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OIG Advisory Opinion Permits a Pharmaceutical Manufacturer to Provide Financial Assistance to Needy Patients Receiving Risky Cell Therapy

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The Office of Inspector General for the U.S. Department of Health and Human Services (OIG) recently issued a favorable Advisory Opinion regarding a proposal by a pharmaceutical manufacturer (Requestor) to provide financial assistance for travel, lodging, and other expenses to certain patients receiving a cell therapy that it offers (the Arrangement). The OIG concluded that the Arrangement could potentially violate the **Anti-Kickback Statute**, as well as the **prohibition on beneficiary inducement in the Civil Monetary Penalties Law** (the Beneficiary Inducement CMP), but ultimately declined to impose administrative sanctions.

Background

Requestor manufactures a cell therapy (the Drug) approved by the Food and Drug Administration (FDA) for a refractory or recurrent disease that generally affects children and young adults and for a relapsed or refractory disease that generally affects adults. The Drug is personalized medicine made from the patient's own cells and is a one-time, potentially curative treatment that carries a black box warning – the strongest warning required by FDA – indicating life-threatening or potentially fatal reactions. FDA thus requires Requestor to implement a Risk Evaluation and Mitigation Strategy (REMS). Only REMS-certified physicians may prescribe the Drug, and, consistent with the REMS, the Drug may be administered only in certain facilities chosen unilaterally by Requestor based on specific criteria (Centers). In addition, FDA also requires that the physicians and Centers continuously monitor Drug recipients for signs and symptoms of a particular fatal reaction for at least four weeks after infusion. Improper post-infusion treatment could inhibit the effectiveness of the Drug and even result in patient death.

Requestor developed the Arrangement to serve indigent patients and those living in rural areas who may benefit from the Drug but who may otherwise be unable to access qualified physicians and Centers nearby, or stay in the vicinity of a Center in the weeks following infusion. Requestor provides eligible patients and up to two caregivers (depending on the patient's age) assistance with travel, lodging, meals, and certain out-of-pocket expenses incurred during and after the patient's Drug infusion.

Analysis

Anti-Kickback Statute

According to the OIG, the financial assistance offered through the Arrangement implicates the AKS because: (i) it constitutes remuneration that may encourage beneficiaries to purchase Requestor's Drug; and (ii) such benefits could allow a beneficiary to select a Center that he or she may not have otherwise chosen for treatment. The Arrangement may drive federally insured and other patients toward Requestor's Drug – and therefore certain physicians and Centers – which would result in remuneration to the physicians and Centers "in the form of the opportunity to earn fees related to administering the Drug." The OIG also noted its general concern that manufacturers that provide travel and lodging expenses may use this type of benefit to steer patients to their drugs over competing drugs that may be just as effective but less expensive and, in turn, cause the federal health care programs to incur increased costs.

Despite these concerns, the OIG decided not to impose sanctions under the AKS for the following reasons:

1. The Arrangement increases access to care for indigent patients and those living in rural areas who may not otherwise be able to travel to and stay near a Center for the entirety of the FDA-required

monitoring period. The Requestor offers assistance to patients with a household income of up to 600 percent of the Federal Poverty Level, which is a high threshold for a financial assistance program, but the Requestor certified that the median household income for patients receiving assistance was only $28,000 per year.

2. The financial assistance allows qualifying patients to obtain the care required by the Drug's prescribing information during and following infusion of the Drug. If FDA did not impose these requirements, and the potential for life-threatening reactions was not present, the OIG possibly could have reached a different result.
3. The likelihood that Requestor uses the Arrangement to reward certain physicians is low because the need for the limited network of physicians and Centers is dictated by the REMS imposed by FDA. Further, any provider who meets the uniform prescribing requirements may participate, and Requestor does not require prescribers or Centers to prescribe the Drug exclusively.
4. Given the fact that the Drug is prescribed for refractory indications and is meant to be a one-time treatment, the Requestor (which certified that it does not advertise the Arrangement) is unlikely to use it as a marketing tool.
5. The ability to use the Arrangement as a marketing tool is undercut by the threshold requirements that the patient must live a considerable distance from the nearest Center and must travel to the closest Center rather than one that the patient may choose based on personal preference. Also, lodging is not included with the Arrangement if the patient is eligible to receive lodging from the Center.
6. Finally, the OIG was not aware of any avenue through which the Secretary could pay for the non-medical items offered by the Arrangement.

Beneficiary Inducements CMP

As noted by the OIG, Requestor is not a "provider, practitioner, or supplier" under the Beneficiary Inducements CMP, but its offer of financial assistance constitutes remuneration that could influence a beneficiary's choice of provider, practitioner, or supplier (*i.e.*, the REMS-certified physicians and the Centers). In this context, the OIG's concern is that the financial assistance could result in a patient selecting a physician or Center that it may not have chosen absent the financial assistance. However, the OIG determined that the Arrangement met the requirements of the Promotes Access to Care Exception (the Exception).

The Exception protects remuneration that "promotes access to care and poses a low risk of harm to patients and Federal health care programs." To comply with the Exception, the Arrangement must improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid. The OIG concluded that it does so because Requestor provides financial assistance only if the patient qualifies and cannot obtain lodging through other means, and it removes or reduces economic barriers to receiving necessary care. In addition, the Arrangement must pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs. For the reasons discussed in the AKS analysis above, the OIG found that the Arrangement complies with this requirement.

Takeaways

Given that **the cell therapy market is expanding rapidly**, pharmaceutical manufacturers are likely to continue to find that patients in need of these therapies are encountering economic barriers limiting access to care. In this instance, the OIG allowed the Arrangement primarily because FDA's requirements dictated that only certain providers could offer the necessary care, only qualifying patients could receive the assistance, the Arrangement was not used as a marketing tool, and the REMS-certified physicians and Centers did not agree to exclusivity. While the OIG previously approved of a similar program offered by an academic medical center in another **Advisory Opinion**, pharmaceutical manufacturers and others seeking to implement similar arrangements should keep in mind that an Advisory Opinion is limited to its facts and is binding only with respect to the requesting party.

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