

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: October 23, 2012

Posted: October 30, 2012

Corrected: March 8, 2013

[Name and address redacted]

Re: OIG Advisory Opinion No. 12-15

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding an existing arrangement under which a hospital pays a *per diem* fee to physicians for providing oncall coverage for the hospital's emergency department (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes 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, 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 Office of Inspector General ("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 tax-exempt, charitable, not-for-profit hospital located in [city redacted], [state redacted] (the "State"). Requestor operates an emergency department ("ED") that is open 24 hours per day, 7 days per week. The Requestor certified that approximately 19% of patients seen in the ED receive uncompensated care provided by Requestor and the remaining 81% are beneficiaries of Federal health care programs, or privately insured by other third-party payors.¹

An independent group of emergency medicine physicians provides basic staffing for the ED. At times, however, the services of specialist physicians are required, and it is necessary to have these physicians on-call. Some specialties, such as obstetrics, have restricted call arrangements, which require the physician to be physically present at Requestor's facility during call hours. Most specialties are subject to unrestricted call, meaning a physician may be off-site as long as he or she can respond, in-person, to a call on Requestor's campus within 30 minutes.

Under the Arrangement, Requestor pays a *per diem* fee to specialist physicians ("Participating Physicians") to provide unrestricted call coverage for the ED. There are

¹The Requestor certified that the percentage of ED patients who receive uncompensated care provided by physicians on Requestor's medical staff is unknown. We believe it is reasonable to assume, however, that the percentage is similar to the percentage of ED patients who receive uncompensated care from Requestor.

²The hospital has separate call arrangements with specialties that provide restricted call. Intensivists, hospitalists, interventional cardiologists, and general surgeons also have separate service arrangements with Requestor. We have not been asked to opine on, nor do we express an opinion about, these ancillary arrangements.

currently 130 Participating Physicians. Requestor offers the opportunity to participate in the Arrangement to all specialists on its staff who are subject to unrestricted call.³ Participating Physicians enter into one-year, written agreements, containing automatic renewal provisions, with Requestor to serve on its ED call coverage panel. Participating Physicians must be available and respond by Requestor's required response times. Participating Physicians who admit ED patients must provide care to the patients during their inpatient stays and must see the patients for follow-up care in their office practices within the timeframe specified by an ED physician. These requirements apply regardless of the patient's insurance status or ability to pay. Participating Physicians must also prepare all medical records timely and participate in medical staff committee appointments.

ED physicians typically request that Participating Physicians provide one or more of the following services while on-call:

- Consultation by telephone;
- Consultation in-person by the Participating Physician at Requestor's facility and performance of any necessary inpatient care; and
- Provision of follow-up care on behalf of the patient with at least one follow-up office visit, provided that the patient arranges an appointment.

In each of these circumstances, the ED physician decides which type of assistance is needed from the Participating Physician to ensure the appropriate level of care for the patient.

Each year, Requestor allocates an aggregate annual payment amount per specialty for oncall coverage payments to Participating Physicians based on: (1) the likely number of days per month the specialty would be called; (2) the likely number of patients a Participating Physician would see per call day; and (3) the likely number of patients requiring inpatient care and post-discharge follow-up care in a Participating Physician's office. This aggregate amount per specialty is divided by 365 days per year to create the per diem fee for on-call coverage paid to Participating Physicians in the particular specialty. Participating Physicians receive a per diem fee for each day of coverage

³The following specialties participate in the Arrangement: cardiology, otolaryngology, gastroenterology, general dentistry, hematology/oncology, nephrology, neurology, neurosurgery, ophthalmology, oral surgery, orthopedics, pediatrics, plastic surgery, pulmonology, thoracic surgery, urology, and vascular surgery.

provided under the Arrangement.⁴ They receive this payment regardless of whether they are contacted by the ED to treat a patient during their periods of coverage. Requestor engaged an independent consultant to evaluate the *per diem* rates and compare them to national survey data. The consultant's analysis incorporated proprietary data concerning payment rates for each specialty. Based on this independent valuation, Requestor certified that the *per diem* rates paid under the Arrangement are, and will be, commercially reasonable and fair market value for the services provided and do not, and will not, take into account in any way the volume or value of referrals or business generated between the parties. Requestor further certified that the *per diem* payments are administered uniformly for all doctors in a given specialty without regard to the individual Participating Physician's referrals to, or other business generated for, Requestor.

