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 associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: December 29, 2017

Posted: January 5, 2018

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 17-09

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding an arrangement in which certain neurosurgeons have agreed to implement cost-reduction measures in designated surgical procedures performed at a medical center, and the medical center will share with such neurosurgeons a percentage of its cost savings resulting from these measures (the "Arrangement"). You have inquired whether the Arrangement constitutes grounds for the imposition of sanctions arising under: (i) the civil monetary penalty provision for a hospital's payment to a physician to induce the reduction or limitation of medically necessary 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 submissions, 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, including your certification that none of the recommendations contained within the Arrangement will reduce or limit medically necessary services for patients, we conclude that: (i) the Office of Inspector General ("OIG") will not impose sanctions under sections 1128A(b)(1)-(2) of the Act on the requestors of this advisory opinion, [names redacted], in connection with the Arrangement; and (ii) although the 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 will not impose administrative sanctions on [names redacted], 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 Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than [names redacted], the requestors 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

A. The Parties

1. The Medical Center

[Name redacted] (the "Medical Center") is a non-profit acute care hospital in [city redacted, state redacted] that provides a range of inpatient and outpatient hospital services, including the spinal fusion surgeries selected for the cost-reduction measures developed under the Arrangement. The Medical Center is a participating provider in the Medicare and Medicaid programs.

2. The Subsidiary

[Name redacted] (the "Subsidiary") is a wholly owned subsidiary of the Medical Center that provides administrative and managerial infrastructure for the Arrangement and coordinates with [name redacted] (the "Program Administrator") regarding the calculation of any incentive payments to the neurosurgeons participating in the Arrangement. The Subsidiary

also facilitated the formation of a committee that oversees and monitors the Arrangement and supports the ongoing activities of that committee.

3. The Group

[Name redacted] (the "Group") is a multi-specialty physician group consisting of more than one hundred physicians. Physicians in the Group are either shareholders or non-shareholder Group employees. A physician must both be in the Group and practice as a spine surgeon to be eligible to participate in the Arrangement. Four neurosurgeons in the Group meet these criteria and currently participate in the Arrangement (the "Neurosurgeons"). Three Neurosurgeons are shareholders who have participated in the Arrangement since its inception (the "Original Neurosurgeons"). The Group employed a fourth, non-shareholder neurosurgeon in the second year of the Arrangement; this neurosurgeon will be eligible to share in any incentive payments for the third performance year only.

All of the Neurosurgeons have active medical staff privileges at the Medical Center. The Neurosurgeons refer patients to the Medical Center for inpatient and outpatient hospital services, and perform the majority of their spinal surgeries at the Medical Center. In fact, all of the Medical Center's spinal surgeries are furnished by the Neurosurgeons.

4. The Program Administrator

The Medical Center engaged the Program Administrator to administer and manage the Arrangement. The Medical Center pays the Program Administrator a fixed monthly fee that the Medical Center, the Subsidiary, the Group, and the Program Administrator ("Requestors") certified is fair market value in an arm's length transaction for the services the Program Administrator provides in connection with the Arrangement. The fee is not tied in any way to cost savings or to the compensation paid to the Group under the Arrangement.

B. The Arrangement

Under the Arrangement, the Medical Center, through the Subsidiary, will pay[1] the Neurosurgeons a share of three years of cost savings attributable to changes the Neurosurgeons make when selecting and using products during spinal fusion surgeries. The

[1] According to Requestors, the Subsidiary will make payments under the Arrangement following issuance of this advisory opinion.

Original Neurosurgeons have initiated these changes under the terms of the Arrangement. In addition, Requestors have begun performance of their respective duties under the terms of the Arrangement.[2]

1. Development of the Arrangement

The Program Administrator conducted a study of historical practices in spinal fusion surgeries performed by the Original Neurosurgeons at the Medical Center and identified 34 cost-saving opportunities. To identify the opportunities, the Program Administrator collected, measured, and analyzed data on spinal fusion surgeries using a software product it created to track supply costs, quality of patient care, and utilization on a national level. The Program Administrator then worked with the Medical Center, the Subsidiary, and the Group to co-develop the document, [name redacted] (the "Executive Summary"), which contains 34 recommendations based on the cost-saving opportunities.[3] The Medical Center, the Subsidiary, and the Group have reviewed and approved the Executive Summary for medical appropriateness and are in the process of adopting its recommendations and conclusions. The Executive Summary proposes that the Neurosurgeons consider certain changes to their operating room practices for spinal fusion surgeries, with the recommendations falling into two categories.

a. Use Bone Morphogenetic Protein on an As-Needed Basis

Three recommendations suggest that the Neurosurgeons use Bone Morphogenetic Protein ("BMP") only on an as-needed basis for surgeries performed on three specific regions of the spine. The Original Neurosurgeons reviewed guidelines published by the U.S. Food and Drug Administration and performed an evidence-based medical review of relevant literature to develop clinical guidelines for implementing these recommendations.

