[*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: April 18, 2006

Posted: April 18, 2006

[Name and address redacted]

Re: OIG Advisory Opinion No. 06-03

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a pharmaceutical company patient assistance program that provides free outpatient prescription drugs to financially-needy Medicare Part D enrollees entirely outside of the Part D benefit (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes 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 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 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 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.

1. FACTUAL BACKGROUND

[Name redacted] ("Requestor") manufactures and markets numerous prescription drug products. For several years, Requestor has operated two patient assistance programs (the "PAPs") that provide Requestor's drugs[1] for free to qualifying financially-needy patients who lack insurance coverage for outpatient prescription drugs. Under the Arrangement, Requestor expanded eligibility for both PAPs to include Medicare beneficiaries who are enrolled in a Part D plan.[2]

Requestor's PAPs are called [name redacted] ("PAP A") and [name redacted] ("PAP B"). The following describes how the PAPs operate under the Arrangement for Part D enrollees.

PAP A

Under the Arrangement, Requestor uses PAP A to provide free outpatient prescription medications to eligible PAP A enrollees (including Part D enrollees) for the treatment of

[1]Collectively, the PAPs include virtually all of Requestor's own drugs, but do not include some drugs that Requestor manufactures or markets in cooperation with another company; are subject to a co-promotion, licensing, or marketing agreement with another company; or are manufactured in extremely limited quantities.

[2]For ease of reference, we use the term "Part D plan" to refer to any plan offering Medicare outpatient prescription drug coverage under 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.

cancer and hepatitis.[3] With the exception of Medicare beneficiaries enrolled in Part D, patients do not qualify for PAP A assistance unless they lack insurance coverage for outpatient prescription drugs.[4] To qualify for assistance from PAP A, patients must use one or more of PAP A's covered drugs and demonstrate financial need. PAP A assesses qualifying financial need using two tests. First, all PAP A applicants must have an income below 325% of the Federal poverty level.[5] In addition, Part D enrollees who apply for PAP A assistance must meet a further test: they must have already spent at least three percent (3%) of their household income on outpatient prescription drugs that coverage year.[6] Requestor has certified that this additional financial need test reflects the generally different levels of potential exposure to out-of-pocket health care and drug costs faced by uninsured and Part D enrollees with comparable income levels.[7]

Requestor has certified that assistance is 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, assistance continues for the remainder of that

---

[3]Many of the uses of these drugs involve physician administration and coverage under Medicare Part B. The 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 does not provide free drugs to Medicare beneficiaries for uses that are eligible for coverage under Medicare Part B.

[4]When a patient applies for assistance from PAP A, PAP A first helps the patient explore whether other avenues of assistance are available to the patient (e.g., private insurance, veterans' benefits, or Medicare or Medicaid benefits), and helps the patient obtain assistance from these other sources as appropriate. If other sources of assistance are available to, and appropriate for, patients seeking assistance from PAP A, those patients will be directed to these other sources of assistance instead of PAP A. In the case of applicants who are Medicare beneficiaries who have not enrolled in Part D, PAP A will require the applicants to apply, and be rejected, for the Part D low-income subsidy, and attest that they cannot find an affordable Part D plan, before qualifying for PAP A assistance.

[5]In some geographic regions, patients may qualify for PAP A assistance with incomes up to 340% of the Federal poverty level.

[6]Requestor has certified that, if it were to expand PAP A to include patients with other types of insurance for outpatient prescription drugs, those insured patients would also be required to meet the additional 3% spending test.

[7]Requestor applies the same additional test to Medicare beneficiaries who have not enrolled in Part D and has proffered the same rationale with respect to evaluating financial need.

year, even if the patient's use of the drug is periodic. A patient's eligibility for assistance in subsequent years is reassessed each year, and assistance does not begin until the patient has met the eligibility criteria in that year.

PAP A employs the services of a specialty mail order pharmacy to dispense the free drugs.[8] Requestor has certified that some of these drugs require special handling (e.g., refrigeration or other storage restrictions) that renders them unsuitable for certain shipping methods or unattended delivery. Based on the patient's preference, the specialty pharmacy ships the drugs directly to the patient or to the patient's physician.[9] Patients receive the drugs free of charge and without any information regarding their value or cost.

