



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:** November 28, 2016

**Posted:** December 5, 2016

[Name and address redacted]

**Re: OIG Advisory Opinion No. 16-12**

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a laboratory's proposal to provide services consisting of the labeling of test tubes and specimen collection containers at no cost to dialysis facilities (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 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. 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 letter 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 "Lab") provides laboratory testing services to dialysis patients pursuant to service contracts with dialysis facilities.<sup>1</sup> Under the Proposed Arrangement, the Lab would provide some of the dialysis facilities with services consisting of the labeling of test tubes and specimen collection containers that would be used by such dialysis facilities in sending specimens to the Lab for testing. These services would be performed by personnel located in the Lab's own facilities, and no personnel of the Lab would be stationed in the dialysis facilities.

The Lab would retain sole discretion regarding the selection of which dialysis facilities would be offered the labeling services and, according to the Lab, such selection would be based upon whether offering such services would be necessary to obtain or retain the business of a particular dialysis facility. The Lab would not charge the dialysis facilities for the labeling services, which are currently performed internally by the dialysis facilities' own personnel. The Lab represents that some of its competitors currently offer the services that the Lab would offer under the Proposed Arrangement.

The Proposed Arrangement is factually identical to the proposed arrangement described in a previous advisory opinion the OIG issued to the Lab—OIG Advisory Opinion 08-06. Importantly, however, at the time the OIG issued that opinion, Medicare employed a composite rate reimbursement system for the laboratory testing services at issue. At that time, the Lab provided both composite rate tests, which were included in the composite rate that Medicare paid the dialysis facilities and, therefore, were not separately

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<sup>1</sup> We have not been asked, and express no opinion, about the application of the fraud and abuse laws or regulations to the service contracts between the Lab and the dialysis facilities.

reimbursable, and separately reimbursable laboratory tests that were not covered by the Medicare composite rate.

Since the OIG issued Advisory Opinion 08-06, the Centers for Medicare & Medicaid Services (“CMS”) has implemented a prospective payment system to reimburse facilities for furnishing renal dialysis services to patients with end-stage renal disease (the “ESRD PPS”). See Medicare Program; End-Stage Renal Disease Prospective Payment System, 75 Fed. Reg. 49,029 (Aug. 12, 2010). The ESRD PPS final rule became effective January 1, 2011, and instituted a bundled payment system in place of the previous case-mix adjusted composite payment system and reimbursement methodologies for separately reimbursable outpatient items and services related to end-stage renal disease (“ESRD”).

Under the bundled payment system, all ESRD-related laboratory tests are reimbursed as part of the ESRD PPS bundle. However, CMS recognizes that, while a patient is in an ESRD setting, a physician may order laboratory tests that are unrelated to the patient’s ESRD. Because of this, CMS created a process to allow independent laboratories, hospital-based laboratories, and ESRD facilities to continue to receive separate payment for certain tests ordered in the ESRD facility setting when such tests are furnished for reasons other than for the treatment of ESRD. See 75 Fed. Reg. at 49,054. CMS implemented billing modifiers for such non-ESRD-related laboratory tests. As was the case under the composite rate reimbursement system, CMS makes no separate payment under the ESRD PPS for administrative tasks associated with laboratory tests, such as labeling test tubes or specimen collection containers.

The Lab has asked us to consider whether the Proposed Arrangement, which is otherwise factually identical to the arrangement proposed in OIG Advisory Opinion 08-06, would constitute grounds for the imposition of sanctions if implemented under the ESRD PPS.

## **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.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), is potentially applicable to the Proposed Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the compensation paid for services be consistent with fair market value in an arms-length transaction. See 42 C.F.R. § 1001.952(d)(5). The Proposed Arrangement would not fit in the safe harbor because the dialysis facilities would not pay any compensation to the Lab for the labeling services, despite the fact that the labeling services would have value to the dialysis facilities. The cost of such services would otherwise be borne by the dialysis facilities, because CMS makes no payment to dialysis facilities under the ESRD PPS for administrative tasks associated with laboratory tests, such as labeling of test tubes or specimen collection containers. However, the absence of safe harbor protection is not fatal. Instead, arrangements that do not fit in safe harbors must be evaluated on a case-by-case basis.

## **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. In 1994, the OIG issued a Special Fraud Alert describing certain laboratory practices that implicate the anti-kickback statute. See Special Fraud Alert, "Arrangements for the Provision of

Clinical Lab Services,” 59 Fed. Reg. 65,372, 65,377 (Dec. 19, 1994). The 1994 Special Fraud Alert explained that when a laboratory offers or gives an item or service for free or less than fair market value to a referral source, an inference arises that the item or service is offered to induce the referral of business. Also, with respect to laboratory pricing at dialysis facilities, the 1994 Special Fraud Alert identified suspect “swapping” arrangements, in which a laboratory offers discounts to a dialysis facility for composite rate tests payable out of the facility’s pocket in exchange for referrals of all or most of the dialysis facility’s non-composite rate tests billable by the laboratory directly to Medicare or other Federal health care programs.<sup>2</sup>

Following consultation with CMS, we conclude that the changes to the reimbursement structure for laboratory tests implemented through the ESRD PPS alter neither the concerns we articulated in the 1994 Special Fraud Alert nor our conclusion in OIG Advisory Opinion 08-06 that the Proposed Arrangement poses more than a minimal risk of fraud and abuse. Accordingly, for the reasons set forth below, we once again conclude that the Proposed Arrangement poses more than a minimal risk of fraud and abuse.

The Lab’s provision of services to the selected dialysis facilities at no cost would be a tangible benefit to the dialysis facilities. Dialysis facilities are reimbursed for all ESRD-related laboratory tests as part of the ESRD PPS bundle. As was the case under the previous case-mix adjusted composite payment system, Medicare makes no separate payment for the administrative tasks associated with those tests, such as labeling test tubes and specimen collection containers. Therefore most, if not all, of the services the Lab would provide under the Proposed Arrangement would substitute for services the dialysis facilities otherwise would be required to perform at their own expense.

In these circumstances, an inference arises that the free labeling services would be intended to influence the dialysis facilities’ selection of a laboratory. This inference is consistent with, and supported by, the Lab’s representation that the labeling services would be offered to the dialysis facilities when necessary to retain or obtain their business. By capturing referral streams from the dialysis facilities, the Lab likely would be able to generate substantial revenue, because dialysis patients typically need lifelong laboratory testing services associated with their receipt of dialysis services. While this risk may be lessened in circumstances where laboratories bill for fewer separately reimbursable tests, it remains a concern under the ESRD PPS because CMS continues to permit laboratories to receive separate payment for certain tests ordered in the ESRD

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<sup>2</sup> The safe harbor for discounts does not protect price reductions that are offered to induce the referral of other tests or that are offered to one payor but not offered to Medicare or Medicaid. See 42 C.F.R. § 1001.952(h)(5)(ii)–(iii); 64 Fed. Reg. 63,518, 63,528 (Nov. 19, 1999).

setting when furnished for reasons other than for the treatment of ESRD. Comparable competitor arrangements may similarly run afoul of 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 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. 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 letter 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 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