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: June 10, 2026

Posted: June 15, 2026

[Address block redacted]

Re: OIG Advisory Opinion No. 26-14 (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 program to sponsor antibody testing for eligible patients to determine whether it may be appropriate to prescribe a certain drug manufactured by Requestor (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) the Arrangement does not generate prohibited remuneration under the Beneficiary Inducements CMP.

This advisory opinion may not be relied on by any person[1] 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

A. The Product and the Test

Requestor manufactures [redacted] (the "Product"), which is FDA-approved for the treatment of [redacted] (the "Condition") in adults and pediatric patients 6 years of age and older. The Condition [redacted] causes severe and progressive muscle weakness. The Product is the only FDA-approved therapy for the Condition, although some patients with the Condition may receive off-label therapies (e.g., [redacted]) or no treatment, depending on severity, comorbidities, and clinical priorities (e.g., treatment of underlying malignancy). Requestor certified that it does not promote the use of the Product for patients without a diagnosis of the Condition.

The Condition is characterized by [redacted]. For patients with the Condition, antibodies target [redacted] channels ("Channels") on motor neurons, impairing acetylcholine release and muscle contraction. According to Requestor, the Condition is frequently under- or misdiagnosed due to overlapping symptoms with other conditions. For a substantial proportion of patients, the Condition presents as [redacted], most commonly associated with [redacted]. For a patient presenting with clinical symptoms consistent with the Condition, a diagnosis of the Condition can be confirmed via Channel antibody ("Antibody") testing (i.e., testing the patient's blood for elevated levels of the Antibody).

B. The Arrangement

Under the Arrangement, Requestor contracts with a third-party laboratory (the "Vendor") to provide no-cost Antibody testing (the "Test") to eligible patients. The Arrangement is open to all patients in all 50 states and the District of Columbia—regardless of income or insurance status—who: (i) present with clinical symptoms consistent with the Condition; or (ii) are diagnosed with cancer and for whom clinical practice guidelines recommend paraneoplastic screening (the "Eligible Patients"). Requestor certified that no patient or payor (including Federal health care programs) is billed for the Test under the Arrangement. The Test is typically covered by Federal health care programs and private insurance. Outside of the Arrangement, Federal health care program beneficiaries who receive the Test are responsible for any applicable cost sharing. Requestor certified that, because the Condition is ultra-rare and shares clinical features with other neuromuscular disorders, the majority of Tests ordered through the Arrangement are negative. A positive Test may indicate several conditions, including the Condition, and Requestor estimates that approximately 1.6 percent of Antibody tests performed in the United States demonstrate elevated levels of Antibodies that may be indicative of the Condition. Requestor certified that health care providers are often unaware of the Test and the Condition. According to Requestor, the Arrangement is intended to: (i) increase awareness, access, and utilization of Antibody testing as a diagnostic resource for patients with

[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.

neuromuscular symptoms suggestive of the Condition; and (ii) support the awareness and diagnosis of the Condition in oncology contexts where paraneoplastic syndromes are suspected, potentially facilitating earlier cancer evaluation.

1. The Vendor and Health Care Providers

Requestor certified that Requestor and the Vendor are parties to a written services agreement that prohibits the Vendor from: (i) billing any patient or payor—including Federal health care beneficiaries or programs—for Tests provided to Eligible Patients; (ii) using the Arrangement to market other Vendor services; or (iii) offering any inducement to health care providers to prescribe the Product. Requestor further certified that it compensates the Vendor through itemized fixed set-up fees, fixed monthly operations fees, and per-unit fees for collection and testing services and that the fees reflect fair market value and were negotiated at arm's length.[2] The Vendor operates the laboratory where the Tests are performed and provides Test results directly to the ordering health care provider and does not provide individual Test results to Requestor or Eligible Patients.

The Vendor hosts the form that health care providers use to order a Test (the "Order Form") on its website. The Vendor provides Requestor with limited, aggregated, de-identified operational data: specifically, the number of Tests performed under the Arrangement. Requestor certified that the Vendor does not furnish any information that would enable Requestor to identify individual patients or ordering health care providers. Requestor restricts access to Vendor-provided data from the Arrangement to limited personnel responsible for verifying the amount invoiced by the Vendor, and sales representatives do not have access to data from the Arrangement. The Vendor is contractually prohibited from promoting Requestor's Product, as well as the Vendor's other products or services, to health care providers and patients using the Arrangement, and the Vendor does not promote the Arrangement. Requestor certified that it does not use data provided by the Vendor for sales and marketing activities.

