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: December 12, 2024

Posted: December 17, 2024

[Address block redacted]

Re: OIG Advisory Opinion No. 24-12 (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 genetic testing, related genetic counseling, and disease-state awareness education regarding certain hereditary conditions that may cause kidney stones (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 or have been misrepresented, 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) 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 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 Condition

[Redacted] (the "Condition" or "[redacted]") is an ultra-rare genetic condition that is caused by genetic mutations that result in the overproduction and accumulation of oxalate. The overproduction and accumulation of oxalate in the kidneys leads to recurrent kidney stones and chronic kidney disease, which can progress to end-stage renal disease. Oxalate also can accumulate in other organs, including the skin, bones, eyes, and heart. There are three known subtypes of the Condition, each resulting from one of the following mutations: (i) a mutation in the [redacted] gene, which results in [redacted] type 1 ("Subtype 1"); (ii) a mutation in the [redacted] gene, which results in [redacted] type 2 ("Subtype 2"); and (iii) a mutation in the [redacted] gene, which results in [redacted] type 3 ("Subtype 3"). Requestor certified that only 3 in every 1,000,000 people have the Condition and that Subtype 1 is the most severe and most common subtype, with approximately 80 percent of patients with the Condition having this subtype.[2]

Requestor certified that clinical diagnosis of the Condition often is delayed for a number of reasons. For example, symptoms of recurrent kidney stone disease overlap, are non-specific, and are similar across multiple diagnoses. In addition, Requestor cited to research showing that the traditional method of determining whether a patient has persistent elevated oxalate—collecting all of a patient's urine over a 24-hour period, possibly twice—historically has poor compliance and accuracy due to factors such as inconvenience, cost, and difficulty with collection methods.[3]

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[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] Based on the U.S. population, Requestor estimates that approximately 1,005 individuals in the United States have the Condition, with approximately 805 individuals having Subtype 1, approximately 100 individuals having Subtype 2, and approximately 100 individuals having Subtype 3.

[3] See, e.g., Alice Xiang et al., *Improving Compliance with 24-H Urine Collections: Understanding Inadequacies in the Collection Process and Risk Factors for Poor Compliance*, 22 Current Urology Reports 38 (2021) (indicating that in multiple studies approximately half of the samples collected were inadequate).

Requestor also indicated that there is a general lack of awareness about the Condition due to its ultra-rare nature, and there is limited insurance coverage available for genetic testing that would diagnose the Condition.

Requestor manufacturers [redacted] (the "Drug"), a drug that received approval from the U.S. Food and Drug Administration (the "FDA") to treat Subtype 1 in patients who are 9 years old or older.[4] While a genetic test confirming that the patient has Subtype 1 was a requirement to participate in clinical trials for the Drug, it is not a requirement for prescribing the Drug under the FDA-approved labeling. The Drug specifically targets the genes associated with the Condition and is the second drug of this type approved to treat Subtype 1. However, Requestor certified that not all patients diagnosed with Subtype 1 would be prescribed the Drug. To determine whether the Drug (or another treatment option) would be appropriate for a patient, the patient's treating health care professional would consider factors such as the patient's average oxalate levels, the possibility of managing the Condition through routine monitoring coupled with lifestyle and dietary changes, and the appropriateness of other competing products and medications.

B. Genetic Testing

As explained above, the Condition is characterized by a mutation in one of three genes. The Arrangement could involve one of three types of genetic testing panels. One genetic testing panel is the nephrolithiasis panel, which consists of a 45-gene panel that tests for multiple genetic disorders associated with kidney stone diseases. Requestor certified that the known hereditary conditions being tested within the nephrolithiasis panel are largely rare or ultra-rare diseases, some of which do not have specific treatments. Thus, for most patients, the testing would be used to rule out a condition as a potential cause of the patient's symptoms rather than to diagnose a specific genetic condition. A second type of genetic test is a Condition-specific panel that tests only for the three subtypes of the Condition. Requestor certified that a health care professional might choose the narrower test for a variety of reasons, such as when a patient has a family history of the Condition or the patient completed the 24-hour urine test, and it showed a high oxalate level, which is a strong indication of the Condition. The third type of test is familial variant testing, which Requestor certified is a narrow genetic test for a specific variant or mutation that has already been seen in a direct relative (i.e., a biological parent, child, or sibling).

