



*[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 21, 2007

**Posted:** January 3, 2008

[Name and address redacted]

**Re: OIG Advisory Opinion No. 07-19**

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding whether an arrangement whereby a radiology group practice prepares a written report of its interpretations of radiology tests for a critical access hospital without charge to the hospital (the "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 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] (“Hospital”) 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**

The Hospital is a small, rural, critical access hospital located in [city and state redacted], which offers inpatient and outpatient services, including radiology services.<sup>1</sup> [name redacted] (the “Group”), is a radiology group located in [city and state redacted], which performs radiology services on an exclusive basis on behalf of the Hospital. The Hospital, via teleradiology, transmits digitized images of Hospital patients to the Group for interpretation. The Group interprets the images, prepares a written report documenting the physician’s interpretation, and bills third-party payors, including Medicare, Medicaid and other payors, for professional radiology services rendered by the Group’s physicians. Under the Arrangement, the Group prepares written reports of its interpretations for inclusion within the patient’s medical record maintained by the Hospital, without charge to the Hospital. The Hospital has certified that overall, its exclusive relationship with the Group is and will continue to be at fair market value in an arm’s-length transaction, including the value of the exclusivity (but not including the value attributable to referrals to the Group). We have been asked by the Hospital whether, in these circumstances, the Group’s preparation of the written report for a Hospital patient’s medical record without charge to the Hospital implicates the Federal anti-kickback statute.<sup>2</sup>

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<sup>1</sup> The Hospital certified that its service area is a Federally designated Health Professional Shortage Area (“HPSA”) and Medically Underserved Area (“MUA”).

<sup>2</sup> According to the Hospital, the Group has requested payment of [amount redacted] per written report provided by the Group to the Hospital. We have not been asked to opine on, and express no opinion regarding, this request.

## 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.

### B. Analysis

The Hospital has asked whether the Federal anti-kickback statute is implicated when the Group prepares a written report of its radiology interpretation for inclusion in the patient’s medical record maintained by the Hospital without charge to the Hospital. The concern is whether the Hospital is receiving something of value from the Group (free written reports) in return for referring Federal payor patients to the Group for professional radiology services, pursuant to the Hospital’s exclusive contract with the Group.

Arrangements between traditional hospital-based physicians (such as radiologists) may implicate the anti-kickback statute if the hospital solicits or receives something of value – or the physicians offer or pay something of value – for access to the hospital’s Federal health care program business.<sup>3</sup> While the Arrangement could implicate the Federal anti-kickback

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<sup>3</sup> See e.g., Supplemental Hospital Compliance Program Guidance, 70 Fed. Reg. 4858, 4867 (January 31, 2005).

statute, for the reasons set forth below, we have determined that we would not impose administrative sanctions on the Hospital in connection with the Arrangement.

## **1. Applicable CMS Payment Rules**

We have been advised by CMS that, according to the applicable Medicare payment rule, a Medicare carrier pays for radiology interpretations by a radiologist for patients in a hospital setting only if the radiologist prepares a written report for inclusion in the hospital's medical record.<sup>4</sup> Thus, the preparation of the written report for radiology services furnished to hospital patients is part of the covered professional service that is reimbursed to the radiologist under Medicare Part B, and the radiologist is obligated to prepare a written report for such patients in order to receive Medicare reimbursement.

In addition, under applicable regulations regarding conditions of participation and proper cost reporting for critical access hospitals, the Hospital is obligated to maintain legible, complete, accurately documented, readily accessible, and systematically organized medical records.<sup>5</sup> However, as advised by CMS, the Hospital is not obligated to incur the costs of preparing a written report documenting professional services of radiologists provided to its patients.<sup>6</sup>

## **2. Preparation of the Report on behalf of Medicare Patients**

Based on the Medicare payment rules, we conclude that the Hospital does not receive remuneration from the Group when the Group prepares a written report of its radiology services for a Medicare patient for inclusion within the Hospital's records without charge to the Hospital. The Hospital – a critical access hospital -- is obligated to maintain the written report within its clinical records system, but is not obligated to prepare a written report for the Group's radiology services. The Group's preparation of the written report at its own cost is proper, according to the applicable payment rules. If the Hospital reimbursed the Group for costs incurred for preparing the written report, the Group would receive double payment for the same incurred costs, that is, a payment from the Hospital and a payment from Medicare. Moreover, by preparing a written report for inclusion within the Hospital's records, the Group is not relieving the Hospital of any financial cost the Hospital is otherwise obligated to incur for Medicare patients. Thus, the free reports for Medicare patients do not constitute remuneration to the Hospital.

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<sup>4</sup> See 42 C.F.R. § 415.120(a).

<sup>5</sup> See 42 C.F.R. 485.638(a)(3) and (4)(critical access hospital conditions of participation; clinical records); 42 C.F.R. 413.9(b)(2) (necessary and proper costs related to patient care may be claimed on critical access hospital cost reports).

<sup>6</sup> The facts presented here involve a critical access hospital. Accordingly, we express no opinion regarding similar facts in other provider settings.

### 3. Preparation of the Report on Behalf of Non-Medicare Patients

With respect to preparing free written reports for non-Medicare patients, we are unable to conclude definitively that the Hospital receives no remuneration under the Arrangement, because, absent factual investigation, we cannot be certain how every other payor treats costs incurred in the preparation of written radiology reports for the Hospital's patients. However, for a combination of the following reasons, we conclude that the Arrangement poses a low risk under the anti-kickback statute.

The Hospital has certified that overall its exclusive relationship with the Group is and will continue to be at fair market value in an arm's-length transaction, including the value of the exclusivity (but not including the value attributable to referrals to the Group).<sup>7</sup> As we have observed previously:

Depending on the circumstances, an exclusive contract can have substantial value to the hospital-based physician or group, as well as to the hospital, that may well have nothing to do with the value or volume of business flowing between the hospital and the physicians. By way of example only, an exclusive arrangement may reduce the costs a physician or group would otherwise incur for business development and may eliminate administrative costs otherwise incurred by the hospital. In an appropriate context, an exclusive arrangement that requires a hospital-based physician or physician group to perform *reasonable* administrative or *limited* clinical duties *directly related* to the hospital-based professional services at no or a reduced charge would not violate the anti-kickback statute, provided that the overall arrangement is consistent with fair market value in an arm's-length transaction, taking into account the value attributable to the exclusivity.<sup>8</sup>

In the circumstances presented here, the Group's preparation of such reports without charge appears to be a reasonable and limited service that directly relates to the professional radiology services provided by the Group under its exclusive relationship with the Hospital.

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<sup>7</sup> 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. Therefore, we do not express an opinion about whether the arrangement between the Hospital and the Group is fair market value. If the arrangement is not fair market value, this opinion is without force and effect.

<sup>8</sup> Supplemental Hospital Compliance Program Guidance, 70 Fed. Reg. 4858, 4867 (January 31, 2005) (emphasis in original).

Additionally, the Arrangement is unlikely to result in overutilization of Federally payable services or increased costs to the Federal programs. The Group's ability to generate additional Medicare Part B billings to recoup the costs it incurs for the written reports for non-Medicare beneficiaries provided to the Hospital is limited by the nature of its hospital-based specialty.

Accordingly, based on the totality of facts and circumstances, we conclude that, although the Arrangement may implicate the Federal anti-kickback statute, we would not impose administrative sanctions arising in connection with the anti-kickback statute on the Hospital in connection with the Arrangement.

### **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 Hospital 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