



[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: April 30, 2010

Posted: May 6, 2010

[Name and address redacted]

Re: OIG Advisory Opinion No. 10-04

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposal by several imaging providers to offer free insurance pre-authorization services to patients and physicians (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 [names 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 for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than [names redacted], the requestors 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”), [name redacted] (the “Clinic”), and [name redacted] (the “Physician Corporation”) (collectively, the “Requestors”) are subsidiaries of [name redacted] (the “Parent Company”).¹

The Medical Center is a [State redacted] not-for-profit corporation that owns and operates two community hospitals that include outpatient departments offering diagnostic imaging services. The Medical Center also employs physicians in certain specialties. The Clinic is a [State redacted] not-for-profit organization whose operations include free-standing outpatient diagnostic imaging centers and urgent care centers, and it employs physicians to provide professional services therein. The Physician Corporation is a [State redacted] taxable not-for-profit corporation that employs physicians.

The Medical Center and the Clinic (together, the “Imaging Providers”) offer outpatient diagnostic imaging services, including MRIs, CT scans, and various cardiac and nuclear tests, at hospital-based and free-standing locations.

Requestors certify that some third-party insurers, *i.e.*, commercial insurers, use a practice known as pre-authorization to control over-utilization of diagnostic imaging services.² Such

¹ The Parent Company is also the sole member of two other entities that are not requestors: [name redacted], a philanthropic foundation; and [name redacted], which provides healthcare-related billing services.

² The Centers for Medicare and Medicaid Services (“CMS”) informs us that Medicare generally does not require pre-authorization for imaging services; however, the Proposed Arrangement would include some Medicare and Medicaid patients who have enrolled in health maintenance organizations that require pre-authorization for some or all of the subject diagnostic imaging services.

pre-authorization programs require that the insurer authorize certain imaging services prior to their being provided. Under the Proposed Arrangement, the Imaging Providers would institute a program to obtain any required pre-authorization from insurers for subject diagnostic imaging services provided at the Imaging Providers in the following manner. The Imaging Providers would establish a call center to receive calls from patients and the offices of referring physicians to request pre-authorization services. The call center's services would be free and made available on an equal basis to all patients and referring physicians using the Imaging Providers without regard to any physician's overall volume or value of expected or past referrals. Requestors have certified that no payments would be made to physicians under the Proposed Arrangement, and that they have no explicit or implicit arrangements with any referring physicians in connection with the Proposed Arrangement.

The call center would collect from physician offices and/or patients, and submit to insurers, documentation of medical necessity, and otherwise assist referring physicians and patients in assessing the sufficiency of such documentation. Call center personnel would identify themselves to insurers as representatives of the Imaging Providers and would disclose to insurers the nature of the program. The Imaging Providers would follow any rules, directions or requirements imposed by insurers. Requestors would provide each physician with a copy of all the information the call center submits to insurers to obtain pre-authorization for that physician's patients, and it would make such documentation available to the Secretary of Health and Human Services upon request.

Each insurer may have its own requirements concerning which party, e.g., the referring physician, the imaging provider, or the patient, is responsible for obtaining pre-authorization from the insurer. When the physician is responsible for obtaining pre-authorization, the Proposed Arrangement would relieve the physician of that responsibility in some circumstances discussed in greater detail below. Regardless of which party may be responsible for obtaining pre-authorization, it is the imaging provider that may be refused reimbursement by the insurer.

According to Requestors, physician practices and imaging providers typically contract with a number of different commercial insurers, each of which may have multiple different plans, each of which are governed by separate contracts. A provider typically will have separate contracts with a single commercial insurer for several plans offered by that insurer, the coverage and payment details of which may change from year to year. Requestors add that in their experience most insurer contracts do not include specific language governing the pre-authorization process; rather, they typically incorporate by reference plan documents (such as quality assurance program requirements, provider handbooks, and manuals) that can be changed at the discretion of the insurer.

The Imaging Providers would comply with all state and Federal privacy laws in the conduct of the call center and the pre-authorization services. The Imaging Providers would make no assurances to the physicians or patients regarding whether the insurer would approve any request for pre-authorization.

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 OIG’s position on the provision of free or below-market goods or services to actual or potential referral sources is longstanding and clear: such arrangements are suspect and may violate the anti-kickback statute, depending on the circumstances. For example, in 2005, the OIG issued its Supplemental Compliance Program Guidance for Hospitals, which explained that “[t]he general rule of thumb is that any remuneration flowing between hospitals and physicians should be at fair market value.... Arrangements under which hospitals... provide physicians with items or services for free or less than fair market value... [or] relieve physicians of financial obligations they would otherwise incur... pose significant risk.” 70 F.R. 4858, 4866 (Jan. 31, 2005). In particular, the OIG consistently

has distinguished between a provider that offers free items and services that are integrally related to that provider's services, and those that are not. For instance, we have stated that a laboratory that provides a free computer to a physician, which computer can only be used as part of a particular laboratory service being provided, such as printing out laboratory test results, has no independent value apart from the service that is being provided. See 56 Fed. Reg. 35978 (July 29, 1991) (preamble to the 1991 safe harbor regulations).

