DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

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

Issued: September 3, 2026

Posted: September 9, 2026

[Address block redacted]

Re: OIG Advisory Opinion No. 26-18 (Favorable)

Dear [redacted]:

The Office of Inspector General ("OIG") is writing in response to your request for an advisory opinion on behalf of [redacted] ("Requestor"), regarding a referral service that Requestor would operate to connect patients requiring specialized ear and hearing health care services with hearing professionals (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement, if undertaken, would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (the "Act") or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act (the "Federal anti-kickback statute").

Requestor has 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 Proposed Arrangement, and we have relied solely on the facts and information Requestor provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestor. This advisory opinion is limited to the relevant facts presented to us by Requestor in connection with the Proposed Arrangement. If material facts have not been disclosed, have been misrepresented, or change, then this advisory 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 the Proposed Arrangement, if undertaken, would not generate prohibited remuneration under the Federal anti-kickback statute. Accordingly, OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement under section 1128A(a)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute 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.

This advisory opinion may not be relied on by any person[1] other than Requestor, has no applicability to any arrangements other than the Proposed Arrangement, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[redacted]—the parent company of Requestor—manufactures an ear, nose, and throat ("ENT") medical device (the "Hearing System"). The Hearing System provides an ear and hearing health care platform that combines three different assessment and treatment tools into one hand-held portable system. The Hearing System: (i) acts as a high-definition digital otoscope that facilitates examination of the ear canal and ear drum, with the capability to capture and store high-definition images and video of the examination; (ii) facilitates the use of a microsuction pump that removes cerumen (ear wax) from the ear canal; and (iii) includes a hearing check program that allows a primary care clinician to perform an initial assessment of potential hearing loss through the Hearing System (collectively, the "Hearing Services").

A. Hearing Referral Service Overview

Under the Proposed Arrangement, Requestor would operate a referral service (the "Hearing Referral Service") that would connect patients requiring specialized ear and hearing health care services furnished by an audiologist, hearing aid specialist, or ENT specialist (a "Hearing Professional") with a group of Hearing Professionals (the "Hearing Professionals Group") that has paid a set membership fee to participate in the Hearing Referral Service so that the patient may receive specialized ear and hearing health care services, including, but not limited to, a diagnostic hearing evaluation, hearing aid fitting, and more advanced clinical interventions ("Audiological Care").

B. Primary Care Clinicians and the Hearing Referral Service

Primary care clinicians (generally through their group practice) would pay a set subscription fee to Requestor for the use of the Hearing System when treating patients in their practice.[2] The primary care clinician would perform one or more of the Hearing Services for a patient using the Hearing System. When a hearing check is performed, the results of the hearing check display on the screen of the Hearing System. A software algorithm programmed into the Hearing System reviews the patient's audiogram (i.e., a graph showing the results of a hearing check) and determines if the results fall outside of normal hearing ranges. The software algorithm triggers an option on the screen of the Hearing System for the primary care clinician to select "Refer" for the patient if the results of the hearing check were outside of normal hearing range. The primary

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

[2] We have not been asked to opine on, and express no opinion regarding, the financial arrangement between Requestor and the primary care clinicians.

care clinician would make a decision, based on their knowledge and clinical judgment, either to select "Refer" or to end the session with the Hearing System.

If the primary care clinician selects the "Refer" option on the screen, information about the Hearing Referral Service would appear on the screen for review by the patient. This information would explain the Hearing Referral Service, including: (i) the participation criteria for a Hearing Professionals Group to participate; (ii) how Requestor selects the Hearing Professionals Group to which it makes the referral; (iii) any restrictions that would exclude a Hearing Professionals Group (or its Hearing Professionals) from participating in the Hearing Referral Service; (iv) the nature of the relationship between Requestor and the Hearing Professionals Group; and (v) that the Hearing Professionals Group has paid a fee to Requestor to participate in the Hearing Referral Service.

After review of this information about the Hearing Referral Service, if the patient consents to a referral to a Hearing Professionals Group, then: (i) the patient's name, ZIP code, email, and phone number would be entered into the Hearing System; (ii) the patient would select a box to confirm that they consent to the referral; and (iii) the patient would affix their signature below the box confirming that they consent to the referral. The primary care clinician would select the "Submit" option on the screen of the Hearing System, and the referral would be transmitted to a licensed audiologist employed by Requestor (or other appropriately trained individual employed by Requestor) (the "Referral Coordinator") who would review the information about the patient captured through the use of the Hearing System. The Referral Coordinator would validate that: (i) the ear canal was clear (i.e., cerumen had been removed) before testing; (ii) the results of the hearing check fell outside of normal hearing ranges; and (iii) there are no other concerns that would indicate that something else needs to be done for the patient before being referred to a Hearing Professional (collectively, the "Referral Criteria"). The Referral Coordinator would forward a PDF report for a patient that met the Referral Criteria to a Hearing Professionals Group participating in the Hearing Referral Service. A Hearing Professional would complete the outcomes template provided by the Refer Coordinator to report back on the outcome of the treatment (if any) provided to the patient.

