PUBLICATION

OIG Allows Pharmaceutical Manufacturer to Provide Financial Assistance for Travel, Lodging and Other Expenses to Certain Patients Prescribed the Manufacturer's Drug in Advisory Opinion 20-09

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A pharmaceutical manufacturer has received a green light from the Office of Inspector General (OIG) to provide financial assistance for travel, lodging and other expenses to certain patients prescribed the manufacturer's drug. The OIG reviewed the arrangement in Advisory Opinion No. 20-09, issued in December 2020, and determined that the financial assistance, as proposed by the manufacturer, presents a low risk of fraud and abuse under the federal anti-kickback statute or the beneficiary inducements civil monetary penalties (CMP) and does not constitute grounds for the imposition of penalties.

The manufacturer produces a drug, approved by the U.S. Food and Drug Administration (FDA), for the treatment of adult patients with a relapsed or refractory disease. The drug is a personalized medicine made from the patient's own cells, which is generally administered as a one-time infusion. The drug treatment requires one visit by a patient to a leukapheresis facility or an inpatient or outpatient facility (center) and a second visit to a center where the patient undergoes conditioning chemotherapy, drug infusion and post-infusion monitoring. The drug's prescribing information, approved by the FDA, requires center physicians and other risk evaluation and mitigation strategy (REMS) trained health care staff at a center or a leukapheresis facility to monitor patients for signs or symptoms of certain life-threating or fatal reactions.

The manufacturer has an arrangement where they assist eligible patients and one caregiver with travel, hotel lodging and certain out-of-pocket expenses (e.g., meals) they incur related to obtaining leukapheresis, receiving conditioning chemotherapy, infusing the drug and monitoring after drug infusion (the arrangement). The manufacturer offers this arrangement for patients, including federal health care program beneficiaries, who: (i) have been prescribed the drug for an FDA-approved indication; (ii) have a household income that does not exceed 600 percent of the Federal Poverty Level; (iii) live more than two hours driving distance or 100 miles from the nearest leukapheresis facility and center that accepts the patient's insurance, as applicable; and (iv) lack third-party insurance coverage for the travel and lodging expenses associated with the patient's treatment. The stated purpose for this arrangement is to ensure patient safety and promote quality-of-care, particularly for indigent and rural patients.

The OIG has long expressed that it is a criminal offense to knowingly and willfully offer, pay, solicit or receive any remuneration to induce or reward, among other things, referrals for, or purchases of, items or services reimbursable by a federal health care program. Where remuneration is paid purposefully to induce or reward referrals or purchases of items or services payable by a federal health care program, the federal anti-kickback statute is violated. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

In determining that the actions pursuant to the arrangement between the manufacturer and the patients would present a low risk of fraud and abuse under the federal anti-kickback statute, the OIG's analysis turned on seven factors:

- The arrangement increases access to care that complies with the drug's REMS, which includes elements to assure safe use (ETASU) for financially needy patients and those living in rural areas;

- The modest lodging the manufacturer provides under the arrangement following infusion enables physicians to meet the FDA requirements in the drug's prescribing information and to mitigate patient harm from potentially lethal drug side effects;

- The limited center network is necessary for patient safety reasons and to ensure compliance with the drug's REMS with ETASU. Furthermore, the manufacturer certified that it does not require providers to prescribe its drug exclusively;

- The drug is a treatment of last resort for patients with the disease. Furthermore, the drug is a one-time, potentially curative treatment, so the arrangement does not raise the seeding concerns sometimes present in other arrangements;

- Requiring patients to reside a significant distance from a leukapheresis facility and center mitigates the risk that the manufacturer uses the arrangement as a marketing tool for patient referrals. The manufacturer also certified that it does not authorize lodging under the arrangement to patients treated by a leukapheresis facility or center when the manufacturer has knowledge, or based on available information should have knowledge, that the patient is eligible to receive free lodging from the leukapheresis facility or center, and such lodging is available for that patient's use;

- The support provided by the manufacturer allows an eligible patient and his or her caregiver to follow the requirements of the drug's prescribing information; and

- The manufacturer certified that, due to the unique characteristics of the drug's manufacturing process and its safety risks, leukapheresis cannot take place at a medical facility unless it is either part of, or affiliated with, a center and has been evaluated and approved as part of the manufacturer's process for qualifying centers to perform all stages of drug treatment. The manufacturer's qualification process ensures that the leukapheresis facility is capable of correctly collecting, storing, packing and shipping a patient's cells and that the drug can be properly matched to each individual patient.

In determining that the actions pursuant to the arrangement between the manufacturer and the patients would present a low risk of fraud and abuse under the beneficiary inducements CMP, the OIG's analysis turned on three factors:

- The assistance under the arrangement will not duplicate other available charitable assistance from a center or leukapheresis facility;

- The remuneration provided during drug treatment removes or reduces economic barriers to receiving safe treatment and patient monitoring required by the drug's prescribing information and REMS with ETASU; and

- The drug is unlikely to be overutilized because the drug is prescribed only for patients with relapsed or refractory disease who have undergone two or more lines of systemic therapy and is a one-time potentially curative treatment.

For more information please contact any member of Baker Donelson's Health Law Group.