Obtaining pre-authorization from insurers is an administrative service with potential independent value to physicians; however, whether that service confers a benefit upon a particular referring physician depends on the facts and circumstances. Where a referring physician's contract with an insurer specifically allocates responsibility for obtaining pre-authorization to the physician, an imaging provider's free pre-authorization service would relieve that physician of having to perform administrative services on which he or she would otherwise have to expend his or her own resources. In cases where a referring physician's contract with an insurer allocates responsibility for obtaining pre-authorization to imaging providers or patients—or does not allocate responsibility to any party—an imaging provider is not relieving an express financial obligation the physician would otherwise be required to incur, but the physician may be receiving remuneration nonetheless (e.g., a physician whose staff is devoting considerable time to pre-authorizations might realize significant savings).

When a party in a position to benefit from referrals provides free administrative services to an existing or potential referral source, there is a risk that at least one purpose of providing the services is to influence referrals. For a combination of the following reasons, we conclude that the Proposed Arrangement presents a low level of such risk, and we will not impose administrative sanctions arising under the anti-kickback statute on Requestors in connection with the Proposed Arrangement.

First, while the Proposed Arrangement could result in some remuneration to physicians who have been expending administrative resources to obtain pre-authorizations for their patients, we believe that in the context of the Proposed Arrangement the risk of fraud and abuse in such situations is low. The Proposed Arrangement would not target any particular referring physicians. In the majority of cases—given the multitude of insurance plans and plan requirements—Requestors are unlikely to know a physician's obligations with respect to an order for a particular patient. Where Requestors may unwittingly relieve some physicians of their pre-authorization obligations, such relief would occur by chance, not design. This fact, together with the fact that the call center would be made available on an equal basis to all patients and physicians, without regard to any physician's overall volume or value of expected or past referrals, significantly lowers the risk that Requestors could use the Proposed Arrangement to reward referrals.

Second, the Proposed Arrangement contains safeguards that further lower the risk of fraud and abuse. Requestors will not make payments to physicians under the Proposed Arrangement, and they have no ancillary agreements with referring physicians that would otherwise reward referrals to the Imaging Providers. Requestors have certified that the Imaging Providers would make no assurances to physicians or patients that use of its call center would result in pre-authorization being approved, and they will collect and provide to insurers only such documentation of medical necessity as they receive from patients and referring physicians. Finally, the Imaging Providers would comply with all state and Federal privacy laws in the conduct of the call center and the pre-authorization services.

Third, the call center handling the pre-authorizations would operate transparently. Personnel would identify themselves to insurers as representatives of the Imaging Providers, disclose to insurers the nature of the program, and would provide each physician with a copy of all the information it submits to insurers to obtain pre-authorization for that physician's patients. The call center staff would have little opportunity to influence referrals because patients would have already selected the Imaging Providers. In this way, the Proposed Arrangement contrasts with arrangements where referral seekers provide referral sources with staff who have a greater ability to influence referrals, for example discharge planners, home care coordinators, or home care liaisons.

Fourth, importantly, Requestors have a legitimate business interest in offering uniform pre-authorization services. Whereas insurers may place responsibility for pre-authorization on imaging providers, referring physicians, or patients, only the Imaging Providers' payments are at stake. The Imaging Providers' financial interest in ensuring that pre-authorization is diligently pursued provides a rationale for the Proposed Arrangement wholly distinct from a scheme to curry favor with referral sources. These circumstances lower the risk that the Proposed Arrangement is a stalking horse for illicit payments to the Imaging Providers' referral sources.

Finally, we emphasize that nothing in this opinion should be read to suggest that imaging providers are required to offer or provide free pre-authorization services to patients or referring physicians.³

³ We note that section 1128A(a)(5) of the Act provides for the imposition of civil monetary penalties against any person who gives something of value to a Medicare or state health care program, including Medicaid, beneficiary that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a state health care program, including Medicaid. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs. With respect to any potential inducement to patients who, in the absence of the Proposed

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 [names 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 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 [names redacted], the requestors 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.

Arrangement, might have to obtain pre-authorization on their own, we conclude that because the Proposed Arrangement implicates only a limited number of Federal health care program beneficiaries who are enrolled in managed care plans with pre-authorization requirements, and for the reasons noted above, the Proposed Arrangement would not constitute grounds for administrative sanctions under section 1128A(a)(5).

- 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 the Requestors 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 the Requestors 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