Before implementation of the Arrangement, the Original Neurosurgeons used BMP in approximately 29 percent of their spinal fusion surgeries performed at the Medical Center. The Program Administrator analyzed national data and studied objective historical and clinical measures reasonably related to the Original Neurosurgeons' practices and the patient population at the Medical Center, and determined that it would be reasonable for the Neurosurgeons to reduce the use of BMP to no lower than four percent of their spinal fusion

[2] For these reasons, we treat the Arrangement as an existing arrangement for the purposes of this advisory opinion.

[3] Requestors certified that these recommendations remain applicable with the addition of the fourth Neurosurgeon.

surgeries. The Neurosurgeons will not receive any share of savings that result from reducing the use of BMP beyond this four percent floor. Requestors certified that the Neurosurgeons must adopt a new clinical process to carry out these recommendations.

b. Product Standardization

The Executive Summary contains 31 recommendations for the Neurosurgeons to standardize certain devices and supplies used in spinal fusion surgeries. The Original Neurosurgeons worked in conjunction with the Medical Center to evaluate and clinically review vendors and products, and selected preferred products using a three-step process.[4] First, the Original Neurosurgeons determined whether all of the products under consideration were clinically safe and effective. Next, they assessed whether the proposed product standardization measures were appropriate on the basis of clinical criteria. As a last step, the Original Neurosurgeons selected products based on prices available to the Medical Center. The Neurosurgeons have all agreed to use the preferred products where medically appropriate, which may require additional training or changes in their clinical practice.

2. Features of the Arrangement

The Arrangement includes safeguards, including monitoring and documentation requirements, intended to maintain patients' quality of care and protect against inappropriate reductions in services. Requestors certified that the recommendations will not reduce or limit medically necessary services for patients. Pursuant to the guidelines developed, the Neurosurgeons must make a patient-by-patient determination as to whether BMP is clinically indicated. For the product standardization recommendations, the Neurosurgeons must select the most appropriate device or supply for each patient.

For both categories of recommendations, the Neurosurgeons have the same devices and supplies available for spinal fusion surgeries performed while the Arrangement is in place as they did prior to the Arrangement. Requestors certified that the economies gained through the Arrangement result from the clinical and fiscal value of standardizing products or using BMP on an as-needed basis, and not from restricting the availability of products.

[4] According to Requestors, no Neurosurgeon has an ownership interest in any preferred product.

a. Monitoring

To confirm the Arrangement does not result in a reduction or limitation of medically necessary services, Requestors developed an oversight committee composed of representatives of the Subsidiary, the Medical Center, and the Neurosurgeons, with a representative of the Program Administrator serving in an advisory role (collectively, the "Program Committee"). The Program Administrator works with the Program Committee to monitor the Arrangement's implementation and operation by: (1) collecting, measuring, and analyzing changes in the costs of the spinal surgery products and data on quality measures; and (2) evaluating resource utilization for patients whose spinal surgeries are covered by the Arrangement. The Program Administrator reports to the Program Committee quarterly on the costs of the products and the quality measures.

The Arrangement also extends such oversight to the Neurosurgeons. To mitigate the risk of cherry-picking or steering away more costly patients, the Neurosurgeons are prohibited from selecting patients to participate in, or withdrawing patients from, the Arrangement. To enforce these restrictions, the Program Committee periodically reviews data on patient ages, case severity, and payors for the patient population undergoing spinal fusion surgeries in order to confirm a historically consistent selection of patients. If the Program Committee finds a Neurosurgeon is not admitting a historically consistent selection of patients, the Program Committee has the right to terminate the Neurosurgeon from the Arrangement. The Program Committee also may terminate a Neurosurgeon for a material violation of the Arrangement's clinical or administrative guidelines.

