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OIG Issues Favorable Opinion on Pharmaceutical Manufacturer's Free Product Program

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In its first advisory opinion of the year, the Office of Inspector General for the U.S. Department of Health and Human Services (OIG) assessed a pharmaceutical manufacturer's free product program and found that, although the program at issue generated prohibited renumeration under the federal anti-kickback statute, it was sufficiently low risk that a favorable opinion was warranted.

Traditionally, OIG has warned that manufacturers operating free product programs could be conveying improper kickbacks and inducements to patients and providers. OIG has expressed that these programs, among other things, could be improperly seeding and steering patients to products (simply because they are free) and, critically, interfering with independent clinician decision-making. Free product programs also raise the specter of increased costs, for example, if patients start on expensive products for free that Medicare later is obligated to cover. Free product programs can also reduce patient incentives to find lower cost, equally effective medications.

Despite these concerns, OIG has issued guidance and several favorable advisory opinions on free product programs; however, most have involved Medicare Part D covered products (e.g., oral medications) that were not also linked to other services or items payable by a federal program. In these opinions, OIG has explicitly cautioned that it "might reach a different result were we to evaluate an arrangement similar to the Arrangement arising other than in the Part D context,"[1] raising the question of how free product programs involving Part B or physician-administered products might fare under scrutiny.

This latest advisory opinion — Advisory Opinion No. 25-01 (AO-25-01)[2] — stands as one of the few opinions addressing manufacturer free product programs for Part B, provider-administered therapies. The opinion favorably addresses an arrangement that allows eligible Medicare patients to receive free product and permits infusion sites to bill Medicare Part B for administering that free product in instances where patients have Medicare coverage for the product but are unable to afford the Part B coinsurance. Even though the OIG has previously cautioned against free product programs that are "linked to a service payable by a Federal program,"[3] OIG concluded here that the risk was low that the ability to bill for an administration fee would induce a prescribing physician to select the product over a competing product — even if the infusion site was affiliated with the prescribing physician — since existing competing products were also infusion drugs with billable administration fees.

As the OIG always warns in its advisory opinions, its assessment of any request is case-specific, but the parameters of the free gift program at issue in this advisory opinion and the resulting favorable opinion letter are nevertheless instructive. We discuss the latest terms of this arrangement below.

The Requestor's Product and Federal Program Coverage

The requestor's product is approved to treat patients with both mild cognitive impairment or mild disease-related dementia and confirmed presence of amyloid pathology. The product is intended to target the underlying disease, not simply manage the symptoms of the disease. Patients who are prescribed the product receive the product by infusion once every two weeks in an outpatient setting and, on average, use the product for approximately 3.6 years.

When covered by Medicare, the product is covered as a Medicare Part B outpatient infusion therapy and patients are reimbursed for both (1) the product and (2) its administration fee. The standard 20 percent Part B coinsurance applies for Medicare Part B fee-for-service enrollees once they meet their deductible. The provider may only bill Medicare for administering the product if the product itself is covered by Medicare. As of 2024, the administration fee reimbursed by Medicare was approximately $129.16 per infusion. While OIG did not comment on the administration cost individually or in the aggregate, the 2024 reimbursement rate was noted.[4]

Currently, only one other drug is available on the market to treat the underlying disease, which is also reimbursable under Part B. The requestor is also developing a subcutaneous formulation of the product, which it anticipates would be reimbursed under Medicare Part D.

Eligibility Criteria for the Free Product Program

To qualify for free product under this program, patients:

- Must be at least 18 years old, reside in the United States and have an on-label prescription for the therapy;
- Must either (1) be uninsured, (2) be insured but with no insurance coverage for the product or (3) have Medicare coverage for the product, but be unable to afford the coinsurance (e.g., the standard 20 percent Part B coinsurance); and
- Must have a household income equal to or below 500 percent of the Federal Poverty Level.[5]

Program Guardrails

As an initial matter, OIG acknowledged key features of the parties involved in supporting the arrangement and their roles. First, the requestor's patient services organization responsible for managing the arrangement is independent from sales and marketing, and personnel do not receive incentive compensation tied to product sales. Second, a noncommercial pharmacy with significant experience supporting manufacturer free product programs is contracted to support the arrangement. The pharmacy does not make patient referrals elsewhere, e.g., to copay assistance foundations, or other insurers, or other resources.

