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 5, 2015

Posted: August 12, 2015

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 15-11

Dear [Names redacted]:

We are writing in response to your request for an advisory opinion regarding a program to provide a drug for free for a limited time to patients who experience a delay in the insurance approval process (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of 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 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, although 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 Office of Inspector General ("OIG") will not impose administrative sanctions on [name redacted] or [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. In addition, the OIG will not impose administrative sanctions on [name redacted] or [name redacted] under section 1128A(a)(5) 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 for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than [name redacted] and [name redacted], the requestors 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] and [name redacted] (the "Requestors") co-promote [drug name redacted] (the "Drug"),[1] which first was approved by the U.S. Food and Drug Administration (the "FDA") for patients with [FDA-approved indication redacted].[2] The Drug has since been approved for patients with [FDA-approved indication redacted], for patients with [FDA-approved indication redacted], and for patients with [FDA-approved indication redacted] (collectively with [FDA-approved indication redacted], the "Diseases"). The Drug was approved under FDA's Breakthrough Therapy Designation for certain indications. This designation is available only for drugs: (1) intended to treat a serious or life-threatening disease or condition (alone or in combination with one or more other drugs); and (2) for which preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.[3] The Drug is an antineoplastic drug that is taken orally and is obtained through specialty pharmacies.[4] The Requestors certified that limited other on-

[1] [Name redacted], the predecessor to [name redacted], co-developed the Drug with [name redacted].

[2] Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trials.

[3] See 21 U.S.C. § 356(a).

[4] The Requestors certified that physicians receive no financial benefit for prescribing the Drug under the Arrangement. Because the Drug is orally administered and dispensed through specialty pharmacies, the Requestors certified that physicians cannot receive an

label treatments exist for patients with the Diseases at the point at which the Drug is prescribed (e.g., after receiving a prior therapy), and most of those alternative treatments have boxed warnings.[5] However, there is no clinical barrier to switching from the Drug to another therapy; for example, a patient could start a different treatment within two days of discontinuing use of the Drug. Moreover, the Requestors certified that response time to the Drug is rapid; the median time to first response for patients with [FDA-approved indications redacted] is under two months.

The Requestors work with [name redacted] (the "Vendor") and its affiliated pharmacy, [name redacted] (the "Pharmacy"), to run the [program name redacted] program (the "Free Supply Program"). The Pharmacy is a specialty pharmacy licensed in all 50 states. However, it does not fulfill prescription orders for the general public; it dispenses drugs only for various client programs, such as the Free Supply Program. To be eligible for the Free Supply Program, patients must meet five requirements. The patient must: (1) be a new patient; (2) have received a prescription for the Drug; (3) have an on-label diagnosis; (4) be insured (by, for example, a commercial insurer or a Federal health care program); and (5) have experienced a delay in a coverage determination of at least five business days. If the pharmacy to which the patient or prescriber submitted a prescription for the Drug does not receive a coverage determination from an insurer within five business days (and the other criteria listed above are met), the patient's prescriber or pharmacy could submit a request to the Pharmacy to dispense the Drug to the patient.[6] After verifying

---

administration fee for the Drug when provided under the Arrangement or for any of the patients' future uses of the Drug.

[5] Boxed warnings, when required, appear in full prescribing information. FDA regulations indicate that: "[c]ertain contraindications or serious warnings, particularly those that may lead to death or serious injury, may be required by the FDA to be presented in a box. The boxed warning ordinarily must be based on clinical data, but serious animal toxicity may also be the basis of a boxed warning in the absence of clinical data." 21 C.F.R. § 201.57(c)(1).

[6] Some patients may have enrolled in the related [program name redacted] (the "Support Program"), which is run by another entity affiliated with the Vendor. The Support Program is designed to help patients with insurance verification and, if necessary, the appeals process. If a patient in the Support Program meets the requirements for the Free Supply Program, the patient's information may be transferred directly to the Pharmacy from the Support Program. In addition, under the Support Program, patients sign an authorization that allows the Requestors to contact them for specified activities related only to the Drug. Absent patient consent, the Requestors do not receive information about patients, their prescribers, or their insurers through the Support Program. We have not been asked about, and express no opinion regarding, the Support Program.

eligibility, the Pharmacy asks the original prescriber for a new prescription for the sole purpose of dispensing the Drug under the Free Supply Program, and, upon receipt of the new prescription, the Pharmacy dispenses the free supply of the Drug. However, after the patient is no longer eligible for the Free Supply Program, any subsequent prescriptions are filled by the specialty pharmacy of the patient's choice (which cannot include the Pharmacy, because it does not fulfill prescription orders for the public). The Requestors certified that they pay the Pharmacy a fair market value dispensing fee, as validated by an independent third party.[7]

Under the Arrangement, the Requestors provide one free 30-day supply of the Drug to patients who meet the Free Supply Program criteria. If the coverage delay persists, or the insurer provides a coverage denial after the five-business-day period required to qualify for the Free Supply Program, but the patient is diligently pursuing appeal rights, the patient may be eligible for one 30-day refill of the Drug. No further free supplies of the Drug are dispensed under the Arrangement regardless of the status of the appeal.

