A Look At HHS' New Opinion On Patient Assistance Programs

By **Dominick DiSabatino and Audrey Mercer** (February 18, 2025)

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On Jan. 15, the U.S. Department of Health and Human Services' Office of Inspector General released Advisory Opinion 25-01, clearing a pharmaceutical manufacturer's arrangement to provide free access to its infusion drug, plus related infusion services, for certain low-income patients, including federal patients.

The opinion is the newest piece in the tapestry that is the OIG's policy on manufacturer-funded patient assistance programs for federally reimbursable products and services vis-à-vis the federal Anti-Kickback Statute[1] and the civil monetary penalty,[2] and illustrates the OIG's continued willingness to justify lower-risk arrangements in the name of patient access.

Proposed Arrangement

The Product

The unnamed requestor of the advisory opinion manufactures an infusion drug, which is reimbursable under Medicare Part B as an outpatient infusion therapy. Unlike several other drugs on the market, the product targets the underlying process of the relevant ailment rather than simply managing the disease symptoms.

Consistent with the prescribing information, patients prescribed the product receive intravenous infusions once every two weeks for approximately one hour in an outpatient setting, which may be the treating physician's office, an outpatient setting affiliated with the treating physician or an independent infusion center.

When covered by Medicare, reimbursement under Part B is made for both the product and its administration, where the standard 20% Part B coinsurance applies for qualified Medicare patients who meet their deductible.

Importantly, the drug is not intended to be taken for life — rather, patients use the drug for an average of three-and-a-half years and there are no known clinical barriers to discontinuing the product or switching to an alternative therapy.

Currently, only one other drug, which is also an infusion drug reimbursable under Part B, is available on the market to treat symptoms of the disease, with two other subcutaneous formulation drugs in development, which will be reimbursable under Part D if they make it to market.

The Arrangement

Under the proposed arrangement, the requestor would offer the product at no cost to patients, including but not limited to Medicare patients, who meet certain age, prescribing and financial eligibility criteria.

The requestor certified that (1) eligibility determinations would be made without regard to

the patient's insurer or insurance plan, physician or infusion provider; (2) patients would be free to change physicians or infusion providers at any time; and (3) eligibility would not be contingent on past, present or future purchases of the product.

If a patient qualifies for free product, the requestor's vendor would ship it directly to the administration site in patient-specific vials limited to two administrations per patient.

Of course, the patient's provider would not purchase or be reimbursed for the free product, and patients, treating physicians and infusion providers may not seek reimbursement for the product.

However, if the product is being given for free to a patient who cannot afford the applicable cost-sharing amount, the provider who administers the infusion of the product would be permitted to bill Medicare for the infusion administration cost and the patient for any cost-sharing related to only the infusion administration cost. The proposed arrangement provides no subsidy for patient cost-sharing in this regard.

With respect to promotion of the arrangement, neither the requestor, nor anyone acting on the requestor's behalf would be permitted to promote the patient assistance program as a reason to prescribe the product, and the requestor would not promote the patient assistance program through any direct-to-consumer advertising of the product.

Instead, healthcare professionals might learn about the patient assistance program through approved printed materials for general awareness and reimbursement personnel, who do not receive sales-based incentive compensation and are permitted to educate providers about the patient assistance program.

Patients might learn about the program through their treating physicians, the requestor's patient support hub (only after a prescribing decision has been made or if a patient or caregiver calls asking about financial support options) or the requestor's website.

The OIG's Favorable Opinion

Although the OIG acknowledged — as if often does — that the proposed arrangement would implicate the Anti-Kickback Statute or civil monetary penalty if the requisite intent were present, and would not fit within a safe harbor regulation, it ultimately determined that the purported provision of free product to certain Medicare beneficiaries, even where associated infusion services may be billed to Medicare, presents a sufficiently low risk.

Here, the OIG provided three key conclusions that differentiate the proposed arrangement from other arrangements involving manufacturers' provision of free, federally reimbursable products that the OIG has determined to be improper under the AKS and civil monetary penalty.[3]

First, the proposed arrangement is unlikely to inappropriately increase costs to federal healthcare programs because:

- Reimbursement for the product itself will not be billed to any government program;

- The only cost that might be billed to a government program is the administration fee for the infusion, which would only be billed for government patients who cannot afford cost-sharing associated with the product; and

- The risk of patient-seeding is low since there is no barrier to switching between the product and an alternative therapy, eligibility for free product is not contingent on past, present or future purchases of the product, and the requestor manufacturer intends to offer the program indefinitely, even if the product receives expanded Medicare coverage or new products enter the market.

Second, the proposed arrangement is unlikely to interfere with clinical decision-making because patients, treating physicians and infusion providers may not submit for reimbursement of the product.

Also, although the administering infusion provider could receive payment, in limited circumstances, for administration of the product, under arrangement from other manufacturers, the administering provider could receive payment for both the product itself and administration of the product, so the administering provider loses potential profits when patients receive the product through the requestor's proposed arrangement.

Third, the proposed arrangement would not steer patients to any particular provider, practitioner or insurance plan because (1) eligibility determinations are based solely on financial need; and (2) patients are free to change physicians or infusion providers at any time without affecting their eligibility for free product.

Big Picture

Although the opinion follows the OIG's recent trend of blessing patient assistance program arrangements that implicate the AKS but don't fall squarely within a safe harbor — as long as they are structured with appropriate safeguards to minimize the risk of fraud and abuse — the opinion is unique is a couple of interesting ways, which we assume informed the requestor's decision to submit the arrangement for review.

