



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 29, 2022

Posted: July 5, 2022

[Address block redacted]

Re: OIG Advisory Opinion No. 22-15

Dear [redacted]:

The Office of Inspector General (“OIG”) is writing in response to a request for an advisory opinion by [redacted] (“University A”), by and on behalf of [redacted] (the “University A School of Medicine”) and [redacted], doing business as [redacted] (the “University A Management Entity”); and [redacted] (“University B”) by and on behalf of [redacted] (the “University B Medical Group”) (collectively, “Requestors” and individually, each a “Requestor”). Requestors propose to use bona fide charitable contributions to: (i) furnish specialized, medically necessary care to United States military service veterans who meet certain criteria; and (ii) provide financial assistance to such veterans related to care provided at or arranged by a Requestor (the “Proposed Arrangement”). Specifically, you have inquired whether the Proposed Arrangement, if undertaken, would constitute grounds for the imposition of sanctions under: the civil monetary penalty provision at section 1128A(a)(7) of the Social Security Act (the “Act”), as that section relates to the commission of acts described in section 1128B(b) of the Act (the “Federal anti-kickback statute”); the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act (the “Beneficiary Inducements CMP”); or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute and the Beneficiary Inducements CMP.

Requestors have certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Proposed Arrangement, and we have relied solely on the facts and information Requestors provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestors. This opinion is limited to the relevant facts presented to us by Requestors in connection with the Proposed 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 Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG would not impose administrative sanctions on Requestors in connection with the Proposed 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 Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Beneficiary Inducements CMP, the OIG would not impose administrative sanctions on Requestors in connection with the Proposed 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 person¹ other than Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Relevant Parties

The Proposed Arrangement would involve entities from two universities, located in different, non-contiguous states, providing certain treatment and specialty care for United States military service veterans. The University A Requestors include two entities: (i) the University A School of Medicine, a component of an academic medical center, which employs the University A physicians and non-physician practitioners and operates [redacted] (the “Institute”); and (ii) the University A Management Entity, which is a nonprofit corporation that provides support for the education, research, and patient care mission of the University A School of Medicine, including by providing the full range of business management services to the University A School of Medicine physicians and non-physician practitioners. The University A Management Entity is enrolled in Federal health care programs as a clinic location and also is a component of an academic medical center.

University B employs the physician and non-physician practitioners of University B Medical Group, which is a component of an academic medical center and operates [redacted] (the “Center”). These physician and non-physician practitioners provide services at University B Medical Group clinics as well as non-University B Medical Group facilities. The University B Medical Group intends to provide the services contemplated in the Proposed Arrangement through the Center at University B Medical Group clinics. The University B Medical Group’s practitioners are enrolled in Federal health care programs.

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.

The Institute and the Center were created as interdisciplinary programs (each, a “Clinical Program” and collectively, the “Clinical Programs”)² to provide intensive outpatient treatment and specialty care for United States military service veterans with mild-to-moderate traumatic brain injuries (“TBI”) and associated physical and psychological health conditions connected to their military service, including post-traumatic stress (“PTS”). Requestors certified that they used the model of care developed by the National Intrepid Center of Excellence (“NICOE”) at Walter Reed National Military Medical Center (“Walter Reed”) to serve as a basis for the Clinical Programs. The NICOE program also served as a model for the Department of Defense’s Intrepid Spirit Centers (collectively with NICOE, the “Intrepid Centers”). The Intrepid Centers’ intensive outpatient program is available only to active-duty service members; therefore, they are not available to veterans who would qualify for services under the Proposed Arrangement.

B. The Proposed Arrangement

1. Intensive Outpatient Program

Requestors certified that the Clinical Programs are designed to assist veterans with TBI, who also may have PTS, and who have unmet health needs due to the lack of access to specialty care for the treatment of TBI in their own communities. These veterans are not eligible for the Intrepid Centers’ intensive outpatient program because that program is limited to active-duty service members. Under the Proposed Arrangement, Requestors would use a three-step process set forth below for screening and treatment.

