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: September 25, 2023

Posted: September 28, 2023

[Address block redacted]

Re: OIG Advisory Opinion No. 23-06 (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 the proposed purchase of the technical component of anatomic pathology services from certain laboratories (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.

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 prohibited remuneration under the Federal anti-kickback statute, if the requisite intent were present, 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 operates anatomic pathology laboratories across the United States. Commercial payors reimburse Requestor for anatomic pathology services through two components: technical and professional. Requestor stated that, as a general matter, the technical component covers the physical preparation of the specimen, which results in the production of a glass slide for review by a pathologist. The professional component covers the analysis of the slide by the pathologist, the outcome of which is then reported to the referring physician. Requestor certified that a significant proportion of the anatomic pathology testing it performs at its laboratories is a result of referrals from physicians who order tests to assist them in diagnosing and treating patients.

Requestor has been approached by certain laboratories that propose to enter into arrangements with Requestor involving anatomic pathology services performed for patients insured by commercial payors, i.e., the arrangements would not involve the referral of or billing for anatomic pathology services reimbursable by Federal health care programs. The laboratories that have contacted Requestor fall into one of two categories: (i) laboratories owned, in whole or in part, by physicians who may refer patients for anatomic pathology laboratory services ("Referring Physicians") and laboratories that employ Referring Physicians ("Physician Laboratories"); or (ii) laboratories that are not owned by Referring Physicians and do not employ Referring Physicians ("Non-Physician Laboratories"). According to Requestor, Physician Laboratories, including their Referring Physician-owners and Referring Physician-employees, and Non-Physician Laboratories would be in a position to refer laboratory business to Requestor, including laboratory services billable to Federal health care programs.

Under the Proposed Arrangement, Requestor would enter into written agreements[2] with Physician Laboratories and Non-Physician Laboratories that would require Requestor to purchase the technical component of anatomic pathology services from the Physician Laboratory or Non-Physician Laboratory for certain anatomic pathology tests for commercially insured patients. Specifically, (i) the Physician Laboratory or Non-Physician Laboratory would perform the technical component of the referred sample; (ii) Requestor then would perform the professional component and would bill commercial insurers as an in-network provider for both

[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] Requestor certified that the Proposed Arrangement, as would be documented through written agreements, would satisfy the conditions set forth in the personal services and management contracts and outcomes-based payment arrangements safe harbor except the requirement that the aggregate services contracted for would not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

the technical and professional components;[3] and (iii) Requestor would pay the referring laboratory a fair market value, per-specimen fee[4] for performing the technical component of the referred tests.

According to Requestor, although some Physician Laboratories and Non-Physician Laboratories may have the capability to perform both the professional and technical components themselves, they wish to enter into the Proposed Arrangement because they are unable to bill certain commercial payors for anatomic pathology services, or they are not in-network with certain commercial payors. Under the Proposed Arrangement, Physician Laboratories and Non-Physician Laboratories would have the opportunity to perform, and receive payment for, a portion of those services, while Requestor—which has contracts with third-party payors allowing it to bill for anatomic pathology services—would perform the remaining portion and bill payors for both components of the service.

Requestor also certified that, although the fee it would pay to Physician Laboratories and Non-Physician Laboratories under the Proposed Arrangement would be fair market value for technical component services, Requestor, in most instances, has the capability to perform both components itself. According to Requestor, performing both components itself is generally both more efficient and more cost-effective than paying a third-party laboratory to perform the technical component. In other words, Requestor generally can perform the technical component in-house at a lower cost than the amount it would pay a Physician Laboratory or Non-Physician Laboratory to perform that component. Without implementation of the Proposed Arrangement, Requestor itself would have the opportunity to perform, bill for, and retain the full reimbursement for anatomic pathology services billable to commercial payors, rather than sharing a portion of the work—and a portion of the reimbursement—with a third-party laboratory such as a Physician Laboratory or Non-Physician Laboratory. In addition, Requestor certified that, because Physician Laboratories and Non-Physician Laboratories currently lack contracts that would give them the ability to bill certain commercial insurers for anatomic pathology services as in-network providers, Referring Physicians would be more likely to refer anatomic pathology services to other laboratories—including Requestor—that maintain contracts with commercial insurers to bill for those services.

Physician Laboratories and Non-Physician Laboratories would not be required to refer any Federal health care program business to Requestor as a condition of participating in the Proposed Arrangement, and they would retain the right to refer patients to other laboratories. Nevertheless, Requestor certified that entering into the Proposed Arrangement likely would result in referrals of Federal health care program business to Requestor from Physician Laboratories and Non-Physician Laboratories. Conversely, Requestor predicted that if it did not enter into the Proposed Arrangement, it likely would not receive a significant volume of referrals

[3] Requestor certified that the commercial insurers with which it contracts allow billing in this manner.

[4] We are precluded by statute from opining on whether fair market value shall be, or was, paid for goods, services, or property. Section 1128D(b)(3)(A) of the Act.

of Federal health care program business from Physician Laboratories or Non-Physician Laboratories.

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 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 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.

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[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).

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

[9] 42 C.F.R. § 1001.952.

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 it would involve the payment of remuneration by Requestor to a party that is in a position to make referrals to Requestor for items and services that may be paid for, in whole or in part, by a Federal health care program. In particular, according to Requestor, Physician Laboratories (including their Referring Physician-owners and Referring Physician-employees) and Non-Physician Laboratories would be in a position to refer laboratory business to Requestor, including laboratory services billable to Federal health care programs.

