DEPARTMENT OF HEALTH AND HUMAN SERVICES **Office of Inspector General**

Washington, D.C. 20201

[*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: March 30, 2007

Posted: April 6, 2007

[name and address redacted]

Re: OIG Advisory Opinion No. 07-04

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a pharmaceutical company's patient assistance programs, which will provide free 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 will 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 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") is a wholly-owned subsidiary of [name redacted], a pharmaceutical company that manufactures and markets numerous prescription drug products.[1] For several years, Requestor has operated various patient assistance programs (collectively referred to herein as the "PAPs") that provide some of Requestor's drugs for free to qualifying financially-needy patients who lack insurance coverage for outpatient prescription drugs. Under the Proposed Arrangement, Requestor will expand eligibility for its PAPs to include financially-needy Medicare beneficiaries who are enrolled in a Part D plan.[2]

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

[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. The exclusion from the PAPs of Medicare beneficiaries who elect not to enroll in Part D is not required by this opinion or by any Federal law or regulation. Indeed, 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 for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005).

The following describes how the PAPs will operate under the Proposed Arrangement for Part D enrollees. Requestor will use its PAPs to provide certain of Requestor's drugs for free to eligible PAP applicants who are Part D enrollees.[3] PAP applicants must meet a number of eligibility criteria in order to participate.[4] To qualify for assistance from the PAPs, each patient must use one or more of the PAPs' covered drugs and demonstrate financial need. The Requestor will define qualifying financial need based on household income levels below set multiples of the Federal poverty level.[5] In addition to the income level tests, Part D enrollees must meet a certain spending test in order to qualify for assistance from the PAPs. To meet the spending threshold, a Part D enrollee applicant must have incurred outpatient prescription drug costs equal to 4% of household income during the coverage year and must anticipate, absent participation in the PAPs, that he or she will incur costs equal to or exceeding 10% of household income on outpatient prescription drug costs that coverage year. Requestor has certified that this additional financial need test will reflect the generally

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[3]The PAPs will offer approximately [number redacted] of Requestor's self-administered and physician-administered prescription drug products. Some uses of these drugs may involve physician administration under Medicare Part B. The Proposed Arrangement is limited to the uses of these drug 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 drug product. The PAPs will 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 the PAPs, the PAPs will help the patient explore whether the patient may be eligible for the Part D low-income subsidy and, if the patient appears to be eligible, will help the patient apply for the subsidy, as appropriate. For Medicare beneficiaries with incomes below 135% of the Federal poverty level, the PAPs will require a showing that the beneficiary was denied the Part D low-income subsidy or is ineligible for the subsidy. Medicare beneficiaries who are eligible for the Part D low-income subsidy or are dually eligible for Medicare and Medicaid will not qualify for assistance from the PAPs.

[5]The PAPs will assess qualifying financial need for all enrollees using certain income level tests. For instance, PAPs for self-administered drugs will admit patients with an annual income of 200% of the Federal poverty level or less and PAPs for physician-administered drugs will admit patients with an annual income of 275% of the Federal poverty level or less. Requestor has certified that the financial need tests are applicable to all of the PAPs' beneficiaries, not only those beneficiaries enrolled in Part D.

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.[6]

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

An enrollee may receive self-administered drugs either from a physician of the enrollee's choice or from any duly licensed retail pharmacy of his or her choosing through the use of a PAP's retail-based pharmacy program.[7] A PAP enrollee will receive physician-administered drug products directly from the physician of the enrollee's choice. In the case of self-administered drugs dispensed by a pharmacy, the patient will present a valid prescription from the patient's prescribing physician, and the pharmacy will dispense up to a 30-day supply of the PAP drug. According to the Requestor, the pharmacy will receive fair market value for providing the applicable PAP drug. When drugs are shipped directly to the

[6]Requestor does not intend to expand its PAPs to include other patients with some insurance for outpatient prescription drugs.

[7]We have not been asked to opine upon, and we express no opinion regarding the retail-based pharmacy program, or any agreements between or among the Requestor, the PAPs, dispensing physicians, or any pharmacy.

patient's physician, the patient will pick up the drugs from the physician.[8] In all circumstances, patients will receive the drugs free of charge and without any information regarding their value or cost.

