



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: May 13, 2026

Posted: May 18, 2026

[Address block redacted]

Re: OIG Advisory Opinion No. 26-10 (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”), an orthopedic medical technology company, regarding Requestor’s proposal to enter into agreements with individuals—often physicians—who would provide consulting services for its product lines (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.

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 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.

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 develops, manufactures, and distributes a wide range of implant and replacement products (“Products”) in the orthopedic specialty areas of hip, knee, shoulder, spine, and sports medicine (each, a “Product Line”). In order to develop, manufacture, and distribute the Products, Requestor collaborates with individuals, often physicians, who have extensive experience and expertise in connection with those orthopedic specialty areas (the “Consultants”) and who purchase Requestor’s Products and utilize them in the provision of services to patients, including Federal health care program enrollees. Requestor currently engages the Consultants in the design, development, and evaluation of a particular Product (the “Development Services”). Requestor enters into a written agreement (the “Product Development Agreement”) with each Consultant prior to such Consultant providing the Development Services to Requestor.²

Under the Proposed Arrangement, in addition to engaging the Consultants to perform the Development Services, Requestor would engage certain Consultants to advise and consult on a full Product Line (rather than on a specific Product). Relative to the Product Line consultation and advice services, Requestor would enter into a written agreement with the Consultant (the “Product Line Agreement”) pursuant to which the Product Line Consultant would: (i) provide teaching, training, and proctoring services related to Products included in the relevant Product Line, (ii) contribute to the development of the overall Product Line by reviewing and providing feedback regarding, among other things, clinical results, designs, testing, and technologies related to a Product Line; (iii) attend and contribute to regular meetings relating to the Product Line to discuss and review design features or relevant technologies; (iv) meet with Requestor’s personnel to discuss strategic initiatives regarding the Product Line’s design and development; and (v) review and evaluate implant or instrument designs and prototypes within the Product Line and provide written clinical evaluations of the same (collectively, the “Product Line Services”).³ Requestor certified that it does not view the Product Line Services as marketing or promotional activities intended to generate revenue; however, Requestor is unable to certify that

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 specific terms of the Product Development Agreement.

³ Requestor certified that prospective Product Line Consultants would be identified using factors such as breadth of published papers and peer-reviewed articles on relevant subjects; academic appointments; academic presentations; and clinical research. Requestor further certified that it would not identify or select Product Line Consultants on the basis of past, present, or future utilization of Requestor’s Products.

none of the Product Line Services would contribute to the generation of revenue from the Products.

Under the terms of the Product Line Agreement, the Product Line Consultants would be required to provide Product Line Services: (i) for a minimum number of hours per year; and (ii) to a satisfactory level⁴ (together, “Product Line Requirements”). Relative to the Product Line Agreements, Requestor certified that:

- It would require the Product Line Consultant to complete time records, documenting the Product Line Consultant’s time providing the Product Line Services to ensure that a Product Line Consultant is meeting the Product Line Requirements and to validate that actual, legitimately needed Product Line Services are provided by each Product Line Consultant. The Product Line Consultant would be required to review and confirm the accuracy of the time records. Requestor’s Compliance Department would review the time records, which would detail the Product Line Services performed, dates of service, and the amounts of services provided.
- It would require that the time records documenting the Product Line Services not reflect any time that is covered by a separate agreement between the Product Line Consultant and Requestor (e.g., a Product Development Agreement). The time record would include an express certification that the time record does not reflect any time that is covered by a separate agreement between the Product Line Consultant and Requestor.
- The Evaluation Panel would have the sole decision-making authority to determine whether the Product Line Consultant had provided satisfactory Product Line Services (which would be indicated by a rating of “royalty-eligible” to the Product Line Consultant).

According to Requestor, if the Evaluation Panel determined that a Product Line Consultant did not meet the Product Line Requirements during a particular quarter (i.e., if the Product Line Consultant’s time record did not show the minimum time required or the Evaluation Panel determined the Product Line Consultant did not render the Product Line Services at a satisfactory level), then the Product Line Consultant would be paid an hourly rate for the Product Line Services actually provided and documented by the Product Line Consultant. The Product Line Agreement would state this hourly rate in advance, and Requestor asserts that the hourly rate would be consistent with fair market value.

⁴ To assess whether the Product Line Consultant provided Product Line Services to a satisfactory level, Requestor would create an evaluation panel to qualitatively assess each Product Line Consultant’s contributions (the “Evaluation Panel”). On a quarterly basis, the Evaluation Panel would review the Product Line Consultant’s time records, attendance, participation, quality of interaction, and each Product Line Consultant’s novel, significant, or innovative contributions made to the Product Line.

