[*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: June 23, 2009

Posted: June 30, 2009

To: Attached Distribution List

Re: OIG Advisory Opinion No. 09-06

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion concerning an existing arrangement in which a hospital has agreed to share with a cardiology group, a vascular surgical group, and an interventional radiology group a percentage of the hospital's cost savings arising from the physicians' implementation of a number of cost-reduction measures in certain cardiac catheterization procedures[1] (the "Arrangement"). The cost savings are measured based on the physicians' use of specific medical devices and supplies during designated cardiac catheterization procedures. You have inquired whether the Arrangement constitutes grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce the reduction or limitation of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

[1] The request refers to cardiac catheterization laboratory and special procedures laboratory procedures, services, and practices. For purposes of this opinion, we will refer to these collectively as "cardiac catheterization procedures."

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: (i) the Arrangement could constitute an improper payment to induce the reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on [names redacted] (collectively, the "Requestors"), in connection with the Arrangement; and (ii) 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, but that the OIG would not impose administrative sanctions on the Requestors 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 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. Parties

The Hospital. At all times relevant to this advisory opinion, [name redacted] (the "Hospital") was an acute care hospital in [city and state names redacted] that offered a broad range of inpatient and outpatient hospital services, including cardiac catheterization procedures, and was a participating provider in the Medicare and Medicaid programs.[2]

The Cardiology Group. [Name redacted] (the "Cardiology Group") is a professional corporation that employs exclusively cardiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. At all times relevant to this advisory opinion, the Cardiology Group referred patients to the Hospital for

[2] After the contract year (see infra definition note 8), there was a restructuring and the Hospital became an outpatient facility.

inpatient and outpatient hospital services. The Cardiology Group entered into a contract with the Hospital that set forth the projected savings opportunities available to it.

The Interventional Radiology Group. [Name redacted] (the "Interventional Radiology Group") is a professional corporation that employs exclusively interventional radiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. At all times relevant to this advisory opinion, the Interventional Radiology Group referred patients to the Hospital for inpatient and outpatient hospital services. The Interventional Radiology Group entered into a contract with the Hospital that set forth the projected savings opportunities available to it.

The Vascular Surgical Group. [Name redacted] (the "Vascular Surgical Group") is a professional corporation that employs exclusively vascular surgeons who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. At all times relevant to this advisory opinion, the Vascular Surgical Group referred patients to the Hospital for inpatient and outpatient hospital services. The Vascular Surgical Group entered into a contract with the Hospital that set forth the projected savings opportunities available to it.

In combination, the Cardiology Group, the Interventional Radiology Group, and the Vascular Surgical Group, herein referred to, individually, as a "Group" and, collectively, as the "Groups," perform nearly all of the cardiac catheterization procedures at the Hospital.[3] Occasionally a procedure is performed by another group or by solo practitioners.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Arrangement. The Program Administrator has collected data and analyzed and manages the Arrangement.[4] The Hospital paid the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Arrangement. The fee was not tied in any way to cost savings or the Groups' compensation under the Arrangement.

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[3] The Groups have members who also practice at other hospitals in the region; however, at all times relevant to this advisory opinion, the Hospital was the primary practice location for most of the physicians in the Groups.

[4] The Program Administrator has developed a software product that measures cost, quality, and utilization on a national basis. The product is certified by the American College of Cardiology ("ACC").

B. The Arrangement

Under the Arrangement, the Hospital has agreed to pay each Group a share of the cost savings directly attributable to specific changes in that particular Group's cardiac catheterization procedures. The Requestors implemented the Arrangement—and the Groups began performance of the specific changes in cardiac catheterization procedures—prior to requesting this advisory opinion. The Hospital has not paid amounts owed to the Groups under the Arrangement, however, pending the outcome of this opinion.[5] Thus, we are treating the Arrangement as an existing arrangement for purposes of this advisory opinion. The Requestors have certified that the Hospital will make payments owed under the Arrangement upon receipt of a favorable advisory opinion. The Groups are the only physician practices participating in the Arrangement.

