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: October 20, 2023

Posted: October 25, 2023

[Address block redacted]

Re: OIG Advisory Opinion No. 23-08 (Unfavorable)

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 its proposal to offer and provide a free compatible hearing aid to certain patients, including Federal health care program beneficiaries, who receive one of the cochlear implants it manufactures (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement, if undertaken, would constitute 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.

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 opinion is limited to the relevant facts presented to us by Requestor in connection with the Proposed Arrangement.

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement, if undertaken: (i) would generate prohibited remuneration under the Federal anti-kickback statute, if the requisite intent were present, which would constitute grounds for the imposition of sanctions under sections 1128A(a)(7) and 1128(b)(7) of the Act; and (ii) would generate prohibited remuneration under the Beneficiary Inducements CMP, which would constitute grounds for the imposition of

sanctions under the Beneficiary Inducements CMP and section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

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

I. FACTUAL BACKGROUND

Requestor manufactures and distributes implantable hearing solutions, including [redacted] (the "Device").[2] The Device includes an internal cochlear implant and an external sound processor and is sold as a system to hospitals and ambulatory surgical centers ("ASCs"). The Device may be implanted in one or both ears depending on the patient's presentation of symptoms and the medical judgment of the patient's health care provider (the "Provider"). Requestor certified that the Device is reimbursable by Federal health care programs, including Medicare, for certain indications and subject to limitations on coverage.[3] Requestor also certified that, in most cases, particular patient needs do not make the Device a more clinically appropriate option from a cochlear implant and sound processor manufactured by another device manufacturer. Requestor further certified that, in conjunction with their Provider's clinical judgment and recommendations, patients are able to choose the manufacturer from which their Provider orders the cochlear implant and sound processor.

Requestor certified that some patients who receive the Device may be candidates for bimodal hearing (i.e., combined use of a hearing aid in one ear and a cochlear implant in the other ear). To be a bimodal hearing candidate, a patient must have a cochlear implant and sound processor like the Device implanted in one ear and moderate-to-severe hearing loss in the ear that does not have the cochlear implant. Bimodal hearing candidates may benefit from using a hearing aid in the ear that does not have the cochlear implant to help with localizing sound and hearing better in noisy environments. Hearing aids are not covered by Medicare.[4] Requestor certified that

[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.

[2] Requestor is a Medicare-enrolled durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS") supplier for the limited purpose of furnishing repair services and replacements for the Device's external sound processors and bills Medicare for those items and services. Requestor also is a DMEPOS supplier that submits claims to other Federal health care programs for external sound processor repairs and replacements. Additionally, Requestor is a DMEPOS supplier that submits claims for payment for the Device to Medicaid programs and Medicaid managed care plans in three states.

[3] See Centers for Medicare & Medicaid Services ("CMS"), Medicare National Coverage Determinations Manual, Pub. 100-03, Ch. 1, § 50.3–Cochlear Implantation, https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/ncd103c1_part1.pdf.

[4] 42 C.F.R. § 411.15(d); CMS, Medicare Benefit Policy Manual, Pub. 100-02, Ch. 16, § 100, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c16.pdf.

although the pairing of the Device with a hearing aid in the other ear can improve hearing outcomes for bimodal hearing candidates, the Device works properly with or without the use of a hearing aid in the other ear.

Under the Proposed Arrangement, Requestor would offer a bimodal hearing bundle consisting of the Device and a free compatible hearing aid (the "Hearing Aid")[5] to eligible bimodal hearing candidates. To be eligible to receive the Hearing Aid, a patient would need to: (i) meet the Medicare coverage requirements for a cochlear implant, including that the Device would be used in accordance with the U.S. Food and Drug Administration-approved labeling for the Device; and (ii) have moderate-to-severe hearing loss in the ear that would not have the Device, as determined by a Provider. Under the Proposed Arrangement, the Device would be purchased by the hospital or ASC, as applicable, from Requestor at the request of the patient's Provider; the Hearing Aid would be provided by Requestor for free along with the Device.[6] The Device then would be implanted by the Provider at the hospital or ASC, and the Hearing Aid later would be programmed and fitted by an audiologist. The free Hearing Aid would be conditioned on the purchase of the Device, and Requestor expects that both patients and Providers would be aware that Requestor offers and provides the Hearing Aid for free.

