[*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: August 31, 2010

Posted: September 8, 2010

To: The Attached Distribution List

Re: OIG Advisory Opinion No. 10-15

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a joint venture between two components of an academic medical center to build and own an ambulatory care center on a 50-50 basis (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 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 Office of Inspector General ("OIG") would 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 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 the [names redacted] (the "Affiliated Requestors"), or [name redacted] (the "Newco Requestor") (collectively, the "Requestors") and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Background

The three Affiliated Requestors of this opinion are all part of an academic medical center.[1] According to the Requestors, [name redacted] (the "University") is a constitutional corporation and is considered, for tax purposes, to be an "integral part" of the state. The University manages the colleges of health sciences, including its medical school, through its [name redacted] (the "AHC").

The Health System, a regional health delivery system, is a nonprofit, tax-exempt, corporation that employs over 600 physicians. The Health System operates the [name redacted] (the "University Hospital"); additional outpatient clinics associated with the AHC that are housed in several locations on the University campus; and other hospitals, clinics and health care facilities.

The third requestor, the [name redacted], is a nonprofit, tax-exempt corporation that employs over 800 physicians. The Physician Organization has no corporate or individual shareholders and does not make any distributions to its employed physicians. The physicians are compensated on a salary basis and may be eligible for performance-based

[1] The Affiliated Requestors have disclosed that they have a number of compensation, affiliation, and other ancillary agreements among themselves, and with their employed physicians, under which they currently operate. [name redacted] (the "Physician Organization") and [name redacted] (the "Health System") also contract with physicians or physician groups for services that they do not provide themselves. The Requestors have certified that these agreements comply with the physician self-referral law and the anti-kickback statute, as applicable. We express no opinion about these agreements.

bonuses. The Requestors have certified that neither the salary, nor the bonuses, take into account (or will take into account), in any manner, the volume or value of referrals or other business generated for their own clinics or for the Health System. The Requestors have further certified that the physicians' compensation is and will be consistent with fair market value in an arm's-length transaction. The Physician Organization operates certain outpatient clinics associated with AHC and located on the University campus.

The relationship among the Affiliated Requestors took its current form more than a decade ago. At that time, the Health System purchased the University Hospital and the outpatient clinics from the University, and the departmental practice groups through which the medical school faculty operated their clinical practices came together to form the Physician Organization. Since that time, the Affiliated Requestors have been associated with one another as an academic medical center as follows: the University (through the AHC) operates an accredited medical school; the Physician Organization is the only faculty practice plan affiliated with the medical school (with over 90% of its physicians on the faculty); the majority of the active medical staff at the University Hospital (which is operated by the Health System and is the major teaching hospital for the University's medical school) is composed of medical school faculty; and over two-thirds of the admissions to the University Hospital are attributed to the faculty. In addition, the Affiliated Requestors have a number of affiliation agreements with each other. For example, the Health System has a 99-year Affiliation Agreement with the University, which includes operation of the University Hospital; the Physician Organization provides numerous professional services to the Health System; and the University and the Health System have agreements regarding research and education at the University Hospital and other parts of the Health System. Further, in accordance with certain agreements between the University and the Physician Organization, the Physician Organization transfers funds annually to the University to support research and education efforts.[2]

B. The Proposed Arrangement

Presently, the University Hospital is located on two separate sites. Similarly, the outpatient clinics operated by both the Health System and the Physician Organization are spread throughout various buildings on the University's campus. The Requestors have certified that these clinics currently serve approximately five times more patients than was anticipated at the time they were built. Moreover, the space is not well-suited for teaching purposes.

Pursuant to the Affiliated Requestors' Clinical Sciences Campus Planning Project ("Planning Project"), the Affiliated Requestors would replace and consolidate certain health

[2] We express no opinion regarding these agreements or transfers.

care facilities and services by developing an ambulatory care center that would house many of the adult-focused outpatient clinics and would have space devoted to research and other administrative and teaching activities (conference rooms, etc.). The new facility would have larger exam rooms to accommodate the presence of residents and other providers. The Affiliated Requestors assert that the ambulatory care center would provide a better experience for patients both by easing overcrowding and providing for more parking availability, while enhancing the research and educational opportunities for faculty and students of the University's medical school. In addition, the Proposed Arrangement would reduce overall costs by eliminating duplicative technology, equipment, and supplies when the clinics and other facilities are consolidated in one building.

