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

Issued: October 6, 2008

Posted: October 14, 2008

Re: OIG Advisory Opinion No. 08-15

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion concerning an existing arrangement in which a hospital shares with groups of cardiologists a percentage of the hospital's cost savings arising from the cardiologists' implementation of a number of cost reduction measures in certain procedures (the "Arrangement"). The cost savings are measured based on the cardiologists' use of specific supplies during designated cardiac catheterization laboratory 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 reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

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

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce 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 the requestors of this advisory opinion, [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 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. [Name redacted] (the "Hospital") is an acute care hospital in [city and state names redacted] that offers a broad range of inpatient and outpatient hospital services, including cardiac catheterization laboratory services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Cardiology Groups. [Name redacted] ("Group A") is a limited liability company that employs exclusively cardiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. Group A refers patients to the Hospital for inpatient and outpatient hospital services. [Name redacted] ("Group B") is another limited liability company that employs exclusively cardiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. Group B also refers patients to the Hospital for inpatient and outpatient hospital services (Group A and Group B are herein referred to, individually, as "a Cardiology Group" and, in combination, as "the Cardiology Groups").[1] The Cardiology Groups perform nearly all of the cardiac catheterization laboratory services at the Hospital. Occasionally a case is completed by another group or by solo practitioners.

[1]Groups A and B both have members who also practice at other hospitals in the region; however, the Hospital is the primary practice location for most of the cardiologists in Groups A and B.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Arrangement. The Program Administrator collects data and analyzes and manages the Arrangement.[2] The Hospital pays 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 is not tied in any way to cost savings or the Cardiology Groups' compensation under the Arrangement.

B. The Arrangement

Under the Arrangement, the Hospital agrees to pay each Cardiology Group a share of three years of cost savings directly attributable to specific changes in that particular group's cardiac catheterization laboratory practices. The Requestors have implemented the three-year Arrangement under which payments are owed to each of the Cardiology Groups at the end of each year (as described in greater detail below). The Cardiology Groups have initiated the specific changes in cardiac catheterization laboratory procedures and the Arrangement is still on-going. The Hospital has not paid amounts owed to the Cardiology Groups under the Arrangement, however, pending the outcome of this opinion.[3] The Requestors have certified that the Hospital will make payments owed under the Arrangement should the Requestors receive a favorable advisory opinion. The Cardiology Groups are the only physician practices participating in the Arrangement.

To develop the Arrangement, the Program Administrator conducted a study of the historic practices of the Cardiology Groups at the Hospital's cardiac catheterization laboratory and identified thirty specific cost savings opportunities. The results of the Program Administrator's study and the specific cost savings opportunities were summarized in a document entitled, "Executive Summary [name redacted] Valueshare for Cardiology" (the "Executive Summary").[4] The Hospital and the Cardiology Groups reviewed the Executive Summary for medical appropriateness and each adopted its recommendations and conclusions.

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[2]The Program Administrator's software product that measures cost, quality, and utilization on a national basis is certified by the American College of Cardiology.

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

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

In general, the Executive Summary recommends that the Cardiology Groups change current cardiac catheterization laboratory practices to standardize use of medical devices and supplies and to curb the inappropriate use or waste of medical devices and supplies. The thirty recommendations can be roughly grouped into three categories.

- *Product Standardization.* For the first category, involving twenty-five recommendations, the Executive Summary recommends that the Cardiology Groups standardize the types of cardiac catheterization devices (stents, balloons, interventional guidewires and catheters, vascular closure devices, diagnostic devices, pacemakers and defibrillators) they employ.[5] The Cardiology Groups are 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 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.

- *"Use as needed" Devices.* The second category, consisting of four recommendations, involves limiting the use of specific vascular closure devices to an "as needed" basis (hereinafter, the "use as needed" recommendations) for coronary and peripheral interventional procedures and diagnostic procedures. The Requestors certified that the cardiologists make patient-by-patient determinations as to whether the devices are clinically indicated, and that any resulting limitation in use of these devices does not adversely affect patient care. The Requestors further certified that the specific vascular closure devices remain readily available in the procedure room.

- *Product Substitution*. The third category involves a single recommendation to substitute, as appropriate, less costly anti-thrombotic medication for other products being used by the cardiologists (hereafter, the "product substitution"). This recommendation may have an appreciable clinical significance. The Requestors certified that the identified product substitution does not adversely impact patient care.