Requestor uses a uniform methodology across all specialties participating in the Arrangement to ensure that call is distributed evenly among Participating Physicians. The chief of each specialty department allocates the call schedule for Participating Physicians in his or her specialty in accordance with Requestor's methodology. Requestor's Medical Executive Committee (the "Committee") oversees the equitable assignment of call among Participating Physicians. Requestor certified that every effort is made to divide the 365 days of call per year evenly among Participating Physicians within each specialty.

Requestor monitors performance by Participating Physicians under the Arrangement through medical staff department peer review processes overseen by the Committee. Requestor reviews performance of call obligations on a post hoc basis to ensure that Participating Physicians perform and adhere to the schedule. Specifically, Requestor's Performance Improvement Department tracks Participating Physicians' compliance with response times, completion of medical records, attendance at committee meetings, and participation in peer review and performance improvement activities. Requestor also monitors the Participating Physicians' obligation to provide follow-up care through patient feedback. Requestor certified that it absorbs all costs associated with the Arrangement, and that none accrue to Federal health care programs.⁵

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⁴When an ED patient has a pre-existing relationship with a staff physician in the relevant specialty, that physician is called to treat the patient, even if he or she is not the specialist on-call at the time. The Arrangement does not apply to these situations; no per diem is paid unless the physician is on-call.

⁵Under State law, costs associated with hospital payments for call coverage are not reimbursable. Additionally, Requestor certified that under Section 1814(b) of the Act, Medicare reimburses State hospitals according to the State's Federal waiver rules, which apply in lieu of Medicare reimbursement principles. Requestor certified that it excludes

Requestor certified that it developed the Arrangement in response to shortages it experienced in the neurosurgery and neurology specialties, and because many members of its medical staff no longer wished to take call. According to Requestor, its physicians' concerns regarding taking call included: (i) the overall amount of time devoted to call availability each month; (ii) the disruption to lifestyle required by the need to remain within 30 minutes of Requestor's facility and by multiple trips to the hospital after hours or on weekends; (iii) the provision of uncompensated care for Requestor's uninsured patients; (iv) the requirement for follow-up care in a physician's office, which requires working ED patients into the physician's existing patient schedule; and (v) the adverse effect on physician malpractice premiums because of the requirement that physicians provide malpractice coverage for themselves while providing services during periods oncall. Requestor certified that it implemented the Arrangement to establish a compensated call panel to meet the needs of its ED, to meet the requirements of EMTALA, and to increase physician morale.

II. LEGAL ANALYSIS

A. Law

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.

all payments under the Arrangement from Requestor's Health Services Cost Review Commission Annual Cost Report, which it submits to the State.

⁶Under the Emergency Medical Treatment and Labor Act ("EMTALA") hospitals are required to provide an appropriate medical screening examination to individuals who come to an emergency department for examination or treatment for a medical condition. See, section 1867 of the Act. If an individual has an emergency medical condition, the hospital must provide either stabilizing treatment or an appropriate transfer. See id. As a condition of participation in Medicare, hospitals must provide a list of physicians who are on-call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition. See, section 1866(a)(1)(I)(iii) of the Act.

The statute has been interpreted to cover any arrangement where <u>one</u> purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. <u>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); <u>United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985), 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.</u></u>

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 this Arrangement. This 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 at least one year; (v) the aggregate amount of compensation is set in advance, is consistent with fair market value in arm's-length 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 scarcity of certain physicians within a hospital's service area, and 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.

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 fair market value in an arm's-length transaction for actual and necessary items or services, and 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 is possible for parties to structure on-call payment arrangements that are consistent with this standard and, therefore, pose minimal risk under the anti-kickback statute. See, e.g., OIG Advisory Opinion 07-10 (Sept. 20, 2007) and 09-05 (May 14, 2009). Moreover, in some cases, it may be possible to structure on-call coverage compensation to satisfy the personal services safe harbor at 42 C.F.R. § 1001.952(d).

