[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information, unless otherwise approved by the requestors.*]

Issued: September 8, 2025

Posted: September 11, 2025

[Address block redacted]

Re: OIG Advisory Opinion No. 25-10 (Favorable)

Dear [redacted]:

The Office of Inspector General ("OIG") is writing in response to your request for an advisory opinion on behalf of [redacted] doing business as [redacted] (the "Company") and [redacted] doing business as [redacted] (the "Foundation" and collectively with the Company, "Requestors") regarding an arrangement pursuant to which the Company operationalized and makes financial contributions to the Foundation, and the Foundation provides grants to families of children receiving a particular type of therapy (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of sanctions under: the civil monetary penalty provision at section 1128A(a)(7) of the Social Security Act (the "Act"), as that section relates to the commission of acts described in section 1128B(b) of the Act (the "Federal anti-kickback statute"); the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act (the "Beneficiary Inducements CMP"); or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute and the Beneficiary Inducements CMP.

Requestors have certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Arrangement, and we have relied solely on the facts and information Requestors provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestors. This opinion is limited to the relevant facts presented to us by Requestors in connection with the Arrangement. If material facts have not been disclosed, have been misrepresented, or change, then this opinion is without force and effect.

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Arrangement would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, OIG will not impose administrative sanctions on Requestors in connection with the Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute; and (ii) the Arrangement does not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP.

This opinion may not be relied on by any person[1] other than Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Background

The Company's mission is to provide quality care for individuals with [redacted] (the "Disorder"), particularly for those individuals who have struggled to find appropriate therapy because they lack adequate access to care. The Company certified that children with the Disorder typically are eligible to receive [redacted] (the "Therapy"), which generally is covered by health insurance, including Federal health care programs. However, the Company certified that there are a number of challenges to families trying to access the Therapy, including up to a 15-month wait to begin the Therapy and clinics facing a high turnover of the Behavioral Technicians and Board-Certified Behavior Analysts who provide the Therapy.

The Company certified that its focus is providing family-powered Therapy for children with the Disorder. Under the family-powered Therapy model, parents or caregivers of children with the Disorder obtain necessary training to be able to participate in supporting the Therapy for their children, with the clinicians providing the Therapy via telehealth and the parents or caregivers providing support from home. Parents or caregivers then are able to support their children with the Disorder on an ongoing basis, and the Company certified that multiple peer-reviewed studies have demonstrated the increased efficacy of parent or caregiver involvement in the Therapy. The Company also cited to research showing that delivering the Therapy via telehealth resulted in lower costs and improved outcomes over in-person visits.

Parents or caregivers interested in participating in the Company's family-powered Therapy training program apply with the Company and can participate in the family-powered Therapy if they meet certain eligibility requirements, including having a child who has been diagnosed with the Disorder and has an active insurance plan, which could include a Federal health care program, and completing a training program. Under this model of delivering the Therapy, parents or caregivers initially must commit to 15 or more hours of Therapy each week, which often would occur during typical working hours. The Company certified that access to the Therapy can be financially burdensome, particularly for lower-income families. For example, the Company certified that, while the Therapy generally is covered by insurance, including Federal health care programs, coverage can include cost-sharing amounts for each Therapy session. In addition, the

[1] We use "person" herein to include persons, as referenced in the Federal anti-kickback statute and Beneficiary Inducements CMP, as well as individuals and entities, as referenced in the exclusion authority at section 1128(b)(7) of the Act.

time commitment required from parents or caregivers who participate in the family-powered Therapy has an opportunity cost.

B. The Arrangement

1. Operation of the Foundation

Certain Company employees formed the Foundation, a non-profit, tax-exempt charitable organization, to help defray some expenses of qualifying families through the use of grants. Specifically, one of the Company's executives helped with the operational setup at the Foundation and hired an Executive Director, who was not employed by the Company,[2] for the Foundation. The Company executive and the Executive Director of the Foundation set the guidelines and criteria for grant awards (which were subsequently approved by outside legal counsel) and established the Board of Directors. The Board of Directors approved the guidelines and began implementation of the grant program. One of the Company's employees still works with the Foundation on an unpaid, volunteer basis but is not a current member of the Board of Directors; no Company employee is on the Foundation's Board of Directors. By the end of 2025, no employee of the Company will be permitted to work for or volunteer at the Foundation.

The Foundation certified that families qualify to receive Foundation grants if they: (i) have qualified family household income within certain limits; (ii) have a child receiving family-powered Therapy from any Therapy provider[3] (i.e., a Therapy provider must deliver the Therapy according to a completed treatment plan before the family is eligible to receive a grant); and (iii) are not receiving any other compensation for their participation in the Therapy.[4] The Foundation makes determinations regarding which families get assistance by following its own policies and procedures. The Foundation certified that its policy as to the provision of grants to families is based on reasonable, verifiable, and uniform measures of financial need that are applied in a consistent manner. Families are approved on a first-come, first-served basis, up to the full budget amount of the grant program, subject to any caps for each grant level, as referenced below.

