[*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: March 8, 2012

Posted: March 15, 2012

[Name and address redacted]

Re: OIG Advisory Opinion No. 12-01

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding your proposal to establish a group purchasing organization ("GPO") that would be wholly owned by an entity that also wholly owns many of the potential participants in the GPO, and to pass through to participants in the GPO a portion of the payments received by the GPO from vendors (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (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 Federal 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, we conclude that, although 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 Office of Inspector General ("OIG") would not impose administrative sanctions on [Name redacted], [Name redacted], or [Name 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 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 for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than [Name redacted], [Name redacted], or [Name 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

[Name redacted] (the "Parent Organization") is the parent organization of a national health system consisting primarily of nonprofit corporations (the "Nonprofit Corporations") that own and operate local health care facilities. Each Nonprofit Corporation is a separate legal entity, and each is an indirect subsidiary of the Parent Organization. [Name redacted] (the "Subsidiary") is a first tier subsidiary of the Parent Organization and holds governance and oversight responsibility for the Nonprofit Organizations. [Name redacted] (the "LLC") is a wholly owned subsidiary of the Subsidiary. Collectively, the Parent Organization, the Subsidiary, and the LLC are the "Requestors." The LLC houses the [Name redacted] (the "Resource Group"), which is responsible for the Parent Organization, the Subsidiary, and the Nonprofit Corporations' supply chain, resource, and materials management functions and operations. Currently, the LLC contracts on behalf of the Nonprofit Corporations to allow the Nonprofit Corporations to participate in the system-wide contracts. The Subsidiary also maintains a GPO arrangement with an independent GPO under which the Subsidiary opts into certain GPO contracts with various suppliers on behalf of the Nonprofit Corporations and other affiliated organizations.

The LLC seeks to form and operate a GPO (the "Proposed GPO") for the benefit of the Nonprofit Corporations and other related and affiliated organizations in the health care industry. The Proposed GPO would be a division of the LLC, and the leadership of the Proposed GPO would be the same as the leadership of the LLC. The Resource Group would continue to exist as a separate division of the LLC and would continue to be responsible for the Parent Organization, the Subsidiary, and the Nonprofit Corporations' resource and supply management functions and operations. If the Parent Organization can obtain a better cost value from suppliers through independent GPOs, the Parent

Organization has certified that it would direct its purchasing volume through independent GPOs for those supplies.[1] Similarly, the LLC has certified that it would continue its current practice of contracting directly with vendors on behalf of individual Nonprofit Corporations (without going through the Proposed GPO) when such process would be necessary to meet the Nonprofit Corporations' needs. Other departments and groups within the health system would continue to work collaboratively with the LLC to share knowledge about appropriate product utilization, generate cost-savings, and seek out opportunities that would lead to improvement in the delivery of patient care. This collaboration occurs at the system level through decision teams and a clinical excellence department, and extends down to the individual hospitals, many of which are represented by "clinical sponsors" who are designated to work with the Resource Group and be available to discuss clinically sensitive initiatives.

Although the initial participants of the Proposed GPO likely would be the Nonprofit Corporations and other organizations related to, or affiliated with, the Parent Organization or the Subsidiary (the "Affiliated Participants"[2]), the Proposed GPO would also be open to participation by unrelated health systems and other health organizations (the "Non-Affiliated Participants," and collectively with the Affiliated Participants, the "Participants"). The LLC would not charge the Participants fees to participate in the Proposed GPO.

The Requestors have certified that the purposes of the Proposed GPO would be, in part, as follows: (1) to utilize the purchasing power of the Participants to obtain discounts and realize efficiencies from suppliers based upon the collective buying power of the Participants, thereby reducing spending and controlling costs; (2) to negotiate contracts and develop a contract portfolio to provide for the procurement of supplies, services, and goods necessary and desirable for the successful operation of medical and associated facilities; and (3) to allow Participants to obtain savings by standardizing and streamlining purchasing, thus reducing administrative costs currently associated with their individual supply chain operations and to have the potential for receiving distributions of administrative fees received by the Proposed GPO from suppliers.

