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: August 23, 2012

Posted: August 30, 2012

[Name and address redacted]

Re: OIG Advisory Opinion No. 12-10

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposal by a radiology group to offer free insurance pre-authorization services to physicians and patients (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (the "Act"), or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the Federal anti-kickback statute.

You have certified that all of the information provided in your request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

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

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the

Office of Inspector General ("OIG") would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request 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 physician-owned provider of professional radiology services in [city and State redacted].

Requestor certified that some commercial insurers employ a practice known as pre-authorization to control over-utilization of advanced imaging services.[1] Such pre-authorization programs require that the insurer authorize certain imaging services prior to the patient receiving them. Under the Proposed Arrangement, Requestor would offer to obtain any required pre-authorization from insurers for radiology services it provides in the following manner. Where a patient's insurer requires pre-authorization for a radiology service, Requestor would contact the insurer and provide any required documentation showing medical necessity or any other information relating to the radiology service required by the insurer. Requestor's pre-authorization services would be free and made available on an equal basis to all patients and referring physicians using Requestor's radiology services without regard to any physician's overall volume or value of expected or past referrals. In cases where Requestor's contract with an insurer precludes it from performing the pre-authorization, Requestor would not do so. Requestor certified that no payments would be made to physicians under the Proposed Arrangement and that it has no explicit or implicit arrangements with any referring physician in connection with the Proposed Arrangement. Requestor also certified that it has no ancillary agreements with referring physicians that would reward referrals to Requestor.

[1] The Centers for Medicare & 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.

Requestor would obtain from the referring physicians and/or patients the documentation required by insurers. Requestor's representatives would identify themselves to insurers as representatives of Requestor and would disclose to insurers the nature of the Proposed Arrangement. In submitting documents, Requestor would follow all directions or requirements imposed by insurers. To ensure transparency, Requestor would provide each physician with a copy of all the information it submits to insurers to obtain pre-authorization for that physician's patients, and Requestor would make such documentation available to the Secretary of Health and Human Services upon request.

According to Requestor, although specific requirements vary from plan to plan, most commercial insurers require pre-authorization for certain imaging studies either in their contracts or in utilization guidelines. The party responsible for obtaining pre-authorization may differ from plan to plan, and can include the primary care physician, the referring physician, the patient or the provider of imaging services. Although the party responsible for obtaining pre-authorization may vary, Requestor, as the imaging provider, is the party that may be refused reimbursement by the insurer.

Requestor states that referring physicians and imaging providers usually have contracts with multiple insurers and that each insurer may have multiple plans with unique requirements that could change from year to year. Due to the volume of plans and the frequency with which they might be changed or amended, Requestor states that it would not be possible for it to monitor the various plans' requirements.

Requestor would not make any assurances to physicians or patients regarding whether an insurer would approve any request for pre-authorization handled by Requestor. All patient information would be transferred in a Health Insurance Portability and Accountability Act-compliant manner, and Requestor would comply with all state and Federal privacy laws in the conduct of the Proposed Arrangement.

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.

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. 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); 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 Fed. Reg. 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 free computer provided to a physician by a laboratory would have no independent value to the physician if the computer could be used only, for example, to print out test results produced by the laboratory. In contrast, a free personal computer that the physician could use for a variety of purposes would have independent value and could constitute an illegal inducement. 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 that physician, an imaging provider's free pre-authorization service would relieve that physician of having to perform administrative duties for which he or she otherwise would be responsible. 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 would

not be 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 would not impose administrative sanctions arising under the anti-kickback statute on Requestor 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—Requestor is unlikely to know a physician's obligations with respect to an order for a particular patient. Where Requestor 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 pre-authorization service 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 Requestor could use the Proposed Arrangement to reward referrals.

Second, the Proposed Arrangement contains safeguards that further lower the risk of fraud and abuse. Requestor would not make payments to physicians under the Proposed Arrangement, and it has no ancillary agreements with referring physicians that would otherwise reward referrals to Requestor. Requestor certified that it would make no assurances to physicians or patients that its pre-authorization service would result in pre-authorization being approved. Finally, in addition to these fraud and abuse safeguards, Requestor would comply with all state and Federal privacy laws in the conduct of its pre-authorization services.

Third, the Proposed Arrangement would operate transparently. Requestor's representatives would identify themselves to insurers as representatives of Requestor, 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. Requestor would have little opportunity to influence referrals because patients would already have selected Requestor. In this way, the Proposed Arrangement differs from arrangements where referral seekers provide referral sources

with staff who have a greater ability to influence referrals, such as discharge planners, home care coordinators, or home care liaisons.

Fourth, importantly, Requestor has 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 Requestor's payments are at stake. Requestor's 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.

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.[2]

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

[2] 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 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).

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 Proposed 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 Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [name redacted] with respect to any action that is part of the

Proposed 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