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: August 18, 2017

Posted: August 25, 2017

[Name and address redacted]

Re: OIG Advisory Opinion No. 17-03

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a pharmaceutical manufacturer's proposal to replace products that require specialized handling that could not be administered to patients for certain reasons, at no additional charge to the purchaser (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, although the Proposed Arrangement 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, 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] ("Requestor") and its affiliated companies manufacture and sell biologics and other products. Some of these products are sensitive to temperature changes, direct sunlight, or movement, and may require reconstitution in a controlled environment (the "Products"). To ensure quality and patient safety, the Products' labeling includes specific storage and handling requirements and, if applicable, limits on the amount of time that may elapse between when a Product is reconstituted and when it is administered to a patient. Requestor certified that failure to meet these requirements can result in Product spoilage.

Under the Proposed Arrangement, subject to certain limitations and conditions, Requestor would replace, without charge, Products purchased by physicians, clinics, and hospitals located in the United States ("Customers")[1] if the Products spoiled or otherwise became unusable after purchase. To qualify for replacement under the Proposed Arrangement, the Product must not have been administered to a patient after having been rendered unusable after purchase due to one of the following events (any of which would make a Product a "Spoiled Product"):

- the Product was mishandled, dropped, or broken;
- the Product was inappropriately stored or refrigerated, or was frozen;
- there was an admixture error; or

[1] For purposes of this advisory opinion, the scope of "Customer" is a single location, such as a hospital, clinic, or physician office. It is not an individual physician within a group practice.

- the Product was reconstituted but not administered due to an unforeseen patient condition or because the patient missed the appointment.

Requestor certified that it would have a written policy (the "Policy") that would set forth all of the conditions a Customer must satisfy to qualify for a replacement Product. Requestor would notify Customers about the Policy before they purchase a Product.

The Proposed Arrangement would allow only for the replacement of Spoiled Products; Customers could not receive credit for any Spoiled Products, nor could they receive replacements for free samples. In addition, replacement would not be available if a Customer either administered the Spoiled Product or billed an insurer or patient for the Spoiled Product. The Proposed Arrangement would apply only to single Product claims; it would not cover multi-unit losses. The only exception to this limitation would be if the spoilage occurred due to a refrigeration failure (e.g., someone inadvertently left a refrigerator door open or set it to the wrong temperature). In such a circumstance, the Customer could claim a loss of no more than five Products regardless of how many Products spoiled as a result of the refrigeration failure.

To obtain replacement Products, a Customer would be required to submit documentation detailing how the spoilage occurred and return the Spoiled Product. If the Spoiled Product is not returnable (e.g., a broken vial), the Customer must attest to how it became unusable and include a photograph of the Spoiled Product, if available. Customers would be required to sign an acknowledgement that neither the patient nor a payor was billed for the Spoiled Product.

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. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); 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 U.S. 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), potentially applies to the Proposed Arrangement. The safe harbor defines "warranty," in relevant part, as "an agreement made in accordance with the provisions of 15 U.S.C. § 2301(6)." "Written warranty" is defined in 15 U.S.C. § 2301(6) as:

> (A) any written affirmation of fact or written promise made in connection with the sale of a consumer product by a supplier to a buyer which relates to the nature of the material or worksmanship and affirms or promises that such material or worksmanship is defect free or will meet a specified level of performance over a specified period of time, or
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> (B) any undertaking in writing in connection with the sale by a supplier of a consumer product to refund, repair, replace, or take such other remedial action with respect to such product in the event that such product fails to meet the specifications set forth in the undertaking,
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> which written affirmation, promise, or undertaking becomes part of the basis of the bargain between a supplier and a buyer for purposes other than resale of such product.

B. Analysis

The safe harbor for warranties protects remedial actions by suppliers to address products that fail to meet bargained-for requirements. The Spoiled Products that Requestor would replace under the Proposed Arrangement would not be defective or substandard, as would be required to meet the first definition of "written warranty" in 15 U.S.C. § 2301(6)(A).

