



*[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:** July 31, 2008

**Posted:** August 7, 2008

**To: ATTACHED DISTRIBUTION LIST**

**Re: OIG Advisory Opinion No. 08-09**

Ladies & Gentlemen:

We are writing in response to your request for an advisory opinion concerning an arrangement under which a medical center has agreed to share with groups of orthopedic surgeons and a group of neurosurgeons a percentage of the medical center'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 medical devices and supplies during designated spine fusion 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 described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement constitutes 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”) will not impose sanctions on the requestors of this advisory opinion, [names redacted] (collectively, the “Requestors”), in connection with the Arrangement; and (ii) the Arrangement potentially generates 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 will 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 Medical Center.* [Name redacted] Medical Center (the “Medical Center”) is an academic medical center in [city and state names redacted] that offers a broad range of inpatient and outpatient hospital services, including spine fusion surgery services. The Medical Center is a participating provider in the Medicare and Medicaid programs.

*The Orthopedic Surgery Groups.* [Names redacted] (the “Orthopedic Surgery Groups”) are group medical practices that employ only orthopedic surgeons. The members of the Orthopedic Surgery Groups participating in the Arrangement are licensed in the State of [state name redacted] and have active medical staff privileges at the Medical Center.<sup>1</sup> They refer patients to the Medical Center for inpatient and outpatient hospital services. Both groups entered into a separate contract with the Medical Center that set forth the projected savings opportunities applicable to the group.

*The Neurosurgery Group.* [Name redacted] (the “Neurosurgery Group”) employs only neurosurgeons. The members of the Neurosurgery Group participating in the arrangement are licensed in the State of [state name redacted] and have active medical staff privileges at the Medical Center.<sup>2</sup> The Neurosurgery Group refers patients to the

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<sup>1</sup>The Orthopedic Surgery Groups include members who also practice at other hospitals in the region; however, the Medical Center is the primary practice location for most members of the Orthopedic Surgery Groups.

Medical Center for inpatient and outpatient hospital services. The Neurosurgery Group entered into a separate contract with the Medical Center that set forth the projected savings opportunities applicable to the group.

*The Program Administrator.* The Medical Center engaged [name redacted] (the “Program Administrator”) to administer the Arrangement. The Program Administrator collected data and analyzed and manages the Arrangement.<sup>3</sup> The Medical Center 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 to the compensation of the Orthopedic Surgery Groups and the Neurosurgery Group under the Arrangement.

## **B. The Arrangement**

Under the Arrangement, the Medical Center agreed to pay the Orthopedic Surgery Groups and the Neurosurgery Group a share of the first year cost savings directly attributable to specific changes made in the Orthopedic Surgery Groups’ and the Neurosurgery Group’s operating room practices. The Requestors implemented the Arrangement – and the Orthopedic Surgery Groups and the Neurosurgery Group began performance of the specific changes in operating room practices – prior to requesting this advisory opinion. However, the Medical Center has not paid amounts owed to the Orthopedic Surgery Groups and the Neurosurgery Group under the Arrangement pending the outcome of this opinion.<sup>4</sup> Thus, we are treating the Arrangement as an existing arrangement for purposes of this advisory opinion. The Requestors have certified that the Medical Center 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 historic practices in spine fusion surgery by the Orthopedic Surgery Groups and the Neurosurgery Group at the Medical Center and identified thirty-six specific cost-savings opportunities. The Program Administrator summarized the results of the study of the historic practices of the Orthopedic Surgery Groups and the Neurosurgery Group and the specific cost-

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<sup>2</sup>The Neurosurgery Group includes members who also practice at other hospitals in the region; however, the Medical Center is the primary practice location for most members of the Neurosurgery Group.

<sup>3</sup>The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis.

<sup>4</sup>Nonpayment of amounts owed pursuant to a contractual agreement does not, by itself, absolve parties from liability under the fraud and abuse laws.

savings opportunities in a document entitled, “Executive Summary [name redacted] Valueshare for Spine Surgery” (the “Executive Summary”).

The Medical Center, the Orthopedic Surgery Groups and the Neurosurgery Group reviewed the Executive Summary for medical appropriateness and each adopted its recommendations and conclusions.<sup>5</sup>

In general, the Executive Summary recommended that the Orthopedic Surgery Groups and the Neurosurgery Group change their operating room practices to standardize the use of spine fusion devices and supplies. The Executive Summary identified thirty-six specific recommendations that can be roughly grouped into the following two categories.

- *“Use as Needed” Biological.* The first category, containing a single recommendation, involved limiting the use of Bone Morphogenetic Protein (“BMP”) to an as needed basis. The Requestors have certified that the individual surgeon made patient-by-patient determinations as to whether BMP was clinically indicated and that the biological remained readily available to the surgeons. The Requestors further certified that any resulting limitation on the use of BMP did not adversely affect patient care.
- *Product Standardization.* For the second category, involving thirty-five recommendations, the Orthopedic Surgery Groups and the Neurosurgery Group were to standardize the use of certain spine fusion devices and supplies where medically appropriate. For this category, the Orthopedic Surgery Groups and the Neurosurgery Group were required to work in conjunction with the Medical Center to evaluate and clinically review vendors and products.<sup>6</sup> The Orthopedic Surgery Groups and the Neurosurgery Group agreed to use the selected products where medically appropriate, which may have required additional training or changes in clinical practice.