As a first step, a Clinical Program would assess initial eligibility. In particular, for any individual who self-refers or is referred to a Clinical Program by a health care provider, the Clinical Program would perform an intake process that would confirm the individual’s veteran status and include a detailed medical records review. Eligibility would be limited to veterans whose medical records show either: (i) a TBI diagnosis; or (ii) a history of head injury that could have led to TBI or post-concussion syndrome (a “Head Injury”). If the records show that the veteran has PTS but not a TBI or a Head Injury, then the veteran would not qualify for the Proposed Arrangement. The medical records review also would preliminarily assess whether the veteran is psychiatrically stable (*i.e.*, the veteran is not actively suicidal or currently hospitalized for any psychiatric condition) and that there is no indication of an unmanaged substance use disorder. In some situations, a telephone intake could be conducted in addition to the medical records review to assess these initial eligibility criteria.

Second, if the Clinical Program determines that the veteran meets the initial criteria for treatment and should be evaluated further, the veteran would participate in a 3- to 4-day in-person diagnostic evaluation with specialists at a Clinical Program site. During the in-person evaluation, a clinician, such as a licensed clinical social worker or other provider trained in taking veterans’ TBI history, would interview the veteran to obtain further details regarding the TBI or Head Injury event and severity of the injury. To further evaluate whether treatment through the Proposed Arrangement would be appropriate for the veteran, the Clinical Program

² We refer to the “Clinical Programs” collectively because they will operate in essentially the same way. However, they are two separate programs with no joint operations.

would gather additional information regarding the veteran’s medical history, current health status, and management of any psychiatric conditions or substance use. The Clinical Program would obtain neuroimaging reports and review them for any relevant findings; they also would review associated medical records to determine if there are neurological findings separate from a TBI or a Head Injury. The veteran’s treatment history, including past success or failure of treatment, compliance with treatment, and access to treatment, also would be considered in the evaluation. Specialists at the Clinical Program collectively would determine whether the intensive outpatient program furnished by the Clinical Program would be appropriate for the veteran on a case-by-case basis.³

Finally, if the specialists at the Clinical Program determine that the intensive outpatient program would be appropriate, then the veteran would proceed to the third step of the process: the veteran would return for 3 weeks of intensive outpatient treatment. This treatment would include a range of services, including behavioral health, neuropsychology, neurology, clinical pharmacy and pharmacology, physical therapy, speech language pathology, healing arts therapy, integrative therapies, animal-assisted therapy, case management, and veteran relations. The appropriate suite of services would be provided or coordinated by an interdisciplinary team of clinicians at the Clinical Program. During the final week of intensive outpatient treatment, the veteran’s family member(s) may travel to the Clinical Program location to meet with the clinical team about the veteran’s care and needs upon return home.

The Proposed Arrangement would include only medically necessary care and other ancillary services that are integral to the veteran’s specific intensive outpatient treatment program, which may be performed directly by the Clinical Programs or by a third party. If a veteran requires services that are related to treatment of the veteran’s TBI, Head Injury, or PTS that the Clinical Program does not provide directly, the Clinical Program would make arrangements with third parties to ensure the veteran receives such services, and those services would be covered by the Clinical Program through the Proposed Arrangement. If the veteran requires additional medically necessary treatment during the intensive outpatient treatment period that is unrelated to the veteran’s TBI, Head Injury, or PTS (e.g., if the veteran were to experience cardiac symptoms), practitioners at the Clinical Program would refer the veteran elsewhere for treatment. This unrelated treatment would not be covered under the Proposed Arrangement.

Requestors certified that a key feature of the specialty care that Requestors would provide through the Clinical Programs is its interdisciplinary care model. While Requestor acknowledged veterans may be able to find some of the specialty care services offered by the Clinical Programs in their own communities, the Clinical Programs’ approach can address the

³ Requestors certified that the Clinical Programs must assess a veteran’s ability to navigate the intensive outpatient program from a physical, cognitive, and psychological standpoint and that the intensive outpatient treatment would not be appropriate for all veterans with TBI or Head Injuries. For example, if the veteran has unstable medical (e.g., cardiac) conditions, a non-traumatic brain injury (e.g., resulting from an illness rather than external force), severe TBI that is beyond the scope of outpatient treatment, or other conditions that interfere with the Clinical Program’s ability to evaluate or treat the veteran (e.g., excessive substance use or unstable psychiatric conditions), then the veteran would not qualify for the intensive outpatient treatment.

