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

Issued: February 10, 2005

Posted: February 17, 2005

[names and addresses redacted]

Re: **OIG Advisory Opinion No. 05-03**

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion concerning a proposed arrangement in which a hospital will share with a group of cardiac surgeons a percentage of the hospital's cost savings arising from the surgeons' implementation of a number of cost reduction measures in certain surgical procedures (the "Proposed Arrangement"). The cost savings will be measured based on the surgeons' use of specific supplies during designated cardiac surgery procedures. You have inquired whether the Proposed Arrangement would constitute 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 Proposed Arrangement would 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 Proposed Arrangement; and (ii) the Proposed Arrangement would 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 Proposed 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 redacted] that offers a broad range of inpatient and outpatient hospital services, including cardiac surgery services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Surgical Group. [Name redacted], (the "Surgical Group") is a professional association composed exclusively of cardiac surgeons who are licensed in [state redacted] and have active medical staff privileges at the Hospital. The cardiac surgeons refer patients to the Hospital for inpatient and outpatient hospital services. The Surgical Group is the only group of cardiac surgeons that practices at the Hospital and performs 100% of the Hospital's cardiac surgery.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Proposed Arrangement. The Program Administrator will collect data and analyze and manage the Proposed Arrangement.[1] The Hospital will pay 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 Proposed Arrangement. The fee will not be tied in any way to cost savings or the Surgical Group's compensation under the Proposed Arrangement.

B. The Proposed Arrangement

Under the Proposed Arrangement, the Hospital will pay the Surgical Group a share of the first year cost savings directly attributable to specific changes in the Surgical Group's operating room practices. The Program Administrator conducted a study of the historic practices at the Hospital's cardiac surgery department and identified twenty-nine specific

[1]The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis. The products are certified by both the American College of Cardiology and the Society of Thoracic Surgery.

cost-savings opportunities. The results of the Program Administrator's study of the Surgical Group and the specific cost-savings opportunities are summarized in a "Practice Patterns Report."[2] The Hospital and the Surgical Group have reviewed the Practice Patterns Report for medical appropriateness and each has adopted its recommendations and conclusions.

In general, the Practice Patterns Report recommends that the Surgical Group change its current operating room practices to curb the inappropriate use or waste of medical supplies. The Practice Patterns Report identifies twenty-nine specific recommendations that can be roughly grouped into the following four categories.

The first category consists of thirteen recommendations that involve opening packaged items only as needed during a procedure. Most of these "open as needed" items are surgical tray or comparable supplies. These items will be readily available, albeit unopened, in the operating room. One "open as needed" recommendation involves not opening disposable components of the cell saver unit until a patient experiences excessive bleeding. The Requestors have certified that the resulting delay in cell saver readiness should not exceed two to five minutes and will not adversely affect patient care.

The second category is similar and involves performing blood cross-matching only as needed. The Requestors have certified that all patients would be typed and screened prior to the procedure, with a cross-match being performed only when a patient requires a transfusion. The Hospital does not outsource its blood supply. The Requestors have certified that the resulting delay in blood readiness should be minimal when a cross match is necessary and that the delay will not adversely affect patient care.

The third category, involving fourteen recommendations, consists of the substitution, in whole or in part, of less costly items for items currently being used by the surgeons (hereafter, the "product substitution" recommendations). The identified substitutions[3] have no appreciable clinical significance (e.g. slush drape, wrist splints, armboards, aortic punches, or suture boots). For example, wrist splints or armboards are used for support and protection after insertion of a radial artery line. Under one recommendation, surgeons would be asked to utilize a less expensive wrist splint or armboard that has similar characteristics to the surgeons' historic preference.

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[2]The Practice Patterns Report for the Surgical Group, dated October 2004, is attached to this advisory opinion as Appendix A. This opinion is based on the specific cost savings recommendations and associated facts (e.g., specific floors set for each recommendation) set forth in the Practice Patterns Report as appropriate for the Requestors. Similar cost savings recommendations involving different facts could produce a different result.

[3]The Practice Patterns Report clearly identifies with specificity the items and products at issue for each proposed product substitution recommendation.

The final category involves product standardization of certain cardiac heart valves where medically appropriate. For this category, the Surgical Group would be required to work in conjunction with the Hospital to evaluate and clinically review vendors and products.[4] The Surgical Group would agree to use the selected products where medically appropriate, which may require additional training or changes in clinical practice.

The Proposed Arrangement contains several safeguards intended to protect against inappropriate reductions in services. With respect to the cell saver and blood cross-matching recommendations, the Proposed Arrangement would utilize objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital, and in some cases, national averages to establish a "floor" beyond which no savings would accrue to the Surgical Group.

