



[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: July 21, 2009

Posted: July 28, 2009

[Name and address redacted]

Re: OIG Advisory Opinion No. 09-08

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a proposed institutional patient assistance program that would make certain drug products available to people without prescription drug coverage through the provision of replacement stock to certain participating disproportionate share (“DSH”) hospitals (the “Proposed Arrangement”). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for sanctions under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Social Security Act (the “Act”), or under the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision 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 supplemental submissions, 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: (i) the Proposed Arrangement would not constitute

grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while 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, 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 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.

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 pharmaceutical and healthcare company that develops, manufactures, and markets pharmaceutical products. Requestor’s products are reimbursable under Federal health care programs, including Medicare and Medicaid. Requestor 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.

Under the Proposed Arrangement, Requestor will create an Institutional Patient Assistance Program (the “Program”) that will make available at no charge certain of its drug products to indigent patients without prescription drug coverage.¹ The Program will operate by providing bulk replacement of drugs to outpatient pharmacies at participating hospitals (individually a “Participating Hospital” and collectively “Participating Hospitals”) on a quarterly basis. The bulk replacement drugs provided under the Proposed Arrangement (the “Program Drugs”) will replace drugs that Participating Hospitals will have dispensed to eligible patients during the preceding quarter.

Participation in the Program will be limited to Participating Hospitals’ patients who meet certain criteria (“Qualified Patients”). Specifically, Qualified Patients must have incomes at or below 250 percent of the Federal Poverty Level Guidelines, and not have any prescription drug coverage through any private or public insurer or other third-party

¹ Requestor selected the drugs that will be covered by the Program because they are costly and address a variety of disease states that are prevalent among the indigent populations targeted by the Program.

payor, including Medicare, Medicaid, or any other Federal health care program.² Qualified Patients must have a valid prescription from a licensed health care provider. In addition, Qualified Patients will not include inpatients at Participating Hospitals or any other patients for whom a Participating Hospital has a legal or statutory duty to provide drugs. Qualified Patients must be residents of the United States.

Requestor will choose hospitals to participate in the Program that serve the largest populations of uninsured, indigent patients who would be eligible for the Program. Requestor states that the hospitals with the largest numbers of uninsured and indigent patients are typically also the hospitals that have neither the time nor the resources to individually enroll large numbers of indigent patients into Requestor's existing patient assistance programs ("PAPs").

Requestor will invite interested hospitals with 500 or more beds to participate in the Program based on their DSH percentage ranking.³ Requestor will enter into written contracts with a total of no more than 100 DSH hospitals over the course of three years. Requestor will enroll 33 DSH hospitals in the Program in each of the first two years, and 34 in the third year. Neither a hospital's past, present, or future volume or value of purchases of Requestor's products, nor its formulary placement of Requestor's products will be considered in any way in Requestor's selection of hospitals to participate in the Program or in the ongoing operations of the Program. Under the contract, Requestor can only remove a Participating Hospital from the Program for breach of its agreement with Requestor regarding the Program.

Participating Hospitals will receive no direct compensation from Requestor, such as administration or dispensing fees. Likewise, physicians who prescribe Program Drugs will not receive any compensation from Requestor. Requestor has certified that there are no other arrangements or understandings between or among the Requestor and Participating Hospitals or their physicians in connection with the Proposed Arrangement.

Participating Hospitals will be able to receive Program Drugs on behalf of Qualified Patients without charge up to a maximum annual limit of \$2,000,000 per Participating Hospital. The annual limit will be based on the wholesale acquisition cost, also known as WAC, of the Program Drugs in effect as of the date that the Program Drugs are provided by Requestor to the Participating Hospital. Participating Hospitals will be able to order Program Drugs in any combination to replace drugs dispensed to Qualified Patients until the annual limit of \$2,000,000 is reached.

² For example, Medicare beneficiaries with Part D will be excluded from participating in the Program, but Medicare beneficiaries without Part D could be eligible for the Program.

³ Requestor will consider each hospital's DSH percentage as defined in 42 C.F.R. § 412.106(b).

Requestor will enter into an agreement with an as-yet-to-be-identified outside vendor (the “Program Administrator”) that will be responsible for the day-to-day administration of the Program. Requestor intends to select the Program Administrator using a Request for Proposal process, and Requestor will require that the Program Administrator, in its role as a PAP administrator, will function independently of Requestor’s commercial interests (i.e., its non-PAP interests). The Program Administrator will screen each hospital interested in participating in the Program, collect the hospital enrollment documents for each hospital, and verify all of the supporting documentation in each hospital’s enrollment documents. Participating Hospitals will submit their orders for Program Drugs to the Program Administrator, which will be responsible for reviewing and approving quantities of Program Drugs to be shipped to each Participating Hospital. Requestor will not be involved in the day-to-day approval of orders under the Program. Requestor has certified that the Program Administrator will ensure that Participating Hospitals are using the Program Drugs only for Qualified Patients through audits. Specifically, the Program Administrator will screen each Participating Hospital’s request for Program Drugs to ensure that: each requested Program Drug is available through the Program; there is no duplication of patients with the same Program Drug request within the same date range; and the quantity of the Program Drug is within that Participating Hospital’s \$2,000,000 annual limit. In addition, the Program Administrator will audit the drug utilization reports submitted by Participating Hospitals, as described below. The Program Administrator on a regular basis will conduct audits of patient samples to determine whether individual patients satisfy the patient eligibility criteria, but it will not audit every patient participating in the Program.