veterans' unmet health needs that otherwise may result in overutilization of covered services due to the lack of certain types of specialized care in their own communities. Requestors further certified that, to their knowledge, the model of interdisciplinary outpatient treatment offered through the Clinical Programs has been available only at the Intrepid Centers; those programs are available only for active-duty service members. With the exception of veterans who happen to live near a Clinical Program site, veterans would need to travel to the Center or the Institute from their home communities to access the specialized, interdisciplinary care offered by the Clinical Programs. After a veteran has completed the intensive outpatient program through one of the Clinical Programs, case managers at the respective Clinical Program would follow up with the veteran for at least 1 year, or longer as needed, to assist the veteran with navigating resources for follow-up treatment and other services in the veteran's community.

2. Funding for Veterans' Out-of-Pocket Costs

Under the Proposed Arrangement, Requestors would use charitable donations from certain donors, as described in more detail below, to cover expenses veterans would incur while receiving evaluation and treatment by the Clinical Programs, including out-of-pocket costs for treatment related to the veteran's TBI, Head Injury, or PTS diagnosis (whether provided directly by the Clinical Programs or by a third party) and travel-related expenses. In other words, veterans and their families would incur no out-of-pocket costs related to the Proposed Arrangement during the entirety of the three-step screening and treatment process, regardless of a veteran's ability to pay or any potential insurance coverage.⁴

In the absence of the Proposed Arrangement, the treatment provided by the Clinical Programs would result in substantial out-of-pocket costs for the veteran.⁵ More specifically, without the Proposed Arrangement's support, a veteran would be responsible for any cost sharing for covered items and services imposed by the applicable Federal health care program or other third-party payor. In addition, the Clinical Programs likely would provide services that are not typically covered by Federal health care programs or commercial insurance programs, such as art therapy, integrative therapy, and equine and canine-assisted therapy. Without the financial support available through the Proposed Arrangement, most individuals receiving these non-covered services would be required to pay 100 percent of the cost. Finally, because the Clinical Programs are only offered at the Center and the Institute, most veterans who would receive treatment through the Clinical Programs would have to travel to the Center or the Institute for the second and third (if applicable) steps of screening and treatment, and they and their family member(s) would incur travel, lodging, and meal costs. More specifically, Requestors would use charitable donations to provide the following three types of assistance to veterans.

⁴ Requestors certified that they anticipate approximately 10–20 percent of the veterans receiving treatment through the Clinical Programs would be Medicare beneficiaries, 1–2 percent would be Medicaid beneficiaries, and 20–30 percent would be eligible for benefits through the U.S. Department of Veterans Affairs (the "VA") or TRICARE.

⁵ In contrast, Requestors certified that an active-duty service member receiving similar treatment through an Intrepid Center would be subject to no out-of-pocket costs for such treatment.

First, Requestors would use donations to cover all out-of-pocket costs for treatment by the Clinical Programs, including items or services provided by entities other than the Clinical Programs, related to the veteran’s TBI, Head Injury, or PTS diagnosis. Specifically, under the Proposed Arrangement, Requestors would cover all costs for treatment related to the veteran’s TBI, Head Injury, or PTS diagnosis for veterans without insurance coverage. For veterans with insurance coverage, Requestors would cover all cost sharing for covered items and services and would pay for all non-covered services. Requestors would bill insurers, including Federal health care programs, for covered items and services related to the veteran’s TBI, Head Injury, or PTS diagnosis.⁶ If an entity other than the Clinical Programs provides the item or service, then Requestors would instruct that entity to bill the Clinical Programs, rather than the veteran or any payor, including Federal health care programs. Requestors would use donations to cover any costs billed by an entity other than the Clinical Programs as well.