The Arrangement contains several safeguards intended to protect against inappropriate reductions in services. Importantly, in connection with the product standardization, product substitution, and use as needed recommendations, the Requestors certified that the

[5]We note that the Executive Summary identifies with specificity the vendors and products at issue.

individual cardiologists make a patient-by-patient determination of the most appropriate device or supply, and the availability of the full range of devices and supplies is not compromised by the product standardization, product substitution, and use as needed recommendations. The Requestors further certified that individual physicians still have available the same selection of devices and medications after implementation of the Arrangement as before, and that the economies gained through the Arrangement result from inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

With respect to the use as needed recommendations for vascular closure devices, the Arrangement utilizes objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital to establish "floors" beyond which no savings accrue to the Cardiology Groups. For example, according to the Requestors, vascular closure devices for peripheral interventional cases had previously been utilized at the Hospital on 40% of the cases specified under the Arrangement. The Program Administrator determined through analysis of national data that it would be reasonable to reduce the use of vascular closure devices on these cases to 15% of patients and that this reduction would not adversely impact patient care. Thus, the Cardiology Groups receive no share of any savings resulting from the reduction of use of vascular closure devices for peripheral intervention beyond the 15% floor.

For the product substitution, no "floors" were set because substituting usage of the anti-thrombotic medication comported with national guidelines and other quality indicators. However to ensure that this recommendation does not adversely affect the quality of care at the Hospital, the Program Administrator is tracking the Hospital's performance of the covered cardiac procedures against quality indicators established by the American College of Cardiology ("ACC") throughout the base years and contract years. (See infra definitions notes 6 and 7.) 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 catheterization lab practices. The ACC indicators incorporate enough specificity to permit correlation of outcomes with catheterization lab practices. No cost sharing amounts are allocated to the Cardiology Groups for procedures involving reductions in historical ACC quality indicators.

According to the Program Administrator, if implemented in accordance with the Executive Summary's specifications, the thirty recommendations would present substantial cost savings opportunities for the Hospital without adversely impacting the quality of patient care.

Under the Arrangement, the Hospital intends to pay each of the Cardiology Groups separately for 50% of the yearly savings achieved by the particular group when implementing the thirty recommendations in the Executive Summary. At the end of each year of the three-year Arrangement, cost savings are calculated separately for each group and for each of the thirty recommendations; this precludes shifting of cost savings and ensures that savings generated by utilization beyond the set targets, as applicable, are not credited to the Cardiology Groups.

The sum of all three annual payments to each Cardiology Group, when made, will constitute the entire compensation paid to the particular group for services performed under the contract memorializing the Arrangement between that Cardiology Group and the Hospital. The payment to each Cardiology Group will be calculated using the same formula. For purposes of calculating the payment to each Cardiology Group, the actual costs incurred for the items specified in the thirty recommendations when used by cardiologists in the particular Cardiology Group during the specified procedures (the "current year costs"[6]) are subtracted from the costs for the same items when used during comparable procedures in the respective base year (the "base year costs"[7]). The Requestors are rebasing the Arrangement at the end of each year so that the Cardiology Groups will not receive duplicate payments for savings achieved in prior years. Specifically, at the end of the first year, the Requestors calculated the amounts owed to the Cardiology Groups as described above. The Requestors then reset the base year so that the first year of the Arrangement became the base year for the second year of the Arrangement. The same rebasing will occur for the third year. This annual rebasing method removes earlier accomplished savings from the accounting.

The current year costs for each of the three years are adjusted to account for any inappropriate reductions in the use of items beyond the targets set in the Executive

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[6]The term "current year costs" used here represents the actual costs incurred during each of the three twelve-month periods which comprise the Arrangement. Current year costs were calculated for year one of the Arrangement, recalculated for year two, and will be recalculated again for year three.

[7]Figures for three successive "base years" have been calculated from historical costs during the twelve months immediately preceding the contracts' year one, year two, and year three, respectively. For purposes of this opinion, the Arrangement is limited to the three-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 current year and base year costs.

Summary. After receipt of a favorable advisory opinion, year-end payments will separately be made to the groups for 50% of the difference between their respective adjusted current year costs and base year costs for the first, second, and third years, if any. Under the Arrangement, the Hospital is obligated to make these aggregate payments to the Cardiology Groups, both of which distribute profits among members on a per capita basis.

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

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

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

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

The Hospital and the Cardiology Groups document 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 Cardiology Groups disclose the Arrangement to the patients, including the fact that the Cardiology Groups' compensation is based on a percentage of the Hospital's cost savings. The disclosure is made to the patient before the patient is admitted to the Hospital for a procedure covered by the Arrangement; if pre-admission disclosure is impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure is made before the patient consents to the procedure. The disclosures are in writing, and patients have an opportunity, if they desire, 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.[8] 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 establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct

[8]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.

care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. 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.[9]

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 potential impact on patient care.

