[*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: January 28, 2008

Posted: February 1, 2008

[Name and address redacted]

Re: OIG Advisory Opinion No. 08-01

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a non-profit corporation's program that arranges for pharmaceutical manufacturer patient assistance programs to provide donated drugs to free clinics and Federally qualified health centers (FQHCs) for use by financially-needy patients who do not have any form of outpatient prescription drug insurance coverage (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, as well as under the civil monetary penalty provision for violations of the prohibition against inducements to beneficiaries under section 1128A(a)(5) of the Act.

You have certified that all of the information provided in your request 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, we conclude that (i) 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 and (ii) the Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act. 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.

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] (the "Partnership") is a non-profit, tax-exempt corporation that serves as a liaison between the pharmaceutical industry and free clinics and FQHCs to improve access to free pharmaceutical products for low-income persons in [state redacted]. The Partnership is financed through an appropriation from [state redacted], contributions from individuals and foundations, and participation fees paid by affiliated free clinics and FQHCs.[1] On behalf of its affiliated free clinics and FQHCs, the Partnership seeks participation in various bulk replacement patient assistance programs (PAPs) sponsored by pharmaceutical companies that provide in-kind donations in the form of free drugs.

A pharmaceutical company that agrees to work with the Partnership enters into a written contract with the Partnership setting forth the terms and conditions pursuant to which the affiliated free clinics and FQHCs receive free drugs from the company's bulk replacement PAP. Under all of the agreements, the affiliated free clinics and FQHCs may distribute the donated PAP drugs only to patients whose incomes are less than 200% of the Federal Poverty Level ("FPL") and who do not have any form of outpatient prescription drug insurance.[2] Accordingly, donated PAP drugs may not be dispensed to Medicare Part D

[1]The Partnership received a total of $43,000 in cash contributions from pharmaceutical companies during 2004 and 2005, its start-up period, with no single contribution in excess of $7,500. Since then, the Partnership has not received cash contributions from the pharmaceutical industry, other than a $500 contribution from the Pharmaceutical Manufacturers of America in 2007. The total amount of pharmaceutical company cash contributions was never more than 11% of the Partnership's annual budget.

[2] One manufacturer permits Medicare patients who are eligible for, but not enrolled in, Medicare Part D to participate in its programs with the Partnership, while the other manufacturers exclude all Medicare patients from participation. [State redacted] Medicaid beneficiaries have coverage for outpatient prescription drugs and thus do not participate in

enrollees or Medicaid patients. As the bulk replacement PAPs do not enroll particular patients under this Arrangement, the affiliated free clinics and FQHCs are responsible for checking and documenting patient eligibility before dispensing the drugs. After an agreement is in place, the Partnership audits the free clinics and FQHCs at least annually to ensure that they maintain compliance with the requirements of the various participating PAPs.

The pharmaceutical company sponsors of the participating PAPs designate the particular drugs covered under the Arrangement and provide an initial supply of the selected drugs to the affiliated free clinics and FQHCs.[3] The pharmaceutical company sponsors generally replenish each free clinic's and FQHC's inventory for the covered drugs monthly, based on the amounts dispensed during the previous month to eligible patients.[4] In all cases, the drugs are shipped directly to the free clinics and FQHCs.

The agreements prohibit the free clinics and FQHCs from selling any donated PAP drugs and from transferring any PAP drugs to any third party other than the qualifying patients.[5] To that end, the Partnership submits a monthly summary report to the pharmaceutical company sponsor of each participating PAP, providing detailed information about the PAP drugs dispensed to eligible patients during the previous month. The report includes the following information: the PAP drug name and National Drug Code number; the date each prescription was filled; each quantity dispensed; and a unique identification number for the patient to whom each prescription was dispensed.[6] In addition, each pharmaceutical company sponsor has the right to audit the records of the Partnership and affiliated free clinics and FQHCs for compliance purposes.

Free clinics and FQHCs affiliated with the Partnership must meet certain criteria. The Partnership selects the affiliated free clinics and FQHCs in its sole discretion. An affiliated free clinic or FQHC must operate its own licensed pharmacy that complies with all applicable Federal and state laws.[7] The pharmacies must maintain separate records on their

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the Arrangement.

[3] All of the drugs included in the various bulk replacement PAPs are self-administered, outpatient prescription drugs and are not eligible for coverage under Medicare Part B.

[4] In one agreement, the manufacturer makes monthly shipments based on projected usage, subject to periodic reconciliation based on actual usage.

