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HHS Advisory Opinion Serves As Free Drug Program Guide

By **Dominick DiSabatino and Cortney Inman** (March 20, 2023, 5:13 PM EDT)

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On Feb. 28, the Office of Inspector General for the U.S. Department of Health and Human Services posted Advisory Opinion No. 23-02, relating to a program to provide a drug for free for a limited time to patients experiencing a delay in the insurance approval process.[1]

In the opinion, the inspector general's office, or OIG, determined that the proposed arrangement was sufficiently low risk under the federal Anti-Kickback Statute and did not trigger the beneficiary inducements civil monetary penalty.

The opinion builds on a recent string of the OIG's opinions on so-called free drug programs, providing an opportunity to reevaluate and reexamine the OIG's stance on these programs.

The Arrangement

Under the arrangement, the requestor provides, via a specialty pharmacy, a free 14-day supply of the drug to eligible patients, with the possibility of one free 14-day refill. The drug in question is an enzyme replacement therapy, or ERT, for the sole indication of treatment of a rare and life-threatening inherited genetic disorder that results in a severely compromised immune system.

There are only two U.S. Food and Drug Administration-approved treatments for the condition — ERT and a bone marrow transplant. The requestor's drug is the only currently available ERT treatment for the condition, and given the complexities of a bone marrow transplant, is often a first-line treatment. The drug is typically self-administered, and the patient must take the drug for life unless cured by a bone marrow transplant.

To be eligible to receive the free supply of the drug, a patient must be diagnosed with the condition, have received their first prescription for the drug, be insured and "have experienced a delay in coverage determination for the Drug of at least 48 hours," according to the opinion.[2]

After that, a patient may be eligible for one free 14-day refill supply of the drug if the patient is "still awaiting a coverage determination or has received a denial and is diligently pursuing appeal rights," the opinion says.

However, if the patient's insurer makes a favorable coverage decision within 48 hours, then the patient would be ineligible. The drug is then distributed exclusively by the specialty pharmacy and shipped directly to the patient.

Overall, it is expected that only a very small percentage — 0.0078% — of all prescribed vials of the drug would be provided under the arrangement.

Federal Anti-Kickback Statute Analysis

The OIG concluded that the arrangement presented minimal risk of fraud and abuse under the Anti-Kickback Statute for five key reasons.

First, the OIG underscored that eligibility turns on that small portion of patients experiencing at least a 48-hour delay in insurance coverage determination, with a maximum supply of 28 days.

Second, the OIG explained that given the limited circumstances in which the free supply of the drug may be available, the arrangement is unlikely to influence patients or prescribers to choose this drug over alternative therapies, thereby distinguishing the arrangement from so-called seeding programs.

The OIG noted that at the time of prescribing, patients and physicians likely assume that insurance will cover the drug, and additionally, there is only one other treatment option available, i.e., a bone marrow transplant.

Third, given that the drug is self-administered and dispensed directly to the patient via the specialty pharmacy, the OIG determined that there is no opportunity for prescribers to bill for the drug. Even if the prescriber were to assist in administration of the first dose of the drug, the prescriber is prohibited from billing any administration fee.

Fourth, the OIG reiterated the safeguards in place under the arrangement that prevent any billing of the drug or administration of the drug to patients, pharmacies, payers or other third parties, including explicit notification to all parties that the free drug was only provided outside the Medicare benefit and should not count against the patient's true out-of-pocket for any Part D enrollee.

Last, the OIG highlighted that "[t]he remuneration is the free Drug, and the Specialty Pharmacy is the only pharmacy that dispenses the Drug," however, "[a]ccepting the free Drug under the terms of the Arrangement does not obligate a patient to continue obtaining the Drug, or any other item or service, from the Specialty Pharmacy in the future."

Of note, the OIG completed the Anti-Kickback Statute analysis with a caution to manufacturers considering similar programs, noting that:

> We might reach a different conclusion on different facts, such as if the Arrangement were used as a marketing tool or if Requestor were providing free Drug outside of the context of a legitimate delay in a coverage determination or appeal.

Beneficiary Inducements Civil Monetary Penalty Analysis

Next, the OIG considered whether the arrangement potentially implicated the beneficiary inducements civil monetary penalty. Ultimately, the OIG found that while the specialty pharmacy is considered a supplier under the statute, the remuneration offered by the requestor under the arrangement is not likely to influence a beneficiary to purchase the drug from the specialty pharmacy.

This was because the specialty pharmacy is the only pharmacy that dispenses the drug, so all patients prescribed the drug have to obtain it from that source, regardless of the arrangement.

Further, the OIG reasoned that

> it is unlikely that the possibility of receiving an initial free supply of the Drug following a coverage delay (with one possible refill) is likely to influence a patient to purchase other federally reimbursable products from the Specialty Pharmacy in the future.

Analysis of the OIG's History With Free Drug Programs

This opinion should provide helpful insight to manufacturers considering similar free drug programs, specifically those that contemplate insurance coverage delays as a basis for providing free drugs to patients. The immediate questions, though, are why this opinion, and why now?

To be sure, any OIG advisory opinion is decided narrowly on the facts, and the facts here strongly counsel in favor — an ultra-rare disease where treatment is, in nearly all cases, immediately covered by insurance.

But the "coverage delay" flavor of free drug programs has been more closely scrutinized by the OIG,

which may have been the impetus for the requestor to seek an advisory opinion in any event.

This makes sense, given the OIG's admonition in the opinion that the decision would have gone the other way outside the context of legitimate insurance coverage delays, but it is not like the OIG has been mum on the issue of free drug programs as of late.