To accomplish the Affiliated Requestors' goal, the Physician Organization and the Health System formed a nonprofit organization, the Newco Requestor. Under the Proposed Arrangement, the Physician Organization and the Health System would remain the sole owners of the Newco Requestor; no entity outside of the academic medical center would have a chance to invest in the Newco Requestor. When it is operational, the Newco Requestor would have a ten-member Board of Directors. Five directors would be from the Health System, and five directors would be allocated to the Physician Organization. Up to two of the Physician Organization's allocated directors would be representatives of the University. The terms on which their investments are made would have no relationship to past or expected value or volume of referrals or other business generated for the Newco Requestor or each other. The Physician Organization and the Health System would contribute equal assets to the Newco Requestor to achieve a 50-50 ownership split.

The investors would not contribute hard assets, because the building and equipment would be new. Instead, the organizations would contribute the clinics and associated intangible assets that go along with the business. The Health System would contribute assets that include the following clinics: audiology and aural rehabilitation; blood and marrow transplant; breast center; ear, nose and throat; ophthalmology; orthopedics; physical therapy and hand; radiation therapy; surgery; and urology/prostate cancer. The Physician Organization would contribute an imaging center and assets associated with the cancer clinic that is located on the University Hospital's campus. The Affiliated Requestors have engaged a health care valuation expert to conduct a fair market value analysis. To the extent that the above-listed contributions are not valued equally, the party whose clinics are valued lower would contribute cash to achieve a 50-50 investment.[3] In addition, the parties

[3] We are not authorized to opine on whether fair market value shall be, or was paid or received for any goods, services, or property. See section 1128D of the Act. Therefore, we rely on the certification of the Requestors that the valuation will represent fair market value in an arm's-length transaction without taking into account the volume or value of referrals or other business generated between the parties.

would return their current clinic space to the University, and the University would lease the land on which the ambulatory care center would be located to the Newco Requestor for a de minimus fee.

The Requestors have certified that none of the Affiliated Requestors could reasonably finance the project alone. The University not only does not have the funds, but also does not want to be involved in owning health care facilities. The Physician Organization and the Health System represent that other financial commitments prevent them from financing this project alone at the present time within the context of their current capital capacity and debt ratings. Therefore, the Affiliated Requestors formed the Newco Requestor, which likely would finance the project by issuing tax-exempt bonds, through charitable donations, and possibly through contributions from the Health System and the Physician Organization. Because the Newco Requestor would largely finance the project, the Requestors expect most of the revenue from clinical operations to remain with the Newco Requestor initially to support the financing and repay the debt. When net distributions eventually occur, they would be directly proportional to each party's capital contribution.[4] No distributions from the Newco Requestor would go to the physicians. The Newco Requestor will be owned by the Physician Organization and the Health System, and neither of these entities have physician owners or make distributions to their employed physicians.

The Newco Requestor would own the building and would bill third-party payors, including Federal health care programs, for services. The Newco Requestor would also enter into various agreements for professional, management, and administrative services with the Affiliated Requestors such that the parties would provide essentially the same services to the Newco Requestor as they currently perform for each other and for the existing clinics that will relocate to the new facility under the Newco Requestor's ownership. The Requestors would also continue to ensure that these ancillary agreements would be at arm's-length and would comply with the physician self-referral law and the anti-kickback statute.[5]

Neither the Physician Organization, the Health System, nor either entity's physicians would be required to make referrals to each other or to the Newco Requestor (or any of its clinics).

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[4] Because both investors in the Newco Requestor are 501(c)(3) nonprofit entities and are engaged in the provision of academic medicine, Requestors have certified that they are eligible to receive distributions from the Newco Requestor under both state and Federal law.

[5] We express no opinion on these ancillary agreements. We rely on the Requestors' certifications with respect to these agreements. If such certifications are inaccurate, then this opinion is without force and effect.

The Requestors certified that the physicians' compensation would not reflect the volume or value of referrals to the Newco Requestor (or any of its clinics) because physicians cannot earn more revenue by referring patients to the Newco Requestor (or any of its clinics). Moreover, no individual physicians would receive profit distributions from the Newco Requestor. The Newco Requestor would not track referrals from the Physician Organization or the Health System, nor would the Newco Requestor distribute information to the Physician Organization, the Health System, or to their employed physicians about referrals between or among the parties. The Requestors would have a policy whereby referrals would not be made to the Newco Requestor (or its clinics) if a patient expresses a preference for a different provider, the patient's insurance determines that a different provider should be used, or a referral to the Newco Requestor (or its clinics) would not be in the patient's best medical interests (according to the treating physician's judgment). The Newco Requestor would annually inform the Physician Organization and Health System physicians of these measures.

The Requestors do not anticipate that the Proposed Arrangement will result in a significant increase in patient volume for the clinics that will be housed in the new facility and owned by the Newco Requestor. That is, the Requestors expect that the patients who will receive treatment at the new facility will be the same patients who would have received services at the current clinics. The Requestors have certified that the Proposed Arrangement would maintain the current clinical, teaching, and research relationships among the parties.[6] However, by co-locating scattered clinics and office space in an updated facility, the Requestors, as an academic medical center, will be able to offer their clinical care and teaching opportunities in a more efficient manner.