Health care providers order the Test using the Order Form. As part of the ordering process, the health care provider must attest that: (i) the health care provider is authorized to order the Test under applicable law; (ii) the patient for whom the Test is ordered is an Eligible Patient; (iii) no claim will be submitted to any third party—including Federal health care programs—for the Test; (iv) the health care provider's medical decisions will not be influenced by participation in the Arrangement; and (v) the health care provider understands that no purchase or prescription of any product or service is a condition of participation. Specimen collection may occur either: (i) at one of the Vendor's patient service centers (where the collection is performed by Vendor personnel with no charge to patients or health care providers); or (ii) in the health care provider's

[2] The Vendor is not a party to the advisory opinion request. We have not been asked to opine on, and express no opinion regarding, the specific terms of the written agreement between Requestor and the Vendor, other than those terms expressly described herein. Further, 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.

office (with Vendor pick-up and processing). Requestor certified that it does not pay health care providers for specimen collection.[3]

2. Marketing

Requestor's sales representatives distribute approved, non-branded materials about the Arrangement that do not reference the Product. Requestor certified that its sales representatives do not distribute materials in a manner that takes into account a health care provider's history prescribing Requestor's products (including the Product). Requestor certified that sales representatives are prohibited from proactively discussing or promoting the Arrangement and from discussing the Arrangement in connection with the Product. Requestor certified that it also does not directly pay any remuneration to any health care providers who order the Test under the Arrangement to recommend, prescribe, or administer any products manufactured by Requestor, including the Product. Additionally, Requestor does not condition a health care provider's ability to order the Test pursuant to the Arrangement on their purchase of any products manufactured by Requestor, including the Product.

Requestor certified that it does not market or promote the Arrangement to patients. An unbranded disease-state awareness website is directed at health care providers and notes the availability of the Arrangement with a link to the Vendor website. Requestor certified that, as part of its marketing efforts, it purchases certain commercially available laboratory data relating to Antibody testing performed in the United States from two commercial data vendors (the "Commercial Data").[4]

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.[5] The statute's prohibition also extends to

[3] Requestor certified that, while the specimen collection may be reimbursable under a Federal health care program, such circumstances would be uncommon, and any payment amount would be nominal.

[4] According to Requestor, the Tests make up a small portion of the tests included in the Commercial Data. Requestor estimates that, between July 2024 and June 2025, the Tests comprised less than one-tenth of 1 percent of the total number of tests included in the Commercial Data. Requestor certified that it is impossible for Requestor to identify if any given test included in the Commercial Data was provided through the Arrangement (i.e., whether the test was performed by the Vendor and paid for by Requestor). We have not been asked to opine on, and express no opinion regarding, any arrangement between Requestor and the vendors that provide the Commercial Data.

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

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.

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. Section 1128A(i)(6)(F) of the Act provides that, for purposes of the Beneficiary Inducements CMP, the term "remuneration" does not include "remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in section 1128B(f) and designated by the Secretary under regulations)" (the "Promotes Access to Care Exception"). We have interpreted this provision to apply to:

> [i]tems or services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs by—(i) [b]eing unlikely to interfere with, or skew, clinical decision making; (ii) [b]eing unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) [n]ot raising patient safety or quality-of-care concerns …[8]

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[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] 42 C.F.R. § 1003.110 (defining "remuneration").

B. Analysis

1. Federal Anti-Kickback Statute

The Arrangement implicates the Federal anti-kickback statute because it results in remuneration to Eligible Patients and their health care providers that may induce Eligible Patients to purchase, or their providers to prescribe, the Product. With respect to Eligible Patients, the free Test provided through the Arrangement has value because, if the Test was covered by insurance, Eligible Patients would have to pay associated cost sharing for the Test, and if the Test was not covered by insurance, Eligible Patients would have to pay the entire cost of the Test. With respect to health care providers, the Arrangement confers value by enabling them to offer a service, at no cost to them or their Eligible Patients, that may create an opportunity for health care providers to bill for other services, such as an additional visit with the Eligible Patients to review the results from the testing or other follow-up appointments. No safe harbor applies to the Arrangement.

We have longstanding and continuing concerns regarding the provision of free items or services by individuals and entities, including pharmaceutical manufacturers, to health care providers and patients that could lead to the ordering and provision of an item or service payable by Federal health care programs. However, for a 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.