For example, the cell saver is currently set-up for 100% of the cases, but is utilized in approximately 5% of the cardiac procedures specified under the Proposed Arrangement. Accordingly, the Surgical Group will receive no share of any savings resulting from any reductions in cell saver use for cases beyond the established 10% floor set by the Program Administrator based upon national averages. Similarly, blood cross-matching is currently performed for 100% of the cases, with less than 50% of the cases actually resulting in a transfusion. Thus, the Surgical Group will receive no share of any savings resulting from the reduction of blood cross-matching beyond the 50% floor. With respect to the product substitution recommendations in the Proposed Arrangement, the Practice Patterns Report clearly identifies with specificity each substitution recommendation under this category. No floors will be set, because the identified substitutions will have no appreciable clinical significance.[5]

Importantly, with respect to the product standardization recommendations for cardiac devices, the Requestors have certified that the individual surgeons will make a patient-by-patient determination of the most appropriate device and the availability of the full range of cardiac devices will not be compromised by the product standardization. The Requestors have further certified that individual physicians will still have available the same selection of devices after implementation of the Proposed Arrangement as before and that the economies gained through the Proposed Arrangement will result from inherent clinical and fiscal value and not from restricting the availability of devices.

According to the Program Administrator, if implemented in accordance with the Practice Patterns Report's specifications, the twenty-nine recommendations would present substantial cost savings opportunities for the Hospital without adversely impacting the

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[4]We note that the Practice Patterns Report identifies with specificity the vendors and products at issue.

[5]We note that for product substitution recommendations that have clinical significance, we would require additional safeguards, including, for example, the establishment of appropriate quality thresholds beyond which no cost savings would be credited.

quality of patient care.

The Hospital will pay the Surgical Group 50% of the cost savings achieved by implementing the twenty-nine recommendations in the Practice Patterns Report for a period of one year. At the end of the year, cost savings will be calculated separately for each of the twenty-nine recommendations; this will preclude shifting of cost savings and ensure that savings generated by utilization beyond the set targets, as applicable, will not be credited to the Surgical Group. This payment will constitute the entire compensation paid to the Surgical Group for services performed under the contract memorializing the Proposed Arrangement between the Surgical Group and the Hospital. For purposes of calculating the payment to the Surgical Group, the cost savings will be calculated by subtracting the actual costs incurred for the items specified in the twenty-nine recommendations when used by surgeons in the Surgical Group during the specified surgical procedures (the "current year costs"[6]) from the historic costs for the same items when used during comparable surgical procedures in the base year (the "base year costs"[7]). The current year costs will be adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Practice Patterns Report. The payment to the Surgical Group will be 50% of the difference between the adjusted current year costs and base year costs, if any.

The Hospital will make an aggregate payment to the Surgical Group, which distributes its profits to each of its members on a per capita basis. Payments to the Surgical Group will also be subject to the following limitations:

- If the 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, there will be no sharing of cost savings for the additional procedures.

- To minimize the surgeons' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Proposed Arrangement will be monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If there are significant changes from historical measures, the surgeon at issue will be terminated from participation in the Proposed Arrangement.

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[6]The current year will be the twelve-month term of the contract for which the Surgical Group will be compensated under the Proposed Arrangement.

[7]The "base year" will be the twelve months preceding the effective date of the contract. For purposes of this opinion, the Proposed Arrangement is limited to the one-year term of the contract; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Proposed Arrangement. Notwithstanding, we note that any renewal or extension of the Proposed Arrangement should incorporate updated base year costs.

- The aggregate payment to the Surgical Group will not exceed 50% of the projected cost savings identified in the Practice Patterns Report.

The Hospital and the Surgical Group will document the activities and the payment methodology under the Proposed 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 Surgical Group will disclose the Proposed Arrangement to the patient, including the fact that the Surgical Group's compensation is based on a percentage of the Hospital's cost savings. The disclosure will be made to the patient before the patient is admitted to the Hospital for a procedure covered by the Proposed 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 will be made before the patient consents to the surgery. The disclosures will be in writing, and patients will have an opportunity, if desired, to review details of the Proposed Arrangement, including the specific cost savings measures applicable to the patient's surgery.

II. LEGAL ANALYSIS

Arrangements like the Proposed 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 Proposed 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 Proposed 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 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 Proposed Arrangement will induce physicians to reduce or limit items or services. Given the specificity of the Proposed Arrangement, it is possible to review the proposed opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the twenty-nine individual recommendations, we conclude that, except for the unopened surgical tray items and the product substitutions (discussed in more detail below), the recommendations implicate the CMP. Simply put, with respect to the recommendations regarding the disposable cell saver components, the blood cross-matching, and the standardization of devices, the Proposed Arrangement constitutes an inducement 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

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[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 Proposed Arrangement.

[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).

medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

With respect to the recommendations regarding "open as needed" surgical tray items and product substitutions, we reach a different conclusion. To the extent that the sole delay in providing items or services is the insubstantial time it takes to open a package of supplies readily available in the operating room, we believe there will be no perceptible reduction or limitation in the provision of items or services to patients sufficient to trigger the CMP. However, this conclusion does not apply to the disposable cell saver components. Because the cell saver components must be attached to the machine and the machine must be started up, there will be an additional delay in the cell saver's availability beyond merely opening the disposable components. Accordingly, we conclude that the cell saver incentive is subject to the statutory proscription of the CMP. With respect to the specific product substitution recommendations, the identified substitutions will have no appreciable clinical significance; therefore, we believe there will be no perceptible reduction or limitation in the provision of items or services to patients sufficient to trigger the CMP.

