

[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: December 15, 2000

Posted: December 28, 2000

[Name and Address Redacted]

Re: OIG Advisory Opinion No. 00-10

Dear [Name Redacted]:

We are writing in response to your request for an advisory opinion regarding the [program name redacted] (the “Program”), a program designed to promote [drug name redacted] (the “Drug”), an expensive new drug used to prevent certain respiratory infections caused by [condition X] disease in pediatric patients. Specifically, the question raised by your request is whether the Program constitutes grounds for sanctions under the anti-kickback statute, section 1128B(b) of the Social Security Act (the “Act”), or the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act, in the circumstances presented.

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 information provided, we conclude that: (i) the Program could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce referrals were present, but that the Office of Inspector General (“OIG”) will not subject [Company A] to sanctions for violations of the anti-kickback statute under sections 1128(b)(7) or 1128A(a)(7) of the Act in connection with the Program, as described and certified in your request letter and supplemental submissions; and (ii) the OIG will not impose a civil monetary penalty under section 1128A(a)(5) of the Act on [Company A] in connection with the Program, as described and certified in your request letter and supplemental submissions.

This opinion may not be relied on by any persons other than [Company A], the requestor of this opinion, and is further qualified as set out in Part V below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. The Drug and Its History

[Company A] (the “Company”) is a publicly-traded corporation engaged in the development, manufacture, and sale of pharmaceuticals, including the Drug. The Drug is used in the prevention of serious lower respiratory tract infections caused by [condition X] disease in high-risk pediatric patients.

According to the Company, [condition X] disease is the most common cause of pneumonia and bronchiolitis in infants and children and is responsible for as many as 126,000 hospitalizations annually. The fatality rate associated with [condition X] infections is approximately two percent in hospitalized high-risk infants and five percent in infants with chronic lung disease (“CLD”). Infants at risk for [condition X] infections include certain infants who were born prematurely and certain infants with CLD.

The American Academy of Pediatrics (the “Academy”) has issued guidelines recommending that physicians consider preventive treatment for infants and toddlers at high risk for [condition X] disease.¹ [Citation redacted.] Currently, there are only two

¹Pursuant to Academy guidelines, only the following infants and children should be considered for [condition X] prophylaxis: (i) infants and children who are younger than two years of age with CLD who have required medical therapy for their CLD within six months before the anticipated [condition X] season; (ii) infants who are born at thirty-two weeks of gestation or earlier; and (iii) infants who are born between thirty-two to

drugs approved by the Food and Drug Administration for the prevention of respiratory infections caused by [condition X] disease, both of which are made by the Company. The other drug has not been widely used, especially among infant populations, in part because it can only be administered through an intravenous line using a constant infusion pump. According to the Academy, the Drug is the preferred treatment for most children at high risk for [condition X] disease “because of ease of administration (intramuscular), lack of interference with measles-mumps-rubella vaccine and varicella vaccine, and lack of complications associated with intravenous administration of human immune globulin products.” Id.

Treatment with the Drug is expensive. Since the Drug is currently available only through intramuscular injection, it must be administered by a physician or some other health care professional. The Drug is administered once a month during the [condition X] season, which varies regionally and annually, but typically runs from October through April. A course of treatment consists of a series of five or six intramuscular injections at a total cost to physicians of approximately \$5,000 to \$6,000 (or about \$1,000 per injection).

The Drug is potentially reimbursable by various State health care programs (collectively, “Medicaid”) and other Federal health care programs. Most third party payors, including most Medicaid programs, limit coverage to patients at high risk of [condition X] disease, and many payors follow the Academy’s guidelines in determining medical necessity.

B. The Program

The Program, which is generally open to all physicians,² comprises several components, including pre-qualification of patients for third party coverage and reimbursement, extended payment terms for participating physicians, and credits for denied claims. Services provided under the Program are in addition to the general reimbursement support

thirty-five weeks of gestation and who have additional risk factors, including other underlying conditions that predispose them to respiratory complications (e.g., neurologic disease in very low birth weight infants), exposure to young siblings, child care center attendance, exposure to tobacco smoke in the home, anticipated cardiac surgery, and distance to and availability of hospital care for severe respiratory illness.