Participants are instructed that no patient, pharmacy, or payor should be billed for the free supplies of the Drug. If a Medicare Part D beneficiary receives a free supply of the Drug under the Arrangement, the Pharmacy notifies the patient's Part D plan sponsor that the Drug is being provided to the patient outside the Part D benefit, that no part of the costs of the Drug provided under the Arrangement should be counted toward the patient's true out-of-pocket ("TrOOP") costs, and that no claim should be submitted to the Part D plan sponsor for the free supply of the Drug. The Requestors certified that receiving a free supply of the Drug is not contingent on any future purchases of the Drug or other products manufactured or marketed by the Requestors. In addition, Part D beneficiary participants who choose to stay on the Drug after receiving the free supply or supplies (or beneficiaries who do not qualify for the Free Supply Program, and thus never receive a free supply) are responsible for substantial cost-sharing amounts.[8]

The Requestors certified that they do not, and would not in the future, advertise the Free Supply Program in direct-to-consumer advertisements, on third-party websites, in newspapers, on television or radio, or in magazines commonly read by potential Free Supply Program enrollees. The Requestors' own websites contain information about the

[7] 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. Therefore, we do not express an opinion about whether the dispensing fee is fair market value. If the fee is not fair market value, this opinion is without force and effect.

[8] Some patients may qualify for copayment assistance from a patient assistance program that supports one or more of the Diseases. The Requestors certified that the Pharmacy does not dispense the Drug to patients under any such patient assistance programs.

Free Supply Program, and sales representatives distribute approved printed materials about the program to health care providers. Because of Part D formulary requirements and the timeframe in which Part D plan sponsors are required to make coverage determinations,[9] the Requestors do not expect the Arrangement to be utilized by a significant number of Part D beneficiaries. However, when Part D or other Federal health care program beneficiaries do encounter delays in coverage determinations, a free supply of the Drug is available to them through the Arrangement, under the conditions described herein. The Requestors have certified that since the Drug was first approved and the Arrangement began, only 0.0008 percent of all shipments of the Drug have been shipped under the Arrangement, approximately one-third of which went to Medicare or Medicaid beneficiaries.

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. 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

[9] The Centers for Medicare & Medicaid Services Medicare Prescription Drug Benefit Manual (the "Manual"), Chapter 6, section 30.2.5, indicates that sponsors must include all or substantially all antineoplastic drugs, such as the Drug, on their prescription drug plan formularies. In addition, according to Chapter 18, section 40.2 of the Manual, Part D plan sponsors are required to notify enrollees of a coverage determination within 72 hours of receiving the request. There is, however, the possibility to request a redetermination after the initial unfavorable coverage determination.

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 "Beneficiary Inducements CMP") provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration 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 the Beneficiary Inducements CMP as including "transfers of items or services for free or for other than fair market value."

B. Analysis

Under the Arrangement, the Requestors provide up to two free 30-day supplies of the Drug to patients, some of whom are Federal health care program beneficiaries. Thus, we must analyze whether the Requestors are offering a free supply of the Drug to Federal health care program beneficiaries as an inducement to the patients to self-refer for the Drug[10] or to the Pharmacy in the future. We also must analyze whether the Arrangement is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for items or services reimbursed by Medicare or a State health care program. We address these two issues in turn and, for a combination of the following reasons, we conclude that the Arrangement presents a low risk of fraud and abuse.

1. Anti-kickback Statute

The Requestors, via the Pharmacy, provide patients with a free 30-day supply of the Drug if the patients experience a delay in receiving a coverage determination from their insurer of at least five business days, with the possibility of one free 30-day refill if the delay continues beyond the initial 30-day period. For the following reasons, we find the Arrangement to be low risk under the anti-kickback statute.

