DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

[*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 31, 2012

Posted: January 7, 2013

[Name and address redacted]

Re: OIG Advisory Opinion No. 12-22

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding an arrangement in which a hospital pays a cardiology group compensation that includes a performance bonus based on implementing certain patient service, quality, and cost savings measures associated with procedures performed at the hospital's cardiac catheterization laboratories (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of sanctions arising under: (i) sections 1128A(b)(1)–(2) of the Social Security Act (the "Act"), the civil monetary penalty for a hospital's payment to a physician to induce the reduction or limitation of services to Medicare or Medicaid beneficiaries under the physician's direct care; 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 Federal anti-kickback statute.

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

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

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Arrangement could constitute an improper payment to induce the reduction or limitation of services pursuant to sections 1128A(b)(1) – (2) of the Act, the Office of Inspector General ("OIG") will not impose sanctions on [name redacted] in connection with the Arrangement; and (ii) although 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, the OIG will not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than [name redacted], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[Name redacted] ("Requestor") is a large, rural acute care hospital located in a medically underserved area in [town, state redacted] ("the Town"). Requestor operates four cardiac catheterization laboratories (the "Labs"), all of which are located in Requestor's main building on its campus. Requestor operates the only cardiac catheterization laboratories within a fifty-mile radius of its campus. Requestor bills for and collects all non-professional fees generated for services provided in the Labs. Requestor provides space, certain non-physician staff, equipment and supplies for the Labs. Requestor certified that the Labs are operated as a provider-based department of Requestor's hospital, in accordance with 42 C.F.R. § 413.65.

Requestor entered into a cardiac catheterization co-management agreement (the "Management Agreement"), with [name redacted] (the "Group") for a term of three years. The Group consists of approximately eighteen full-time physicians, including general cardiologists, interventional cardiologists, and electrophysiologists. Six interventional cardiologists who are members of the Group perform procedures in the Labs. The Group bills Medicare Part B and other payors for cardiology services rendered by its physicians. The Group is the only cardiology group on Requestor's medical staff and the only physician group in the Town that provides cardiac catheterization services.[1]

[1] The Arrangement is not exclusive. If additional cardiologists were to join Requestor's medical staff, Requestor would consider including those individuals within the Arrangement.

The Group does not provide cardiac catheterization services at any location other than the Labs. The Group refers patients to Requestor for inpatient and outpatient procedures, in addition to the cardiac catheterization procedures.

Under the Management Agreement, the Group provides management and medical direction services for Requestor's Labs in exchange for a co-management fee comprised of two components: (1) a guaranteed, fixed payment equal to [amount redacted] per year (the "Fixed Fee"), and (2) a potential annual performance-based payment equal to a maximum of [amount equal to Fixed Fee redacted] per year (the "Performance Fee"). Requestor pays an installment of the Fixed Fee and an estimated installment of the Performance Fee to the Group quarterly. Every year, Requestor reconciles the quarterly installment payments of the Performance Fee under the Arrangement.[2]

Payment under the Arrangement is made by Requestor to the Group. Requestor certified that the Group has agreed that, to the extent revenue derived from the Arrangement results in dividends payable to the Group's shareholders, the Group distributes such dividends based on each shareholder's *pro rata* share of ownership, and that distributions have no relation to an individual physician's participation in the Arrangement.

In exchange for the Fixed Fee and Performance Fee, the Group performs the following duties under the Management Agreement: overseeing Lab operations; providing strategic planning and medical direction services; developing Requestor's cardiology program; serving on medical staff committees; providing staff development and training; providing credentialing for Lab personnel; recommending Lab equipment, medical devices, and supplies; consulting with Requestor regarding information systems; providing assistance with financial and payor issues; and providing public relations services.

