

October 2, 1997

[Name and Address redacted]

Re: Free Services Performed by Clinical Laboratories

Dear [Name redacted]:

This letter is in response to your letter of September 8, 1997, concerning the provision of certain free services. Specifically, your letter requested guidance as to whether the provision of chart review and infection control services for free by clinical laboratories to

nursing homes implicates the Medicare and Medicaid anti-kickback statute, 42 U.S.C. § 1320a-7b(b).

This office has established a procedure for formally responding to requests for advice concerning the anti-kickback statute for a specific arrangement that either is in existence or is one in which the requester in good faith plans to undertake. See 42 C.F.R.

§ 1008.15; 62 Fed. Reg. 7350, 7358. The request for such an opinion must come from a party that is a participant in the arrangement. Since your request does not concern a particular arrangement we cannot provide you with a formal opinion. However, we can make some general observations regarding the practices described.

In general, the anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce the referral of items or services for which payment may be made, in whole or in part, by a Federal health care program. In other words, the statute prohibits payments made purposefully to induce referrals of business payable by a Federal health care program. Violation of the anti-kickback statute is a felony punishable by a maximum fine of \$25,000, imprisonment for up to five years, or both. The Department of Health and Human Services may also exclude persons who violate the anti-kickback statute from the Medicare and Medicaid programs.

The OIG has stated on numerous occasions its view that the provision of free services to an actual or potential referral source can constitute prohibited remuneration under the anti-kickback statute, depending on the circumstances. For example, in a Special Fraud Alert concerning placement by clinical laboratories of phlebotomists in physicians' offices, we observed:

"While the mere placement of a laboratory employee in the physician's office would not necessarily serve as an inducement prohibited by the anti-kickback statute, the statute is implicated when the phlebotomist performs additional tasks that are normally the responsibility of the physician's office staff. These tasks can include taking vital signs or other nursing functions, testing for the physician's office laboratory, or performing clerical services."

Where the phlebotomist performs clerical or medical functions not directly related to the collection or processing of laboratory specimens, a strong inference arises that he or she is providing a benefit in return for the physician's referrals to the laboratory. In such a case, the physician, the phlebotomist, and the laboratory may have exposure under the anti-kickback statute. This analysis applies equally to the placement of phlebotomists in other health care settings, including nursing homes, clinics, and hospitals. 59 Fed. Reg. 242 (December 19, 1994).

Your letter alleges that nursing homes in many areas of the country are asking clinical laboratories to

provide a variety of chart review and infection control services for the nursing homes free of charge. These services include: reviewing doctors' orders and establishing, changing, or discontinuing "standing orders" for certain tests based upon that review; determining whether doctors' orders for laboratory tests have been carried out and recorded, along with the results, in patients' charts; reviewing patients' drug regimens and determining whether there is a need for laboratory monitoring or tests; and providing infection control services, including testing and reporting areas where acceptable limits are exceeded. You have indicated that Federal and/or State law requires nursing homes to perform these services.

The provision of services that the recipient would otherwise be obligated to provide for free or at less than fair market value confers a benefit on the recipient. This benefit may constitute prohibited remuneration under the anti-kickback statute if one purpose of the remuneration is to secure referrals of Federal program business. Under the circumstances described in your letter, a strong inference is that the clinical laboratories are being asked to provide the free chart review and infection control services in exchange for referrals of the nursing homes' laboratory business, including services payable in whole or in part by a Federal program. We would view such arrangements as highly suspect.

Finally, we point out that in addition to potential criminal liability under the anti-kickback statute, there is legal authority that any claim tainted by a kickback arrangement is a "false or fraudulent" claim under the Federal False Claims Act, 31 U.S.C. § 3729. See U.S. ex rel. Pogue v. American Healthcorp, Inc., 914 F. Supp. 1507 (M.D. Tenn. 1996). Parties to such arrangements risk exposure not only to the government but also to qui tam suits by their employees and customer's employees.

If you can provide us with specific details on particular parties involved in the types of activities identified in your letter and the arrangements into which they have entered, we would be interested in investigating them.

Very truly yours,

/s/

Kevin G. McAnaney

Chief, Industry Guidance Branch

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