The Spoiled Products also would fail to meet the second definition of "written warranty" in 15 U.S.C. 2301(6)(B) that "such product fails to meet the specifications set forth in the undertaking." Requestor certified that to ensure quality and patient safety, the Products' labeling specifies the required storage and handling requirements, and, if applicable, limits on the amount of time that may elapse between when a Product is reconstituted and when it is administered to a patient. The Proposed Arrangement would apply to Products that were spoiled or otherwise rendered unusable after they had been delivered due to Customer error or the Customer's unforeseen inability to administer the Product after the Product was prepared for a patient. In other words, if the Customer had implemented the specifications that were part of the undertaking, the Product would not have spoiled.[2] Therefore, we conclude that the Products subject to the Proposed Arrangement would not fail to meet the specifications, as characterized in the definition of "written warranty."[3] Accordingly, the warranties safe harbor does not apply to the Proposed Arrangement.

Arrangements that do not fit in a safe harbor must be evaluated on a case-by-case basis, based on the totality of the facts and circumstances. For the combination of the following reasons, we conclude that the Proposed Arrangement poses a sufficiently low risk of fraud and abuse under the anti-kickback statute.

First, the replacement of Spoiled Products would be restricted to certain unintentional, unplanned circumstances, and could increase patient safety and quality of care. In cases of accidental spoilage (e.g., a vial that has been exposed to light or the wrong temperature), the

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[2] By way of contrast, a company could have a lifetime warranty on a zipper on its jackets. That warranty essentially indicates that the zipper is unbreakable, but if the zipper breaks for any reason (and thus, is not unbreakable), the company would repair or replace it. In the Proposed Arrangement, however, Requestor clearly states that the Products will spoil unless the Customer takes certain steps to ensure the Products' integrity.

[3] Although this arrangement does not fall within the definition of "written warranty," we note that a product could "fail to meet the specifications in the undertaking" for many reasons, including failure to meet quality standards or failing to achieve patient clinical results specified as targets at the time of sale. In such circumstances, the warranty safe harbor could apply, if other conditions of the safe harbor were met.

availability of a replacement Product under the Proposed Arrangement decreases the risk that a Customer might administer a potentially spoiled Product to avoid financial loss.

Second, the risk is low that the Proposed Arrangement would lead to increased costs or overutilization. The Proposed Arrangement would apply only to Products that Customers already selected and intended to use but did not administer to a patient or bill to a patient or third-party payor. If a Customer administered a Product to a patient, or billed a patient or payor, including a Federal health care program, for a Product, then a replacement Product would not be available under the Proposed Arrangement. Therefore, the Proposed Arrangement should not lead to increased costs or overutilization.

Third, the Proposed Arrangement would cover only individual claims of Spoiled Products—not large losses. In addition, the only remedy would be replacement of the same Product that the Customer had intended to use had it not been spoiled. Thus, although we recognize that the Proposed Arrangement potentially could have some impact on competition, we believe the risk is acceptably low that a Customer would select Requestor's Products over a competitor's products on the basis that Requestor would replace a Product that was inadvertently spoiled.

Finally, the Proposed Arrangement would bear some similarity to an insurance policy, the cost of which Requestor certified would be bundled into the price of the Products. Just as an insured driver or homeowner is unlikely to act recklessly in reliance on a vehicle or homeowner's insurance policy, we believe it is unlikely that the Proposed Arrangement would cause a Customer to change its behavior (e.g., a Customer would be unlikely to reduce costs currently expended to maintain an environment that should prevent spoilage). Moreover, the fact that a Customer would be required to complete an administrative process, including providing proof or an attestation of the spoilage and returning the Product or explaining why it can't be returned, further reduces the risk that the Proposed Arrangement would unduly influence the purchase of Products, or be abused, by Customers.

For the combination of the reasons set forth above, we conclude that the Proposed Arrangement poses a sufficiently low risk of fraud and abuse under the anti-kickback statute.

III. CONCLUSION

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