



[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: November 2, 2006

Posted: November 9, 2006

[Name and address redacted]

Re: OIG Advisory Opinion No. 06-21

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a pharmaceutical company's proposal to establish a patient assistance program to provide outpatient prescription drugs to financially-needy Medicare Part D enrollees entirely outside of the Part D benefit (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (the "Act") or the civil monetary penalty 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, the Federal anti-kickback statute.

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 could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the Office of Inspector General (“OIG”) would not impose administrative sanctions on [name redacted] 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.

This opinion may not be relied on by any persons other than [name redacted], 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

[Name redacted] (“Requestor”) manufactures and markets numerous prescription drug products.¹ For several years, Requestor has operated various patient assistance programs that provide Requestor’s drugs to qualifying financially-needy patients who lack insurance coverage for outpatient prescription drugs. Under the Proposed Arrangement, Requestor would establish a program (the “PAP”) to provide some of Requestor’s products to financially-needy Medicare beneficiaries who are enrolled in a Part D plan.² The following describes how the PAP would operate under the Proposed Arrangement.

Medicare beneficiaries seeking to enroll in the PAP would submit an application to Requestor. To qualify for enrollment in the PAP, Medicare beneficiaries would have to

¹Requestor has certified that it does not own or operate, directly or indirectly, pharmacies, pharmacy benefits management companies, or any entities that file claims for payment under the Medicare or Medicaid programs.

²For ease of reference, we use the term “Part D plan” to refer to any plan offering Medicare outpatient prescription drug coverage under Medicare Part D, including freestanding private prescription drug plans (often referred to as “PDPs”) and drug plans offered as part of a Medicare Advantage plan (often referred to as “MA-PDs”); we use the term “Part D enrollees” to refer to Medicare beneficiaries who are enrolled in any of these plans.

demonstrate that they use one or more of the PAP's covered drugs,³ are enrolled in Part D,⁴ and have financial need. The PAP would define qualifying financial need based on (i) household income below a set multiple of the Federal poverty level; and (ii) the patient already having spent a substantial portion of that income on outpatient prescription drugs already that coverage year.⁵ Requestor has certified that assistance would be awarded without regard to any provider, practitioner, supplier, or Part D plan used by the applicant. Once a Part D enrollee qualifies for PAP assistance in a given year, PAP

³Initially, the PAP would offer seventeen of Requestor's prescription drug products. The PAP is limited to uses of these products that are eligible for coverage under Medicare Part D, without regard to whether or not an individual enrollee's Part D plan actually covers that product. The PAP would not provide medications for uses that are eligible for coverage under Medicare Part B. Requestor has indicated that it may, from time to time, change the products offered by the PAP.

⁴Medicare beneficiaries who are not Part D enrollees, including Medicare beneficiaries who had enrolled in the PAP but are later disenrolled due to loss of Part D enrollment, remain eligible for help from Requestor's existing patient assistance programs for uninsured patients. As we have frequently indicated, nothing in the Federal fraud and abuse laws prevents a pharmaceutical manufacturer from giving free outpatient prescription drugs to patients who do not have insurance for outpatient prescription drugs, including Medicare beneficiaries who have not enrolled in Part D. See, e.g., Special Advisory Bulletin on Patient Assistance Programs, 70 Fed. Reg. 70623 (Nov. 22, 2005).

⁵Initially, the PAP would require the patients to have spent 3% of their income on outpatient prescription drugs before the patient would qualify for PAP assistance. Requestor has certified that this financial need test reflects Requestor's expectations regarding this patient population's ability to absorb out-of-pocket health care and drug costs. Requestor has further certified that, if it were to expand its program to include other patients with some insurance coverage for outpatient prescription drugs, it would impose a similar spending threshold on those insured patients.

assistance would continue for the remainder of that year,⁶ even if the patient's use of the drug were periodic. A patient's eligibility for assistance in subsequent years would be reassessed each year, and assistance would not begin until the patient met the eligibility requirements for that year.