b. Documentation

Several documentation and notice requirements increase the Arrangement's transparency. First, the Medical Center, the Subsidiary, and the Group must retain all relevant documentation that is necessary to certify the nature and cost of services furnished under the Arrangement. In addition, the Medical Center, the Subsidiary, and the Group must provide patients with written notice of the Arrangement and the compensation relationship between the Subsidiary and the Group, including the fact that the Subsidiary compensates the Group based on a percentage of the Medical Center's cost savings. This disclosure must be made to the patient before he or she is admitted to the Medical Center. If pre-admission disclosure is impracticable, however, the disclosure must be made before the patient consents to surgery. The patient must be given an opportunity, if desired, to review the details of the Arrangement and to learn the specific cost-saving measures applicable to his or her surgery.

3. Payments Under the Arrangement

a. Calculation of the Total Performance Year Savings

At the end of every year in the three-year Arrangement, cost savings are calculated separately for each recommendation using a multi-step process. First, to determine the historical cost for each product covered by the Arrangement (the "base year cost"), the Program Administrator identifies the universe of spinal surgeries covered by the Arrangement in the base year, and then calculates each product's total costs[5] and divides the total costs by the total number of units of that product. The base year for the first year of the Arrangement is the most recent twelve-month period prior to the start of the Arrangement. Requestors reset the base year annually, so that the first year of the Arrangement becomes the base year for the second performance year, and the second year of the Arrangement becomes the base year for the third performance year. Requestor certified this annual rebasing removes all earlier-accomplished savings from the accounting.[6]

Second, the total costs for each product used in the universe of spinal surgeries covered by the Arrangement in the performance year is divided by the total number of products used in the surgeries during the performance year (the "performance year cost"). To calculate both the base year cost and the performance year cost, Requestors include the product's costs for every spinal surgery the Neurosurgeons performed at the Medical Center, regardless of the patients' insurance coverage.

Third, the performance year cost is compared to the base year cost for each product to determine the performance year savings. If the Neurosurgeons' total number of procedures payable by a Federal health care program in a performance year exceeds the total number of like procedures payable by a Federal health care program in the applicable base year, no savings for the additional procedures are shared.[7] This amount is also adjusted to account for any inappropriate reductions in the use of items beyond the limits set in the Executive Summary.

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[5] Requestors use the Medical Center's out-of-pocket acquisition costs for these calculations.

[6] The Arrangement is limited to the three-year term of the contract; accordingly, this opinion is without force and effect with respect to any renewal or extension of the Arrangement.

[7] For the second performance year, the midyear addition of the fourth neurosurgeon will be taken into account.

As a final step, the savings from each recommendation are added together to arrive at the total savings in the applicable performance year (the "total performance year savings"). The cost savings for each product are calculated separately up to this point to preclude shifting of cost savings and to ensure that savings generated by utilization beyond set targets, as applicable, are not credited to the Neurosurgeons.

b. Distribution of the Adjusted Total Performance Year Savings

Once the total performance year savings have been calculated, the Medical Center will transfer an amount equal to 50 percent of the total performance year savings to the Subsidiary, after first deducting the Program Administrator's fee for administering the Arrangement (the "adjusted total performance year savings"). Following issuance of this advisory opinion, the Subsidiary will make separate payments to the Group for the first, second, and third performance years for any adjusted total performance year savings for the applicable performance year. The sum of the three annual payments to the Group constitutes the entire compensation paid to the Group for services performed under the Arrangement. According to Requestors, this aggregate amount will not exceed 50 percent of the total potential cost savings estimated by the Program Administrator at the beginning of the term of the Arrangement (after deducting the Program Administrator's fee for administering the Arrangement).

After the Group receives the adjusted total performance year savings from the Subsidiary, the Group will distribute that amount to the Neurosurgeons on a per capita basis.[8] The amount allocated to each Neurosurgeon is subject to a pre-existing provision in the Group's operating agreement that requires the Group to withhold a percentage of the collections earned by all physicians (both shareholder and non-shareholder) for their personally performed services to fund an equitable share of the Group's administrative expenses. The Group's operating agreement also requires an additional percentage to be taken from the collections for the personally performed services of each non-shareholder physician to pay for recruitment and establishment of a newly recruited physician's practice. According to Requestors, this provision applies to the distribution to the fourth Neurosurgeon.