First, the opinion concerns a patient assistance program for a drug that is reimbursable as a plan medical benefit under Part B, while most patient assistance program-related OIG advisory opinions — at least those issued since 2006[4] — have addressed drugs that are reimbursable as a plan pharmacy benefit under Part D.

This could just be a numbers game — after all, far more drugs are covered under Part D[5] — but Part B drugs encompass some unique considerations from a fraud and abuse standpoint in addition to those that apply in the Part D context.[6]

Part B drugs, as part of the plan medical benefit, are typically physician-administered and accompanied by one or more ancillary services provided by someone in a prescribing capacity, which increases the likelihood that improper incentives may be exchanged somewhere between the selection of a reimbursable drug and its ultimate delivery to the patient.

The fact that the OIG did not object to a patient assistance program arrangement for a

product with a potentially riskier federal reimbursement structure signals the agency's willingness to consider the patient benefit in view of the hard work put in by the industry over the years to ensure that these programs mitigate the kinds of fraud and abuse risks raised by the OIG.

Second, the arrangement does not fit squarely within previously issued OIG guidance on free drug programs and out-of-pocket waivers — two elements that are central to the proposed arrangement.

For one thing, the OIG has previously not objected manufacturers' proposals to provide free drugs to Medicare beneficiaries, but has been clear that the provision of free drugs to federal patients may be appropriate only in limited, special circumstances, such as where provision of a free drug is intended to treat a rare disease and/or is limited to (1) a two-week supply to address a patient's gap in insurance coverage, (2) samples provided for hospital use in compliance with the Prescription Drug Marketing Act, or (3) a one-time, potentially curative treatment.[7]

Here, by contrast, a patient is eligible to receive free, nonsample doses of the product year after year, as long as the patient continues to meet eligibility requirements.

Nevertheless, the requestor's proposal to furnish free drugs to Medicare patients appears to be sufficiently limited in the OIG's view, perhaps because of the limited average duration of use of the drug per patient, i.e., about 3.5 years; the limited nature of the drug regimen, i.e., once every two weeks; and the two-vial limit per patient per shipment.

Furthermore, a cornerstone of the OIG's policy on manufacturer-led patient assistance program, which has been around since the policy's early days, is that waiving copays on a routine basis should be avoided, as it presents a heightened risk of fraud and abuse.[8]

Although, under the arrangement, the requestor does not necessarily propose to waive patient copays, the arrangement appears to operate in a manner that relieves the patient of the need to pay the out-of-pocket cost, regardless of the patient's insurance.

However, the distinguishing consideration here, compared to copay waivers that the OIG has traditionally found problematic,[9] seems to be that the requestor would be supplying the product to certain patients for no cost at all, rather than waiving the patient's portion of the fee but billing Medicare for an artificially elevated product charge.[10]

Ultimately, the OIG just doesn't want the government to be left on the hook for payment when other shareholders are not — and the structure of the arrangement appears to avoid that where it matters, aside from limited circumstances for accompanying infusion services.

Despite the OIG's continued willingness to allow manufacturer-run patient assistance programs, such arrangements should be structured with great care, as striking an acceptable level of risk is clearly a tight-rope walk.

Where a contemplated patient assistance program does not fit squarely within one of the categories previously addressed by the OIG — such as independent charity patient assistance programs, direct-to-patient free drug programs for limited durations or purposes (e.g., coverage gaps), replacement drug programs, coalition model coupons or cost-sharing coupons[11] — manufacturers may consider submitting to the OIG.

However, where applicable, manufacturers structuring patient assistance programs for

therapies covered under Part B, or that incorporate a free drug program and eligibility criteria based on a patient's ability to pay the out-of-pocket cost, can use this opinion as a blueprint.

Such manufacturers may be able to get away with furnishing free drugs to federal patients, even where the government is still billed for ancillary services, as long as such provision is sufficiently limited and adheres to the OIG's core principles for manufacturer-backed patient assistance programs — that is, to avoid increased cost, overutilization, interference with clinical decision-making, and patient steering or seeding.

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[1] See 42 U.S.C. § 1320a–7b(b).

[2] See 42 U.S.C. § 1320a–7b(b).

[3] OIG did not mention over-utilization, but the limited drug regimen here may have had some influence.

[4] Medicare Part D was established in 2006. See Part D Prescription Drug Benefits.

[5] See Drug Coverage under Different Parts of Medicare (Mar. 2023); 2023 Medicare Part B Drug List.

[6] See 70 Fed. Reg. 70623 (Nov. 22, 2005); see also OIG Adv. Ops. 02-13 and 03-13 (concerning Part B drugs and addressing the same fraud and abuse considerations).

[7] See, e.g., OIG Adv. Ops. 23-02; 22-22; 21-16; and 21-01.

[8] See, e.g., OIG Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B (Dec. 19, 1994).

[9] See, e.g., Adv. Op. 03-13.

[10] See id., stating that routinely waiving Medicare copayments or deductibles misstates the actual charge for the product/service and that "as a result of the supplier's misrepresentation, the Medicare program is paying … more than it should for the item."

[11] See, e.g., 70 Fed Reg. 70623-70628; OIG Adv. Op. 23-02; Special Advisory Bulletin – Pharmaceutical Manufacturer Copayment Coupons, OIG (Sept. 2014).