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[2] The original Executive Director had worked for the Company in the past, but the individual's duties with the Company had ceased before beginning employment with the Foundation. The Executive Director initially hired for the Foundation has left the Foundation. A new Executive Director, also not employed by the Company, has been hired.

[3] A family would meet criterion (ii) if the child receives family-powered Therapy from any provider of the Therapy, whether employed by or affiliated with the Company or a wholly independent individual or entity that provides the Therapy.

[4] Requestor certified that there are additional resources available to families supporting individuals with the Disorder, some of which also offer financial grant programs. Families receiving those types of grants are not eligible for grants from the Foundation. In addition, any families who are reimbursed by their provider or their insurer for family caregiving would not qualify for a grant from the Foundation.

Requestors certified that the Foundation is developing a list of Therapy providers that may accept clients and has held meetings with over a dozen such Therapy providers to educate such providers about the grant program. The Foundation intends to make the list publicly available when it is more complete. Requestors certified that this list will be non-exhaustive and will continue to be updated as the Foundation learns of providers that offer the Therapy and are accepting new clients.[5] Several of the providers (independent of the Company) that the Foundation has contacted have referred clients to the Foundation to apply for grants, qualifying applications have been approved, and grants have been disbursed. Grant eligibility requirements do not vary based on a family's choice of Therapy provider. The Foundation certified that it allows families to change Therapy providers, and grant eligibility is based on information verified by the family's Therapy provider on a monthly basis. If a family changes Therapy providers, then the Foundation will connect with the new Therapy provider to verify the family's continued eligibility. Provided all the eligibility criteria are met, the family will continue receiving the grant once services resume with the new Therapy provider.

The grant amount for qualifying families is tiered, based on a combination of the number of hours of prescribed Therapy and the level of adherence to those hours of Therapy as reported by the Therapy provider.[6] Treatment plan hours are verified on a rolling monthly basis by the rendering Therapy provider. The grant funding goes directly to the qualifying family to help defray some of the expenses related to the care and support of the child (e.g., out-of-pocket expenses related to the cost of Therapy or tools and supplies to facilitate Therapy delivery).

2. The Company's Donations to the Foundation

The Company has donated approximately $300,000 to the Foundation. Requestors certified that the Foundation's discretion as to the use of the donations is absolute, independent, and autonomous. Requestors further certified that the donations are unrestricted and not contingent upon any future actions (e.g., referrals) by the Foundation. The Company does refer patients who request financial assistance to the Foundation, but the Foundation is mandated to make decisions regarding grants without regard to the interest of any donor, including the Company. In particular, the Foundation is required to make decisions without regard to the applicant's choice of Therapy provider or the identity of the referring person or organization. As long as a family continues receiving family-powered Therapy from any Therapy provider, remains within the qualifying income limits, and is not receiving any other compensation for their participation in the Therapy, the family remains eligible for grant funding from the Foundation (provided that there is available funding).

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[5] The Foundation certified that the list, once published and available on its website, would not be presented as a list of "approved" providers but rather would be presented in a neutral format (either alphabetical or distance from an address, if in-person options are available).

[6] The grant amounts currently range from $50 per month for the lowest combination of treatment hours and adherence to $1,800 per month for the highest combination of treatment hours and adherence. As noted above, the Foundation caps the number of grantees eligible for funding at each grant level.

Requestors certified that the Company does not solicit or receive any data from the Foundation regarding how its donations are being used.[7] In the future, the Foundation may produce anonymized reports that include the number of grant recipients, number of participating providers, total grant awards, and other aggregated data in the form of an annual report (released to the general public) in order to highlight the achievements of the Foundation over the previous year, as is ordinary in the course of business for a non-profit organization.

3. Marketing

Requestors certified that neither the Company nor the Foundation has engaged in any marketing for donations or to potential grantees, beyond creating a public-facing website regarding the Foundation to allow families to learn about and apply to the grant program. As grant eligibility is based on verified enrollment with a Therapy provider, to date, the Foundation has found all of its current grantees via outreach to existing Therapy providers. In the future, the Foundation may do more outreach and advertising for donations to help more families with financial challenges access family-powered Therapy and may market its internally created resources, such as a list of eligible Therapy providers, which would be provided in a neutral format, not emphasizing any particular Therapy provider.

II. LEGAL ANALYSIS

A. Law

1. Federal Anti-Kickback Statute

The Federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an individual to a person for the furnishing of, or arranging for the furnishing of, any item or service reimbursable under a Federal health care program.[8] The statute's prohibition also extends to remuneration to induce, or in return for, the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by a Federal health care program.[9] For purposes of the Federal anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

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[7] Any Therapy provider with a client who receives grant funding will receive communications from the Foundation requesting documentation to confirm the amount and type of clinical services delivered to a recipient-family (in a manner compliant with health information privacy laws and regulations), to ensure that the family continues to qualify for grant funding. The Therapy providers, including the Company, therefore will know which families are receiving funding. However, the providers do not receive any type of reporting from the Foundation, including information about the amount of funding any family receives.