[8] We express no opinion regarding whether the Federal physician self-referral law, section 1877 of the Act, would be violated by the distribution to the Neurosurgeons. The issuance of a favorable OIG advisory opinion is not intended to be, and should not be construed as, a determination that an arrangement complies with the physician self-referral law or satisfies a statutory or regulatory exception to that law.

II. LEGAL ANALYSIS

A. Law

1. Hospital Payments to Physicians to Induce the Reduction or Limitation of Medically Necessary Services

Section 1128A(b)(1) of the Act (the "Gainsharing CMP") prohibits a hospital from knowingly making payments, directly or indirectly, to a physician to induce the physician to reduce or limit medically necessary services[9] to Medicare or Medicaid beneficiaries who are under the physician's direct care. Hospitals that make (and physicians who receive) payments prohibited by this provision are liable for civil money penalties for each patient for which the prohibited payment was made. See sections 1128A(b)(1)–(2) of the Act.

2. Anti-kickback Statute

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) 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 one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. See, 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), cert. denied, 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

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[9] Section 512(a) of the Medicare Access and CHIP Reauthorization Act of 2015, Public Law 114-10, revised the Gainsharing CMP so that it applies to payments hospitals knowingly make to physicians to induce them to reduce or limit "medically necessary" services.

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.

B. Analysis

The payments from the Medical Center implicate both the Gainsharing CMP and the anti-kickback statute. We consider the application of each law in turn.

1. Gainsharing CMP

Under the Arrangement, payments from the Medical Center flow to the Neurosurgeons (through the Subsidiary and the Group), thus potentially implicating the Gainsharing CMP. A threshold inquiry is whether the Arrangement could induce the Neurosurgeons to reduce or limit medically necessary services to their Medicare and Medicaid patients. Requestors certified that none of the recommendations in the Executive Summary will reduce or limit medically necessary services for patients, and that the Program Administrator monitors the Arrangement by tracking any changes in cost, resource utilization, or quality of patient care, and reports quarterly to the Program Committee on its findings. Although we reviewed the Executive Summary, we cannot opine on whether the recommendations it includes would reduce only services that are not medically necessary.[10] However, we evaluated the methodology Requestors used to develop the cost-saving recommendations, the monitoring and documentation safeguards Requestors implemented, and the methodology Requestors will use to calculate each performance year's savings, and concluded that they appear reasonable. We believe that these features, taken together, reduce the risk that the payments the Medical Center makes to the Neurosurgeons under the Arrangement would induce the Neurosurgeons to reduce or limit medically necessary services to their Medicare or Medicaid patients.

We therefore rely on the veracity of Requestors' certifications in reaching our conclusion that we will not impose sanctions on Requestors under the Gainsharing CMP. Nothing in this advisory opinion, however, should be construed as an endorsement or conclusion as to the medical propriety of the activities undertaken for the Arrangement.

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[10] We note that OIG does not issue advisory opinions on subject matters when an informed opinion can only be made after extensive investigation, clinical study, testing or collateral inquiry. 42 C.F.R. § 1008.15(c)(3).

2. Anti-kickback Statute

Under the Arrangement, remuneration flows indirectly from the Medical Center to the Neurosurgeons, thus implicating the anti-kickback statute. In gainsharing arrangements such as the Arrangement, our typical kickback concern is that the payments a hospital makes to the surgeons for implementing cost-saving measures actually are payments to induce or reward the surgeons' referrals or to attract referring physicians. While we believe the Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, for the combination of the following reasons we conclude that the Arrangement presents a sufficiently low risk of fraud and abuse under the anti-kickback statute.

First, we note that gainsharing arrangements can encourage participating physicians to admit patients to the participating hospital, because the physicians may receive a share of the hospital's reimbursement if the changes they make to their operating room practices generate cost savings. However, the Arrangement includes a combination of safeguards that, taken together, mitigate any incentive the Neurosurgeons might otherwise have to increase their referrals to the Medical Center. First, the incentive payments will be distributed to the Neurosurgeons on a per capita basis, which reduces the risk that the Arrangement may create an incentive for any particular Neurosurgeon to generate disproportionate cost savings. Second, the potential savings are capped based on the number of spinal fusion surgeries performed by the Neurosurgeons on Federal health care program beneficiaries in the relevant base year. Third, Requestors certified that the aggregate payment to the Group, when made, will not exceed 50 percent of the projected cost savings estimated by the Program Administrator at the beginning of the term of the Arrangement (after deducting the Program Administrator's fee for administering the Arrangement). Finally, the Program Committee collects and reviews data on patient severity, age, and payor for the spinal surgeries covered by the Arrangement to confirm a historically consistent selection of patients. While we do not believe the incentive to increase referrals to the Medical Center has been entirely eliminated, it has been substantially reduced through the combination of these safeguards.[11]