Once patients apply for assistance with the support of their physicians, the requestor takes specific steps to administer the program, which are generally summarized below:

- **Income verification**: Patient incomes are verified through soft credit checks or income documentation. Exceptions due to unanticipated hardships may be available to patients who exceed the 500% income threshold.
- **Eligibility determinations are made exclusively based on the specific requirements listed above**. The manufacturer ensures that eligibility determinations are made without regard to: (1) the patient's insurer or insurance plan, (2) the patient's physician or (3) the patient's infusion

provider. Eligibility also is not contingent on past or present product use or promises to make future purchases.

- **Eligible patients make certain certifications**. Patients receiving the free product must certify that they will not submit a request for the free product to any payor, including a federal health care program, and that they understand that, with limited exceptions, no part of the free product, or costs associated with the free product, will count toward their applicable out-of-pocket costs.

- **Providers also makes certain certifications that they will not seek any reimbursement**, **with one important exception for administering the product**. The treating physicians must certify in writing that they prescribed the product for on-label use, and that they will not submit a request for payment for the free product to any payor. The only important exception is that when a product is given for free to a Medicare patient specifically because the Medicare enrollee cannot afford the cost-sharing amount, the provider who administers the free product may bill Medicare for the administration cost (approximately $129.16 per infusion) and also the patient for any cost sharing related to only the administrative cost.

Once the patient qualifies, AO-25-01 highlighted key aspects of the program in operation:

- **The noncommercial pharmacy ships only the number of free product vials that are needed for two administrations of the product**. While in the past only enough product for a single dose was shipped at a time, because many of the administering sites administered the infusions in precise two-week intervals, shipping only one dose at a time led to missed doses and delay in treatment. Accordingly, the pharmacy now ships only enough product for two treatments, and the provider must confirm in writing the exact number of vials that are clinically appropriate for the particular patient for two administrations of the product.

- **The infusion site that is receiving the free product provides an oral acknowledgment that it understands the terms and requirements of the program**.

- **Each shipment includes a letter reiterating the requirements of the program**. These requirements include but are not limited to the requirements that the provider agrees: (1) not to submit a request for payment for the free product; (2) the quantities of free product shipped are limited to only what is needed for two administration of the product; (3) to segregate the free product from product used for commercial purposes; (4) to administer the product only to the designated patient; and (5) to refrain from selling, trading or returning the product for credit.

- **Unused products must be returned or disposed of pursuant to manufacturer instructions**. Finally, if the product ends up not being needed, the provider agrees to either return the product to the manufacturer or certify that the product has been disposed of in accordance with the manufacturer's instructions.

Education Allowed, but No Promoting the Free Product Program

As outlined in its request to OIG, the manufacturer — including any sales and marketing representatives working on the manufacturer's behalf — is prohibited from promoting the free product program as a reason to prescribe the product, including through any direct-to-consumer advertisement. Instead, health care professionals may learn about the program through approved printed materials for general awareness, or through reimbursement personnel who do not receive any sales-based incentive commission. The patients are expected to learn about the program through their treating physician, the manufacturer's patient support hub or the manufacturer's patient support website, and not through any direct-to-consumer advertisement.

The Arrangement Implicates the Federal Anti-Kickback Statute

OIG concluded in its advisory opinion that the above arrangement does implicate the federal anti-kickback statute for at least two reasons.

First, receiving a product for free constitutes remuneration to federal health care program enrollees and, for those federal health care program enrollees whose program does not cover the free product, the free product might induce federal health care program enrollees to continue using the product once it does become reimbursable under their federal health care program.

Second, the program provides remuneration to administering providers to the extent they are able to earn an administration fee when such fee is billable to a federal health care program (i.e., when a patient is a federal health care program enrollee and their federal health care program covers the product, but they are unable to pay their share of the coinsurance).

Additionally, OIG found there was no safe harbor to the federal anti-kickback statute that applied to the program.

The Risks Under the Program Were Sufficiently Limited

OIG concluded that, although the free product program implicates the federal anti-kickback statute for the reasons identified above, the risk of harm to federal programs was sufficiently minimal that a favorable advisory opinion was justified for at least three reasons.

- **First**, **OIG concluded that the arrangement did not inappropriately increase cost to federal health care programs**.

Numerous steps were in place to make sure that no product given under the program could be billed to a federal health care program. The only cost that could be billed to a federal health care program was the administration fee for the infusion, and that could only be billed in circumstances where Medicare could have also been billed for the product itself (i.e., where a patient was covered by Medicare but could not afford the cost-sharing associated with the product).

OIG recognized there was a risk that the program could become a seeding program for the product — for example, when a patient's insurer began to cover the product, including as new products are approved or become covered under Medicare Part D, or when a patient has a change in financial status. However, OIG concluded the arrangement was unlikely to inappropriately increase cost to federal health care programs because: (1) there is no barrier to switching products (and in this instance, there is at least one competitor product, and more options forthcoming); (2) eligibility for the free product is not contingent on past, present or future purchases of the product; and (3) the manufacturer intends to offer the program indefinitely, even if the product receives expanded Medicare coverage or new products come to market.