Under the Proposed Arrangement, a PAP enrollee would obtain PAP drugs from any duly licensed retail pharmacy of his or her choosing. The patient would present a valid prescription and the pharmacy would dispense the PAP drugs in an amount up to a three month's supply. PAP enrollees would not receive the medications entirely free of charge. Rather, the PAP would require enrollees to pay a cost-sharing amount for each supply of drugs dispensed through the PAP. The cost-sharing amount would not vary based on which PAP drug the patient obtained, but would vary based on the patient's income and the number of month's supply of drug obtained. The patient would pay the cost-sharing amount to the pharmacy, and the PAP would pay the pharmacy an additional payment such that the total payment to the pharmacy constitutes fair market value for dispensing the PAP drug.⁷

The PAP would maintain accurate and contemporaneous records of all PAP drugs provided to Part D enrollees. The PAP's payment for the drugs would not count as drug expenses incurred by the enrollee. This means that the PAP's payment for the drugs would not count toward true out-of-pocket ("TrOOP") costs under the Part D program. Once an enrollee begins receiving a drug from the PAP, such assistance would continue for the remainder of that year (except for patients who voluntarily disenroll from the PAP and patients whom the PAP acts to disenroll based on ineligibility), and neither Medicare, nor any Part D plan or enrollee, would be charged for provision of that drug to the enrollee for the remainder of the coverage year. Requestor proposes to work with the Centers for Medicare and Medicaid Services ("CMS") to negotiate appropriate data sharing agreements to enable the PAP to notify enrollees' Part D plans regarding enrollees' participation in the PAP. Such coordination would ensure that neither Medicare nor any Part D plan would pay for the drugs and also would allow the patient's Part D plan to conduct appropriate drug utilization and medication therapy management

⁶The PAP may disenroll patients from the PAP prior to the end of the coverage year if the patient is determined to not meet the eligibility requirements. Patients may also voluntarily disenroll from the PAP if they so choose. Requestor has certified that it will not in any way act to encourage such voluntary disenrollments.

⁷We have not been asked about, and we express no opinion regarding, the arrangement between the PAP and the retail pharmacies.

activities. Requestor has certified that the PAP would operate in compliance with all then-existing CMS guidance.

Finally, PAP enrollees would be required to certify that they: (i) will not submit any claim for reimbursement to any third party insurer, including, without limitation, a Medicare Part D plan, for any product provided by the PAP; and (ii) will not claim TrOOP costs from a Medicare Part D plan for the value of the product provided by the PAP. The PAP would provide enrollees with written notice confirming that they are eligible to receive the PAP drugs from the PAP for the remainder of the coverage year, that the PAP drugs should not be reimbursed by the enrollee's Part D plan, and that the PAP's payment for the drugs will not count towards the enrollee's TrOOP.

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 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. 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, 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 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. 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.⁸

B. Analysis

As we observed in our Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees (70 Fed. Reg. 70623 (Nov. 22, 2005)), manufacturer PAPs that subsidize the cost-sharing amounts for the manufacturer's drugs payable in whole or in part by the Part D program present all of the usual risks of fraud and abuse associated with kickbacks, including steering enrollees to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing enrollees' incentives to locate and use less expensive, equally effective drugs.

However, in this case, Requestor proposes to operate its PAP entirely outside of the Part D benefit. This means the enrollees would obtain their drugs without using their Part D insurance benefit. No claims for payment for the drugs provided would be filed with a Part D plan or the beneficiary, and the assistance would not count toward the enrollee's

⁸Section 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 Medicare or Medicaid. Generally speaking, pharmaceutical manufacturers are not "providers, practitioners, or suppliers" for the limited purposes of section 1128A(a)(5), unless they also own or operate, directly or indirectly, pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs. Requestor has certified that it does not own or operate, directly or indirectly, pharmacies, pharmacy benefits management companies, or any entities that file claims for payment under the Medicare or Medicaid programs. The Proposed Arrangement would not be expected to steer beneficiaries to any particular pharmacy or any other particular provider, practitioner, or supplier. Thus, in these circumstances, section 1128A(a)(5) would not be implicated by the Proposed Arrangement.

TrOOP or total Part D spending for any purpose.⁹ Having reviewed the Proposed Arrangement, we conclude that it contains safeguards sufficient to ensure that the PAP would, in fact, operate entirely outside the Part D benefit, and, therefore, would pose minimal risk of fraud and abuse under the Part D program.¹⁰

First, the PAP would notify enrollees' Part D plans that the PAP drugs are being provided outside the Part D benefit. The PAP plans to accomplish this via a data sharing agreement with CMS. In conjunction with the PAP's patient notification procedure, a data arrangement would help ensure that no payment would be made for the PAP drugs by Medicare or by any Part D plan, and no part of the PAP's payment for the drugs would be counted toward any Part D enrollee's TrOOP. Effective coordination with the enrollee's Part D plan may also enhance patient safety and quality of care.