² Physicians practicing in group practices that are fully-capitated for products such as the Drug or group practices that account for such products as part of their negotiated rates, with the practice assuming full risk (e.g., staff model HMOs), cannot participate in the Program.

services (e.g., advice regarding payor coverage and benefits, coding, and claims processing requirements) that the Company makes available to any provider seeking advice about the Drug. To participate in the Program, a physician must (i) plan to administer the Drug in the office setting, and (ii) sign a Physician Agreement.³ For each physician, participation in the Program is limited to a maximum of three years, which must run consecutively.

A detailed description of the Program is set forth below. While the Company has contracted with another company for the administration of the Program, for purposes of our analysis, we will attribute all such activities to the Company.

- Patient Insurance Pre-Qualification. Participating physicians submit a Patient Enrollment Form and a Patient Consent Form to the Company. Prior to enrolling a patient of a participating physician in the Program, the Company verifies that the patient (i) has insurance coverage,⁴ and (ii) is a medically appropriate candidate for [condition X] prophylaxis with the Drug.⁵ Once the patient is enrolled, the Drug is shipped directly to the physician by a participating distributor. The Company continues to monitor the shipments of the Drug, the patients' Drug treatment schedules, and the status of insurance claims filed by physicians.
- Prompt Payment Discount and Extended Payment Terms. Under the Program, the distributors' markup to physicians cannot exceed 6% of the wholesale acquisition cost, and the distributors must give physicians a prompt payment discount, if the

³ Under the Physician Agreement, the physician agrees to file each insurance claim within ten days of administering the Drug, provide a copy of each filed claim to the Company, and pay the distributor of the Drug within fifteen days after receiving insurance reimbursement.

⁴Candidates who have no private or public health insurance and who do not have the financial resources to pay for the Drug may be eligible to receive the Drug without charge under a separate, independent program sponsored by the Company (the "Assistance Program"). Last year, the Company provided 256 free vials of the Drug to 86 patients under the Assistance Program.

⁵In verifying that the patient is a medically appropriate candidate for the Drug, the Company does not make an independent assessment of medical necessity. Instead, the Company merely determines whether the treatment would be covered by the applicable third party payor based upon coverage guidelines provided by the payor and patient information provided by the physician.

distributors are paid within sixty days of shipment. In addition, distributors must give physicians up to 180 days after the Drug is shipped to pay for the Drug. To reimburse distributors for the carrying costs associated with the extended payment terms, the Company gives distributors a credit of 0.5% of the cost of the Drug once every thirty days, beginning on the 61st day and ending on the earlier of the date that payment is received or 211 days after shipment (i.e., thirty days after the 180-day extended payment period ends).

- Invoice Credit for Denied Claims. If the claim is denied, notwithstanding the Company's prior verification of insurance coverage, or if the physician does not receive reimbursement from the third party payor within 180 days, the Company makes the distributor whole and the distributor in turn makes the physician whole. If the physician has not paid the distributor, the distributor provides an invoice credit to the physician for the amount the distributor charged for the Drug, and the Company provides a replacement vial of the Drug to the distributor. If the physician has paid the distributor, the distributor provides a replacement vial of the Drug to the physician, instead of an invoice credit, and the Company provides a replacement vial of the Drug to the distributor. If the physician is reimbursed by the third party payor after receiving the invoice credit or replacement vial of the Drug, the physician is required to pay the distributor for the Drug, and the Company charges the distributor for the replacement vial of the Drug.

Under the Program, physicians are required to collect and manage patients' deductibles and copayments in accordance with their routine business practices and the requirements of their patients' health plans. A participating physician is not permitted to receive an invoice credit or replacement vial of the Drug through the Program in connection with an enrolled patient's insurance claim if (i) the patient makes a full payment or percentage-based copayment (e.g., 20% of the charge) for the Drug,⁶ or (ii) the physician receives any reimbursement from the third party payor for the claim. The Program does not reimburse physicians for the difference between the amount billed to the third party payor and the amount received therefrom.

