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, unless otherwise approved by the requestor(s).*]

Issued: December 1, 2021

Posted: December 6, 2021

[Name and address redacted]

Re: OIG Advisory Opinion No. 21-19

Dear [Name redacted]:

The Office of Inspector General ("OIG") is writing in response to your request for an advisory opinion on behalf of [name redacted] ("Requestor") regarding Requestor's provision of free eye drops that mitigate side effects for patients using one of its products (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of sanctions under: the civil monetary penalty provision at section 1128A(a)(7) of the Social Security Act (the "Act"), as that section relates to the commission of acts described in section 1128B(b) of the Act (the "Federal anti-kickback statute"); the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act (the "Beneficiary Inducements CMP"); or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute and the Beneficiary Inducements CMP.

Requestor has certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Arrangement, and we have relied solely on the facts and information you provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestor. This opinion is limited to the relevant facts presented to us by Requestor in connection with the Arrangement. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Arrangement would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts

described in the Federal anti-kickback statute; and (ii) the Arrangement does not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP.

This opinion may not be relied on by any person[1] other than Requestor and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

Requestor, a pharmaceutical manufacturer, manufactures [drug name redacted] (the "Product").[2] The U.S. Food and Drug Administration ("FDA") approved the Product to treat [disease state redacted] in patients who have received at least four prior therapies. Requestor certified that the Product has a Risk Evaluation and Mitigation Strategy ("REMS") with Elements to Assure Safe Use ("ETASU") to manage the risk of ocular side effects from using the Product. Specifically, one potential side effect of the Product is keratopathy (changes to the corneal surface), which a study showed to occur in over 70 percent of patients using the Product. All patients prescribed the Product must enroll in the FDA-mandated REMS to obtain the Product. To reduce the risk of ocular side effects, including keratopathy, the FDA-approved literature (i.e., the Product's label, the Medication Guide distributed with the Product, and the REMS Patient Guide) recommends, among other things, that patients: (i) receive ophthalmic examinations, including visual acuity and slit lamp exams, at baseline, prior to each dose and promptly for worsening symptoms; and (ii) use preservative-free lubricant eye drops ("Eye Drops") at least four times a day while undergoing treatment with the Product. Requestor certified that the Eye Drops are non-prescription, cost up to approximately $17 per month, and typically are not reimbursed by Federal health care programs.

Under the Arrangement, Requestor offers free Eye Drops to all patients who have been prescribed the Product for an on-label indication, enroll in the REMS, and enroll in Requestor's free Eye Drop program ("Eligible Patients"), without regard to the prescriber or the patient's insurer. The prescribing physician, an Eligible Patient's eye care professional, or the Eligible Patient submits an enrollment application to Requestor's REMS, which is managed by a third-party vendor that is not a health care provider, practitioner, or supplier (the "REMS Vendor"). The REMS Vendor confirms the patient's enrollment in the REMS and seeks consent from the patient to use the patient's REMS data to facilitate the accurate timing and tracking of the Eye Drop shipments. Requestor certified that the enrollment documents that an Eligible Patient signs make clear that Requestor sponsors the free Eye Drop program.

Each Eligible Patient receives a 60-vial supply of Eye Drops for the initial phase of treatment and then receives an additional 60-vial supply once every 50 days for each subsequent 2-month

[1] We use "person" herein to include persons, as referenced in the Federal anti-kickback statute and Beneficiary Inducements CMP, as well as individuals and entities, as referenced in the exclusion authority at section 1128(b)(7) of the Act.

[2] Requestor does not own or operate, directly or indirectly, any providers or suppliers that administer the Product.

period through the earlier of: (i) the end of the Eligible Patient's treatment with the Product[3] (i.e., the point at which the patient no longer has the Product in their system); or (ii) the date the Eligible Patient opts out of receiving the Eye Drops.[4] The Eligible Patient interacts exclusively with the REMS Vendor regarding the Eye Drop shipments. The Eye Drops are shipped directly to the Eligible Patient; neither Product prescribers nor eye care professionals take possession of the Eye Drops nor have any role in the ordering, shipment, delivery, or receipt of the Eye Drops. Prior to each new Eye Drop shipment, the REMS Vendor confirms that the Eligible Patient is still actively enrolled in the REMS; if a patient's status is "inactive," then the patient is no longer an Eligible Patient. Before discontinuing shipments of Eye Drops, the REMS Vendor contacts the prescribing physician to confirm that the inactive patient has discontinued treatment.

Requestor certified that it neither covers any patient costs for the Product in connection with the Arrangement nor provides any remuneration to the physicians who prescribe the Product in connection with the Arrangement.

II. LEGAL ANALYSIS

A. Law

1. Federal Anti-Kickback Statute

The Federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an individual to a person for the furnishing of, or arranging for the furnishing of, any item or service reimbursable under a Federal health care program.[5] The statute's prohibition also extends to remuneration to induce, or in return for, the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by a Federal health care program.[6] For purposes of the Federal 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 is to induce referrals for items or services reimbursable by a Federal health care

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[3] Requestor certified that, during a study of the Product, the median amount of time that all patients in the trial used the Product was 2.1 months. For patients who responded to the Product (approximately one-third of the patients), however, the median estimated duration of response was 11 months.

[4] Eligible Patients may request an additional, one-time 60-vial supply if: (i) a shipment is lost or damaged; or (ii) the Eligible Patient is traveling and forgets the Eye Drops. If the Eligible Patient requests this emergency supply, the REMS Vendor updates the Eligible Patient's file with the emergency supply shipment information and adjusts the next shipment accordingly.