[5] The free clinics and FQHCs are not permitted to bill any patient or insurer for the donated PAP drugs under the Arrangement; the donated PAP drugs are only dispensed to eligible patients free of charge.

[6] The reports do not give manufacturers any personal identifying information about qualifying patients or their prescribing health care professionals.

[7] Apart from their participation in the Partnership's programs, the free clinics are not obligated to provide free drugs to their patients. The free clinics have chosen to embrace

premises of all donated PAP drugs that they receive as an affiliate of the Partnership. The pharmacies must further maintain systems for separating inventory received as a Partnership affiliate from other drugs they receive. Lastly, the pharmacies must have computerized dispensing systems that have the capacity to generate reports necessary for auditing the dispensing of PAP drugs obtained through the Partnership.

Other criteria to qualify as an affiliated free clinic or FQHC include: (1) the free clinic or FQHC must be an Internal Revenue Code Section 501(c)(3) tax-exempt organization organized for the purpose of providing health services to low-income patients; (2) for purposes of distributing PAP drugs received through the Partnership to eligible patients, the free clinic or FQHC must agree to screen for patients whose income is at or below 200% of the FPL and who do not have any form of outpatient prescription drug insurance; and (3) the free clinic or FQHC must agree to cooperate with compliance monitoring of program requirements by the Partnership.

The affiliated free clinics and FQHCs may purchase drugs from multiple manufacturers that may include products manufactured by participating PAP sponsors. The free clinics and FQHCs are not required, however, to purchase any of the PAP sponsors' drugs to participate in the Partnership's program. The Partnership does not permit any of its staff or the staff of any participating PAP sponsors to be involved in the formulary decision-making process of any affiliated free clinic or FQHC.[8] The Partnership does not permit sales or marketing representatives of any participating PAP sponsor to communicate with affiliated free clinics and FQHCs, or their physicians and medical staff, with respect to the Arrangement; all such communications must be directed through the Partnership.

The affiliated free clinics and FQHCs encourage physician employees and volunteers to choose PAP drugs when prescribing for eligible patients in order to minimize the patients' financial hardship, but only in cases where the physician believes that the prescription is medically appropriate.[9] The physicians are not limited to prescribing drugs available

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providing free drugs as part of their charitable mission. The free clinics provide care only to uninsured individuals. As discussed further below, the FQHCs may furnish some drugs as part of the care they provide to FQHC patients funded by Public Health Service (PHS) section 330 grants. Like the free clinics, they provide drugs as part of their charitable mission. The FQHCs provide care to all patients in their service area, regardless of payer status.

[8] The Partnership has certified that the participating affiliated FQHCs shortly will adopt (if they have not already done so) a conflicts of interest policy that prohibits employees involved in the formulary decision-making process from accepting employment with, or remuneration from, any participating PAP sponsor. Adoption of such a policy by affiliated FQHCs will be a condition of participation in the Arrangement.

[9] All of the physicians working at the affiliated free clinics are unpaid volunteers, with the

through a PAP; each physician is free to exercise his or her independent professional judgment when making prescribing decisions. The Partnership has certified that any compensation paid by a free clinic or FQHC to a physician does not and will not take into account directly or indirectly the volume or value of prescriptions for PAP or other drugs.[10] The affiliated FQHCs and free clinics will provide written notice of the above statements to their paid physicians on an annual basis. The physicians receive no compensation from the Partnership or any PAP sponsor under the Arrangement.

Seventeen affiliated free clinics participate in the Arrangement. The Partnership has certified that it is in the process of adopting a policy that PAP sponsors must provide drugs uniformly to all participating affiliated free clinics: they cannot pick and choose the particular affiliated free clinics to which they donate PAP drugs. The affiliated free clinics receive no compensation from any pharmaceutical company, participating PAP, or the Partnership, directly or indirectly, for their drug dispensing or administrative activities under the Arrangement. The affiliated free clinics do not bill patients, nor do they bill Medicare, Medicaid, or any other third-party for their services. The affiliated free clinics treat only uninsured patients; they refer insured patients who present at the clinics to other providers.

Two affiliated FQHCs participate in the Arrangement.[11] Again, the Partnership has certified that shortly it will adopt a policy that PAP sponsors must provide drugs uniformly to all participating affiliated FQHCs: they cannot pick and choose the particular affiliated FQHCs to which they donate PAP drugs.[12] The affiliated FQHCs receive no compensation from any pharmaceutical company, affiliated PAP, or the Partnership, directly or indirectly, for their drug dispensing or administrative activities under the Arrangement.

