



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 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: August 7, 2014

Posted: August 15, 2014

[Name and address redacted]

Re: OIG Advisory Opinion No. 14-06

We are writing in response to your request for an advisory opinion regarding a specialty pharmacy's proposal to pay local retail pharmacies a fee for support services they provide in connection with patient referrals to the specialty pharmacy (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed 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, the Federal 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 the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the Office of Inspector General ("OIG") could potentially 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. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

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") dispenses specialty pharmaceuticals, which may be unavailable at local retail pharmacies for various reasons. Requestor states, for example, that some manufacturers limit distribution of their specialty drugs to a small network of pharmacies to dispense to patients. Some managed care payors designate certain pharmacies to dispense specialty drugs to their members. Additionally, local retail pharmacies may be prohibited or restricted from dispensing specialty drugs due to challenges associated with special handling requirements and inventory management.

Requestor dispenses specialty pharmaceuticals prescribed for patients with a wide variety of chronic and life-threatening diseases, including various forms of cancer, HIV/AIDS, multiple sclerosis, and hemophilia (the "Specialty Drugs"). The Specialty Drugs include pharmaceuticals payable by Federal health care programs. Requestor dispenses the Specialty Drugs directly to patients through its nationwide distribution channel for prescriptions received by licensed physicians. Requestor also operates eight free-standing pharmacies in locations across the country. When Requestor fills prescriptions through its distribution channel or at one of its locations, it also provides the following services to the patient: (1) counseling by a team of health professionals consisting of a patient care coordinator and a pharmacist or nurse; (2) proactive renewal reminders as well as utilization and adherence assessments tailored to the patient's day supply versus dispensed quantity; and (3) support finding financial assistance through third-party foundations for financially needy patients.¹

In some instances, a patient who is prescribed a Specialty Drug may present the prescription at a local pharmacy that is unable to fill it for reasons that may include any of those described above. Requestor states that the local pharmacy may not have the information necessary to direct the patient to a pharmacy that has the ability to dispense the Specialty Drug. Under the Proposed Arrangement, Requestor would enter into contracts with various local pharmacies and pharmacy networks (the "Local Pharmacies") to help these patients obtain their Specialty Drugs from Requestor. The

¹ This opinion is limited to the Proposed Arrangement, and we therefore express no opinion about these services provided by Requestor.

Local Pharmacy would be required to provide various support services, including: (1) accepting new Specialty Drug prescriptions from patients or their prescribers; (2) gathering patient and prescriber demographic information; (3) recording patient-specific medication history and use, including drug names, strength, and directions; (4) counseling patients on appropriate use of their medications; (5) informing the patients about Specialty Drug access and services generally provided by specialty pharmacies;² (6) obtaining patient consent to forward the Specialty Drug prescription to Requestor; (7) transferring the Specialty Drug prescription information to Requestor; and (8) providing ongoing assessments for subsequent refills, including transmitting information on any changes in the patients' medication regimens to Requestor (the "Support Services").

Requestor certified that it would compensate the Local Pharmacy for the fair market value of the Support Services performed on a per-fill basis, *i.e.*, upon Requestor's receipt of the initial prescription for the Specialty Drug and upon each subsequent refill throughout the course of the patient's therapy (the "Per-Fill Fees").³

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense to knowingly and willfully 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. See, e.g., United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v.

² Under the Proposed Arrangement, the Local Pharmacy would be required to inform the patient of the availability of his or her Specialty Drug at specialty pharmacies other than Requestor and that the patient has the right to fill the prescription at the specialty pharmacy of the patient's choice.

³ We are not authorized to opine on whether fair market value shall be, or was, paid or received for any goods, services, or property. See section 1128D(b)(3) of the Act.

Greber, 760 F.2d 68 (3d Cir. 1985), 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.

B. Analysis

The Proposed Arrangement would implicate the anti-kickback statute because Requestor would pay Local Pharmacies a fee for Support Services each time the services result in a referral to Requestor to dispense a Specialty Drug, including those payable by Federal health care programs. We therefore must determine whether, given all of the relevant facts, the Proposed Arrangement would pose no more than a minimal risk of fraud and abuse under the anti-kickback statute. For the following reasons, we conclude that the Proposed Arrangement would pose more than a minimal risk of fraud and abuse.

The Per-Fill Fees, which Requestor would pay on the basis of orders for Specialty Drugs, are inherently subject to abuse because they would be directly linked to business generated by the Local Pharmacies for Requestor. Specifically, the amount of Per-Fill Fees the Local Pharmacy would receive would be directly tied to the number of patients with Specialty Drug prescriptions that the Local Pharmacy would refer to Requestor. While we recognize that the Support Services to be provided by the Local Pharmacies would include certain patient care coordination services that could benefit patients, the Local Pharmacy would receive compensation under the Proposed Arrangement only when the Support Services result in referrals of patients to Requestor to fill prescriptions for Specialty Drugs. Requestor does not propose to pay Local Pharmacies for such services for patients who are not referred to it by the Local Pharmacies.⁴ The anti-kickback statute is violated if one purpose of the remuneration is to induce referrals of Federal health care program business. There is significant risk that the Per-Fill Fees would represent compensation for the Local Pharmacies generating business, including Federal health care program business, rather than solely compensation for bona fide, commercially reasonable services.

⁴ We are also skeptical of Requestor's assertion that local pharmacies sometimes lack the information necessary to direct a patient to a pharmacy with the ability to dispense a Specialty Drug. Such information should be readily available from Specialty Drug manufacturers, among other sources (e.g., third-party payors and prescribers). In addition, Requestor could inform local pharmacies of its services without offering remuneration in connection with referrals of patients with prescriptions for Specialty Drugs.

Because the Proposed Arrangement would include potentially problematic financial incentives that could influence the Local Pharmacies' referral decisions in a material way, we cannot conclude that the Proposed Arrangement would pose no more than a minimal risk of fraud and abuse under the anti-kickback statute.

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 and that the OIG could potentially 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. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

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 by a person or entity other than [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.
- 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 (or that provision's application to the Medicaid program at section 1903(s) 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 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.

Sincerely,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General