

Office of Inspector General

Washington, D.C. 20201

[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.]

Issued: October 7, 2008

Posted: October 14, 2008

[Name and address redacted]

#### Re: OIG Advisory Opinion No. 08-16

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposed arrangement by which your hospital would share with a physician-owned entity certain performance-based compensation available to the hospital under a quality and efficiency agreement with a private insurer (the "Proposed Arrangement"). You have inquired whether the Proposed Arrangement would constitute grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplemental letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect. Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude: (i) the Proposed Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to Sections 1128A(b)(1)-(2) of the Act, but the Office of Inspector General ("OIG") would not impose sanctions pursuant to Sections 1128A(b)(1)-(2) on the Requestor in connection with the Proposed Arrangement; and (ii) while the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG would not impose administrative sanctions on the Requestor under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

This opinion may not be relied on by any persons other than [name redacted], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

# I. FACTUAL BACKGROUND

[Name redacted] (the "Requestor") is a [state redacted] non-profit corporation that owns and operates an acute care general hospital (the "Hospital"). The Hospital participates in a payfor-performance program (the "Program") implemented by [name redacted] (the "Private Insurer"). Pursuant to the Program, in addition to the aggregate amount the Private Insurer pays the Hospital for the care of patients in a given year ("Base Compensation"), the Private Insurer will pay the Hospital an additional percentage of the Base Compensation ("Bonus Compensation"), based on the extent to which the Hospital meets certain standards of quality and efficiency. The maximum Bonus Compensation payable in 2008 is four percent of the Base Compensation.

A portion of the Bonus Compensation is attributable to achieving certain quality of care standards. For example, the standards for 2008 relate to six conditions or procedures. With regard to two of the conditions or procedures, the Private Insurer will give credit (and thus compensation) simply for reporting data. With respect to the remaining four conditions or procedures, earning Bonus Compensation requires meeting certain performance standards ("Quality Targets"). These Quality Targets are among the measures described in the Specifications Manual for National Hospital Quality Measures (the "Quality Measures Manual" or the "Manual"). The Quality Measures Manual is published by the Joint Commission (formerly the Joint Commission on Accreditation of Health Care Organizations) and represents the joint efforts of CMS and the Joint Commission to publish

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a uniform set of national hospital quality measures. See

http://www.jointcommission.org/PerformanceMeasurement/PerformanceMeasurement/Curr ent+NHQM+Manual.htm. These measures are subject to revision and update as the consensus in the medical community changes as to what constitutes the appropriate standard of care.

In determining compliance with the Quality Targets for purposes of calculating the Bonus Compensation, all of the Hospital's inpatients having a designated condition or procedure are counted, not only those insured by the Private Insurer. This includes Medicare and Medicaid beneficiaries. In order for the Hospital to receive credit with regard to a particular patient, every standard for the designated condition or procedure must be met, except where a specific standard is contraindicated for that patient.

The Requestor has certified that the Hospital cannot achieve these Quality Targets without the assistance and cooperation of its medical staff.

[name redacted] (the "Physician Entity" or the "Entity") is a proposed [state redacted] professional limited liability company, whose members will be physicians who are licensed to practice medicine or osteopathic medicine and surgery in the State of [stated redacted], have been members in good standing of the Hospital's active medical staff for at least one year, and meet the qualifications set forth in the Physician Entity Operating Agreement. Each physician who joins the Physician Entity will make an equal capital contribution in its formation, which, in the aggregate, will provide for the Entity's working capital needs. While the exact number of physician owners of the Physician Entity is not known prior to its formation, the Requestor has certified that it will not go forward with the Proposed Arrangement unless at least ten of the physicians on its staff agree to participate.

Under the Proposed Arrangement, the Hospital will enter into a quality enhancement professional services agreement (the "Agreement") with the Physician Entity.<sup>1</sup> The Agreement will be for an initial term of three years and will be subject to automatic renewal unless terminated.<sup>2</sup> Pursuant to the Agreement, the Physician Entity will require its members to undertake various tasks to ensure that the Quality Targets are achieved, including developing policies and procedures, conducting peer review, and auditing medical records.

Pursuant to the Agreement, the Hospital will pay the Physician Entity a percentage of the Bonus Compensation it receives as a result of achieving the Quality Targets (the "Physician

<sup>&</sup>lt;sup>1</sup> The Private Insurer will not be a party to the Agreement.

 $<sup>^{2}</sup>$  As discussed below, this opinion applies only to the initial three-year term of the Agreement.

