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: April 25, 2022

Posted: April 28, 2022

[Address block redacted]

Re: OIG Advisory Opinion No. 22-09

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 compensate hospitals for certain specimen collection services for laboratory tests furnished by Requestor (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 in connection with the Proposed Arrangement 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 a network of clinical laboratories, including a number of locations that collect, process, and handle specimens sent to these laboratories for testing. Under the Proposed Arrangement, Requestor would enter into contracts with hospitals throughout the country (the "Contract Hospitals"), pursuant to which Requestor would pay the Contract Hospitals on a per-patient-encounter basis to collect, process, and handle specimens that are then sent to Requestor's clinical laboratories for testing (the "Services"). Requestor would bill any applicable third-party payor, including Federal health care programs, for the testing. The Services would be performed by a hospital-employed or hospital-contracted phlebotomist at the Contract Hospital. Under the Proposed Arrangement, Requestor would compensate Contract Hospitals only for the Services performed in connection with individuals who present with orders for testing and who are not currently inpatients or registered outpatients of the Contract Hospital; Requestor would not compensate Contract Hospitals if the Services are performed in connection with individuals who are currently inpatients or registered outpatients of the Contract Hospital. When individuals present to a Contract Hospital with laboratory testing orders that do not specify which laboratory will conduct the testing, the Contract Hospital would have the opportunity to choose to which laboratory it would send the specimens.

Requestor certified that the Proposed Arrangement would: (i) be set out in a writing signed by the parties; (ii) cover all of the services to be provided; and (iii) be for a term of at least 1 year. Requestor further certified that the Services performed under the Proposed Arrangement would not exceed those that are reasonably necessary to accomplish the commercially reasonable business purpose of the Proposed Arrangement. Requestor also certified that the per-patient-encounter compensation rate would be consistent with fair market value for the Services in an arm's-length transaction. Contracts between Contract Hospitals and Requestor would prohibit Contract Hospitals from separately billing any payors or patients for the Services performed under the Proposed Arrangement.[2]

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[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] As discussed more fully in OIG's Special Fraud Alert: Laboratory Payments to Referring Physicians, "Medicare allows the person who collects a specimen to bill Medicare for a nominal specimen collection fee in certain circumstances, including times when the person draws a blood sample through venipuncture (i.e., inserting into a vein a needle with syringe or vacuum tube to draw the specimen). . . . Medicare [also] reimburses . . . for processing and packaging specimens for transport to a clinical laboratory through a bundled payment." OIG Special Fraud Alert: Laboratory Payments to Referring Physicians (June 25, 2014), https://oig.hhs.gov/documents/special-fraud-alerts/866/OIG_SFA_Laboratory_Payments_06252014.pdf.

The Contract Hospitals directly employ or contract with physicians. Additionally, physician practices or medical groups may be owned by or under common ownership with the Contract Hospitals ("Affiliated Practices"). Requestor certified that, under the Proposed Arrangement, each Contract Hospital would be required to represent and warrant that none of the Contract Hospital's employed physicians, contracted physicians, or Affiliated Practices: (i) would be required or directed to refer to Requestor; and (ii) would receive any remuneration from the Contract Hospital for any referrals to Requestor.

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.[3] 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.[4] 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.[5] 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, the OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. The 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.[6] 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-

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

[4] Id.

[5] 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).

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

kickback statute and do not serve as the basis for an exclusion.[7] 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, 42 C.F.R. § 1001.952(d), is potentially applicable to the Proposed Arrangement. In relevant part for purposes of this advisory opinion, this safe harbor requires that the methodology for determining the compensation paid for services not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties.[8]

B. Analysis

The Proposed Arrangement would implicate the Federal anti-kickback statute because it would involve remuneration from a laboratory to a party that is in a position to make referrals to the laboratory for, or otherwise arrange for the laboratory to furnish, items and services that may be paid for in whole or in part by a Federal health care program. Specifically, where an individual—who may be a Federal health care program beneficiary—presents to a Contract Hospital without a laboratory specified on the order for laboratory services, the Contract Hospital could refer specimens from that individual to Requestor for reimbursable testing. Indeed, because of the per-patient-encounter fees paid by Requestor for the Services (which Contract Hospitals agree to receive in lieu of any reimbursement for the Services from a third-party payor), Contract Hospitals have a financial incentive to direct any such specimens to Requestor for the furnishing of laboratory services. The Proposed Arrangement would not be protected by the safe harbor for personal services and management contracts and outcomes-based payment arrangements because the per-patient-encounter compensation methodology would take into account the volume or value of referrals or other business generated for which payment may be made in whole or in part under a Federal health care program.

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. The Proposed Arrangement warrants careful scrutiny because: (i) in our experience, laboratory services may be particularly susceptible to the risk of steering; and (ii) the Proposed Arrangement would involve a "per-click" fee structure (in the form of a per-patient-encounter compensation methodology), which generally is inherently reflective of the volume or value of referrals or business otherwise generated between the parties. Here, the per-patient-encounter fee that would be offered under the Proposed Arrangement could induce Contract Hospitals to refer specimens to Requestor for testing, including testing that may be reimbursable, in whole or in part, by a Federal health care program. While Requestor certified that the compensation it would pay Contract Hospitals for the Services would be consistent with fair market value and that contracts for the Proposed Arrangement would specify that the Contract Hospitals would be

[7] 42 C.F.R. § 1001.952.

[8] See 42 C.F.R. § 1001.952(d)(1)(iv).

prohibited from separately billing any payors or patients for the Services performed, these safeguards do not overcome the risk of inappropriate steering to Requestor given the financial incentive inherent to a per-patient-encounter compensation methodology.[9]

In addition, while Requestor certified that, under the Proposed Arrangement, the Contract Hospitals would be required to represent and warrant that none of their employed physicians, contracted physicians, and Affiliated Practices would be required to refer, or directed to refer, to Requestor, this safeguard also does not sufficiently mitigate the risk of inappropriate steering. Contract Hospitals have an incentive to encourage their employed physicians, contracted physicians, and Affiliated Practices to order laboratory services from Requestor because the amounts paid by Requestor to the Contract Hospitals could be used by the Contract Hospitals to offset the costs they incur to employ or contract with personnel to perform specimen collection services for all of the Contract Hospital's patients, including those carved out of the Proposed Arrangement.

Based on the foregoing, because of the possibility that the per-patient-encounter fee would be used to induce or reward referrals to Requestor and the corresponding risk of inappropriate steering to Requestor, we conclude that the Proposed Arrangement would pose more than a minimal risk of fraud and abuse 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 generate prohibited remuneration under the Federal anti-kickback statute, if the requisite intent were present, which would constitute grounds for the imposition of sanctions in connection with the Proposed Arrangement 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.

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[9] As we have previously stated, "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." OIG Special Fraud Alert: Laboratory Payments to Referring Physicians (June 25, 2014), https://oig.hhs.gov/documents/special-fraud-alerts/866/OIG_SFA_Laboratory_Payments_06252014.pdf.

- 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. 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.

Sincerely,

/Robert K. DeConti/

Robert K. DeConti
Assistant Inspector General for Legal Affairs