The Arrangement contained several safeguards intended to protect against inappropriate reductions in services. With respect to the use as needed recommendation, the Arrangement utilized objective historical and clinical measures reasonably related to the

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<sup>5</sup>The Executive Summary, dated December 31, 2006, is attached to this advisory opinion as Appendix A. The approaches of the orthopedic surgeons and the neurosurgeons to spine fusion surgery overlap, often making use of same methods, devices, and supplies. No distinctions are made in the Executive Summary between the two types of surgeons in terms of past practices or gainsharing recommendations.

<sup>6</sup>The Executive Summary identified with specificity the vendors and products at issue.

practices and the patient population at the Medical Center to establish a “floor” beyond which no savings would accrue to the Orthopedic Surgery Groups or the Neurosurgery Group. The Arrangement used specific, objective, generally-accepted clinical indicators reasonably related to the practices of the Medical Center and its patient population to determine medical appropriateness.

Before the implementation of the Arrangement, BMP had been used in approximately 15% of patients undergoing spine fusion procedures by the Orthopedic Surgery Groups and the Neurosurgery Group. The Program Administrator determined through analysis of national data that it was reasonable to reduce the use of BMP on these cases to 11% of patients and that this reduction would not adversely impact patient care. Under the Arrangement, savings from reduced use of BMP were not credited to the Orthopedic Surgery Groups and the Neurosurgery Group if the savings resulted from utilization of BMP in less than 11% of cases or if the savings resulted from failure to use BMP in a case that met the clinical indicators. All surgical cases – including cases in which BMP was not administered – were reviewed by the Program Administrator to determine if the surgeons followed the objective clinical indicators for determining whether BMP was used appropriately.

Importantly, with respect to the product standardization recommendations, the Requestors certified that the individual surgeons made a patient-by-patient determination of the most appropriate spine fusion devices and supplies and the availability of the full range of devices and supplies was not compromised by the product standardization. The Requestors further certified that individual physicians still had available the same selection of devices and supplies after implementation of the Arrangement as before and that the economies gained through the Arrangement resulted from inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

According to the Program Administrator, if implemented in accordance with the Executive Summary’s specifications, the thirty-six recommendations presented substantial cost savings opportunities for the Medical Center without adversely impacting the quality of patient care.

Under the Arrangement, the Medical Center intends to pay each of the Orthopedic Surgery Groups and the Neurosurgery Group individually for 50% of the cost savings achieved by the respective group when implementing the thirty-six 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 group and for each of the thirty-six recommendations; this precluded shifting of cost savings and ensured that savings generated by utilization beyond set targets, as applicable were not credited to the Orthopedic Surgery Groups or the Neurosurgery Group.

The payments, when made, to the Orthopedic Surgery Groups and Neurosurgery Groups, respectively, will constitute the entire compensation paid to the Orthopedic Surgery Groups and the Neurosurgery Group for services performed under the contracts memorializing the Arrangement between the respective groups and the Medical Center. For purposes of calculating the payments to the Orthopedic Surgery Groups and the Neurosurgery Group, the cost savings were calculated by subtracting the actual costs incurred during the contract year<sup>7</sup> for the items specified in the thirty-six recommendations when used by surgeons in each respective group, as applicable, during the specified surgical procedures (the “contract year costs”) from the historic costs for the same items when used by the particular group during comparable surgical procedures in the base year (the “base year costs”<sup>8</sup>). The contract year costs were adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Executive Summary. The payments to the Orthopedic Surgery Groups and the Neurosurgery Group, when made, will be 50% of the difference between each respective group’s adjusted current year costs and the base year costs less 50% of the costs incurred by the Medical Center to administer the Arrangement.

Under the Arrangement, the Medical Center is obligated to make aggregate payments to the practices which comprise the Orthopedic Surgery Groups and the Neurosurgery Group, each of which distributes its respective profits among its members on a per capita basis.

Calculation of payments to the Orthopedic Surgery Groups and the Neurosurgery Group was subject to the following limitations:

- If the volumes of procedures payable by a Federal health care program performed by each of the three physician groups in the gainsharing year exceeded that individual group’s 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

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<sup>7</sup>The contract year was the twelve-month term for which the Orthopedic Surgery Groups and the Neurosurgery Group were compensated under the Arrangement.

<sup>8</sup>The “base year” was the twelve months preceding the effective date of the contracts. For purposes of this opinion, the Arrangement is limited to the one-year term of the contracts; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Arrangement. Notwithstanding, we note that any renewal or extension of the Arrangement should incorporate updated base year costs.