The Performance Fee consists of the following components: Requestor's employee satisfaction ("Employee Satisfaction Component"), 5%; patient satisfaction with Requestor's Labs ("Patient Satisfaction Component"), 5%; improved quality of care within the Labs ("Quality Component"), 30%; and implementation of certain measures to reduce costs attributable to Lab procedures ("Cost Savings Component"), 60%. Requestor selected performance measures within these components based on its financial, purchasing, employee satisfaction, patient satisfaction, and quality measurement data systems, as well as certain national cardiology quality measures.

Most measures within the Performance Fee components incorporate three possible achievement levels that trigger payment. If the Group fails to achieve the lowest, baseline achievement level for a measure within a component, it receives no payment for

[2] In the event that the annual reconciliation shows that the Group received a Performance Fee that exceeds the amount it earned, the Group will refund any excess to Requestor.

that measure. The baseline achievement level for any measure reflects improvement over Requestor's *status quo* performance for that measure prior to the effective date of the Agreement. If the Group meets the baseline achievement level for a measure within a Performance Fee component, it receives 50% of the total compensation available for that measure; if it meets the middle benchmark, it receives 75%; and if it achieves the highest benchmark, it receives 100%.

To obtain the portion of the Performance Fee allocable under the Employee Satisfaction Component, the Group must receive a rank between 94.5th–96th percentile as compared to other hospitals surveyed nationally following a bi-annual employee opinion survey of Requestor's employees, performed by Requestor.

To obtain the portion of the Performance Fee allocable under the Patient Satisfaction Component, the Group must meet the following measures on behalf of the Labs:

- Labs must be ranked at the 96th percentile in an annual independent patient satisfaction survey.[3]
- Group physicians must start the first Lab surgical case each day by 8:15 a.m., at least 85% of the days the Lab operates.
- The Group must reduce the time a physician spends between surgical cases in Labs to 25 minutes or less in at least 50% of cases.

To obtain the portion of the Performance Fee allocable under the Quality Component, the Labs must improve their performance as measured by standards promulgated by the Joint Commission, the Centers for Medicare and Medicaid Services ("CMS"), the American College of Cardiology (the "ACC"), and the National Cardiovascular Data CathPCI® Registry (the "NCDR")[4], each of which develops national cardiology quality measures for hospitals. Requestor's performance is measured against hospitals' performance nationally and given a percentile ranking.[5] These standards are subject to revision and update to reflect the appropriate standard of care and currently consist of the following:

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[3] The ranking is based on an independent survey analysis that compares Requestor's patient satisfaction survey data with survey data from a proprietary database of hospitals nationwide.

[4] The NCDR is a cardiovascular data repository developed by the ACC.

[5] Requestor used standards published in the Specifications Manual for National Hospital Quality Measures, Version 4.1 (the "Manual") to establish certain measures within the Quality Component. The Manual is published by the Joint Commission (formerly the Joint Commission on Accreditation of Health Care Organizations) and represents the joint efforts of CMS and the Joint Commission to publish a uniform set of national hospital quality measures. See http://www.jointcommission.org/specifications_manual_

- Reduce "door to balloon time" so that at least 85% of Lab patients' "door to balloon" time is below 90 minutes.[6]
- Prescribe a Beta blocker at discharge[7] to rank between the 70th and 90th percentile of hospitals measured.
- Prescribe an ACE-1 or ARB for left ventricular systolic dysfunction at discharge[8] to rank between the 70th and 90th percentile of all hospitals measured.
- Prescribe an Aldosterone blocking agent at discharge[9] to rank between the 70th and 90th percentile of hospitals measured.
- Document LDL-c level in hospital record[10] to rank between the 70th and 90th percentile of hospitals measured.
- Reduce occurrence of Percutaneous Coronary Intervention complications[11] to a level between 1.4% and 1.7% of patients.
- Reduce the incidence of bleeding in Lab patients within 72 hours of surgery[12] to a level between 0.9% and 1.1% of patients.
- Reduce Percutaneous Intervention Risk Adjustment Complications Index[13] to between 1.25% and 0.96% of patients.

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for_national_hospital_inpatient_quality_measures.aspx.