Requestor certified that the Hearing Aid would be manufactured by a third-party hearing aid manufacturer, and the cost of the Hearing Aid would range from $1,180 to $2,240.[7] Under the Proposed Arrangement, Requestor would require hospitals and ASCs to certify that they: (i) would not bill patients or Federal health care programs for the Hearing Aid; and (ii) would advise patients and audiologists in writing that they may not claim insurance reimbursement for the Hearing Aid and that the audiologists may charge patients only their usual and customary fee for fitting the Hearing Aid.

Requestor proposes to either: (i) not impose any financial need criteria for the provision of the Hearing Aid; or (ii) establish financial need criteria to provide the Hearing Aid only to those whose household incomes are at or below 300 percent of the Federal Poverty Level.

---

[5] Requestor certified that a compatible hearing aid is a hearing aid that can be programmed by an audiologist together with the Device to optimize loudness and balance between the Device and the Hearing Aid and enable wireless streaming from smart phone applications to both the Device and the Hearing Aid without an intermediary device.

[6] Requestor certified that the Hearing Aid would be included as one of a limited number of optional accessories that Requestor offers at no additional charge. We have not been asked to opine, and we express no opinion, on Requestor's offer and provision of these accessories, except in connection with the Proposed Arrangement.

[7] Requestor certified that the Department of Veterans Affairs, certain state Medicaid programs, and certain Medicare Advantage plans may cover hearing aids, in whole or in part, but Requestor is unsure whether these or other Federal health care programs would cover the Hearing Aid. However, under the Proposed Arrangement, the Hearing Aid would be provided for free as an optional accessory regardless of whether it is covered by a Federal health care program.

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.

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.

Congress has developed several statutory exceptions to the Federal anti-kickback statute.[11] 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.[12] 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 arrangements for patient engagement and support to improve quality, health outcomes, and efficiency protects certain in-kind items, goods, or services furnished by a VBE

---

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

[9] Id.

[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).

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

[12] 42 C.F.R. § 1001.952.

participant (as defined in 42 C.F.R. § 1001.952(ee)(14)(ix)) to a patient in the target patient population (as defined in 42 C.F.R. § 1001.952(ee)(14)(v)), if all of the conditions of the safe harbor are squarely satisfied.[13] The safe harbor contains a number of limitations, including that the aggregate retail value of patient engagement tools and supports furnished to a patient by a VBE participant on an annual basis cannot exceed a monetary cap, which for calendar year 2023 is $570.

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."

The definition of "remuneration" in section 1128A(i)(6) of the Act includes a number of exceptions that are potentially applicable to the Proposed Arrangement. For example, section 1128A(i)(6)(F) of the Act provides that, for purposes of the Beneficiary Inducements CMP, the term "remuneration" does not apply to "remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in section 1128B(f) and designated by the Secretary under regulations)" (the "Promotes Access to Care Exception"). We have interpreted this provision to apply to "[i]tems or services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs . . . ."[14]

In addition, section 1128A(i)(6)(H) of the Act (the "Financial Need-Based Exception") provides that, for purposes of the Beneficiary Inducements CMP, the term "remuneration" does not apply to the offer or transfer of items or services for free or less than fair market value if the items or services: (1) are not advertised; (2) are not tied to the provision of other reimbursable items or services; (3) are reasonably connected to the medical care of the individual; and (4) are provided only after a good-faith determination that the recipient is in financial need.

B. Analysis

1. Federal Anti-Kickback Statute

The Proposed Arrangement would implicate the Federal anti-kickback statute because Requestor would offer and provide remuneration in the form of a free hearing aid to eligible patients that may induce them to arrange for the ordering (by the patients' Providers) and purchasing (by the hospital or ASC) of the Device, which is an item reimbursable by Federal health care programs.

[13] Id. § 1001.952(hh).

[14] Id. § 1003.110 (defining "remuneration").

The safe harbor for arrangements for patient engagement and support to improve quality, health outcomes, and efficiency would not apply because, among other reasons, the value of the Hearing Aid exceeds the current monetary cap, $570, imposed by that safe harbor. For the following reasons, we believe the risk of fraud and abuse presented by the Proposed Arrangement is not sufficiently low under the Federal anti-kickback statute for OIG to issue a favorable advisory opinion.

