



[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: December 28, 2007

Posted: January 14, 2008

[Name and address redacted]

Re: OIG Advisory Opinion No. 07-21

Ladies & Gentlemen:

We are writing in response to your request for an advisory opinion concerning an arrangement in which a hospital has agreed to 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 "Arrangement"). The cost savings are measured based on the surgeons' reduction of waste and use of specific supplies during designated cardiac surgery 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 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 limited liability company comprised only 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 engaged [name redacted] (the “Program Administrator”) to administer the Arrangement. The Program Administrator collected data

and analyzed and manages the Arrangement.¹ 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 provided by the Program Administrator under the Arrangement. The fee was not tied in any way to cost savings or the Surgical Group's compensation under the Arrangement.

B. The Arrangement

Under the Arrangement, the Hospital agreed to pay the Surgical Group a share of cost savings directly attributable to specific changes in the Surgical Group's operating room practices. The Requestors implemented the Arrangement – and the Surgical Group began performance of the specific changes in operating room practices – prior to requesting this advisory opinion. However, the Hospital has not paid amounts owed to the Surgical Group under the Arrangement pending the outcome of this opinion.² 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.

To develop the Arrangement, the Program Administrator conducted a study of the historic practices at the Hospital's cardiac surgery department and identified twenty-five specific cost-savings opportunities. The Program Administrator summarized the results of the study of the Surgical Group and the specific cost-savings opportunities in a document entitled [title redacted] (the "Executive Summary").³ The Hospital and the Surgical Group reviewed the Executive Summary for medical appropriateness, and each adopted its recommendations and conclusions.

In general, the Executive Summary recommended that the Surgical Group change its operating room practices to curb the inappropriate use or waste of medical supplies. The

¹The 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.

²Nonpayment of amounts owed pursuant to a contractual agreement does not, by itself, absolve parties from liability under the fraud and abuse laws.

³The Executive Summary for the Surgical Group 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 or measurable quality indicators set for each recommendation) set forth in the Executive Summary. Similar cost savings recommendations involving different facts could produce a different result.

Executive Summary identified twenty-five specific recommendations that can be grouped roughly into the following four categories.

- *Disposable Cell Saver Components.* This category involved one recommendation that the Surgical Group refrain from opening disposable components of the cell saver unit until a patient experiences excessive bleeding, and, at the same time, that the Surgical Group implement specific alternative clinical practices. The Requestors have certified that the resulting delay in cell saver readiness did not exceed two to five minutes and did not adversely affect patient care.
- *“Use as Needed” Supplies.* For the second category, involving eight recommendations, the Surgical Group was to limit the use of certain surgical supplies to an as needed basis (hereafter, the “use as needed” recommendations). The Requestors have certified that the individual surgeons made patient-by-patient determinations as to whether these items were clinically indicated and that the surgical supplies remained readily available to the surgeons. The Requestors have further certified that any resulting limitations on the use of these products did not adversely affect patient care. Included in this category was a recommendation to limit use of Aprotinin— a medication given to many surgical patients pre-operatively to prevent hemorrhaging – to patients at higher risk of perioperative hemorrhage as indicated by objective clinical standards, as well as recommendations to eliminate the use of Vancomycin and Triple Antibiotic Ointment for particular procedures covered by the Arrangement.
- *Product Substitutions.* For the third category, involving eleven recommendations, the Surgical Group was to substitute, in whole or in part, less costly items for items then being used by the surgeons (hereafter, the “product substitution” recommendations). Some of the identified substitutions⁴ would have no appreciable clinical significance (e.g., elbow pads, wrist splints, or skin staplers). For example, under one recommendation, surgeons were asked to utilize a reusable blanket instead of a disposable blanket. Other product substitutions involved pharmacy items and supplies that may have had appreciable clinical significance. With respect to these substitutions, the Requestors certified that the individual surgeon made a patient-by-patient determination whether the item or supply was clinically indicated and that all of the items and supplies remained readily available to the surgeons. The Requestors further certified that none of the identified product substitutions adversely impacted patient care.

⁴The Executive Summary identified with specificity the product substitution recommendations.

- *Product Standardization.* For the fourth category, involving five recommendations, the Surgical Group was to standardize the use of certain cardiac devices and supplies where medically appropriate. For this category, the Surgical Group was required to work with the Hospital to evaluate and clinically review vendors and products.⁵ The Surgical Group agreed to use the selected products where medically appropriate, which might have required additional training or changes in clinical practice.