[6] For this measure, Requestor selected a published guideline set forth in the Manual and adopted by the ACC for measuring the time between a patient's entry to the Emergency Department, when experiencing a heart attack, and the time the physician opens the blocked vessel.

[7] For this measure, Requestor selected a published guideline set forth in the Manual and the ACTION Registry®-GWTG™, which is part of the NCDR. According to Requestor, a Beta blocker is a medication prescribed at discharge that reduces heart rate and blood pressure by dilating blood vessels.

[8] For this measure, Requestor selected a published guideline set forth in the Manual and the ACTION Registry®-GWTG™.

[9] For this measure, Requestor selected a published guideline set forth in the ACTION Registry®-GWTG™.

[10] For this measure, Requestor selected a published guideline set forth in the ACTION Registry®-GWTG™.

[11] For this measure, Requestor selected a published guideline adopted by the ACC, as set forth in the NCDR.

[12] For this measure, Requestor selected a published guideline adopted by the ACC, as set forth in the NCDR.

To obtain the portion of Performance Fee allocable under the Cost Savings Component, the Group must reduce the cardiac catheterization costs per case from [amount redacted] to an amount ranging from [amount redacted] to [amount redacted] per case; and average contrast costs per case from [amount redacted] to an amount ranging from [amount redacted] to [amount redacted] per case. Similar to the other components of the Performance Fee, if the Group meets the baseline achievement level for the cost savings measure, it receives 50% of the total compensation available for that measure; if it meets the middle benchmark, it receives 75%; and if it achieves the highest benchmark, it receives 100%.

Requestor certified the following information. It bases purchasing decisions on the best interests of patient care and utilizes products that are clinically safe and effective. An Interventional Cardiology Committee consisting of all interventional cardiologists who utilize the Labs generates initial product recommendations. It selects products and supplies following a review of evidence-based medicine, empirical trial data, and proven effectiveness. Performance standards drive selection of supplies and equipment in the Labs.

Requestor further certified as follows. It collaborated with the Group's physicians to reduce cardiac catheterization costs by contracting with a single vendor for drug-eluting and bare metal stents, from whom they obtained a highly competitive price. Cost savings also are achieved through better management of the usage of coronary stents and product standardization. Unique-sized stents or other types of drug-eluting stents remain available upon request by an interventional cardiologist, and no physician is ever prohibited from requesting a particular device or supply required to address a patient's unique health needs. Unless otherwise clinically indicated, the Group's physicians adhere to clinical guidelines developed by the ACC regarding the use of bare metal rather than drug-eluting stents. The parties also reduce costs by implementing better management practices with other devices, items, and supplies. For example, Requestor purchases frequently used supplies directly from manufacturers to obtain a better price, and adjusts supply stock levels to reduce shipping costs. The parties also reduce wasted supplies by evaluating necessary items and supplies used during cardiac catheterization procedures and restricting certain items for use only "as needed" during a procedure.

Additionally, Requestor certified that the Group receives [amount redacted] as part of the annual Performance Fee, subject to the aggregate Performance Fee cap, if Requestor

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[13] For this measure, Requestor selected a published guideline adopted by the ACC, as set forth in the NCDR.

achieves a designation as one of Thomson Reuters Top 50 Cardiovascular Hospitals for that year.[14]

Requestor certified that it and the Group's physicians protect against inappropriate reductions in services in the following ways. A team of Requestor's medical staff, including members of the Group, the nurse manager, and administrative leadership, developed the cost savings measures based on evidence and clinical outcomes. The team based product standardization decisions on clinical outcomes ascertained through reviews of clinical studies and documented clinical outcomes.[15] Requestor obtained an independent, third-party valuation regarding the Fixed Fee and Performance Fee paid under the Arrangement. According to Requestor, both the Fixed Fee and the potential Performance Fee are consistent with fair market value and are commercially reasonable. We rely on Requestor's fair market value certification in issuing this opinion.

