



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: May 15, 2026

Posted: May 20, 2026

[Address block redacted]

Re: OIG Advisory Opinion No. 26-11 (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 an arrangement pursuant to which Requestor provides consenting patients a supplemental report at no cost in connection with a cancer screening test (the “Arrangement”). Specifically, you have inquired whether the Arrangement constitutes 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 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 advisory opinion is limited to the relevant facts presented to us by Requestor in connection with the Arrangement. If material facts have not been disclosed, have been misrepresented, or change, then this advisory 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: (i) although the Arrangement would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts

described in the Federal anti-kickback statute; and (ii) although the Arrangement generates prohibited remuneration under the Beneficiary Inducements CMP, OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under the Beneficiary Inducements CMP or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

This advisory opinion may not be relied on by any person¹ other than Requestor, has no applicability to any arrangements other than the Arrangement, 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 precision oncology company that offers a proprietary blood-based biomarker test for colorectal cancer (“CRC”) screening (the “CRC Screening Test”), which is the first blood-based biomarker test approved by the U.S. Food & Drug Administration (the “FDA”) for primary CRC screening. Requestor certified that the CRC Screening Test typically is ordered by a patient’s primary care provider. Then, Requestor performs the CRC Screening Test in its laboratory.² The CRC Screening Test is covered by Medicare once every 3 years for patients who meet the coverage requirements.³ Requestor certified that the CRC Screening Test may find the presence of cancer types other than CRC.

Requestor has developed an algorithmic analysis that identifies risks for multiple cancers simultaneously (the “Algorithm”). The Algorithm is part of an investigational assay under development for submission to the FDA as an in vitro diagnostic medical device (the “MCD

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 Requestor’s laboratory is certified to perform high complexity clinical testing under the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”). No other laboratory performs the CRC Screening Test.

³ While the CRC Screening Test is covered by Medicare, it is not currently listed in the U.S. Preventive Services Task Force (“USPSTF”) Guide to Clinical Preventive Services (the “Guide,” which recommendations, we note, are now reflected on the USPSTF website at <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics>). The Guide recommends that all Americans aged 45 to 75 receive routine CRC screening, and Requestor certified that the Guide’s recommendation is written broadly to include high-sensitivity CRC screening modalities like the CRC Screening Test. However, the CRC Screening Test was approved by the FDA after the last update to the Guide and thus is not currently included.

Test”⁴). The MCD Test received Breakthrough Device designation⁵ in June 2025 and has been validated in accordance with CLIA. Prior to FDA approval, which Requestor believes is needed to establish the MCD Test as a stand-alone test covered by Medicare and other third-party payors, Requestor is offering the MCD Test as optional, medically relevant additional information in connection with orders for the CRC Screening Test. The MCD Test generates information on the detection of different types of cancer: e.g., bladder, breast, CRC, esophageal, gastric, liver, lung, ovarian, pancreatic, and prostate.⁶

Requestor certified that, for 6 of the cancers detected by the MCD Test, there currently is no USPSTF-recommended screening test due to the lack of available screening tests where the benefit outweighs the harm (e.g., options are too invasive or complicated for population-wide screening).

Under the Arrangement, for consenting patients, including Federal health care program enrollees, Requestor provides for free a supplemental report expressing the MCD Test results (the “Supplemental Report”) in addition to the primary results report from the CRC Screening Test.⁷ The Supplemental Report includes a positive or negative result for each of the types of cancer based on the MCD Test.

To be eligible to receive the Supplemental Report under the Arrangement: (i) the patient must have a valid order for the CRC Screening Test from an independent physician who is not affiliated with Requestor and who will use the results in the management of the patient;⁸ (ii) the

⁴ We use the defined term “MCD Test” for simplicity. However, at this time, no separate test is run on the blood sample; the Algorithm is run on the same blood sample used for the CRC Screening Test to generate information about the different cancer types.

⁵ Requestor certified that the FDA grants Breakthrough Device designation to a limited set of qualifying devices that have the potential to provide for more effective treatment or diagnosis of life-threatening diseases than current options. See also, FDA, Breakthrough Devices Program, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program> (accessed May 11, 2026).

⁶ Requestor certified that these listed cancer types account for nearly 400,000 deaths each year in the United States and approximately 64 percent of all cancer-related deaths. See National Institutes of Health, Cancer State Facts: Common Cancer Sites, <https://seer.cancer.gov/statfacts/html/common.html> (accessed May 11, 2026).

⁷ The CRC Screening Test is the only test in Requestor’s screening portfolio in the United States. While Requestor offers other non-screening oncology tests, the Supplemental Report is not and will not be offered in connection with the other tests.