All of the genetic testing panels referenced above are commercially available tests—not designed for the Arrangement—and offered by Blueprint Genetics, a subsidiary (the "Subsidiary") of Quest Diagnostics (the "Lab"). Requestor certified that the tests are performed by Clinical Laboratory Improvement Amendments ("CLIA")-certified personnel at a CLIA-certified, College of American Pathologists ("CAP")-accredited laboratory. Further, the panels use sample types known to produce high-quality DNA yields, which increase the likelihood of a clinically

[4] Requestor certified that the Drug is approved only to treat Subtype 1 and is not approved to treat other subtypes of the Condition or any other condition. Requestor further certified that it will not market the Drug for any treatment other than the treatment of Subtype 1 (unless the FDA approves the Drug for another indication in the future).

meaningful result; the collection method for the panels requires either a buccal swab or a venous blood sample.

C. The Arrangement

Requestor certified that it instituted the Arrangement with the goals of increasing awareness, access, and utilization of genetic testing as a diagnostic resource to identify, diagnose, and treat inherited diseases, and particularly, to support disease awareness around hereditary conditions that may cause kidney stones (the "Stated Goals"). As described in greater detail below, under the Arrangement, Requestor provides general disease-state awareness education and pays for genetic testing and associated genetic counseling for patients that meet specified criteria ("Eligible Patients"). No patient or payor, including Federal health care programs, is billed for any of the genetic testing or genetic counseling services under the Arrangement. Receipt of any of the services is not conditioned on use of the Drug or any other item or service provided or sold by Requestor, the Lab, or the Subsidiary. Requestor notes that the Arrangement could result in a prescribing health care professional scheduling, conducting, and billing Eligible Patients and their payors for an additional visit with the Eligible Patient to review the results from the genetic testing and update the Eligible Patient's treatment regimen. However, no additional visits or services are required for an Eligible Patient to take part in the Arrangement.

1. Disease-State Awareness Education

Requestor provides general, unbranded disease state awareness facts and information about the Condition. Requestor offers one website that is geared toward the general public, including patients, caregivers, and family members. The website describes the Condition, gives general guidance about managing the condition, and provides other informational resources to patients with the Condition, including connecting individuals to foundations or other organizations where patients can learn about support available to patients with the Condition. This website also includes information about the Arrangement and how to access the genetic testing. However, the website does not include information about specific therapeutic options and is not branded with any logos relating to the Drug.[5] Requestor also maintains a second website, which is directed at health care professionals. This website provides general disease-state education around the Condition and information on how genetic testing can be used as a diagnostic tool for the Condition. Like the patient-focused website, the second website does not discuss specific therapeutic options and includes no branding for the Drug.

2. Genetic Testing

Under the Arrangement, one of the three genetic testing panels referenced above would be available to Eligible Patients without charge. To qualify as an Eligible Patient, the patient must meet one of the following criteria:

[5] Requestor certified that, for transparency, the website would identify Requestor as the sponsor of the content.

- have a family history of recurrent kidney stones or monogenic disorders, including the Condition, that results in recurrent kidney stones;
- have undergone a genetic test, the results of which came back inconclusive with respect to the three genes that indicate the Condition;
- have a laboratory indication (e.g., urine/blood biochemistry or stone analysis composition) of monogenic disorder resulting in recurrent kidney stones (i.e., elevated oxalate in urine or plasma, or oxalate within stone analysis);
- be suffering from chronic kidney disease of an unknown etiology;
- be suffering from nephrocalcinosis;
- have a history of kidney stones, defined as: (a) having one or more kidney stones if the individual is less than eighteen years old, or (b) having bilateral stones, multiple stones, or recurrent stones; or
- be a child two years old or younger who is failing to thrive and has impaired renal function.

A health care professional must attest that the patient meets the eligibility criteria to order the chosen test under the Arrangement. The health care professional can choose to order only one type of testing panel for the same Eligible Patient. To obtain the collection kit, the patient's health care professional orders the genetic test and the collection kit through the Subsidiary's portal. The Subsidiary sends the collection kits to the ordering health care professional to perform the collection. Alternatively, the collection kit may be sent to the patient's home for sample collection by the patient. The health care professional is not permitted to charge any fee for collecting the sample to either the Eligible Patient or to any third-party payors.

Requestor certified that approximately 20 percent of the time, a genetic test might identify a "variant of uncertain significance" ("VUS"), rendering the test inconclusive.[6] If the test results in a VUS for one of the three genes that indicate the Condition, Requestor would sponsor a Condition Urine Metabolic Assay (the "Assay"). The decision to order this additional test is in the sole discretion of the patient's treating health care provider.

