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: July 1, 2025

Posted: July 7, 2025

[Address block redacted]

Re: OIG Advisory Opinion No. 25-08 (Unfavorable)

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 Requestor's proposal to pay a third-party vendor to access an electronic billing system operated by the vendor that is used by some of Requestor's customers for certain billing operations (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 ("CMP") 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.

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 generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, which would constitute grounds for the imposition of sanctions under sections 1128A(a)(7) and 1128(b)(7) of the Act.

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 is a medical device company that supplies, among other offerings, "bill-only" surgical medical devices to hospitals, health systems, and ambulatory surgery centers ("Customers"). "Bill-only items" are items that are not part of a Customer's regularly purchased inventory but rather are purchased in real time, such as when a surgeon is selecting the right size or component of a device to use during a surgery. Typically, for bill-only items, a representative of Requestor delivers a selection of these items to a Customer the day before or the day of a patient's procedure so that the surgeon can select the specific items needed for that specific patient. Some of these bill-only items are used in procedures that may be reimbursable by Federal health care programs.

According to Requestor, Requestor's typical process for bill-only items involves a surgeon selecting and using one or more bill-only items in surgery, a member of the Customer's staff recording the items used, the Customer generating a purchase order, Requestor generating an invoice based on the purchase order, and the Customer paying Requestor for the invoiced items. Requestor certified that a third-party vendor is not required by Requestor for this process. Some Customers have engaged a third-party vendor, [redacted] (the "Vendor"), for the purpose of using the Vendor's software to facilitate their purchases of bill-only items from Requestor. Requestor certified that some Customers have begun requesting or requiring Requestor to use the Vendor to facilitate the Customers' purchases of the bill-only items instead of Requestor's typical process.

Specifically, under the Proposed Arrangement, the Vendor would charge Requestor to access the Vendor's bill-only portal (the "Bill-Only Portal") to process bill-only items for Customers that have selected the Vendor's software to facilitate their purchases. The Vendor would charge Requestor a licensing fee of approximately $395 a year for each of Requestor's representatives to use the Bill-Only Portal.[2] As a general matter, Requestor certified that there is one representative involved in each transaction, and the estimated number of Requestor's representatives that would need a Vendor license to submit bill-only invoices for any given year is 3,000 if each representative had at least one Customer that requested or required that Requestor pay the Vendor to use the Bill-Only Portal.[3] Based on this figure and the Vendor's

[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] The Vendor would assess separate licensing fees for each of Requestor's representatives who use the Bill-Only Portal. For example, if 10 representatives were working with 5 different Customers, the Vendor would charge Requestor the licensing fee 10 times.

[3] Requestor proposed paying one license fee per Customer to the Vendor, which Requestor would invoice back to each Customer, to ensure a centralized billing function in connection with

current undiscounted pricing, Requestor estimates that it would pay annual fees to the Vendor of around $1.2 million for Requestor's representatives. Requestor certified that it would not be a party to any agreements between Customers and the Vendor. While Requestor stated that the Vendor charges hospitals and other providers, including Customers, that use the Vendor's services ("Provider Clients"), Requestor certified that, despite multiple inquiries to the Vendor, Requestor has no visibility into the specific amounts the Vendor charges Provider Clients.[4]

Requestor certified that the Vendor asserts on its website that its Bill-Only Portal provides a host of benefits and services to Provider Clients. The Vendor would provide these benefits to any Customers that hire the Vendor. The Bill-Only Portal provides the following services to facilitate Provider Clients' purchases of bill-only items: capturing purchasing data when the Customer decides to purchase the bill-only item, confirming the accuracy of the data, routing the bill to the appropriate Provider Client personnel for approval, securing approval of the bill by the appropriate Provider Client personnel, and issuing the purchase order to Requestor's representative. Requestor certified that the Vendor's advertisements appear to Requestor to be geared exclusively toward potential Provider Clients and that its website focuses entirely on the benefits of the Bill-Only Portal to the Provider Clients, without discussing any benefits to manufacturers like Requestor. For example, one Vendor case study available on the Vendor's website states that one hospital working with the Vendor achieved $4 million in annual, recurring savings.

Requestor stated that it has not identified any appreciable benefits or services that it would receive by using the Bill-Only Portal, and it would not otherwise receive any necessary or desired services from the Vendor. Requestor stated that its understanding of the Bill-Only Portal is that Requestor's representatives would login and submit invoices and charges to the Bill-Only Portal and then receive purchase orders via the Bill-Only Portal. However, Requestor certified that it has well-established accounts receivable processes and teams that are intended to ensure that Customers timely receive and pay invoices. Requestor certified that the Bill-Only Portal is redundant to Requestor's existing activities and operations, which it would continue to operate

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the Bill-Only Portal. The Vendor objected to this proposal and indicated that Requestor must pay a license fee for each individual field representative working with Customers that use the Bill-Only Portal.