Requestor uses an independent, third-party utilization review firm to annually review data related to the components of the Performance Fee as well as the clinical appropriateness of the cardiac catheterization procedures performed at the Labs. This firm also annually reviews the Group's performance under the Arrangement to confirm that the Arrangement does not adversely impact patient care. Requestor certified that implementation of the Arrangement has not adversely affected patient care.

Under the Arrangement, all commercially available stents and balloons are available as needed. A Group physician may use the device or supply he or she determines to be most clinically appropriate for each patient. Moreover, receipt of any part of the Performance Fee under the Arrangement is conditioned upon the Group's physicians not taking any of the following actions: 1) stinting on care provided to Requestor's patients; 2) increasing referrals to Requestor; 3) cherry-picking healthy patients or those with desirable insurance for treatment in the Labs; or 4) accelerating patient discharges.

To monitor the Group's performance under the Arrangement, Requestor uses several approaches. First, Requestor's internal audit department reviews all supporting data and

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[14] See Thomson Reuters Top 50 Cardiovascular Hospitals *available at* http://100tophospitals.com/top-cardio-hospitals/. Requestor has not received this designation for a number of years. If the Group achieves the top achievement level for all performance measures, it earns the maximum annual Performance Fee and receives no additional compensation for this top hospital designation.

[15] Members of both Requestor's and the Group's leadership jointly evaluate supply, equipment, and purchasing decisions. The Group participates in evaluation and selection of medical supplies and equipment used in the Labs and evaluates, advises, and assists Requestor in the vendor negotiation process.

documentation related to the Quality and Cost Savings Components. An independent accounting firm then reviews the internal audit department's findings. The firm reports its independent findings to Requestor's compliance officer, who reports to Requestor's Board of Directors. Requestor's Board of Directors' Compliance and Audit Committee reviews the independent accounting firm's findings and approves payment of any amount under the Performance Fee.

Requestor also uses multiple hospital committees to monitor performance of the Group under the Arrangement. The Performance Monitoring Committee, consisting of key hospital management and Lab staff, provides direct oversight to ensure that stinting on patient care, patient cherry-picking, and other improper practices do not occur. Requestor's Credentials and Peer Review Committee monitors and reports on the quality of care provided by the Group and performs peer case review. This committee reports its results to the Medical Executive Committee of the Medical Staff and the Board of Directors' Quality Standards Committee.[16] Also, Requestor's Best Practices Utilization Review Committee, led by physicians on Requestor's medical staff, reviews quality assurance and utilization of the Labs.[17]

Patients and their families are notified in writing of the existence of the Arrangement and their physician's participation in the Arrangement prior to performance of a Lab procedure and concurrent with obtaining the patient's consent to the procedure.

II. LEGAL ANALYSIS

Incentive compensation arrangements like the Arrangement are designed to align incentives by offering physicians compensation in exchange for implementing strategies to meet quality, service, and cost savings targets. However, like any payment arrangement between a hospital and physicians who refer business to the hospital, payments purportedly intended to encourage quality improvements and cost savings might be misused by unscrupulous parties to induce limitations or reductions in care or to disguise kickbacks for Federal health care program referrals. Therefore, such arrangements must be evaluated in light of applicable Federal statutes and the potential for abuse.

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[16] The Board of Directors' Quality Standards Committee monitors the overall quality of care provided by Requestor.

[17] No opinion is expressed or implied in this advisory opinion regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or conduct directly or indirectly related to the Arrangement.

Properly structured, arrangements that compensate physicians for achieving hospital 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 to induce patient referrals, and (iv) unfair competition among hospitals offering incentive compensation 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 services provided to Medicare and Medicaid 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.[18] 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 therefore 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 (the "CMP") establish a civil monetary penalty against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician who receives such a payment) as an inducement to reduce or limit services[19] provided with respect to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians who receive) such payments are liable for civil monetary penalties of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of services provided to Medicare and Medicaid fee-for-

[18] 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.