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Percentage").<sup>3</sup> While the Private Insurer may change the Quality Targets from year to year, the Physician Percentage will apply only to Bonus Compensation attributable to meeting standards included in the then-current Quality Measures Manual. The Hospital and the Physician Entity will negotiate the Physician Percentage annually, but it will not exceed 50 percent of the amount the Hospital earns from the Private Insurer as a result of achieving the Quality Targets. The Requestor has certified that this compensation will be fair market value for services rendered to the Hospital pursuant to the Agreement, and will not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.<sup>4</sup> The Physician Entity will, in turn, distribute its earnings under the Agreement to its members on a *per capita* basis.

The compensation payable to the Physician Entity pursuant to the Agreement will be limited as follows: If the amount of Base Compensation the Private Insurer pays to the Hospital for inpatient care in a given year exceeds the amount of Base Compensation paid in the fiscal year prior to the execution of the Agreement (the "Base Year"), adjusted for inflation, then the Physician Entity's compensation will be calculated on the basis of the inflation-adjusted Base Compensation paid in the Base Year. As a result, any increase in patient referrals to the Hospital, resulting in an increase to the Base Compensation, would not increase compensation to the Physician Entity.

The Requestor has certified that it will monitor the Quality Targets and their implementation throughout the term of the Agreement to protect against inappropriate reductions or limitations in patient care services. It will terminate the application of any Quality Target that is determined to have an adverse effect on the quality of care. It will also monitor for changes in physician referral patterns (including changes in patient mix) potentially attributable to efforts to meet the Quality Targets. If the Requestor determines that a physician's referral patterns have changed significantly in a manner beneficial to the Requestor, due in any part to the financial awards available to the physician under the Proposed Arrangement, the physician in question will be terminated from the Physician Entity. The Requestor will maintain records of its performance in meeting the Quality Targets and make them available to the Secretary upon request. It has also certified that all

<sup>&</sup>lt;sup>3</sup> The Agreement will also provide that the Hospital will pay the Physician Entity a portion of any compensation received as a result of meeting similar pay-for-performance standards established by CMS. At the present time, the Hospital does not participate in any CMS pay-for-performance program.

<sup>&</sup>lt;sup>4</sup> We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestor has certified that the payments under the Proposed Arrangement will be consistent with fair market value, we do not rely on that certification in this opinion, nor have we made an independent fair market value assessment.

patients who are admitted to the Hospital with one of the conditions subject to the Quality Targets will be informed of the Program in writing. Whenever feasible, such notice will be provided in advance of the patient's admission.

## II. LEGAL ANALYSIS

Incentive compensation arrangements like the Proposed Arrangement are designed to align incentives by offering physicians a portion of a hospital's compensation related to meeting quality targets, in exchange for implementing strategies to help the hospital meet those targets. Properly structured, such arrangements can serve legitimate business and medical purposes by improving efficiency and quality of care. However, like any payment arrangement between a hospital and physicians who refer business to the hospital, payments purportedly intended to encourage quality improvements might be misused by unscrupulous parties to induce limitations or reductions in care or to disguise kickbacks for Federal health care program referrals. Therefore, such arrangements must be evaluated in light of applicable Federal statutes and the potential for abuse.

## A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Section 1128A(b)(1)-(2) of the Act establishes a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to \$2,000 per patient covered by the payments. <u>See id.</u> There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.<sup>5</sup>

<sup>&</sup>lt;sup>5</sup> Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). <u>See</u> OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at <u>http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm.</u> See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

The Proposed Arrangement applies to compensation paid by the Private Insurer and shared by the Hospital with the Physician Entity. It is nevertheless necessary to evaluate whether the Proposed Arrangement might induce physicians to reduce or limit items or services to Federal health care program beneficiaries. Under the Program, the Bonus Compensation attributable to achieving the Quality Targets is calculated on the basis of care provided to *all* the Hospital's inpatients, including Medicare and Medicaid beneficiaries, not only those insured by the Private Insurer. Even if this were not the case, the efforts of the Physician Entity to meet the Quality Targets would, as a practical matter, necessarily be directed at all patients.<sup>6</sup>

Having reviewed the Quality Targets adopted by the Private Insurer in 2008, we conclude that, notwithstanding their purpose of improving patient care, compensation from the Hospital to the Physician Entity for achieving these targets might implicate the CMP by inducing physicians to reduce or limit the current level of certain items or services provided to Federal health care beneficiaries at the Hospital. For example, one Quality Target requires a prophylactic antibiotic to be administered prior to select surgeries and to be discontinued within specified times. If adherence to this standard results in physicians discontinuing prophylactic antibiotics sooner than would be their practice in the absence of the Proposed Arrangement, then a limitation of items or services would occur. Other Quality Targets that might be selected by the Private Insurer in future years might also implicate the CMP.

