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 27, 2025

Posted: July 2, 2025

[Address block redacted]

Re: OIG Advisory Opinion No. 25-07 (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 a companion laboratory test for eligible patients before a provider can prescribe a certain prescription 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 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 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 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

A. The Drug

Requestor manufactures [redacted] (the "Drug"), a [redacted] (the "Enzymes") inhibitor, which was approved by the U.S. Food and Drug Administration (the "FDA") for the maintenance treatment of [redacted] (collectively, the "Conditions"), among other indications. The Drug is an inhibitor of the Enzymes, which are involved in normal cellular functions, such as DNA transcription and repair. Human cells depend on DNA repair to survive, and there are multiple pathways to repair damage to DNA. One such pathway relies on the Enzymes for DNA repair and survival. Accordingly, inhibition of this Enzymes-dependent pathway through the Enzymes inhibitors, such as the Drug, prevents [redacted] cells from repairing the damaged DNA within the cells through the Enzymes-dependent pathway. The inhibition of the Enzymes-dependent pathway may cause the [redacted] cells to die, particularly if another DNA repair pathway is defective. Tumors that have deficient [redacted] pathways (i.e., are [redacted] Deficiency (the "Deficiency") positive) depend on the Enzymes pathway for DNA repair and are thus particularly sensitive to the Enzymes inhibitors like the Drug. About half of patients with the Conditions are Deficiency-positive.

Certain therapies to treat the Conditions, such as the Drug, have been found to be particularly effective in patients with specific molecular alterations. The Drug is approved by the FDA for three indications of the Conditions, including, in combination with [redacted], for the maintenance treatment of adult patients who are in complete or partial response to first-line platinum-based chemotherapy and where the Conditions are associated with Deficiency-positive status by either a [redacted] gene mutation (the "Mutation") or [redacted] (together with the Mutation, the "Companion Diagnostic Indication"). According to Requestor, treatment with the Drug for the Companion Diagnostic Indication has shown clinically significant improvement in overall survival and progression-free survival in Deficiency-positive patients. The Drug is covered by Federal health care programs and private insurance for the Companion Diagnostic Indication.

B. The Test

A test was developed and is performed by [redacted] (the "Lab") as an FDA-approved companion diagnostic for the Drug (the "Test"). The Test is a next generation sequencing-based *in vitro* diagnostic test that aids in identifying patients with the Conditions who have the

[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.

Deficiency and who are eligible for certain therapies like the Drug. The Test is typically covered by Federal health care programs and private insurance. Outside of the Arrangement, Federal health care program enrollees who receive the Test are responsible for any applicable cost sharing.[2]

To initiate the Test, first the ordering provider obtains a tumor tissue sample and ships the sample to the Lab,[3] and the Lab extracts DNA from the sample. Test results consist of two major components, communicated as either "positive" or "negative" for each component: (i) tumor Mutation status; and (ii) [redacted] status. A positive result for either of these components indicates that the Conditions have the Deficiency, which in turn indicates whether treatment with the Drug may be appropriate.[4] Notably, unlike the Drug—which is approved by the FDA for only Deficiency-positive patients—the Competitor Drug is approved by the FDA for both Deficiency-positive and Deficiency-negative patients. Requestor asserted that, because the Test identifies only whether a patient who has the Condition also has the Deficiency and is only useful for purposes of determining whether the Drug or the Competitor Drug would be an appropriate treatment for the patient, the Test does not have other independent value to providers or patients.

C. The Arrangement

i. Eligibility

Under the Arrangement, Requestor offers the Test, for free, to eligible patients, including Federal health care program enrollees. The Arrangement applies only to patients with the Conditions. To be eligible for the Arrangement: (i) the patient must have a negative test result from a prior genetic test for the Mutation; (ii) the patient must have a previously collected tumor tissue sample that is able to be tested using the Test; (iii) the use of the Test must be for an indication consistent with the FDA labeling for the Test; and (iv) the patient may not have previously received the Test (collectively, the "Eligibility Criteria," and patients who meet the Eligibility Criteria are "Eligible Patients"). Requestor certified that the Eligibility Criteria are designed to help providers identify patients who may have the Deficiency and may otherwise have gone undetected, so they can better determine whether use of the Drug may be indicated.