[8] Section 1128B(b) of the Act.

[9] Id.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to induce referrals for items or services reimbursable by a Federal health care program.[10] Violation of the statute constitutes a felony punishable by a maximum fine of $100,000, imprisonment up to 10 years, or both. Conviction also will lead to exclusion from Federal health care programs, including Medicare and Medicaid. When a person commits an act described in section 1128B(b) of the Act, OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

2. Beneficiary Inducements CMP

The Beneficiary Inducements CMP provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. OIG also may initiate administrative proceedings to exclude such person from Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of the Beneficiary Inducements CMP as including "transfers of items or services for free or for other than fair market value."

B. Analysis

The Arrangement includes two types of remuneration that implicate the Federal anti-kickback statute. First, the Company invested resources in establishing the Foundation, participating in the initial operations, providing initial staffing, and has made (and intends to continue making) monetary donations to the Foundation. Second, the Foundation uses the donations to provide grants to families to help defray costs associated with family-powered Therapy; these grants also implicate the Beneficiary Inducements CMP. We consider these types of remuneration together because the remuneration from the Company to the Foundation bears on the independence of the Foundation and whether its grants to families could be remuneration to generate referrals for the Therapy in general or to the Company in particular. However, for the following reasons, we believe the risk of fraud and abuse presented by the Arrangement is sufficiently low under the Federal anti-kickback statute for OIG to issue a favorable advisory opinion, and the Arrangement does not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP.

The Arrangement is unlikely to lead to overutilization or inappropriately increased costs to Federal health care programs. Families must have a family-powered Therapy plan in place before applying for a grant from the Foundation. While the grant value may increase with the number of prescribed Therapy hours and adherence rates, the family's expenses likely increase

[10] E.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985).

as well. The grant funding would be unlikely to incentivize a Therapy provider to prescribe more Therapy than is necessary for a child because the grant funding goes to the families and is not required to be used for cost-sharing amounts; the only restriction is that the grant funding go directly to the qualifying family to be used to defray expenses directly related to the care and support of the child.

The Arrangement also is unlikely to lead to inappropriate steering or unfair competition for a number of reasons:

First, the donations from the Company to the Foundation are unrestricted and not contingent upon any future actions by the Foundation, including any referrals. Requestors certified that the Foundation operates with absolute, independent, and autonomous discretion as to the use of donor contributions. In particular, Requestors certified that the Foundation is mandated to make decisions regarding grants without regard to the interest of any donor and without regard to the applicant's choice of Therapy provider or the identity of the referring person or organization. Further, Requestors certified that the Company neither solicits nor receives any data regarding how its donations are used.

Second, the Foundation is a non-profit, tax-exempt charitable organization that awards grants to families in an objective manner that is not associated with any remuneration provided by the Company. Although the Company was involved in establishing and operationalizing the Foundation, the Company currently has no employees on the Foundation's Board of Directors and by the end of 2025 will not have any employees who work for or volunteer with the Foundation. Additionally, the guidelines and criteria for grant awards were approved both by the independent Board of Directors and outside legal counsel.

Third, a family's eligibility for grant funding is not dependent on the use of any particular Therapy provider; funding is available to families meeting income guidelines, regardless of which Therapy provider the family selects (i.e., whether or not the Therapy provider is affiliated with the Company). The Foundation is developing a list of Therapy providers who work with families that might qualify for grants, which also may help families who might benefit from the Therapy even if they would not qualify for a grant; the list will be updated on an ongoing basis to include any provider of which the Foundation is aware that offers the Therapy and is accepting new clients. In addition, families may change Therapy providers and continue to qualify for grant funding, as long as they remain eligible (i.e., meet income requirements, receive family-powered Therapy, and do not receive funding from another source).

Therefore, for the combination of the reasons described above, we believe the risk of fraud and abuse presented by the Arrangement is sufficiently low under the Federal anti-kickback statute for OIG to issue a favorable advisory opinion. With respect to the Beneficiary Inducements CMP, for the same reasons listed above, we do not believe that the grant funding would be likely to influence a family to choose the Company to receive the Therapy, and thus it does not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Arrangement would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute; and (ii) the Arrangement does not constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is limited in scope to the Arrangement and has no applicability to any other arrangements that may have been disclosed or referenced in your request for an advisory opinion or supplemental submissions.

- This advisory opinion is issued only to Requestors. This advisory opinion has no application to, and cannot be relied upon by, any other person.

- This advisory opinion may not be introduced into evidence by a person other than Requestors to prove that the person did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

- This advisory opinion applies only to the statutory provisions specifically addressed in the analysis above. We express no opinion herein with respect to the application of any other Federal, State, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- We express no opinion herein regarding the liability of any person under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

OIG will not proceed against Requestors with respect to any action that is part of the Arrangement taken in good-faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, OIG will not proceed against Requestors with respect to any action that is part of the Arrangement taken in good-faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to OIG.

Sincerely,

/Susan A. Edwards/

Susan A. Edwards
Assistant Inspector General for Legal Affairs