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: March 18, 2015

Posted: March 25, 2015

[Name and address redacted]

Re: OIG Advisory Opinion No. 15-04

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a laboratory's proposal to enter into agreements with physician practices to provide all laboratory services for the practices' patients and waive all fees for those practices' patients who are enrollees of certain insurance plans that require the patients to use a different laboratory (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. We also analyze the Proposed Arrangement to determine whether it would constitute grounds for permissive exclusion under the exclusion authority at section 1128(b)(6)(A) of the Act. 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 could potentially generate 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 Proposed 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. In addition, we conclude that the Proposed Arrangement could constitute grounds for permissive exclusion under the exclusion authority at section 1128(b)(6)(A) of the Act.

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 multi-regional medical laboratory that provides clinical laboratory, anatomic pathology, and forensic pathology services to hospitals, long-term care and assisted living facilities, physicians, businesses, and government agencies. The Requestor operates 45 patient service centers in [states redacted]. Typically, when the Requestor's physician-practice clients order laboratory tests, their patients go to one of these patient service centers where the patient's blood is drawn, or other sample is collected, and then is tested at a laboratory site. The Requestor transmits the results back to the physician practice in the manner the physician requested (hard copy, facsimile, or electronically).[1]

According to the Requestor, some physician practices have expressed a desire to work with a single laboratory for ease of communication and consistency in the reporting of test results. The Requestor notes that, for example, different laboratories use different reference ranges in reporting test results, and each laboratory requires a different interface for transmitting test reports electronically.[2] However, the Requestor certified

[1] The Requestor currently has a small number of physician-practice clients that draw their patients' samples themselves, send the samples to the Requestor for testing, and bill their patients' health plans for the tests. The Requestor would not offer the Proposed Arrangement to these physician practices.

[2] The Requestor currently provides a limited-use interface to physician practices for these electronic transmissions and would continue to do so under the Proposed Arrangement. The Requestor certified that some electronic medical record system

that approximately 70 percent of the Requestor's physician-practice clients have patients who are enrolled in insurance plans that require their enrollees to use a particular laboratory ("Exclusive Plans"), and physician practices have indicated that between 10 percent and 40 percent of their patients are enrollees of Exclusive Plans. If the Requestor is not the Exclusive Plan's designated laboratory, then the Exclusive Plan would not pay the Requestor for any testing performed on the Exclusive Plan's enrollees (even as an out-of-network provider). The Requestor certified that the Exclusive Plans do not include any individuals with Federal health care program coverage as their primary insurance, but some plan enrollees could have Federal health care program coverage as their secondary insurance.

Under the Proposed Arrangement, the Requestor would enter into agreements with physician practices to provide all laboratory services required by the physician practices' patients, regardless of the patients' health plan coverage.[3] If a physician whose practice has an agreement with the Requestor orders a laboratory test from the Requestor for an Exclusive Plan enrollee, the Requestor would not bill the patient, the physician practice, the Exclusive Plan, or any secondary insurer for the test. The Requestor would bill all other patients, whether privately insured or covered by a Federal health care program,[4] in accordance with fee schedules or contracted rates. Under the written agreement between the parties, physicians would be required to represent that neither the physician nor the practice would receive any financial benefit from the Requestor's provision of laboratory services at no charge to Exclusive Plan enrollees, including any financial benefit by virtue of participating in an incentive plan that would pay the physician practice or the physicians a bonus or issue a penalty based upon the physician practice's or physician's utilization of laboratory services. The Requestor certified that it would provide no items, services, or financial benefits, other than the limited-use interface, to physician practices in connection with the Proposed Arrangement.

---

vendors charge physician practices a monthly maintenance fee for the interface, but the Requestor would not pay these fees on behalf of physician practices.

[3] The Requestor stated that physicians may recommend the Requestor to the patient, but, because of state and Federal laws regarding patient choice, physicians may not require that the patient use the Requestor.

[4] The Requestor has a separate program to assist uninsured patients. We have not been asked to opine on, and we express no opinion regarding, this separate program.

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.