- **Second**, **OIG concluded the arrangement was unlikely to interfere with clinical decision-making**.

Given that providers are required to certify they will not submit a request for payment for the free product, prescribers generally do not have a financial incentive to order the product when it is covered by the program. In fact, the only potential billing opportunity arises if a patient has Medicare coverage for the product but cannot afford the cost-sharing amount of the product — in only that unique scenario the administering provider can bill the fee for administering the product. But OIG concluded the risk was low that such a fee would induce a treating physician to select the product over a competing product (particularly where they can also bill the administration fee for the competing product).

- **Third**, **OIG concluded the arrangement did not steer patients to any particular provider or insurance plan**.

The OIG opinion noted that patients are free to change physicians or infusion providers at any time without impacting their eligibility for the free product. Moreover, eligibility for the program does not take into account the patient's provider, practitioner or insurance plan — it is based only on a reasonable assessment of financial need.

Finally, OIG also concluded that the program did not implicate the Beneficiary Inducements CMP because the provision of free products to qualifying federal health care program enrollees was not likely to influence any enrollee's selection of a particular provider, practitioner or provider. Pharmaceutical manufacturers are not "providers, practitioners, or suppliers" unless they also own or operate, directly or indirectly, pharmacies, pharmacy benefit management companies or other entities that file claims for payment under the Medicare or Medicaid programs for purposes of the Beneficiary Inducement CMP, and the manufacturer certified to OIG that it did not own or operate any such facilities.

It should be noted that, in one prior advisory opinion, AO-08-04, OIG concluded that a free product program (involving trial supplies of product) under Medicare Part B for children with a certain hemophilia who were suffering from hemorrhagic episodes also did not raise substantial concerns. Unlike the Arrangement in AO-25-01, the arrangement in AO-08-04 only allowed for one to ten treatments per eligible patient, and the requestor limited its availability. Because the product was intended for episodic bleeding, OIG expressed less concern for risks of overutilization. The product was shipped to the patients, rather than the providers, which OIG viewed as further curtailing the risk of providers improperly billing Medicare for free goods. Importantly, the opinion did not confront issues of physician administration services. Finally, patients also could safely switch between the product, or other treatment options, which further persuaded OIG of the reduced risks of the program. OIG concluded that the circumstances presented were different than other free product programs that might be geared to "generating consumer demand" or as a way to "seed" or introduce new products into the market.

Takeaways for Manufacturers and Others Developing Free Product Programs

There are at least three key takeaways for any company looking to develop or assess its own free product or patient assistance programs in view of this latest opinion:

1) In many respects, the opinion hews to long-standing principles and considerations in analyzing similar programs, ultimately assessing program terms for any features that may cause improper seeding of or steering to product due to the "free" aspect of the program. Participation in the free product or patient assistance program should not be contingent on past or continued use of the product; patients should be able to safely switch therapies (if available) even if they initially start treatment through a free product program.

2) Companies should continue to impose restrictions on patients, physicians and third-party partners/vendors to prohibit — and to the fullest extent possible preclude — billing of federal programs for free product extended through these programs. Having noncommercial personnel — independent of sales and marketing — managing and implementing these programs, as well as avoiding direct-to-consumer advertising of the program, can also help mitigate the risk that the free product program will be viewed as a commercial effort to "seed" patients.

3) Where companies can demonstrate a low risk that provider-administered free product is being utilized to seed or steer patients to the product (e.g., where competitor products also require provider administration), providers who administer free product to eligible Medicare patients may bill Medicare for the administration fee (and may bill the patient the coinsurance amount for the service), even if those Medicare patients are unable to afford the Part B cost-sharing amounts for the drug.

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

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[1] *See*, *e.g.*, AO-06-03, AO-06-19, AO-06-21.

[2] AO-25-01 was issued on January 10, 2025, and posted on January 15, 2025. *See* https://oig.hhs.gov/documents/advisory-opinions/10162/AO-25-01.pdf

[3] See AO-06-03.

[4] Additionally, all state Medicaid programs cover the product as of the time the request was made, and the advisory opinion notes that the manufacturer is continuing to seek coverage for the product under other federal health care programs.

[5] For illustrative purposes, in 2025, 500% of the federal poverty level (FPL) for a household of one person is $78,250; for a household of four people, 500% of the FPL is $160,750.