Second, although the Group retains a portion of the savings that otherwise would be distributed to the Neurosurgeons under the Arrangement, the Arrangement's structure minimizes the risk that the Group's retention of this portion would be used to induce or reward referrals from the Group's non-participating physicians to the Medical Center.

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[11] The Group recruited a fourth Neurosurgeon during the second performance year. We do not believe it meaningfully raises the risk of the Arrangement for the fourth Neurosurgeon to participate during the final year of the Arrangement, given the Arrangement's safeguards.

Specifically, the Group, rather than individual physicians, retains a percentage of the adjusted total performance year savings. The amount retained by the Group must be used exclusively for the Group's administrative expenses and recruitment expenses, which lowers the risk that it would be used to reward particular physicians. Requestors certified that the Group retains this percentage because of a longstanding formula in the Group's operating agreement and is applied to every physician's collections. We caution that we might reach a different conclusion if these amounts were used for anything other than administrative expenses, or if the formula were not a pre-existing feature of the Group's compensation structure.

Third, we typically have concerns with multiple-year gainsharing arrangements because they can inappropriately carry over savings from previous performance years, effectively accounting for such savings more than once and resulting in unearned duplicate payments that could constitute unlawful kickbacks. Requestors' annual rebasing method removes savings from prior years and ensures that the performance year savings are calculated only as compared to the most recent base year, which prevents improper duplicate payments to the Neurosurgeons.

Fourth, the Original Neurosurgeons reviewed guidelines published by the U.S. Food and Drug Administration and performed an evidence-based medical review of relevant literature to develop clinical guidelines for the use of BMP. With respect to the product standardization recommendations, they conducted an evaluation and clinical review of vendors and products to determine whether the products under consideration were clinically safe and effective. Requestors certified that the product standardization recommendations may require additional training or changes in the Original Neurosurgeons' clinical practices, and the recommendations to use BMP on an as-needed basis necessitate a new clinical process for the Neurosurgeons. As a result, it is not unreasonable for the Medical Center to compensate the Neurosurgeons during the Arrangement's limited term for these activities.

Fifth, Requestors separately identified each cost-saving recommendation and its estimated cost savings in the Executive Summary. The Arrangement ties the Neurosurgeons' incentives to the actual, verifiable cost savings attributable to each recommendation implemented during spinal fusion surgeries. This transparency reduces the risk that any of the Requestors will manipulate Medical Center accounts to generate phantom savings or otherwise game the Arrangement to generate income for the Neurosurgeons.

Sixth, for products covered by the product standardization recommendations, the Neurosurgeons have available the same selection of devices and supplies while the Arrangement is in place as they did prior to the Arrangement. In addition, the Neurosurgeons continue to make patient-by-patient determinations as to the most appropriate device or supply. The structure of the Arrangement allows the Neurosurgeons

to share in savings when they choose less expensive but equally cost-effective products and also preserves the Neurosurgeons' ability to use the most clinically appropriate devices for their patients.

Finally, no neurosurgeons from other physician groups participate in the Arrangement, thus reducing the likelihood that the Medical Center uses the Arrangement to attract neurosurgeons from competitor hospitals to perform surgeries at the Medical Center.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, including your certification that none of the recommendations contained within the Arrangement will reduce or limit medically necessary services for patients, we conclude that: (i) OIG will not impose sanctions under sections 1128A(b)(1)-(2) of the Act on the requestors of this advisory opinion, [names redacted], in connection with the Arrangement; and (ii) although the 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 will not impose administrative sanctions on [names redacted], 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 Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors 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 by a person or entity other than [names redacted], to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

- 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 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.

- 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 [names redacted], with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. 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 [names redacted], 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 the OIG.

Sincerely,

/Robert K. DeConti/

Robert K. DeConti
Assistant Inspector General for Legal Affairs