

[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 3, 2001

Posted: July 10, 2001

[name and address redacted]

Re: OIG Advisory Opinion No. 01-8

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a comprehensive program (the "Program") that [company's name redacted] (the "Company") markets and sells to State-licensed nursing facilities ("Facilities") to manage pressure ulcers. Specifically, the Program couples the purchase of the Company's therapeutic mattresses with the purchase of skin and wound care products and a Program warranty. The question raised by your request is whether the Program constitutes 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.

You have certified that all of the information provided in your request, including all supplementary letters, 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 Program could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the Office of Inspector General ("OIG") would not impose administrative sanctions on [company's 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 Program. This opinion is limited to the Program and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

This opinion may not be relied on by any persons other than [company's 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

The Company, a wholly-owned subsidiary of [parent company's name redacted], manufactures and sells therapeutic mattresses and other support surfaces used for the treatment and prevention of pressure ulcers. The Program is a 3-year contractual arrangement consisting of three conjoined components: (i) the discounted sale of the Company's therapeutic mattresses and other support surfaces, together with limited replacement warranties; (ii) a prospectively-fixed, per resident/per diem payment for skin and wound care products; and (iii) a limited warranty (the "Program Warranty") for certain monetary liabilities resulting from the Program's failure to meet its stated objective: managing pressure ulcers. The Company offers the Program only to Facilities, some of which are Medicare-certified skilled nursing facilities ("SNFs").

The crux of the Program is the replacement of all of a Facility's existing mattresses with the Company's therapeutic mattresses. More specifically, the first component of the Program requires the Facility to pay a negotiated, fixed, discounted price per bed in exchange for which the Facility receives: (i) a non-powered therapeutic mattress for each bed; (ii) a specified number of wheelchair cushions and therapy pads ("other support surfaces") based upon the number of residents in the Facility; (iii) a sufficient quantity of advanced powered therapeutic mattresses to address residents' wound care needs; and (iv) online access to a wound documentation system and a certified wound care specialist.¹ Under the Program, ownership of the non-powered mattresses and the other support surfaces is transferred from the Company to the participating Facility; ownership of the powered mattresses remains with the Company. The non-powered mattresses and other support surfaces are subject to a 7-year and 3-year replacement warranty, respectively. The Company has certified that the aggregate payment for the first component of the Program represents a fair market value payment.²

The second component of the Program requires a participating Facility to pay a fixed, daily fee per resident in exchange for an extensive skin and wound care program which includes all non-

¹The Company permits Facilities to finance the aggregate payment for the first component of the Program and, if financed, the Company adjusts the aggregate payment to include the cost of financing.

²We 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). For purposes of this advisory opinion, we rely on the Company's certification of fair market value.

prescription skin and wound care products required to meet the needs of the Facility's residents.³ In addition to the skin and wound care products, the Company also furnishes to participating Facilities certain support services relating to skin and wound care, including protocols⁴ and in-service training and continuing education for the Facility's staff. The Company has certified that the capitation fee represents a fair market value payment for the skin and wound care products and services, based on its good faith estimation of the costs of the Program, taking into account the average quantity of goods typically consumed in the clinically sound care of residents and the projected decrease in incidence of pressure ulcers attributable to use of the Company's therapeutic mattresses.⁵

The final component of the Program is the Program Warranty. Under the Program Warranty, the Company agrees to reimburse a participating Facility for the first \$[X] of liability insurance deductibles actually paid (excluding legal and research costs and liability resulting from medical, surgical, or hospital expenses incurred by a Facility resident) per incident during the contract term and resulting from judgments for skin or wound care deficiencies. In order to qualify for the Program Warranty, a participating Facility must comply with Program obligations and objectives, including following Company-approved skin and wound care protocols, providing certain in-service training to Facility staff, using the Company's online wound documentation tools and, when necessary, using the services of the Company's certified wound specialist.

The items and services provided under the Program are potentially reimbursable by Medicare and State health care programs ("Medicaid"). They are not, however, separately reimbursable under Medicare Part A. Rather, all costs resulting from a Medicare Part A covered stay, including Program costs for mattresses, other support surfaces, and skin and wound care products, are included in a per diem payment under the SNF prospective payment system ("PPS"). If a resident is not eligible for a Medicare Part A covered stay, then, except for reimbursement for certain wound care supplies in limited situations, Medicare Part B provides no reimbursement for Program items or services.⁶ The Company has further certified that, typically, Program-provided wound care supplies that are potentially reimbursable under Medicare Part B (the "surgical wound

³A participating Facility must use the generic and brand name skin and wound care products provided by the Company. In addition, if a resident of a participating Facility develops pressure ulcers and if non-prescription products other than those ordinarily provided under the Program are required, the Company will supply those products at no additional charge.

⁴A participating Facility may continue to use its own pre-existing skin and wound care protocols only if the protocols are approved by the Company.

⁵See supra note 2.

