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, unless otherwise approved by the requestor(s).*]

Issued: June 25, 2025

Posted: June 30, 2025

[Address block redacted]

Re: OIG Advisory Opinion No. 25-05 (Favorable)

Dear [redacted]:

The Office of Inspector General ("OIG") is writing in response to your request for an advisory opinion on behalf of [redacted] ("Requestor"), regarding a proposed arrangement pursuant to which Requestor would offer up to $2,500 to reimburse purchasers for actual costs incurred associated with a needle stick injury caused by the failure of a device that Requestor manufactures (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement, if undertaken, 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").

Requestor has certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Proposed Arrangement, and we have relied solely on the facts and information Requestor provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestor. This opinion is limited to the relevant facts presented to us by Requestor in connection with the Proposed Arrangement. If material facts have not been disclosed, have been misrepresented, or change, then this opinion is without force and effect.

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement, if undertaken, would not generate prohibited remuneration under the Federal anti-kickback statute. Accordingly, OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement under section 1128A(a)(7) of the Act, as that section relates to the commission of acts described

in the Federal anti-kickback statute or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute.

This opinion may not be relied on by any person[1] other than Requestor and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

Requestor manufactures and distributes a device called the [redacted] (the "Device"). Purchasers of the Device include pharmacies, hospitals, clinics, and laboratories (the "Purchasers"). Health care practitioners employed by (or otherwise contracted with) Purchasers—including pharmacists, registered nurses, and medical doctors—administer immunizations and other drugs to patients via injections using the Device ("Authorized Users"). The Device has a safety mechanism that covers a needle except when the needle penetrates patient tissue during an injection, which safety mechanism is designed to protect Authorized Users from accidental needle contact. Requestor certified that, when Authorized Users suffer a needle stick injury, their employers typically cover the costs of services required as a result of the injury. According to Requestor, these costs may include retraining staff; staff absence and replacement; counseling for injured workers; and certain legal consequences.[2] The cost of one unit of the Device is [redacted], which is higher than typical needles.

Requestor proposes to offer up to $2,500 to reimburse a Purchaser for actual costs, such as those listed above, that the Purchaser incurs associated with a needle stick injury caused by the failure of the Device (and not Authorized User error). The Proposed Arrangement would apply only when the Purchaser has acknowledged and agreed to the terms of the Device's warranty, which provides that:

- the Proposed Arrangement benefits only the Purchaser and not third parties;

[1] We use "person" herein to include persons, as referenced in the Federal anti-kickback statute, as well as individuals and entities, as referenced in the exclusion authority at section 1128(b)(7) of the Act.

[2] For example, in some instances, an Authorized User subject to a needle stick may sue the Purchaser (i.e., their employer) for injuries allegedly related to the needle stick. In those cases, the Purchaser would be subject to litigation expenses such as legal fees and costs and payment of damages or settlement. If this type of litigation is covered by insurance, that may result in an increased premium. As another example, a needle stick that results in a worker's compensation claim (submitted by an Authorized User) may result in the Purchaser incurring an increased worker's compensation premium.

- Requestor warrants that the Device, if used in accordance with its descriptions and intended purpose, will not cause a needle stick injury to an Authorized User[3];

- Requestor's sole obligation, and the Purchaser's sole remedy, is a payment to the Purchaser equal to the amount of documented actual costs incurred by the Purchaser because of the failure of the Device and resulting needle stick injury to an Authorized User, up to the $2,500 limit;

- Requestor will not be liable to the Purchaser or any third party for any needle stick injury nor will Requestor indemnify any Purchaser or third party related to a needle stick injury; and

- the "warranty period" lasts for 1 year, starting from the date of purchase of the Device.

Requestor offers a warranty on only one item—the Device—and no services.[4] Requestor further certified that it does not condition the Proposed Arrangement on a Purchaser's exclusive use of, or a minimum purchase of, the Device.

II. LEGAL ANALYSIS

A. Law

The Federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an individual to a person for the furnishing of, or arranging for the furnishing of, any item or service reimbursable under a Federal health care program.[5] The statute's prohibition also extends to remuneration to induce, or in return for, the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by a Federal health care program.[6] For purposes of the Federal 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 is to induce referrals for items or services reimbursable by a Federal health care

[3] In the event an Authorized User is a Federal health care program enrollee, Requestor certified that it will not pay any remuneration to any individual or entity—including Purchaser—for any medical, surgical, or hospital expense incurred by the Authorized User.

[4] Requestor certified that no Purchaser has submitted a claim under the warranty from the date of the Device's FDA clearance ([redacted]) to March 20, 2025 (the date upon which Requestor last checked) and that it has no reason to believe any claims have been submitted since then.

[5] Section 1128B(b) of the Act.

[6] Id.

program.[7] Violation of the statute constitutes a felony punishable by a maximum fine of $100,000, imprisonment up to 10 years, or both. Conviction also will lead to exclusion from Federal health care programs, including Medicare and Medicaid. When a person commits an act described in section 1128B(b) of the Act, OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

Congress has developed several statutory exceptions to the Federal anti-kickback statute.[8] In addition, the U.S. Department of Health and Human Services ("HHS") has promulgated safe harbor regulations that specify certain practices that are not treated as an offense under the Federal anti-kickback statute and do not serve as the basis for an exclusion.[9] However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor. Compliance with a safe harbor is voluntary. Arrangements that do not comply with a safe harbor are evaluated on a case-by-case basis.

