[*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: May 14, 2009

Posted: May 21, 2009

[Name and address redacted]

Re: OIG Advisory Opinion No. 09-05

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposal to compensate physicians for on-call services performed on behalf of your hospital's uninsured patients (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (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 while the Proposed 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 Office of Inspector General ("OIG") would 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 Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter 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" or the "Hospital") is a non-profit, 400-bed general hospital located in [city and state redacted]. The Hospital is the sole provider of acute care, inpatient hospital services in [county and state redacted]. The Hospital serves a broader five county area with a combined population of 526,479. There are nine hospitals in the adjoining four counties, one of which is a twenty-five bed critical access hospital located 18.5 miles from the Hospital.

[State redacted] participates in a Federal matching-funds program known as [state program redacted]. [State program redacted] is the [state agency redacted] mechanism for meeting the Federal requirement to provide additional payments to hospitals that provide a disproportionate share of uncompensated services to the indigent and uninsured. While most [state redacted] hospitals receive some form of [state program redacted] reimbursement for providing services to the indigent and uninsured, [state redacted] physicians do not have a similar mechanism for compensating them for such services. As a result, physicians generally render services to this indigent population without compensation.

The Hospital's Emergency Department On-Call Coverage Policy

Under the Hospital's current By-laws, all members of its active medical staff provide on-call coverage for its Emergency Department and care for patients referred to them while they are providing Emergency Department coverage.[1]

Currently, the Hospital has no arrangements to compensate its physicians for on-call services they render to Emergency Department patients who are indigent and uninsured. The Hospital reports that most physicians dislike the duty of performing on-call coverage

[1] The Hospital's Medical Staff By-laws are approved by the medical staff and the Hospital's Board of Directors. There are 149 active members of the medical staff at the Hospital.

for its Emergency Department because telephone calls requesting the physician to respond to the Emergency Department come at all hours, disrupting their professional and personal lives. In addition, the on-call obligation creates additional medical liability for care rendered to persons with whom there is often no previously established patient-physician relationship, increasing the risk of claims of medical malpractice. The Hospital also reports that its [specialty practice group redacted] has reduced its weeks of Emergency Department coverage to the minimum required under the Hospital's policy, citing no payment for on-call services. As a result of these trends, there are weeks each month when the Hospital does not have needed specialists on-call, and the Hospital is forced to outsource emergency care pursuant to transfer agreements and protocols with other hospitals. In sum, the Hospital states that, whereas its physicians historically performed on-call coverage out of a sense of duty to their profession, that sentiment is no longer shared by all; rather, the physicians commonly view on-call coverage as an unwanted obligation, jeopardizing the Hospital's ability to serve patients.

Under the Proposed Arrangement, the Hospital's By-laws will be amended to reflect a new on-call coverage policy: the [Hospital's program name redacted], which will allow participating physicians to submit claims to Requestor for payment for services rendered to certain indigent and uninsured patients presenting to the Hospital's Emergency Department.

Patients Covered by the Proposed Arrangement

Patients presenting to the Hospital's Emergency Department will be covered by the Proposed Arrangement if they are deemed "Eligible Patients." In order to qualify as an Eligible Patient, an individual must have no sponsoring insurance plan,[2] and must eventually qualify for [state program redacted] as determined independently by [state agency redacted] and verified by the Hospital's Patient Accounting Department.

Physician Eligibility for the Proposed Arrangement

Physicians must meet the following conditions to be eligible to participate in the Proposed Arrangement.[3] First, the physician must be an active member of the Hospital's medical staff.

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[2] A sponsoring insurance plan includes Medicare, Medicaid, Workers Compensation, any private commercial insurance, a hospice program, and/or motor vehicle accident or a home owner's insurance policy (when an event occurs applicable to that policy coverage).

[3] Physicians providing hospital-based services to the Hospital (~~e.g.,~~ adult hospitalists, pediatric hospitalists, anesthesiologists, radiologists, Emergency Department physicians, and pathologists) are ineligible to participate in the Proposed Arrangement.