To develop the Arrangement, the Program Administrator conducted a study of the historical practices of the Groups with respect to cardiac catheterization procedures performed at the Hospital and identified twenty-one specific cost-savings opportunities. The Program Administrator summarized the results of its study and the specific cost-savings opportunities in a document entitled, "EXECUTIVE SUMMARY [NAME REDACTED] VALUESHARE FOR CARDIOLOGY" (the "Executive Summary").[6] The Hospital and the Groups reviewed the Executive Summary for medical appropriateness and each adopted its recommendations and conclusions.

The Executive Summary identified twenty-one specific recommendations that can be grouped roughly into the category of product standardization. The Executive Summary recommended that the Groups change current cardiac catheterization procedures to standardize the types of cardiac catheterization devices and supplies (stents, balloons, interventional guidewires and catheters, vascular closure devices, diagnostic devices, pacemakers, and defibrillators) they employ.[7] The Groups were required to work in conjunction with the Hospital to evaluate and clinically review vendors and products. The Requestors have certified that they selected the preferred products eligible for payments under the Arrangement based on a process that first considered whether the products were clinically safe and effective. An assessment was then made whether the proposed standardization measures were appropriate on the basis of clinical criteria. Only thereafter

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[5] Nonpayment of amounts owed pursuant to a contractual agreement does not, by itself, absolve parties from liability under the fraud and abuse laws.

[6] The Executive Summary is attached to this advisory opinion as Appendix A.

[7] The Executive Summary identified with specificity the products at issue.

did the Requestors consider cost. To the extent costs were a consideration, final selections of vendors and products were made on the basis of prices available to the Hospital for those particular products.

The Arrangement contained several safeguards intended to protect against inappropriate reductions in services. Importantly, the Requestors certified that the individual physicians made a patient-by-patient determination of the most appropriate device or supply and the availability of the full range of devices and supplies was not compromised by the product standardization. The Requestors have further certified that individual physicians still had available the same selection of devices and supplies after implementation of the Arrangement as before, and that the economies gained through the Arrangement resulted from inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

In addition, to ensure that the recommendations did not adversely affect the quality of care at the Hospital, the Program Administrator tracked the Hospital's performance of the covered cardiac catheterization procedures against the quality indicators established by the ACC throughout the base year and contract year. (See infra definitions notes 8 and 9.) According to the Requestors, the ACC quality indicators, against which all of the Arrangement's recommendations were evaluated, reflect objective hospital baselines. The indicators are action-specific and not simply based on isolated patient outcome data unrelated to specific changes in cardiac catheterization procedures. The ACC indicators incorporate enough specificity to permit correlation of outcomes with cardiac catheterization procedures. The Hospital will not allocate any cost-sharing amounts to the Groups if the cardiac catheterization procedures performed by the Groups involve reductions in the Hospital's quality as measured against the ACC quality indicators.

According to the Program Administrator, to the extent implemented in accordance with the Executive Summary's specifications, the twenty-one recommendations presented substantial cost-savings opportunities for the Hospital without any adverse impact on the quality of patient care.

Under the Arrangement, the Hospital intends to pay each of the Groups separately for 50% of the savings achieved by the particular Group when implementing the applicable recommendations in the Executive Summary. At the end of the applicable year (the "contract year" [8]), cost savings were calculated separately for each Group for each of the applicable recommendations; this precluded shifting of cost savings and ensured that

[8] The contract year was the twelve-month period for which the Groups will be compensated under the Arrangement.

savings generated by procedures involving reductions in historical ACC quality indicators were not credited to the Groups.

The payments to each Group, when made, will constitute the entire compensation paid to the particular Group for services performed under the contract memorializing the Arrangement between that Group and the Hospital. The payment to each Group will be calculated using the same formula. For purposes of calculating the payment to each Group, the actual costs incurred during the contract year for the items specified in the applicable recommendations when used by physicians of the particular Group during the specified procedures (the "contract year costs") are subtracted from the historical costs for the same items when used during comparable procedures in the base year[9] (the "base year costs"[10]).