If the referred patient receives Audiological Care from a Hearing Professional affiliated with a Hearing Professionals Group participating in the Hearing Referral Service, then the Hearing Professionals Group would securely send information about the outcome of the patient's treatment back to the referring primary care clinician. The primary care clinician would therefore receive confirmation that the patient accessed Audiological Care, and the results of those services could be added to the patient's medical record maintained by the patient's primary care clinician. Under the Proposed Arrangement, Requestor certified that it would neither offer subscription fee discounts contingent on primary care clinicians using the "Refer" option nor impose any exclusivity requirements or minimum referral expectations in agreements with primary care clinicians.

C. Hearing Professionals Groups

Under the Proposed Arrangement, Requestor would contract with one or more Hearing Professionals Groups that meet the criteria below.[3] Each participating Hearing Professionals Group would pay an annual set fee—consistent with the estimated cost of operating the Hearing Referral Service—to participate in the Hearing Referral Service. The annual fee would be set in advance and paid regardless of the number of referrals that each Hearing Professionals Group receives through the Hearing Referral Service and regardless of whether a patient receives any Audiological Care from a Hearing Professional as a result of the referral. If more than one Hearing Professionals Group participates in the Hearing Referral Service, then the annual fee would be apportioned equally based on the number of Hearing Professionals affiliated with each Hearing Professionals Group so that the total amount of fees collected would remain in alignment with the estimated cost of operating the Hearing Referral Service.[4]

Requestor certified that it would implement a periodic reconciliation process (the "True-Up") to ensure that the annual fee paid by participating Hearing Professionals Groups remains consistent with the operating costs of the Hearing Referral Service. On an annual basis, Requestor would calculate the total actual operating costs of the Hearing Referral Service for the previous year, including software maintenance, labor costs associated with the Hearing Referral Service, and administrative overhead. In the first year of the Proposed Arrangement (i.e., 2026), the annual fee would be prorated based on the number of months in which the Hearing Referral Service would operate. In the second year, actual costs would be compared against the initial projections used to set the annual fee paid by participating Hearing Professionals Groups in the first year. In each subsequent year, actual costs would be compared against the projections used to set the annual fee in the previous year. If actual operating costs were higher than had been projected for the previous year, Requestor would increase the annual set fee for the following annual term to ensure the Hearing Referral Service is not being subsidized. If actual costs were lower than had been projected for the previous year, Requestor would reduce the annual set fee for the following annual term. Requestor further certified that the True-Up calculation would be based on the aggregate cost of operating the Hearing Referral Service and would not be calculated or adjusted based on the number of patient referrals to any Hearing Professionals Group. Requestor certified that it would maintain detailed records of the annual True-Up calculations.

The following criteria for a Hearing Professionals Group to participate in the Hearing Referral Service would be applied equally to all Hearing Professionals Groups seeking to join the Hearing Referral Service:

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[3] Requestor certified that, while it plans to contract with independent Hearing Professionals in the future, it is more efficient to initially work with Hearing Professionals Groups that credential the Hearing Professionals in the group. Requestor certified that it plans to contract with independent Hearing Professionals when Requestor has a quality control program in place to ensure it contracts with Hearing Professionals who can furnish high-quality Hearing Services.

[4] For example, if two Hearing Professionals Groups contract to participate in the Hearing Referral Service, the annual set fee for each Hearing Professionals Group will be determined based on the total number of Hearing Professionals affiliated with each Hearing Professionals Group.

- The Hearing Professionals Group employs or manages the practice of Hearing Professionals.
- Each Hearing Professional affiliated with a Hearing Professionals Group must maintain a current, active license to practice in the applicable state.
- The Hearing Professionals Group is responsible for maintaining proof of each Hearing Professional's licensure.
- A Hearing Professional will be removed from the Hearing Referral Service if: (i) they leave employment with a Hearing Professionals Group (and are not immediately employed by another Hearing Professionals Group); (ii) their license is revoked; (iii) there are findings of malpractice or quality concerns; (iv) they are excluded from participation in Federal health care programs; or (v) they fail to follow the protocols established in the contractual agreement between Requestor and the Hearing Professionals Group (e.g., if they consistently fail to complete the outcomes template provided by the Refer Coordinator to report back on the outcome of the treatment (if any) provided to the patient).

Under the Proposed Arrangement, Hearing Professionals Groups participating in the Hearing Referral Service would receive patient referrals from the Referral Coordinator. When the Hearing Professionals Group accepts a patient referral, the Hearing Professionals Group would contact the patient—who has consented to the referral—to schedule an appointment for Audiological Care with a Hearing Professional affiliated with the group. The Hearing Professional would be selected by the Hearing Professionals Group based on the patient's ZIP code to ensure that the patient can be seen at a location that is convenient for the patient. Requestor certified that it would not impose any requirements on Hearing Professionals related to the manner of furnishing Audiological Care (e.g., clinical protocols, restrictions on products used (such as brand of hearing aids), or pricing demands). Once the patient was seen by a Hearing Professional, the Hearing Professional would complete the outcomes template provided by the Referral Coordinator, and the Hearing Professionals Group would transfer the completed template back to the Referral Coordinator so that it could be further transmitted to the patient's primary care clinician.