Pursuant to current data from the 1999/2000 [condition X] season, 2,078 claims have been filed in connection with the Program, of which less than 2% were initially denied by third party payors and less than 7% took more than 180 days for third party payors to

⁶No such proscription exists in connection with claims for which the patient has paid a fixed copayment designated by the patient's insurer (e.g., \$10 per visit).

process.⁷ To date, approximately 35% to 40% of the patients enrolled in the Program have been Medicaid beneficiaries.

II. THE ANTI-KICKBACK STATUTE

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. Specifically, the statute provides that:

Whoever knowingly and willfully offers or pays [or solicits or receives] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person -- to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony.

Id. Thus, 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. The OIG may also initiate administrative proceedings to exclude persons from Federal and State health care programs or to impose

⁷Appeals are pending on all of the denied claims.

civil monetary penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.⁸

B. Analysis

Drug manufacturers often offer free assistance to physicians and other providers by serving as a clearinghouse for information regarding insurance coverage criteria and reimbursement levels for their products. Since these services have no independent value to providers apart from the products, they are properly considered part of the products purchased and their cost is already included in the products' price. Therefore, standing alone, these services have no substantial independent value and do not implicate the Federal anti-kickback statute.⁹

However, the Federal anti-kickback statute may be implicated when drug manufacturers combine these types of reimbursement support services with other services or programs which do confer an independent financial benefit upon referring providers. For example, coupling a reimbursement support service with a program either requiring payment for ordered products only if the referring provider is paid or guaranteeing a minimum "spread" between the purchase price and third party reimbursement levels would implicate the anti-kickback statute. Such programs eliminate the normal financial risks facing providers, potentially raising the risk of overutilization and increased Federal health care program costs.

The Program falls into this latter category and, therefore, implicates the Federal anti-kickback statute. Under the Program, the Company couples reimbursement support services with extended payment terms and, if necessary, an invoice credit or replacement vial of the Drug. These additional elements confer an independent financial benefit upon referring physicians by shifting the financial risk of unanticipated delays and denials associated with obtaining third party payor reimbursement from the prescribing physicians to the Company.

Notwithstanding, we will not subject the Company to sanctions under the anti-kickback statute in connection with the Program for the reasons set forth below. First, the Program

⁸Because both the criminal and administrative sanctions related to the anti-kickback implications of the Program are based on violations of the anti-kickback statute, the analysis for purposes of this advisory opinion is the same under both.

⁹We express no opinion regarding liability of the Company under the False Claims Act or other legal authorities in connection with any improper billing or claims submission directly or indirectly related to, or arising from, the reimbursement support services or the Program.

is narrowly-tailored to address the unique access problems caused by the cumulative effect of certain verifiable characteristics of the Drug, including its cost, target population, and preventive nature. Specifically, the Program is limited to one product – a new, expensive, prophylactic drug. Moreover, a substantial portion of the patients, who are at high risk for [condition X] disease and would benefit from prophylaxis with the Drug, are members of low-income families that typically do not have the financial resources necessary to prepay, or personally guarantee payment, for the Drug. Thus, for these low-income families and their physicians, the cost of the Drug, coupled with the possibility of unanticipated reimbursement delays and denials and the lack of urgency often associated with curative treatments, can create a formidable hurdle to obtaining a recommended preventive treatment.

Second, based on historical experience, the remuneration actually provided to physicians is minimal. Pursuant to current data from the 1999/2000 [condition X] season, less than 2% of the claims filed in connection with the Program were initially denied by third party payors and less than 7% of the claims took more than 180 days for third party payors to process. In this case, it appears that the Program provides as much psychological support as financial support. In addition, physician participation in the Program is limited to three years, further limiting the potential remuneration. While the amount of the remuneration is not determinative of whether an arrangement violates the anti-kickback statute, it is one factor that we consider in determining whether to exercise our sanction authority.