Second, eligibility for PAP assistance for Part D enrollees would be determined based solely on patients' financial need, using a methodology (*i.e.*, percent of Federal poverty level and expenses) that would be entirely divorced from considerations related to a Part D enrollee's choice of Part D plan, the benefit design of the enrollee's Part D plan, or where a Part D enrollee is on his or her Part D plan's benefit spectrum (*i.e.*, at a given

⁹Requestor has structured the Proposed Arrangement so that PAP enrollees would be required to pay a fixed cost-sharing amount for each month's supply of drugs obtained through the PAP. Imposition of the fee is a business decision of Requestor and is neither compelled by, nor material to the outcome of, this advisory opinion. Should Requestor decide to modify the PAP to reduce or eliminate the fixed fee, this opinion would remain in force and effect. We note that imposition of variable cost-sharing fees for different PAP drugs might raise concerns not addressed here.

¹⁰The facts of the Proposed Arrangement are readily distinguishable from problematic situations involving routine cost-sharing waivers or the provision of free or deeply discounted goods or services to beneficiaries. *See, e.g.*, Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries (August 2002), available at www.oig.hhs.gov; Special Fraud Alert on Routine Waiver of Part B Co-payments/Deductibles, available at www.oig.hhs.gov. Simply put, the facts here do not involve any waiver of cost-sharing amounts by a provider or supplier to whom the amounts are otherwise owed, nor do the facts involve the provision of a free good or service linked to a good or service payable by a Federal program. Because the application of the anti-kickback statute is necessarily fact-specific, we caution that we might reach a different result were we to evaluate an arrangement similar to the Proposed Arrangement arising in a context other than Part D.

point in time, what percentage of the drug costs are borne by the Medicare program or the Part D plan as opposed to the enrollee).¹¹ For Part D enrollees, financial need would be determined in a reasonable, uniform, and consistent manner, without regard to the providers, practitioners, or suppliers used by the patient or the Part D plan in which the patient is enrolled. Moreover, the PAP would provide assistance for the whole Part D coverage year (or for the portion of the coverage year remaining after the patient begins receiving PAP assistance),¹² and the PAP would continue to provide assistance even if the patient's use of the PAP drug is periodic during the coverage year. In addition, the PAP would operate in compliance with all then-existing guidance from CMS. Finally, the PAP would maintain accurate and contemporaneous records of the PAP drugs provided to the Part D enrollees. This would facilitate appropriate transparency and accountability.

Taken as a whole, these safeguards substantially mitigate the risk: (i) that the PAP drugs would be used to tie Medicare beneficiaries to particular outpatient prescription drugs payable by the Medicare Part D program; or (ii) that the PAP drugs would be used to increase costs to the Medicare Part D program (for example, by increasing the number of beneficiaries who reach the catastrophic benefit, by hastening the point during the coverage year at which a beneficiary reaches the catastrophic benefit, or by inducing

¹¹The additional 3% spending test appears to be reasonably related to the financial need of the PAP's patient population and does not appear to be related to any Part D plan benefit. Imposition of the spending test is a business decision of Requestor that is neither compelled by, nor material to the outcome of, this advisory opinion. Moreover, we would likely reach the same outcome in the advisory opinion were Requestor, in the future, to eliminate the 3% spending test and rely solely on income level tests to assess financial need.

¹²We note that this feature of the Arrangement, which ensures that the Part D plan will not be billed for the same drug later in the coverage year, is consistent with our observation in several advisory opinions that 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." See, e.g., OIG Advisory Opinion Nos. 02-13 and 03-3. We note that patients may voluntarily disenroll from the PAP without forfeiting their right to obtain benefits through the Part D program. Requestor has certified that it would not in any way encourage such voluntary disenrollments. If Requestor were to encourage voluntary disenrollments, the safeguard afforded by providing assistance through the end of the coverage year would be vitiated. We note that if Requestor were to encourage voluntary disenrollments, this might raise concerns not addressed here.

beneficiaries to use higher cost drugs during the catastrophic benefit instead of equally effective, lower cost alternatives).

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the Office of Inspector General would not impose administrative sanctions on [name redacted] 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. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], 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 will not proceed against [name redacted] with respect to any action that is part of the Proposed Arrangement 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 Proposed Arrangement 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, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [name redacted] 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/

Lewis Morris
Chief Counsel to the Inspector General