Whereas Requestor will develop the criteria governing who is a Qualified Patient, it will be up to each Participating Hospital to determine if a particular patient meets those criteria, and each Participating Hospital will be responsible for ensuring that Program Drugs are only provided to Qualified Patients. Participating Hospitals will not have to communicate all of a patient’s eligibility information to Requestor on a patient by patient basis as is required for enrollment in existing PAPs. However, as a condition of participation in the Program, Participating Hospitals will have to agree to periodic audits by the Program Administrator to further ensure that only Qualified Patients receive Program Drugs. A Participating Hospital may not order Program Drugs to replace any drugs provided to any of its other patients. Finally, a Participating Hospital may not sell Program Drugs or order Program Drugs to replace drugs for which it charged anyone.

Participating Hospitals also will be required to submit to the Program Administrator a summary report of all Program Drugs dispensed by the Participating Hospital to Qualified Patients during the preceding month (the “Utilization Report”). Each Utilization Report will include the following information for each prescription for which the Participating Hospital seeks replacement with Program Drugs: a patient identification number that is unique to the Participating Hospital and no other patient identifying information; the National Drug Code (“NDC”) number for each Program Drug; the units dispensed to each

Qualified Patient; and the date each prescription was filled. The Utilization Reports will be signed by the Medical Director or Pharmacy Director of each Participating Hospital, which signature will be the Participating Hospital's certification that the information in the Utilization Report is true and accurate and that each of the patients listed on the Utilization Report is a Qualified Patient.

The Program Administrator will direct Requestor's distribution facilities regarding what quantities of Program Drugs are approved for shipment to Participating Hospitals. Requestor or the Program Administrator will be responsible for filling orders for Program Drugs from Participating Hospitals, and shipping Program Drugs to Participating Hospitals.

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.

Section 1128A(a)(5) of the Act (the "CMP") provides for the imposition of civil monetary penalties against any person who gives something of value to a Medicare or state health care program, including Medicaid, 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 a state health care program, including Medicaid. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs.

B. Analysis

1. The Anti-Kickback Statute

PAPs sponsored by pharmaceutical manufacturers have long provided important safety net assistance to uninsured patients of limited means, including Medicare beneficiaries who do not have outpatient prescription drug coverage.⁴ The Program is a “bulk replacement” model PAP, which is different from PAPs that provide assistance directly to patients. As OIG previously has observed, bulk replacement model PAPs—also known as institutional PAPs—allow health care facilities such as pharmacies, health centers, and clinics to obtain bulk quantities of medications for qualifying uninsured patients seen at their institutions rather than applying for each patient individually. See Special Advisory Bulletin: Patient Assistance Programs for Part D Enrollees, 70 F. R. 70623, 70628 (Nov. 22, 2005). Bulk replacement PAPs, as contrasted with individual patient enrollment PAPs that require hospitals to communicate each patient’s eligibility information to the PAPs on a patient by patient basis, can represent a more efficient and practical means for health care providers to ensure that financially-needy patients get enrolled for PAP assistance.

Here, the central concern is whether the Program may be a vehicle through which Requestor offers or pays remuneration to Participating Hospitals either: (1) to induce Participating Hospitals to purchase or order (or arrange for, or recommend, the purchasing or ordering of) the Requestor’s products that are payable by a Federal health care program; or (2) to influence the prescribing patterns of physicians at Participating Hospitals with respect to the Requestor’s products that are payable by a Federal health care program. Participating Hospitals will be in a position to generate Federal health care program business because they treat Federal health care program patients, purchase and dispense pharmaceutical products that may be payable by Federal health care programs, and have physicians who prescribe pharmaceutical products that may be payable by Federal health care programs. Thus, there is a risk that Requestor could be using the Program to provide Program Drugs for Qualified Patients as an inducement to Participating Hospitals to purchase or prescribe Requestor’s drugs for other patients. We believe these risks are low in the Proposed Arrangement for a combination of the following reasons.

⁴ Some PAPs also provide assistance to financially-needy patients with prescription drug coverage who need assistance affording their cost-sharing or premium amounts.

First, the manner in which Requestor will invite hospitals to join the Program will not be related to any hospital's utilization of Requestor's products, and a hospital's participation in the Program will not be conditioned on where Requestor's products rank on a hospital's formulary. Rather, Requestor's plan to issue invitations to join the Program based on a hospital's size and DSH percentage ranking appears reasonably calculated to allow the Program to benefit as many indigent patients as possible while minimizing the Program's administrative costs. Participating Hospitals will retain control over their own formularies; Participating Hospitals will not be asked or required to improve the formulary rank of any of Requestor's products. In sum, the Program will ensure that Participating Hospitals' overall utilization of Requestor's products is decoupled from participation in the Program: Requestor has certified that a hospital's past, present, or future volume or value of purchases of Requestor's products will not be considered in any way in Requestor's selection of hospitals to participate in the Program or in the Program's ongoing operations, and once a hospital becomes a Participating Hospital, Requestor will have no ability to use continued participation in the Program as a means of rewarding or punishing it for increases or decreases in purchases of Requestor's products.