Second, the physician must sign a letter of agreement with the Hospital that provides, among other things, that the physician agrees to participate in the Proposed Arrangement and follow its policies. This includes an agreement to respond timely (within 30 minutes) to a request from the Hospital's Emergency Department when consulted, to evaluate the patient in person, and to provide such additional evaluation and care as are clinically deemed appropriate by the physician with input from the patient's family or guardian as available. Further, the letter of agreement binds the physician to follow the Proposed Arrangement's claim request process.

Third, the physician must provide on-call coverage at the Hospital's Emergency Department as part of the organized on-call schedule for the physician's Medical Staff Department or specialty. In departments with four or more active medical staff members, each physician is required to provide at least one week of Emergency Department on-call coverage within that specialty on a rotating basis, i.e., until every physician has been on-call, at which point the rotation schedule repeats. In departments with less than four active medical staff members, the departments prepare their own call schedule such that each physician is required to provide not more than one week of Emergency Department on-call coverage per month. Any member of the medical staff may request additional days or weeks of coverage.

Physician Compensation under the Proposed Arrangement

Under the Proposed Arrangement, after a physician has completed his or her provision of care for an Eligible Patient, the physician will submit a completed claim request form to the Hospital's Patient Financial Services office. Physicians who are not on-call and who do not respond on-site to the Emergency Department to initiate and render care are not eligible to submit a claim request for services rendered to an otherwise Eligible Patient under the Proposed Arrangement. Physicians receiving compensation under the Proposed Arrangement agree to waive all billing or collection rights, or claims against any third party payer or the Eligible Patient for services rendered.

Claims must include the date of service, description of service, dollar amount, patient's full name, and patient's social security number. The Hospital's Patient Accounting Department will review each claim to determine whether [state program redacted] has deemed the patient care rendered eligible for reimbursement. Eligible claims will be processed for payment. If the Hospital determines that another payer source, including Medicaid, is available to the patient for the billed service, the Hospital will return the claim request form to the physician's office so that the physician may pursue the alternative payer source. If a claim is still pending action on approval of Medicaid

coverage,[4] a payment will not be made until Requestor receives a determination of coverage from the [state agency redacted]. If the patient is subsequently approved for Medicaid coverage for the service, the Hospital will not make a payment and will return the claim to the physician as described above.

Under the Proposed Arrangement, physicians will be compensated according to the following plan:

> Emergency consultations on an Eligible Patient presenting[5]: $100 flat fee.
>
> Care of Eligible Patients admitted as inpatients from the Emergency Department (the admission to physician's service must be while physician is on-call for Requestor's Emergency Department, and includes inpatient care and management, history and physical, daily rounds, discharge summary, etc.): $300 per admission.
>
> Surgical procedure or procedures performed on an Eligible Patient admitted from the Emergency Department: $350 flat fee for the primary surgeon of record.
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> Endoscopy procedure or procedures performed on an Eligible Patient admitted from the Emergency Department: $150 flat fee for the physician performing the endoscopic procedure.

The Hospital has certified that payments made under the Proposed Arrangement will be made solely on the basis of services actually needed and provided, and without regard to referrals or any other business generated between the Hospital and the physicians. It has further certified that the payment amounts are within the range of fair market value for services rendered.

The Hospital calculated the compensation amounts set forth above by using a valuation methodology that took into account the following factors: patient acuity levels for Emergency Department patients; a blended fee incorporating fees across public, private, and self payers; an overall average length of stay based on actual average lengths of stay for public, private, and self payers; payer mix; and physicians' likely time commitment for the service.

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[4] All patients applying for [state program redacted] must also file a Medicaid application and be denied Medicaid coverage before [state program redacted] will approve the claim for coverage under [state program redacted].