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[1] We have not been asked, and we express no opinion, about these independent GPO arrangements.

[2] The vast majority of the related and affiliated entities constituting "Affiliated Participants" are wholly owned by the Parent Organization or the Subsidiary and/or are nonprofit entities in which the Parent Organization or the Subsidiary is the sole corporate member. Those Affiliated Participants that are not wholly owned by the Parent Organization or the Subsidiary may be affiliated through management agreements, joint venture agreements, or similar contractual arrangements. We have not been asked about, and we express no opinion regarding, any of these agreements or relationships.

To accomplish these goals, the Proposed GPO would enter into written agreements with Participants ("Participation Agreements") and suppliers ("Supplier Agreements"). Pursuant to the Participation Agreements and Supplier Agreements, the Proposed GPO would arrange for initial discounts when Participants purchase discounted products directly from the suppliers and may also provide rebates to its Participants by distributing administrative fees to Participants that it collects in excess of its costs.

The Supplier Agreements would specify the method for calculating any administrative fees owed by the supplier to the Proposed GPO, which could be a percentage of the purchases of products by Participants or a flat fee. If the fee would not be fixed at three percent or less of the purchase price of the goods or services, the Supplier Agreement would specify the amount (or maximum amount) that the Proposed GPO would be paid by the supplier. The Proposed GPO would also require suppliers to provide the Proposed GPO with records and reports detailing each Participant's spending and purchasing volume under the contracts for purposes of calculating and allocating such fees.[3] The terms of any rebate would be fixed at the time of the first sale, and the Proposed GPO would disclose to each Participant the aggregate administrative fees that the Proposed GPO received from each supplier during that annual period with respect to purchases made by or on behalf of that Participant. The Proposed GPO would also make such disclosures available to the Secretary upon request. Further, the Proposed GPO would inform Participants in a manner reasonably calculated to give the Participants notice of their obligations to report such discounts and rebates to satisfy the discount safe harbor to the Federal anti-kickback statute, described in more detail in Part II below, and the Proposed GPO would refrain from doing anything that would impede the Participants' ability to meet their obligations under that safe harbor.

The Proposed GPO would maintain a website containing general information about its structure and operations. The website would include access points for vendors to obtain and provide information about the contracts maintained with the Proposed GPO and the purchasing activity of its Participants. The Proposed GPO would include on its website, along with the other general information, a statement indicating that it attempts to operate as efficiently as possible to minimize its costs and that the Proposed GPO may, in its discretion, distribute all or portions of administrative fees it receives from vendors to its Participants. Some vendors that contract with the Proposed GPO may have reporting requirements related to administrative fees that do not qualify as bona fide service fees,

[3] This tracking of the spending and purchasing volume for each Participant and the associated administrative fees will allow the Proposed GPO to determine what, if any, portion of a particular vendor's administrative fees were passed through to Participants, which will enable the Proposed GPO and the Participants to comply with any reporting obligations. The tracking will also enable Participants to comply with any disclosure requirements imposed through vendor contracts to enable vendors to comply with their own reporting obligations related to Average Manufacturer Price and Best Price.

such as the requirements imposed on pharmaceutical manufacturers with respect to price reporting. The Proposed GPO would inform such vendors directly that administrative fees in excess of the Proposed GPO's operating costs may be passed through to the Participants.

The Participation Agreements would require compliance with any contractual obligations contained in the Supplier Agreements, as well as compliance with all applicable laws, regulations, and the rules, standards and policies of the Proposed GPO, including cost reporting rules.[4] Pursuant to the Participation Agreements, Non-Affiliated Participants would be required to report the full amount of actual distributions as rebates and net such amounts against the cost of purchases. Affiliated Participants would be required to: (1) report the full amounts of their allocated administrative fees as rebates; and (2) net such amounts against the costs of purchases, whether or not the administrative fees were distributed.[5] The Requestors certified that the Parent Organization, the Subsidiary, the LLC, the Proposed GPO, and the Affiliated Participants would comply with the Medicare cost reporting rules applicable to central purchasing activities[6] (i.e., for Affiliated Participants, all discounts, allowances, refunds, and rebates received from vendors would be credited directly against the costs of the purchasing providers, even if these amounts are not distributed to the purchasing providers).