In sum, while the recommendations for the "open as needed" surgical tray items and the specific product substitutions do not run afoul of the CMP, we find that the CMP would apply to the remaining recommendations involving the cell saver components, blood cross-matching, and the standardization of devices. Notwithstanding, the Proposed 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 are clearly and separately identified. The transparency of the Proposed Arrangement will allow for public scrutiny and individual physician accountability for any adverse effects of the Proposed Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures will also facilitate accountability through the medical-legal professional liability system.

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

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[10]We have had the Proposed Arrangement reviewed by an independent medical expert, as well as a government medical expert. Both have concluded that the proposed 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 Proposed Arrangement.

Third, the payments under the Proposed Arrangement are based on all surgeries regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the surgical procedures to which the Proposed Arrangement applies are not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings are calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Proposed Arrangement protects against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the Surgical Group. The Requestors have certified that these baseline measures are reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards are action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in operating room practices.

Fifth, the product standardization portion of the Proposed Arrangement further protects against inappropriate reductions in services by ensuring that individual physicians will still have available the same selection of devices after implementation of the Proposed Arrangement as before. The Proposed Arrangement is designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices.

Sixth, the Hospital and the Surgical Group will provide written disclosures of their involvement in the Proposed Arrangement to patients whose care may be affected by the Proposed Arrangement and will provide 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 surgery). 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.[11]

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

Eighth, because the Surgical Group's profits are distributed to its members on a per capita basis, any incentive for an individual surgeon to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Proposed 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").

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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 Proposed Arrangement, which focuses on items used in operating rooms, we believe that patient satisfaction surveys would not be effective.

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 Proposed Arrangement is markedly different from many "gainsharing" plans, particularly those that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Proposed 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 Proposed Arrangement on quality of care and ensures that the identified actions will be the cause of the savings.

By contrast, many gainsharing plans contain features that heighten the risk that payments will lead to inappropriate reductions or limitations of services. These features include, but are not limited to, the following:

- There is no demonstrable direct connection between individual actions and any reduction in the hospital's out-of-pocket costs (and any corresponding "gainsharing" payment).

- The individual actions that would give rise to the savings are not identified with specificity.

- There are insufficient safeguards against the risk that other, unidentified actions, such as premature hospital discharges, might actually account for any "savings."

- The quality of care indicators are of questionable validity and statistical significance.

- There is no independent verification of cost savings, quality of care indicators, or other essential aspects of the arrangement.

Simply put, many "gainsharing" plans present substantial risks for both patient and program abuse – risks that are not present in the Proposed Arrangement. Given the limited duration and scope of the Proposed Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are longer in duration or more expansive in scope than the Proposed 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 Proposed 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 Proposed Arrangement would not fit in the safe harbor because the Surgical Group will be paid on a percentage basis, and thus the compensation would not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Proposed 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 Proposed Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Surgical Group. Specifically, the Proposed Arrangement could encourage the surgeons to admit Federal health care program patients to the Hospital, since the surgeons would 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 surgeon performs at the Hospital, the more money he or she is likely to receive under the Proposed Arrangement.

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

First, the circumstances and safeguards of the Proposed Arrangement reduce the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Proposed Arrangement will be limited to surgeons already on the medical staff, thus limiting the likelihood that the Proposed Arrangement will attract other surgeons. In addition, the potential savings derived from procedures for Federal health care program beneficiaries will be capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract term will be limited to one year, reducing any incentive to switch facilities, and admissions will be monitored for changes in severity, age, or payor. Thus, while the incentive to refer will not necessarily be eliminated, it will be substantially reduced.

Second, the structure of the Proposed Arrangement eliminates the risk that the Proposed Arrangement will be used to reward cardiologists or other physicians who refer patients to the Surgical Group or its surgeons. The Surgical Group is the sole participant in the Proposed Arrangement and is composed entirely of cardiac surgeons; no cardiologists or other physicians are members of the Surgical Group or share in its profit distributions. Within the Surgical Group, profits are distributed to its members on a per capita basis, mitigating any incentive for an individual surgeon to generate disproportionate cost savings.

Third, the Proposed Arrangement sets out with specificity the particular actions that will generate the cost savings on which the payments are based. While many of the recommendations in the Practice Patterns Report are simple common sense, they do represent a change in operating room practice, for which the surgeon is responsible and will have liability exposure. While most of the recommendations would appear to present minimal risk, the preparation of the cell saver, blood cross-matching, and product standardization each carry some increased liability risk for the physicians. It is not unreasonable for the surgeon to receive compensation for the increased risk from the proposed change in practice. Moreover, the payments will represent a portion of one year's worth of cost savings and will be 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 by appropriate utilization levels). The payments under the Proposed Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to implement the twenty-nine recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Surgical Group.[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.

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[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 have certified that the payments under the Proposed 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.

In light of these circumstances and safeguards, the Proposed 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 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: (i) the Proposed Arrangement would 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 Proposed Arrangement; and (ii) the Proposed Arrangement would 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 Proposed 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 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 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 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,

/s/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A Redacted]