Having reviewed the thirty recommendations, we conclude that the recommendations implicated the CMP. Simply put, with respect to the recommendations under the Arrangement regarding the standardization of devices and supplies, the limitations on the use of vascular closure devices, and product substitution of the anti-thrombotic medication, the Arrangement might induce physicians to reduce or limit the current medical practice at the Hospital. We recognize that the current medical practice may involve care that exceeds 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 the standardization of devices, limiting the use of vascular closure devices, and product substitution of the anti-thrombotic medication. 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 have been clearly and separately identified. The transparency of the Arrangement has allowed 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

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[9]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).

transparency of the incentives for specific actions and specific procedures has also facilitated accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations does not adversely affect patient care. The Arrangement has been periodically reviewed by the Requestors to confirm that the Arrangement does not have an adverse impact on clinical care.[10]

Third, the amounts to be paid under the Arrangement have been based on all procedures 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 applies have not been disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings have been calculated based on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

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

Fifth, the product standardization portion of the Arrangement has further protected against inappropriate reductions in services by ensuring that individual physicians still have 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.

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[10]We have had the Arrangement reviewed by an independent medical expert who has concluded that the cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect 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.

Sixth, the Hospital and the Cardiology Groups have provided written disclosures of their involvement in the Arrangement to patients whose care might be affected by the Arrangement and have provided patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent is 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 disclosures offer some protection against possible abuses of patient trust.[11]

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

Eighth, because each of the Cardiology Groups distributes its profits to its members on a per capita basis, any incentive for an individual cardiologist to generate disproportionate cost savings is 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 Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate 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 sets out the specific actions to be taken and ties the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allows an assessment of the likely effect of the Arrangement on quality of care and ensures that the identified actions are the cause of the savings.

"Gainsharing" plans can present substantial risks for both patient and program abuse – risks that are not present in the Arrangement. Given the limited duration and scope of the Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are more expansive in scope or less specific than the Arrangement, are likely to require additional or different safeguards.

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[11]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 and medications used in cardiac catheterization laboratory procedures, we believe that patient satisfaction surveys would not be effective.

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 to be owed the Cardiology Groups is to be calculated on a percentage basis, and thus the aggregate compensation is 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 Cardiology Groups. Specifically, the Arrangement could encourage the cardiologists to admit Federal health care program patients to the Hospital, since the cardiologists 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 cardiologist performs at the Hospital, the more money he or she is likely to receive under the Arrangement.

Multiple-year gainsharing arrangements raise a particular concern, in that they can inappropriately carry over earlier-accomplished savings across years, effectively accounting for them more than once. The resulting unearned duplicate payments can amount to unlawful kickbacks from hospitals to physicians, if accompanied by illicit intent. The annual rebasing method adopted by the Requestors removes earlier accomplished savings from the accounting and thereby avoids improper duplication of physician payments, reducing the accompanying risk of kickbacks.

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 have reduced the likelihood that the Arrangement is being used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Arrangement has been limited to cardiologists already on the medical staff, thus limiting the likelihood that the Arrangement attracts other cardiologists. In addition, the potential savings derived from procedures for Federal health care program beneficiaries have been capped based on the physicians' prior year's admissions of Federal health care program beneficiaries. The period for which payments are calculated has been limited to one year (and the Arrangement is rebased annually as described above), and the overall amount of available cost savings payments over the entire three-year term of the contract has been capped, reducing any incentive to switch facilities. Finally, admissions have been monitored for changes in severity, age, or payor. Thus, while the incentive to refer has not necessarily eliminated, it has been substantially reduced.

Second, the structure of the Arrangement has eliminated the risk that the Arrangement is used to reward cardiologists or other physicians who refer patients to the Cardiology Groups, or their cardiologists. The Cardiology Groups have been the sole participants in the Arrangement and are composed entirely of cardiologists; no surgeons or other physicians are members of the Cardiology Groups or share in their profit distributions. Within the

Cardiology Groups, profits are distributed to their members on a per capita basis, mitigating any incentive for an individual cardiologist to generate disproportionate cost savings.

Third, the Arrangement has set out with specificity the particular actions that generate the cost savings on which the payments are based. The recommendations in the Executive Summary have represented a change in catheterization laboratory practice, for which the cardiologist is responsible and has liability exposure. The product standardization, limitation on use of vascular closure devices, and product substitution have each carried some increased liability risk for the physicians. It is not unreasonable for the cardiologists to receive compensation for the increased risk from the change in practice. Moreover, the payments to be made represent portions of three years' worth of cost savings and have been limited in amount (i.e., the rebasing and 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 by appropriate utilization levels). The payments under the Arrangement do not appear unreasonable, given, among other things, the nature of the actions that have been required of the physicians to implement the thirty recommended actions, the specificity of the payment formula, the annual rebasing, and the cap on total remuneration to the Cardiology Groups.[12] 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.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate 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

[12]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 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.

limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) 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, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [names redacted] with respect to any action 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