DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

[*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: June 24, 2013

Posted: July 1, 2013

[Name and address redacted]

Re: OIG Advisory Opinion No. 13-07

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a tiered rebate program in which the rebate tiers would be reached based on the combination of purchases of both Federally reimbursable products and non-Federally reimbursable products (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 would not generate prohibited remuneration under the anti-kickback statute. Accordingly, the Office of Inspector General ("OIG") would not 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. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

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 corporation that manufactures products used to treat ophthalmologic disorders and to improve vision, including pharmaceutical products, surgical equipment, vision aids, and related products. Some, but not all, of the Requestor's products are reimbursable directly or indirectly by Federal health care programs.

Under the Proposed Arrangement, the Requestor would establish a rebate program that would provide a tiered, percentage rebate based on purchases of surgical supplies and devices[1] ("Surgical Products"). The rebate would be calculated based on a customer's total annual purchases of Surgical Products, regardless of whether those Surgical Products are reimbursable by Federal health care programs. Thus, for example, a customer who purchases $X of Surgical Products during a calendar year would receive a 5% rebate, a customer who purchases $2X of Surgical Products would receive a 10% rebate, and a customer who purchases $4X of Surgical Products would receive a 20% rebate.

The Requestor certified that the rebate amount would not vary based on the number of Federally reimbursable products a customer purchases. Thus, a customer who purchases $X of Surgical Products would receive a 5% rebate regardless of whether all of those Surgical Products were reimbursable by Federal health care programs, half were reimbursable by Federal health care programs, or none were reimbursable by Federal health care programs.

The Requestor certified that it would notify all customers receiving rebates of their obligation to report any rebates received based on sales of Federally reimbursable Surgical

[1] All of the Requestor's surgical supplies and devices would be included in the Proposed Arrangement, but capital equipment (e.g., lasers) would not be included.

Products. The Requestor would present this notification in three formats. First, the contract that the parties would execute prior to the initial qualifying purchase would include a description of the program. This program description would set forth the products or product categories that would be included in the rebate program, the methodology or formula that would be used to calculate the percentage of the customer's total qualifying purchases to be reflected by the rebate, an explanation of how to calculate the portion of the rebate applicable to any specific products that might be reimbursed by Federal health care programs, and a notification that the buyer may have obligations under the discount safe harbor to report the portion of the rebate applicable to Federally reimbursed products. Second, the invoices that the Requestor would send to participating customers would state that items included on the invoice may be subject to a later rebate and thus may trigger reporting obligations to Federal health care programs. Finally, at the end of each calendar year, the Requestor would give each participating customer a year-end report that would include a summary of the customer's total qualifying purchases, an explanation of the rebate program tier for which the customer qualified, and a calculation of the total rebate to which the customer is entitled. Thus, the statement would provide those customers with the information necessary to report the rebate amounts on products that are reimbursed by Federal health care programs. Finally, the Requestor certified that it would refrain from doing anything that would impede the buyer from meeting its obligations under the discount safe harbor.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense to knowingly and willfully 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. See, e.g., United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); 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.

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.

Initially created by statute, the safe harbor for discounts potentially applies to the Proposed Arrangement. This safe harbor interprets the statutory exception, which protects "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." Section 1128B(b)(3)(A) of the Act. This discount exception reflects Congress' intent to encourage price competition that benefits the Federal health care programs. The requirements of the safe harbor are further enumerated at 42 C.F.R. § 1001.952(h). The discount safe harbor contains different requirements for sellers, buyers, and offerors of discounted items and services. For the remuneration offered under the Proposed Arrangement to be protected under the discount safe harbor, the Requestor would have to comply with the requirements for sellers. See 42 C.F.R. § 1001.952(h)(2).

B. Analysis

Determining whether the Proposed Arrangement would qualify for protection under the safe harbor requires a multi-part analysis. First, we must determine whether the proposed rebate program involves a "discount" as defined in the safe harbor. Then we must determine whether the Requestor would meet the requirements of a seller under the safe harbor. As described further below, based on the Requestor's certifications, we believe that the Proposed Arrangement qualifies for safe harbor protection.

1. Discounts

Under the safe harbor, the term "discount" is defined as "a reduction in the amount a buyer…is charged for an item or service based on an arms-length transaction." 42 C.F.R. § 1001.952(h)(5). This definition includes certain caveats. Most relevant to the Proposed Arrangement, a discount does not include:

> [s]upplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology.

We have expressed concerns about discounts on bundled items for multiple reasons. Such discounts can shift costs among reimbursement systems and distort the true cost of items. See 64 Fed. Reg. 63,518, 63,530 (Nov. 19, 1999) ("1999 Final Rule"). For example, a company might offer a discount to a hospital on items reimbursable under Part A to induce the purchase of items reimbursable under Part B. Not only would the cost be shifted among reimbursement systems, but it would be difficult to determine the net price of any item for reporting purposes. We noted in the preamble to the 1999 Final Rule, however, that "discounts offered on one good or service to induce the purchase of a different good or service where the net value can be properly reported do not pose a risk of program abuse and may benefit the programs through lower costs or charges achieved through volume purchasing and other economies of scale." Id. That particular statement was made to support the concept of allowing bundled discounts when the goods and services are reimbursed by the same payment methodology. However, the principle also applies to the Proposed Arrangement.

