PUBLICATION

OIG Okays Assistance Arrangement Offered to Drug Patients in Advisory Opinion 20-02

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In Advisory Opinion 20-02, the Office of Inspector General (OIG) approved certain lodging and travel assistance offered by a pharmaceutical manufacturer to patients being administered a drug manufactured by the pharmaceutical manufacturer during the period post-administration when the patient is at risk for reactions and requires monitoring. The OIG opined that, while the arrangement implicated the Anti-Kickback Statute (AKS) and the civil monetary provision related to beneficiary inducements (the Beneficiary Inducement CMP), the OIG would not impose sanctions related to the arrangement for the reasons outlined below.

The drug at issue is personalized to the patient and made from the patient's own cells. It treats two diseases – one generally affecting children and young adults and one generally affecting adults. The drug carries a black box warning for certain life-threatening reactions. Because of those potential reactions, the U.S. Food and Drug Administration (FDA) requires physicians to monitor patients who are administered the drug for an extended post-administration period and requires the pharmaceutical manufacturer to implement a Risk Evaluation and Mitigation Strategy (REMS). Only physicians who are REMS-certified and implement necessary safety protocols may prescribe and administer the drug.

The pharmaceutical manufacturer has entered into agreements with certain inpatient and outpatient facilities (Center or Centers) to safely administer the drug. The Centers also collect and ship the patient's white blood cells to the pharmaceutical manufacturer to allow it to manufacture the drug for the individual patient. The Centers must meet certain criteria to be certified, and the pharmaceutical manufacturer will enter into an agreement with any facility meeting those criteria. Additionally, neither the physicians nor the Centers are required to prescribe the drug exclusively.

The pharmaceutical manufacturer certified that proximity to the Center following infusion is very important for patient safety because physicians in the patient's community often do not have the appropriate training. This would likely affect indigent and rural patients disproportionately. Because of these risks, the pharmaceutical manufacturer established a lodging and travel assistance arrangement to offer to patients.

The assistance arrangement would be offered to patients, including federal health care beneficiaries, who are prescribed and administered the drug. For patients up to 25 years of age, the pharmaceutical manufacturer provides assistance for the patient and up to two caregivers, and for patients 26 years or older, provides the same assistance for the patient and one caregiver. The pharmaceutical manufacturer does not provide any assistance for initial consultations, the leukapheresis (the process by which the patient's blood is taken to generate the drug), or follow-up visits beyond the post-infusion monitoring required by the drug's prescribing information. The pharmaceutical manufacturer does not provide the assistance when the patient is eligible to receive such assistance from the applicable Center (particularly, lodging assistance). The pharmaceutical manufacturer certified that the purpose of the assistance arrangement is to help defray costs incurred by patients to remain close to the Centers and ensure that the drug is administered in accordance with the drug's prescribing information. The pharmaceutical manufacturer also certified that it would not advertise the assistance arrangement and that patients would not be informed of the available assistance until after being prescribed the drug.

Under the arrangement, the pharmaceutical manufacturer provides the following assistance:

- Reimbursement for gas and tolls or arrangement of transportation via bus, rail, rental car, or air travel for the patient and caregiver(s) to and from the closest Center accepting patients

- Modest, single shared hotel room located near a Center for the patient and caregiver(s) during administration and post-administration monitoring

- Reimbursement of out-of-pocket expenses up to $50 per day per person (e.g., meals, parking, taxi fare to the Center)

Patients must submit receipts to receive reimbursement. The assistance is available for four weeks post-infusion, except when a longer monitoring period is deemed necessary by the physician.

To qualify, the patient (i) must not have a household income that exceeds 600 percent of the Federal Poverty Level, (ii) must live more than two hours' driving distance or 100 miles from the nearest Center accepting patients, and (iii) must not have insurance for non-emergency medical transportation. The assistance is offered regardless of the patient's insurance status. The eligibility criteria are applied uniformly and consistently.