PAP B

Under the Arrangement, Requestor uses PAP B to provide free outpatient prescription medications to eligible PAP B enrollees (including Part D enrollees) for a broad spectrum of indications other than cancer and hepatitis. With the exception of Medicare beneficiaries enrolled in Part D, patients do not qualify for PAP B assistance unless they lack insurance coverage for outpatient prescription drugs.[10] To qualify for assistance from PAP B, patients must use one or more of PAP B's covered drugs and demonstrate financial need. PAP B assesses qualifying financial need using two tests. First, all PAP B applicants must have an income below 250% of the Federal poverty level. In addition, Part D enrollees who apply for PAP B assistance must meet a further test: they must have

---

[8]The medications are first transferred from Requestor to a charitable organization. The charitable organization contracts with the specialty pharmacy to ship the medications. Requestor underwrites the administrative costs of this dispensing arrangement. We have not been asked to opine upon, and we express no opinion regarding, any agreements between or among PAP A, the charitable organization, or the specialty pharmacy.

[9]PAP A allows any duly licensed physician of the patient's choosing to serve as a recipient of the medications. The physician does not receive any compensation directly or indirectly for receiving the medications from the specialty pharmacy and transferring them to the patient. Pursuant to a notice sent by PAP A, participating physicians agree that they will not bill any party for medications provided free from the PAP. All medications shipped under the Arrangement are clearly designated for use by a particular patient. Quantities of medications shipped under the Arrangement are limited to the amount ordered for the designated patient, and, except in one limited circumstance, do not exceed the usual therapeutic quantity necessary for one month of treatment. Participating physicians also must agree that they will dispense the medications only for use by the designated patient.

[10]Pursuant to the Arrangement, Medicare beneficiaries who have not enrolled in Part D cannot qualify for PAP B unless they have applied, and been rejected, for the Part D low-income subsidy and have attested that they cannot find an affordable Part D plan.

already spent at least three percent (3%) of their household income on outpatient prescription drugs that coverage year.[11] Requestor has certified that this additional financial need test reflects the generally different levels of potential exposure to out-of-pocket health care and drug costs faced by uninsured and Part D enrollees with comparable income levels.[12]

Requestor has certified that assistance is 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, assistance continues 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 is reassessed each year, and assistance does not begin until the patient has met the eligibility criteria in that year.

PAP B ships the drugs to the patient's physician. The patient then picks up the drugs from the physician.[13] Patients receive the drugs free of charge and without any information regarding their value or cost.

Coordination with Coverage Under Medicare Part D

The PAPs maintain accurate and contemporaneous records of all drugs provided to Part D enrollees. The PAPs coordinate the assistance they provide with coverage under

[11]Requestor has certified that, if it were to expand PAP B to include patients with other types of insurance for outpatient prescription drugs, those insured patients would also be required to meet the additional 3% spending test.

[12]Requestor applies the same additional test to Medicare beneficiaries who have not enrolled in Part D and has proffered the same rationale with respect to evaluating financial need.

[13]PAP B allows any duly licensed physician of the patient's choosing to serve as a recipient of the medications. In order to participate, the physician must sign a participation agreement with the Requestor. The physician does not receive any compensation directly or indirectly for receiving the medications and dispensing them to the patients. Participating physicians must also agree that they will not bill any party for medications provided free from PAP B. All medications shipped under the Arrangement are clearly designated for use by a particular patient. Quantities of medications shipped under the Arrangement are limited to the amount ordered for the designated patient and in almost all cases do not exceed the usual therapeutic quantity for three months of treatment. Participating physicians must also agree that they will dispense the medications only for use by the designated patient.

