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: December 12, 2012

Posted: December 19, 2012

[Name and address redacted]

Re: OIG Advisory Opinion No. 12-20

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a hospital's proposal to provide free access to an electronic interface to community physicians and physician practices that would allow those physicians and practices to transmit orders for certain services to, and receive the results of those services from, the hospital (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 the Proposed Arrangement would not generate prohibited remuneration under the anti-kickback statute. Accordingly, 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] (the "Requestor") is a hospital operated by a county government and located in a Health Professional Shortage Area in [state name redacted]. Under the Proposed Arrangement, the Requestor would provide free access to an electronic interface (the "Interface")[1] to community physicians and physician practices (the "Physicians"). The Requestor would offer free access to the Interface to all Physicians who request it.[2] The Physicians could use the Interface to transmit to the Requestor orders for laboratory and diagnostic services to be performed by the Requestor and to receive the results of those services.[3] In addition, the Requestor would provide, through a contractor, support services necessary to maintain the Interface, including software updates. The Physicians who chose to participate in the Proposed Arrangement would remain responsible for all aspects (e.g., acquiring, installing, and maintaining) of their own electronic health records system, including all necessary hardware and connectivity services, that would allow them to communicate with the Requestor through the Interface. The Interface would be used by the Requestor to communicate with all Physicians who participate in the Proposed Arrangement. The Requestor certified that the Interface would serve no purpose other than to transmit the orders and results.

[1] The Interface is a form of software technology that allows two separate systems to communicate with each other.

[2] The geographic area of those Physicians who would be eligible to participate in the Proposed Arrangement would be unlimited, but the realities of the services for which the Interface is intended would likely limit participation to those located within reasonably close proximity to the Requestor.

[3] While the Interface would not convey any other data, incorporated within the laboratory and diagnostic services information transmitted via the Interface would be a patient's name, insurance information, and any other information necessary to properly process the laboratory and diagnostic orders and results.

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. 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.

B. Analysis

The anti-kickback statute is not implicated if remuneration is not offered, paid, solicited, or received. Therefore, a threshold question is whether the free access to the Interface and the related support services that the Requestor would provide under the Proposed Arrangement would constitute remuneration to the participating Physicians under the anti-kickback statute. We conclude that they would not.

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 has distinguished between free items and services that are integrally related to the offering provider's or supplier'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. 35952, 35978 (July 29, 1991) (preamble to the 1991 safe harbor regulations).

Under the Proposed Arrangement, the Requestor would provide free access to the Interface to all Physicians who request it. The Requestor would also provide support services necessary to maintain the Interface. Access to the Interface would be used by Physicians only to transmit orders for laboratory and diagnostic services to the Requestor and to receive the results of those services. Under the Proposed Arrangement, Interface access would be integrally related to the Requestor's services, such that the free access would have no independent value to the Physicians apart from the services the Requestor provides. Accordingly, we conclude that the Proposed Arrangement would not, under these particular facts, implicate the anti-kickback statute.

We take this opportunity to note that, under the Proposed Arrangement, access to the Interface would be a contemporary analog to the limited-use computer described in the above example from the 1991 preamble. Our analysis reflects the application of the same underlying principles to the current state of available technology.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement would not generate prohibited remuneration under the anti-kickback statute. Accordingly, 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.

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