[19] We have interpreted services under the CMP to include items used or provided as part of a service.

service beneficiaries.[20] The CMP prohibits payments by hospitals to physicians as an inducement to a physician to reduce or limit services furnished to Medicare and Medicaid patients. A threshold inquiry is whether the Arrangement induces the Group's physicians to reduce or limit services. Given the specificity of the Arrangement, it is possible to review the opportunities for savings individually and evaluate their impact on patient care.

Having reviewed the Performance Fee components, we conclude that the Cost Savings Component implicates the CMP. With respect to the measures under the Arrangement regarding standardization of devices and supplies and limiting use of specific stents, contrast agents, and medical devices, the Arrangement might induce physicians to alter their current medical practice to reduce or limit services.[21] However, based on Requestor's certifications, we conclude that the Fixed Fee, Employee Satisfaction, Patient Satisfaction, and Quality Components contained in the Arrangement do not involve an inducement to reduce or limit services and, therefore, do not implicate the CMP. Notwithstanding that the CMP applies to the Cost Savings Component, the Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against Requestor for the Arrangement under sections 1128A(b)(1)–(2) of the Act.

First, Requestor certified that the Arrangement has not adversely affected patient care.[22] Requestor also certified that it monitors both the performance of the Group under the

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[20] Physician incentive arrangements related to Medicare and Medicaid risk-based managed care contracts and Medicare Advantage plans 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).

[21] We recognize that the physicians' medical practice may have involved care that exceeded the requirements of medical necessity and thus would be reduced without posing a risk of harm to patients. However, liability under the CMP does not require that the payments be tied to a reduction in medically necessary care.

[22] An independent medical expert reviewed the Arrangement on behalf of OIG. The medical expert concluded that the quality and 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 Requestor's certifications, and nothing in this opinion should be construed as an

Arrangement and its implementation of the Cost Savings Component throughout the term of the Management Agreement to protect against inappropriate reductions or limitations in patient care or services. Requestor's Board of Directors, internal auditing staff, and certain hospital staff committees also monitor the Group's performance under the Arrangement. Additionally, Requestor uses an independent, external third-party utilization review firm to annually review data related to the components of the Performance Fee and the clinical appropriateness of the cardiac catheterization procedures performed at the Labs.

Second, the risk that the Arrangement will lead the Group's physicians to apply a specific cost savings measure, such as the use of a standardized or bare metal stent, in medically inappropriate circumstances is low. The parties structured the benchmarks within the Cost Savings Component of the Performance Fee to allow the Group's physicians flexibility to use the most cost-effective clinically appropriate items and supplies. Requestor certified that unique-sized stents or other types of drug-eluting stents remain available upon request by an interventional cardiologist, and that no physician is ever prohibited from requesting a particular device or supply required to address a patient's unique health needs. Thus, each of the Group's physicians has access to the device or supply he or she determines to be most clinically appropriate for each patient. The Arrangement is designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices and supplies. The three-tiered benchmarks within the Cost Savings Component allow the Group to receive a portion of the Performance Fee based on the aggregated performance by the Group and not based on meeting a specific standard in the case of a particular patient if the standard is contraindicated with regard to that patient.

Third, the financial incentive tied to the Cost Savings Component is reasonably limited in duration and amount. The Performance Fee is subject to a maximum annual cap and the term of the Arrangement is limited to three years.

Fourth, receipt of any part of the Performance Fee under the Arrangement is conditioned upon the Group's physicians not taking any of the following actions: 1) stinting on care provided to Requestor's patients; 2) increasing referrals to Requestor; 3) cherry-picking healthy patients or those with desirable insurance for treatment in the Labs; or 4) accelerating patient discharges. While we believe such a contract provision alone would not sufficiently reduce the risk of harm to patients or Federal health care programs, in combination with other features of the Arrangement, it provides an additional safeguard on which we rely.

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endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Arrangement.