Second, Requestors would use charitable funds to pay for the cost of travel (including air travel, if necessary) to the Clinical Program sites, modest lodging, and meals for the in-person evaluation and for the outpatient treatment (if applicable) for the veteran and, as needed, a companion. For veterans who can drive to a Clinical Program site, the charitable funds would cover the cost of ground transportation through a standard per-mile reimbursement.

Third, if the veteran is accepted into intensive outpatient treatment, Requestors would use the charitable funds to cover the cost of travel, lodging, and meals for the veteran’s family member(s) for the last week of outpatient treatment. The number of family members per veteran would be limited to the minimum necessary to meet the veteran’s future care needs.

3. Donors

Requestors certified that any donors contributing to the Proposed Arrangement would be individuals and organizations that support veterans’ needs and would not be individuals or entities in the health care industry, including entities that manufacture or furnish items or render services that are billable to Federal health care programs. By way of example, the primary donor Requestors expect to cover out-of-pocket expenses related to treatment provided as part of the Proposed Arrangement is [redacted] (the “Charitable Program”), which is a program of [redacted] (the “Charity”), a tax-exempt public charity established to expand access to specialized care for veterans with a goal of expanding NICOE’s work to veterans with TBI and Head Injuries.⁷

⁶ While Requestors would bill for covered items and services that they provide, Requestors certified that they would not bill a payor for any facility fees (e.g., if a diagnostic service were performed at a hospital, a Requestor would bill the physician’s fees to the insurer, but they would direct the hospital to bill a Clinical Program for the facility fees, which the Requestor would pay for with donations).

⁷ The Charitable Program has contributed its gift based on the past success of the treatment model available through NICOE and a desire to bring that level of multi-disciplinary, integrated care to veterans who can no longer access similar treatment through the Intrepid Centers.

4. Additional Facts

Requestors certified that the Clinical Programs are a charitable and research-oriented endeavor and are effective in helping veterans who have not responded to other treatment. Requestors further certified that, even with donor support, the cost of furnishing services by the Clinical Programs would result in financial losses to Requestors because: (i) Requestors' costs exceed reimbursement rates or services are not covered; and (ii) donor support would help but is not expected to cover all of Requestors' costs. While Requestors would advertise the availability of specialized services for veterans through the Clinical Programs, Requestors would not advertise the availability of financial assistance. Further, Requestors would not shift any costs of supplying the financial assistance to Federal health care programs.

In addition, University A previously conducted a beta test of the Proposed Arrangement at the Institute and certified that the majority of veterans who sought care as part of that beta test did not have full-time employment, and almost half of the applicants reported having a VA disability rating of 90 percent or higher. Therefore, Requestors asserted that any out-of-pocket costs associated with treatment furnished through the Clinical Programs would create substantial financial barriers to accessing care.

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.⁸ 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.⁹ 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

According to Requestors, the Charitable Program's donation reflects the Charity's perspective that veterans with TBI and Head Injuries who have not responded to traditional treatment should have access to the same type of care available to active-duty service members without out-of-pocket expenses, regardless of any financial need assessment.

⁸ Section 1128B(b) of the Act.

⁹ Id.

program.¹⁰ 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, the OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. The 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. The 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, as further explained in regulations, contains two exceptions to the definition of "remuneration" that may apply in the context of the Proposed Arrangement: (i) section 1128A(i)(6)(F) of the Act permits certain remuneration that promotes access to care and poses a low risk of harm to patients and Federal health care programs; and (ii) section 1128A(i)(6)(H) of the Act permits the transfer of items and services that meet certain criteria, including a determination of financial need.

B. Analysis

The Proposed Arrangement would implicate both the Federal anti-kickback statute and the Beneficiary Inducements CMP. Requestors would offer remuneration to veterans who receive treatment from the Clinical Programs by using donations to cover veterans' cost-sharing amounts otherwise owed for billable items and services; out-of-pocket costs for non-covered items and services; and certain travel, lodging, and meals. There is no exception or safe harbor that would apply to protect the remuneration under the Federal anti-kickback statute. While certain aspects of the remuneration could meet the requirements of the exception to the Beneficiary Inducements CMP for remuneration that promotes access to care and poses a low risk of harm (*e.g.*, the travel assistance), no exception would protect other aspects of the remuneration (*e.g.*, the cost-sharing subsidies, particularly without an individualized financial need determination). Nevertheless, because of the unique circumstances present in the Proposed Arrangement, and for the reasons below, we conclude that the Proposed Arrangement would present a minimal risk of fraud and abuse under the Federal anti-kickback statute and that we would not impose sanctions under the Beneficiary Inducements CMP.