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 Medical Center 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 of payments to the Orthopedic Surgery Groups and the Neurosurgery Group, when made, will not exceed 50% of the group's share of projected cost savings; each group, furthermore, will be compensated solely for its own savings under the Arrangement.

The Medical Center, the Orthopedic Surgery Groups, and the Neurosurgery 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 Medical Center, the Orthopedic Surgery Groups, and the Neurosurgery Group disclosed the Arrangement to the patients, including the fact that compensation of the Orthopedic Surgery Groups and the Neurosurgery Group was based on a percentage of the Medical Center's cost savings. The disclosure was made to the patient before the patient was admitted to the Medical Center for a procedure covered by the Arrangement; if pre-admission disclosure was impracticable (e.g., the patient was admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure was made before the patient consented to the surgery. The disclosures were made in writing, and patients had 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.<sup>9</sup> 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 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.<sup>10</sup>

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<sup>9</sup>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.

<sup>10</sup>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/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).



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

Having reviewed the thirty-six individual recommendations, we conclude that the recommendations implicated the CMP. Simply put, the Arrangement might have induced physicians to reduce or limit the then-current medical practice at the Medical Center.<sup>11</sup> 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.

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

First, the specific cost-saving actions and resulting savings were clearly and separately identified. The transparency of the Arrangement allows 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 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.<sup>12</sup>

Third, the amount to be paid under the Arrangement was calculated based on all surgeries regardless of the patients' insurance coverage, subject to the cap on payment for Federal

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<sup>11</sup>This is true even though the Medical Center has not yet paid the Orthopedic Surgery Groups and the Neurosurgery Group.

<sup>12</sup>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 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.

health care program procedures. Moreover, the surgical procedures to which the Arrangement applies were not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings are calculated from the Medical Center'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 beyond which no savings accrued to the Orthopedic Surgery Groups or the Neurosurgery Group. The Requestors have certified that these baseline measures were reasonably related to the Medical Center's or comparable hospitals' practices and patient populations. These safeguards were action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in operating room practices.

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 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.

Sixth, the Medical Center, the Orthopedic Surgery Groups, and the Neurosurgery 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 Medical Center (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.<sup>13</sup>

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

Eighth, because the Orthopedic Surgery Groups and the Neurosurgery Group distribute profits to their respective members on a per capita basis, any incentive for an individual surgeon to generate disproportionate cost savings was mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Arrangement is an exercise of our discretion and is consistent with our Special Advisory

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<sup>13</sup>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 focused on items used in operating rooms, we believe that patient satisfaction surveys would not have been effective.

Bulletin on “Gainsharing Arrangements and CMPs for Medical Center 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 many “gainsharing” plans that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Arrangement set out the specific actions to be taken and tied the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allowed an assessment of the likely effect of the Arrangement on quality of care and ensured that the identified actions caused the savings.

Many “gainsharing” plans present substantial risks for both patient and program abuse – risks that were 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 Orthopedic Surgery Groups and the Neurosurgery Group was calculated on a percentage basis, and thus the compensation could not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Arrangement must be subject to case-by-case evaluation.

We are concerned that the Arrangement, like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, could be used to disguise remuneration from the Medical Center to reward or induce referrals by the Orthopedic Surgery Groups or the Neurosurgery Group. Specifically, the Arrangement could have encouraged the surgeons to admit Federal health care program patients to the Medical Center, since the surgeons would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Medical Center's payment, depending on cost savings. In other words, the more procedures a surgeon performed at the Medical Center, the more money he or she is likely to have received under the Arrangement.

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

First, the circumstances and safeguards of the Arrangement reduced the likelihood that the Arrangement 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 participating physicians' prior year's admissions of Federal health care program beneficiaries. Finally, the contracts' terms were limited to one year, reducing any incentive to switch facilities, and admissions were monitored for changes in severity, age, or payor. Thus, while the incentive to refer was not necessarily eliminated, it was substantially reduced.

Second, the structure of the Arrangement eliminated the risk that the Arrangement might be used to reward surgeons or other physicians who refer patients to the Orthopedic Surgery Groups, the Neurosurgery Group, or their surgeons. The Orthopedic Surgery Groups and the Neurosurgery Group, the only participants in the Arrangement, were composed entirely of surgeons who perform spine fusion surgery; no other types of physicians were members of the Orthopedic Surgery Groups or the Neurosurgery Group, or shared in their profit distributions. Within each of the three practices, profits were distributed to 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 will be based. The recommendations represented a change in operating room practice, for which the surgeon was responsible and had liability exposure. Product standardization and limiting the use of BMP 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 thirty-six recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Orthopedic Surgery Groups and the Neurosurgery Group.<sup>14</sup> 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

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<sup>14</sup>We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we made an independent fair market value assessment.

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 information provided and the totality of the facts described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement constitutes an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG will not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Arrangement; and (ii) the Arrangement potentially generates 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 will 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,

/s/

Lewis Morris  
Chief Counsel to the Inspector General

[Appendix A and Distribution List redacted]