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: January 13, 2026

Posted: January 16, 2026

[Address block redacted]

Re: OIG Advisory Opinion No. 26-01 (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 proposal to waive any applicable cost sharing for certain commercially insured patients who receive a test manufactured and performed 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 civil monetary penalty provision at section 1128A(a)(7) of the Social Security Act (the "Act"), as that section relates to the commission of acts described in section 1128B(b) of the Act (the "Federal anti-kickback statute"); the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act (the "Beneficiary Inducements CMP"); 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 and the Beneficiary Inducements CMP.

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 or Beneficiary Inducements CMP. 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; the Beneficiary Inducements CMP; 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 and the Beneficiary Inducements CMP.

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 [redacted] (the "Test"), a clinical laboratory test for colorectal cancer screening approved by the U.S. Food & Drug Administration ("FDA") in 2024. Requestor certified that the Test is the first and only FDA-approved, non-invasive, stool-based RNA colorectal cancer screening test available to patients who are age 45 years or older and at average risk for developing colorectal cancer.[2] Requestor is the only laboratory that performs the Test.

The U.S. Preventive Services Task Force ("USPSTF") has designated colorectal cancer screening as a grade "A" recommendation for patients aged 50-75, a grade "B" recommendation for patients aged 45-49, and a grade "C" recommendation for patients aged 76-85.[3] The USPSTF specifies certain categories of colorectal cancer screening tests in its recommendation. The Test was approved by the FDA in 2024, and this type of test is not currently included in the USPSTF recommendation. The USPSTF has not updated its guidelines for colorectal cancer screening since 2021, and Requestor understands that they may not update this recommendation for several years. Requestor certified it will seek inclusion of stool-based RNA colorectal cancer

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

[2] Other colorectal cancer screening methods include a high-sensitivity guaiac fecal occult blood test, a fecal immunochemical test ("FIT"), a stool DNA-FIT, a computed tomography colonography, a flexible sigmoidoscopy, a flexible sigmoidoscopy + annual FIT, and a colonoscopy.

[3] USPSTF, Final Recommendation Statement, Colorectal Cancer: Screening (May 18, 2021), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening. A grade "A" designation means that the "USPSTF recommends the service [and] there is high certainty that the net benefit is substantial." A grade "B" designation means that the "USPSTF recommends the service [and] there is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial." A grade "C" designation means the "USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences [and] [t]here is at least moderate certainty that the net benefit is small." USPSTF, Grade Definitions, https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/methods-and-processes/grade-definitions.

screening tests in the USPSTF colorectal cancer screening recommendation in the next update to the guidelines.

Commercial health insurers are required to cover preventive services with an A or B rating from the USPSTF without cost sharing.[4] Since the Test is not covered under the USPSTF recommendation, Requestor understands that some commercial health insurers are likely to impose cost-sharing requirements on the Test—typically between $100 and $135—but not on similar, competing tests currently included in the USPSTF recommendation. Requestor certified that, currently, no Federal health care program, other than fee-for-service Medicaid programs in 16 states and certain Medicaid Managed Care Organizations ("MMCOs"), covers the Test. Further, Requestor certified that, while most state Medicaid plans do not have cost sharing for laboratory tests, even if there is cost sharing, Requestor's provider enrollment agreements with the Medicaid programs prohibit it from collecting any cost sharing from Medicaid patients. Additionally, to the extent that any MMCOs impose cost sharing, Requestor certified that those patients have an income that qualifies them for its financial assistance policy and waives any applicable any cost-sharing obligation pursuant to that policy.[5]

Under the Proposed Arrangement, Requestor would waive any applicable cost-sharing amounts for commercially insured individuals who receive the Test and who do not otherwise qualify for Requestor's financial assistance policy ("Eligible Patients").[6] The cost-sharing waiver would apply uniformly to all Eligible Patients regardless of which provider orders the Test and would not be tied to any other health care item or service. Requestor would comply with all applicable Federal and State billing requirements and would not shift any costs associated with the Proposed Arrangement onto any Federal health care program. The Proposed Arrangement would continue until the USPSTF updates its colorectal cancer screening recommendations to include the Test, regardless of what grade the Test is assigned, which would render the Proposed Arrangement superfluous. Additionally, Requestor would not offer or pay any remuneration to any ordering prescriber in connection with the Proposed Arrangement.

