EPSTEIN BECKER GREEN | Health Care & Life Sciences
CLIENT ALERT

OIG Permits Manufacturer of Personalized Medicine Drug to Cover Patients' Travel, Lodging, and Other Expenses

By Jennifer E. Michael and Bonnie I. Scott

January 2020

On January 21, 2020, the Office of Inspector General for the U.S. Department of Health and Human Services ("OIG") published Advisory Opinion 20-02,[1] approving an arrangement under which a pharmaceutical manufacturer provides financial assistance for travel, lodging, and other expenses to certain patients prescribed the manufacturer's drug (the "Arrangement"). With this favorable opinion, OIG offers additional insight into its interpretation of the federal Anti-Kickback Statute ("AKS") and the "Promotes Access to Care" exception to the Civil Monetary Penalties Law's beneficiary inducement provisions ("Beneficiary Inducements CMP") in the context of patient assistance programs offered directly by manufacturers. Notably, the Arrangement does not include any type of copayment assistance for the requesting manufacturer's products; this feature differentiates it from arrangements involving copayment assistance provided by foundations that are primarily funded by pharmaceutical manufacturers, which have been the subject of recent settlements.[2]

The Arrangement

Background

The requestor pharmaceutical company ("Requestor") manufactures a personalized medicine drug made from a patient's own cells (the "Drug"). The Drug is approved by the U.S. Food and Drug Administration ("FDA") for two indications, Disease A (generally affecting children and young adults) and Disease B (generally affecting adults).

Because the Drug has the potential for certain life-threatening or fatal reactions, its FDA-approved prescribing information requires patients who receive the Drug to be monitored by the administering physicians two to three times during the week following

---

[1] *See* https://oig.hhs.gov/fraud/docs/advisoryopinions/2020/AdvOpn20-02.pdf.

[2] *See, e.g.,* U.S. Department of Justice Press Release, 10/25/19, "Foundations Resolve Allegations of Enabling Pharmaceutical Companies to Pay Kickbacks to Medicare Patients," *available at* https://www.justice.gov/usao-ma/pr/foundations-resolve-allegations-enabling-pharmaceutical-companies-pay-kickbacks-medicare.

infusion, and to stay close to the facility that infused the Drug for at least four weeks after infusion. This proximity is important because providers in the patients' local communities may not have the training to handle potentially serious Drug reactions, which could result in patient harm or even death.

The FDA requires Requestor to implement a Risk Evaluation and Mitigation Strategy ("REMS") to further mitigate the Drug's risks to patients. Only REMS-certified physicians may prescribe and administer the Drug, and Requestor certified nearly 100 inpatient and outpatient facilities in the United States ("Centers"). Any facility that can meet the certification criteria, which Requestor uniformly applies, is eligible to become a Center.

According to Requestor, the Arrangement is intended to help eligible patients cover the costs they incur to travel to the Center and remain close to it after receiving the Drug, and meet the requirements set forth in the Drug prescribing information to ensure patient safety.

Assistance Provided

Under the Arrangement, Requestor provides travel, lodging, meals, and certain out-of-pocket expenses incurred during and after an eligible patient's Drug infusion for the patient and up to two caregivers (for children and young adults), or for the patient and one caregiver (for adults ages 26 years and older). Specifically, Requestor offers the following:

- **travel**—reimbursement for gas and tolls, or patient/caregiver transportation (including by air, when appropriate) to the nearest Center;

- **lodging**—a modest room near the Center during Drug treatment and post-treatment monitoring if the patient is not eligible to receive lodging from the Center; and

- **out-of-pocket expenses**—reimbursement of up to $50 per person per day for out-of-pocket expenses such as meals and parking costs.

Patient Eligibility Criteria

To be eligible for financial assistance, patients must be prescribed the Drug for an FDA-approved indication, have a household income that does not exceed 600 percent of the federal poverty level, live more than two hours or 100 miles from the nearest Center, and have no insurance for non-emergency medical travel. Requestor has a written policy detailing the eligibility criteria, which it applies uniformly and consistently. Requestor does not advertise the Arrangement.

OIG Analysis

AKS

Most of OIG's analysis is devoted to evaluating the Arrangement under the AKS, which makes it a criminal offense to knowingly and willfully offer or receive remuneration to induce or reward the referral of items or services reimbursable by a federal health care program.[3] To start, OIG noted that the Arrangement implicates the AKS, because the assistance that Requestor provides to patients, some of whom are federal health care program beneficiaries, may induce them to purchase the Drug, and allows them to travel to, and stay near, a Center that they may not otherwise have selected for treatment. OIG also highlighted that the assistance constitutes remuneration to the Centers and their physicians, in the form of the opportunity to earn a fee in connection with the Drug's administration, which may induce the physicians to order the Drug. OIG went on to detail its concerns about similar arrangements, including general concerns that such arrangements may result in patient steering and the potential for increases in federal health care program costs; however, OIG ultimately concluded that it would not impose sanctions on Requestor in connection with the Arrangement for a number of reasons, including that the Arrangement:

1. **Improves Access to Care:** The Arrangement is intended to increase access to care. In particular, OIG noted the potentially disproportionate impact that financially needy and rural patients could face if they could not travel to a Center to receive the Drug and stay nearby afterwards for monitoring purposes.