[5] The consultation must be in person, face-to-face in the Emergency Department.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952 (d), is potentially applicable to the Proposed Arrangement. The personal services and management contracts safe harbor provides protection for personal services contracts if all of the following seven standards are met: (i) the agreement is set out in writing and signed by the parties; (ii) the agreement covers and specifies all of the services to be provided; (iii) if the services are to be performed on a periodic, sporadic, or part-time basis, the agreement exactly specifies the schedule, length, and charge for the performance intervals; (iv) the agreement is for not less than one year; (v) the aggregate

amount of compensation is set in advance, is consistent with fair market value in armslength transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made by Medicare, Medicaid, or other Federal health care programs; (vi) the services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law; and (vii) the aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

B. Analysis

1. On-Call Coverage Issues

We are aware that hospitals increasingly are compensating physicians for on-call coverage for hospital emergency rooms. We are mindful that legitimate reasons exist for such arrangements in many circumstances, including: compliance with EMTALA obligations; scarcity of certain physicians within a hospital's service area; or access to sufficient and proximate trauma services for local patients. Simply put, depending on market conditions, it may be difficult for hospitals to sustain necessary on-call physician services without providing compensation for on-call coverage.

Notwithstanding the legitimate reasons for such arrangements, on-call coverage compensation potentially creates considerable risk that physicians may demand such compensation as a condition of doing business at a hospital, even when neither the services provided nor any external market factor (e.g., a physician shortage) support such compensation. Similarly, payments by hospitals for on-call coverage could be misused to entice physicians to join or remain on the hospital's staff or to generate additional business for the hospital.

As noted in our Supplemental Compliance Program Guidance for Hospitals:

> The general rule of thumb is that any remuneration flowing between hospitals and physicians should be at fair market value for actual and necessary items furnished or services rendered based upon an arm's-length transaction and should not take into account, directly or indirectly, the value or volume of any past or future referrals or other business generated between the parties.

70 Fed. Reg. 4858, 4866 (Jan. 31, 2005). Thus, with respect to compensation for on-call coverage, the key inquiry is whether the compensation is: (i) fair market value in an arm's-length transaction for actual and necessary items or services; and (ii) not determined in any manner that takes into account the volume or value of referrals or other

business generated between the parties. We believe it should be possible for parties to structure on-call payment arrangements that are consistent with this standard and therefore pose minimal risk under the statute. See, e.g., OIG Advisory Opinion 07-10 (Sept. 20, 2007). Moreover, in many cases, it should be possible to structure on-call coverage compensation to satisfy the personal services safe harbor at 42 CFR 1001.952 (d).

There is a substantial risk that improperly structured payments for on-call coverage could be used to disguise unlawful remuneration. Covert kickbacks might take the form of payments that exceed fair market value for services rendered or payments for on-call coverage not actually provided. Moreover, depending on the circumstances, problematic compensation structures that might disguise kickback payments could include, by way of example:

(i) "lost opportunity" or similarly designed payments that do not reflect *bona fide* lost income;

(ii) payment structures that compensate physicians when no identifiable services are provided;

(iii) aggregate on-call payments that are disproportionately high compared to the physician's regular medical practice income; or

(iv) payment structures that compensate the on-call physician for professional services for which he or she receives separate reimbursement from insurers or patients, resulting in the physician essentially being paid twice for the same service.

The anti-kickback statute neither compels hospitals to pay for on-call services, nor compels physicians to provide on-call services without compensation. Rather, the statute requires that parties refrain from making unlawful kickback payments in any form. Each on-call coverage arrangement must be evaluated under the anti-kickback statute based on the totality of its facts and circumstances.

2. The Proposed Arrangement

The safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952 (d), is potentially applicable to the Proposed Arrangement. However, this safe harbor requires that the aggregate amount of compensation be set in advance. Because the Hospital's payments to physicians participating in the Proposed Arrangement could vary from month to month, the Proposed Arrangement does not fit squarely within the terms of the safe harbor, and we must analyze it for compliance with the anti-kickback statute by taking into account the totality of facts and circumstances.