Medicare Part D. The free drugs do not count as drug expenses incurred by the enrollee.[14] Once an enrollee begins receiving a drug for free from PAP A or PAP B, such assistance continues for the remainder of that year and neither Medicare, nor any Part D plan or enrollee, is charged for provision of that drug to the enrollee for the remainder of the coverage year. Requestor has certified that the PAPs are working with the Centers for Medicare and 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 will ensure that neither Medicare nor any Part D plan will pay for the free drugs and also will allow the patient's Part D plan to conduct appropriate drug utilization and medication therapy management activities. The PAPs also provide the patients with a written notice that they are 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 drugs do 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" 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.

---

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

B. Analysis

As we observed in our recent Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees (70 Fed. Reg. 70623 (November 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, the Requestor operates the PAPs entirely outside of the Part D benefit. Operating outside of the Part D benefit means the enrollees obtain their drugs without using their Part D insurance benefit. No claims for payment for the drugs provided outside the Part D benefit are filed with a Part D plan or the beneficiary, and the assistance does not count toward the enrollee's TrOOP or total Part D spending for any purpose. Having reviewed the Arrangement, we conclude that the Arrangement contains safeguards sufficient to ensure that the PAPs operate entirely outside the Part D benefit, and, therefore, there is minimal risk of fraud and abuse under the Part D program.[15]

First, the PAPs notify enrollees' Part D plans that the free drugs are being provided outside the Part D benefit. The PAPs will accomplish this via data sharing agreements with CMS. In conjunction with the PAPs' patient notification procedure, this data arrangement helps ensure that no payment is made for the free drugs by Medicare or by any Part D plan, and no part of the cost of the free drug is 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 is determined based solely on patients' financial need, using a methodology (i.e., percent of Federal poverty level combined with percent of household revenues spent on drugs) that is entirely divorced from considerations related to a Part D enrollee's choice of Part D plan, the benefit design

---

[15]The facts of the 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. In addition, we caution that we might reach a different result were we to evaluate an arrangement similar to the Arrangement arising other than in the Part D context.

of the enrollee's Part D plan, or where a Part D enrollee is on his or her Part D plan's benefit spectrum.[16] For Part D enrollees, financial need is 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.[17] Moreover, the PAPs 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),[18] and the PAPs continue to provide assistance even if the patient's use of the free drug is periodic during the coverage year. In addition, the PAPs operate, and will continue to operate, in compliance with all then-existing guidance from CMS. Finally, the PAPs maintain accurate and contemporaneous records of the free drugs provided to the Part D enrollees. This facilitates appropriate transparency and accountability.

Taken as a whole, these safeguards substantially mitigate the risk (1) that the free drugs are or will be used to tie Medicare beneficiaries to particular outpatient prescription drugs

---

[16]The additional 3% spending test for Part D enrollees appears to be reasonably related to the financial need of these patients with outpatient prescription drug coverage and sufficiently unrelated to any particular Part D plan benefit. Requestor also uses the additional 3% spending test for Medicare beneficiaries who have not enrolled in Part D, and therefore are uninsured 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"). Accordingly, application of the additional 3% test to these beneficiaries, as well as the requirements related to applying for the low-income subsidy and attesting to the absence of an affordable Part D plan option, are decisions of the Requestor that are neither compelled by, nor material to the outcome of, this advisory opinion. Moreover, we would likely reach the same outcome in this advisory opinion were Requestor, in the future, to eliminate the 3% test for all PAP A and PAP B applicants (thus relying solely on the income level tests described above to assess financial need).

[17]The 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 and hepatitis 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.

[18]We note that this feature of the Arrangement 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.

payable by the Medicare Part D program; or (2) that the free drugs are or will 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).

We note that the use of physicians to distribute free drugs from pharmaceutical manufacturer PAPs could potentially create additional risk under the anti-kickback statute if the free drugs were to inure to the economic benefit of the physicians. However, in this instance, the risk is mitigated by several safeguards, including the designation of the drugs for use only by particular patients, limitations on the quantities shipped, the physicians' agreement to dispense the drugs only to designated patients and to refrain from billing for the drugs, and the notification processes for both the Part D plans and enrollees.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the 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 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 Arrangement. This opinion is limited to the 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 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 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 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