



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:** April 1, 2014

**Posted:** April 8, 2014

[Name and address redacted]

### **Re: OIG Advisory Opinion No. 14-03**

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a laboratory's arrangement with an electronic health record services vendor under which the laboratory pays a per-order fee for each test order the vendor transmits to the laboratory (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 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 Arrangement potentially generates prohibited remuneration under the anti-kickback statute and that the Office of Inspector General

(“OIG”) could potentially 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. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties’ intent, which determination is beyond the scope of the advisory opinion process.

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 publicly traded corporation that operates a nationwide network of clinical laboratories. Referrals from office-based physicians comprise a significant portion of Requestor’s clinical laboratory testing. In recent years, the electronic transmission of laboratory test orders and results has become increasingly important. Electronic transmission facilitates the submission of accurate test orders and allows laboratories to efficiently incorporate orders into their information systems and bill for the tests. Referring physicians also benefit from the convenience of electronically transmitted test orders and results. Consequently, clinical laboratories that do not offer such services are at a competitive disadvantage as compared to laboratories that do.

Requestor offers all of its clients, including physicians, access to a free, web-based proprietary electronic orders and results software program, [name redacted] (the “Software”). The Software is a stand-alone product that does not require an electronic health record (“EHR”) system to operate. Requestor’s clients can use the Software to submit electronic test orders<sup>1</sup> in a format that allows Requestor to automatically incorporate the test order information into its laboratory information system (“Laboratory Information System”). The clients may then access the Software to retrieve the laboratory test results; test results accessed through the Software are not automatically incorporated into the patients’ electronic charts.<sup>2</sup> Requestor states that, historically, the great majority of its physician-clients used the Software.

In some instances, Requestor may provide a one-way interface that allows physicians to receive test results through their EHR systems and to have those test results incorporated

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<sup>1</sup> Requestor states that, when a physician collects a specimen in his or her office and orders a laboratory test using the Software, the Software produces a unique bar code that the physician’s office personnel then print out and attach to the specimen.

<sup>2</sup> We have not been asked to opine on, and express no opinion regarding, the Software.

into their patients' electronic charts (a "Results Only Interface"). Physician practices that have a Results Only Interface must order laboratory tests from Requestor either by using the Software, by faxing the order to Requestor, or by completing a paper test requisition and forwarding it to Requestor along with the specimen. Requestor must manually input information from the test orders into its Laboratory Information System when physicians fax the order or complete a paper test requisition. If feasible, Requestor also may provide an interface between physicians' EHR systems and Requestor's Laboratory Information System that permits the physicians to: (i) electronically transmit laboratory test orders in a format that allows Requestor to automatically incorporate the test order information into its Laboratory Information System; and (ii) receive results through their EHR systems, and to have the results incorporated into their patients' electronic charts (a "Bi-Directional Interface").

Requestor certified that, before entering into the Arrangement, Requestor and [name redacted], a vendor of cloud-based EHR services and the requestor of OIG Advisory Opinion 11-18 (the "EHR Provider"), operated under an agreement pursuant to which the parties developed a Results Only Interface.<sup>3</sup> As described above, the Results Only Interface allowed the EHR Provider's physician-customers ("Referring Physicians") to receive test results from Requestor through the EHR Provider's EHR service, and to have those test results incorporated into their patients' electronic charts. Although Referring Physicians could use the EHR Provider's EHR service to generate and transmit an order to Requestor by facsimile,<sup>4</sup> they could not use it to send an electronic order that automatically would be incorporated into Requestor's Laboratory Information System. The EHR Provider did not charge Requestor any fees in connection with the Results Only Interface.

Under the Arrangement, Referring Physicians may now use the EHR Provider's EHR service to generate and transmit orders to, and receive results from, Requestor through a Bi-Directional Interface.<sup>5</sup> Whenever a Referring Physician creates an order for a clinical laboratory test using the EHR Provider's EHR service, Requestor is displayed as an "in-network" laboratory. As an "in-network" laboratory, Requestor pays the EHR Provider a per-order fee ("Per-Order Fee") for each set of tests a Referring Physician orders from

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<sup>3</sup> We have not been asked to opine on, and express no opinion regarding, Requestor's historical arrangement with the EHR Provider.

<sup>4</sup> Requestor believes that the Referring Physicians paid a fee to the EHR Provider to generate and transmit these orders.

<sup>5</sup> Requestor states that the EHR Provider is implementing the Bi-Directional Interface on a rolling basis and that, currently, some Referring Physicians continue to use the EHR Provider's EHR service to generate and transmit orders to Requestor by facsimile.

Requestor using the EHR Provider’s EHR service for a patient during a single encounter. Requestor believes that, under the EHR Provider’s arrangements with Referring Physicians, the EHR Provider charges the Referring Physicians a transmission fee of up to \$1.00 each time they use the EHR Provider’s EHR service to order laboratory tests from a laboratory that is not an “in-network” laboratory.<sup>6</sup> But if a Referring Physician uses the EHR Provider’s EHR service to order tests from an “in-network” laboratory, such as Requestor, the Referring Physician is not assessed a transmission fee. Requestor is assessed the Per-Order Fee only if a Referring Physician sends a laboratory test order to Requestor using the EHR Provider’s EHR service; if a Referring Physician orders a test through another mechanism, such as through the Software or via a paper requisition, Requestor may continue to send the test results to the Referring Physician using the Results Only Interface at no cost.