II. LEGAL ANALYSIS

A. Law

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.[5] 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

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

reimbursable by a Federal health care program.[6] 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.

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.[7] 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.

Congress has developed several statutory exceptions to the Federal anti-kickback statute.[8] In addition, the U.S. Department of Health and Human Services has promulgated safe harbor regulations that specify certain practices that are not treated as an offense under the Federal anti-kickback statute and do not serve as the basis for an exclusion.[9] However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor. Compliance with a safe harbor is voluntary. Arrangements that do not comply with a safe harbor are evaluated on a case-by-case basis.

The safe harbor for referral services is potentially applicable to the Proposed Arrangement.[10] The safe harbor for referral services provides that, for the purposes of the Federal anti-kickback statute, "remuneration" does not include any payment or exchange of anything of value between an individual or entity ("participant") and another entity serving as a referral service ("referral service"), as long as all of the following conditions are met:

- The referral service does not exclude as a participant in the referral service any individual or entity who meets the qualifications for participation.
- Any payment the participant makes to the referral service is assessed equally against and collected equally from all participants and is based only on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise

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[6] Id.

[7] 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).

[8] Section 1128B(b)(3) of the Act.

[9] 42 C.F.R. § 1001.952.

[10] 42 C.F.R. § 1001.952(f).

generated by either party for the other party for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs.

- The referral service imposes no requirements on the manner in which the participant provides services to a referred person, except that the referral service may require that the participant charge the person referred at the same rate as it charges other persons not referred by the referral service, or that these services be furnished free of charge or at reduced charge.
- The referral service makes the following five disclosures to each person seeking a referral, with each such disclosure maintained by the referral service in a written record certifying such disclosure and signed by either such person seeking a referral or by the individual making the disclosure on behalf of the referral service:
    - The manner in which it selects the group of participants in the referral service to which it could make a referral;
    - Whether the participant has paid a fee to the referral service;
    - The manner in which it selects a particular participant from this group for that person;
    - The nature of the relationship between the referral service and the group of participants to whom it could make the referral; and
    - The nature of any restrictions that would exclude such an individual or entity from continuing as a participant.

B. Analysis

Under the Proposed Arrangement, when a primary care clinician would refer a patient to a Hearing Professionals Group—which would pay a fee to Requestor to receive referrals—for services that would be reimbursable by a Federal health care program, the Federal anti-kickback statute would be implicated. However, we conclude that the fees that would be paid pursuant to the Proposed Arrangement would be protected by the safe harbor for referral services at 42 C.F.R. § 1001.952(f) because, based on Requestor's factual certifications, the Proposed Arrangement would satisfy all of the conditions of the safe harbor. Specifically, Requestor certified that:

- The Hearing Referral Service would not exclude as a participant any individual or entity who meets the qualifications for participation. The criteria for a Hearing Professionals Group to participate in the Hearing Referral Service would be applied equally to any Hearing Professionals Group seeking to join the Hearing Referral Service.
- Any payment the Hearing Professionals Group would make to the Hearing Referral Service would be assessed equally against and collected equally from all Hearing Professionals Groups and would be based only on the cost of operating the Hearing Referral Service and not on the volume or value of any referrals to or business otherwise generated by either party for the other party for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs. Each participating Hearing Professionals Group would pay an annual set fee—consistent with the estimated cost of operating the referral service—to participate in the Hearing Referral Service. The annual fee would be established regardless of: (i) the number of referrals that each Hearing Professionals Group would receive through the Hearing Referral

Service, and (ii) whether a patient received any Audiological Care from a Hearing Professional as a result of a referral. Requestor would implement a True-Up calculation to ensure that the annual set fee paid by participating Hearing Professionals Groups remains consistent with the operating costs of the Hearing Referral Service.

- The Hearing Referral Service would not impose any requirements on the manner in which the Hearing Professionals Group would provide services to a referred patient, such as clinical protocols, restrictions on products used (such as brand of hearing aids), or pricing demands.
- Requestor would make the five disclosures prescribed by the safe harbor to each person seeking a referral and would maintain evidence of the disclosure in a written record certifying the disclosure. Each disclosure would be signed by the person seeking a referral.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement, if undertaken, would not generate prohibited remuneration under the Federal anti-kickback statute. Accordingly, OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement under section 1128A(a)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute 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.

IV. LIMITATIONS

The limitations applicable to this advisory opinion include the following:

- This advisory opinion is limited in scope to the Proposed Arrangement. This advisory opinion has no applicability to any other arrangements, including, without limitation, any that may have been disclosed or referenced in your request for an advisory opinion or supplemental submissions.
- This advisory opinion is issued only to Requestor. 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 Requestor 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 Proposed 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 advisory opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

OIG will not proceed against Requestor with respect to any action that is part of the Proposed 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 Proposed 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 Requestor with respect to any action that is part of the Proposed 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,

/Andrew J. VanLandingham/

Andrew J. VanLandingham
Acting Assistant Inspector General for Legal Affairs