[*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: June 27, 2006

Posted: June 30, 2006

[Name and address redacted]

Re: OIG Advisory Opinion No. 06-08

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding a free clinic's practice of dispensing drugs on behalf of patient assistance programs ("PAPs") sponsored by pharmaceutical manufacturers that provide free drugs to financially-needy patients, including some patients enrolled in the Medicare Part D outpatient prescription drug benefit (collectively, the "Arrangement"). Specifically, you have inquired whether the 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 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.

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: (i) the Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) 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 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.

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] (the "Requestor") is a non-profit, tax-exempt community-based free clinic in [state redacted] (the "State"). The Requestor provides free medical care, dental care, laboratory services, and other health care services to residents of the State who meet stringent financial need guidelines. With the exception of three salaried nurse practitioners,[1] the Requestor provides these services through volunteer physicians, dentists, nurses, pharmacists, and other medical practitioners, all of whom provide their services without compensation. The Requestor focuses its resources on uninsured patients; it does not treat insured patients, including Medicare and Medicaid patients.[2] Accordingly, the Requestor is not a Medicare or Medicaid provider. Indeed, the Requestor does not bill any patients or insurers and has no billing system.

Pursuant to State law, the Requestor operates an unlicensed pharmacy that maintains a stock of outpatient prescription drugs. The pharmacy dispenses the drugs free of charge to clinic patients, as well as to some financially needy individuals who are not otherwise clinic patients. In some circumstances, the Requestor dispenses free drugs to financially needy Medicare beneficiaries when the cost to the beneficiary of filling a prescription at a local

---

[1]The Requestor has certified that the nurse practitioners are bona fide employees who receive fair market value compensation that does not take into account the volume or value of prescriptions they write.

[2]In very rare circumstances related to continuity and quality of care, the Requestor will provide services to Medicaid patients (but will not bill Medicaid). Of 17,000 current patients, only two are Medicaid patients.

pharmacy would be prohibitive.[3] None of the prescriptions filled for Medicare beneficiaries is generated from care rendered at the free clinic; all prescriptions for Medicare beneficiaries derive from care the beneficiaries receive at settings other than the free clinic. The clinic pharmacy does not bill any patients or insurers for the drugs it dispenses. The clinic pharmacy only dispenses drugs subject to a valid prescription. The clinic pharmacy does not fill prescriptions for Medicaid beneficiaries.

Since the Requestor operates as a free clinic, without revenue from patients and insurers for services rendered, and obtains limited funding from other sources, the Requestor has little ability to purchase medications. The Requestor heavily relies on pharmaceutical manufacturer PAPs to stock its pharmacy with sufficient quantities of medications to fulfill its role as a free safety net provider for patients who lack the financial resources necessary to obtain care elsewhere. Historically, the Requestor has obtained the vast majority of its drug inventory (approximately 99%) from PAPs sponsored by pharmaceutical manufacturers.[4] In 2005, the Requestor purchased about 1% of its medication stock (at a total cost of $62,041) from wholesalers, typically generic products. In order to limit its drug expenditures and marshal scarce resources, where medically appropriate the Requestor requires its volunteer physicians (who only prescribe drugs for uninsured patients) to prescribe for clinic patients drugs that are available from the PAPs.

---

[3]The Requestor dispenses drugs to qualifying Medicare beneficiaries, regardless of whether they have enrolled in Part D. The Requestor may deem a drug prohibitively expensive for a particular beneficiary when the drug is not otherwise covered by the beneficiary's insurance plan, or when the drug is covered, but the beneficiary's cost sharing obligation exceeds the beneficiary's ability to pay. The Requestor seeks to conserve its drug stock to ensure availability for the patients with the greatest financial need and for whom the free clinic is the provider of last resort. If other sources of assistance are available to particular patients, the clinic might direct those patients to seek assistance from those alternate sources. Thus, before dispensing free drugs to a beneficiary enrolled in Medicare Part D, the free clinic might first require the beneficiary to explore ways to purchase an affordable, medically appropriate drug using his or her Part D benefit. For example, the clinic might ask the beneficiary to apply for the Part D low income subsidy; suggest that the beneficiary consult with his or her physician to determine whether it would be medically appropriate to switch to an alternative therapy that is affordable through the beneficiary's Part D plan; or ask the beneficiary to use the Part D plan's appeals process to secure affordable access to the existing therapy.

[4]Unlike some independent charitable programs, the pharmaceutical manufacturer PAPs provide only the sponsoring-manufacturer's products.

The free clinic dispenses drugs for two types of PAPs. For the first type of PAP, individual patients are enrolled with the PAP, and the PAP sends drugs to the Requestor to dispense to the enrolled patients (for purposes of this advisory opinion, "individual-model PAPs"). The individual-model PAP is responsible for establishing the eligibility criteria and checking and documenting patient eligibility for individual-model PAP enrollment. The Requestor receives no compensation from any PAP or PAP sponsor, directly or indirectly, for its role in dispensing the drugs. No insurer or patient is billed for any part of the drugs.