The Per-Order Fees are not capped, and decrease as the number of test orders the EHR Provider transmits to Requestor increases.<sup>7</sup> Requestor states that it is entitled to receive certain limited additional services under the Arrangement that it did not previously receive under its historical Results Only Interface arrangement with the EHR Provider but that these services are either unnecessary or of minimal value. Requestor further certified that some Referring Physicians expressly stated that they would continue to refer laboratory tests to Requestor, without any reduction in volume, only if Requestor entered into the 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”

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<sup>6</sup> Requestor’s assertion is consistent with the EHR Provider’s certifications in OIG Advisory Opinion 11-18. In OIG Advisory Opinion 11-18, the EHR Provider certified that it would charge “Ordering Health Professionals” (referred to herein as Referring Physicians) a transmission fee of up to \$1.00 (subject to a cap) in cases where the practitioner, provider, or supplier receiving the referral has not entered into a “Trading Partner Agreement” with the EHR Provider.

<sup>7</sup> The Per-Order Fee ranges from \$0.30 (for more than 1 million orders per rolling 12-month period) to \$1.00 (for 10,000 or fewer orders per rolling 12-month period).

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 OIG believes that the efficient exchange of health information between health care providers, practitioners, and suppliers is a laudable goal. However, when the exchange takes place in the context of patient referrals, we must evaluate whether the means used to achieve that goal implicate the anti-kickback statute.

Under the Arrangement, Requestor pays a Per-Order Fee to the EHR Provider for each laboratory test order a Referring Physician refers to Requestor using the EHR Provider's EHR service. Referring Physicians, in turn, do not incur transmission fees when they use the EHR Provider's EHR service to refer to "in-network" providers, practitioners, and suppliers, such as Requestor. The Arrangement implicates the anti-kickback statute because Referring Physicians are relieved of a financial obligation when they refer laboratory test orders to Requestor. We therefore must determine whether, given all of the relevant facts, the Arrangement poses no more than a minimal risk of fraud and abuse under the anti-kickback statute. For the following reasons, we conclude that the Arrangement poses more than a minimal risk of fraud and abuse.

First, we recognize that both patients and physicians may benefit from a provider, practitioner, or supplier's ability to efficiently transmit the patients' health information, including laboratory test results, to the patients' physicians, and to have that information automatically incorporated into the patients' electronic charts. We also acknowledge that a particular provider, practitioner, or supplier's ability to offer such transmission services and records management support is a legitimate consideration when making a referral decision. We note, however, that Referring Physicians received these benefits under Requestor's historical Results Only Interface arrangement with the EHR Provider.

Under the EHR Provider's arrangements with Referring Physicians, the Referring Physicians must pay a transmission fee of up to \$1.00 to use the EHR Provider's EHR service to generate and transmit a laboratory test order unless they refer to an "in-network" laboratory. Under the Arrangement, Requestor, as an in-network laboratory, pays the EHR Provider a Per-Order Fee to receive the Referring Physicians' referrals via the EHR service. Referring Physicians therefore have the option to pay a transmission fee or to avoid paying that same fee, with the determinative factor being the Referring Physicians' choice of laboratory. This fee structure could potentially influence the Referring Physicians' referral decisions in a material way.

Charging a Referring Physician a small, per-referral transmission fee may be unlikely to influence the Referring Physician's referral decisions in a meaningful way when the overall number of referrals to a particular type of provider, practitioner, or supplier (e.g., specialists) is relatively low; however, the risk that such a fee could influence a Referring Physician's decision-making increases as the number of referrals increases, and physicians typically order laboratory tests with considerable frequency. Our conclusion regarding the correlation between the number of referrals and the level of risk is supported by Requestor's representation that some Referring Physicians expressly stated that they would continue referring laboratory tests to it, with no decrease in volume, only if Requestor entered into the Arrangement.

Furthermore, based on Requestor's certifications, there appears to be no reason for it to pay the Per-Order Fees other than to secure referrals. Requestor certified that, historically, the great majority of its physician-customers used the Software to submit electronic test orders. Laboratory test orders that Referring Physicians transmit to Requestor using the EHR Provider's EHR system through the Bi-Directional Interface are incorporated into Requestor's Laboratory Information System in the same manner as laboratory test orders Requestor's physician-clients transmit to Requestor using the Software. The Arrangement therefore does not provide any additional technological benefits to Requestor. Additionally, Requestor certified that, under the Arrangement, it continues to have access to the Results Only Interface at no cost, and the limited additional services to which it is entitled under the Arrangement are of minimal value. The Arrangement therefore appears to permit Requestor to do indirectly what it cannot do directly; that is, to pay compensation to the Referring Physicians, by relieving them of a financial obligation, in return for the Referring Physicians' laboratory test referrals.

Because the Arrangement includes potentially problematic financial incentives, it poses more than a minimal risk of fraud and abuse under the anti-kickback statute.

### **III. CONCLUSION**

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Arrangement potentially generates prohibited

remuneration under the anti-kickback statute and that the OIG could potentially 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. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

#### **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 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 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.

Sincerely,

/Gregory E. Demske/

Gregory E. Demske  
Chief Counsel to the Inspector General