PUBLICATION

OIG Approves Limited, Free Drug Program [Ober|Kaler]

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On August 12, 2015, the Department of Health and Human Services, Office of Inspector General (OIG) issued Advisory Opinion 15-11 [PDF], approving two pharmaceutical manufacturers' free starter drug program. Citing the limited scope and duration of the program, the OIG concluded the manufacturers' arrangement posed a low risk under both the federal antikickback statute and the civil monetary penalty provision against inducements to beneficiaries (beneficiary inducement CMP).

Overview of Facts

Two pharmaceutical manufacturers (Manufacturers) sought approval from the OIG for an arrangement (Arrangement) in which certain patients may receive, free of charge, a limited supply of a specified cancer drug (Drug) co-promoted by the Manufacturers. To participate in the Arrangement, patients must (1) not have used the drug previously, (2) have an "on-label" diagnosis and valid prescription for the Drug, (3) be insured, and (4) have experienced a delay in their insurance coverage determination of at least five business days.

Eligible patients may receive only one free 30-day supply of the Drug. If, upon conclusion of the 30-day free supply, a participating patient's insurer still has not made a coverage determination or if the patient's insurer denied coverage and the patient is actively appealing the determination, the Manufacturers may provide one additional 30-day refill. No further refills are provided. To the extent a patient decides to continue to receive the drug through the patient's insurer outside of the Arrangement, patients are subject to sizeable cost-sharing requirements.

The Manufacturers certified that while participating patients may have other treatment options, the alternatives are limited and patients may experience serious side effects. The Manufacturers further certified that there are no clinical barriers to switching from the Drug to another therapy. Absent including information about the Arrangement on the Manufacturers' own website, the Arrangement is not advertised.

The Drug itself is orally administered and may be dispensed only through specialty pharmacies; physicians cannot receive an administration fee for the Drug. Accordingly, to administer the Arrangement, the Manufacturers work with both a vendor and an affiliated specialty pharmacy (Pharmacy). For its services, the Pharmacy receives a fair market value dispensing fee. While the Pharmacy will be responsible for dispensing the Drug to participating patients under the Arrangement, the Pharmacy does not otherwise fulfill prescriptions for the general public outside of special pharmaceutical manufacturer programs like the Arrangement. Consequently, following a patient's participation in the Arrangement, it is unlikely that patients will even have the option of continuing to receive the Drug and/or any other drug produced by Manufacturers from the Pharmacy.

No patient, pharmacy, or payer is billed for the free supplies of the Drug, including Part D plans. Specifically, for Medicare Part D beneficiaries participating in the Arrangement, the Pharmacy will notify the patient's Part D plan sponsor about the Arrangement and ensure that, as part of the Arrangement, (1) no part of the cost of the Drug is counted toward a patient's true out-of-pocket costs and (2) no claim will be submitted to the Part D plan sponsor.

To date, only .0008 percent of all Drug shipments have been part of the Arrangement, just one third of which were provided to Medicare or Medicaid beneficiaries.

Legal Analysis

In determining the Arrangement posed a low risk under both the antikickback statute and beneficiary inducement CMP, the OIG focused in particular on the limited scope and limited duration of the free Drug program.

Antikickback Statute

As outlined below, because the OIG determined the Arrangement was unlikely to cause patients to self-refer for the Drug, or the Pharmacy, the OIG concluded the Arrangement presented a low risk under the antikickback statute.

- *Limited risk of overutilization*: Noting that the Arrangement applies only to on-label uses of the Drug, and that free supplies of the Drug are available for up to just 60 days to a limited subset of patients experiencing insurance coverage determination delays, the OIG concluded it was unlikely that the Arrangement would result in overutilization of the Drug. The OIG also emphasized the fact that, outside of the Arrangement, all patients, including those that participated in the Arrangement, are subject to high cost-sharing amounts.
- *Unlikely to cause patients or prescribers to choose the Drug over alternative therapies*: The OIG concluded the Arrangement was unlikely to "influence patients or prescribers to choose the Drug over alternative therapies," due to (a) the relative lack of alternative therapies to the Arrangement, (b) the fact that the Manufacturers did not actively market the drug, and (c) the Arrangement's narrow patient eligibility criteria.
- *Unlikely to induce beneficiaries to receive federally payable prescriptions from the Pharmacy*: The Pharmacy does not dispense drugs to the general public. As such, the OIG noted, upon the conclusion of a patient's participation in the Arrangement, patients will not be able to obtain future, federally payable prescription refills from the Pharmacy.
- *No costs are imposed on the federal health care program*: Citing the Manufactures' statement, and related certifications, that no patient, pharmacy, or payer is billed for the free supplies of the Drug (including Part D plans), the OIG concluded that the Arrangement imposed no costs on the federal health care program or its beneficiaries (in addition to any other third-party payor or pharmacy).

Beneficiary Inducement CMP

The OIG began by noting that the beneficiary inducement CMP is not applicable to the Manufacturers because they are not "providers, practitioners, or suppliers." The OIG then briefly considered the application of the CMP to the Arrangement as it pertains to the Pharmacy.

Because the Pharmacy neither dispenses drugs or supplies to the general public (outside of special pharmaceutical manufacturer programs like the Arrangement) nor bills any third-party payor under the Arrangement, the OIG determined that the Arrangement was unlikely to induce Medicare or state health care program beneficiaries to select the Pharmacy as their supplier-of-choice for their future prescription needs, either with respect to the Drug or other supplies.