We recognize that the current medical practice may involve care that exceeds the requirements of medical necessity or does not comply with currently accepted best practices. However, whether current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

Nevertheless, several features of the Proposed Arrangement, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act, with regard to the Proposed Arrangement as it applies to the Program currently implemented by the Private Insurer.

<u>First</u>, there is credible medical support for the position that the Proposed Arrangement has the potential to improve patient care and is unlikely to have adverse effects on it. In the Proposed Arrangement, physicians are to be compensated for specific actions which have been recognized as improving patient care. The financial incentives to the physicians will be tied to meeting the Quality Targets. Each of the Quality Targets affecting compensation to the Physician Entity will correspond with a standard published in the Quality Measures

<sup>&</sup>lt;sup>6</sup> Moreover, some patients insured by the Private Insurer may also be Federal health care program beneficiaries.

Manual, a collaborative effort by CMS and the Joint Commission to promulgate a uniform set of national hospital quality measures. These standards are subject to revision and update as the consensus in the medical community changes as to what constitutes the appropriate standard of care.<sup>7</sup>

<u>Second</u>, there will be no incentive for a physician to apply a specific standard in medically inappropriate circumstances. Bonus Compensation from the Private Insurer to the Hospital is not reduced because a specific standard is not met in the case of a particular patient, if the standard is contraindicated with regard to that patient. Therefore the compensation shared with the Physician Entity under the Proposed Arrangement also will not be reduced in those circumstances.

<u>Third</u>, the Quality Targets are reasonably related to the practices and patient population of the Requestor, which is an acute care general hospital. The patients whose care is the subject of the Quality Targets are likely to be treated at this Hospital, and the procedures involved in the Quality Targets are routinely used there.

<u>Fourth</u>, the performance measures that could result in compensation to the Physician Entity are clearly and separately identified, and affected patients will be notified of the Program. The transparency of the Proposed Arrangement allows for public scrutiny and individual physician accountability for adverse effects of the Proposed Arrangement, should any occur.

<u>Fifth</u>, the Requestor has certified that it will monitor the Quality Targets and their implementation throughout the term of the Agreement, to protect against inappropriate reductions or limitations in patient care or services, and will take appropriate steps if problems arise.

We iterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care.<sup>8</sup> Importantly, the Proposed Arrangement ties

<sup>&</sup>lt;sup>7</sup> Because each Quality Target affecting Bonus Compensation to be shared with the Physician Entity appears in the Quality Measures Manual, we have not sought an independent medical review of the Quality Targets. Manual listing suffices to address our typical concerns about adverse clinical impacts of performance standards. In this regard, the Proposed Arrangement is distinguishable from arrangements involving quality measures developed by one or both parties.

<sup>&</sup>lt;sup>8</sup> Quality Targets that do not potentially induce the reduction or limitation of items or services do not implicate the CMP. Payments by insurers directly to physicians also do not implicate the CMP.

physician compensation to specific Quality Targets that have been endorsed by CMS and the Joint Commission through the Quality Measures Manual, thus taking advantage of the continuing review and update of these standards conducted by these entities. Because the measures identified in the Quality Measures Manual are subject to regular update by CMS and the Joint Commission as the consensus regarding appropriate standard of care evolves, they carry a presumption of legitimacy, even where they might implicate the CMP by potentially inducing the reduction or limitation of items and services.

Accordingly, for all of these reasons, in an exercise of our discretion, we choose not to impose sanctions under the CMP as a result of the Proposed Arrangement.<sup>9</sup>

## B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. <u>See section 1128B(b)</u> of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the 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 <u>one</u> purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. <u>United States v. Kats</u>, 871 F.2d 105 (9th Cir. 1989); <u>United States v. Greber</u>, 760 F.2d 68 (3d Cir.), <u>cert. denied</u>, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. <u>See</u> 42 C.F.R. § 1001.952. The safe harbors

<sup>&</sup>lt;sup>9</sup> We express no opinion with regard to any future changes in the Program or Quality Targets that diverge from the patient quality care measures listed in the then-current Quality Measures Manual.

set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Proposed Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance. The Proposed Arrangement does not meet this requirement of the safe harbor. However, the absence of safe harbor protection is not fatal. Instead, the Proposed Arrangement must be subject to case-by-case evaluation.