The Arrangement is unlikely to result in overutilization or inappropriate utilization. The Test determines whether it is possible for the Product to be prescribed and Requestor estimates that only approximately 1.6 percent of Antibody tests performed in the United States demonstrate elevated Antibody levels that may be indicative of the Condition. Because such a small percentage of Antibody tests performed in the United States demonstrate elevated Antibody levels that may be indicative of the Condition, the Test is significantly more likely to show that the Product is not indicated for a particular patient. Requestor certified that it does not directly pay any remuneration to any health care providers who order the Test under the Arrangement to recommend, prescribe, or administer any products manufactured by Requestor, including the Product. Additionally, Requestor does not condition a health care provider's ability to order the Test pursuant to the Arrangement on their purchase of any products manufactured by Requestor, including the Product.

Under the Arrangement, the risk of skewed clinical decision-making or steering is mitigated by the fact that Requestor's sales representatives do not discuss the Product in connection with the Arrangement, and health care providers do not receive any remuneration from Requestor in connection with the Arrangement other than the potential opportunity to bill for other services. Further, there are various safeguards in place to prevent use of the Arrangement as a marketing or sales tool to steer health care providers to order any items or services from Requestor or the Vendor, including the Product. In particular, Requestor certified that its sales representatives do not distribute materials in a manner that takes into account a health care provider's history prescribing Requestor's products, including the Product. Additionally, there are various limitations on the exchange of data relating to the Arrangement that foreclose the potential for Requestor to use the Arrangement to target specific health care providers or patients for further testing or to encourage prescribing or purchasing the Product. Specifically, the Vendor provides Requestor with the aggregate number of Tests performed under the Arrangement and does not

furnish any information that would enable Requestor to identify individual patients or ordering health care providers. Requestor restricts access to Vendor-provided data from the Arrangement to limited personnel responsible for verifying the amount invoiced by the Vendor, and sales representatives do not have access to data from the Arrangement. Requestor further certified that it does not use data from the Vendor for sales and marketing activities.

2. Beneficiary Inducements CMP

Although Requestor is a pharmaceutical manufacturer and therefore not a "provider, practitioner, or supplier" for purposes of the Beneficiary Inducements CMP, an offer of remuneration by a pharmaceutical manufacturer to a beneficiary that is likely to influence the beneficiary to select a particular provider, practitioner, or supplier implicates the Beneficiary Inducements CMP. Here, the Arrangement implicates the Beneficiary Inducements CMP because Requestor provides remuneration to beneficiaries in the form of a free Test, and the Arrangement could influence a beneficiary to seek follow-up care from the health care provider who ordered the Test.

We conclude that the Arrangement satisfies the Promotes Access to Care Exception. To reach this conclusion, we first examined whether the remuneration that is offered under the Arrangement improves a beneficiary's ability to obtain items and services payable by Medicare or Medicaid. Under the Arrangement, Requestor furnishes the Test to an Eligible Patient to determine whether the patient has elevated Antibodies indicative of the Condition and, therefore, whether the Product may be effective. Moreover, Requestor certified that health care providers are often unaware of the Test and the Condition, and therefore, the Test may remove a barrier to awareness—and potentially diagnosis and treatment—of the Condition.[9] For this reason, it is likely that the free Test could improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid (when the Product is payable by Medicare or Medicaid).

Next, we examine whether the Arrangement poses a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs. The Promotes Access to Care Exception states that remuneration poses a low risk of harm if it: (i) is unlikely to interfere with, or skew, clinical decision-making; (ii) is unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) does not raise patient safety or quality-of-care concerns.

First, the risk that the Arrangement interferes with, or skews, clinical decision-making or raises patient safety or qualify-of-care concerns is sufficiently low. Other than providing health care providers with a potential opportunity to earn a fee due to the follow up care, Requestor does not incentivize health care providers who order the Test under the Arrangement to recommend, prescribe, or administer any products manufactured by Requestor, including the Product. Additionally, Requestor does not condition a health care provider's ability to order the Test pursuant to the Arrangement on their purchase of any products manufactured by Requestor,

[9] See OIG, Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88,368, 88,393 (Dec. 7, 2016) (stating "We recognize that there are socioeconomic, educational, geographic, mobility, or other barriers that could prevent patients from getting necessary care (including preventive care) or from following through with a treatment plan. Our interpretation of items or services that 'promote access to care' encompasses giving patients the tools they need to remove those barriers.").

including the Product. Second, the Arrangement is unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization because the Test determines whether it is appropriate for the Product to be prescribed. Third, the Arrangement does not raise patient safety or quality-of-care concerns, as the Test determines whether there are elevated levels of Antibodies that may be indicative of the Condition, thereby providing information that enhances patient safety. Therefore, we conclude that the Arrangement poses a low risk of harm and satisfies the Promotes Access to Care Exception. The Arrangement thus does not generate prohibited remuneration under the Beneficiary Inducements CMP.

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) the Arrangement does not generate prohibited remuneration under 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