Under the Arrangement, Requestor covers the entire cost of one genetic test and, if necessary, the Assay for each Eligible Patient for whom the test (and possible Assay) is ordered. The order form includes language that the ordering provider must acknowledge stating that the ordering provider agrees not to bill the patient or their insurer for any genetic testing services (or genetic counseling) offered under the Arrangement. No Eligible Patient or payor is billed for the testing, and Requestor certified it does not shift any costs to Eligible Patients, health care providers, Federal health care programs, or other payors. Requestor further certified that it takes steps to ensure that third parties (including any laboratories, genetic counselors, or ordering health care professionals) do not shift any cost of the Arrangement to patients, health care providers, Federal health care programs, or other third-party insurers. Specifically, Requestor prohibits, by

[6] Requestor certified that VUS means that a mutation is identified, but it is not known if the variant is causing the disease.

contract, any laboratory or genetic counselor from billing any third-party payor, health care provider, or Eligible Patient for the genetic tests or related services.

3. Genetic Counseling

Under the Arrangement, Requestor sponsors genetic counseling for Eligible Patients who elect to receive, and their health care providers who elect to order, a genetic test under the Arrangement. The genetic counseling is provided in 15-minute increments both before receiving the test and after receiving the results. Genetic counseling is optional; it is not required to receive the free testing under the Arrangement. Genetic counselors answer questions about whether the testing may be appropriate and help interpret the results. They can provide information on hereditary diseases associated with kidney stones that are the subject of the tests included in the testing panel, but they are prohibited from discussing therapeutic options with individuals (i.e., they cannot discuss the Drug or any other available treatment with Eligible Patients or health care providers). The genetic counselors are agents of the Lab and only help Eligible Patients and health care professionals interpret the results of the genetic test rendered by the Lab that was ordered by a licensed health care professional under the Arrangement.

4. Agreements with the Lab and the Subsidiary

Requestor entered into written agreements with the Lab where the Lab or the Subsidiary will furnish (i) the genetic tests and the Assay, (ii) genetic counseling services, and (iii) certain administrative functions related to the Arrangement (e.g., responding to questions about how to order the genetic tests, where to retrieve the test results, and where to go to learn more about the services offered through the Arrangement). Specifically, Requestor pays the following fees to the Lab, which are set in advance, in writing, and consistent with fair market value: (i) a flat, standard fee for each Assay performed; (ii) a flat, standard fee for each 15-minute increment of genetic counseling provided under the Arrangement; (iii) flat, standard fees for each type of genetic test performed; (iv) fees for each collection kit type; and (v) fixed management fees for administrative services that are performed.

5. Data

Neither the Lab nor the Subsidiary provides any identifiable patient data to Requestor; Requestor does not receive any information that would allow Requestor to determine if a patient received a genetic test, what the results were for a specific patient, or whether a specific patient received genetic counseling. Similarly, Requestor does not receive any information that identifies the health care professionals who order the tests or the institutions with which the ordering health care professionals are affiliated.

The Lab and the Subsidiary provide Requestor limited, de-identified information about the operations of the Arrangement (e.g., aggregate patient demographics and test result data, as well as program activity information, such as the number of genetic tests performed, the types of genetic tests, information needed to confirm how long it took to furnish the tests, and how long it took for the health care professional to retrieve the test results). Requestor certified that it receives only information necessary to: (i) monitor whether the Arrangement is operating efficiently and as intended with respect to the Stated Goals; (ii) confirm that the contractual

obligations of the Lab and the Subsidiary are being met; and (iii) determine the proper fees for the legitimate services rendered. Requestor certified that only two individuals, the program lead and the data lead, have access to the aggregate information, and neither of these individuals has performance objectives tied to, or receives compensation based on, the value or volume of prescriptions, sales, revenue, or profits derived from any specific products of Requestor, including the Drug. Requestor certified that the data lead pulls the information and prepares data reports when requested by the program lead. The program lead uses the information to administer and support the Arrangement and to manage the operational and contractual relationships with the Lab and the Subsidiary. According to Requestor, the program lead occasionally disseminates aggregated data about the performance of the Arrangement to others within the medical and commercial groups at Requestor to provide general information and feedback about the Arrangement's operations and for educational and training purposes (e.g., if the data show that test results are routinely delayed because collection kits are being returned without sufficient documentation demonstrating patient consent, the program lead can inform the field-based employees about the deficiencies so that they can provide clearer information to health care professionals who might order the testing). Requestor certified it does not, will not, and could not, use the Arrangement to target specific health care professionals who might prescribe the Drug because Requestor (including the data lead and program lead) do not and will not receive any information identifying the health care professionals who order the genetic tests or the patients who receive a positive Condition diagnosis.

