



[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: February 3, 2003

Posted: February 12, 2003

[name and address redacted]

Re: OIG Advisory Opinion No. 03-3

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposed modification to your existing patient assistance program to pay Medicare Part B cost-sharing amounts for financially needy beneficiaries using your drugs for immunosuppressive therapy after organ transplant surgery (the "Proposed Arrangement"). You have asked whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under section 1128A(a)(5) of the Social Security Act (the "Act") or under the exclusion authority at section 1128(b)(7) of 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.

You have certified that all of the information provided in your request, including all supplementary letters, 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 would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act, but that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the Office of Inspector General (“OIG”) could impose administrative sanctions on [Company P] 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 may not be relied on by any persons other than [Company P], 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

[Company P] (the “Requestor”) is a pharmaceutical company that manufactures and markets branded pharmaceuticals, including two cyclosporine products used for immunosuppressive therapy after organ transplant surgery (the “Drugs”). The immunosuppressive therapy involves a daily regimen of immunosuppressive drugs that begins immediately following surgery while the patient is still in the hospital and continues for the rest of the patient’s life. Each of the Drugs is self-administered on an outpatient basis and costs several thousand dollars a year per patient. While for many years one of the Drugs was effectively the only drug available for immunosuppressive therapy, other pharmaceutical manufacturers are currently marketing three other forms of cyclosporine, which the Food and Drug Administration has determined are therapeutically equivalent.

Prior to 2000, Part B of the Medicare program provided coverage and payment for self-administered immunosuppressive drugs in outpatient settings for thirty-six months after a transplant. In 2000, Congress eliminated the 36-month limitation, effectively creating lifetime coverage under Part B for self-administered immunosuppressive drugs.¹ Part B payment is made for these products to dispensing pharmacies at 95% of the published average wholesale price (“AWP”) of the cyclosporine product with the lowest AWP.² As with other Part B benefits, Medicare beneficiaries must pay coinsurance equal to 20% of the allowable Medicare benefit.³ Part B cost-sharing amounts for the Drugs are estimated

¹ 42 U.S.C. § 1395x(s)(2)(J) (Supp. 2001).

² 42 U.S.C. § 1395u(o).

³ 42 U.S.C. § 1395l(a)(1)(S); 42 C.F.R. § 410.152(b).

to exceed \$1,200 per patient per year.

The Requestor has historically provided access to its pharmaceutical products to financially needy, uninsured patients through a Patient Assistance Program (“PAP”). Prior to the expansion of Medicare coverage for immunosuppressive drugs, the Requestor’s PAP provided the Drugs at no cost to financially needy, uninsured patients, including Medicare beneficiaries who had exhausted their thirty-six months of Part B coverage, met the relevant income criteria, and lacked secondary insurance coverage.

Medicare beneficiaries who received the Drugs at no cost after their thirty-six months of Medicare coverage became ineligible for PAP assistance once Medicare extended the coverage period. As a result, these beneficiaries are now liable for their Medicare cost-sharing amounts for the Drugs. Pending issuance of this advisory opinion, the PAP has continued to provide the Drugs to those beneficiaries who lost their prior eligibility for PAP assistance at no cost to Medicare or the beneficiary

The Requestor proposes to modify its PAP to permit participation by financially needy Medicare transplant patients who are using, or intend to use, the Drugs. However, rather than providing the Drugs for free to these patients, the Requestor would reimburse them for cost-sharing amounts incurred in connection with the Drugs. These patients would be subject to somewhat stricter financial need guidelines than patients seeking PAP assistance for the Requestor’s other drugs. Under the Proposed Arrangement, patients would be free to obtain the Drugs from the pharmacies of their choice.

Potential applicants would learn about the Proposed Arrangement from a variety of sources, including transplant physicians, health care providers, and patient advocacy groups, as well as the Requestor’s own PAP. The Requestor would also advertise the availability of the Proposed Arrangement to transplant physicians who could prescribe, or influence the prescription of, the Drugs.

II. LEGAL ANALYSIS

A. Law

Section 1128A(a)(5) of the Act provides for the imposition of civil monetary penalties against any person who gives something of value to a Medicare or Medicaid program beneficiary that the benefactor knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by the Medicare or Medicaid. The OIG may also initiate administrative proceedings to exclude such party from the federal health care programs. Section 1128A(i)(6) of the Act defines “remuneration” for purposes of section 1128A(a)(5) as including “the waiver of

coinsurance and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value.”