Under the Proposed Arrangement, the Requestor would offer a tiered discount program. All purchases of Surgical Products—whether or not reimbursable by Federal health care programs—would be aggregated to determine the percentage amount of the rebate. For purposes of illustration only, assume a customer would receive a 10% rebate if the annual purchasing volume reached $1,000,000. Thus, a customer spending $1,100,000 would receive a rebate in the amount of $110,000. The customer would know that the net price of any item that cost $100 would actually be $90. This structure is distinguishable from a bundled discount where a customer might receive a free surgical pack if the customer purchased five surgical devices.[2] Because of the difficulties inherent in accurately

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[2] The Proposed Arrangement is also distinguishable from prohibited arrangements in which an entity might offer a "reward," such as a computer or travel vouchers, in return for a

allocating and reporting such a discount, a bundled discount could be protected under the safe harbor only if the items are reimbursed under the same methodology. The Surgical Products in the Proposed Arrangement are not necessarily reimbursable under the same methodology. However, that is not essential here because the Proposed Arrangement does not involve a "bundle." Not only would a discount on one product not be contingent on the purchase of another product, the discount also would be readily attributable to each item purchased. Therefore, we deem the rebates offered under the Proposed Arrangement to meet the definition of "discount" under the safe harbor.

A second definition relevant to the Proposed Arrangement is the term "rebate." The safe harbor defines a "rebate" as "any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale." 42 C.F.R. § 1001.952(h)(4). The rebates offered in the Proposed Arrangement meet this definition. The program description that the Requestor would provide to customers in the program contract would explain the terms of the rebate program. The customer would know the types of products involved and the purchasing volume required to reach each tier of the rebate program at the time of the initial purchase. Once the total annual volume is known, the actual rebate amount would be known and then would be distributed. Thus, the Proposed Arrangement's rebates would meet the terms of the definition.

2. Sellers' Obligations

To meet the requirements of the safe harbor, sellers have certain notification requirements, depending on the type of buyer. See 42 C.F.R. § 1001.952(h)(2). In general, the seller must provide the buyer with sufficient information to meet the buyer's reporting requirements. With respect to cost-reporting buyers, when the value of the discount is not known at the time of sale, the seller must fully and accurately report the existence of a discount program on the invoice and inform the buyer of its obligation to report such discount and to provide information in accordance with the buyer's requirements set forth at 42 C.F.R. § 1001.952(h)(1). When the amount of the discount is known, the seller must provide the buyer with documentation of the calculation, identifying the specific goods and services to which the discount will be applied, and refrain from doing anything that would impede the buyer's obligations. See 42 C.F.R. § 1001.952(h)(2)(ii). The requirements for sellers are

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certain purchasing volume. See, e.g., 56 Fed. Reg. 35,952, 35,978 (July 29, 1991): "One of the most common features of a serious kickback violation exists when a seller offers a valuable good, for example a car or a trip, in return for that person's participation in an activity prohibited under the statute, for example, referral of business payable by the Medicare and Medicaid programs."

similar under 42 C.F.R. § 1001.952(h)(2)(iii)(B) with respect to discounts offered to other types of buyers.

The Requestor certified it would meet all of the obligations of a seller under the safe harbor. Specifically, the Requestor would provide a program description to customers describing the terms of the rebate program and a notification that the customer may have obligations under the discount safe harbor to report the portion of the rebate applicable to Federally reimbursed products. Next, the Requestor would provide invoices to customers participating in the program that would state that items included on the invoice may be subject to a later rebate and thus may trigger reporting obligations to Federal health care programs. Finally, at the end of each calendar year, the Requestor would send each participating customer a year-end report that would include a summary of the customer's total qualifying purchases, an explanation of the rebate program tier for which the customer qualified, and a calculation of the total rebate to which the customer is entitled. In addition, the Requestor certified that it would refrain from doing anything that would impede the customer from meeting its obligations under the discount safe harbor.

Based on the Requestor's certifications, the Proposed Arrangement would meet the requirements of the discount safe harbor. The Requestor has committed to meet the seller's requirements as specified in 42 C.F.R. § 1001.952(h)(2).

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement would not generate prohibited remuneration under the anti-kickback statute. Accordingly, the OIG would not 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. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

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 by a person or entity other than [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

- 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 (or that provision's application to the Medicaid program at section 1903(s) 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 will not proceed against [name redacted] with respect to any action that is part of the Proposed 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, and 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, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [name

redacted] with respect to any action that is part of the Proposed Arrangement 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,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General