OIG: PROVISION OF FREE DRUGS BY DRUG MANUFACTURER TO ELIGIBLE PATIENTS PRESENTS LOW RISK OF FRAUD AND ABUSE AND DOES NOT IMPLICATE BENEFICIARY INDUCEMENTS CMP

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In Advisory Opinion 21-01, issued January 8, 2021, the OIG recently determined that an arrangement whereby a drug manufacturer provides a free drug to patients meeting specific clinical, health insurance and income criteria was a low risk of fraud and abuse under the Federal anti-kickback statute and did not implicate the Beneficiary Inducements CMP.

THE ARRANGEMENT

The party requesting the opinion is a drug manufacturer manufacturing a drug approved by the FDA for two indications: 1) patients up to twenty-five (25) years of age with (disease redacted) that is refractory or in second or later relapse; and 2) adult patients with relapsed or refractory (disease redacted) after two or more lines of systemic therapy. The drug was a treatment of last resort and for patients who did not respond to their initial treatments. The drug was a personalized medicine made from the patient's own cells and was intended to be a one-time, potentially curative treatment. As a result of patient safety risks, the FDA required implementation of a Risk Evaluation and Mitigation Strategy ("REMS") including elements to assure safe use ("ETASU"). Consistent with the REMS with ETASU, the drug could only be administered at a health care facility certified by the manufacturer to meet certain drug safety requirements and prescribed only by a physician trained to meet the requirements of the drug's REMS with ETASU.

The manufacturer offered the drug at no charge to patients who:

1. Were U.S. residents;

2. Had been prescribed the drug by a certified physician, in accordance with the FDA approved indication;

3. Had a) no health insurance, b) no insurance coverage for the drug, c) received a denial of prior authorization and first-level appeal from their insurer, or d) a first-level appeal for coverage that had been pending for at least 10 days; and

4. Had an annual income equal to or less than $75,000 for a single-person household and no more than an additional $25,000 per each additional household member.

The drug was provided free of charge to all eligible patients for all FDA-approved indications regardless of 1) whether the drug was administered as inpatient or outpatient; and 2) the eligible patient's type of insurance, if any, (including federal health care programs). Other features of the arrangement included:

1. Eligible patients could choose any certified health care facility and certified physician;
2. Provision of drug would not be contingent on any future orders of the drug;
3. The Physician prescribing the drug would have to certify that he or she prescribed the drug based on one of the two indications;
4. Neither the health care facility nor the physician could submit any claim for payment to any Federal health care program for the cost of the drug;
5. The facility or physician could bill third-party payors, including Federal health care programs, for professional services, facility fees or other fees related to administering the free drug to eligible patients; and
6. Neither facility nor physician would incur any acquisition costs for the drug when used for an eligible patient under the arrangement.

ANALYSIS

A. Federal Anti-Kickback Statute

While the OIG found that the provision of the drug constituted remuneration to both the providers and eligible patients and implicated the Federal anti-kickback statute, the OIG ultimately determined that the arrangement presented a low risk of fraud and abuse under the anti-kickback statute for the following reasons:

1. The drug was generally only administered once and individually manufactured from the patient's own cells;
2. The drug was only available to those patients prescribed the drug in accordance with the FDA-approved indication;
3. Provision of the drug was not contingent on future orders of the drug;
4. The arrangement was distinguishable from other potentially problematic arrangements in which a manufacturer provides drugs for free, such as situations where a free initial dose for a chronic condition is provided to induce the patient to purchase the drug in the future;
5. The free drug was available to patients for both FDA-approved indications unlike the problematic situation in which a manufacturer offers a free drug for one clinical indication to maintain a high price for all of the drug's indications when paid for by Federal health care programs;
6. The drug was provided free to all eligible patients regardless of whether the drug was administered to an inpatient or outpatient;

7. The drug was offered free to all similarly situated patients, regardless of payor; and

8. While the providers of the free drug may receive a financial benefit from professional and facility fees related to the administration of the drug, the risk of overutilization of the drug and possible increased fees was reduced as the drug was generally administered one-time and was a treatment of last resort.

B. Beneficiary Inducements CMP

In its analysis, the OIG indicated that the provision of the free drug could constitute remuneration under the Beneficiary Inducements CMP if the free drug were likely to influence the beneficiary to select drug treatment by a particular provider. In concluding that the arrangement was not likely to influence a beneficiary and therefore, did not implicate the Beneficiary Inducements CMP, the OIG found significant that:

1. Eligibility for the free drug was not dependent on the patient/beneficiary's use of a particular health care facility or provider.

2. Any certified physician could prescribe the drug.

3. While eligible patients were limited to receiving the drug from certified centers, this requirement was imposed by the FDA, not the manufacturer.

CONCLUSION

Even though the OIG found that the provision of the free drug to eligible patients implicated the Federal anti-kickback statute, the OIG determined that such provision presented a low risk of fraud and abuse. Furthermore, the OIG concluded that the arrangement did not implicate the Beneficiary Inducements CMP. Significant in its analysis was the very limited administration potential of the drug, eligible patients were required to meet specific clinical indications, as well as insurance and income criteria, and the drug was administered to all similarly situated eligible patients regardless of the clinical setting of the administration, i.e., inpatient versus outpatient.

Please contact a member of Hancock Daniel's Fraud & Abuse team with any questions.