The affiliated FQHCs, however, differ from the affiliated free clinics in that they receive federal funding under section 330 of the Public Health Service Act. Some portion of the

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exception of one clinic that employs a physician as a medical director. Physicians working at the FQHCs are paid employees. Some free clinics and FQHCs also employ nurse practitioners and physician assistants who are licensed to prescribe drugs to patients. For ease of reference, our use of the term "physician" throughout this opinion also includes these other practitioners with prescription-writing authority.

[10] The affiliated FQHCs do not track any physician prescribing patterns of PAP drugs.

[11] There are four affiliated FQHCs, but two of the affiliated FQHCs have chosen not to participate in the Arrangement pending the outcome of the Partnership's advisory opinion request. All four affiliated FQHCs are PHS section 330 grant recipients. See 42 U.S.C. § 254b.

[12] The availability of drugs under the PAPs is not conditioned on the volume or value of Federal health care program business generated by an FQHC or on the inclusion of other non-PAP products of the PAP sponsors on the FQHC's formulary.

grant funds may cover drugs. The FQHCs also participate in the Medicare and Medicaid programs. Medicare and the [state redacted] Medicaid program generally reimburse FQHCs on the basis of all-inclusive rates per visit. 42 C.F.R. §405.2462; [state law citation redacted]. The FQHCs operate pharmacies that may participate in Medicare Part D plans and receive payments for outpatient prescription drugs dispensed to Medicare Part D enrollees. See HRSA Contracting with Medicare Drug Plans for Safety Net Providers at http://www.hrsa.gov/medicare/contracting.htm. Similarly, the FQHCs may bill Medicaid separately for self-administered prescription drugs dispensed to Medicaid recipients. [State law citation redacted.] Under the Arrangement, however, donated PAP drugs may not be dispensed to Medicare Part D enrollees or Medicaid patients. Thus, the affiliated FQHCs are not reimbursed by Medicare or Medicaid for PAP drugs distributed to qualifying patients.

The Partnership has certified that there are no other arrangements or understandings between or among the Partnership, the PAP sponsors, and the affiliated free clinics and FQHCs or their physicians in connection with the Arrangement.

II. LEGAL ANALYSIS

A. Law

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 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. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of section 1128A(a)(5) as including "transfers of items or services for free or for other than fair market value."

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referral 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 statue is violated. By its terms, the statue 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.

The Department of Health and Human Services (the "Department") has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

B. Analysis

The new safe harbor for certain FQHC arrangements, 42 C.F.R. § 1001.952(w), is potentially applicable here to the portion of the Arrangement involving FQHCs. While the Arrangement shares many features of the safe harbor, it does not fit squarely for several reasons. For example, under the Arrangement, the FQHCs are not required to make the requisite determinations regarding benefit to underserved populations, 42 C.F.R. § 1001.952(w)(3-4), and the free drugs offered by PAP sponsors are not offered to all FQHC patients regardless of payer status, 42 C.F.R. § 1001.952(w)(6). Notwithstanding, the failure to fit in a safe harbor is not fatal; arrangements that do not fit in safe harbors must be evaluated on a case-by-case basis based on the totality of facts and circumstances.

We begin by recognizing that 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. Here, the various bulk replacement PAPs that have arrangements with the Partnership 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. Accordingly, we necessarily limit our analysis in this opinion to the role of the Partnership and its affiliated free clinics and FQHCs in dispensing the PAP drugs to qualifying patients. As the Arrangement involves both free clinics and FQHCs, we

analyze the Arrangement with respect to each type of provider under the anti-kickback statute and section 1128A(a)(5) of the Act.

1. Arrangement Involving Affiliated Free Clinics

The central concern is whether the Arrangement may be a vehicle through which the pharmaceutical company PAP sponsors offer or pay remuneration to the Partnership or affiliated free clinics: (1) to induce the free clinics to purchase or order (or arrange for, or recommend, the purchasing of) the sponsors' products that are payable by a Federal health care program; or (2) to influence the prescribing patterns of the free clinic physicians with respect to the sponsors' products that are payable by a Federal health care program.

