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Regulatory Update

OIG Gives Green Light to Free Eye Drops Through Manufacturer Patient Support Program

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In Advisory Opinion No. 26-13 (AO-26-13)[1], issued on June 4, the Department of Health and Human Services' Office of the Inspector General (HHS-OIG) considered whether a pharmaceutical manufacturer's proposal to offer free nonprescription eye drops to patients through its patient support program (PSP) warranted the imposition of sanctions under the federal Anti-Kickback Statute (AKS) and Beneficiary Inducements Civil Monetary Penalties Law (CMPL). OIG concluded that the arrangement implicated the AKS but was sufficiently low-risk for fraud and abuse to warrant a favorable opinion. OIG further concluded that it would not impose sanctions under the CMPL because the manufacturer is not a provider, practitioner or supplier, and the program was unlikely to influence a beneficiary's selection of one.

AO 26-13 replaces Advisory Opinion No. 21-19 (AO-21-19), which addressed an earlier version of the program.[2] On the same day AO 26-13 was published, OIG published a Notice of Termination for AO-21-19 explaining that the prior arrangement was no longer operational and that AO-26-13 reflects the current program. OIG had terminated only five advisory opinions previously.[3]

The Arrangement

The requestor is the pharmaceutical manufacturer of an FDA-approved product that carries a risk of ocular toxicity. To manage this risk, all patients must enroll in the Requestor's Risk Evaluation and Mitigation Strategy (REMS) before receiving treatment, and the product's label, medication guide and REMS patient guide recommend the use of preservative-free, nonprescription eye drops at least four times daily during treatment. These eye drops are typically not reimbursed by federal healthcare programs.

To support adherence to these recommendations, the requestor offers a free 60-day supply of eye drops for every two months of treatment until the patient stops treatment or the patient opts out of the program and emergency supplies for lost, damaged or forgotten eye drops. The program is available to all patients with a valid prescription who enroll in the REMS and the free eye drop program, regardless of prescriber or insurance status. The requestor does not subsidize Medicare beneficiaries' out-of-pocket costs for the drug and provides no remuneration to prescribing healthcare providers in connection with the program. Eye drops are shipped directly to patients and neither the prescriber nor eye care professionals are involved in ordering, dispensing or receiving the product.

The requestor's patient support hub, operated by third party vendors, facilitates enrollment in the eye drop program. Patients may opt-in through an enrollment form, and hub personnel may provide information about the program and offer patients an opportunity to enroll if they initially do not opt in. Hub communications about the eye drop program are limited to approved, nonpromotional, high-level and factual messaging or approved printed materials. Hub personnel may not promote the program as a reason to initiate or continue to prescribe and must verify that patients remain enrolled in the REMS and are actively receiving therapy before each shipment.

The requestor also promotes awareness of the program through its websites and field-based personnel. All communications are limited to approved, high-level, factual information, and field teams may distribute approved materials to healthcare providers, eye care professionals and payors. The requestor prohibits personnel from promoting the program as a reason to prescribe the product, including for off-label uses, and reinforces this restriction through regular training and compliance.

Federal Anti-Kickback Statute Analysis

OIG concluded that the arrangement implicates the AKS because the free eye drops constitute remuneration to federal healthcare program beneficiaries and could potentially encourage continued use of the manufacturer's products. Nonetheless, OIG found the risk of fraud and abuse sufficiently low to warrant a favorable advisory opinion for several reasons.

1. **Low-Value Ancillary Benefit**. The eye drops are relatively low-cost, nonprescription products that are unlikely to drive overutilization or inappropriate utilization of federally reimbursable items or services. OIG also noted that the manufacturer does not subsidize Medicare beneficiaries' cost-sharing obligations for the drug itself, and patients would continue to be responsible for other expenses associated with treatment, such as physician visits.

2. **Patient Safety and Treatment Adherence**. The product's labeling, medication guide and REMS materials recommend using the eye drops to manage a known risk of ocular toxicity. OIG concluded that providing access to the eye drops supports the safe use of the drug and may help patients remain on the therapy.

3. **Limited Fraud and Abuse Concerns**. The eye drops are not billed to federal healthcare programs and therefore do not increase program costs. In addition, prescribers receive no financial benefit from the arrangement, reducing the risk that clinical decision-making will be influenced by the program.

Beneficiary Inducements Civil Monetary Penalties Law Analysis

OIG concluded that the arrangement does not warrant sanctions under the CMPL. Although a manufacturer is not a provider, practitioner or supplier under the CMPL — except in limited circumstances — a manufacturer may offer remuneration that implicates the CMPL if it is likely to influence a beneficiary's choice of provider, practitioner or supplier to receive the manufacturer's product. OIG found that risk absent here. All eligible patients may receive the free eye drops regardless of which provider prescribes the product, and the enrollment materials clearly identify the manufacturer and not the prescriber as the sponsor of the program.

