

CLIENT ALERT

OIG Issues Advisory Opinion on Contributions to Charitable Foundations for Therapy Services

OCTOBER 16, 2025

On September 11, 2025, the U.S. Department of Health and Human Services Office of Inspector General (the OIG) issued a favorable advisory opinion (AO 25-10 or the Opinion) regarding an arrangement between a healthcare services company (the Company) and a charitable foundation (the Foundation), whereby the Company makes financial contributions to the Foundation, which then provides grants to families of children receiving a particular type of therapy (the Arrangement). Pursuant to AO 25-10, the OIG will not impose sanctions with respect to the Arrangement, despite the Arrangement potentially generating prohibited remuneration under the federal Anti-Kickback Statute (the AKS) and implicating the civil monetary penalty provision prohibiting inducements to beneficiaries (the Beneficiary Inducements CMP).

THE ARRANGEMENT

The Company provides families with “family-powered” therapy services (the Therapy Services) for children with an unspecified disorder. The Therapy Services consist of children, along with their parents and caregivers, participating in telehealth therapy sessions with a clinician. Parents or caregivers initially must commit to 15 or more hours of Therapy Services each week. The Company stated that access to the Therapy Services can be financially burdensome, particularly for lower-income families. For example, the Company stated that, while the Therapy Services are generally covered by insurance, including federal health care programs, coverage can include cost-sharing amounts for each Therapy Service session. In addition, the time commitment required from parents or caregivers who participate in the Therapy Services has an opportunity cost, as the Therapy Services typically occur during working hours.

To help support families receiving Therapy Services, the Company formed the Foundation. The Foundation supports qualifying families receiving the Therapy Services by providing financial grants ranging from \$50 to \$1,800 per month. The Company donated approximately \$300,000 to the Foundation, to be used for grants at the independent discretion of the Foundation with no regard to the interest of any donor or future actions by the Foundation (i.e., referrals). The Company did not solicit data on how donations are being used, and neither the Company nor the Foundation engaged in marketing of the Foundation beyond the Foundation’s public-facing website. The Company referred patients who have requested financial assistance to the Foundation.

The description of the Arrangement in the Opinion indicated that families must qualify to receive Foundation grants by meeting specific financial criteria and producing a completed treatment plan from Therapy Service providers as

outlined in the Foundation's policies and procedures, which were approved by both the Foundation's independent Board of Directors and outside legal counsel. The Foundation determines which families receive grants based on information that is provided by the families, which is verified on a monthly basis and does not take into consideration the family's choice of Therapy Service provider or the identity of the donor or referring person or organization.

FRAUD AND ABUSE IMPLICATIONS

The OIG notes that the Arrangement includes two types of remuneration implicating the AKS and the Beneficiary Inducements CMP. The first type of remuneration relates to the Company's initial investment in establishing the Foundation and its monetary donations thereafter, while the second type of remuneration involves the Foundation's use of donations to provide grants to families for the Therapy Services.

The OIG reasoned that the Arrangement is unlikely to: (i) lead to overutilization or inappropriately increased costs to federal health care programs, (ii) incentivize a Therapy Service provider to prescribe more Therapy Services than necessary, or (iii) lead to inappropriate steering or unfair competition. The OIG highlighted the following features of the Arrangement to support its conclusion that the Arrangement presented low risk of fraud and abuse under the AKS and its further conclusion that it lacks grounds for sanctions under the Beneficiary Inducements CMP:

- Objective Eligibility Requirements. Families must continually meet predefined eligibility requirements, disconnected from any particular Therapy Service provider or referral source, to receive grants, which are awarded to families by the Foundation on a first-come, first-serve basis.
- Foundation Independence. The Opinion referenced the following factors regarding the Foundation's independence:
 - The Company and the Foundation are each independently operated without shared governance and minimal overlap in personnel.
 - The Company will have no employees working or volunteering for the Foundation or serving on its Board of Directors as of the end of 2025.
 - The Foundation maintains complete discretion on how to issue grants.
 - Company contributions to the Foundation are unrestricted and are not contingent upon any future actions by the Foundation.
 - The Foundation is not required to produce any data or information to the Company with respect to the grant recipients.
- Parental/Caregiver Discretion. The ability for families and caregivers to make independent determinations regarding the Therapy Services provider was also a key feature of the Opinion. Specifically, the Opinion referenced the following factors with respect to family and caregiver discretion:
 - Families and caregivers exercise full discretion in their choice of Therapy Service provider, as grant determinations are made without regard to whether the Therapy Services are provided by the Company.
 - Families and caregivers can change Therapy Services providers at any time and maintain eligibility for participation in the Foundation's program.
 - The Foundation did not place limitations on how families or caregivers may utilize the grant funding beyond a general requirement that it be used to cover expenses related to the care and support of the child.
- Low Risk of Provider Influence. The clinical decision-making of Therapy Service providers is unlikely to be influenced by the Arrangement, as a predetermined treatment plan is required prior to the rewarding of any grants and grant funding is not required to be used for cost-sharing amounts.
- Written Policies and Procedures. The Foundation's guidelines for awarding grants were approved by its independent Board of Directors and outside legal counsel, were made publicly available, and applied uniformly to all applicants independent of any donor or referral interest.

KEY TAKEAWAYS

AO 25-10 marks the fourth favorable advisory opinion issued by the OIG regarding patients qualifying to receive financial assistance for a specific drug product or therapy service. The Opinion emphasizes similar principles in determining the Arrangement as low risk from a fraud and abuse perspective, including (1) a lack of donor or referral influence over the charitable foundations or patients; (2) a low risk of overutilization or influence over provider decision-making; and (3) predefined, objectively applied guidelines for financial assistance eligibility. Finally, the lack of patient marketing of the program is notable in instances where the OIG approved patient assistance programs.

In the Opinion, OIG indicated that the Arrangement improves overall health outcomes by cutting costs of care and expanding access to the Therapy Services. Organizations considering similar charitable models for healthcare services should consult legal counsel in structuring and developing policies and procedures that comply with fraud and abuse laws. The Opinion provides helpful guidelines that can be used for other healthcare providers desiring to create patient assistance programs.

If you have additional questions or need further assistance, please reach out to Banee Pachuca (Partner, Houston), Eric Knickrehm (Partner, Washington D.C.), Meredith Heim (Associate, Chicago), Ryan Greenberg (Associate, Houston), or your Winston & Strawn relationship attorney.

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