The safe harbor for warranties, 42 C.F.R. § 1001.952(g), potentially applies to the Proposed Arrangement. Under that provision, safe harbor protection is available to a "manufacturer or supplier" offering a warranty on an item, a bundle of items, or a bundle of one or more items and related services, and the safe harbor sets forth disclosure and reporting obligations that apply to the manufacturer or supplier and the "buyer." The warranties safe harbor also contains a definition of the term "warranty" specific to that safe harbor.

B. Analysis

The Proposed Arrangement implicates the Federal anti-kickback statute because Requestor would offer Purchasers something of value (i.e., a payment not to exceed $2,500 for actual costs incurred associated with a needle stick injury caused by the failure of the Device), which could induce Purchasers to buy the Device. However, we conclude that the Proposed Arrangement would be protected by the regulatory safe harbor for warranties.

The safe harbor for warranties defines "warranty" as:

> [a]ny written affirmation of fact or written promise made in connection with the sale of an item or bundle of items, or services in combination with one or more related items, by a manufacturer or supplier to a buyer, which affirmation of fact or written promise relates to the nature of the quality of workmanship and affirms or promises that such quality or

[7] 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).

[8] Section 1128B(b)(3) of the Act.

[9] 42 C.F.R. § 1001.952.

> workmanship is defect free or will meet a specified level of performance over a specified period of time.[10]

The terms of Requestor's warranty meet this definition. The warranty provides that the Device, if used in strict accordance with its descriptions and instructions for use and for its intended purposes, will not cause a needle stick injury to an Authorized User. The terms of the warranty also establish a specified period of time during which the Device will not cause a needle stick injury (i.e., for a 1-year period, beginning on the date of purchase of the Device).

In order to be protected by the safe harbor for warranties, both the buyer of an item under warranty and the manufacturer of the item offering the warranty must comply with each of the applicable elements set forth in the safe harbor. We address these elements in turn.

With respect to the elements assigned to the buyer, the buyer (unless the buyer is a Federal health care program enrollee) must fully and accurately report any price reduction of an item or service that was obtained as part of the warranty in the applicable cost reporting mechanism or claim for payment filed with HHS or a State agency.[11] In addition, the safe harbor for warranties requires that the buyer fully and accurately report any price reduction obtained via the warranty and provide it to the Secretary or State agency upon request.[12] Since the Proposed Arrangement does not include any price reductions—only a reimbursement for actual costs incurred associated with a covered needle stick injury—these standards are not applicable.

With respect to the standards assigned to the manufacturer, the safe harbor for warranties requires compliance with four elements. First, manufacturers must comply with certain requirements for reporting price reductions.[13] As discussed above, however, under the facts of the Proposed Arrangement there is no price reduction for Requestor to report, so this element is not applicable.

Second, the manufacturer must not pay any remuneration to any individual or entity for any medical, surgical, or hospital expense incurred by a Federal health care program enrollee other than for the cost of the items and services subject to the warranty.[14] Requestor certified that it would not pay remuneration to any individual or entity—including Purchaser—for any medical, surgical, or hospital expense incurred by an enrollee. Therefore, this element of the safe harbor is satisfied.

Third, if a manufacturer offers a warranty for more than one item or one or more items and related services, then the federally reimbursable items and services subject to the warranty must

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[10] 42 C.F.R. § 1001.952(g)(7)(i).

[11] 42 C.F.R. § 1001.952(g)(1).

[12] 42 C.F.R. § 1001.952(g)(2).

[13] 42 C.F.R. § 1001.952(g)(3).

[14] 42 C.F.R.§ 1001.952(g)(4).

be reimbursed by the same Federal health care program and in the same Federal health care program payment.[15] Here, Requestor offers a warranty on only one item—the Device—and no services, so there is no issue with respect to multiple Federal health care program payments, and this element is satisfied.

Fourth, a manufacturer must not condition a warranty on a buyer's exclusive use of, or a minimum purchase of, any of the manufacturer's items.[16] Requestor certified that it does not condition the Proposed Arrangement on a Purchaser's exclusive use of, or a minimum purchase of, the Device.

For the foregoing reasons we conclude that the Proposed Arrangement would be protected by the safe harbor for warranties and therefore would not generate prohibited remuneration under the Federal anti-kickback statute.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement, if undertaken, would not generate prohibited remuneration under the Federal anti-kickback statute. Accordingly, OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement under section 1128A(a)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is limited in scope to the Proposed Arrangement and has no applicability to any other arrangements that may have been disclosed or referenced in your request for an advisory opinion or supplemental submissions.

- This advisory opinion is issued only to Requestor. This advisory opinion has no application to, and cannot be relied upon by, any other person.

- This advisory opinion may not be introduced into evidence by a person other than Requestor to prove that the person did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

- This advisory opinion applies only to the statutory provisions specifically addressed in the analysis above. We express no opinion 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-

[15] 42 C.F.R. § 1001.952(g)(5).

[16] 42 C.F.R. § 1001.952(g)(6).

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 HHS.

- We express no opinion herein regarding the liability of any person 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.

OIG will not proceed against Requestor 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. 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, OIG will not proceed against Requestor 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 OIG.

Sincerely,

/Susan A. Edwards/

Susan A. Edwards
Assistant Inspector General for Legal Affairs