⁾ The compensation covers the cost of selling activities, delivery, follow-up, and assistance in the collections process when necessary. Company A has certified that the compensation represents fair market value in an arms-length transaction.⁽³⁾ Payment for the mattresses will be made by the SNF customers directly to Company A. The contracted sales agents may market to SNFs products of other manufacturers and suppliers that are reimbursable under either Part A or Part B of the Medicare program.

Company A will require each DME supplier to provide Company A with an ownership statement and to agree not to market Company A's therapeutic mattresses to SNFs with which the DME supplier has a financial relationship. Company A has certified that it will monitor the DME supplier's compliance with these conditions. In addition, Company A will require the DME sales agents to disclose the special mattress pricing to their SNF customers in writing and to inform the customers of their obligation to report discounted prices accurately as required by any Federal or state agency, in a manner consistent with the requirements of 42 C.F.R. § 1001.952(h)(2)(ii).

All ordering and billing for the Proposed Arrangement will be done by Company A, regardless of whether the order is generated by Company A or by a contracting DME supplier. Company A's invoices for mattress packages purchased pursuant to the Proposed Arrangement will fully, accurately, and clearly reflect the discounted price of the package. For powered/non-powered mattress packages, Company A will apportion the discount between the two products in proportion to their fair market values. For one package, it will calculate the rental rate net of discount for the powered mattress by multiplying the ratio of the undiscounted rental rate for the powered mattress ($\$x$) to the undiscounted bundled or combined price ($\$(x+y)$) by the discounted combined price ($\$x$). It will thus report a net rental rate of $\$z$ [where $z = (x)(x/(x+y))$] for the powered mattress on the invoice. Using the same methodology, it will report a net sales price for the non-powered mattress of $\$w$ [where $w = (x)(y/(x+y))$]. For additional consecutive months' rental of the powered mattress, Company A will report the total price on the invoice ($\$(1/2x)/\text{month}$). The invoice will clearly state that the buyer has an obligation to report the discounted price on any cost reports or other reports required by any Federal or state agency, in a manner consistent with the requirements of 42 C.F.R. § 1001.952(h)(2)(ii).

Company A states that the market for the Proposed Arrangement will primarily be SNFs that are being reimbursed for Medicare Part A services using the new prospective payment system. The Balanced Budget Act of 1997, Public Law 105-33, required the implementation of a prospective payment system ("PPS") covering all costs (routine, ancillary, and capital) related to SNF services furnished to beneficiaries under Part A of the Medicare program. The PPS for SNFs is being implemented for the cost reporting period beginning after July 1, 1998. The basic methodology is a prospectively fixed per diem payment adjusted to reflect the resident's health status and needs and regional wage rate (the "Federal case mix adjusted rate"). The per diem payment is based on classifications of patients according to the amount and type of resources they use (resource utilization groups, or "RUGs"). There is a transition phase during the first three cost reporting years, during which SNFs will receive a blend of the Federal case mix adjusted rate and a facility specific rate based on the facility's allowable costs for SNF services for the fiscal 1995 cost reporting period.

One purpose of the Proposed Arrangement is to encourage SNFs to use the non-powered mattress as a routine step-down treatment and to demonstrate that such use can help prevent recurrences of ulcers, thereby saving costs and minimizing the SNFs' risk under the new PPS system.

Company A has certified that the Company A powered mattress and the non-powered Company A pressure relieving mattress included in the Proposed Arrangement are the only items marketed or provided by Company A that are covered by Medicare Part A. Moreover, Company A has certified that neither mattress is reimbursable under Part B of the Medicare program for patients in nursing facilities. In addition, Company A does not market or provide other items or services to potential SNF customers that are reimbursable under Part B of the Medicare program. Company A has also certified that, to its knowledge, only three State health care programs (New York, Ohio, and California) may, in infrequent circumstances, provide separate reimbursement for support surfaces used in long-term care facilities.

Company A has further certified that (i) Company A will have no financial arrangements with any SNF that participates in the Proposed Arrangement apart from the Proposed Arrangement; and (ii) Company A will have no commission-splitting or other financial arrangements with any of the DME suppliers that will market the Proposed Arrangement, except as disclosed in the request for an advisory opinion.

