# PUBLICATION

## OIG Permits Pharmaceutical Manufacturer to Offer Free Drug to Patients in Advisory Opinion 21-01

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**May 2021**

**In its March 18, 2021 Advisory Opinion (AO), AO 21-01, HHS Office of Inspector General (OIG) determined that a pharmaceutical manufacturer that produces a drug as a one-time, potentially curative treatment (the Drug) may offer the Drug at no charge to patients unable to afford the Drug who are either uninsured or insured under plans that will not cover the Drug (the Arrangement). OIG concluded that it would not impose administrative sanctions under the federal Anti-Kickback Statute and that the Arrangement does not constitute grounds for the imposition of sanctions under the Beneficiary Inducement CMP.**

The manufacturer's Drug is approved by the U.S. Food and Drug Administration (FDA) for the treatment of patients with a relapsed or refractory disease. The Drug is a personalized medicine made from the patient's own cells and is intended to be a one-time, potentially curative treatment. The Drug's prescribing information requires the Drug to be administered only 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 Risk Evaluation and Mitigation Strategy (REMS) mandated by the FDA.

The Arrangement is designed to benefit patients who do not have insurance coverage for and cannot afford the Drug. Under the Arrangement, the manufacturer offers the Drug at no charge to patients, including federal health care program beneficiaries, who:

- Are U.S. residents;
- Have been prescribed the Drug by a physician, in accordance with the Drug label for an FDA-approved indication;
- Have (i) no health insurance, (ii) no insurance coverage for the Drug, (iii) received a denial of prior authorization and first-level appeal from their insurer, as determined by the administering health care facility, or (iv) a first-level appeal for coverage of the Drug that has been pending for at least 10 days; and
- Have an annual household 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.

OIG concluded that, although the Arrangement would generate prohibited remuneration under the federal Anti-Kickback Statute if the requisite intent were present, OIG would not impose administrative sanctions on the manufacturer. In reaching this conclusion, OIG determined that the Arrangement would present a sufficiently low risk of fraud and abuse based on four factors:

- **First**, the Arrangement is distinguishable from other potentially problematic arrangements in which a manufacturer provides drugs for free because the Drug is a potentially curative treatment, generally administered only once, and individually manufactured for the patient using the patient's own cells. Because of this, the OIG noted that there is limited risk of "seeding" (offering the first dose free to a chronic patient to induce the patient to continue to use the drug which would result in future referrals). The manufacturer also certified that provision of the free Drug is not contingent on any future orders

of the Drug by a physician.

- **Second**, the Arrangement is available to patients for all of the Drug's FDA-approved indications, distinguishing it from a suspect arrangement where 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.

- **Third**, the manufacturer provides the Drug at no cost to all eligible patients regardless of whether the Drug is administered in an inpatient or outpatient setting.

- **Fourth**, the risk that a physician would overutilize the drug to earn income, including professional service fees and facility fees in connection with administration of the free Drug, is low because (i) the Drug is a potentially curative treatment and generally administered only once; and (ii) the free Drug is only available as a treatment of last resort.

Under the Beneficiary Inducements CMP, OIG *considered whether the manufacturer* would know or should know that the remuneration it offers to beneficiaries is likely to influence their selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. OIG concluded that the remuneration offered by the manufacturer under the Arrangement is not likely to influence a beneficiary to select a particular provider, practitioner, or supplier to administer the Drug, and therefore the Beneficiary Inducements CMP is not implicated. In reaching this conclusion, OIG reasoned that the pharmaceutical manufacturer does not make eligibility for the free Drug dependent on a beneficiary's use of a particular provider, practitioner, or supplier. Although patients are limited to receiving the drug from manufacturer-certified health care facilities, this requirement is based on the REMS imposed by the FDA to ensure patient safety, not the remuneration offered by the manufacturer under the Agreement.

Of note, OIG clarifies for purposes of the Beneficiary Inducements CMP, pharmaceutical manufacturers are not "providers, practitioners, or suppliers" unless they own or operate (directly or indirectly), pharmacies, pharmacy benefit management companies, or other entities that file claims for payment under Medicare or Medicaid. In Advisory Opinion 21-01, OIG clarified that the CMP Law *can* apply to pharmaceutical manufacturers even if they do not own or operate an entity that files claims for payment if the pharmaceutical manufacturer offers remuneration to a patient that the manufacturer knows or should know is likely to influence that patient to select a particular provider, practitioner, or supplier, and therefore, could be subject to the CMP Law. However, based on the fact of the arrangement presented, the CMP is not implicated.

## Baker Notes

The manufacturer of this particular Drug was able to obtain a favorable opinion from OIG based on the specific facts of the Drug and the circumstances under which it is offered to patients for free. This opinion provides insight into how OIG reviews these arrangements with certain factors routinely considered. OIG continues to evaluate arrangements with a focus on concerns considered in the opinion including any impact on patient care, seeding, the potential influence on providers, and effects on federal health care reimbursement for the drug. Pharmaceutical manufacturers should remain cautious when implementing programs to help patients who cannot afford certain drugs.

For more information on this Advisory Opinion, please contact Mary Grace Griffin or any member of Baker Donelson's Health Law Group.