⁶The Company has certified that wound care supplies are reimbursable under Medicare Part B only if they are used for treatment of surgical or debrided wounds, in which case they might be reimbursable as a surgical dressings.

supplies”) should represent substantially less than 1% of the Program’s price. Because Medicaid reimbursement varies from state to state, some of the items and services provided under the Program may be separately reimbursable in some states. Most states, however, use a fixed, per diem reimbursement methodology for nursing facility residential care that would not reimburse Facilities separately for the vast majority of items and services (by number or value) provided under the Program.⁷

The Company has certified that: (i) the Company will have no financial arrangements with any Facility that participates in the Program apart from the Program; (ii) the Program will not be marketed or sold by any other party, including any durable medical equipment supplier; (iii) the Company does not directly or indirectly market or provide to Facilities other items or services that are reimbursable under Medicare Part A or Part B; (iv) the Company fully and accurately reports the Program’s pricing arrangement and the existence of the Program Warranty on the invoice provided to each participating Facility; (v) with respect to the Program Warranty, the invoice also contains a statement informing the purchasing Facility that the Facility must fully and accurately report any payments made under the Program Warranty in accordance with the rules governing the applicable Federal health care program, and that the Facility must provide, upon request by the Secretary of the Department of Health and Human Services or a State agency, information regarding the Program Warranty provided to the Facility by the Company; and (vi) if any payment is made in connection with the Program Warranty, the remittance statement will reflect the amount of the payment and the specific formal action for which payment is being made.

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 Federal health care programs. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward 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 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, 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 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.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine

⁷The Company has certified that, to its knowledge, only three State Medicaid programs (i.e., New York, Ohio, and California) may, in infrequent circumstances, provide separate reimbursement for mattresses and other support surfaces provided under the Program.

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.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 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 afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for warranties, 42 C.F.R. § 1001.952(g), is potentially applicable to the Program Warranty. Safe harbor protection is available as long as the buyer complies with the standards of 42 C.F.R. § 1001.952(g)(1)-(2) and the manufacturer or supplier complies with the following standards of 42 C.F.R. § 1001.952(g)(3)-(4):

- The manufacturer or supplier must comply with either of the following two standards -- (i) The manufacturer or supplier must fully and accurately report the price reduction of the item (including a free item), which was obtained as part of the warranty, on the invoice or statement submitted to the buyer, and inform the buyer of its obligations under paragraphs (g)(1) and (g)(2) of this section.⁸ (ii) Where the amount of the price reduction is not known at the time of sale, the manufacturer or supplier must fully and accurately report the existence of a warranty on the invoice or statement, inform the buyer of its obligations under paragraphs (g)(1) and (g)(2) of this section, and, when the price reduction becomes known, provide the buyer with documentation of the calculation of the price reduction resulting from the warranty.
- The manufacturer or supplier must not pay any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the item itself.

B. Analysis

⁸Paragraph (g)(1) of 42 C.F.R. § 1001.952 provides that the buyer must fully and accurately report any price reduction of the item (including a free item), which was obtained as part of the warranty, in the applicable cost reporting mechanism or claim for payment filed with the Department or a State agency. Paragraph (g)(2) of 42 C.F.R. § 1001.952 provides that the buyer must provide, upon request by the Secretary or a State agency, information provided by the manufacturer or supplier in paragraph (g)(3) of that section.

The advent of the SNF PPS has sparked a variety of innovative arrangements between ancillary suppliers and SNFs seeking to control and reduce their costs for PPS-covered items and services. The Program is one such response and addresses an obvious marketing problem facing the Company: how to convince Facility operators to buy the Company's therapeutic mattresses when the Facilities are being paid primarily on a fixed, all-inclusive, per diem rate. As a practical matter, the Program is designed to show potential customers that the Company is willing to put its money at risk if its therapeutic mattresses do not perform as intended by reducing substantially the incidence of pressure ulcers. Specifically, the Program's pricing arrangement puts the Company at risk for: (i) the costs of powered mattresses necessary to treat pressure ulcers; (ii) the costs of skin and wound care products that result from the failure of the non-powered and powered mattresses to reduce the incidence of pressure ulcers; and (iii) to a limited extent, the costs of legal liability resulting from pressure ulcers.

As a threshold matter, we will consider the Program's pricing arrangement and the Program Warranty separately. The Program's pricing arrangement cannot fit into the discount safe harbor, 42 C.F.R. § 1001.952(h), since it bundles several distinct items and services. The OIG has consistently stated that the provision of one item or service for free or at less than fair market value to induce the purchase of another item or service constitutes remuneration within the meaning of the anti-kickback statute and is not protected by the discount safe harbor. Therefore, we must carefully scrutinize the Program's pricing arrangement in its entirety to determine whether, based upon a totality of the facts and circumstances presented, it poses a risk of fraud and abuse.

The Program's pricing arrangement contains the following factors which, taken together, lead us to conclude that the Program's pricing arrangement for therapeutic mattresses, other support surfaces, and skin and wound care products poses minimal risk of fraud or abuse.