II. LEGAL ANALYSIS

A. Law

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. 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.

[6] We express no opinion about these arrangements.

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. 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. The safe harbor for investment interests in small entities, 42 C.F.R. § 1001.952(a)(2), is potentially applicable to the Proposed Arrangement.

B. Analysis

The OIG has longstanding concerns about problematic joint venture arrangements between those in a position to refer business, such as physicians, and those furnishing items or services for which a Federal health care program pays. See, e.g., OIG's 1989 Special Fraud Alert on Joint Venture Arrangements, reprinted in the Federal Register in 1994, 59 FR 65372, 65373 (Dec. 19, 1994) (the "Special Fraud Alert"). As noted in the Special Fraud Alert, joint ventures may take a variety of forms and may be formed by equity or contract. Joint venture arrangements raise concerns under the anti-kickback statute because they pose a risk that income from the venture may be payment for referrals to the venture or to co-investors. The Proposed Arrangement is based on a joint venture between the Physician Organization and the Health System—two parties in a position to refer Federally reimbursable health care business to each other.

Notwithstanding our concerns about joint ventures, the OIG has established several safe harbors applicable to joint ventures, one of which is potentially relevant to the Proposed Arrangement: the safe harbor at 42 C.F.R. § 1001.952(a)(2) protects small entity investments that meet certain criteria. However, the Proposed Arrangement does not meet two key criteria of the safe harbor, because: (1) more than 40% of the investment interests are held by investors who are in a position to make or influence referrals for the entity; and

(2) more than 40% of the entity's gross revenue related to health care items or services is likely to come from business generated by the investors. Consequently, safe harbor protection is not available, and we must carefully scrutinize the Proposed Arrangement in its entirety.

Ordinarily, joint ventures with 100% interested investors pose a significant risk of fraud and abuse. However, based on the totality of facts and circumstances certified to by the Requestors, we conclude that for the combination of the following reasons, we would not impose administrative sanctions arising under the anti-kickback statute on the Requestors in connection with the Proposed Arrangement. We emphasize that a similar arrangement with different facts and circumstances might lead to a different conclusion.

First, the Requestors are all components of an academic medical center with longstanding institutional relationships that integrate clinical, research, and teaching missions. The majority of the doctors in the Physician Organization are faculty members at the medical school, and the majority of the active medical staff at the University Hospital is composed of medical school faculty. The Health System and the Physician Organization own and operate outpatient clinics affiliated with the University and located on the University campus, and the Health System, the Physician Organization, and the University have a variety of affiliation agreements,[7] which Requestors certify comply with the physician self-referral law and the anti-kickback statute, as described above. The structure of the new joint venture will permit the investors to continue their clinical, research, and teaching missions in a more efficient way.

Second, this joint venture's structure mitigates concerns that the Proposed Arrangement would result in improper payments for referrals. In accordance with a fair market value analysis conducted by a health care valuation expert, the investors would make equal contributions of financial, capital, and human resources to the joint venture and receive proportional distributions (or equally share the risk of losses). There would be no individual physician investors. Neither investor would borrow from the other.

Third, concerns about improper payments for referrals are further mitigated by the constraints on compensation to physicians. The physicians employed by the Physician Organization and the Health System are not, and will not be, compensated in a way that reflects the volume or value of referrals to an investor or to the Newco Requestor or its clinics. Moreover, the physicians would not receive distributions from the Newco Requestor because they have no ownership interest in either the Physician Organization or the Health System, and these entities do not make distributions to their employed physicians. Neither the Physician Organization, the Health System, nor their physicians

[7] We express no opinion on these agreements.

would be required to make referrals to each other or to the Newco Requestor, and the Newco Requestor would not track referrals that are made. The Requestors would implement a policy to ensure that patients are referred elsewhere if medically necessary, based on the patient's insurance, or if the patient prefers another location.

Lastly, the Proposed Arrangement furthers the core mission of the academic medical center. Rather than jointly providing care in a fragmented way across the University's campus, the Requestors expect that the Proposed Arrangement will reduce costs by: eliminating duplicative technology, equipment, and supplies; better accommodating the academic medical center's current patients; and permitting greater access to educational opportunities for the medical school students and residents at the University.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that 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 [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 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 [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 in any matter involving an entity or individual that is not a requestor of this opinion.

- 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 the Requestors with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors 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

DISTRIBUTION LIST FOR
OIG ADVISORY OPINION NO. 10-15

[Names and addresses redacted]