OIG Issues Two Advisory Opinions Regarding the Provision of Patient Travel and Fertility Subsidies in Connection to Gene Therapy

8/30/2024

On July 22, 2024, the U.S. Department of Health and Human Services Office of Inspector General (OIG) issued Advisory Opinion 24-05 allowing a biotechnology company to provide travel support for patients and caregivers undergoing gene therapy, and on July 23, 2024, issued Advisory Opinion 24-06 prohibiting (due to lack of data to analyze fraud and abuse risk) the same biotechnology company from providing fertility support for patients undergoing gene therapy.

Under the proposed arrangements, the biotechnology company sought to provide round-trip transportation, lodging, and a daily per diem of $50 to eligible patients undergoing gene therapy who have a household income at or below 600% of the Federal Poverty Level (FPL), reside more than 100 miles or a two-hour drive from the nearest approved treatment center, and certify that they have exhausted any insurance benefit that would cover travel. The company also sought to provide two types of fertility subsidies, up to either $22,500 or $70,000, to eligible patients for the costs associated with gamete collection and storage and IVF procedures, because the gene therapy drug may affect fertility.

Travel Support

Although the proposed arrangement may induce patients to receive the treatment and contribute to the company's opportunity to earn associated fees, thereby implicating the Federal Anti-Kickback Statute, the OIG concluded that the risk of fraud and abuse was sufficiently low based on the following:

1. Due to the limited number of approved treatment centers, travel support removes a barrier to accessing medically

necessary care.

2. Since the FDA label requires patients to travel to a treatment center and remain there for several weeks, providing travel support, even for caregivers, is reasonable.
3. Because each drug is provided as a one-time treatment, it is unlikely for patients to be induced to obtain additional services payable by a federal health care program.
4. Other safeguards are in place to mitigate the risk of fraud and abuse, such as the fact that support is not provided for expenses payable by a third-party and the company will not use travel support as a marketing tool.

The OIG also concluded that the proposal falls under the "Promotes Access to Care" exception to the civil monetary penalty provision of the Social Security Act prohibiting inducements to beneficiaries, which allows incentives to be offered to Medicare and Medicaid beneficiaries, if the incentive promotes access to care, rather than providing a reward. Because travel support is unlikely to interfere with clinical decision making, unlikely to increase costs to federal health care programs, and does not raise patient safety or quality of care concerns, the OIG found that this exception applied.

Fertility Support

In applying the same Federal Anti-Kickback analysis to two proposed fertility support arrangements, the OIG declined to issue a favorable advisory opinion, citing a lack of data to assess the risk of fraud and abuse. The OIG stated that fertility support would implicate the Federal Anti-Kickback Statute because, if a patient would choose not to receive the drug therapy due to a lack of funds for fertility preservation, the proposed support might influence a patient to purchase the drug and that would constitute remuneration. However, the OIG explained that it lacked data to assess whether fertility support would pose a risk of fraud and abuse under the Federal Anti-Kickback Statute. Specifically, the OIG could not evaluate the impact on access to health care services, costs to Federal health care programs, patient outcomes, competitive effects, and the risk of improper steering. The OIG acknowledged that more data may become available and therefore did not foreclose the possibility that the proposed arrangement may be permitted in the future.

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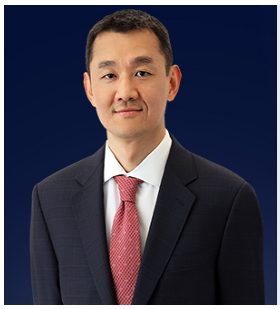

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