

[Posted November 10, 1998]

[Issued November 3, 1998]

[Name and address redacted]

Re: Advisory Opinion No. 98-16

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion, in which you ask whether a proposed arrangement under which [Name redacted] would assign an employee pharmacist to work in designated hospital transplant centers for the purpose of providing pharmacy-related products and services (the "Proposed Arrangement") would constitute prohibited remuneration under the anti-kickback statute, section 1128B(b) of the Social Security Act (the "Act"), and, if so, whether the Proposed Arrangement 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.

You have certified that all of the information you provided in your request, including all supplementary information, is true and correct and constitutes a complete description of the material facts regarding the Proposed Arrangement. In issuing this opinion, we have relied solely on the facts and information you presented to us. We have not undertaken any independent investigation of such information.

Based on the facts certified in your request for an advisory opinion, we conclude that the Proposed Arrangement may constitute prohibited remuneration under section 1128B(b) of the Act.

I. FACTUAL BACKGROUND

A. The Requestor

[Name redacted] (the "Pharmacy"), is a mail-order pharmacy, wholly owned by [Name redacted]. The Pharmacy specializes in supplying medications and pharmaceuticals to organ transplant recipients. The Pharmacy offers a number of services, including express medication delivery, medication counseling, and direct insurance billing.

B. Organ Transplantation

Organ transplantation involves the surgical replacement of a failed organ. In order to prevent rejection of the organ, transplant patients require life-long immunosuppressive drug therapy. The drug therapy begins immediately after transplantation and involves a plan of treatment developed by a team of clinicians, including a pharmacist. Federal health care programs provide drug coverage for this immunosuppressive therapy. Medicare provides a maximum of thirty-six months of coverage for immunosuppressive therapy after a transplant (see 42 U.S.C. § 1395x(s)(2)(J)), and state Medicaid programs cover immunosuppressive drug therapy under their outpatient drug benefits (see 42 U.S.C. § 1396d).

Approximately 275 hospitals perform organ transplantation in this country. In order to be eligible for Medicare reimbursement, these hospitals are required to meet conditions of Medicare participation. Relevant to this opinion are the conditions applicable to pharmacy management (42 C.F.R. § 482.25) and discharge planning (42 C.F.R. § 482.43). These regulatory standards require hospitals to provide or furnish qualified personnel and quality pharmaceutical services, either directly or through contractual arrangements, and to have in effect a discharge planning process that applies to all patients.

C. The Proposed Arrangement

Through employee services agreements, the Pharmacy proposes placing a licensed pharmacist in hospital transplant centers (the "Centers") interested in the Pharmacy's services. The Pharmacy would employ the pharmacist and would be

responsible for all employee costs, such as wages, benefits, and taxes. To fill the pharmacist position, the Pharmacy may offer the position to current or former employees or independent contractors of a Center.

The pharmacist's duties would include: working with transplant teams to facilitate the patient's post-transplant care; preparing pharmaceutical care plans; overseeing patient compliance with pharmaceutical care plans after discharge; securing the patient's insurance coverage for pharmaceuticals and services provided by the Pharmacy; and processing prescriptions through the Pharmacy's pharmaceutical distribution center. The pharmacist would also perform all billing and collections for Pharmacy services. These items and services may be paid in whole or in part by a Federal health care program.

The Centers would incur no cost under the Proposed Arrangement, but would be responsible for providing the pharmacists with a work area and access to their patients. The Centers could submit recommendations for the on-site pharmacist position and could rehire any former employee hired and subsequently terminated by the Pharmacy.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by any Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce referrals of items or services for which payment may be made 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, 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 was to obtain money for the 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 and state 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. [\(1\)](#)

The Department of Health and Human Services has published safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would unlikely 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 only afforded to those arrangements that precisely meet all of the conditions set forth in the safe harbor. The regulatory safe harbor potentially applicable to the Proposed Arrangement is the personal services and management contracts safe harbor. See 42 C.F.R. § 1001.952(d). The Proposed Arrangement does not qualify under this safe harbor, however, since there is no compensation paid by the Centers to the Pharmacy, despite the fact that at least some of the services will have value to the Centers, which are obligated to provide them in accordance with the Health Care Financing Administration's ("HCFA") conditions of participation. The personal services safe harbor requires that the compensation paid for services be set at fair market value in arms-length transactions. See 42 C.F.R. § 1001.952(d)(5).

B. Prior Guidance

The OIG has stated on numerous occasions its view that the provision of free goods or services to an actual or potential referral source may violate the anti-kickback statute, depending on the circumstances. For example, in the preamble to the 1991 safe harbor regulations, we stated that giving free goods that have an independent value to a physician may violate the anti-kickback statute. See 56 Fed. Reg. 35978 (July 29, 1991). The OIG has also issued a Special Fraud Alert relating to the provision of free services by a clinical laboratory phlebotomist placed in a physician's office:

"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 not 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. 65372, 65377 (Dec. 19, 1994). This analysis generally applies to the provision of any free or below market rate goods or services to actual or potential referral sources. If the intent of providing free goods or services is to induce or reward referrals of Federal health care program business, the anti-kickback statute would be violated.