The OIG indicated that the assistance arrangement implicates the AKS in two ways. First, the OIG found that the assistance provided under the arrangement (free travel, lodging, meals, and other assistance) is remuneration to the patients that could induce them to purchase the drug. Second, the OIG found that the assistance arrangement could be viewed as providing a benefit to both the Center and the physician providing care. Essentially, the OIG argued that by providing assistance to the patient that allows the patient to choose to receive care from the Center and the physician, which the patient otherwise might not have been able to choose, the pharmaceutical manufacturer provides a benefit to the Center and the physician in the form of the opportunity to earn fees related to administering the drug. This latter analysis relies heavily on the fact that the AKS applies to both direct and indirect remuneration.

Despite finding that the arrangement implicates the AKS in two different ways and after expressing general concerns about the influence of drug manufacturers providing travel and lodging assistance in connection with the prescribing of a particular drug, the OIG ultimately concluded that it would not impose sanctions based on the specific circumstances of this arrangement. The OIG cited the following factors:

1. The assistance arrangement increases access to appropriate care for financially needy patients and those living in rural areas.

2. The assistance arrangement enables physicians to meet FDA requirements in the drug's prescribing information in order to avoid potentially lethal side effects of the drug.

3. The number of physicians prescribing the drug is limited by the number willing to accept responsibility to implement the onerous safety requirements that the FDA has imposed on it.

4. The drug is a one-time, potentially curative treatment, so the assistance arrangement does not raise the "seeding" concerns that may be present in other arrangements (and the pharmaceutical manufacturer does not advertise the arrangement).

5. Safeguards are in place to ensure that assistance under the arrangement is not duplicative of other assistance and is focused on those patients who truly need it. (e.g., the patient must live a certain

distance from the Center and the patient must use the Center closest to the patient.)

6. Federal health care programs do not currently pay for these non-medical items and services. In a footnote, the OIG specifically notes the importance of the specific items and services provided under the assistance arrangement. Other items and services, such as ambulance transportation, child care, lost wages, or stipends may not present the low risk presented by the items and services offered under the assistance arrangement.

In a somewhat surprising outcome, the OIG concluded that this benefit provided by the pharmaceutical manufacturer directly to the patient implicates the Beneficiary Inducement CMP. As a general rule, the Beneficiary Inducement CMP is not associated with payments by pharmaceutical manufacturers. The Beneficiary Inducement CMP applies to payments designed to influence Medicare or Medicaid patients to receive an item or service from a *particular provider, practitioner, or supplier*. A drug is not a provider, practitioner, or supplier and, typically, a pharmaceutical manufacturer does not have a preference for which provider, practitioner, or supplier provides its drug to the patient. Under the facts of the arrangement at issue, however, the OIG viewed the payment from the pharmaceutical manufacturer to the patient as having an influence on the patient's choice of from which Center and/or physician to receive the drug. Therefore, the OIG concluded that the assistance arrangement implicates the Beneficiary Inducement CMP.

Having found that the Beneficiary Inducement CMP is implicated, the OIG next examined whether an exception applies. The OIG found that the Promotes Access to Care Exception is applicable. First, the OIG found that the assistance arrangement improves beneficiaries' ability to obtain items and services payable by Medicare or Medicaid. The OIG noted the lodging and other benefits available under the arrangement are not offered under federal health care programs, and therefore the arrangement would remove or reduce economic barriers to receiving the necessary patient monitoring. Next, the OIG found that the arrangement poses a low risk of harm to federal health care programs and beneficiaries for the reasons discussed in the AKS analysis outlined above.

Notable Takeaways

Advisory Opinion 20-02 is interesting for two reasons. First, it shows that in certain, limited circumstances with appropriate safeguards, transportation, lodging, and other similar benefits can be provided directly to program beneficiaries to improve access to appropriate care. However, meaningful future application of this opinion is likely limited given the narrowly tailored nature of the subject arrangement. Second, this advisory opinion is important because it reminds the industry that the indirect effects of payments by drug and device manufacturers must be considered under the Beneficiary Inducement CMP.