



[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: September 20, 2007

Posted: September 27, 2007

[Name and address redacted]

Re: OIG Advisory Opinion No. 07-10

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding the physicians' on-call coverage and uncompensated care arrangement employed by a medical center (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 supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

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

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that while 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 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] (the “Medical Center”) is a tax-exempt, not-for-profit medical center located in [location redacted], with a charitable mission to help the poor and less fortunate. As required by state law, the Medical Center operates an emergency department (the “ED”) that always remains open and accepts all people regardless of their ability to pay. Nearly one in four patients visiting the ED has no form of health insurance, whether private or governmental. Underinsured and uninsured patients often present through the ED and move on to follow-up care as Medical Center inpatients. Approximately one in ten of the uninsured patients who present at the ED is subsequently admitted to the Medical Center for further care.

According to the Medical Center, prior to the Arrangement, the growing financial burdens of uncompensated patient care and malpractice insurance costs, as well other factors, had depleted the local supply of various types of physicians providing ED on-call coverage and uncompensated inpatient follow-up care for patients that initially presented at the ED. Physicians in some specialties, in fact, proved altogether unwilling to provide ED on-call services without compensation. The lack of available physicians constrained the Medical Center’s ability to meet community needs. The Medical Center consequently had to transfer ED patients to other medical facilities both for emergency treatment and necessary inpatient care that might have been handled more conveniently and efficiently at the Medical Center. Given the special role of the ED in caring for the underinsured and uninsured, the shortage of available physicians hindered the Medical Center in fulfilling its charitable mission.

As a result, the Medical Center formed an *ad hoc* committee comprised of Board Members, as well as leading staff and administration. The committee studied the problem of physician unwillingness to take calls to the ED, to provide inpatient care to patients admitted through the ED, and to provide inpatient consultative services for uninsured patients while on-call. Under the Arrangement, developed along the lines of the committee’s recommendations, physicians on the Medical Center’s staff in certain medical specialties provide ED on-call coverage, respond to patient emergencies in the

ED, and provide inpatient care for uninsured patients.¹ All the physicians on the Medical Center staff within the relevant specialties are offered the opportunity to contract for two-year terms under the Arrangement. The basic obligations under the Arrangement include the following:

- 1) Participation in Call Rotation -- At the beginning of each month the medical staff department or division head for each relevant specialty establishes a call rotation schedule for his or her specialty. Physicians within each specialty who participate in the Arrangement divide the monthly call obligation as equally as possible.
- 2) Inpatient Care and Consultative Services -- Physicians are obligated to provide inpatient care to any patient seen at the ED while on-call, if the patient is admitted to the Medical Center. This obligation applies regardless of the patient's ability to pay for the care delivered and continues until the patient is properly discharged.
- 3) Timely Response to Calls -- Physicians are required to respond to calls from the ED in a reasonable time. The Medical Center monitors response times to ensure that the Arrangement does not lengthen the Medical Center's historically short response times. All participating physicians must adjust their work schedules and lifestyles accordingly.
- 4) Cooperation with Care Management/Risk Management and Quality Initiatives -- Physicians are required to collaborate with the Medical Center's Care Management Staff and participate in the initiatives of the Medical Center's Risk Management and Performance Improvement Committees on issues including discharge planning, utilization issues, and review of observation patients.
- 5) Medical Record Completion -- Physicians are required to document their services in timely medical records for all patients seen under the Arrangement.

Different quality of care criteria are monitored under the program. The Arrangement calls on the Medical Center to take specific measures to ensure that different aspects of performance do not deteriorate under the Arrangement. Physicians who fail to adhere to requirements or refuse to cooperate with the oversight and planning of the Medical Center's Care Management, Risk Management, and Performance Improvement Committees have their payments under the Arrangement suspended until they

¹Specialties included in the Arrangement are Pulmonary, Cardiology, Hospitalists, Gastroenterology, Infectious Disease, Renal/Nephrology, Neurology, Endocrinology, Hematology/Oncology, General Surgery, OB/GYN, Neurosurgery, Orthopedics, Urology, Anesthesiology, Ophthalmology, Oral/Maxillofacial Surgery and Otolaryngology.

demonstrate compliance. Continuation of noncompliance will result in termination of the physician's involvement with the Arrangement. Physicians participating in the Arrangement are paid a *per diem* rate for each day spent on-call at the ED, except for one and one-half days that each physician must contribute *gratis* to the rotation schedule monthly (amounting to eighteen days contributed annually by each). The *per diem* rate varies based on two factors: physician specialty and whether call coverage is on a weekday or a weekend (to reflect the fact that weekend availability places a greater demand on the physician). The difference in *per diem* rates among specialties is based on the following factors:

- 1) Severity of illness typically encountered by that specialty in treating a patient presenting at the ED;
- 2) Likelihood of having to respond when on-call at the ED;
- 3) Likelihood of having to respond to a request for inpatient consultative services for an uninsured patient when on-call; and,
- 4) Degree of inpatient care typically required of the specialty for patients that initially present at the ED.

The Medical Center has certified that the *per diem* rates paid under the Arrangement are, and will be, fair market value for the services provided and are not, and will not, take into account in any way the volume or value of referrals or business generated between the parties. The Medical Center engaged [name redacted] (the "Consultant"), an independent health care industry consultancy, to provide advice on, among other things, the reasonableness of the *per diem* rates paid under the Arrangement. The Consultant's analysis incorporated both publicly available data and proprietary data concerning practices and pay rates at dozens of medical facilities. The Consultant developed benchmarks from the data and then compared the Arrangement to both the data and the benchmarks. The details of the Consultant's analysis, as well as its conclusions that the *per diem* rates meet acceptable industry standards and represent fair market value for the services provided, were set out in an opinion letter, a copy of which was provided to OIG.

