

[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requester.]

Issued: November 30, 1999

Posted: December 7, 1999

[name and address redacted]

Re: OIG Advisory Opinion No. 99-13

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding certain arrangements for discounted pathology services provided to physicians (the "Proposed Arrangement"). You have asked whether the Proposed Arrangement would result in prohibited remuneration under the anti-kickback statute, section 1128B(b) of the Social Security Act (the "Act") or would constitute grounds for the imposition of sanctions under the anti-kickback statute, section 1128B(b) of the Act, the exclusion authority related to kickbacks, section 1128(b)(7) of the Act, or the civil monetary penalty provision for kickbacks, section 1128A(a)(7) of the Act. In addition, you have asked whether the Proposed Arrangement would constitute grounds for a permissive exclusion for charging Medicare or Medicaid substantially in excess of the usual charges, section 1128(b)(6)(A) of the Act.

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, we conclude that the Proposed Arrangement might constitute prohibited remuneration under the anti-kickback statute if the requisite intent to induce referrals of Federal health care program business were present and might be subject to sanctions arising under sections 1128B(b), 1128(b)(7), and 1128A(a)(7) of the Act, as well as grounds for a permissive exclusion under section 1128(b)(6)(A) of the Act.

This opinion may not be relied on by any person other than the addressee and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. [Company A]

Company A is a State X professional corporation with three shareholders, all of whom are specialists in pathology and are licensed to practice medicine in State X. Company A employs five pathologists and fourteen technicians. It provides pathology services (including clinical and anatomic pathology services)⁽¹⁾ to five hospitals, as well as to the patients of physicians in private practice.

B. Billing Procedures

Company A has several billing methodologies depending upon the payor. For Federal health care program patients, Company A bills its charges to the government payor and bills the patients for any applicable copayments or deductibles.

For non-Federal health care program patients, referring physicians have two payment options. One option is for Company A to bill its charges directly to the applicable third-party payor, and bill the patients for any copayments or deductibles. The alternative is for Company A to bill the physicians for the pathology services and accept that payment as payment in full. The physicians then bill the third-party payors and patients for the

purchased pathology services. This option is commonly referred to as "account billing".

Under its account billing arrangements, Company A has traditionally offered physicians a discount off its usual charges which reflects the cost savings it realizes. Company A generates a single monthly statement to the referring physician who is required to pay on a prompt basis. Company A has represented that an account billing arrangement saves time and expense because: (i) claims are not submitted to a wide range of payors; (ii) Company A need not consider the claims submission criteria of the various payors; and (iii) Company A is not responsible for determining and collecting applicable copayments and deductibles owed by the patients. In addition, Company A realizes a better collection rate under account billing. Most physicians who have an account billing arrangement with Company A refer virtually all of their patients to Company A, whether the patients' specimens are covered under the account billing arrangement or are directly billed to the Federal health care programs.⁽²⁾

C. The Proposed Arrangement

Under the Proposed Arrangement, Company A will offer its account billing customers discounts that are greater than its cost savings, in order to match the prices of its competitors. Some of the discounted charges will be below the actual cost of providing the pathology services. In addition, Company A's profit margin for the non-Federal health care program business under the Proposed Arrangement would be less than the profit margin on the services that it bills directly to Federal health care programs. The discount will not be conditioned upon the physicians sending Company A its Federal health care program business. However, Company A has assumed that the physicians receiving discounts under the Proposed Arrangement will send virtually all of their patients to Company A. If Company A does not match the discounts of its competitors, Company A has represented that it will lose both the account billing business and the Federal health care program business of those clients.

II. LEGAL ANALYSIS

A. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and wilfully to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by Federal health care programs. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce referrals of items or services paid for by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes 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, in cash or in-kind, directly or indirectly, covertly or overtly.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to obtain money for referral of services or to induce further referrals. 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. This Office may also initiate administrative proceedings to exclude persons from Federal health care programs or to impose civil monetary penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.⁽³⁾

1. Special Fraud Alert Relating to Arrangements for the Provision of Clinical Laboratory Services

In 1994, we issued a Special Fraud Alert describing certain laboratory practices that implicated the anti-kickback statute. The Special Fraud Alert set forth our analysis that when a laboratory offers or gives to a referral source anything of value for less than fair market value, an inference may be made that the thing of value is offered to induce the referral of business. Specifically, we gave the example of laboratories waiving charges for laboratory tests to physicians for managed care patients, in order to retain the high-paying non-managed care business. In that example, the free laboratory services for managed care patients could be a kickback between the laboratory

and the physician for the fee-for-service patients.

2. The Discount Exception and Safe Harbor

The anti-kickback statute contains a statutory exception for "a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program." Section 1128B(b)(3)(A) of the Act. This discount exception reflects the intent of Congress to encourage price competition that benefits the Medicare and Medicaid programs. The Department of Health and Human Services has published regulations implementing this discount "safe harbor" exception. See 42 C.F.R. § 1001.952(h).

To determine whether Company A's proposed discount practice implicates the anti-kickback statute, we must determine whether the Proposed Arrangement fits within the discount safe harbor. We conclude that the Proposed Arrangement does not fit within the safe harbor. The statutory exception for discounts, as implemented by the regulatory safe harbor, does not protect price reductions -- like those at issue here -- offered to one payor but not offered to Medicare or Medicaid. See 42 C.F.R. § 1001.952(h)(3)(iii).

Specifically, the preamble to the discount safe harbor illustrated the potential problem with laboratory price reductions:

[W]e are aware of cases where laboratories offer a discount to physicians who then bill the patient, but do not offer the same discount to the Medicare program. In some of these cases, the discount offered to the physician is explicitly conditioned on the physician's referral of all of his or her laboratory business. Such a "discount" does not benefit Medicare, and is therefore inconsistent with the statutory intent for discounts to be reported to the programs with costs and charges reduced appropriately to reflect the discounts. 56 Fed. Reg. 35977 (July 29, 1991).