Although the Proposed Arrangement would "carve out" Federal health care program business, i.e., it would not involve the referral of or billing for anatomic pathology services reimbursable by Federal health care programs, this carve out is not dispositive with respect to whether the Proposed Arrangement implicates the Federal anti-kickback statute. OIG has a longstanding concern about arrangements under which parties carve out referrals of Federal health care program beneficiaries or Federal health care program business from otherwise questionable financial arrangements. Such arrangements implicate, and may violate, the Federal anti-kickback statute by disguising remuneration for Federal health care program business through the payment of amounts purportedly related to non-Federal health care program business.[12]

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[10] Id. § 1001.952(d).

[11] Id. § 1001.952(d)(1)(vi).

[12] OIG elaborated on the fraud and abuse risks of carve outs in certain laboratory specimen processing arrangements in 2014:

> OIG's concerns regarding Specimen Processing Arrangements are not abated when those arrangements apply only to specimens collected from non-Federal health care program patients. Arrangements that "carve out" Federal health care program beneficiaries or business from otherwise questionable arrangements implicate the anti-kickback statute and may violate it by disguising remuneration for Federal health care program business through the payment of amounts purportedly related to non-Federal health care program business. Because physicians typically wish to minimize the number of laboratories to which they refer for reasons of convenience and administrative efficiency, Specimen Processing Arrangements that carve out Federal health care program business

Under the Proposed Arrangement, the remuneration paid from Requestor to Physician Laboratories and Non-Physician Laboratories may increase the likelihood that these entities or their affiliated Referring Physicians would order services from Requestor that are billable to Federal health care programs. We cannot conclude that there would be no nexus between the remuneration paid as part of the Proposed Arrangement and potential referrals to Requestor for services reimbursable by Federal health care programs.

The Proposed Arrangement would not be protected by the safe harbor for personal services and management contracts and outcomes-based payment arrangements. In particular, Requestor was unable to certify that the aggregate services contracted for would not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

Arrangements that do not fit in a safe harbor must be evaluated under the Federal anti-kickback statute on a case-by-case basis, based on the totality of the facts and circumstances. Here, the Proposed Arrangement would allow Requestor to give Physician Laboratories and Non-Physician Laboratories the opportunity to bill and receive payment for services they otherwise would not be able to bill for as in-network providers. Requestor has certified that: (i) in most instances, it is already capable of performing both components of anatomic pathology services without referring the technical component to a third-party lab; (ii) performing both components in-house is generally more efficient and cost-effective than paying a third-party lab; and (iii) at present, Referring Physicians are more likely to refer anatomic pathology services to laboratories that have contracts with commercial payors, like Requestor. It is difficult to discern any commercially reasonable business purpose for Requestor to enter into the Proposed Arrangement—forgoing the opportunity to bill and retain payment for both components of the anatomic pathology services, in an arrangement that is both less efficient and more costly—other than the possibility that such payment may induce referrals of patients, including Federal health care program beneficiaries.

Indeed, Requestor certified that the Proposed Arrangement is likely to result in referrals of Federal health care program business from Physician Laboratories and Non-Physician Laboratories to Requestor. Based on these certifications, the Proposed Arrangement appears designed to influence Physician Laboratories (or their Referring Physician-owners and Referring Physician-employees) and Non-Physician Laboratories to refer other specimens to Requestor for testing, including testing that may be reimbursable, in whole or in part, by a Federal health care program. As a result, there is a significant risk that the Proposed Arrangement would function, at least in part, as an opportunity for Requestor to pay valuable remuneration to a potential source of referrals for laboratory services to induce Physician Laboratories and Non-Physician

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may nevertheless be intended to influence physicians' referrals of Federal health care program business to the offering laboratories.

OIG, Special Fraud Alert: Laboratory Payments to Referring Physicians 5 (2014), https://oig.hhs.gov/documents/special-fraud-alerts/866/OIG_SFA_Laboratory_Payments_06252014.pdf.

Laboratories to refer laboratory services reimbursable by Federal health care programs to Requestor.

Requestor certified that the compensation it would pay to Physician Laboratories and Non-Physician Laboratories under the Proposed Arrangement would be consistent with fair market value and that Physician Laboratories and Non-Physician Laboratories would not be required to refer Federal health care program business to Requestor. These facts would not protect the Proposed Arrangement from implicating, and potentially violating, the Federal anti-kickback statute. As we have previously stated:

> The anti-kickback statute is implicated when a clinical laboratory pays a physician for services. Whether an actual violation of the statute occurs depends on the intent of the parties—the anti-kickback statute prohibits the knowing and willful payment [by a clinical laboratory for services] if even one purpose of the payment is to induce or reward referrals of Federal health care program business. This is true regardless of whether the payment is fair market value for services rendered.[13]

Here, the Proposed Arrangement could give rise to a significant incentive for the Physician Laboratories and Non-Physician Laboratories to refer patients, including Federal health care program beneficiaries, to Requestor. The Proposed Arrangement could result in the selection of a laboratory that offers the most remuneration to the Physician Laboratories and Non-Physician Laboratories—remuneration they otherwise would not have been able to realize—rather than the highest quality and most appropriate laboratory for patients. Not only would the Proposed Arrangement create the potential for patient steering, but it also could result in unfair competition by favoring laboratories in the competitive marketplace that are willing and able to pay Physician Laboratories and Non-Physician Laboratories technical component fees.

Based on the foregoing, we conclude that the risk of fraud and abuse presented by the Proposed Arrangement is not sufficiently low under the Federal anti-kickback statute 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 prohibited remuneration under the Federal anti-kickback statute, if the requisite intent were present, 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:

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[13] Id. at 4.

- 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 or entity other than Requestor 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 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
Acting Assistant Inspector General for Legal Affairs