II. LEGAL ANALYSIS

The Anti-Kickback Statute

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 the 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.⁽⁴⁾

The anti-kickback statute contains a statutory exception for "a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(3)(A). The Department of Health and Human Services has published regulations implementing this discount "safe harbor" exception. See 42 C.F.R. § 1001.952(h).

The Bundled Pricing

The statutory discount exception, as implemented by the regulatory safe harbor, does not protect "the practice of a seller giving away, or reducing the price of, one good in connection with the purchase of a different good." See 56 Fed. Reg. 35952, 35978 (July 29, 1991). One of our major concerns with such arrangements is the difficulty in ensuring that the monetary value of the discount is appropriately apportioned and fully reported to the Federal health care programs. Id. In other words, such "discounts" may shift costs among reimbursement systems or distort the true costs of the items, making it difficult for the Federal health care programs to determine

appropriate reimbursement levels. Accordingly, the final discount safe harbor specifically excludes from the definition of discounts "furnishing one good or service without charge or at a reduced charge in exchange for any agreement to buy a different good or service." See 42 C.F.R. § 1001.952(h)(3)(ii).

The Proposed Arrangement involves a bundled therapeutic mattress package consisting of an initial thirty day powered mattress rental, which includes a non-powered mattress, and, if needed, additional thirty day rental periods at half price. Where items are bundled, we will examine the circumstances to determine the desirability of prosecuting such arrangements. The factors that we will look at may include: (1) the amount of the benefit that is reported and passed along to the programs, (2) whether the items are separately reimbursable, and (3) the intent behind the arrangement. See 56 Fed. Reg. at 35978.

The Proposed Arrangement, as described and certified by Company A, poses a minimal risk of kickback violations, and accordingly we would not subject it to sanctions under the anti-kickback statute. The methodology used by Company A to apportion the discount between the powered and non-powered mattresses is reasonable and, assuming proper reporting by the SNF purchasers,⁽⁵⁾ will assure that the price reported to any Federal health care program for each product will fairly reflect the value of the discount. Moreover, the mattresses that are the subject of the Proposed Arrangement will be used primarily in SNFs that will be reimbursed a fixed prospectively determined amount for Part A beneficiaries. Because the SNFs receive fixed per diem payments based on the patient's RUG classification, regardless of the costs of the services provided to the patient, the SNFs have an incentive to be prudent purchasers, i.e. to seek the lowest price for mattresses and not to pay for any mattresses unless absolutely necessary. In sum, so long as the discounted price for the package of mattresses is reflected properly on the SNFs' cost reports, there is minimal risk of program fraud or abuse from the Proposed Arrangement.

In addition, the Proposed Arrangement poses a minimal risk that discounts on Part A items and services will be "swapped" for referrals of Part B business. Many items that are included in the Part A SNF PPS payment may be separately reimbursable on a charge or fee schedule basis under Part B when provided to Medicare beneficiaries who are not eligible for skilled nursing care under Part A, but who reside in a nursing facility with a SNF unit. In such situations, there is a significant risk that suppliers might offer the SNF an excessively low price for items or services provided to SNF Part A patients reimbursed under the PPS methodology in return for the opportunity to service and bill nursing facility patients with Part B coverage. Such arrangements are highly suspect under the anti-kickback statute. In this case, however, Company A has certified that neither the powered nor the non-powered mattress is separately reimbursable by Medicare under Part B of the Medicare program for patients in Medicare and Medicaid certified nursing facilities. Moreover, Company A does not market or provide any items or services that are reimbursable under Part B to potential SNF customers. Thus, Company A has no incentive to offer SNFs a discounted price for mattresses to induce orders for Part B covered items or services.

Finally, some SNFs may also utilize the powered or non-powered mattresses for their residents receiving care pursuant to a State health care program. While reimbursement methodologies vary widely among states, Company A has certified that, to its knowledge, only three State health care programs (New York, Ohio, and California) may, in infrequent circumstances, provide separate reimbursement for support surfaces used in long-term care facilities. Except in these three states, the cost of the mattresses would typically be included in the facility's daily room and board rate. In a small number of states, the rate may be adjusted based on a RUGS-type assessment. In any case, Company A's method of allocating the discount between the two mattresses on the invoice will permit apportionment among payors, including State health care programs, according to the appropriate cost reporting principles in the same manner as other items and services used for patients in such programs.