The PAPs will maintain accurate and contemporaneous records of all drugs provided to Part D enrollees. The PAPs will coordinate the assistance they provide with coverage under Medicare Part D. The free drugs will not count as drug expenses incurred by the enrollee. This means that the value of free drugs does not count as true out-of-pocket spending ("TrOOP") under the Part D program. Once an enrollee begins receiving a drug for free from the PAPs, such assistance will continue for the remainder of that year and neither Medicare, nor any Part D plan or enrollee, will be charged for provision of that drug to the enrollee for the remainder of the coverage year. Requestor has certified that the PAPs will work with the Centers for Medicare and Medicaid Services ("CMS") to use a data sharing agreement 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 will also provide the patients with a written certification that will: notify them that they will be eligible to receive the free drug from the PAPs for the remainder of the coverage year and that the drugs should not be reimbursed by the enrollee's Part D plan; require the patient to certify that he or she will not attempt to submit any claims for the drugs received; and acknowledge that the 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.

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[8]In the case of drugs shipped directly to a physician (including certain self-administered and physician-administered drugs), the PAPs will allow any duly licensed physician of the enrollee's choosing to serve as a recipient of the medications. The physician will not receive any compensation directly or indirectly for receiving the medications from Requestor and transferring them to the enrollee. Participating physicians will provide the PAPs with an attestation that they will not bill any party for medications provided free from the PAPs. All medications shipped under the Proposed Arrangement will be clearly designated for use by a particular enrollee. Quantities of medications shipped under the Proposed Arrangement will be limited to the amount ordered for the designated patient, and will not exceed a 90-day supply of the PAP drug. Participating physicians also must agree that they will dispense the medications only for use by the designated patient.

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.[9]

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[9]Section 1128A(a)(5) of the Act provides for the imposition of civil monetary penalties against any person who gives something of value to a Medicare or Medicaid program beneficiary that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by 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 other entities that file claims for payment under the Medicare or Medicaid programs. The Proposed Arrangement will 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) will not be implicated by the Proposed Arrangement.

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, the Requestor proposes to operate its PAPs entirely outside of the Part D benefit. This means the enrollees will obtain their drugs without using their Part D insurance benefit. No claims for payment for the drugs to be provided outside the Part D benefit will be filed with a Part D plan or by an enrollee, and the assistance will not count toward the enrollee's TrOOP or total Part D spending for any purpose. Having reviewed the Proposed Arrangement, we conclude that the Proposed Arrangement contains safeguards sufficient to ensure that the PAPs will operate entirely outside the Part D benefit, and, therefore, there is minimal risk of fraud and abuse under the Part D program.[10]

First, the PAPs will notify enrollees' Part D plans that the free drugs are being provided outside the Part D benefit. The PAPs will accomplish this via a data sharing agreement with CMS. In conjunction with the PAPs' patient certification 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.

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[10]The 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.

Second, eligibility for the PAPs' assistance for Part D enrollees will be determined based solely on patients' financial need, using a methodology (i.e., percent of Federal poverty level and expenses) that will 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.[11] For all PAP 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.[12] Moreover, the PAPs will 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),[13] and the PAPs will continue to provide assistance even if the patient's use of the free drug is periodic during the coverage year. In addition, the PAPs will operate so as to remain in compliance with all then-existing guidance from CMS. Finally, the PAPs will maintain accurate and contemporaneous records of the PAPs' drugs provided to the Part D enrollees. This will facilitate appropriate transparency and accountability.

Taken as a whole, these safeguards substantially mitigate the risk: (1) that the PAPs' drugs will be used to tie Medicare beneficiaries to particular outpatient prescription drugs payable by the Medicare Part D program; or (2) that the PAPs' drugs will be used to increase costs to the Medicare Part D program (for example, by increasing the number of beneficiaries who

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[11]The additional spending test for Part D enrollees appears to be reasonably related to the financial need of the PAPs' patients with outpatient prescription drug coverage and sufficiently unrelated to any particular Part D plan benefit. Application of the additional spending test to these beneficiaries, as well as the requirements related to applying for the low-income subsidy, are business 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 additional spending test for its PAPs' applicants and rely solely on income level tests to assess financial need.

[12]The fact that PAPs may have different income eligibility levels for certain types of PAP drugs appears reasonable given the difference in the relative magnitude of expenditures likely to be incurred by patients in the PAPs (i.e., those patients taking expensive physician-administered drugs may experience greater overall financial need related to their health care), and does not appear related to any Part D benefit.

[13]We 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.

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).

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 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 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