After receipt of a favorable advisory opinion, payments will be made to the Groups for 50% of the difference between their respective contract year costs and base year costs, if any. Under the Arrangement, the Hospital is obligated to make aggregate payments to each Group, each of which distributes profits among members on a per capita basis.

Calculation of payments to the Groups is subject to the following limitations:

- If a physician's volume of procedures payable by a Federal health care program in the contract year exceeded the volume of like procedures payable by a Federal health care program performed in the base year, there is no sharing of cost savings for the additional procedures.

- To minimize the physicians' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Arrangement were monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If significant changes from historical measures indicated that a physician had altered his or her referral patterns in a manner beneficial to the Hospital as a result of the Arrangement, the physician at issue would have been terminated from participation in the Arrangement. No physicians were terminated.

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[9] The base year was the twelve-month period immediately preceding the contract year.

[10] Figures for the base year costs were calculated from historical costs during the base year. For purposes of this opinion, the Arrangement is limited to the one-year term of the contracts; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Arrangement. Notwithstanding, we note that any renewal or extension of the Arrangement should incorporate updated base year costs.

- The Executive Summary identified projected cost savings, and the aggregate of payments paid to each Group, when made, will not exceed 50% of the Group's share of the projected cost savings identified in the base year. Each Group will be compensated solely for its own savings under the Arrangement.

The Hospital and the Groups documented the activities and the payment methodology under the Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Groups disclosed the Arrangement to the patients, including the fact that the Groups' compensation was based on a percentage of the Hospital's cost savings. The disclosure was made to the patient before the patient was admitted to the Hospital for a procedure covered by the Arrangement; if pre-admission disclosure was impracticable (e.g., the patient was admitted for an unscheduled procedure or the need for the procedure was determined after admission), the disclosure was made before the patient consented to the procedure. The disclosures were in writing, and each patient had an opportunity, if they desired, to review details of the Arrangement, including the specific cost-savings measures applicable to the patient's procedure.

II. LEGAL ANALYSIS

Programs like the Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost-saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost-savings programs to foster physician loyalty and to attract more referrals.

Hospital cost-savings programs in general, and the Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care

program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[11] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Arrangement.

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

Sections 1128A(b)(1)-(2) of the Act ("CMP") establish a civil monetary penalty against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician who receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians who receive) such payments are liable for civil monetary penalties of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[12]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Arrangement induces physicians to reduce or limit items or services. Given the specificity of the Arrangement, it is possible to review the opportunities for savings individually and evaluate their impact on patient care.

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[11] In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Arrangement.

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

Having reviewed the twenty-one recommendations, we conclude that all of the recommendations implicated the CMP. Simply put, with respect to the recommendations under the Arrangement regarding standardization of devices and supplies, the Arrangement might induce physicians to reduce or limit the then-current medical practice at the Hospital. We recognize that the then-current medical practice may have involved care that exceeded the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

In sum, we find that the CMP applies to the recommendations for product standardization. Notwithstanding, the Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings were clearly and separately identified. The transparency of the Arrangement allowed, and continues to allow, for public scrutiny and individual physician accountability for any adverse effects of the Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures also facilitates accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations did not adversely affect patient care. The Arrangement was periodically reviewed by the Requestors to confirm that the Arrangement was not having an adverse impact on clinical care.[13]

Third, the amounts to be paid under the Arrangement have been calculated based on all procedures performed, regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the procedures to which the Arrangement applied were not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings have been calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

[13] We have had the Arrangement reviewed by an independent medical expert. The medical expert concluded that the cost-savings measures, as described in the advisory opinion request and supplemental submissions, should not have adversely affected patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications, and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Arrangement.

Fourth, the Arrangement protected against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrued to the Groups. The Requestors have certified that these baseline measures were reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards were action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in cardiac catheterization procedures.