---

[10] Because the Requestors only receive information about patients through the Support Program with patient consent, and the patient authorization allows the Requestors to contact them for specified activities related only to the Drug, we do not believe the Arrangement can be used by the Requestors to market other products they make or sell.

First, the risk of overutilization is limited under the Arrangement. The Drug is an antineoplastic drug indicated for treatment of particular types of cancer, and the Arrangement applies only to on-label uses of the Drug. In addition, if the patient's insurer makes a favorable coverage decision before five business days have elapsed, then the Arrangement is not triggered; the patient would be subject to the standard substantial cost-sharing amounts required to acquire the Drug (unless the patient qualifies for and receives aid from a patient assistance program). Regardless of whether insurance coverage is ultimately approved or denied, the patient is eligible for no more than two 30-day free supplies of the Drug under the Arrangement.

Second, the Arrangement is distinguishable from problematic "seeding" programs in which a manufacturer might offer a drug for free or at a greatly reduced cost to induce a patient onto that drug and for the patient to obtain subsequent supplies that would be billed to Federal health care programs. For example, the Arrangement is not actively marketed to patients. Moreover, according to the Requestors, only 0.0008 percent of shipments of the Drug have been shipped pursuant to the Arrangement. Thus, patients and prescribers assume that the patient's insurance will cover the Drug, and the patient will be subject to applicable cost-sharing amounts at the time the Drug is prescribed. Having the Arrangement in place for those rare cases in which insurance approval decisions extend beyond five business days is unlikely to influence patients or prescribers to choose the Drug over alternative therapies, particularly where, as here, the alternatives are limited.

Third, the prescriber receives no financial benefit under the Arrangement. The self-administered Drug is dispensed directly to the patient from the Pharmacy under the Arrangement (and other pharmacies, if the patient receives future prescriptions for the Drug). Therefore, prescribers have no opportunity to earn any kind of administration fee in connection with the Drug.

Fourth, the Arrangement is unlikely to induce a beneficiary to obtain federally payable prescriptions from the Pharmacy. A patient who receives a free supply (and possible free refill) of the Drug under the Arrangement cannot obtain future prescription refills from the Pharmacy. Further, because the Pharmacy's dispensing is limited to certain client programs, it is unlikely that the Arrangement would induce the patient to obtain other federally reimbursable drugs from the Pharmacy.

Fifth, the Arrangement entails no cost to Federal health care programs. No patient, pharmacy, payor, or other third party is billed for the free supplies of the Drug. The Requestor also certified that if a Part D beneficiary receives a free supply of the Drug, the Pharmacy notifies the beneficiary's Part D plan sponsor that it is providing the Drug to the patient outside of his or her Part D benefit, that no part of the costs of the Drug provided under the Arrangement should be counted toward the patient's TrOOP, and that no claim should be submitted to the Part D plan sponsor for the free supplies of the Drug.

Our conclusions with respect to the anti-kickback statute are based on the particular facts of this Arrangement. We might reach a different conclusion on different facts, such as if the Arrangement were used as a marketing tool or if the Arrangement appeared to be used at a greater rate than would be expected based on typical insurance approval rates.

2. Beneficiary Inducements CMP

We also must determine whether the Arrangement is likely to influence a 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. Because the Requestors are pharmaceutical manufacturers, and therefore are not "providers, practitioners, or suppliers" for purposes of the Beneficiary Inducements CMP, the Arrangement does not implicate the statute with respect to the Requestors.[11] As a pharmacy licensed in all 50 states, the Pharmacy could be a "supplier." However, the Pharmacy does not dispense drugs to the general public outside of client programs, such as the Free Supply Program, and does not bill third-party payors under the Free Supply Program. Therefore, beneficiaries could not select the Pharmacy as a supplier for the Drug for refills payable by Medicare or a State health care program. Because the Pharmacy's other business is limited to similar client programs, it is not likely that the free Drug offered in the Arrangement would influence a beneficiary to select the Pharmacy to supply other products paid for by Medicare or a State health care program. For the combination of the foregoing reasons, we will not subject the Requestors to administrative sanctions under the Beneficiary Inducements CMP in connection with the Arrangement.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although 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 will not impose administrative sanctions on [name redacted] or [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. In addition, the OIG will not impose administrative sanctions on [name redacted] or [name redacted] under section 1128A(a)(5) of the Act in connection with the Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about

---

[11] See Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries, August 2002, available at: http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf.

any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted] and [name redacted], the requestors 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] or [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 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 will not proceed against [name redacted] or [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] or [name redacted] with respect to any action that is part of the Arrangement 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,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General