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: June 4, 2026

Posted: June 9, 2026

[Address block redacted]

Re: OIG Advisory Opinion No. 26-13 (Favorable)

Dear [redacted]:

The Office of Inspector General ("OIG") is writing in response to your request for an advisory opinion on behalf of [redacted] ("Requestor"), regarding Requestor's provision of free eye drops to mitigate ocular toxicity for patients using one of its products (the "Arrangement").[1] 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 advisory opinion is limited to the relevant facts presented to us by Requestor in connection

[1] We issued OIG Advisory Opinion 21-19 ("AO 21-19"), which is a favorable opinion protecting a previous version of this Arrangement, to Requestor on December 1, 2021. Concurrently with issuing this opinion, we are terminating AO 21-19 as of the effective date of this opinion solely because the arrangement protected by that opinion is no longer in operation, and this opinion reflects the current Arrangement.

with the Arrangement. If material facts have not been disclosed, have been misrepresented, or change, then this advisory 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—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, 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 advisory opinion may not be relied on by any person[2] other than Requestor, has no applicability to any arrangements other than the Arrangement, 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 [redacted] (the "Product").[3] The U.S. Food & Drug Administration ("FDA") approved the Product in combination with [redacted] and [redacted] to treat [disease state redacted], in patients who have received at least two prior therapies, including [redacted] and [redacted]. Requestor certified that the Product has a Risk Evaluation and Mitigation Strategy ("REMS") with Elements to Assure Safe Use to manage the risk of ocular toxicities associated with using the Product; the ocular toxicity is managed with dose holds, dose modifications, and, in severe cases, discontinuation of the Product.[4] All patients prescribed the Product must enroll in the FDA-mandated REMS to obtain the Product. To help manage ocular toxicities, which are known to occur and require pausing or discontinuing [redacted] treatment with the Product, the FDA-approved literature (i.e., the Product's label, the Medication Guide distributed with the Product, and the REMS Patient Guide) all recommend, among other things, that patients use preservative-free artificial tears ("Eye Drops") at least four times a day while undergoing treatment with the Product. Requestor certified that the Eye Drops are non-prescription single-use vials that are typically not reimbursed by Federal health care programs, and retail prices currently are between $108 to $145 for a 60-day supply (i.e., 240 single-use vials). Requestor provides a 60-day supply for every two months of treatment with the Product because the Product prescribing information recommends that patients use the Eye Drops at least four times per day.

---

[2] 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.

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

[4] For example, Requestor certified that a clinical trial showed that 83 percent of patients using the Product required a dosage modification of the Product due to ocular toxicity.

Under the Arrangement, Requestor offers free Eye Drops to all patients, including Federal health care program beneficiaries, who have a valid prescription for the Product, enroll in the REMS, and enroll in the free Eye Drop program, without regard to the prescriber or the patient's insurer. Requestor certified that it does not cover any patient costs for the Product in connection with the Arrangement, nor does it provide any remuneration in connection with the Arrangement to the health care providers who prescribe the Product.[5]

Under the Arrangement, Requestor operates a patient support program hub (the "Hub") serviced by various third-party vendors. While the Hub assists with enrollment into the Eye Drop program, a different third-party vendor ships the Eye Drops to patients. None of the vendors own or operate, directly or indirectly, any providers or suppliers that administer the Product. Patients enroll in the Eye Drop program by checking an opt-in box on the Hub enrollment form, which serves as a single application for the Product's patient support programs, including the Eye Drop program. If the patient does not check the opt-in box before submitting the enrollment form, then the Hub will describe the Eye Drop program to the patient using approved, high-level talking points and provide them an opportunity to enroll by submitting an updated Hub enrollment form. Requestor certified that: (i) the Hub generally provides information about the Eye Drop program to patients only after a prescribing decision has been made;[6] and (ii) Requestor prohibits the Hub from promoting the Eye Drop program to health care providers as a reason to prescribe, or to patients as a reason to start or remain on, the Product. Finally, prior to enrolling patients in the Eye Drop program, the Hub is responsible for verifying that the patient is enrolled in the REMS.[7]

Each patient prescribed the Product who opts into the Eye Drop program receives a 60-day supply of Eye Drops for the initial phase of treatment and then receives an additional 60-day supply once every 50 days for each subsequent 2-month period through the earlier of: (i) the end

---

[5] Requestor certified that it offers a separate program that provides cost-sharing support to commercially insured patients, but Federal health care program beneficiaries are excluded from the program. We have not been asked to opine on, and express no opining regarding, any patient support programs offered by Requestor, other than the Arrangement.

[6] Requestor noted that, if a patient contacts the Hub seeking information about the Product patient support offerings, the Hub may reactively provide a high-level list of the various support programs, including the Eye Drop program. The Hub may not provide additional information about the Eye Drop program unless the patient is enrolled in the Hub.