---

[2] Currently, cost sharing for the Test under Medicare Part B is $606. Cost-sharing amounts for patients with Medicare Advantage or other Federal health care programs vary, and certain Medicaid programs may require prior authorization before the Test can be performed.

[3] The Test requisition form requests the current location of the specimen, which is typically a pathology lab. The Lab contacts the location where the specimen is being stored to coordinate the Lab's receipt of the specimen, which involves the Lab sending a tumor specimen collection kit. The Lab returns the specimen to this location after the Test is complete.

[4] A competitor drug, [redacted] (the "Competitor Drug"), is an inhibitor of the Enzymes indicated for [redacted]. Requestor certified that market research shows that providers are more likely to prescribe the Competitor Drug for Deficiency-positive than Deficiency-negative patients.

The Arrangement is open to all Eligible Patients in all 50 states and the District of Columbia, regardless of income or insurance status. To order the Test as part of the Arrangement, a provider must make the following attestations: (i) the patient satisfies the Eligibility Criteria; (ii) the provider believes the Test is clinically appropriate for the patient; (iii) the provider is not seeking reimbursement for the Test or for other services provided in connection with the Arrangement; and (iv) the provider has obtained the patient consent necessary to comply with applicable law. The Lab is responsible for ensuring the provider has submitted an adequate attestation, receiving and testing of all specimens, and delivering the Test results to providers in connection with the Arrangement. The patient has no out-of-pocket costs associated with the Arrangement. Requestor does not provide any remuneration to the ordering provider or otherwise subsidize the cost for any specimen collection or other medical service associated with the Arrangement. The Test requisition form for the Arrangement requires that providers attest that they will not bill any third party for any medical services performed for the Arrangement. Providers must order the Test directly from the Lab; neither the Lab's nor Requestor's field personnel distribute any component of the Test, like a specimen collection kit, directly to providers.

ii. Agreement Between the Lab and Requestor

Requestor and the Lab have entered into a written agreement specifying that, under the Arrangement, Requestor pays the Lab a fixed fee for each Test that the Lab performs for an Eligible Patient.[5] The agreement specifies that the Lab is prohibited from billing any patient, payor, or third party other than Requestor for testing conducted pursuant to the Arrangement.[6] Requestor does not provide payment for any Test provided outside of the Arrangement. Requestor and the Lab are otherwise responsible for their own costs associated with the Arrangement.

iii. Data

Requestor certified it does not and will not receive any provider-identifiable or patient-identifiable information or data from the Lab as part of the Arrangement. The Lab provides certain limited, aggregated, de-identified data regarding the Test via monthly data reports. These reports include: (i) de-identified aggregate number of Tests performed in connection with the Arrangement;[7] (ii) the cumulative results of all Tests performed in connection with the

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

[6] Requestor does not pay the Lab for Tests when the Lab determines that not enough tumor tissue has been delivered to the Lab for it to run the Test.

[7] These results are deidentified and associated only with the U.S. state of the provider and, therefore, Requestor certified that this information could not be used to identify specific providers who order the Test as part of the Arrangement.

Arrangement; and (iii) certain digital awareness results, which include the number of clicks on the program QR code in a leave-behind pamphlet about the Arrangement, the number and source of qualified visits to the website dedicated to the Arrangement, the number of downloads of the requisition form for the Test, and the number of calls to the Lab's telephone helpline.

Requestor certified it uses the de-identified data about the utilization of the Arrangement only to: (i) verify the amount invoiced to Requestor by the Lab; (ii) audit that the Arrangement is being conducted in accordance with the terms of the agreement between the Lab and Requestor; and (iii) use real-world evidence to validate Requestor's understanding of the number of patients with the Conditions missed by standard testing protocols. Requestor certified that it has implemented a number of limitations around the use of this data, including:

- Limited individuals at Requestor's headquarters receive and review this information. It is not broadly accessible within Requestor's organization, and field personnel have no access to this information.

- All of Requestor's personnel, including its field personnel, are explicitly prohibited from using data related to the Arrangement to target patients or providers.

- The data is not used by Requestor to direct any field activities.