[5] Section 1128B(b) of the Act.

[6] Id.

program.[7] Violation of the statute constitutes a felony punishable by a maximum fine of $100,000, imprisonment up to 10 years, or both. Conviction also will lead to exclusion from Federal health care programs, including Medicare and Medicaid. When a person commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. The OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

2. Beneficiary Inducements CMP

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 beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. The OIG also may initiate administrative proceedings to exclude such person from 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

We must analyze whether the Arrangement implicates the Federal anti-kickback statute, as well as whether it is likely to influence a beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service reimbursed by Medicare or a State health care program under the Beneficiary Inducements CMP. We address these issues in turn, and for the combination of the reasons discussed below, we conclude that the Arrangement poses a sufficiently low risk of fraud and abuse under the Federal anti-kickback statute and that the Arrangement does not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP.

1. Federal Anti-Kickback Statute

Under the Arrangement, Requestor, through the REMS Vendor, provides free Eye Drops to Eligible Patients, including Federal health care program beneficiaries, who use the Product. The free Eye Drops constitute remuneration under the Federal anti-kickback statute. This remuneration could induce Eligible Patients who are Federal health care program beneficiaries to continue purchasing the Product or purchase other federally reimbursable items manufactured by Requestor. However, for the following reasons, we believe the Arrangement poses a sufficiently low risk of fraud and abuse under the Federal anti-kickback statute.

[7] E.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); 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).

First, the FDA-approved Product label, Medication Guide, and REMS Patient Guide all recommend that patients use Eye Drops at least four times a day. While the Eye Drops are not integrally related to the Product, in that the Product can be used without them and the Eye Drops can be used for other indications, they are recommended to mitigate one common side effect of the Product, keratopathy. Therefore, having ready access to the Eye Drops through the Arrangement mitigates a known safety risk identified in the REMS for patients using the Product.

Second, the Eye Drops are relatively low-cost, non-prescription items, and receiving them for free should not lead to overutilization or inappropriate utilization of the Product or related items or services. Requestor certified it does not cover any other patient costs associated with the Product in connection with the Arrangement. Therefore, many patients, including Federal health care program beneficiaries, are responsible for other medical expenses (e.g., cost-sharing for the Product and physician visits) when they use the Product. Because patients must consider all costs associated with treatment, and because the Eye Drops may be one of the less significant potential out-of-pocket costs inherent in treatment with the Product, we believe it is unlikely that the provision of the Eye Drops would induce the patient to choose the Product.

Finally, the Arrangement presents a sufficiently low risk with respect to other fraud and abuse concerns we consider when examining arrangements under the Federal anti-kickback statute. For example, the Arrangement should not result in increased costs to Federal health care programs because the Eye Drops are not billed to any payors and are intended to manage or avoid a potential side effect to a prescribed treatment. The Arrangement should not corrupt medical decision-making because: (i) the Product is FDA-approved to treat [disease state redacted] only for patients who have received at least four prior therapies; and (ii) the free Eye Drops are not a financial benefit to prescribers and are likely only a relatively small financial benefit to patients compared to other costs patients potentially incur in connection with the Product.

2. Beneficiary Inducements CMP

In evaluating the Arrangement under the Beneficiary Inducements CMP, we consider whether Requestor knows or should know that the remuneration it offers to beneficiaries is likely to influence their selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. For purposes of the Beneficiary Inducements CMP, pharmaceutical manufacturers are not "providers, practitioners, or suppliers" unless they also own or operate, directly or indirectly, pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs. Here, Requestor is a pharmaceutical manufacturer, and it does not own or operate, directly or indirectly, any providers or suppliers of the Product. Therefore, Requestor is not a "provider, practitioner, or supplier" for purposes of the Beneficiary Inducements CMP. Requestor also certified that the REMS Vendor is not a provider, practitioner, or supplier of health care items or services.

A pharmaceutical manufacturer, such as Requestor, can be the offeror or transferor of remuneration that implicates (and violates) the Beneficiary Inducements CMP if the remuneration were likely to influence the beneficiary to select a particular provider, practitioner,

or supplier (e.g., physician or pharmacy) to receive the Product. Under the Arrangement, all patients, including Federal health care beneficiaries, are eligible to receive the free Eye Drops through the REMS Vendor regardless of which physician prescribed the Product. Moreover, enrollment documents that the patient signs make clear that Requestor—not the prescriber—sponsors the free Eye Drop program. Therefore, we conclude that the remuneration offered by Requestor under the Arrangement is not likely to influence a beneficiary to select a particular provider, practitioner, or supplier.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Arrangement would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute; and (ii) the Arrangement does not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is limited in scope to the Arrangement and has no applicability to any other arrangements that may have been disclosed or referenced in your request for an advisory opinion or supplemental submissions.

- This advisory opinion is issued only to Requestor. This advisory opinion has no application to, and cannot be relied upon by, any other person.

- This advisory opinion may not be introduced into evidence by a person other than Requestor to prove that the person did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

- This advisory opinion applies only to the statutory provisions specifically addressed in the analysis above. We express no opinion 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.

- We express no opinion herein regarding the liability of any person under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against Requestor with respect to any action that is part of the 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 Requestor 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,

/Robert K. DeConti/

Robert K. DeConti
Assistant Inspector General for Legal Affairs