The Use of DME Sales Agents

The proposed use of independent DME sales agents to provide sales and service support to some customers raises different issues. 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 regulatory safe harbor potentially applicable to the Proposed Arrangement is the personal services and management contracts safe harbor. See 42 C.F.R. § 1001.952(d). The Proposed Arrangement cannot qualify under this safe harbor, however, since the nature of the services to be provided by the DME sales agents precludes an exact specification of the schedule for performance of services and a determination of the total aggregate compensation in advance, as required by the safe harbor 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; and
- marketing of items or services that are separately reimbursable by a Federal health care program (e.g., items or services not included in the SNF PPS 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.

In this case, while the sales agent compensation will be based on a percentage of collections attributable to the Proposed Arrangement and may involve contact between the sales agent and persons in a position to order the services, the particular products being sold and rented, i.e., powered and non-powered mattresses, are not separately reimbursable for patients in Medicare and Medicaid certified nursing facilities and are used almost exclusively for SNF patients. To the extent that the purchasers of the mattresses will be SNFs reimbursed under the new Part A PPS, the cost of the mattresses will represent an expense to the SNFs that must be covered by the fixed PPS payment and will necessarily reduce the amount of profit for the SNF. Accordingly, the risk of overutilization and excessive program costs will largely be offset by the inability of the SNFs to pass on the costs of the items purchased to the Federal health care programs. In addition, the percentage compensation to be paid to the DME sales agents is a fixed percentage, which Company A has represented will be fair market value in an arms-length transaction.⁽⁶⁾

In the circumstances of the Proposed Arrangement, the fact that the sales agents may be marketing other products should not affect this conclusion. Because the price for the therapeutic mattress package is fixed and collected by Company A, there is no financial benefit to be gained by the DME sales agents from "swapping" the Part A mattress arrangement for other Part B business or Part B business for the Part A mattress business.

Finally, this opinion is premised on Company A's certifications that: (i) Company A will have no financial arrangements with any SNF that participates in the Proposed Arrangement apart from the Proposed Arrangement; and (ii) Company A will have no commission-splitting or other financial arrangements with any of the DME suppliers that will market the Proposed Arrangement, except as specifically disclosed in the request for an advisory opinion.

III. CONCLUSION

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

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to Company A, the requester 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 requester 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 Proposed 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.
- 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 requester with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion as long as (i) all of the material facts have been fully, completely, and accurately presented, (ii) the certified values of the mattresses reflect fair market rental rates and sales prices, (iii) the compensation paid to sales agents represents fair market value in an arms-length transaction, and (iv) 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, 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 (i) all of the relevant facts were fully, completely, and accurately

presented, (ii) the certified values of the mattresses reflect fair market rental rates and sales prices, (iii) the compensation to sales agents represents fair market value in an arms-length transaction, and (iv) 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

FOOTNOTES:

1. Company A has not previously rented the power mattress and has based its fair market rental rate on rates for comparable products rented by other distributors; we are not authorized to opine on "fair market value" (see section 1128D(b)(3) of the Act) and therefore assume the truth of Company A's fair market value certifications for purposes of this opinion. We express no opinion as to whether the rental rates selected by Company A are, in fact, fair market value. If they are not fair market value, this opinion is without force and effect.

2. Company A has certified that the compensation rate is tentatively set at 20% and that it reserves the right to adjust the amount of compensation as necessary. This opinion is limited to the compensation terms described in this advisory opinion. We express no opinion about any different compensation terms.

3. As we are not authorized to opine on "fair market value" (see section 1128D(b)(3) of the Act), we assume the truth of Company A's fair market value certification for purposes of this opinion. If the certification is not true, this opinion is without force and effect.

4. 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.

5. The OIG will not hold Company A liable for omissions of the SNFs in connection with their claims filing and reporting obligations, provided that Company A does everything it reasonably can to ensure that the SNFs understand their obligations to report the discount accurately.

6. As noted above, we are not authorized to opine on "fair market value" in an advisory opinion. See section 1128D(b)(3) of the Act. Therefore, for purposes of this opinion, we have assumed fair market value compensation based on Company A's certification. If the compensation paid to DME sales agents under the Proposed Arrangement is not fair market value, this opinion will be without force and effect.