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 in cases where 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.

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. Problematic compensation structures that might disguise kickbacks 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 Arrangement

The safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), potentially applies to the Arrangement. However, this safe harbor requires that the aggregate amount of compensation to the recipient to be set in advance. Although Requestor's allocation of funds to each specialty department for on-call coverage is subject to an aggregate annual cap, Requestor's monthly payments to individual Participating Physicians could vary. In addition, the safe harbor requires that, if the services are to be provided on a periodic, sporadic, or part-time basis, the agreement between the principal and the agent specifies the schedule exactly, which is not the case here. The Arrangement, therefore, does not fit squarely within the terms of the safe harbor, and we must analyze the totality of facts and circumstances to determine if the Arrangement presents minimal risk of fraud and abuse.

For a combination of the following reasons, we believe the Arrangement presents a low risk of fraud and abuse.

<u>First</u>, Requestor certified that, based on an independent valuation, the *per diem* payment amounts are commercially reasonable, within the range of fair market value for actual and necessary services provided without regard to referrals or other business generated

between the parties. We rely on this certification in issuing this opinion. We note that several features of the Arrangement appear to support the certification. The *per diem* rate paid to Participating Physicians appears tailored to reflect the burden on a Participating Physician and the likelihood that a Participating Physician in a particular specialty will actually be required to respond while on-call, as well as the likelihood that he or she will have to provide uncompensated treatment, and the likely extent of that treatment. The *per diem* payments under the Arrangement also are tailored to cover substantial, quantifiable services, a portion of which are furnished to uninsured patients in the ED and afterwards.

<u>Second</u>, Requestor allocates funds for call coverage for each participating specialty and calculates the *per diem* annually, in advance, based on the methodology described herein. It uniformly administers the *per diem* payments for all Participating Physicians in a given specialty without regard to the individual Participating Physician's referrals to, or other business generated for, Requestor. These factors mitigate the risk that the payments are determined in a manner to selectively reward high-volume referrers or incentivize low-volume referrers to generate business for the Requestor.

Third, Participating Physicians provide actual and necessary services, for which they are not otherwise compensated. For instance, Participating Physicians must respond within 30 minutes to a request from the Requestor's ED and, in some cases, must provide follow-up care. A Participating Physician's obligation to provide care to any patient seen while on-call begins in the ED. In the event that the patient is admitted, the Participating Physician's obligation to provide inpatient care continues through the patient's discharge and, when applicable, an initial follow-up visit. Throughout this time, the Participating Physician remains at risk for furnishing additional services for no additional payment. In addition, the requirement that Participating Physicians document their services in patient records promotes transparency and accountability.

We recognize that in some cases a Participating Physician could collect the *per diem* payment under the Arrangement, and receive separate reimbursement from the patient or an insurer. However, the Arrangement is not intended to compensate the Participating Physicians for all care they provide to ED patients. Given the percentage of uncompensated care provided to ED patients by Requestor, it is apparent that the Arrangement requires Participating Physicians to provide a significant amount of care for which they receive no compensation, other than the *per diem* payment.

⁷We are not authorized to opine on whether fair market value shall be, or was, paid or received for any goods, services, or property. <u>See</u> section 1128D(b)(3) of the Act. Therefore, we do not express an opinion about whether the *per diem* fee is fair market value. If the fee is not fair market value, this opinion is without force and effect.

<u>Fourth</u>, Requestor offers the opportunity to participate in the Arrangement to all specialists on its staff who are required by its bylaws to take unrestricted call. Moreover, the method of scheduling on-call coverage is governed by Requestor's bylaws, is uniform within each specialty, and appears to be an equitable policy that is not used to selectively reward the highest referrers.

<u>Fifth</u>, the Arrangement is structured so that Requestor absorbs all costs and none accrue to Federal health care programs.

In short, as structured, the 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 Requestor 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 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, 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.

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