Such price reductions create a risk that a laboratory may be offering remuneration in the form of discounts on business for which the purchaser pays the laboratory, in exchange for the opportunity to service and bill for higher paying Federal health care program business reimbursed directly by the program to the laboratory. In such circumstances, neither Medicare nor Medicaid benefits from the discount; to the contrary, Medicare and Medicaid may, in effect, subsidize the other payor's discounted rates. Moreover, laboratories may have an incentive to engage in abusive billing practices to recoup losses on the discounted business. Accordingly, the Proposed Arrangement does not fit in the discount safe harbor.

Having concluded that the Proposed Arrangement does not fit in the safe harbor, we must consider whether the discount arrangement between Company A and physicians utilizing account billing under the Proposed Arrangement may involve illegal remuneration to the physicians for their referrals of Federal health care program business not covered by the account billing arrangement and not subject to the discount. We conclude that it may.

The circumstances surrounding the Proposed Arrangement suggest that a nexus may exist between the discount to the physicians for non-Federal health care program business and referrals of Federal health care program business. First, the physicians are in a position to direct a significant amount of Federal health care program business to Company A that is not covered by the account billing component of the Proposed Arrangement. Second, both parties have obvious motives for agreeing to trade business: the physicians have the opportunity to make a larger profit on the non-Federal health care program business, and Company A is able to secure profitable Federal health care program business in a highly competitive market. Third, Company A has represented that it is likely that physicians who have account billing arrangements with Company A will refer Federal health care program business to Company A as a matter of practical convenience.

In evaluating whether an improper nexus exists between a discount and referrals of Federal business in a

particular arrangement, neither the size nor structure of the discount is determinative of an anti-kickback violation. Rather, the appropriate question to ask is whether the discount -- regardless of its size or structure -- is tied or linked directly or indirectly to referrals of other Federal health care program business. Evidence that the discount is not commercially reasonable in the absence of other, non-discounted business is highly probative. In this regard, discounts on account billing business that are particularly suspect include, but are not limited to:

- discounted prices that are below the laboratory's cost,⁽⁴⁾ and
- discounted prices that are lower than the prices that the laboratory offers to a buyer that (i) generates a volume of business for the supplier that is the same or greater than the volume of account billing business generated by the physician, but (ii) does not have any potentially available Federal health care program business.

This is an illustrative, not exhaustive, list of suspect discounts; other arrangements may be equally suspect. Each of the above pricing arrangements independently gives rise to an inference that the laboratory and the physicians may be "swapping" discounts on account billing business in exchange for profitable non-discounted Federal health care program business.

Based on the facts presented here, we are unable to exclude the possibility that Company A may be offering improper discounts under the Proposed Arrangement with the intent to induce referrals of more lucrative Federal health care program business. Nor are we able to exclude the possibility that the physicians may be soliciting improper discounts on business for which they have the opportunity to earn money in exchange for referrals of business for which they have no opportunity, but for which the laboratories can receive additional revenue. Indeed, the Proposed Arrangement poses a significant risk of such improper "swapping" of business, especially in light of Company A's representation that many of its competitors are agreeing to such discounts. These competitor discount arrangements may similarly run afoul of the anti-kickback statute. The risk of improper "swapping" is compounded by the likelihood that physicians will refer Federal health care program business to their account billing laboratory as a matter of practical convenience.

B. Permissive Exclusion for Billing Medicare Substantially in Excess of Usual Charges

Price reductions offered to physicians that are not offered to Medicare or Medicaid raise additional issues under section 1128(b)(6)(A) of the Act, which provides for permissive exclusion from the Federal health care programs of individuals or entities that submit or cause to be submitted bills or requests for payment (based on charges or costs) under Medicare or Medicaid that are substantially in excess of such individual's or entity's usual charges or costs, unless the Secretary finds good cause for such bills or requests. In determining an individual's or entity's "usual" charges, we will look at the amounts charged to non-Federal payors, including physicians. If the charge to Medicare or Medicaid substantially exceeds the amount the laboratory most frequently charges or has contractually agreed to accept from non-Federal payors, the laboratory may be subject to exclusion under section 1128(b)(6)(A) of the Act.

The limited information submitted by Company A is insufficient to make a determination as to whether the Proposed Arrangement may run afoul of section 1128(b)(6)(A).⁽⁵⁾

III. CONCLUSION

Based on the facts certified in the request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement might constitute prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals of Federal health care program business were present, and might be subject to sanctions arising under the anti-kickback statute pursuant to sections 1128(b)(7), 1128A(a)(7), or 1128B(b) of the Act, and the permissive exclusion provision under section 1128(b)(6)(A).

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to Company A, the requester 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 in any matter involving an entity or individual that is not a requester to this opinion.
- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is herein expressed or implied 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.
- 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 that 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 Office of Inspector General reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, rescind, modify, or terminate this opinion.

Sincerely,

/s/

D. McCarty Thornton

Chief Counsel to the Inspector General

1. Throughout this opinion, the term pathology services is synonymous with laboratory services.
2. We express no opinion regarding the legality of their existing account billing arrangement under the anti-kickback statute, permissive exclusion, or any other legal authority.
3. Because both the criminal and administrative sanctions related to the Proposed Arrangement are based on violations of the anti-kickback statute, the analysis for purposes of this advisory opinion is the same for both.
4. In determining whether a discount is below cost, we look, for example, at the total of all costs (including labor, overhead, equipment, etc.) divided by the total number of laboratory tests.
5. We express no opinion regarding the legality of the current account billing arrangement under the permissive exclusion or any other legal authority.