[4] Requestor asserts that the Vendor has represented to Requestor that Provider Clients that have engaged the Vendor have made significant financial payments or commitments for their subscription for the Bill-Only Portal well before Requestor or other manufacturers are asked to use the Bill-Only Portal. According to Requestor, the Vendor also noted that the price paid by manufacturers (or their representatives) does not influence or offset the amount paid by Provider Clients (i.e., Provider Clients do not pay less based on the number of representatives who register to use the Bill-Only Portal). Requestor certified that neither the Vendor nor any Customer has provided any documentation or other information to support these assertions.

for its Customers. As such, Requestor cannot certify that the fees that the Vendor would charge Requestor under the Proposed Arrangement are commercially reasonable.

Requestor stated that it would pay the Vendor's fees for one reason: to access the Bill-Only Portal in order to sell medical devices to Customers that opt to use the Vendor and that request or require, as a condition of doing business, that Requestor use the Bill-Only Portal. Nevertheless, Requestor certified that it would implement the Proposed Arrangement if it received a favorable advisory opinion as part of an effort to retain and potentially expand business from Customers that are Provider Clients. Requestor certified that at least one Customer removed Requestor from the Customer's preferred vendor list for bill-only products because Requestor objected to paying the Vendor to use the Bill-Only Portal. Because Requestor asserted to the Customer that it objected to the arrangement, the Vendor agreed to a temporary solution to provide Requestor one free, 12-month license to use the Bill-Only Portal for purposes of working with that Customer. However, Requestor certified that the Vendor indicated that this solution was not acceptable for future cases. Requestor stated that, notwithstanding this temporary arrangement, the Customer subsequently put Requestor's supply contract out to bid via a formal request for proposal.

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 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

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

[6] Id.

[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).

CMPs 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 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 personal services and management contracts and outcomes-based payment arrangements[10] is potentially applicable to the Proposed Arrangement. In relevant part for purposes of this advisory opinion, the safe harbor requires that the services contracted for must not exceed those reasonably necessary to accomplish the commercially reasonable business purpose of the services.[11]

B. Analysis

The Proposed Arrangement would implicate the Federal anti-kickback statute because Requestor would pay the Vendor fees to use the Bill-Only Portal through which the Vendor would arrange for Customers' purchases of its bill-only items used in procedures, some of which may be reimbursable by Federal health care programs. Additionally, Requestor's use of the Bill-Only Portal and corresponding payments to the Vendor, which would enable Customers to use the Vendor to purchase bill-only items from Requestor, may result in cost savings to Customers, and thus Requestor's payments to the Vendor may constitute remuneration to Customers to induce the purchase of medical devices that may be reimbursable by a Federal health care program.

No safe harbor applies to the Proposed Arrangement. Because Requestor cannot certify that the aggregate services contracted for would not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the service, the Proposed Arrangement would not be protected by the safe harbor for personal services and management contracts and outcomes-based payment arrangements. In the absence of safe harbor protection, we analyze the Proposed Arrangement based on the totality of the facts and circumstances.

Under the Proposed Arrangement, Requestor would pay substantial fees to access the Bill-Only Portal as part of an effort to retain and potentially expand business from Customers that are Provider Clients. This would be true even though the Bill-Only Portal would be redundant to

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

[9] 42 C.F.R. § 1001.952.

[10] Id. § 1001.952(d).

[11] Id. § 1001.952(d)(1)(vi).

Requestor's well-established accounts receivable processes and teams that are intended to ensure that Customers timely receive and pay invoices (which Requestor would continue to operate for its Customers).

The Proposed Arrangement presents anti-competitive risks and risks of inappropriate steering. Because the Bill-Only Portal evidently has value to Customers—as demonstrated by the fact that some Customers would require use of the Bill-Only Portal as a condition of doing business, as well as Vendor marketing materials touting cost savings for Provider Clients—the payments Requestor would make to the Vendor under the Proposed Arrangement could inappropriately steer Customers to Requestor over Requestor's competitors that are not able or willing to pay those fees. In fact, one Customer removed Requestor from the Customer's preferred vendor list for bill-only products because Requestor did not agree to pay the Vendor to use the Bill-Only Portal, and the Customer subsequently put Requestor's supply contract out to bid via a formal request for proposal.

We acknowledge that there are myriad ways for parties to structure business arrangements to allocate responsibilities and that there may be different fact patterns that would result in OIG reaching a favorable conclusion in an advisory opinion; however, we are limited to opining on the facts before us, and here—where the Proposed Arrangement does not serve a commercially reasonable business purpose for Requestor—the payments Requestor would make to the Vendor appear to be for the purpose of accessing referrals from Customers that are Provider Clients. Indeed, Requestor certified that the Proposed Arrangement would be part of an effort to retain and potentially expand business from Customers that are Provider Clients.

For the foregoing reasons, we conclude that the Proposed Arrangement is not sufficiently low risk for OIG to issue a favorable advisory opinion.

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 generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, which would constitute grounds for the imposition of sanctions under sections 1128A(a)(7) and 1128(b)(7) of the Act.

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-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.

- 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 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.

Sincerely,

/Susan A. Edwards/

Susan A. Edwards
Assistant Inspector General for Legal Affairs