2. **Helps Achieve Compliance with FDA Requirements:** The Arrangement allows financially needy patients and their physicians to adhere to the Drug's FDA-approved prescribing information and avoid potential patient harm associated with the Drug, thus mitigating OIG's concerns about manufacturers providing financial assistance in connection with their own products.

3. **Is Unlikely to Be Used to Reward a Limited Number of Physicians Who Prescribe/Administer the Drug:** OIG acknowledged that the limited network of REMS-certified physicians is necessary to ensure patient safety and compliance with FDA REMS requirements, and viewed favorably the fact that any facility that meets Requestor's uniform requirements may become a Center.

4. **Is Unlikely a Marketing Tool to Drive Patients to the Drug:** OIG listed several aspects of the Arrangement that limit the likelihood that Requestor is using it as a marketing tool to promote its Drug, including that Requestor does not advertise the Arrangement, the Drug is a one-time, curative treatment (therefore mitigating any seeding concerns), and the Drug is prescribed only for refractory indications.

[3] 42 U.S.C. § 1320a-7b(b).

Beneficiary Inducements CMP

OIG also assessed the Arrangement under the Beneficiary Inducements CMP, which prohibits a person or entity from offering or providing any remuneration to a Medicare or Medicaid beneficiary that the offeror knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier.[4] OIG found that the Arrangement implicates the Beneficiary Inducements CMP, because the assistance Requestor provides to beneficiaries could influence them to select a physician or Center they may not otherwise have selected, but that the Arrangement satisfies the "Promotes Access to Care" exception.

OIG first determined that, because the Arrangement removes or reduces economic barriers to patients receiving the necessary patient monitoring required by the Drug's prescribing information and does not duplicate other available charitable assistance, it improves a beneficiary's ability to obtain items and services payable by Medicare or Medicaid. OIG then found that the Arrangement poses a low risk of harm to Medicare and Medicaid programs and beneficiaries for the reasons it described in its AKS analysis, and concluded that the Arrangement therefore (i) is unlikely to interfere with, or skew, clinical decision making; (ii) is unlikely to increase costs to federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) does not raise patient safety or quality-of-care concerns.

Takeaways

With this opinion, OIG appears to have created a pathway for manufacturers to directly subsidize the travel and lodging expenses of patients who are prescribed the manufacturers' own drugs, albeit only in very limited circumstances. The opinion suggests that OIG may view such arrangements in a more favorable light in circumstances where access to care for financially needy patients is enhanced and "seeding" is not a concern, thus potentially opening the door for manufacturers of other curative gene therapies to enter into similar arrangements. It appears clear, however, given recent settlements and the lengths to which OIG went to distinguish the Arrangement from similar arrangements with which it remains concerned, that manufacturers will continue to be precluded under the fraud and abuse laws from providing copayment assistance to patients using the manufacturers' products.

Finally, while OIG's perspective certainly is important, any arrangement under which a manufacturer provides financial assistance to patients also should be evaluated for compliance with any applicable state anti-kickback provisions.

* * *

This Client Alert was authored by **Jennifer E. Michael** *and* **Bonnie I. Scott.** *For additional information about the issues discussed in this Client Alert, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*

[4] 42 U.S.C. § 1320a-7a(a)(5).

This document has been provided for informational purposes only and is not intended and should not be construed to constitute legal advice. Please consult your attorneys in connection with any fact-specific situation under federal law and the applicable state or local laws that may impose additional obligations on you and your company.

About Epstein Becker Green
Epstein Becker & Green, P.C., is a national law firm with a primary focus on health care and life sciences; employment, labor, and workforce management; and litigation and business disputes. Founded in 1973 as an industry-focused firm, Epstein Becker Green has decades of experience serving clients in health care, financial services, retail, hospitality, and technology, among other industries, representing entities from startups to Fortune 100 companies. Operating in locations throughout the United States and supporting domestic and multinational clients, the firm's attorneys are committed to uncompromising client service and legal excellence. For more information, visit www.ebglaw.com.

If you would like to be added to our mailing list or need to update your contact information, please contact Kristen Vetula at kvetula@ebglaw.com or 202-861-1845.