First, there is no apparent remuneration provided by the PAPs or PAP sponsors to the Partnership or its affiliated free clinics. The Partnership has received minimal financial support from the pharmaceutical industry – limited primarily to start-up costs – and is funded almost exclusively by affiliate fees and non-pharmaceutical industry contributions. The Partnership does not receive or distribute the donated drugs. The Partnership has certified that its affiliated free clinics receive no compensation from any PAP or PAP sponsor for any dispensing or administrative services. The affiliated free clinics cannot benefit economically by selling any of the PAP drugs, since they do not bill patients or insurers for any items or services, and they are prohibited from transferring the PAP drugs to anyone other than qualifying patients. Nor do the free drugs constitute remuneration in the form of relief from a financial obligation, since, while the affiliated free clinics have embraced providing free drugs as part of their charitable mission, they are under no obligation to do so. Moreover, while the Arrangement more generally benefits the affiliated free clinics through the 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 affiliated free clinics are not in a position to generate business for any PAP sponsor that would be payable by a Federal health care program. The affiliated free clinics treat only uninsured patients. None of the affiliated free clinics bills any Federal health care program for drugs they purchase. Additionally, compensation arrangements with employed physicians and other prescribers do not create any financial incentive to prescribe particular brands or types of drugs or otherwise create a financial benefit based on business generated for the PAP sponsors.

Concerning impermissible inducements to Medicare and Medicaid beneficiaries under the Arrangement, section 1128A(a)(5) of the Act prohibits offers or transfers of remuneration likely to induce a beneficiary to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made under the Medicare and

Medicaid programs. The affiliated free clinics do not bill Medicare or Medicaid for any items or services they provide, nor do they treat Medicare or Medicaid beneficiaries.[13] Accordingly, with respect to the affiliated free clinics, the Arrangement does not implicate the civil monetary penalty prohibiting beneficiary inducements.

In light of all of the foregoing considerations, we would not subject the Requestor to administrative sanctions in connection with the Arrangement as it applies to the affiliated free clinics under sections 1128A(a)(7) or 1128B(7) (as these sections relate to the anti-kickback statute) or 1128A(a)(5) of the Act.

2. Arrangement Involving Affiliated FQHCs

The Arrangement with the FQHCs raises the same basic concerns as the Arrangement with the free clinics. The Arrangement might be a vehicle through which the pharmaceutical company PAP sponsors offer or pay remuneration: (1) to induce the FQHCs to purchase or order (or arrange for, or recommend, the purchasing of) the sponsors' products that are payable by a Federal health care program; or (2) to influence the prescribing patterns of the FQHC physicians with respect to the sponsors' products that are payable by a Federal health care program. The concern is greater in the case of the FQHCs than the free clinics because the FQHCs are in a position to generate Federal health care program business: 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 a PAP sponsor could be using the Partnership to provide PAP drugs for eligible uninsured patients as an inducement to the FQHCs to purchase or prescribe the sponsor's drugs for other patients.

As with the free clinics, the FQHCs receive no compensation from any PAP or PAP sponsor for dispensing or administrative services under the Arrangement, and the FQHCs are not permitted to bill any insurer or patient for the PAP drugs. Thus, remuneration to the FQHCs, if any, under the Arrangement is indirect: for example, through the offsetting of drug costs otherwise borne by the FQHC. Notwithstanding the potential opportunities for affiliated FQHCs to generate Federal business for PAP sponsors and the potential remuneration to the FQHCs, a combination of features of the Arrangement mitigates the risk of improper kickbacks.

First, the structure of the Arrangement safeguards against the risk that the FQHCs might obtain excess stocks of drugs. The Arrangement is limited to the provision of outpatient

[13] To the extent that services might be provided to a Federal program beneficiary in the case of an emergency or administrative mistake, such isolated incidents do not raise significant concern.

prescription drugs, and the PAP sponsors ship the drugs monthly based on amounts dispensed to eligible patients during the previous month or based on projected usage (with subsequent reconciliation). In either case, the FQHCs do not obtain any surplus of donated PAP drugs. In essence, the FQHCs serve as conduits for dispensing PAP drugs to uninsured patients who meet the financial eligibility criteria of the PAPs themselves.