Indeed, the OIG has now spoken on the issue of free drugs to patients five times in the last five years.[3]

Given economic headwinds and tightening consumer budgets, now might be a good time for industry to reevaluate free drug programs to ensure that the foundational rationales upon which the programs are built stay true to the elements that the OIG typically relies upon in exercising enforcement discretion.

In each of these five advisory opinions, the following factors have generally been considered favorable to drug manufacturers:

- Whether the product is priced similarly and/or is clinically superior to competitors or class;
- Whether there are no clinical or physiological barriers in switching to competitor products;
- Whether provision of free drugs is designed to address clinical benefit or risk profile;
- Whether provision of free drugs is intended to address insurance approval issues for emergent or life-threatening conditions;
- Whether strict limits are placed on distribution — e.g., maximum amounts, limited locations, limited or no advertising;
- Whether controls are placed to prevent billing for free product;
- Whether there is limited involvement with health care providers; and
- Whether usage is expected to be low.

Aside from the opinion, the OIG has previously considered and approved a similar free drug program in Advisory Opinion No. 15-11.[4] There, the OIG concluded that it would not impose administrative sanctions for an arrangement that facilitated the provision of a 30-day free supply, and the possibility of a 30-day free refill, of a breakthrough, clinically superior to class anti-neoplastic therapy drug via a specialty pharmacy.

Although the timeline for awaiting coverage determination was significantly shorter in Advisory Opinion No. 15-11 as compared to Advisory Opinion No. 23-02, i.e., five days versus 48 hours, and the characteristics of their respective fulfillment pharmacies differed — i.e., in Advisory Opinion No. 15-11, the specialty pharmacy did not dispense to the general public versus in Advisory Opinion No. 23-02, the specialty pharmacy was the exclusive distributor of the requestor's drug — the OIG appears to have approved of the two programs for similar overarching reasons.

In both opinions, the OIG found that the arrangements:

- Had limited risk of overutilization;
- Lacked characteristics suggestive of a problematic seeding program;
- Imposed no cost to federal health care programs; and
- Did not have any other inducement factors, such as a financial benefit to the prescriber or an incentive for a federal health care beneficiary to make future purchases from the specialty

pharmacy utilized under the arrangement.

These factors were similarly important in another, less favorable OIG advisory opinion — Advisory Opinion No. 18-14 — where the OIG concluded that a program to provide free vials of a drug to hospitals and to patients unable to secure insurance coverage following their hospital stay did implicate the Anti-Kickback Statute.[5]

The OIG emphasized, among other things, that the program:

- Was likely to induce hospitals to prescribe the requestor's drug;
- Was comparable to a problematic seeding program because of the adverse effects of ceasing treatment, which in effect did induce future purchases of the drug because patients would likely continue treatment to avoid negative consequences of discontinuing treatment; and
- Any cost-saving that the hospital would receive from the free supply would not be passed on to federal health care programs, which would still reimburse costs associated with inpatient stays while patients receive the drug.

Although this program did not include an insurance delay component, it provides an important point of comparison given that it is the only recent advisory opinion where the OIG has blocked a proposal for a free drug program.

In the opinion, the OIG discussed at length publicly available information regarding significant price increases of the drug and the drug's anti-competitive history — information that served as a critical basis for the OIG's conclusion.

Ultimately, although the drug at issue was a first-line treatment for a serious condition, these facts were not enough to outweigh the concerns relating to risk of fraud and abuse.

Final Takeaways

Now is as good a time as any to vet your free drug program, especially if one of its purposes is to address insurance coverage delays. This opinion provides yet another example of the OIG's understanding that, for certain disease states, free drug programs for severe, life-threatening conditions pose a low risk of enforcement, despite technically meeting the elements of the Anti-Kickback Statute.

Moreover, manufacturers and other stakeholders considering similar arrangements should heed the OIG's explicit caution that an arrangement may be viewed less favorably where: it is "used as a marketing tool"; the requestor is "providing free [d]rug outside the context of a legitimate delay in coverage"; or "it appears that the arrangement is being used a greater rate than would be expected based on typical insurance approval rates."

It has been a good track record thus far for the OIG finding favorably for manufacturers providing free drugs for insurance delays, but manufacturers should be mindful of the concepts and questions laid out in the above section when considering whether and how to implement any similar free drug programs.

Today, many manufacturers have some form of free drug program, especially in the rare and difficult-to-treat disease spaces.

These drug products are, of course, typically quite expensive, which raises the risk profile when considering whether to premise a free drug program on insurance coverage delay.

However, a careful analysis of the OIG's treatment to date provides a rubric for ensuring that free drug programs are viewed favorably.

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[1] https://oig.hhs.gov/documents/advisory-opinions/1104/AO-23-02.pdf.

[2] The basis for this 48-hour coverage delay timeline was: "(i) the severe nature of the Condition; (ii) existing payor policies; and (iii) Federal and state laws and regulations, some of which Requestor certified already require payors to make coverage determinations within 48 hours or less in like circumstances."

[3] See OIG AO 23-02; OIG AO No. 22-22 (arrangement to provide trial units of a long-acting antipsychotic injection drug for free to hospitals for inpatient use); OIG AO No. 21-16 (same); OIG AO No. 21-01 (proposal to provide a free, one-time, potentially curative treatment made from patient's own cells to patients meeting certain eligibility criteria); OIG AO No. 18-14 (proposal to provide free vials of a drug to hospitals for inpatient treatment).

[4] https://oig.hhs.gov/documents/advisory-opinions/700/AO-15-11.pdf.

[5] https://oig.hhs.gov/documents/advisory-opinions/757/AO-18-14.pdf.