For the second type of PAP, the free clinic receives bulk shipments of free drugs, pursuant to an agreement to dispense the drugs to patients who meet the PAP's eligibility criteria (for purposes of this advisory opinion, "institutional PAPs"). The institutional PAP defines the eligibility criteria for patients to receive the free drugs, but, as the institutional PAP does not enroll particular patients, the free clinic is responsible for checking and documenting patient eligibility before dispensing the drugs.[5] The Requestor may dispense drugs from institutional PAPs to any patient it determines meets the institutional PAP's eligibility criteria. Because the vast majority of the Requestor's patients are uninsured and low income, virtually all of the Requestor's patients qualify. The Requestor receives no compensation from any PAP or PAP sponsor, directly or indirectly, in connection with its administrative or dispensing activities. No insurer or patient is billed for any part of the drugs.

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

---

[5]The institutional PAP sponsors periodically audit the records of the Requestor to ensure compliance with the eligibility criteria.

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 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. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of section 1128A(a)(5) as including "the waiver of coinsurance and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value."

B. Analysis

We begin by recognizing that patient assistance programs 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. Properly structured patient assistance programs can also help ensure that financially needy Medicare beneficiaries who enroll in the Part D outpatient prescription drug benefit can obtain the drugs they need.[6]

Here, the various PAPs that interact with the Requestor are not parties to the advisory opinion request, and, while nothing in the request suggests that the PAPs are problematic, we have insufficient information about them to determine whether they are, in fact, properly structured. We observe that it should not be difficult for pharmaceutical manufacturers to structure PAPs to provide drugs to Part D enrollees entirely outside the Part D benefit in a manner that poses little, if any, risk under the fraud and abuse laws. This would seem to be

---

[6]See, e.g., Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70627 (November 22, 2005), and OIG Advisory Opinion 06-03 (available at http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2006/AdvOpn06-03F.pdf).

particularly true when the drugs are dispensed through a free clinic with no ability to submit claims for dispensed drugs,[7] such as the Requestor.

In this opinion, we necessarily limit our inquiry to the Requestor's role in dispensing PAP drugs. In this regard, the first question presented is whether the Arrangement between the PAPs and the Requestor to dispense PAP drugs implicates the anti-kickback statute. In other words, the question is whether the Arrangement may be a vehicle through which the PAP sponsors offer or pay remuneration to induce the Requestor to purchase or order (or arrange for or recommend the purchasing or ordering of) the sponsors' products that are payable by a Federal health care program. For the reasons noted below, we conclude that the Arrangement would not constitute a vehicle to induce or reward referrals of Federal health care program business from the Requestor to any PAP sponsor.[8]

First, there is no apparent remuneration provided by the PAPs to the Requestor. The Requestor has certified that it accepts no compensation from any PAP for any dispensing or administrative services.[9] The Requestor does not benefit economically by selling any of the PAP drugs, since it does not bill patients or insurers for any items or services. Nor do the free drugs constitute remuneration in the form of relief from a financial obligation, since, while the free clinic has embraced providing free drugs as part of its charitable mission, it is under no obligation to do so. Moreover, while the Arrangement more generally benefits the Requestor through conservation of clinic funds that might otherwise be used to purchase medications, the benefit inures to the public good in the form of increased availability of health care items and services for an underserved population.

Second, the Requestor is not in a position to generate business for any PAP sponsor that would be payable by a Federal health program. Any prescriptions filled for Medicare

---

[7]The absence of a billing system should eliminate the risk that a drug provided by a PAP would be paid by Medicare Part D or count toward a beneficiary's true out-of-pocket costs (the "TrOOP") under the Part D benefit. See id. (discussing PAPs that operate outside the Part D benefit). We note, of course, that drugs need not be dispensed through a free clinic to be part of a properly structured PAP.

[8]For ease of reference in this opinion, we consider the PAPs and their sponsors sufficiently related to refer to them as one entity.

[9]We note that, in other contexts not relevant here, the provision of free dispensing, administrative, or other services furnished to an actual or potential referral source could constitute unlawful remuneration under the anti-kickback statute.

patients derive from care the beneficiaries receive at settings other than the free clinic.[10] While some of the physicians or other health care professionals who write these prescriptions may also volunteer at the clinic, none of them receives any compensation from the clinic. The clinic purchases a small volume of drugs from multiple manufacturers, some of which may be products manufactured by PAP sponsors, but none of these drugs is billed to any Federal health care program.

For these reasons, there is minimal risk that the Arrangement would involve impermissible payments from the PAP sponsors to the Requestor for Federal health care program business.

The second question posed by the Arrangement is whether the free clinic, by dispensing drugs obtained through the PAPs to Medicare beneficiaries, offers an impermissible inducement to the beneficiaries to generate business that would be payable by a Federal health care program. We conclude it does not. While beneficiaries receive something of value in the form of free drugs, there is no corresponding opportunity for the Requestor to influence these beneficiaries to obtain Federally payable items or services. The Requestor does not bill any Federal program for any items or services. Moreover, as noted previously, the Requestor is not in a position to influence beneficiaries to choose PAP sponsors' products payable by Federal health care programs.

Accordingly, we further conclude that there is minimal risk that the Arrangement would involve impermissible inducements to Federal health care program beneficiaries.

III. CONCLUSION

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

---

[10]The Requestor requires Part D enrollees to attempt to obtain an affordable, medically appropriate drug through their Part D plan before seeking free drugs from the clinic. In the circumstances presented here, we would not consider the Requestor to be generating Federal health care program business through this requirement. Moreover, any potential benefit to a PAP sponsor from business generated in this manner would be offset by the larger number of uninsured clinic patients who would be enrolled in the PAP for free drugs.

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