¹⁰ *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).

First, the Proposed Arrangement would be unlikely to increase costs inappropriately for Federal health care programs and could result in overall cost savings. For example, some of the services offered would not be billable services because: (i) the services are not covered at all (e.g., certain art or animal-assisted therapies) or are frequently denied; or (ii) the services are provided by an entity other than the Clinical Programs and, even if they could be billed to a Federal health care program, they would be billed to the Clinical Programs instead. These costs would be funded by charities that have made contributions to help veterans receive treatment through the Clinical Programs and would not be billed to Federal health care programs. In addition, Requestors certified that they would provide only medically necessary care and other ancillary services integral to a veteran's treatment and expect the Clinical Programs' treatment to address unmet health needs that, without appropriate treatment, could lead to overutilization of covered services.

Second, Requestors certified that donors to the Proposed Arrangement, including the Charitable Program, would not be involved in the health care industry and, specifically, would not manufacture or furnish items or render services that are billable to Federal health care programs. Instead, donors typically would be supporters of veterans' needs. Therefore, donors would not have a financial interest in veterans obtaining any particular items or services.

Third, while the Proposed Arrangement could induce veterans to receive certain services from Requestors that they might have received elsewhere (or not have received at all), there is a low risk that it would induce veterans to receive any services from Requestors outside of those offered through the Clinical Programs. Because Requestors are components of academic medical centers, we recognize that veterans might receive services from other components of such academic medical centers that may result in claims to a Federal health care program. For example, if the veteran were to need emergency treatment for unrelated conditions during the time of the intensive outpatient treatment, and the hospital that is part of the academic medical center is the closest hospital, the veteran may receive treatment there. However, based on the unique facts and circumstances of the Proposed Arrangement, there is a low risk that the remuneration offered to beneficiaries would be used to create the opportunity to provide services that would result in claims to a Federal health care program. The Proposed Arrangement is designed to enable the veteran to access the services of the Clinical Programs, not other covered services that are not part of the Clinical Programs. In addition, veterans would return to their home communities after the 3-week program, so any future treatment for both related and unrelated conditions most likely would be from health care providers in those communities rather than from Requestors.

Fourth, Requestors would not advertise the availability of financial assistance in connection with the Clinical Programs. All veterans who meet the clinical criteria to receive treatment from the Clinical Programs would receive treatment and transportation at no cost to them, regardless of financial need or insurance status.

Finally, the Proposed Arrangement would be unlikely to result in "leapfrogging" concerns. Requestors would offer the Proposed Arrangement to veterans diagnosed with TBI or a Head Injury, who, if they were active-duty service members, could receive similar services through the Intrepid Center programs at no cost. Requestors certified that, to their knowledge, no other entities provide a similar, coordinated suite of services. Therefore, Requestors' subsidization of

out-of-pocket costs for care and travel, lodging, and meals for the veterans and their family members appears to be a reasonable means to facilitate veterans' access to these services.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG would not impose administrative sanctions on Requestors in connection with the Proposed 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 Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Beneficiary Inducements CMP, the OIG would not impose administrative sanctions on Requestors in connection with the Proposed 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 Proposed Arrangement and has no applicability to any other arrangements that may have been disclosed or referenced in your request for an advisory opinion or supplemental submissions.
- This advisory opinion is issued only to Requestors. 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 Requestors to prove that the person did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.
- This advisory opinion applies only to the statutory provisions specifically addressed in the analysis above. We express no opinion herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-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.

The OIG will not proceed against Requestors with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The 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, the OIG will not proceed against Requestors with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Susan A. Edwards/

Susan A. Edwards
Acting Assistant Inspector General for Legal Affairs