The Arrangement contained several safeguards intended to protect against inappropriate reductions in services. For many of the recommendations, the Arrangement used objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital, and, in some cases, national data to establish “floors” below which no savings would accrue to the Surgical Group. For example, the cell saver was previously being set up for 100% of the cardiac procedures specified under the Arrangement, but was not actually used in all cases. The Arrangement established a 30% “floor” based upon best practice utilization. The Surgical Group has not been credited with any savings resulting from any reductions in cell saver use below this 30% floor. In other words, if cell saver use dropped below 30% of cases, no cost savings were allocated to the surgeons. Similarly for Aprotinin, the Arrangement established a 10% “floor” based upon national best practice data.⁶ Under the Arrangement, savings from reduced use of Aprotinin have not been credited to the Surgical Group if the savings resulted from utilization of Aprotinin in fewer than 10% of cases or if the savings resulted from failure to use Aprotinin in a case that met the clinical indicators. All surgical cases – including cases in which Aprotinin was not administered – were reviewed by the Program Administrator to determine if the surgeons followed the objective clinical indicators.

For some recommendations, no “floors” were set because the identified substitutions had no appreciable clinical significance (e.g., use of blankets) or because eliminating usage of a pharmaceutical or supply comported with national best practice data and other quality indicators. However, to ensure that these recommendations did not adversely affect the quality of care at the Hospital, the Program Administrator tracked the Hospital’s performance of the covered cardiac procedures against the quality indicators established by the Society of Thoracic Surgeons (“STS”) throughout the base year and contract year (as defined below). According to the Requestors, the STS quality indicators against which all of the Arrangement’s recommendations were evaluated reflect objective hospital baselines

⁵The Executive Summary identified with specificity the products at issue.

⁶According to the Requestors, the 10% floor represented a change in the national best practice baseline from an earlier 20% floor.

and incorporate specificity sufficient to correlate outcomes with operating room practices. The indicators are action-specific and not simply based on isolated patient outcome data unrelated to specific changes in operating room practices. No cost sharing amounts were allocated to the Surgical Group for procedures involving reductions in historical STS quality indicators.

Importantly, with respect to the product standardization recommendations for cardiac devices and supplies, the Requestors have certified that the individual surgeons made patient-by-patient determinations of the most appropriate device and the availability of the full range of cardiac devices was not compromised by the product standardization. The Requestors have further certified that individual physicians still had available the same selection of devices under 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.

According to the Program Administrator, to the extent implemented in accordance with the Executive Summary's specifications, the twenty-five 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 the Surgical Group 50% of the cost savings achieved by implementing the twenty-five recommendations in the Executive Summary for a period of one year. At the end of the applicable year (the "contract year"), cost savings were calculated separately for each of the twenty-five recommendations; this precluded shifting of cost savings and ensured that savings generated by utilization reduced below the set targets, as applicable, were not credited to the Surgical Group. The payment, when made, will constitute the entire compensation paid to the Surgical Group for services performed under the contract memorializing the Arrangement between the Surgical Group and the Hospital. For purposes of calculating the payment to the Surgical Group, the cost savings were calculated by subtracting the actual costs incurred during the contract year⁷ for the items specified in the twenty-five recommendations when used by surgeons in the Surgical Group during the specified surgical procedures (the "contract year costs") from the historic costs for the same items when used during comparable surgical procedures in the base year⁸ (the "base year costs"). The contract year costs were adjusted to account for any

⁷The contract year was the twelve-month term for which the Surgical Group would be compensated under the Arrangement.

⁸The "base year" was the twelve months preceding the contract year term. For purposes of this opinion, the Arrangement was limited to the one-year term of the contract; accordingly, this opinion is without force and effect with respect to any renewal or extension of the

inappropriate reductions in use of items beyond the targets set in the Executive Summary or in connection with reductions in the STS quality indicators. The payment to the Surgical Group was calculated to be 50% of the difference between the adjusted contract year costs and base year costs. Under the Arrangement, the Hospital is obligated to make an aggregate payment to the Surgical Group, which distributes its profits to each of its members on a *per capita* basis.

Calculation of the payment to the Surgical Group was also subject to the following limitations:

- If the Surgical Group'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 was 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 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 surgeon had altered his or her referral patterns in a manner beneficial to the Hospital as a result of the Arrangement, the surgeon at issue would have been terminated from participation in the Arrangement. No surgeons were terminated.
- The Executive Summary identified projected cost savings, and the aggregate payment to the Surgical Group, when made, will not exceed 50% of those amounts.