Fifth, the Arrangement further protected against inappropriate reductions in services by ensuring that individual physicians still had available the same selection of devices and supplies after implementation of the Arrangement as before. The Arrangement was designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices and supplies. As described above, clinical criteria guided the Requestors' process for selecting products to be standardized, and, to the extent cost considerations influenced selections from among products determined to be clinically safe and effective, the cost considerations were limited to prices available to the Hospital for the particular products.

Sixth, the Hospital and the Groups provided written disclosures of their involvement in the Arrangement to patients whose care might have been affected by the Arrangement and provided patients an opportunity to review the cost-savings recommendations prior to admission to the Hospital (or, where pre-admission consent was impracticable, prior to consenting to the procedure). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[14]

Seventh, the financial incentives under the Arrangement were reasonably limited in duration and amount.

Eighth, because each of the Groups distributes profits to its members on a per capita basis, any incentive for an individual physician to generate disproportionate cost savings was mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or

[14] Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Arrangement, which focuses on items used in cardiac catheterization procedures, we believe that patient satisfaction surveys would not be effective.

Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We iterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Arrangement is markedly different from "gainsharing" plans that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Arrangement set out the specific actions to be taken and tied the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allowed an assessment of the likely effect of the Arrangement on quality of care and ensures that the identified actions are the cause of any savings.

"Gainsharing" plans can present substantial risks for both patient and program abuse—risks that are not present in the Arrangement. The limited duration and scope of the Arrangement, in combination with the other safeguards described above, provided sufficient protections against patient and program abuse. Other arrangements, including those that are longer in duration or more expansive in scope than the Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. 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. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), 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 personal services and management contracts, 42 C.F.R. § 1001.952(d), is potentially applicable to the Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Arrangement cannot fit in the safe harbor because the payment owed to the Groups was calculated on a percentage basis, and thus the aggregate compensation was not set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Groups. Specifically, the Arrangement could encourage the physicians to admit Federal health care program patients to the Hospital, since the physicians receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a physician performs at the Hospital, the more money he or she is likely to receive under the Arrangement.

While we believe the Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we will not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Arrangement reduced the likelihood that the Arrangement has been used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Arrangement was limited to physicians already on the medical staff, thus limiting the likelihood that the Arrangement would attract other physicians. In addition, the potential savings derived from procedures for Federal health care program beneficiaries were capped based on the physicians' prior year's admissions of Federal health care program beneficiaries. The period for which payments were calculated was limited to one year, and the overall amount of available cost-savings payments over the one-year term of the contracts was capped, reducing any incentive to switch facilities. Finally, admissions were monitored for changes in severity,

age, or payor. Thus, while the incentive to refer was not necessarily eliminated, it was substantially reduced.

Second, the structure of the Arrangement eliminated the risk that the Arrangement has been used to reward surgeons or other physicians who refer patients to the Groups or their physicians. The Groups were the sole participants in the Arrangement and each was composed entirely of physicians in a single specialty (i.e., cardiology, interventional radiology, and vascular surgery, respectively); no surgeons or other physicians are members of the Groups or will share in their profit distributions. Within the Groups, profits are distributed to members on a per capita basis, mitigating any incentive for an individual physician to generate disproportionate cost savings.

Third, the Arrangement set out with specificity the particular actions that generated the cost savings on which the payments will be based. The recommendations in the Executive Summary represented a change in cardiac catheterization procedures, for which the physicians were responsible and had liability exposure. The product standardization carried some increased liability risk for the physicians. It is not unreasonable for the physicians to receive compensation for the increased risk from the change in practice. Moreover, the payments to be made under the Arrangement represent portions of one year's worth of cost savings and are limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited). The payments under the Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to have implemented the twenty-one recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Groups.[15] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost-savings formulae, could well lead to a different result.

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

[15] We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

III. CONCLUSION

Notwithstanding the foregoing, we iterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce the reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions on the Requestors in connection with the Arrangement; and (ii) 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, but that the OIG would not impose administrative sanctions on the Requestors 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.

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 to 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 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 that 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, 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 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

[Appendix A and Distribution List redacted]