[7] Requestor certified that these communications occur after a patient submits a Hub enrollment form. Specifically, the Hub places phone calls to all patients who submit a completed Hub enrollment form. For patients who check the Eye Drop program opt-in box on the Hub enrollment form, the Hub confirms the following during this call: (i) that the patient is enrolled in the REMS; (ii) when the patient's infusions will start (in order to time the first Eye Drop shipment); and (iii) the patient's home address for the shipment. For patients who do not check the opt-in box to receive Eye Drops, the Hub educates the patient on the Product safety information and makes them aware that they have the option to enroll in the Eye Drop program.

of the patient's treatment with the Product[8] (as determined by confirming with the prescriber that the patient has discontinued treatment and that the Eye Drops are no longer needed); or (ii) the date the patient opts out of the Eye Drop program.[9] The patient interacts exclusively with the Hub regarding the Eye Drop shipments, and the enrollment materials, which the patient must sign, make clear that Requestor sponsors the Eye Drop program. The Eye Drops are shipped directly to the patient; neither Product prescribers nor eye care professionals take possession of the Eye Drops, nor do they have any role in the ordering, shipment, delivery, or receipt of the Eye Drops. Prior to each new Eye Drop shipment, the Hub confirms with the patient that he or she is still taking the Product and that the patient remains enrolled in the REMS. If a patient confirms that he or she has discontinued treatment with the Product, before discontinuing shipments of Eye Drops, the Hub first contacts the prescriber to confirm Eye Drops are no longer needed in light of potential ongoing ocular toxicity.

To raise awareness about the Eye Drop program, Requestor: (i) includes high-level, factual information about the Eye Drop program on both health care provider- and patient-accessible websites; (ii) permits its field sales team, field access and reimbursement team, and field payor account team to distribute approved printed materials (including the Hub enrollment form) describing the program to health care providers who might prescribe the Product, eye care professionals, and payors; (iii) permits its field sales team and field access and reimbursement team to distribute approved, patient-facing printed materials describing the program to health care providers to provide to patients who have been prescribed the Product; (iv) permits its Hub to distribute approved, patient-facing, printed materials describing the program directly to patients who are enrolled in the Hub; and (v) allows its Hub representatives and field teams to provide approved, non-promotional, high-level, and factual messaging about the program to health care providers (including eye care professionals), payors, or patients, as applicable. Requestor prohibits its personnel, including its field teams, from promoting the Eye Drop program as a reason to prescribe the Product for any use, including off-label use.[10] Requestor also reinforces this prohibition through regular direction and training.

---

[8] Requestor certified that, during a study of the Product, the median time using the Product (in combination with [redacted] and [redacted]) for all patients in the trial who were receiving the Product for the now-approved FDA indication was 16 months, which resulted in a median progression-free survival rate of 31.3 months.

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

[10] While the Eye Drop program is not limited to patients who receive a prescription for the Product for an on-label indication, Requestor certified that no program-related communications state or will state that the program is available for off-label use; rather, program materials, websites, and field team communications state that patients with a valid Product prescription are eligible for the Eye Drop program to support safe use of their prescribed treatment.

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.[11] 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.[12] 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 program.[13] 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, OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. 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. 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."

---

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

[12] Id.

[13] 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).

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 to issue a favorable advisory opinion, 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 Hub, 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 patients who are Federal health care program beneficiaries to continue purchasing the Product or to 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 to issue a favorable advisory opinion.

First, the Eye Drops are relatively low-cost, non-prescription items and receiving them for free is unlikely to 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 free Eye Drops would induce the patient to choose or inappropriately utilize the Product.

Second, the FDA-approved Product label, Medication Guide, and REMS Patient Guide all recommend that patients taking the Product use Eye Drops at least four times a day. Failure to manage the ocular toxicity associated with use of the Product can impact the patient's [reacted] treatment by having to modify their dosage of the Product or discontinue use of the Product. Therefore, having ready access to the low-cost Eye Drops through the Arrangement mitigates a known safety risk identified in the REMS for patients using the Product and potentially preserves the patient's ability to continue receiving the Product to treat the patient's condition.

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. The Arrangement should not corrupt medical decision-making because the free Eye Drops are not a financial benefit to prescribers, and as noted above, likely are 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 Hub 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, however, patients, including Federal health care beneficiaries, are eligible to receive the free Eye Drops through the Hub regardless of which provider prescribed the Product. Moreover, enrollment documents that the patient signs make clear that Requestor—not the prescriber—sponsors the 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—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, 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 advisory opinion include the following:

- This advisory opinion is limited in scope to the Arrangement. This advisory opinion has no applicability to any other arrangements, including, without limitation, any 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 advisory opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

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. 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, 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 OIG.

Sincerely,

/Spencer K. Turnbull/

Spencer K. Turnbull
Acting Assistant Inspector General for Legal Affairs