- First, the Program covers all beds and all residents of a participating Facility and pricing is uniform, regardless of the resident's payor.
- Second, participating Facilities are reimbursed pursuant to a global, all-inclusive rate, either by Medicare Part A or State Medicaid programs, for the vast majority of the items and services included in the Program. Thus, there is little apparent risk of abuse from the bundling of items and services all of which are reimbursed primarily by a single, global, all-inclusive rate, since the financial incentive for the Facility receiving a fixed payment is to reduce total costs. To the extent that a State uses a cost-based reimbursement system to determine the global rate, the total cost of the Program should be reflected on the participating Facility's cost report.⁹

⁹We express no opinion regarding liability of any Facility under the False Claims Act or other legal authorities in connection with any improper billing or claims submission directly or indirectly related to, or arising from, the Program.

- Third, of all of the items and services provided in connection with the Program's bundled pricing arrangement, only surgical wound supplies are potentially separately reimbursable under Medicare Part B. In general, we are concerned with bundled payments for items and services that are separately reimbursable because it is difficult to ensure that Federal health care programs receive their appropriate share of any savings. Bundled arrangements are especially problematic in cases where the financial benefit inures primarily to the purchaser and not to the Federal fisc, or where the bundled arrangement increases utilization of a particular item or service on which profit margins from Federal reimbursement are unusually high. However, in this case, the Company has certified that (i) except for surgical wound supplies, no separate reimbursement is available for the items and services provided under the Program, so the opportunity to bill separately for any of the Program's items or services is rare, and (ii) the value of the surgical wound supplies provided under the Program represents a very small percentage of the Program's price. The foregoing makes it highly unlikely that the limited opportunity to separately bill surgical wound supplies under Medicare Part B will significantly increase the risk of fraud and abuse.¹⁰
- Fourth, the Program is the only financial arrangement between the Company and the participating Facilities. Accordingly, there is no risk of potential "swapping" of low Program prices for the Company's opportunity to provide other unrelated items or services to participating Facilities.

With respect to the Program Warranty, we begin with the warranty safe harbor, 42 C.F.R. § 1001.952(g). The definition of warranty in the warranty safe harbor incorporates the Federal Trade Commission's definition of warranty which includes "any undertaking in writing . . . to refund, repair, replace, or take other remedial action with respect to such product in the event that such product fails to meet the specifications set forth in the undertaking." 15 U.S.C. § 2301(6)(B). In the instant case, for each purchasing Facility, the "product" is the entire Program. The promise to indemnify a participating Facility from certain liabilities resulting from judgments for skin or wound care deficiencies, notwithstanding the Facility's strict adherence to the Program, constitutes remedial action resulting from failure of the Program to perform as promised. Specifically, in the preamble to the final warranty safe harbor, we stated that payments made by a manufacturer or supplier to settle claims or satisfy judgments arising out of product liability claims were protected by the warranty safe harbor to the extent they comply with all of

¹⁰For purposes of this opinion, we assume that any Medicare Part B claim submitted by a participating Facility will accurately describe the item and include the appropriate code from the HCFA Common Procedure Coding System ("HCPCS"). See 42 C.F.R. § 424.32(a)(5). We express no opinion regarding liability of the Company or any Facility under the False Claims Act or other legal authorities in connection with any improper billing or claims submission directly or indirectly related to, or arising from, the Program.

the other conditions of that safe harbor. See 56 Fed. Reg. at 35977 (July 29, 1991). In this case, all other conditions are met.¹¹

The sole issue with respect to the Program Warranty is that the “product” is a combination of items (i.e., the support surfaces, skin and wound care products, and protocols) and some services (i.e., the wound specialist’s advice and in-service training). Since the warranty safe harbor only protects warranties on “items”, a warranty on a combination of items and services does not technically qualify for protection. In this case, however, the Program’s items, especially its mattresses and other support services, are the linchpin of the Program and the Program Warranty. The vast majority of the costs of the Program are for the items and the anticipated benefit is principally attributed to the mattresses and other support surfaces. Thus, we conclude that the fact that the Program Warranty covers a small service component, as well as items, does not significantly increase the risk of fraud and abuse.

Finally, if the Program works as intended and reduces the incidence of pressure ulcers, patients and Federal health care programs will benefit. In many respects, global payments are intended to encourage Facility operators to re-engineer the delivery of care to reduce costs and increase quality. Given the absence of any identifiable opportunity for abuse, we are reluctant to chill innovative and potentially beneficial arrangements. We caution, however, that if we subsequently become aware of problems not apparent to us today, we reserve the right, as provided by regulation, to modify this opinion.

For all of the foregoing reasons, we will not subject the Company to administrative sanctions 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 Program.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Program could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on [company’s 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 Program. This opinion is limited to the Program and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

IV. LIMITATIONS

¹¹The Program Warranty expressly prohibits the Company from making any payments for liability resulting from medical, surgical, or hospital expenses incurred by a Facility resident.

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [company's name redacted], who is 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 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 Program.
- 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 the Company with respect to any action that is part of the Program 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 Program 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 Company 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,

/s/

D. McCarty Thornton