⁸ Requestor certified that the CRC Screening Test may be ordered in other circumstances (e.g., at events for cancer awareness) but that those tests are not billed to Medicare and are not included in the Arrangement. We have not been asked about, and we express no opinion regarding, CRC Screening Tests or Supplemental Reports that are provided outside of the Arrangement.

ordering physician must opt in to receive results for other cancers beyond CRC; and (iii) the patient must sign a form consenting to receive the Supplemental Report and participate in a data collection initiative. Requestor certified that the data collection initiative is for the purposes of evaluating clinical utility of the Supplemental Report and supporting its application for FDA approval and future payor coverage of the MCD Test, among other uses related to the MCD Test. Specifically, patients who wish to receive the Supplemental Report sign an authorization that Requestor certified complies with State and Federal privacy requirements pursuant to which the patient agrees to release medical information⁹ such as medical visit notes, medications, discharge summaries, imaging reports (along with associated images), laboratory results (including those performed at external laboratories), consultation reports, and any other information related to potential cancer diagnoses that are covered by the MCD Test. Requestor certified that the updated medical information would be requested no more than four times over a period of up to 5 years. After the data collection initiative period has ended,¹⁰ Requestor will remove this requirement and require only that: (i) a patient has a valid physician order for the CRC Screening Test; and (ii) the ordering physician opts in to receiving the Supplemental Report. Requestor certified that physicians are not compensated for ordering the CRC Screening Test or for opting in to receiving the Supplemental Report; the Supplemental Report is available to any physician who orders the CRC Screening Test regardless of the volume or value of their referrals for the CRC Screening Test, the MCD Test, or any other test manufactured or provided by Requestor.

Requestor certified that it does not actively market the Supplemental Report as a benefit to providers; the primary focus of Requestor's educational efforts is on the use of the CRC Screening Test.¹¹ However, Requestor makes information about the Supplemental Report available to physicians through certain pre-approved materials that Requestor certified are written in a neutral and objective tone. When the Arrangement first launched, Requestor sent an email to ordering accounts alerting them that the Supplemental Report is available and providing information about how to opt in to receive the results. Requestor also has pre-approved materials describing the Supplemental Report (e.g., describing the types of cancer included within the Supplemental Report, the performance of the MCD Test for each type of cancer, and the process for opting in to receive the Supplemental Report that sales representatives can discuss or share with physicians). Requestor certified that these materials are provided to ensure that physicians have the necessary information to make informed decisions about ordering the CRC Screening Test and, if appropriate, electing to receive the Supplemental Report. Requestor further certified that there is no targeted or incentivized marketing campaign for the Supplemental Report; in

⁹ Requestor does not and would not request any information relating to sexual orientation, sexually transmitted diseases, acquired immunodeficiency syndrome, human immunodeficiency virus, mental health, or substance use.

¹⁰ Requestor certified that the data collection period will end upon the earlier of: (i) completion of the 5-year period for the last patient opting into the data collection initiative or (ii) the FDA approval of the MCD Test or coverage by Medicare.

¹¹ Requestor certified that all marketing or educational materials referencing the CRC Screening Test or the MCD Test accurately disclose the sensitivity rates of cancer detection (e.g., any limitations in detection of cancers for which the tests screen).

particular, Requestor does not engage in direct-to-consumer advertising or promotional activities for the Supplemental Report, including in any consumer-facing advertising for the CRC Screening Test (e.g., radio, television, social media). Requestor certified that it instructs potential ordering physicians not to issue social media posts related to free Supplemental Report offered under the Arrangement. Further, Requestor certified that it routinely monitors social media platforms to proactively identify any third-party promotion or statements about Requestor’s products and services through a combination of automated “listening” and manually reviewing social media posts and promptly seeks to have such posts removed.

Requestor certified it will continue the Arrangement until: (i) the MCD Test is approved by the FDA as a medical device; or (ii) the MCD Test is covered by Medicare under a National Coverage Determination.

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.¹² 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.¹³ 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.¹⁴ 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

¹² Section 1128B(b) of the Act.

¹³ Id.

¹⁴ 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).

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."