The Medical Center has certified that since the Arrangement was instituted, the ED is running much more efficiently. Physician responses to on-call requests have improved dramatically. The ED physicians have indicated to the management of the Medical Center that the cooperation they receive from on-call physicians has improved significantly. Patient survey results indicate that overall satisfaction with the ED has increased as well.

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 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 arms-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: 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 (January 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. 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 rendered² 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.

Each on-call coverage arrangement must be evaluated based on the totality of its facts and circumstances.

²In some circumstances not present here, a physician offering to provide call coverage at below fair market value rates might also implicate the statute, if one purpose of the arrangement is to induce referrals.

2. The Arrangement

The safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), is potentially applicable to the Arrangement. However, this safe harbor requires that the aggregate amount of compensation be set in advance. Because the Hospital's monthly payments to participating physicians can vary from month to month, the 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 Arrangement presents a low risk of fraud and abuse.

First, the Medical Center has certified that the payments are fair market value for actual services needed and provided, without regard to referrals or other business generated between the parties.³ 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 physicians appears tailored to reflect the burden on a physician and the likelihood that a 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. Moreover, the Arrangement places additional demands on the physician beyond the actual time spent on-call. The 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 to the Medical Center, the physician's obligation to provide inpatient care continues until the patient's discharge. Throughout this time, which varies depending on the patient's condition and finances, the physician remains at risk of having to furnish additional services for no additional payment. The physician is also required to provide eighteen days of uncompensated care annually as part of the overall Arrangement. Furthermore, the physician assumes responsibility for medical recordkeeping, and for cooperation with Medical Center care and risk management and performance improvement efforts. In sum, the *per diem* payments under the Arrangement are tailored to cover substantial, quantifiable services, a large portion of which are furnished to uninsured patients in the ED and afterwards. They sharply contrast with payments that are less plainly tied to tangible physician responsibilities, and which may represent little more than illicit payments for referrals.

³We 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. 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.

Additional aspects of the Medical Center’s methodology for establishing the *per diem* amount also lower the risk that the Arrangement is a vehicle to disguise payments for referrals. The *per diem* payments are administered uniformly for all doctors in a given specialty without regard to the individual physician’s referrals to, or other business generated for, the Medical Center. Indeed, the only variable in calculating the *per diem* rate within a specialty is whether the on-call service is performed on a weekday or on the weekend. This appears reasonable because, when on-call, physicians need to make themselves available in short response times. They must adjust their work schedules and lifestyles to accommodate the Arrangement, an accommodation that typically involves a greater imposition over the weekend. The difference in *per diem* rates among specialties is based on the different extent of the uncompensated responsibilities that likely fall on physicians from each specialty under the Arrangement. Factors considered in calculating the rates include the severity of illness that physicians in a given specialty typically encounter when on-call; the likelihood they will need to respond to an ED call; the likelihood they will provide on-call care for an uninsured patient; and the degree of inpatient care they typically provide patients admitted from the ED. An independent third-party valuation of the services provided under the Arrangement concluded that the compensation allotted in the *per diem* payments is within the fair market value range for the services provided.⁴

Second, the circumstances giving rise to the Arrangement suggest that the Medical Center had a legitimate, unmet need for on-call coverage and uncompensated care physician services. Prior to entering into the Arrangement, the ED was understaffed for lack of capable and willing physicians. Prior to the Arrangement, the Medical Center resorted to the outsourcing of emergency care and other related treatment to other medical facilities. These circumstances lower the risk that the Arrangement was instituted as a way to funnel unlawful remuneration to physicians for referrals.

Third, the Arrangement includes features that further minimize the risk of fraud and abuse. The Arrangement is offered uniformly to all physicians in the relevant specialties. Monthly call obligations in each specialty are divided as equally as possible, a practice that suggests that call scheduling is not being used to selectively reward the highest referrers. Physicians must provide inpatient follow-up care to any patient seen on the ED while on-call, if the patient is admitted to the Medical Center. This obligation applies regardless of the patient’s ability to pay for care and lessens the risk that physicians might “cherry-pick” only those emergency room patients that are likely to be lucrative. Moreover, the requirement that the on-call physicians document their services in medical records promotes transparency and accountability.

In short, as structured, the Arrangement appears to contain safeguards sufficient to

⁴We express no opinion about the accuracy of the fair market value assessment contained in the Consultant’s report.

reduce the risk that the remuneration is intended to generate referrals of Federal health care program business. Moreover, the Arrangement promotes an obvious public benefit in facilitating better emergency on-call and related uncompensated care physician services at the Medical Center. Since the institution of the Arrangement, the Medical Center has seen greater efficiency in the ED, improved on-call physician performance, and achieved greater overall patient satisfaction. These advances should, in turn, aid the Medical Center in better fulfillment of its charitable mission. Finally, the Arrangement is structured so that all costs are absorbed by the Medical Center and that none accrue to Federal health care programs. In light of the totality of facts and circumstances presented, we conclude that we would not subject the Health System 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 medical center 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 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 the Medical Center 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 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 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 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 taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if

the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General