Third, the structure of the Program should not result in overutilization. Prior to enrolling a patient of a physician in the Program, the Company verifies that the patient meets the medical coverage guidelines established by the patient's third party payor. Given the cost of the Drug, most third party payors, including most Medicaid programs, limit coverage to patients at high risk of [condition X] disease, and many payors follow the Academy's guidelines.

In light of all of the foregoing, we would not subject the Company to sanctions under the anti-kickback statute in connection with the Program.

III. SECTION 1128A(a)(5) OF THE ACT

A. Law

Section 1128A(a)(5) of the Act provides for the imposition of civil monetary penalties against any person who:

offers or transfers remuneration to any individual eligible for benefits under [Medicare or a State health care program] that such person knows or should know is likely to influence such individual 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 [Medicare or a State health care program].

See also 42 C.F.R. § 1003.102(b)(13). Unlike the anti-kickback statute, section 1128A(a)(5) of the Act is solely concerned with remuneration offered or transferred to Medicare or State health care program beneficiaries.

Section 1128A(i)(6) of the Act defines "remuneration" for purposes of section 1128A(a)(5) of the Act as including, among other things, "transfers of items or services for free or for other than fair market value" and as excluding, among other things, "incentives given to individuals to promote the delivery of preventive care as determined by the Secretary in regulations so promulgated." In 42 C.F.R. § 1003.101, the new final rule addressing section 1128A(a)(5) of the Act, we defined "preventive care" to mean any service that "(1) [i]s a prenatal service or post-natal well-baby visit or is a specific clinical service described in the current U.S. Preventive Services Task Force's Guide to Clinical Preventive Services, and (2) is reimbursable in whole or in part by Medicare or an applicable State health care program." 65 Fed. Reg. 24400, 24415 (April 26, 2000).

B. Analysis

The Program potentially implicates section 1128A(a)(5) of the Act. A low-income Medicaid beneficiary who receives prophylaxis with the Drug and whose Medicaid claims are subsequently denied will incur a financial obligation totaling approximately \$5,000 to \$6,000. However, under the Program, if Medicaid denies a physician's claim after the Company has verified coverage, the Company (indirectly through a participating distributor) provides an invoice credit or replacement vial of the Drug to the physician, thereby relieving the patient of his or her obligation to pay for the denied Medicaid claims. Fulfilling a financial obligation owed by a patient constitutes remuneration to the patient which may influence the patient's choice of provider.

Notwithstanding, we will not subject the Company to sanctions under section 1128A(a)(5) of the Act in connection with the Program. First, although the Drug is not listed in the current U.S. Preventive Services Task Force's Guide to Clinical Preventive Services and, therefore, does not qualify for the preventive care exemption, it is very similar to services listed therein. Second, the financial benefit to the beneficiary is more theoretical than real, since few Medicaid beneficiaries will be in a position to discharge a

\$5,000 obligation. The more tangible benefit accrues to the physician who will not have to write off the cost of the Drug. Since we have already decided not to seek sanctions for benefits accruing to physicians under the Program for the reasons set out in the prior section, we will not seek sanctions for the resulting incidental benefits accruing to beneficiaries.

IV. CONCLUSION

Based on the information provided, we conclude that: (i) the Program could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce referrals were present, but that the OIG will not subject the Company to sanctions for violations of the anti-kickback statute under sections 1128(b)(7) or 1128A(a)(7) of the Act in connection with the Program, as described and certified in your request letter and supplemental submissions; and (ii) the OIG will not impose a civil monetary penalty under section 1128A(a)(5) of the Act on the Company in connection with the Program, as described and certified in your request letter and supplemental submissions.

V. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [company name redacted], who is the requestor of this opinion. This advisory opinion has no application, 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 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 Program.
- 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 will not proceed against the Company with respect to any action that is part of the Program taken in good faith reliance upon this advisory opinion as long as all of the material facts have been fully, completely, and accurately presented, and the Program in practice comports with the information provided. The OIG 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. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Company with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely and accurately disclosed to the OIG.

Sincerely,

/s/

D. McCarty Thornton
Chief Counsel to the Inspector General