The Hospital and the Surgical Group documented the activities and the payment methodology under the Arrangement and agreed to 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 disclosed the Arrangement to patients, including the fact that the Surgical Group's 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 is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure was made before the patient consented to the surgery. The disclosures were made in writing, and patients had

Arrangement. Notwithstanding, we note that any renewal or extension of the Arrangement would need to have incorporated updated base year costs.

an opportunity, if desired, to review details of the Arrangement, including the specific cost savings measures applicable to the patient's surgery.

II. LEGAL ANALYSIS

Arrangements 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.⁹ 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

⁹In 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.

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.¹⁰

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 might have induced 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 twenty-five individual recommendations, we conclude that, except for a limited number of the identified product substitutions,¹¹ the recommendations implicated the CMP. Simply put, with respect to all but a handful of the recommendations, the Arrangement might have induced physicians to reduce or limit the then-current medical practice at the Hospital.¹² We recognize that the then-current medical practice may have involved care that exceeded the requirements of medical necessity. However, whether current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

¹⁰Physician 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/gletter.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).

¹¹As described in Section I.B of this opinion, a few of the product substitution recommendations involved actions that should have had no appreciable clinical significance, such as substituting a reusable blanket for a disposable one. For these recommendations, we believe there would be no perceptible reduction or limitation in the provision of items or services to patients sufficient to trigger the CMP.

¹²This is true even though the Hospital has not yet paid the Surgical Group.

Notwithstanding, several features of the Arrangement, in combination, provided 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 amount to be paid under the Arrangement has been calculated 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 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.

Fourth, the Arrangement protected against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds (or similar benchmarks) beyond which no savings accrued to the Surgical Group. The Requestors have certified that these baseline measures were reasonably related to the Hospital's or comparable hospitals' practices and patient populations. Moreover, the Requestors have certified that the STS quality indicators against which all of the Arrangement's recommendations were evaluated reflect objective hospital baselines and incorporate specificity sufficient to correlate outcomes with operating room practices; the indicators are action-specific and not simply based on isolated patient outcome data unrelated to specific

¹³We 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 undertaken as part of the Arrangement.

changes in operating room practices. No cost sharing amounts were allocated to the Surgical Group where there were reductions in historical STS quality indicators.

Fifth, the product standardization portion of the Arrangement further protected against inappropriate reductions in services by ensuring that individual physicians still had available the same selection of devices and supplies under 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.

Sixth, the Hospital and the Surgical Group 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 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.¹⁴

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

Eighth, because Surgical Group distributes profits 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 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 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

¹⁴Ordinarily, 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 focused on items used in operating rooms, we believe that patient satisfaction surveys would not have been effective.

effect of the Arrangement on quality of care and ensured that the identified actions caused 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 provided 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.

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 can not fit in the safe harbor because the payment owed to the Surgical Group 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.

As with any compensation arrangement between a hospital and a physician who admits or refers patients to the hospital, we are concerned that the Arrangement could have been used to disguise remuneration from the Hospital to reward or induce referrals by the Surgical Group or its surgeons. Specifically, the Arrangement could have encouraged 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 performed at the Hospital, the more money he or she was likely to receive under the Arrangement.

While we believe the Arrangement might have resulted 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 Arrangement reduce the likelihood that the Arrangement was used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Arrangement was limited to surgeons already on the medical staff, thus limiting the likelihood that the Arrangement would attract other surgeons. In addition, the potential savings derived from procedures for Federal health care program beneficiaries were capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract year for which payments were calculated was limited to one year, reducing any incentive for physicians to switch facilities to earn cost savings payments, and patient admissions were monitored for changes in severity, age, or payor to ensure that the Arrangement did not result in inappropriate changes in referral patterns. 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 might have been 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 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 Arrangement set out with specificity the particular actions that generated the cost savings on which the payments are based. While many of the recommendations in the Executive Summary are simple common sense, they did represent a change in operating room practice, for which the surgeon was responsible and has liability exposure. While most of the recommendations appear to present minimal risk, the preparation of the cell saver, limiting the use of certain surgical supplies, product substitution of pharmacy items and supplies, and product standardization each carried some increased liability risk for the physicians. It is not unreasonable for the surgeon to receive compensation for the increased risk from the change in practice. Moreover, the payments to be made under the Arrangement represent a portion 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 could be achieved from the implementation of any one recommendation were limited by appropriate utilization levels). 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-five recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Surgical Group.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.

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

¹⁵We 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 owed under the Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we made an independent fair market value assessment.

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 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 the Requestors 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 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]