Second, the Program is structured so that Program Drugs merely pass through Participating Hospitals, which safeguards against the risk that Participating Hospitals might obtain excess stocks of drugs from which they could benefit. The Proposed Arrangement will be limited to the provision of outpatient prescription drugs, and the Requestor will ship these Program Drugs each quarter based on amounts dispensed to Qualified Patients during the previous quarter. In essence, Participating Hospitals will serve as conduits for the Program to dispense Program Drugs to Qualified Patients. The Program Administrator will conduct audits to further ensure that only Qualified Patients receive Program Drugs.

Third, Participating Hospitals will receive no administration, dispensing, or other fees in connection with the Program. In addition, Participating Hospitals will not have the opportunity to use Program Drugs to generate remuneration because they will be prohibited from selling Program Drugs or ordering Program Drugs to replace drugs for which they charge anyone. Nor does the Program provide remuneration to Participating Hospitals by offsetting costs for drugs for which the Participating Hospitals receive payment from Medicare or other payors, such as hospital inpatients covered by Part A.⁵

⁵ It is possible that some Participating Hospitals would be relieved of costs for drugs they have theretofore elected to purchase and voluntarily provide for uninsured patients. While Participating Hospitals may initially benefit from the relief of these costs for uninsured care, the Program, taken as a whole, contains safeguards sufficient to mitigate the risk that it would be a vehicle to reward Hospitals for their referrals. Further, any relief of costs previously devoted to uninsured care could have the salutary effect of increasing the availability of other charity care.

Fourth, the structure of the Program limits the risk that Requestor could influence the prescribing patterns of physicians at Participating Hospitals to generate business for Requestor's products that are payable by a Federal health care program. The Proposed Arrangement contains no mechanism to reward physicians for prescribing Program Drugs. The Program will not be available to patients with prescription drug coverage through any Federal health care program; therefore, the physicians prescribing drugs to Qualified Patients will not be able to generate Federal health care program business for Requestor as to those patients. Furthermore, Requestor has certified that there are no other arrangements or understandings between or among Requestor and Participating Hospitals or their physicians in connection with the Proposed Arrangement, such as requiring physicians at Participating Hospitals to prescribe Requestor's products to patients who have prescription drug coverage.

Fifth, the Program will be transparent, with the terms documented in a written, signed agreement between Requestor and each Participating Hospital that covers all of the Program Drugs to be provided. Requestor will engage an independent Program Administrator to manage the Program and scrutinize its operations to ensure that the Program Drugs are, in fact, dispensed to the Qualified Patients who are the intended beneficiaries of the Requestor's largesse. Each Participating Hospital will be obligated to provide the Program Administrator with Utilization Reports signed by its Medical Director or Pharmacy Director certifying that Program Drugs are only replacing drugs provided to Qualified Patients, and each Participating Hospital will be audited regularly.

Sixth, the ultimate recipients of the Program Drugs are solely those financially-needy patients who lack outpatient prescription drug coverage. Providing remuneration on the basis of payer status or ability to pay can be problematic; however, here the Program Drugs will be targeted at vulnerable, needy patients who are presenting at hospitals that typically lack the time and resources to individually enroll large numbers of indigent patients into Requestor's existing PAPs. Finally, the Proposed Arrangement will help ensure the availability of drug products for otherwise underserved patients. Donations of drugs by pharmaceutical companies can play an important role in strengthening the health care safety net.

2. The CMP

We also examine the Proposed Arrangement for implications under the CMP prohibiting inducements to beneficiaries. We find none.

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. Therefore, the Proposed Arrangement does not implicate the CMP as to any beneficiary’s choice of Requestor’s products.

Moreover, regarding the Proposed Arrangement’s potential to influence Medicare or Medicaid beneficiaries to choose Participating Hospitals, we make two observations. First, the CMP is not implicated with respect to Medicaid beneficiaries and Medicare beneficiaries with Part D or other outpatient prescription drug coverage because such beneficiaries will not be eligible to receive free Program Drugs. Second, to the extent that any financially needy Medicare beneficiaries without outpatient prescription drug coverage receive free Program Drugs,⁶ they will be supplied by the Requestor and not the hospital, which serves only as a conduit for a PAP into which the beneficiary otherwise could enroll individually with greater difficulty and less efficiency. Therefore, we conclude that the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under the CMP.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while 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, 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, therefore, we express no opinion about any ancillary agreements

⁶ Many financially-needy Medicare beneficiaries qualify for Part D’s low income subsidy and can thus obtain Part D coverage for low cost and minimal if any copayment obligations. For this reason, we expect that relatively few Medicare beneficiaries without outpatient prescription drug coverage would need the Program.

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 Requestor 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 Requestor 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,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General