For all of these reasons, in an exercise of our discretion, we choose not to impose sanctions under the CMP as a result of the Arrangement.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense to knowingly and willfully 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. See, e.g., United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); 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), potentially applies 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 does not fit in the safe harbor because the aggregate payment to the Group is not set in advance. However, the absence

of safe harbor protection is not fatal. Instead, we evaluate the facts and circumstances specific to the Arrangement.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Arrangement could be used to disguise remuneration from Requestor to reward or induce referrals by the Group. Specifically, the Arrangement could encourage the physicians to admit Federal health care program patients to Requestor, because the physicians receive not only their Medicare Part B professional fee, but also may receive the Fixed Fee and the Performance Fee. While we believe the Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, for the following reasons we will not impose sanctions in the particular circumstances presented here and as qualified below.

First, Requestor certified that the compensation paid to the Group under the Management Agreement, which includes both the Fixed Fee and the Performance Fee, is fair market value for the services provided.[23] These services include overseeing Lab operations; providing strategic planning and medical direction services; developing Requestor's cardiology program; serving on medical staff committees; providing staff development and training; providing credentialing for Lab personnel; recommending Lab equipment, medical devices, and supplies; consulting with Requestor regarding information systems; providing assistance with financial and payor issues; and providing public relations services. The fact that the Group provides substantial services under the Management Agreement reduces the risk that compensation paid by Requestor is a payment for referrals, rather than for actual services rendered.

Second, the compensation paid to the Group does not vary with the number of patients treated. Thus, an increase in patient referrals to Requestor does not result in an increase in compensation paid to the Group under the Arrangement.[24]

Third, because Requestor operates the only cardiac catheterization laboratories within a fifty-mile radius, and because the Group does not provide cardiac catheterization services

[23] We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See Section 1128D(b)(3)(A) of the Act. If the fees are not fair market value, this opinion is without force and effect.

[24] We note that the Group distributes dividends *pro rata,* based on percentage ownership in the Group. We have no facts indicating that the Group allocates ownership interests or other compensation based on an individual physician owner's participation or performance under the Arrangement. We might have reached a different conclusion had this been the case.

at any location other than Requestor's Labs, it is unlikely that Requestor offered compensation to the Group under the Arrangement as an incentive for the Group's physicians to refer business to the Labs instead of to a competing cardiac catheterization lab.

Fourth, the specificity of the measures within the Arrangement helps ensure that its purpose is to improve quality, rather than reward referrals. The Arrangement specifically defines the Quality Component and bases the included measures on nationally recognized standards. The Arrangement sets out particular actions that generate the quality improvements on which the payments are based. The measures contained in the Quality and Cost Savings Components represent specific changes in cardiac catheterization laboratory procedures, which the Group's physicians are responsible for implementing. Additionally, the lowest, baseline achievement level for any measure reflects improvement over Requestor's *status quo* performance for that measure prior to the effective date of the Agreement.

Fifth, the Management Agreement is a written agreement with a three-year term, and thus is limited in duration.[25]

In light of these circumstances and safeguards, the Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.[26]

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Arrangement could constitute an improper payment to induce the reduction or limitation of services pursuant to sections 1128A(b)(1) –(2) of the Act, the OIG will not impose sanctions on [name redacted] in connection with the Arrangement; and (ii) although the Arrangement could potentially

[25] We note that the Arrangement contains an automatic renewal provision, unless terminated; however, this advisory opinion applies only to the current three-year term. We express no opinion with respect to future extensions of the Arrangement. We would expect that quality improvement and cost saving measures under the Arrangement would be subject to adjustment over time, to avoid payment for improvements achieved in prior years and to provide incentives for additional improvements in the future. Continuing compensation for conduct that has come to represent the accepted standard of care could, depending on the circumstances, implicate the anti-kickback statute.

[26] We express no opinion with regard to any future changes in the Arrangement (particularly changes to the Quality or the Cost Savings Components) that diverge from those to which Requestor certified.

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, the OIG will not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

IV. LIMITATIONS

- The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor 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 by a person or entity other than [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

- 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 (or that provision's application to the Medicaid program at section 1903(s) 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 which 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 [name 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 [name redacted] with respect to any action that is part of the Arrangement 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,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General