II. LEGAL ANALYSIS

A. Law

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

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[4] Similar provisions would be included in the Supplier Agreements, including agreements with drug manufacturers.

[5] As explained above, the tracking reports the vendors would provide regarding each Participant's spending would allow the Proposed GPO to allocate the earned fees among Participants. However, only the administrative fees the Proposed GPO collects in excess of its costs would be distributed to the Participants.

[6] The Requestors certified that the Proposed GPO would constitute a "central purchasing organization" under chapter 8, section 808 of the CMS Provider Reimbursement Manual. Under section 808 and the home office cost reporting process, the Affiliated Participants would be required to report the administrative fees as cost reductions, whether or not these amounts are actually distributed to the purchasing providers.

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. Borrasi, 639 F.3d 774 (7th Cir. 2011); 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 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. See 42 C.F.R. § 1001.952. The safe harbors 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.

Two safe harbors, both of which were created by statute and interpreted by regulation, potentially apply to the Proposed Arrangement. The Proposed Arrangement would involve: (1) discounts that the Proposed GPO would negotiate from vendors on behalf of its Participants; (2) the Proposed GPO's distribution to Participants of administrative fees that exceed its costs, which the Proposed GPO would also require the Participants to treat as discounts; and (3) the administrative fees that the Proposed GPO would collect from vendors and retain. The discount safe harbor, 42 C.F.R. § 1001.952(h) could apply to remuneration included in items (1) and (2), and the GPO safe harbor, 42 C.F.R. § 1001.952(j), could apply to the remuneration included in item (3).

The discount safe harbor excludes from the definition of "remuneration," for purposes of the anti-kickback statute, a discount on an item or service for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs for a buyer, seller, or offeror of a discount who is not a seller, as long as the relevant entity complies with certain standards. Under the safe harbor, the term "discount" includes a "rebate," which is defined, for purposes of the discount safe harbor, as "any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale." This safe harbor, if applicable, would protect a discount offered by a seller to a GPO, by a seller through a GPO to a buyer, and by a GPO to a buyer. Generally, to comply with the safe harbor, a GPO would have to inform the buyer, or if applicable, the individual or entity submitting a claim to a Federal health care program on behalf of the buyer, of the buyer's or other entity's obligation to report the discount, and the GPO must refrain from doing anything that would impede the buyer's or other entity's ability to meet its reporting requirements. 42 C.F.R. § 1001.952(h)(3).

As noted above, the safe harbor for GPOs is also potentially applicable to the Proposed Arrangement. It excludes from the definition of "remuneration" certain fees paid by vendors to GPOs. To qualify for protection under the GPO safe harbor, a GPO must have a written agreement with each individual or entity for which items or services are furnished. That agreement must either provide that participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of three percent or less of the purchase price of the goods or services provided by that vendor, or, in the event the fee paid to the GPO is not fixed at three percent or less of services, specify the amount (or if not known, the maximum amount) the GPO will be paid by each vendor (where such amount may be a fixed sum or a fixed percentage of the value of purchases made from the vendor by the members of the group under the contract between the vendor and the GPO). Where the entity that receives the goods or service from the vendor is a health care provider of services, the GPO must disclose in writing to the entity at least annually, and to the Secretary upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity. As explained in the preamble to the final regulations, the exception is not intended to protect fees to arrange for referrals or recommendations within a single entity. See Preamble to Final Rule: OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,982 (July 29, 1991). Therefore, the safe harbor provides that "GPO" means an entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs, and who are neither wholly owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly owned entity).

B. Analysis

The Requestors certified that the Proposed GPO would satisfy all the elements of the discount safe harbor set forth at 42 C.F.R. § 1001.952(h).[7] Specifically, the Proposed GPO would inform its Participants in a manner reasonably calculated to give notice to the Participants of their obligations to report any discounts—including rebates—that they receive from vendors. The Requestors assert that the terms of any distributed administrative fees would meet the definition of "rebates" under the safe harbor. The terms of the rebates would be set at the time of the first sale to which the rebate applies and would be disclosed to the Participants.

