



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: April 28, 2026

Posted: May 1, 2026

[Address block redacted]

Re: OIG Advisory Opinion No. 26-08 (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 proposal to enter into certain lease arrangements to create a centralized location for providing a range of items and services to patients with hearing loss who may be candidates for cochlear implants (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 person¹ 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

Requestor is a corporation owned by a physician who practices in several specialties, including otolaryngology. Requestor certified that it is creating a centralized location to provide a range of items and services to patients who suffer from hearing loss and may be candidates for cochlear implants (the “Center”). Requestor certified that the Center would provide community-based care to patients by bringing patients, caregivers, audiologists, physicians, and cochlear implant manufacturers together so that patients may access education and critical hearing care in one place. Requestor’s physician owner would refer patients to the Center.

Requestor currently leases space in an office building where Requestor has modified the space so that there are several suites of varying sizes that can be subleased. Additionally, Requestor has purchased or leased certain equipment relating to hearing care (e.g., audiology booths, audiometers, and microscopes) for certain suites. To effectuate the Center, Requestor proposes to enter into several space and equipment subleases. Certain sublessees (e.g., cochlear implant manufacturers) only would enter into space subleases, while other sublessees (i.e., audiologists, physicians) would enter into space and equipment subleases. Some of the subleases would contemplate that space and equipment, as applicable, would be leased on a full-time basis, and others would contemplate leasing on a part-time basis.

Requestor’s physician owner and each of the sublessees would be in a position to refer to one another. Requestor certified the only remuneration it would receive relating to the operation of the Center would be fair market value space and equipment rental fees and that it would not receive any other remuneration from sublessees. Additionally, Requestor certified that no remuneration would be offered or paid by Requestor or its physician owner to the sublessees nor would remuneration be offered or paid between or among sublessees as part of the operation of the Center. Further, Requestor certified that there would be no referral requirement or pressure for Requestor, its physician owner, or any of the sublessees to refer patients to each other. Requestor certified that it would pass through its costs for the subleased space and equipment to the sublessees and not charge any additional amounts such that Requestor would not profit from the fees derived from the subleases.

With regard to the space and equipment subleases (as applicable), Requestor certified to the following facts:

- Requestor would enter into a written, signed sublease with each of the sublessees.

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.

- Each sublease would specify and cover all of the premises or equipment leased between the parties for the term of the sublease.
- Where the sublease would provide the sublessee with access to the premises for periodic intervals of time or use of the equipment for periodic intervals of time, rather than on a full-time basis for the term of the sublease, the sublease would specify exactly the schedule of such intervals, their precise length, and the exact rent for such intervals.
- Each sublease would be for at least one year.
- The aggregate amount of the space and equipment rental would be fixed in advance, consistent with fair market value in an arm’s-length transaction,² and not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made by Federal health care programs.
- The aggregate space or equipment rented would not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.

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.³ 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.⁴ 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.⁵ Violation of the statute constitutes a felony punishable by a maximum fine of

² We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. Section 1128D(b)(3)(A) of the Act.

³ Section 1128B(b) of the Act.

⁴ Id.

⁵ 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).

\$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.⁶ 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.⁷ 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.

Potentially applicable to the Proposed Arrangement are the safe harbors for space rental and equipment rental.⁸ The safe harbors for space rental and for equipment rental include the same six elements:

- (1) The lease agreement is set out in writing and signed by the parties.
- (2) The lease covers all of the premises or equipment leased between the parties for the term of the lease and specifies the premises covered by the lease.
- (3) If the lease is intended to provide the lessee with access to the premises or use of the equipment for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such intervals.
- (4) The term of the lease is for not less than one year.
- (5) The aggregate rental charge is set in advance, is consistent with fair market value in arm's-length transactions, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.

⁶ Section 1128B(b)(3) of the Act.

⁷ 42 C.F.R. § 1001.952.

⁸ 42 C.F.R. § 1001.952(b), (c).

(6) The aggregate space or equipment rented does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.⁹

B. Analysis

The Proposed Arrangement implicates the Federal anti-kickback statute because Requestor, an entity that is owned by a physician who would refer patients to the Center, would enter into subleases with individuals and entities that may refer patients to Requestor and Requestor's physician owner for items and services reimbursable under a Federal health care program. Additionally, Requestor, through its physician owner, may refer patients to the sublessees for items and services reimbursable under a Federal health care program. The Proposed Arrangement is protected by the safe harbors for the rental of space and equipment, as applicable, because each condition is either met or not applicable based on Requestor's factual certifications. Specifically, Requestor certified that:

- Requestor would enter into a written, signed sublease with each of the sublessees.
- Each sublease would cover all of the premises or equipment leased between the parties for the term of the sublease and would specify the premises or equipment covered by the sublease.
- Where the sublease would provide the sublessee with access to the premises or use of the equipment for periodic intervals of time, rather than on a full-time basis for the term of the sublease, the sublease would specify exactly the schedule of such intervals, their precise length, and the exact rent for such intervals.
- Each sublease would be for at least one year.
- The aggregate amount of the space and equipment rental would be fixed in advance, consistent with fair market value in an arm's-length transaction, and not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made by Federal health care programs.
- The aggregate space or equipment rented would not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.

While we conclude that the Proposed Arrangement is protected by one or more safe harbors, we also have cautioned that “[i]f a sham contract is entered into, which on paper looks like it complies with these provisions, but where there is no intent to have the space or equipment used or the services provided, then clearly we will look behind the contract and find that in reality payments are based on referrals. Thus, these contracts would not be protected under these

⁹ Id.

provisions.”¹⁰ Here we are not concerned these would be sham subleases. In addition to Requestor’s certifications relating to the space and equipment rental arrangements, we relied on the following facts in reaching our conclusion: (1) the only remuneration Requestor would receive from referral sources relating to the operation of the Center would be the space and equipment rental fees, which Requestor certified would consist only of its costs for the subleased space and equipment such that Requestor would not profit from the fees; (2) no remuneration would be offered or paid by Requestor or its physician owner to the sublessees nor between or among sublessees as part of the operation of the Center; and (3) there would be no referral requirement or pressure for Requestor, its physician owner, or any of the sublessees to refer patients to each other.

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.

¹⁰ Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,972 (July 29, 1991). See also, Publication of OIG Special Fraud Alert on Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer, 65 Fed. Reg. 9,274, 9,275 (Feb. 24, 2000) (“OIG is concerned that...rental payments may be disguised kickbacks to the physician-landlords to induce referrals.”). We reiterate longstanding and continued concerns that space and equipment leased by individuals and entities, including device manufacturers, may be disguised as remuneration intended to induce or reward the purchase of the manufacturers’ products.

- 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 advisory 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,

/Spencer K. Turnbull/

Spencer K. Turnbull
Acting Assistant Inspector General for Legal Affairs