Second, the Arrangement is transparent, with the terms documented in a written, signed agreement between each PAP sponsor and the Partnership that covers all of the free drugs to be provided. PAP drugs are shipped to each FQHC pursuant to a fixed methodology that is unrelated to the volume or value of referrals of Federal business generated by the FQHC for the PAP sponsor. The FQHCs are required to segregate inventory[14] and maintain detailed electronic records that create an audit trail for the distribution of PAP drugs to PAP eligible patients. The PAP sponsors monitor those records for compliance.[15]

Third, the PAP sponsors do not control the selection of FQHCs to participate in the Arrangement. The Partnership determines in its sole discretion which FQHCs meet the criteria to become Partnership affiliates, and a pharmaceutical manufacturer that agrees to participate in the Arrangement must provide PAP drugs uniformly to all participating affiliated FQHCs. Accordingly, the Arrangement prevents PAP sponsors from cherry-picking certain FQHCs to receive donated drugs. The Partnership has certified that the availability of drugs under the PAPs is not conditioned on the volume or value of Federal health care program business generated by an FQHC or on the inclusion of other non-PAP products of the PAP sponsors on the FQHC's formulary.

Fourth, the physicians who prescribe drugs for FQHC patients do not receive any compensation that takes into account in any manner the physicians' prescribing patterns for PAP sponsors' products, and the FQHCs do not track any physician's prescribing patterns of PAP drugs. Physicians are encouraged to choose PAP drugs when prescribing for eligible patients in order to minimize the patients' financial hardship, but only where the physician believes the prescription would be clinically appropriate. The Partnership has certified that the affiliated FQHCs shortly will adopt a policy that paid physicians are made aware of these protections by written notice provided annually. In this manner, physician independent professional judgment is protected with respect to prescribing decisions.

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[14] This inventory segregation further reduces any risk that the FQHC might divert restocked PAP drugs to insured patients.

[15] The reports do not give manufacturers any personal identifying information about qualifying patients or their prescribing health care professionals. The Partnership provides line-item dispensing data to the manufacturer to safeguard against diversion of donated PAP drugs to ineligible patients.

Fifth, the Partnership insulates the FQHCs from the PAP sponsors. The Partnership does not permit any of its staff or the staff of any participating PAP sponsors to be involved in the formulary decision-making process of any affiliated FQHC. The participating affiliated FQHCs have adopted (or will soon adopt) a conflicts of interest policy that prohibits employees involved in the formulary decision-making process from accepting employment with, or remuneration from, any participating PAP sponsor. Moreover, the Partnership does not permit sales or marketing representatives of any participating PAP sponsor to communicate with affiliated FQHCs, or their physicians, with respect to the Arrangement; all communications about the Arrangement must be directed through the Partnership.

Sixth, the ultimate recipients of the drugs are solely those financially-needy patients who lack outpatient prescription drug coverage. Although providing remuneration on the basis of payer status or ability to pay can be problematic, here, the PAP drugs are targeted at precisely the type of vulnerable, financially-needy patients the FQHCs are commissioned to serve. Thus, the Arrangement does not involve the kind of cherry-picking of patients on the basis of payer status or ability to pay that raises concerns in other contexts.

Seventh, the Partnership has certified that there are no other arrangements or understandings between or among the Partnership, the PAP sponsors, and the affiliated FQHCs or their physicians in connection with the Arrangement (e.g., to the effect that FQHC physicians agree to prescribe the PAP sponsors' products to insured patients or that the FQHCs agree to place the PAP sponsors' products on their formularies).

Finally, the Arrangement relates directly to the core clinical services provided by the FQHCs and helps ensure the availability of safety net health services for otherwise underserved populations, consistent with the spirit of section 431 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. Law 108-173, which mandated the new safe harbor for donations of goods and services to FQHCs that contribute to the ability of the FQHCs to maintain or increase the availability of, or enhance the quality of, services provided to medically underserved populations. It is reasonable to assume that the Arrangement helps the FQHCs continue to serve as a vital part of the health care safety net. Donations of drugs by pharmaceutical companies to FQHCs – whether through PAPs or directly – can play an important role in ensuring that the FQHC safety net serves vulnerable patients.

With respect to impermissible inducements to beneficiaries, the Arrangement could potentially influence a limited number of financially-needy Medicare beneficiaries who lack outpatient prescription drug coverage to seek treatment at the FQHCs. However, for the reasons stated above, the OIG will not subject the Partnership to sanctions under section 1128A(a)(5) of the Act in connection with the Arrangement as it applies to the affiliated FQHCs.

In light of all of the foregoing considerations, we would not subject the Requestor to administrative sanctions in connection with the Arrangement under sections 1128A(a)(5), 1128A(a)(7), or 1128B(7) of the Act.

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) while 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, the OIG would not impose administrative sanctions on the Partnership 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