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

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

[8] Id.

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."

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 professionals that may induce Eligible Patients to purchase, or their health care professionals to prescribe, the Drug.[10] With respect to Eligible Patients, the free genetic test, possible free Assay, and free genetic counseling services provided through the Arrangement are inherently valuable. With respect to health care professionals who treat Eligible Patients, the Arrangement confers value by enabling them to offer a service, at no cost to them or their patients, that may create an opportunity for physicians to bill for other services, such as an additional visit with the Eligible Patient to review the results from the genetic testing and update the Eligible Patient's treatment regimen. Finally, Requestor pays the Lab and the Subsidiary for services rendered under the Arrangement, and the Lab and the Subsidiary could be referral sources for the Drug. No safe harbor applies to the Arrangement. Nevertheless, for 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. We caution that we likely would reach a different conclusion with

[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).

[10] The disease-state awareness information is purely educational, does not provide information about the Drug, and is available to the general public on websites. We do not consider this information to constitute remuneration for purposes of the Federal anti-kickback statute.

respect to the risk presented by this type of arrangement if any of the facts surrounding the Arrangement were different, including if there were any sharing of data with Requestor that would allow it to target marketing of the Drug based on the Arrangement, or if there were a more direct nexus between the remuneration under the Arrangement and ordering or purchasing the Drug.

First, the safeguards built into the Arrangement regarding how a patient obtains a genetic test or genetic counseling reduce the risk of overutilization or inappropriate utilization. Requestor established specific and narrow eligibility criteria, which generally relate to either symptoms of kidney stones or impaired renal function or are based on a family history of such conditions. Requestor offers, through the Subsidiary, three different genetic tests to Eligible Patients. The Eligible Patient's treating health care professional selects the test that the professional deems appropriate for the patient. If the Eligible Patient elects to receive the genetic test or genetic counseling under the Arrangement, then neither the Eligible Patient nor any payor can be billed for any component of the genetic test (including any fee that might otherwise be charged for collecting the genetic material for the test) or the genetic counseling. Because the Condition is so rare, and the tests are narrowly tailored to test for the Condition or certain other rare (or ultra-rare) genetic disorders associated with kidney stone diseases, in most cases, the test will rule out conditions rather than result in a diagnosis of the Condition.

Second, the Arrangement is unlikely to skew clinical decision-making or raise concerns regarding patient safety or quality of care. The tests offered under the Arrangement are commercially available testing panels not created for the purpose of the Arrangement. Requestor does not require or otherwise incentivize providers who order genetic testing or genetic counseling through the Arrangement to recommend, prescribe, or administer any products manufactured by Requestor. Moreover, the Arrangement presents a low risk of inducing prescriptions of the Drug. The Drug is approved only to treat Subtype 1 and is not approved for other subtypes of the Condition or any other condition. In addition, Requestor certified that not all patients diagnosed with Subtype 1, which is an ultra-rare condition, are prescribed the Drug. For example, a patient might not have sufficiently high oxalate levels to warrant treatment with the Drug, and the Drug is not the only product available to treat Subtype 1. Importantly, Requestor does not receive any information that identifies the prescribers who order the genetic tests or the genetic counseling or the patients who receive the genetic tests or genetic counseling. Therefore, Requestor cannot target any marketing of the Drug based on the Arrangement.

Finally, remuneration that Requestor provides to the Lab and the Subsidiary presents a low risk of fraud and abuse. While there could be opportunities for the Lab and the Subsidiary to be direct or indirect referral sources for the Drug—either through the data that Requestor could receive or through the genetic counseling services—the Arrangement includes certain safeguards that limit this risk. We rely on Requestor's certifications that: (i) Requestor pays fixed fees for each of the services that the Lab and the Subsidiary provide to Requestor and to Eligible Patients; (ii) the genetic counselors discuss only the genetic tests and the hereditary diseases and do not provide any information about treatment options; and (iii) neither the Lab nor the Subsidiary provide any data to Requestor to allow Requestor to identify which providers order the tests or which patients receive them.

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 genetic test, possible free Assay, and free genetic counseling services, and the Arrangement could influence a beneficiary to seek follow-up care from the health care professional who ordered the genetic testing and Assay, as applicable. However, for the reasons stated above with respect to the Federal anti-kickback statute, we conclude that we would not impose administrative sanctions under the Beneficiary Inducements CMP in connection with Requestor's provision of the genetic testing and counseling services to Eligible Patients.

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 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 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