However, even if the initial discounts and administrative fees passed through the Proposed GPO to Participants as rebates would qualify for protection under the discount safe harbor, the discount safe harbor would not protect the portion of the administrative fees retained by the Proposed GPO. The administrative fees retained by the Proposed GPO also would not be protected by the GPO safe harbor, because the Proposed GPO and most of the Affiliated Participants would be wholly owned by the Parent Organization or the Subsidiary. However, absence of safe harbor protection is not fatal. Instead, such arrangements must be considered on a case-by-case basis, to determine their potential for risk to Federal health care programs.

In addressing this issue, we turn to the history of the GPO safe harbor. In 1986, Congress amended the anti-kickback statute to create an exception for amounts paid by vendors to GPOs, as long as certain conditions were met. According to the legislative history, Congress believed that GPOs could "help reduce health care costs for the government and the private sector alike by enabling a group of purchasers to obtain substantial volume discounts on the prices they are charged."[8] Subsequently, the OIG promulgated the regulatory safe harbor described above. However, in the years following, both Congress and the OIG began to question whether GPOs were achieving this key goal—i.e., whether purchases made through GPOs actually reduce health care costs for the government and the private sector.

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[7] The Requestors also certified that discounts other than administrative fees provided by vendors through the Proposed GPO to its participants would meet the discount safe harbor requirements. This opinion is limited to the payments made by vendors to the GPO in the form of administrative fees, and the Proposed GPO's role as the offeror of the discounts. The Requestor is not in a position to certify that vendors will meet their obligations as sellers under the discount safe harbor. Therefore, we express no opinion with regard to that or other forms of remuneration potentially involved in the Proposed Arrangement.

[8] H.R. Rep. No. 99-727, at 73 (1986), reprinted in 1986 U.S.C.C.A.N. 3607, 3663.

Over the past decade, the United States General Accounting Office (the "GAO") and the OIG have conducted several studies on the effect of GPOs on the marketplace. These studies have raised various concerns. For example, one GAO report noted a concern that the financial flows between hospitals, GPOs, and vendors might result in divergent interests between GPOs and hospitals. In fact, small manufacturers claimed that GPOs have an incentive not to seek the lowest price, because the GPO could earn higher administrative fees on higher-priced products.[9] An OIG report found that GPO members did not fully account for net revenue distributions from GPOs on their Medicare cost reports.[10] These are examples of ways in which GPO arrangements can hurt, rather than help, providers and payors. However, the Proposed Arrangement includes a number of protections to guard against these negative results. For the following reasons, we conclude that the Proposed Arrangement presents an acceptably low level of risk to Federal health care programs.

<u>First</u>, we note that the safe harbor preamble cited above explains that when a GPO is wholly owned by the same parent organization as many of the participants, there is an increased risk that administrative fees collected by the GPO could be illegal inducements to induce referrals or recommendations. As explained herein, the Proposed Arrangement includes safeguards that mitigate the risk associated with a wholly owned GPO. Although the Proposed GPO would be under the same Parent Organization as many of the entities on behalf of whom it would be contracting, each of the Nonprofit Corporations under common ownership are separate legal entities. The Proposed GPO would function as a purchasing agent for these entities, and would charge the vendors fees for these services. Moreover, the Proposed GPO would retain only that portion of the administrative fees collected that is necessary to offset its costs of centralized contracting activities and related functions and would distribute the administrative fees that exceed its costs. As discussed in greater detail below, the Participants, in turn, would be required to report their portions of the administrative fees as rebates, in accordance with the requirements of the discount safe harbor. Thus there would be no incentive for the Proposed GPO to negotiate higher administrative fees in lieu of discounts.

<u>Second</u>, the Requestors' certifications regarding the reporting requirements in the Participation Agreements address a particular risk area identified above—that entities purchasing through GPOs do not always fully account for net revenue distributions from the GPOs on their Medicare cost reports. Specifically, the Requestors certified that the Participation Agreements would require Affiliated Participants to: (1) report the full

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[9] <u>Group Purchasing Organizations: Pilot Study Suggests Large Buying Groups Do Not Always Offer Hospitals Lower Prices</u>, GAO-02-690T, Apr. 30, 2002.

