



[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: October 26, 2006

Posted: November 2, 2006

[Name and address redacted]

Re: OIG Advisory Opinion No. 06-19

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 also inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the CMP provision for illegal remuneration to beneficiaries, section 1128A(a)(5) 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 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. We also conclude that the Proposed Arrangement would not constitute grounds for the imposition of sanctions under the CMP provision for illegal remuneration to beneficiaries, section 1128A(a)(5) of the Act.

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 two patient assistance programs (“PAP A” and “PAP B,” collectively the “PAPs”) to provide Requestor’s products to financially-needy Medicare beneficiaries who are enrolled in a Part D plan.² The following describes how the PAPs would operate under the Proposed Arrangement.

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.

PAP A

Under the Proposed Arrangement, Requestor would use PAP A to provide free outpatient prescription medications for the treatment of cancer.³ To qualify for assistance from PAP A, patients would have to use one or more of PAP A's covered drugs and demonstrate financial need. PAP A would assess qualifying financial need using two tests: an income below 350% of the Federal poverty level and expenditure of at least \$600 on outpatient prescription drugs already that coverage year.⁴ Requestor has certified that these financial need tests reflect Requestor's expectations regarding this patient population's ability to absorb out-of-pocket health care and drug costs.

Requestor has certified that assistance would be awarded without regard to any provider, practitioner, or supplier used by the applicant, and without regard to the 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 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). Once a Part D enrollee qualifies for PAP assistance in a given year, assistance would continue for the remainder of that year, even if the patient's use of the drug is periodic. A patient's eligibility for assistance in subsequent years would be reassessed each year, and assistance would not begin until the patient has met the eligibility criteria in that year.

³Many of the uses of these drugs involve physician administration and coverage under Medicare Part B. The Proposed Arrangement is limited to the uses of these drugs 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 drug. PAP A would not provide free drugs to Medicare beneficiaries for uses that are eligible for coverage under Medicare Part B.

⁴Requestor has certified that, if it were to expand its patient assistance programs to include patients with other types of insurance for outpatient prescription drugs, those insured patients would also be required to meet the additional \$600 spending test.

PAP A would ship the drugs to the patient's physician.⁵ Patients would receive the drugs free of charge and without any information regarding their value or cost.

PAP B

Under the Proposed Arrangement, Requestor would use PAP B to provide free outpatient prescription medications, other than the oncology drugs covered in PAP A, to eligible PAP B enrollees (including Part D enrollees) for a broad spectrum of indications. To qualify for assistance from PAP B, patients would have to use one or more of PAP B's covered drugs and demonstrate financial need. PAP B would assess qualifying financial need using two tests: an income below 250% of the Federal poverty level and expenditure of at least \$600 on outpatient prescription drugs already that coverage year.⁶ Requestor has certified that these financial need tests reflect Requestor's expectations regarding this patient population's ability to absorb out-of-pocket health care and drug costs.

Requestor has certified that assistance would be awarded without regard to any provider, practitioner, or supplier used by the applicant, and without regard to the 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 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). Once a Part D enrollee qualifies for PAP assistance in a given year, assistance would continue for the remainder of that year, even if the patient's use of the drug is periodic. A patient's eligibility for assistance in subsequent years would be reassessed each year, and assistance would not begin until the patient has met the eligibility criteria in 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

⁵PAP A would allow any duly licensed physician of the patient's choosing to serve as a recipient of the medications. The physician would not receive any compensation directly or indirectly for receiving the medications from the PAP. Participating physicians would be required to agree that they will not bill any party for medications provided free from the PAP. All medications shipped under the Proposed Arrangement would be clearly designated for use by a particular patient. Quantities of medications shipped under the Proposed Arrangement would be limited to the amount ordered for the designated patient, and would not exceed the usual therapeutic quantity necessary for one month of treatment. Participating physicians would also be required to agree that they will dispense the medications only for use by the designated patient.

⁶Requestor has certified that, if it were to expand its patient assistance programs to include patients with other types of insurance for outpatient prescription drugs, those insured patients would also be required to meet the additional \$600 spending test.

prescription, and the pharmacy would dispense a one month's supply of the PAP drug. Patients would receive the drugs free of charge and without any information regarding their value or cost. The PAP would pay the pharmacy fair market value for providing the PAP drug.⁷

Coordination with Coverage Under Medicare Part D

The PAPs would maintain accurate and contemporaneous records of all PAP drugs provided to Part D enrollees. The PAPs would coordinate the assistance they provide with coverage under Medicare Part D. The free drugs would not count as drug expenses incurred by the enrollee.⁸ Once an enrollee begins receiving a drug for free from PAP A or PAP B, such assistance would continue for the remainder of that year 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 has certified that the PAPs would work with the Centers for Medicare & Medicaid Services ("CMS") to use data sharing agreements to enable the PAPs to notify Part D plans regarding beneficiaries' participation in the PAPs. Such coordination would ensure that neither Medicare, nor any Part D plan, would pay for the free drugs and also would allow the patient's Part D plan to conduct appropriate drug utilization and medication therapy management activities. The PAPs also would provide the patients with a written notice that they will be eligible to receive the free drug from the PAP for the remainder of the coverage year, that the drugs should not be reimbursed by the enrollee's Part D plan, and that the free drugs will not count towards the enrollee's TrOOP. Requestor has certified that the PAPs will operate in compliance with all then-existing CMS guidance.

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"

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

⁸This means that the value of free drugs would not count as true out-of-pocket spending ("TrOOP") under the Part D program.

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.⁹

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.

⁹Section 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.

However, in this case, the Requestor proposes to operate its PAPs entirely outside of the Part D benefit.¹⁰ This means the patients who are Part D 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 TrOOP or total Part D spending for any purpose. Having reviewed the Proposed Arrangement, we conclude that it contains safeguards sufficient to ensure that the PAPs 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.¹¹

First, the PAPs would notify enrollees' Part D plans that the PAP drugs are being provided outside the Part D benefit. The PAPs plan to accomplish this via a data sharing agreement with CMS. In conjunction with the PAPs' 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 cost of the free 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.

¹⁰Requestor's advisory opinion request is limited to Requestor's plan to provide assistance to Part D enrollees. We have not been asked to opine on, and we express no opinion regarding, any existing or planned assistance to patients who do not have insurance for outpatient prescription drugs. We note that nothing in the 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. at 70624 ("... existing PAPs may continue to provide free or reduced price outpatient prescription drugs to Medicare beneficiaries who have not yet enrolled in Part D").

¹¹The 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 other than in the Part D context.

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.¹² 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.¹³ Moreover, the PAPs 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),¹⁴ and the PAPs would continue to provide assistance even if the patient's use of the PAP drug is periodic during the coverage year. In addition, the PAPs would operate in compliance with all then-existing guidance from CMS. Finally, the PAPs 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 beneficiaries to use higher cost drugs during the catastrophic benefit instead of equally effective, lower cost alternatives).

¹²The additional \$600 spending test appears to be reasonably related to the financial need of the PAPs' 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 \$600 spending test and rely solely on income level tests to assess financial need.

¹³The fact that the two PAPs cap eligible income levels differently appears reasonable given the difference in the relative magnitude of expenditures likely to be incurred by patients in the two PAPs (*i.e.*, cancer patients in PAP A may experience greater overall financial need related to their health care), and does not appear to be related to any Part D plan benefit.

¹⁴We note that this feature of the Proposed 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.

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 (“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. We also conclude that the Proposed Arrangement would not constitute grounds for the imposition of sanctions under the CMP provision for illegal remuneration to beneficiaries, section 1128A(a)(5) of the Act. 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