Key Takeaways

AO 26-13 is OIG's first advisory opinion this year addressing a manufacturer's PSP and reinforces several recurring themes in OIG's PSPs framework:

- **The Relative Value of Free Items and Services**. OIG reaffirmed that free PSP items and services implicate the AKS and should be evaluated for their potential to influence product

selection. While OIG has previously analyzed free or below-fair market value PSP items and services in a variety of contexts (e.g., loaner devices, companion diagnostic tests or sponsored genetic testing), the OIG's analysis in AO 26-13 is notable in that it focuses on the relatively low value of the eye drops as compared to the overall cost burden associated with treatment. This suggests that aggregate patient cost considerations may be relevant to fraud and abuse risk — an emphasis less central in prior opinions, which are often more focused on independent value or limited and/or vulnerable patient populations.

- **Patient Adherence and Safety**. Consistent with prior opinions, OIG gave significant weight to clinical integration and safety support. For example, in a 2024 favorable opinion (AO 24-13) concerning a gene therapy manufacturer's proposal to financially support patient travel to a treatment center, the underlying product's labeling effectively recommended such travel; hence, OIG concluded, the travel support removed a barrier to treatment. In a 2019 favorable opinion (AO 19-02) concerning the loan of free smart phone devices to patients, OIG approved of the program because, in part, the smart phone was integrally related to proper use of the manufacturer's product.

- **Promotional and Operational Guardrails**. OIG continued to rely on manufacturer certifications limiting promotional activity to drive awareness of the program. It is typically the case, as occurred here, that manufacturers requesting a PSP advisory opinion certify that they will not promote PSPs as a reason to prescribe their products or for off-label uses and that manufacturers make additional, proposal-specific certifications about limits on promotion and marketing. For example, in opinions concerning free genetic or diagnostic testing services (e.g., AO 25-07) — where PSPs can provide substantial value prior to a prescription — manufacturer certifications limited communications to disease awareness or nonbranded contexts and limited proactive and reactive sales representative discussions. Here, field sales teams are permitted to provide HCPs with high-level, factual information about the program without restriction to the disease awareness or nonbranded context, and the arrangement includes nonpromotional messaging, supported by hub and access, reimbursement and payor team communications. This reflects OIG's broader pattern of imposing tighter restrictions where PSP value or pre-prescription influence is higher than in AO-26-13.

- **CMPL and Beneficiary Choice Considerations**. OIG reiterated that the CMPL risk of PSPs turns on whether the remuneration is likely to influence a patient's selection of a particular provider, practitioner or supplier. In AO-26-13, OIG found that this was not likely because the PSP is not tied to any provider or supplier; enrollment is universal regardless of prescriber; and program materials clearly identify the manufacturer as the sponsor, which reduces the likelihood that patients would change provider relationships to access the program. In other PSP opinions, OIG has found that such influence was likely, particularly where the PSP is actually or apparently tied to a limited set of providers, practitioners or suppliers. For example, in another advisory opinion regarding a gene therapy manufacturer's proposal to provide free travel to treatment centers (AO 25-06), OIG found the arrangement was likely to influence a patient to select particular treatment centers and physicians working there, which qualify as providers and suppliers, given that only a limited number of qualifying treatment centers existed. Additionally, in OIG's advisory opinion concerning a pharmaceutical manufacturer's proposal to provide free smart phone devices (AO 19-02), influence was deemed likely because a patient could reasonably conclude that participation in the program depended on continuing to receive care from the provider who applied for the device on behalf of the patient. In both of these opinions, OIG issued favorable opinions under the CMPL's Promote Access to Care Exception, which the OIG did not analyze in AO 26-13 given CMPL risk was unlikely.

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If you have any questions concerning these developing issues, please do not hesitate to contact either of the following Paul Hastings New York lawyers:

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1 *See* https://oig.hhs.gov/documents/advisory-opinions/11688/AO-26-13.pdf

2 *See* https://oig.hhs.gov/documents/advisory-opinions/1012/AO-21-19.pdf

3 AO-06-09 was terminated on March 30, 2016 (requestor's counsel informed OIG that the requestor did not and had no intention to enter into the proposed arrangement). *See* https://oig.hhs.gov/documents/advisory-opinions/720/AO-06-09-TERMINATION-1.pdf
AO-08-17 was terminated on January 13, 2016 (requestor was ceasing operations and would wind down the proposed arrangement). *See* https://oig.hhs.gov/documents/advisory-opinions/715/AO-08-17-TERMINATION-1.pdf
AO-10-06 was terminated on January 13, 2016 (requestor informed OIG that it did not and had no intention to implement the proposed arrangement). *See* https://oig.hhs.gov/documents/advisory-opinions/716/AO-10-06-TERMINATION-1.pdf
AO-11-18 was terminated on April 1, 2014 (OIG exercised its right to reconsider the questions and issues raised in advisory opinions and reconsidered its conclusions). *See* https://oig.hhs.gov/documents/advisory-opinions/680/AO-11-18-TERMINATION-1.pdf