C. Analysis of the Proposed Arrangement

Our concern under the anti-kickback statute is whether the Pharmacy would be giving a Center something of value in order to induce referrals of business reimbursed by a Federal health care program. This Office has a longstanding antipathy to arrangements where a party gives an existing or potential referral source valuable services or goods for free or below fair market value. In such cases, an inference arises that one purpose of the arrangement is to induce or reward referrals. The Proposed Arrangement has all the hallmarks of such disfavored arrangements.

First, the provision of a transplant pharmacist to a Center at no cost is a tangible benefit to the Center. Prior to entering into the Proposed Arrangement, a Center will have been providing at least some of the same pharmacy and discharge planning services to its transplant patients, including outpatients; such services are required as conditions of participation for hospitals in the Medicare program. It is likely that some services provided by the Pharmacy's pharmacist will substitute for services currently provided by a Center at its expense and for which it will be receiving indirect reimbursement through its DRG payments. In such circumstances, there would be a financial benefit to the Center.

This conclusion is supported by materials submitted by the Pharmacy. First, an advertisement for a similar arrangement promoted by a pharmacy competitor promises Centers savings in costly staff positions and relief of burdens imposed on existing staff. Second, the contract for the Proposed Arrangement specifically permits: (i) the Centers to submit recommendations for the on-site pharmacist position to the Pharmacy; (ii) the Pharmacy to offer employment to current or former employees or independent contractors of the Center; and (iii) the Centers to rehire any former employee terminated by the Pharmacy. In effect, the Proposed Arrangement offers Centers the opportunity to shift payroll or contractual costs to the Pharmacy.

Second, we infer that one purpose of the free services is to induce referrals. Such inference is appropriate with respect to the Proposed Arrangement for the following reasons:

- The services will be offered to a party that is in a position to influence substantially the initial recommendation of a pharmacy to patients.
- Transplant patients need lifetime pharmacy services.
- The services required by the patients are extremely expensive and will generate significant revenue for the Pharmacy. The cost of anti-rejection drugs and other medications can easily exceed \$10,000 per year.
- Immunosuppressive therapy is critical to the success of a transplant. Depending on risk factors and therapy, a significant number of transplant recipients undergo one or more episodes of rejection during the year immediately following transplantation. Common sense suggests that a Center's recommendation of a preferred outpatient pharmacy to a patient will be given great weight.

In short, the Centers will exercise substantial influence over a significant source of revenue for the Pharmacy.

One purpose of the anti-kickback statute is to protect patients from inappropriate medical referrals by providers who may be unduly influenced by financial incentives. The statute seeks to ensure that referrals will be based on sound medical judgment and that providers will compete for business based on quality and convenience, instead of paying for it. Given the significance of the outpatient pharmacy to the transplant patient, any arrangement that might influence medical judgment in recommending a particular pharmacy provider is problematic and must be closely scrutinized. The Proposed Arrangement contains no safeguards, conditions, or controls that mitigate the risk of improper patient steering by Centers improperly influenced by the provision of free services.⁽²⁾

We recognize that close coordination between a transplant center and outpatient pharmacies is desirable and may significantly benefit patients, their families, and their caretakers by improving quality of care and by facilitating patient access to appropriate pharmaceutical supervision in a highly specialized area. HCFA has recognized the value of such services and has made providing them conditions of participation for purposes of Medicare reimbursement. See, e.g., 42 C.F.R. §§ 482.25, .43. A transplant center may provide these services for patients in collaboration with pharmacies or others; however, they may not do so in a manner that provides financial incentives for referrals.

III. CONCLUSION

Based on the facts presented, we conclude that the Proposed Arrangement might constitute prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals were present, and thus the Pharmacy may potentially be subject to sanction under sections 1128B(b), 1128(b)(7), and 1128A(a)(7) of the Act.⁽³⁾

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [Name redacted], which is the requester of this opinion. This advisory opinion has no application, and cannot be relied upon, by any other individual or entity.
- 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 applicable only to the statutory provisions specifically noted in the first paragraph of this advisory opinion. 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 Program.
- 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

FOOTNOTES:

1. Because both the criminal and administrative sanctions related to the anti-kickback implications of the Proposed Arrangement are based on violations of the anti-kickback statute, the analysis for purposes of this advisory opinion is the same under both.
2. Some transplant pharmacies may have special arrangements with particular drug manufacturers or even be affiliated with a drug manufacturer that has products in the immunosuppression market. We would have significant additional concerns with such arrangements.
3. We express no opinion regarding the liability of the requester or any other party under the False Claims Act or other legal authorities for any improper billing, claims submission, or other conduct in connection with the services and products provided under the Proposed Arrangement.