Section 1128(b)(6)(A) of the Act permits the Secretary of Health and Human Services (the "Secretary") to exclude any individual or entity that the Secretary determines submitted or caused to be submitted bills or requests for payment to Medicare or a State health care program containing charges for items or services furnished substantially in excess of such individual's or entity's usual charges (or, in applicable cases, substantially in excess of such individual's or entity's costs) for such items or services, unless the Secretary finds there is good cause for such bills or requests containing such charges or costs.

B. Analysis

Under the Proposed Arrangement, the Requestor would provide free services to certain patients to secure all business, including Federal health care program business, from physician practices. The Proposed Arrangement potentially implicates the anti-kickback

statute and the prohibition on charging Medicare or State health care programs substantially in excess of the provider's or supplier's usual charges.

1. Anti-kickback Statute

To implicate the anti-kickback statute, certain factors must be present, including: (a) an item or service for which payment may be made, in whole or in part, by a Federal health care program; (b) a referral or recommendation (or offer or solicitation of a referral or recommendation) for that item or service; and (c) remuneration (or the offer of remuneration) to a potential source of the referral or recommendation (or the solicitation or receipt of remuneration by a potential referral source). Under the Proposed Arrangement, physicians would refer both privately insured patients and Federal health care program beneficiaries to the Requestor for laboratory testing. The Proposed Arrangement clearly involves referrals and federally payable services; the main purpose of the Proposed Arrangement is to secure all of the referrals, including services that would be rendered to Federal health care program beneficiaries, from participating physician practices. Thus, we must analyze whether any remuneration could flow to a source of referrals or recommendations under the Proposed Arrangement.

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. If the physicians or the physician practices would receive remuneration from the Requestor, the anti-kickback statute would be implicated.[5]

The Requestor certified that physicians and physician practices would receive no financial benefit as a result of the Proposed Arrangement, in part because none of the samples would be drawn in physician offices, and thus the physician practices would not bill for the draw or the testing. The Requestor noted that the OIG has acknowledged that a limited-use interface, such as the interface the Requestor already provides to the

[5] We recognize that patients ultimately may choose which laboratory performs their tests and, in that sense, also could be a source of referrals. Further, because some of the Exclusive Plan enrollees could have Federal health care program coverage as their secondary insurance, the Requestor's services are services for which payment may be made by a Federal health care program. However, because a crucial element of the Proposed Arrangement is that no payor would be billed for services performed for Exclusive Plan enrollees, and we have no facts to suggest that the free services would have any tie to other federally payable services that the Requestor would render to Exclusive Plan enrollees, we believe that the remuneration offered to patients presents a low risk of fraud and abuse under the anti-kickback statute.

physician practices, is not itself remuneration.[6] However, although the physicians and physician practices would not receive direct payments under the Proposed Arrangement, the Requestor certified to other facts that we believe, in combination, would amount to remuneration. First, according to the Requestor, physician practices have expressed a preference to work with a single laboratory because of the convenience of receiving all test results with consistent reference ranges and the efficiency gained from maintaining a single interface with a single laboratory. Second, although the interfaces themselves may be free, the Requestor stated that some electronic medical record system vendors charge physician practices a monthly maintenance fee in connection with the interface. The Proposed Arrangement could relieve physician practices of this expense for any interface that the physician practice no longer would maintain. Thus, under the Proposed Arrangement, by declining to charge certain patients, the Requestor would offer physician practices a means to work solely with the Requestor, reducing administrative and possibly financial burdens associated with using multiple laboratories. For these reasons, we cannot rule out with sufficient confidence the possibility that, for particular agreements with physician practices, the Requestor would be offering remuneration to induce the referral of Federal health care program beneficiaries under the Proposed Arrangement. Further, the Requestor has not presented discernable quality or safety improvements that would be gained by reducing these burdens[7] or any other safeguards that would make this remuneration low risk under the anti-kickback statute; in fact, the Requestor's proposed actions could result in inappropriate steering of patients, including Federal health care program beneficiaries.