[10] <u>Review of Revenue from Vendors at Three Group Purchasing Organizations and Their Members</u>, A-05-03-00074, Jan. 19, 2005.

amounts of their allocated administrative fees as rebates; and (2) net such amounts against the costs of purchases, whether or not the administrative fees were distributed. The Requestors also certified that the Parent Organization, the Subsidiary, the Proposed GPO, and the Affiliated Participants would comply with the Medicare cost reporting rules applicable to central purchasing activities. The Requestors further certified that the Participation Agreements would require Non-Affiliated Participants to report the full amount of actual distributions as rebates and net such amounts against the costs of purchases.[11] Although the Proposed GPO would not have control over the Non-Affiliated Participants' cost reporting activities, the Requestors have committed to provide these entities the information necessary to accurately report their costs (and would require them to engage in accurate cost reporting as part of the Participation Agreement). With respect to the Affiliated Participants, the Proposed GPO's function as a centralized purchasing organization will help ensure that the cost-reporting rules are, in fact, followed. Moreover, the Requestors further certified that the cost reports will reflect not only the cost reductions that the Affiliated Participants actually receive from their purchases, but also the amounts of any administrative fees allocated to each Affiliated Participant, even if such amount will be retained by the Proposed GPO to offset administrative costs.

<u>Third</u>, the Proposed GPO would inform vendors and the public generally, through disclosures on its website, that the administrative fees in excess of its costs may be passed through to Participants. In addition, the Proposed GPO would <u>directly</u> inform vendors that may have reporting requirements related to any administrative fees that do not qualify as <u>bona fide</u> service fees (such as the requirements imposed on pharmaceutical manufacturers with respect to price reporting) that administrative fees may be passed through to the Participants as rebates. As a result, those vendors would be on notice to obtain specific information regarding passed-through fees from the Participants with whom they contract, which would enable the vendors to comply with their own price reporting requirements.

<u>Fourth</u>, the Requestor has certified that the Proposed GPO would not be restricted to Affiliated Participants. To achieve the greater purchasing power that comes with serving a greater number of participants, the Proposed GPO has an incentive to expand its roster of participants. The goal of gaining the Non-Affiliated Participants' business should serve as additional motivation for the Proposed GPO to be competitive in the marketplace, seeking out the best prices and services for all of its Participants.

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[11] For purposes of this advisory opinion, we rely on the Requestors' certification that they will comply, and will require the Participants to comply, with all laws, including all applicable reporting requirements as well as any contractual requirements that would allow vendors to comply with their own legal requirements. If the Requestors materially fail to comply with any such requirements, this opinion is without force and effect.

Fifth, the Requestors certified that the Parent Organization would continue to direct its purchasing volume through independent GPOs when such GPOs can obtain a better cost value from suppliers than the Proposed GPO. Similarly, the LLC would continue to contract directly on behalf of individual Nonprofit Corporations whenever necessary to meet their needs. In other words, the Requestors commit to use multiple resources to seek out the best value for the Participants, even if such purchases would not be through the Proposed GPO. Such a commitment increases the likelihood that the Participants will receive the GPO benefits intended and anticipated by Congress.

In sum, although the Proposed Arrangement cannot receive GPO safe harbor protection because of the ownership structure of the Proposed GPO, the Proposed Arrangement includes a number of features that mitigate the risks present in some GPO arrangements. Therefore, based on the totality of the facts and circumstances described herein, and for the reasons stated above, we conclude that the Proposed Arrangement presents an acceptably low risk of fraud and abuse in connection with the anti-kickback statute.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although 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 [Name redacted], [Name redacted], or [Name 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 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 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 [Name redacted], [Name redacted], and [Name 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 [Name redacted], [Name redacted], and [Name redacted] to provide 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 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.

- 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], [Name redacted], or [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 [Name redacted], [Name redacted], or [Name redacted] 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,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General