The anti-kickback statute makes it a criminal offense knowingly and willfully to 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. 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 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 state health care programs. 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.

B. Analysis

1. Section 1128A(a)(5) of the Act

As a threshold matter, section 1128A(a)(5) of the Act applies to offers or transfers of remuneration likely to induce a Medicare beneficiary to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under the Medicare program. The Proposed Arrangement does not implicate section 1128A(a)(5) of the Act. The Requestor is a pharmaceutical company that manufactures, but does not bill Medicare or Medicaid, for the Drugs, and thus does not constitute “a particular provider, practitioner, or supplier” within the meaning of section 1128A(a)(5) of the Act. Because a beneficiary will be fully reimbursed for any Part B cost-sharing amounts he or she incurs and can obtain the Drugs from any pharmacy, the Proposed Arrangement is not likely to influence the beneficiary’s selection of a particular supplier of the Drugs.

2. Anti-Kickback Statute

The Proposed Arrangement, by which the Requestor would reimburse Medicare beneficiaries for Part B cost-sharing amounts incurred for its Drugs, would clearly

implicate the anti-kickback statute. For the reasons set out below, we believe the Proposed Arrangement would pose a risk of program and patient fraud and abuse.

First, the Proposed Arrangement is squarely prohibited by the statute. Simply put, the Requestor is paying beneficiaries who use its product. Subsidizing Medicare cost-sharing amounts can be very profitable to manufacturers. So long as the manufacturer's sales price for the product exceeds its marginal variable costs plus the cost-sharing amounts, the manufacturer makes a profit. Given that the marginal variable cost of a drug can be quite low, the profit can still be considerable despite the patient subsidy, especially for an expensive drug for a chronic condition.

In addition, the Proposed Arrangement would provide the Drugs with an obvious financial advantage over competing drugs in the market. Since the Requestor would be providing cost-sharing assistance for its Drugs, rational beneficiaries would prefer treatment with the Requestor's Drugs, rather than treatment with other drugs for which they must pay the cost-sharing amounts themselves.

Second, the Proposed Arrangement could result in increased costs to the Medicare program. Since beneficiaries would be insulated from their financial liability for the Requestor's Drugs, there would be no incentive to use competing, equally effective products, even if they were less expensive. The presence of the Requestor's cost-sharing subsidy in the market could distort the pricing of therapeutically equivalent cyclosporine products.

Third, there are non-abusive alternatives for assisting financially needy patients. Manufacturers may provide free drugs to financially needy beneficiaries, so long as no federal health care program is billed for all or part of the drugs. Like the Requestor, many pharmaceutical manufacturers operate such patient assistance programs. Alternatively, the Requestor's desire to help financially needy patients can be achieved without directly subsidizing patients who use its product. For example, in OIG Advisory Opinion No. 02-1, we approved an arrangement whereby drug manufacturers pool contributions in an independent foundation that awards grants based on need, without reference to any specific contributing drug manufacturer or product. We have also approved a comparable program operated by the American Kidney Fund to assist needy patients with end stage renal disease with funds donated by dialysis providers. See OIG Advisory Opinion No. 97-1; see also OIG Advisory Opinion No. 98-17. A similar approach could be used here.

Nothing in this opinion should be construed as precluding a pharmacy that supplies the Drugs to a Medicare patient from waiving cost-sharing amounts on the basis of a good faith, individualized assessment of the patient's financial need, so long as waivers are neither routine, nor advertised, and are offered independently of any arrangements with

the Requestor or other parties. By contrast, under the Proposed Arrangement, the party (i.e., the pharmacy) supplying the Drugs to the patient would receive its full Medicare payment for the Drugs (i.e., 80% from Medicare and 20% from the patient) and the availability of financial assistance would be advertised to transplant physicians, patient advocacy groups, and others.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act, but that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the OIG could impose administrative sanctions on [Company P] 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.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [Company P], which is 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 in any matter involving an entity or individual that is not a requestor of this opinion.
- 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.
- 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,

/s/

Lewis Morris
Chief Counsel to the Inspector General