

August 4, 1997

[Name and Address redacted]

Re: Free Prostate Biopsy Needles

Dear [Name redacted]:

This letter is in response to your letter to D. McCarty Thornton, concerning the provision of free biopsy needles by laboratories. Specifically, your letter requested guidance as to whether the furnishing of prostate biopsy needles by laboratories without charge to urologists, who refer the biopsies to that laboratory for testing, 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 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, or in return for, the referral of items or services for which payment may be made in whole or in part by a Federal health care program. 42 U.S.C. § 1320a-7b(b). In other words, the statute prohibits payments made purposefully in exchange for referrals of business paid for by a Federal health care program. Violation of the anti-kickback statute is a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both. The Department of Health and Human Services may also exclude individuals 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 goods by a seller to an actual or potential referral source may violate the anti-kickback statute depending on the circumstances. In the preamble to the 1991 safe harbor regulations, we stated that giving free goods which have an independent value to a physician may violate the anti-kickback statute. 56 Fed. Reg. 35978 (July 1991). More recently, the OIG Fraud Alert relating to the provision of clinical laboratory services stated:

"whenever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business." 59 Fed. Reg. 65377 (October 1994)

Finally, we note that among the charges settled in the recent \$325 million settlement with SmithKline Beecham Clinical Laboratories, Inc., were allegations that SmithKline provided certain free services and supplies to physicians and other referral sources. Charges alleging the provision of free computer and fax machines were also involved in a case against an Ohio physician. In short, our position on the provision of free goods to a referral source is longstanding and clear--any gift to a referral source that has independent value to such source implicates the anti-kickback statute.

We have recently become aware that some laboratories provide prostate biopsy needles to their physician customers for free. Biopsy needles have a clear independent value to physicians; depending on the type of needle, prices may exceed thirty dollars for a single needle. Further, the cost of these needles may already be included in the practice expense portion of the Medicare payment made to the physician. In these circumstances, an obvious inference is that the biopsy needles are being provided to the physicians by the laboratories in exchange for referrals. Accordingly, we view these arrangements as highly suspect.

With regard to the application of the physician self-referral law, Section 1877 of the Social Security Act, to the conduct in question, the anti-kickback statute and Section 1877 are independent statutory authorities. A physician must comply

with both authorities. In other words, compliance with Section 1877 does not afford protection to conduct that is violative of the anti-kickback statute. Unlike Section 1877 which is a civil non-intent based statute, the anti-kickback statute is a criminal, intent-based statute that requires separate analysis.

We hope this information is helpful.

Very truly yours,

/s/

Kevin G. McAnaney

Chief, Industry Guidance Branch