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HHS-OIG Highlights Anti-Fraud Safeguards of Drug Manufacturer's Free Drug Program for Patients in Financial Need

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Highlights

- The HHS-OIG released a favorable opinion regarding free drugs offered to patients in financial need for a drug manufactured by the pharmaceutical company offering the assistance
- The assistance offered under the proposed arrangement did not satisfy a safe harbor to the Anti-Kickback Statute (AKS)
- The agency said the proposed arrangement included factors that limited concerns under the AKS and the civil monetary penalty laws

The U.S. Department of Health and Human Services' Office of Inspector General (HHS-OIG) recently released OIG Advisory Opinion 25-01, a favorable opinion regarding the federal Anti-Kickback Statute (AKS) and civil monetary penalty laws (CMP) against beneficiary inducements as applied to a financial assistance program that would provide an intravenous drug at no cost or with no cost-sharing. The program was offered by a pharmaceutical manufacturer to patients who receive an intravenous drug and meet certain objective eligibility criteria.

The HHS-OIG concluded that the financial assistance offered to patients under the proposed arrangement constitutes remuneration under the AKS and the proposed arrangement did not satisfy a safe harbor under the AKS. However, due to sufficient safeguards in place to mitigate the risk of fraud and abuse, the HHS-OIG would not impose sanctions against the pharmaceutical manufacturer.

Further, the HHS-OIG found that the proposed arrangement would not implicate the CMP because pharmaceutical manufacturers are generally not considered "providers, practitioners, or suppliers" and, therefore, the arrangement is not likely to influence an enrollee's selection of a provider, practitioner, or supplier. Further, the product is available free of charge to a patient, regardless of the

patient's selection of a prescribing provider or infusion provider, and patients are free to change providers at any time.

Background

The pharmaceutical company manufactures the product, which treats a disease and is intended for use in patients with mild cognitive impairment and confirmed presence of amyloid pathology. Patients prescribed the product receive intravenous infusions every two weeks in an outpatient setting, which could be the treating physician's office, an outpatient location affiliated with the treating physician, or an independent infusion center unaffiliated with the treating physician. There are currently two other drugs available to treat the disease and two additional such drugs are under development.

The Centers for Medicare & Medicaid Services reimburses for both the product and its administration, under certain circumstances, under Medicare Part B with a 20 percent coinsurance for enrollees, and all state Medicaid programs cover the product with various cost-sharing arrangements for patients.

The proposed arrangement provides the product at no cost to patients, including federal healthcare program beneficiaries, who meet the following eligibility criteria:

- Reside in the United States
- Be at least 18 years old
- Be prescribed the product for an on-label indication
- Be uninsured, be insured but with no insurance coverage for the product, or have Medicare coverage for the product but attest that they are unable to afford their out-of-pocket costs associated with the product
- Have a household income equal to or below 500 percent of the federal poverty level

Patients must work with the patient's treating physician to complete an application for assistance and submit the application to the pharmaceutical manufacturer. All eligibility determinations are made without regard to the patient's insurer or insurance plan, prescribing provider, or infusion provider, and patients are free to change physicians or infusion providers at any time without becoming ineligible for the free product.

The provider who administers the free product is permitted to bill Medicare for the administration cost and may bill the patient for any cost sharing related to only the administration cost. If the provider is not able to administer free product to the approved patient, for any reason, the provider is required to return the free product to the manufacturer or certify its disposal pursuant to the manufacturer's instructions.

Patients must certify that they 1) will not submit a request for payment for the product to any payor, including a federal healthcare program, and 2) understand that no part of the free product or the costs associated with the free product will count toward the patient's out-of-pocket costs. Further, treating physicians must certify, in writing, that they prescribed the product for an on-label indication, based on the physician's independent professional judgment of medical necessity taking into account patient safety considerations, and will not submit a request for payment for the free product to any payor and will not seek payment of the free product from the patient.

The facility where the product will be administered must provide an oral acknowledgement that it understands and agrees to follow all requirements associated with receiving the free product, and each shipment includes a letter describing such requirements.

In this request, the manufacturer certified that neither it, nor anyone acting on the manufacturer's behalf, is permitted to promote the financial assistance program as a reason to prescribe the product to patients, and the manufacturer does not promote the program through direct-to-consumer advertising. Under the proposed arrangement, healthcare professionals may only learn about the program through 1) approved printed materials for general awareness or 2) reimbursement personnel who do not receive sales-based incentive compensation and are permitted to educate pharmacists, physicians, and physician office staff about the program.

Further, the manufacturer certified that it expects patients to learn about the program from 1) the patient's treating physician, 2) the manufacturer's patient support hub, or 3) the manufacturer's patient support website.

The HHS-OIG's Findings

The HHS-OIG found that the free product constituted remuneration to both patients and administering providers under the AKS, but relied on the following factors in determining that this posed little risk of fraud and abuse:

- There are safeguards in place to avoid inappropriately increasing costs to federal healthcare programs. The only cost that could be billed to a federal healthcare program is the administration fee for the infusion, and only where Medicare could have otherwise been billed for the product. In addition, the requestor intends to offer the assistance program indefinitely to patients who continue to meet the eligibility criteria, even if Medicare were to cover the product in the future without the current limitations, so no product will be billed to Medicare for patients who attest that they cannot afford the cost-sharing amounts of the product.
- There is a low risk that the program will interfere with clinical decision-making. The treating physician is not permitted to submit a request for payment of the free product to any payor, including but not limited to any federal healthcare program. Although the administering provider may charge the administration fee for patients where Medicare would otherwise reimburse for the product and there is a cost-sharing component for patients, there is a low risk that the administration fee would induct treating physicians to select the product over another product.
- The program does not steer patients to a particular provider, practitioner, or insurance plan. Patients are free to change their treating physician or infusion provider at any time without impacting their eligibility for free product.

Ultimately, the HHS-OIG found that the arrangement poses low risk of fraud and abuse due to the safeguards, and the patient eligibility criteria.

Key Takeaways

This advisory opinion may be of significant interest to drug manufacturers of new pharmaceutical products. Notably, the HHS-OIG identified the risk that the arrangement could serve as a problematic "seeding" program for the product but determined it would not impose sanctions in part because there is no barrier to the patient switching to competing products and that eligibility for the free product is not contingent on past, present, or future purchases of the product.

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