- Requestor has implemented internal rules and controls to prohibit the use of this data to re-identify any provider or patient that is the subject of the data.

The Lab is contractually prohibited from using data from the Arrangement to promote the Arrangement or any other Lab product or service to patients or providers identified through the Arrangement. Requestor certified it does not and will not use the data to target certain providers in its promotion of the Drug or for any incentive-based compensation of its field personnel, including sales representatives. Requestor certified that it does not pay any remuneration to providers, either directly or indirectly through the Lab, in connection with the Arrangement.

iv. Marketing

Requestor certified that, in its experience, providers' lack of awareness of testing for the Deficiency, misunderstandings about testing for the Deficiency, or both are key barriers to patient access to potential treatment with the Drug for the Companion Diagnostic Indication. Specifically, Requestor certified that only 60 percent of providers who treat the Conditions understand that tumor testing at diagnosis is the standard of care and, even among those providers who do have this knowledge, a significant number do not understand the benefit of conducting a comprehensive test for the Deficiency like the Test. Consistent with this purpose, Requestor certified that, to raise awareness about the Deficiency and genomic testing,

particularly with providers that have low rates of testing for the Deficiency,[8] field personnel undertake certain passive, non-promotional disease-awareness activities in connection with the Arrangement as follows:

- Sales representatives make providers aware of the Arrangement by leaving behind a pamphlet with pre-approved information about the Arrangement. This pamphlet does not contain any branding for or reference to the Drug. Sales representatives are not permitted to discuss the Arrangement, including reactively. If providers have questions about testing for the Deficiency or the Arrangement, sales representatives refer providers to Requestor's non-sales personnel, described below, or the Lab, as appropriate. Sales representatives do not distribute the pamphlet in a manner that takes into account a provider's usage of the Arrangement or prescribing of Requestor's products.

- Non-sales personnel with expertise in diagnostic testing make certain pathologists (e.g., those with low rates of testing for the Deficiency) aware of the Arrangement by leaving behind a pamphlet with pre-approved information about the Arrangement. This pamphlet contains no branding for or reference to the Drug. These non-sales personnel may answer unsolicited questions about the Arrangement from providers and also may refer questions about the Test to the Lab. Any questions about the Drug are referred to Requestor's sales representatives or medical personnel.

- Requestor distributes a digital version of the leave-behind pamphlet mentioned above via email to certain providers (e.g., those with low rates of testing for the Deficiency). Like the physical version of the leave-behind pamphlet, this digital version contains no branding for or reference to the Drug.

- Requestor also plans to contract with online search vendors to return results related to the Arrangement when individuals search disease state-related information (e.g., "testing for the Deficiency"). An online search for the Drug would not return results related to the Arrangement.

Requestor certified that all of Requestor's personnel are prohibited from discussing the Drug during any disease-awareness communications that include a discussion of the Arrangement.

The Lab is contractually prohibited from promoting the Arrangement. Requestor certified that it maintains control over all public-facing or other external communications regarding the Arrangement. Subject to Requestor's prior approval, the Lab is permitted to develop educational and other specific informational materials regarding the Test for use in communications regarding the Arrangement. The Lab has published a public, provider-facing website, specific to the Arrangement, from which providers order the Test. This website (and the results from Tests that providers receive from the Lab) contain the FDA-approved Intended Use Statement for the

[8] Requestor certified that it works with data analytics providers that provide these insights by analyzing sources such as patient de-identified claims and electronic medical record data and that this data is not associated with data collected as part of the Arrangement.

Test, which includes a brief, informational reference to the Drug and the Competitor Drug and mentions, in a generalized manner, the Companion Diagnostic Indication. The Lab may proactively communicate with providers in connection with the Arrangement in limited circumstances, such as to obtain provider attestations, verify patient eligibility for the Arrangement, coordinate receipt of tumor tissue samples, communicate Test results, and undertake limited disease-awareness activities about topics such as the importance of testing for the Deficiency. The Lab is contractually prohibited from: (i) including any reference to the Lab's other products or services as part of this public, provider-facing webpage; (ii) promoting any of the Lab's other products or services or Requestor's products in any of these Lab-developed communications to any provider who orders the Test or to any patient who receives the Test in connection with the Arrangement; and (iii) proactively communicating with patients in connection with the Arrangement except where required to comply with law. Requestor requires the Lab to direct any questions about Requestor's products to Requestor.