For a combination of the following reasons, we believe the Proposed Arrangement presents a low risk of fraud and abuse. First, the Hospital has certified that the payment amounts are within the range of fair market value for services rendered, without regard to referrals or other business generated between the parties.[6] We rely on this certification in issuing this opinion. Several features of the Proposed Arrangement appear to support the certification. Foremost, the Proposed Arrangement only will allow payments for tangible services that physicians render pursuant to their on-call duties, such as surgical or endoscopy procedures. No "lost opportunity" or other amorphous payments will be made under the Proposed Arrangement, and, unlike some on-call arrangements that pay regardless of actual emergency department calls, the Proposed Arrangement only reimburses physicians for time they actually spend providing services in the Emergency Department. In addition, physicians only will be able to seek payment for services rendered to uninsured patients, a limitation that eliminates the risk that a physician could be paid twice for the same service by collecting under the Proposed Arrangement and receiving separate reimbursement from an insurer. This feature of the Proposed Arrangement is protected by rigorous safeguards: patient eligibility will be determined by reference to an objective standard—qualification for [state program redacted] as determined independently by [state agency redacted]—verified by the Hospital's Patient Accounting Department, and fortified by a detailed claims request process that includes a waiver of the physician's billing rights. Furthermore, physicians participating in the Proposed Arrangement will be at risk for furnishing additional services without compensation because their obligation will extend to providing follow-up care in the Hospital for Eligible Patients admitted through the Emergency Department. Finally, the rates that will be paid to physicians participating in the Proposed Arrangement appear to be scrupulously tailored to reflect the value of services actually provided in four distinct categories. These four payment rates reflect the variation in the level of service in the four payment categories, and each payment rate is uniform for all physician specialties. In sum, the payments under the Proposed Arrangement are tailored to cover substantial, quantifiable services, all of which will be furnished to uninsured patients that present to

[6] We are not authorized to opine on whether fair market value shall be, or was, paid or received for any goods, services, or property. See section 1128D(b)(3) of the Act.

the Hospital's Emergency Department. These payments sharply contrast with payments that are less plainly tied to tangible physician responsibilities, and which may represent little more than illicit payments for referrals.

Second, the circumstances giving rise to the Proposed Arrangement suggest that the Hospital has a legitimate rationale for revising its on-call coverage policy. The Hospital reports that there are weeks when it does not have needed specialists on-call, that its [specialty practice group redacted] has reduced its on-call coverage to the minimum allowed under the Hospital's Medical Staff By-laws, citing the lack of compensation for on-call coverage, and that it is having to outsource its Emergency Department obligations. These factors, set against the backdrop of a medical staff that the Hospital describes as disliking on-call coverage because of its disruptive nature, liability issues, and lack of compensation, provide a reasonable basis for the Proposed Arrangement and reduce the risk that it will be used as a way to funnel unlawful remuneration to physicians for referrals.

Third, the Proposed Arrangement includes features that further minimize the risk of fraud and abuse. The Proposed Arrangement will be offered uniformly to all physicians and will impose tangible responsibilities on them. For instance, physicians must respond within 30 minutes to a request from the Hospital's Emergency Department when consulted, evaluate the patient in person, and provide such additional evaluation and care as is clinically appropriate. Moreover, the method of scheduling on-call coverage will be governed by the Hospital's Medical Staff By-laws, will be uniform within each department or specialty, and appears to be an equitable policy that will not be used to selectively reward the highest referrers. In addition, the requirement that on-call physicians' claims for payment include the date of service, description of service, dollar amount, patient's full name, and patient's social security number promotes transparency and accountability, and helps ensure that physicians are only paid for services rendered to Eligible Patients.

Fourth, the Proposed Arrangement appears to be an equitable mechanism for the Hospital to compensate physicians who actually provide care that the Hospital must furnish to be eligible for [state program redacted] funding. In this way, the Proposed Arrangement may stanch additional defections from on-call duties, and forestall additional on-call shortages. This would promote an obvious public benefit in facilitating better emergency on-call and related uncompensated care physician services at the Hospital, the sole provider of acute care, inpatient hospital services in [county and state redacted].

In short, as structured, the Proposed Arrangement appears to contain safeguards sufficient to reduce the risk that the remuneration is intended to generate referrals of Federal health care program business. In light of the totality of facts and circumstances presented, we conclude that we would not subject the Hospital to administrative sanctions under

sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

Finally, we note that nothing in this opinion should be construed to require a hospital or other facility to pay for on-call coverage. To the contrary, on-call coverage compensation should be scrutinized closely to ensure that it is not a vehicle to disguise payments for referrals.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that while the Proposed 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 would 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 Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter 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 in any matter involving an entity or individual that is not a requestor of this opinion.

This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those 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 Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [name redacted] with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General