As with any compensation arrangement between a hospital and a physician who admits or refers patients to the hospital, we are concerned that the Proposed Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Physician Entity or its members. Specifically, the Proposed Arrangement could encourage physicians to join the staff of the Hospital in order to be eligible to join the Physician Entity and share in the Quality Compensation. It could encourage physicians to admit additional patients to the Hospital to increase the Base Compensation paid by the Private Insurer to the Hospital, which in turn would increase the available Bonus Compensation on which payments to the Physician Entity are based. The availability of such compensation could influence referrals of or care given to Federal health care program beneficiaries, even though at this time the Proposed Arrangement only involves compensation from the Private Insurer. Some patients insured by the Private Insurer may also be insured by Federal programs. Moreover, physicians may increase their referrals of Federally-insured patients in anticipation of participating in any CMS-sponsored pay-for-performance programs, or the Private Insurer Program may induce them to increase their referrals generally, including referrals of Medicare and Medicaid patients.

While we believe the Proposed Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we would not impose sanctions arising in connection with the anti-kickback statute in the particular circumstances presented here and as qualified below.

<u>First</u>, the circumstances and safeguards of the Proposed Arrangement reduce the likelihood that the Proposed Arrangement will be used to attract referring physicians or to increase referrals from physicians already on the Hospital's staff. Specifically, membership in the Physician Entity will be limited to physicians who have been on the active medical staff of the Requestor for at least a year, thus limiting the likelihood that the Proposed Arrangement will attract physicians specifically for the opportunity to share in the Quality Compensation. In addition, the compensation paid to the Physician Entity will be subject to a cap tied to the

Base Compensation paid by the Private Insurer to the Hospital in the Base Year. Thus an increase in patient referrals to the Hospital would not result in an increase in compensation paid to the Physician Entity. While physicians will be able to increase their compensation under the Agreement by working to achieve the Quality Targets, they will not be able to do so by increasing patient referrals to the Hospital. The Requestor will monitor the implementation of the Quality Targets to protect against changes in referral patterns (including changes in patient mix) resulting from efforts to meet the Quality Targets. If the Requestor determines that a physician's referral patterns significantly changed in a manner beneficial to the Requestor, due in any part to the financial awards available to the physician under the Proposed Arrangement, the physician in question will be terminated from the Physician Entity.

<u>Second</u>, *per capita* distribution of compensation under the Agreement among the members of the Physician Entity will reduce the risk that the Proposed Arrangement might be used to reward individual physicians who refer patients to the Hospital. Participation will not be limited to any particular group of high-referring physicians, but all physicians who have been on the active medical staff of the Requestor for at least a year will be eligible to participate.

<u>Third</u>, the transparency of the Proposed Arrangement will help to ensure that its purpose is to improve quality, rather than reward referrals. The Proposed Arrangement will set out with specificity the Quality Targets on which the compensation to the Physician Entity will be based. The Physician Entity will be paid only for the Quality Targets that appear in the Quality Measures Manual.

<u>Fourth</u>, the oversight role of the Private Insurer in the Proposed Arrangement will provide a safeguard ensuring that payments to the physicians will be based on achieving the Quality Targets, rather than on referrals of patients. The compensation to physicians under the Proposed Arrangement will be a percentage of that portion of the Bonus Compensation paid by the Private Insurer to the Hospital that is attributable to meeting the Quality Targets. The Private Insurer has no incentive to overcompensate either the Hospital directly or the physicians indirectly; it has every incentive to pay this portion of the Bonus Compensation only as earned through the achievement of Quality Targets.

<u>Fifth</u>, the Proposed Arrangement will be implemented through the Agreement, a three-year contract, and thus will be limited in time.<sup>10</sup>

<sup>&</sup>lt;sup>10</sup> We note that the Agreement will be subject to automatic renewal unless terminated; however, this opinion applies only to the initial three-year term. We express no opinion with respect to future extensions of the Proposed Arrangement. We would expect that quality improvement agreements between the Physicians and Hospital would be subject to

Finally, achieving the Quality Targets is an important part of the Program, and the Requestor has certified that it is not feasible to achieve them without the assistance of its medical staff.

In light of the totality of these circumstances and safeguards, the Proposed Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

### III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude: (i) the Proposed Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to Sections 1128A(b)(1)-(2) of the Act, but the OIG would not impose sanctions pursuant to Sections 1128A(b)(1)-(2) on the Requestor in connection with the Proposed Arrangement; and (ii) while the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG would not impose administrative sanctions on the Requestor under sections 1128A(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

### **IV. LIMITATIONS**

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.
- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor of this opinion.

adjustment over time, to avoid payment for improvements achieved in prior years and to provide incentives for additional improvements in the future. Continuing compensation for conduct that has come to represent the accepted standard of care could, depending on the circumstances, implicate the anti-kickback statute.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied 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.
- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.
- No opinion is expressed herein regarding the liability of any party 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 [name redacted] 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 the [name redacted] with respect to any action 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,

/Lewis Morris/

Lewis Morris Chief Counsel to the Inspector General