OIG Does Not Impose Sanctions on Drug Manufacturers for Providing Financial Assistance to Pediatric Patients with Rare Immunodeficiency Disorder



3/30/2023

In advisory opinion No. 23-01, issued on February 17, 2023, the Office of Inspector General (OIG) declined to impose sanctions on a drug manufacturer that provided financial assistance for transportation, lodging, and meals to financially needy pediatric patients and their caregivers in connection with the drug manufacturer's drug. The advisory opinion analyzed whether the arrangement implicated the Anti-Kickback Statute (AKS) and the beneficiary inducement civil monetary penalty rules (Beneficiary Inducements CMP).

Although the OIG determined that the arrangement implicated the AKS because it would generate prohibited remuneration if the requisite intent were present, the OIG did not impose sanctions under the AKS because the unique facts presented collectively reduced the risk of potential for fraud and abuse. Such facts included the following:

•The drug is a one-time potentially curative treatment.

•The drug is the only treatment available to rebuild the patient's immune system.

•The condition is very rare.

•The drug may only be manufactured at one facility and the drug has a short 3-hour shelf life, requiring patients to travel to the specific treatment center.

•Patients must meet certain eligibility criteria, such as a household income threshold, to receive financial assistance.

•Eligibility for financial assistance from the drug manufacturer is contingent on sources of funding or coverage being unavailable.

•Costs of the arrangement are not shifted to federal health care programs and the drug is priced independently of the cost of the arrangement.

The OIG stated that the remuneration offered under the arrangement would not likely influence a patient to select the treatment center where the drug is administered. Rather, it was the limitations related to the manufacturing and distribution of the drug that would likely influence a patient's decision-making.

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