Section 1128A(i)(6) of the Act contains an exception to the definition of "remuneration" that may apply in the context of the Arrangement. Specifically, section 1128A(i)(6)(D) of the Act excludes incentives given to individuals to promote the delivery of preventive care from the definition of "remuneration" for purposes of the Beneficiary Inducements CMP (the "Preventive Care Exception"). The regulations interpreting the Preventive Care Exception exclude from the definition of "remuneration" incentives given to individuals to promote the delivery of preventive care services where the delivery of such services is not tied (directly or indirectly) to the provision of other services reimbursed in whole or in part by Medicare or an applicable State health care program.¹⁵ The regulations define "preventive care" to include any service that is a specific clinical service described in the Guide and is reimbursable by Medicare or an applicable State health care program.¹⁶

B. Analysis

The Arrangement implicates both the Federal anti-kickback statute and the Beneficiary Inducements CMP. The Supplemental Report is remuneration in the form of a valuable service (as evidenced by the fact that Requestor hopes for it to become reimbursable in the future) that Requestor provides at no cost to patients. This remuneration could induce a patient to select the CRC Screening Test over other CRC screening tests and, therefore, to select Requestor's clinical laboratory over other laboratories. It also is possible that the ordering physician could have a billable follow-up visit to discuss results of the CRC Screening Test or the Supplemental Report.

No safe harbor applies to the Arrangement. In addition, the Preventive Care Exception does not apply to the Arrangement because neither the CRC Screening Test nor the MCD Test are listed in the Guide. We have longstanding and continuing concerns regarding the provision of free items or services by individuals and entities to providers and patients that could lead to the ordering and provision of an item or service payable by Federal health care programs. However,

¹⁵ 42 C.F.R. § 1003.110.

¹⁶ Id.

for the combination of the following reasons we believe the risk of fraud and abuse presented by the Arrangement is sufficiently low under the Federal anti-kickback statute for OIG to issue a favorable advisory opinion, and we would not impose sanctions under the Beneficiary Inducements CMP.

First, the Arrangement is unlikely to result in overutilization or inappropriate utilization. The Supplemental Report is available only for patients already eligible for the CRC Screening Test—a test that is reimbursable by Medicare for eligible patients no more than once every 3 years—who have a valid order for the CRC Screening Test from an independent physician who is not affiliated with Requestor and who will use the results in the management of the patient. The MCD Test that results in the Supplemental Report is not reimbursable, and it is performed on the same blood sample taken for the CRC Screening Test. Therefore, providing the Supplemental Report does not result in increased cost to Federal health care programs. While it is possible that a positive result of either the CRC Screening Test or the MCD Test could generate a follow-up appointment with the ordering provider (or referrals to other providers), any such appointments or referrals would be based on the clinical information included in the test results and would not be inappropriately caused by the Arrangement. Moreover, because the Supplemental Report provides information about several types of cancer for which there is no other USPSTF-recommended screening test, it could give patients critical health information and lead to earlier treatment when the Supplemental Report is positive for a cancer type other than CRC.

Second, the Arrangement is unlikely to skew clinical decision-making. A number of factors likely go into a provider's choice to order a CRC screening test for a patient, including, but not limited to, patient eligibility and willingness to take the test, willingness to order or perform a follow-up colonoscopy if there is a positive result, performance characteristics of the screening test compared to alternatives, and cost. Requestor certified that it discloses limitations on detection of the various types of cancer detected both by the MCD Test and the CRC Screening Test in marketing and educational materials. Requestor further certified that: (i) physicians are not compensated for ordering the CRC Screening Test or for opting in to receiving the Supplemental Report; (ii) there is no targeted marketing campaign for the Supplemental Report; (iii) it does not market the Supplemental Report as a remunerative benefit to providers; and (iv) it makes information about the Supplemental Report available to physicians only through certain pre-approved materials that are written in a neutral and objective tone.

Finally, the Arrangement is unlikely to inappropriately result in steering or unfair competition. While the opportunity to get the Supplemental Report attaches only to the CRC Screening Test performed by Requestor's laboratory, Requestor's laboratory is the only laboratory that performs the CRC Screening Test. Therefore, any time an enrollee selects the CRC Screening Test, the enrollee also selects Requestor's laboratory, even in the absence of the Arrangement. In addition, for 6 of the cancers detected by the MCD Test, there currently is no USPSTF-recommended screening test, so there would be limited risk of other laboratories being disadvantaged by the Arrangement, and, in the specific context of these screening tests, the potential disadvantage is likely outweighed by the potential benefit of the Arrangement. Importantly, Requestor does not actively market the Supplemental Report as a benefit to providers, nor does Requestor engage in direct-to-consumer advertising or promotional activities for the Supplemental Report.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Arrangement would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute; and (ii) although the Arrangement generates prohibited remuneration under the Beneficiary Inducements CMP, OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under the Beneficiary Inducements CMP or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

IV. LIMITATIONS

The limitations applicable to this advisory opinion include the following:

- This advisory opinion is limited in scope to the Arrangement. This advisory opinion has no applicability to any other arrangements, including, without limitation, any 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 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 advisory 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 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 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 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,

/Spencer K. Turnbull/

Spencer K. Turnbull
Acting Assistant Inspector General for Legal Affairs