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.[9] 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.[10] 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.[11] 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

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

[10] Id.

[11] 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. 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…[12]

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 providers that may induce Eligible Patients to purchase, or their providers to prescribe, the Drug. With respect to Eligible Patients, the free Test provided through the Arrangement has value because, even if the Test were covered by insurance, patients would have to pay associated cost sharing for the Test. With respect to 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 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 providers and patients

[12] 42 C.F.R. § 1003.110 (defining "remuneration").

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, skew clinical decision-making, or result in unfair competition. Providers already may be considering the Drug or the Competitor Drug for a particular patient, and the Test determines whether it is even possible for the Drug to be prescribed (i.e., the Test is an FDA-approved companion diagnostic for the Drug and is required to determine whether the Drug is indicated for patients with the Conditions). Requestor does not require or otherwise incentivize providers who order the Test under the Arrangement to recommend, prescribe, or administer any products manufactured by Requestor, including the Drug. Indeed, because only approximately half of patients with the Conditions are Deficiency-positive, the Test just as likely could show the Drug is not indicated for a particular patient, and in fact, a Deficiency-negative Test may result in the Competitor Drug being prescribed. Even when a Test result is positive, either the Drug or the Competitor Drug may be appropriate. In addition, the risk of skewed clinical decision-making or steering is mitigated by the fact that Requestor's field personnel do not discuss the Drug in connection with the Arrangement, and providers do not receive any remuneration from Requestor in connection with the Arrangement.

Further, there are various safeguards in place to prevent use of the Arrangement as a marketing or sales tool to steer providers to order any items or services from Requestor or the Lab, including the Drug. In particular, Requestor certified that its sales representatives do not distribute materials in a manner that takes into account a provider's usage of the Arrangement or the provider's history prescribing Requestor's products, including the Drug. In fact, there are various limitations on the exchange of data relating to the Arrangement that constrain the potential for Requestor to use the Arrangement to target specific providers or patients for further testing or to encourage prescribing or purchasing the Drug. Specifically, the Lab does not provide Requestor with any individually identifiable health information regarding patients who receive a Test or any data that would enable Requestor to identify providers who order Tests through the Arrangement. In addition, Requestor does not allow its field personnel to access any data that Requestor receives from the Lab, and Requestor does not use data from the Lab for sales and marketing activities, including sales targeting or incentives. The terms of the contract between the Lab and Requestor also prohibit the Lab from promoting the Arrangement to providers or patients. Finally, Requestor certified that it does not proactively provide information about the Arrangement directly to providers or patients.

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 provider who ordered the Test.

We conclude that the Arrangement satisfies the Promotes Access to Care Exception to the Beneficiary Inducements CMP. 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. As noted above, the Arrangement provides the Test, which is essential to determine whether the Drug could be effective on a particular patient. 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 Drug is payable by Medicare or Medicaid).

Next, we examined 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 to the Beneficiary Inducements CMP 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. This is because the Test informs whether the Drug can be prescribed, and providers already may be considering the Drug or the Competitor Drug for a particular patient. Second, the Arrangement is unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization because: (i) the Drug is a potentially life-extending treatment; (ii) providers already may be considering the Drug for a particular patient; (iii) the Test determines whether it is even appropriate for the Drug to be prescribed, as approximately half of the Eligible Patients will not have a positive result from the Test and thus will not be eligible for the Drug; and (iv) Requestor does not require or otherwise incentivize providers who order the Test under the Arrangement to recommend, prescribe, or administer any products manufactured by Requestor, including the Drug. Third, the Arrangement does not raise patient safety or quality-of-care concerns, as it is designed to determine whether the Drug may be effective on a particular patient. Therefore, we conclude that the Arrangement poses a low risk of harm and satisfies the Promotes Access to Care Exception to the Beneficiary Inducements CMP. 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 opinion include the following:

- This advisory opinion is limited in scope to the 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 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 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,

/Susan A. Edwards/

Susan A. Edwards
Assistant Inspector General for Legal Affairs