2. Substantially in Excess

Section 1128(b)(6)(A) of the Act, the "substantially in excess" provision, is a permissive exclusion authority designed to prevent individuals and entities from charging the Medicare and Medicaid programs substantially more than their usual charges to other payors for the same items or services. The OIG has attempted on numerous occasions to provide definitive guidance on this provision. However, we have not finalized definitions for "substantially in excess" or "usual charges." We have clearly stated that

[6] See, e.g., 78 Fed. Reg. 79202, 79210 (Dec. 27, 2013) ("donation of free access to an interface used only to transmit orders for the donor's services to the donor and to receive the results of those services from the donor would be integrally related to the donor's services. As such, the free access would have no independent value to the recipient apart from the services the donor provides and, therefore, would not implicate the anti-kickback statute."). We have not been asked to opine, and express no opinion, on the particular interface provided by the Requestor.

[7] It is also possible that the Exclusive Plans whose enrollees are referred to the Requestor may not have access to, or a record of, important test results for such enrollees.

we would not use this authority to exclude or attempt to exclude any provider or supplier that provides discounts or free services to uninsured or underinsured patients,[8] but this policy statement does not apply to the Proposed Arrangement. Under the Proposed Arrangement, the Requestor would provide free services to patients who are insured and whose services could be covered if they were to use the laboratory designated by their insurance plan.

We have also stated that "a provider need not even worry about section 1128(b)(6)(A), unless it is discounting close to half of its non-Medicare or non-Medicaid business."[9] Under the facts supplied by the Requestor, however, it is possible that some of the agreements into which the Requestor would enter under the Proposed Arrangement could cause the Requestor to provide free services to a large portion of the non-Medicare/Medicaid business referred to it. According to the Requestor, 70 percent of its physician-practice clients have indicated that between 10 percent and 40 percent of their patients are enrollees of Exclusive Plans. With percentages that high, it is plausible that more than half of the non-Medicare or non-Medicaid patients would be receiving free services, while Medicare and Medicaid would be charged at the regular rate. Thus, the Proposed Arrangement would essentially result in a two-tiered pricing structure. A substantial number of patients (all patients insured by Exclusive Plans) would receive services for free, regardless of financial need. The Requestor has provided no reason to offer free services other than to remove an obstacle to the physician practices referring all of their laboratory business to the Requestor.

The substantially in excess provision is not designed to prevent providers and suppliers from negotiating their rates with private plans. However, the Proposed Arrangement is not an example of negotiating discounts with certain private payors that may result in rates slightly less than the rate Medicare pays. Instead, the Proposed Arrangement would completely relieve patients and their Exclusive Plans of any obligation to pay in order to

---

[8] See "Hospital Discounts Offered to Patients Who Cannot Pay Their Hospital Bills," (February 2004), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/2004/FA021904hospitaldiscounts.pdf ("it will continue to be the OIG's enforcement policy that, when calculating their 'usual charges' for purposes of section 1128(b)(6)(A), individuals and entities do not need to consider free or substantially reduced charges to (i) uninsured patients or (ii) underinsured patients who are self-paying patients for the items or services furnished"); see also "Addendum to Hospital Discounts Offered to Patients Who Cannot Pay Their Hospital Bills," (June 2007), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/2007/revised%20addendum%20to%20uninsured%20guidance%20_4_%20_2_%20_2_.pdf.

[9] Letter from Kevin G. McAnaney, Chief, Industry Guidance Branch, dated April 26, 2000, available at http://oig.hhs.gov/fraud/docs/safeharborregulations/lab.htm.

pull through all of the Federal health care program business, which would be charged at the full rate. Without examining the data from every physician practice with which the Requestor would contract, which would be outside the scope of the advisory opinion process, we cannot determine whether the Requestor would violate the substantially in excess provision. However, we have sufficient information to conclude that the Proposed Arrangement poses too high of a risk of violating that provision to grant it prospective immunity under our authorities.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement could potentially generate 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 Proposed 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. In addition, we conclude that the Proposed Arrangement could constitute grounds for permissive exclusion under the exclusion authority at section 1128(b)(6)(A) of the Act.

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 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