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[4] See 42 U.S.C. § 300gg-13(a)(1).

[5] Requestor has not asked us to opine on, and we express no opinion regarding, Requestor's financial assistance policy.

[6] If an individual has commercial insurance as secondary insurance, then the secondary commercial payor would be billed before the cost-sharing waiver would be applied. If a Federal health care program is the secondary insurer, then Requestor would not bill the Federal health care program as the secondary insurer and would waive the cost sharing. Notwithstanding this, Requestor certified that there may be circumstances in which an individual's commercial insurance would automatically route the claim to a Federal health care program as secondary insurance, and Requestor would be unable to prevent the Federal health care program from being billed as a secondary payor.

II. LEGAL ANALYSIS

A. Law

1. Federal Anti-Kickback Statute

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.[7] 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.[8] 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.[9] 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.

2. Beneficiary Inducements CMP

The Beneficiary Inducements CMP provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. OIG also may initiate administrative proceedings to exclude such person from Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of the Beneficiary Inducements CMP as including "transfers of items or services for free or for other than fair market value."

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

[8] Id.

[9] 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).

B. Analysis

Requestor proposes to waive any applicable cost sharing for Eligible Patients. The Federal anti-kickback statute would not be implicated because there would be no remuneration offered or given to induce any patient to purchase an item or service reimbursable by a Federal health care program; the Beneficiary Inducements CMP would not be implicated because there would be no offer or transfer of remuneration to any Medicare or State health care program enrollee that could influence such individual to order or receive the Test or other items or services from Requestor. Additionally, Requestor would not offer or pay any remuneration to any ordering prescriber in connection with the Proposed Arrangement.[10]

While we recognize that some of the commercially insured individuals could have Federal health care program coverage as their secondary insurance, Requestor certified it would not bill Federal health care programs in that scenario. Additionally, if a Federal health care program is automatically billed by commercial insurance as a secondary payor, then the Federal health care program likely would deny coverage since the Test is not currently covered by any Federal health care programs, except for a few state fee-for-service Medicaid programs (and in those cases Requestor is prohibited from collecting any remaining cost sharing from those individuals).[11] Therefore, even in this circumstance, the Federal anti-kickback statute would not be implicated because the cost-sharing waiver would not be remuneration given to induce the purchase of an item or service reimbursable by a Federal health care program, nor would the Beneficiary Inducements CMP be implicated because there would be no offer or transfer of remuneration to any Medicare or State health care program enrollee that could influence such individual to order or receive the Test or other items or services for which payment might be made by Medicare or a State health care program from Requestor.[12]

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[10] We have previously opined that offering a free test could confer value to a prescriber by enabling them to offer a service at no cost to them or their patients, which may create an opportunity for providers to bill for other services. Here, however, since the remuneration would be offered only to commercially insured patients, and any additional services also would be billed to commercial insurers, the opportunity for a prescriber to earn a fee though the Proposed Arrangement does not implicate the Federal anti-kickback statute.

[11] Requestor certified that, pursuant to Requestor's financial assistance policy, it already waives cost sharing for patients for whom an MMCO is a secondary payor and who otherwise are responsible for any remaining cost sharing required by the MMCO for the Test. We have not been asked to opine, and express no opinion, regarding these cost-sharing waivers.

[12] We note that the limited Federal health care program coverage of the Test minimizes the possibility that Requestor would waive cost sharing for a Federal health care program enrollee for an item or service for which payment might be made by a Federal health care program. Should Federal health care program coverage of the Test expand and include circumstances where enrollees would be responsible for cost sharing, the risk of inadvertently waiving cost sharing for a Federal health care program enrollee increases, and we may come to a different conclusion.

Importantly, the Proposed Arrangement is distinguishable from other arrangements that "carve out" Federal health care program business. OIG has longstanding and continuing concerns about arrangements under which parties carve out referrals of Federal health care program enrollees or Federal health care program business from otherwise questionable financial arrangements.[13] 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. However, such concerns are not present here because of the circumstances described above combined with the fact that Requestor would not offer or pay any remuneration to any ordering prescriber in connection with the Proposed Arrangement.

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 or Beneficiary Inducements CMP. 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; the Beneficiary Inducements CMP; 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 and the Beneficiary Inducements CMP.

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-

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

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 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