We have longstanding and continuing concerns regarding the provision of free items or services to Federal health care program beneficiaries because of the harms that could result from providing such free items or services, including steering, unfair competition, improper utilization, and quality and cost concerns. We have recognized that, "[i]n many cases, these complimentary goods or services have therapeutic, as well as financial, benefits for patients."[15] While we remain "mindful of the hardships that [certain] medical conditions can cause for beneficiaries," we continue to believe, consistent with our established guidance, that "there is no meaningful basis . . . for exempting valuable gifts based on a beneficiary's medical condition . . ."[16]

The Proposed Arrangement could result in the inappropriate steering of patients to the Device over a competitor's cochlear implant or other clinically appropriate items or services used to treat hearing loss. Requestor certified that, in conjunction with their Provider's clinical judgment and recommendations, patients are able to choose the manufacturer from which their Provider orders the cochlear implant and sound processor, which is then purchased by the hospital or ASC. Requestor expects that patients would be aware that Requestor offers and provides the Hearing Aid for free. Requestor further certified that the Hearing Aid is not required for the Device to work properly. Moreover, Requestor certified that, in most cases, particular patient needs do not make the Device a more clinically appropriate option than a cochlear implant and sound processor manufactured by another device manufacturer. Therefore, in the event that a Provider has more than one appropriate option, the Provider could encourage a patient to choose the Device, rather than an alternative, because of the Hearing Aid. Similarly, the offer and provision of the Hearing Aid would be an attractive incentive for a patient to select the Device over a competitor device or another clinically appropriate item or service used to treat hearing loss.

Further, the provision of the Hearing Aid by Requestor to patients could result in unfair competition resulting from only some manufacturers of a competitor device or another clinically appropriate item or service used to treat hearing loss being willing or able to provide such a valuable item. We have previously stated our concern that "[t]he use of giveaways to attract business . . . favors large providers with greater financial resources for such activities,

---

[15] OIG, Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries 4 (2002), http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf. While this guidance relates to the Beneficiary Inducements CMP, the risks identified in this Special Advisory Bulletin relating to the provision of a free item or service are instructive when assessing the risks under the Federal anti-kickback statute.

[16] Id. at 4–5.

disadvantaging smaller providers and businesses."[17] Providing a free Hearing Aid, which would cost Requestor $1,180 to $2,240 per patient, could potentially give Requestor a significant advantage over its competitors (or potential competitors seeking to enter the hearing loss treatment market), who may not be in a position to offer a similar benefit.

2. Beneficiary Inducements CMP

The Proposed Arrangement also would implicate the Beneficiary Inducements CMP because Requestor's offer and transfer of the Hearing Aid could influence a beneficiary located in states where Requestor bills Medicaid or Medicaid managed care plans for the Device to select Requestor, a DMEPOS supplier, for the order and receipt of the Device—an item for which payment may be made, in whole or in part, by Medicare or a State health care program. Additionally, Requestor's offer and transfer of the Hearing Aid could influence a beneficiary to select the Device, which then could result in Requestor, in its role as a DMEPOS supplier, providing repair or replacement services for the Device for which payment may be made, in whole or in part, by Medicare or a State health care program. Because the Hearing Aid is not required for the Device to work properly, the Hearing Aid would not improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and therefore, the Promotes Access to Care Exception would not be applicable. Additionally, the Financial Need-Based Exception would not be met because the free Hearing Aid would be conditioned on the purchase of the Device, which is an item reimbursable by Medicare and Medicaid, and the Financial Need-Based Exception applies only when the items or services being offered for free or less than fair market value are not tied to the provision of other reimbursable items or services.

No exception to the Beneficiary Inducements CMP applies, and for the reasons described above, the Proposed Arrangement could generate prohibited remuneration under the Beneficiary Inducements CMP. Our conclusion that the Proposed Arrangement would cause a risk of steering to Requestor's Device and unfair competition remains the same whether or not the Proposed Arrangement contains a financial need requirement. We have long emphasized that "there is no meaningful statutory basis for a broad exemption based on the financial need of a category of patients . . . [and] that categorical financial need is not a sufficient basis for permitting valuable gifts."[18]

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: (i) would generate prohibited remuneration under the Federal anti-kickback statute, if the requisite intent were present, which would constitute grounds for the imposition of sanctions under sections 1128A(a)(7) and 1128(b)(7) of the Act; and (ii) would generate prohibited remuneration under the Beneficiary Inducements CMP, which would constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP and section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

[17] Id. at 1.

[18] Id. at 5.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is limited in scope to the Proposed 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 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 or entity other than Requestor to prove that the person or entity 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 opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008. 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.

Sincerely,

/Susan A. Edwards/

Susan A. Edwards
Acting Assistant Inspector General for Legal Affairs