If a Product Line Consultant met the Product Line Requirements in the applicable quarter, then they would receive a “royalty”⁵ payment for such quarter equal to a specified percentage of the net invoice price for all Products sold within the applicable Product Line for which the Product Line Consultant provided Product Line Services (the “Product Line Royalty”). Requestor certified that upon the issuance of a favorable advisory opinion from OIG, it would engage a third-party valuation consultant to determine a Product Line Royalty payment amount that would be consistent with fair market value.⁶ Requestor certified that the Product Line Royalty would not take into consideration the volume or value of the Product Line Consultant’s referrals to Requestor, and Requestor proposes to exclude certain sales from the Product Line Royalty payment calculation, including: (i) the sales of a Product for use in a surgery or other medical procedure performed by the Product Line Consultant or their immediate family members or sold to a hospital, ambulatory surgery center or other facility in which the Product Line Consultant performs medical procedures or has an ownership interest; and (ii) the sales of Products for which the Product Line Consultant already receives a royalty or other payment for Development Services. Under the terms of the Product Line Agreement, a royalty-eligible Product Line Consultant would receive Product Line Royalty payments for a particular quarter. A Product Line Consultant may be deemed royalty-eligible—and earn a Product Line Royalty—even if the Product Line Consultant has not provided services in furtherance of the development of one or more Products included in the Product Line, so long as the Product Line Requirements have been met during the applicable quarter.

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.⁷ 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.⁸ For purposes of the Federal anti-kickback

⁵ Requestor uses the term “royalty” to describe these payments, although this usage departs from the dictionary definition of the term. See Merriam-Webster, Merriam-Webster.com Dictionary (Oct. 21, 2025), <https://www.merriam-webster.com/dictionary/royalty> (defining “royalty” as “a payment to an author or composer for each copy of a work sold or to an inventor for each item sold under a patent”). Whether these payments are properly characterized as royalties is outside the scope of this advisory opinion.

⁶ 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.

⁷ Section 1128B(b) of the Act.

⁸ Id.

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.⁹ 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.¹⁰ 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.¹¹ 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 personal services and management contracts and outcomes-based payment arrangements is potentially applicable to the Proposed Arrangement.¹² In relevant part for the purposes of this advisory opinion, the safe harbor requires that the methodology for determining the compensation paid to the agent over the term of the agreement 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.¹³

B. Analysis

The Proposed Arrangement implicates the Federal anti-kickback statute because the Consultants—who purchase and utilize Requestor’s Products to provide services to patients, including Federal health care program enrollees—would enter into Product Line Agreements

⁹ 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).

¹⁰ Section 1128B(b)(3) of the Act.

¹¹ 42 C.F.R. § 1001.952.

¹² Id. § 1001.952(d).

¹³ Id. § 1001.952(d)(1)(iv).

with Requestor, pursuant to which royalty-eligible Product Line Consultants would receive a Product Line Royalty payment. We recognize that royalty payments and consulting arrangements are common in the medical device industry and royalty payments and consulting arrangements may be structured such that they either satisfy a safe harbor or otherwise present low risk under the Federal anti-kickback statute. However, we do not believe that the Proposed Arrangement would present sufficiently low risk under the Federal anti-kickback statute to provide prospective immunity through a favorable advisory opinion.

As a threshold matter, the Proposed Arrangement would not satisfy the safe harbor for personal services and management contracts and outcomes-based payment arrangements. We believe that the Product Line Royalty payments would be determined in a manner that takes into account the volume or value of referrals or other business generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs. Requestor is unable to certify that none of a Product Line Consultant's Product Line Services would contribute to the generation of revenue from the Products, notwithstanding Requestor's assertion that it does not view the Product Line Services as marketing or promotional activities intended to generate revenue. Although Requestor would exclude certain sales of the Products from the Product Line Royalty payment calculation, the Product Line Royalty payments would incentivize loyalty to—and advocacy for—Requestor's Products in a manner that could generate additional business for Requestor.

Notwithstanding Requestor's certifications—including certifications that the Product Line Royalty payments would be consistent with fair market value and that such payments would not take into consideration the volume or value of a Product Line Consultant's referrals to Requestor—the Product Line Royalty payments still could financially motivate Product Line Consultants to recommend Requestor's Products over competing products. This incentive, along with the services the Product Line Consultants must provide under the Product Line Agreement (such as teaching, training, and proctoring), heightens the risk that Product Line Consultants would recommend the Products to others who can order them and generate revenue for Requestor, including revenue from purchases paid for by Federal health care programs. The Product Line Royalty payment calculation would include certain purchases that result from the Product Line Consultants' recommendations to others. Because this revenue—resulting from recommendations of the Product Line Consultant—is part of the Product Line Royalty payment calculation, we conclude that the compensation methodology would take into account business otherwise generated between the parties.

Because the Proposed Arrangement would not qualify for safe harbor protection, we next consider the totality of the facts and circumstances to assess the risk of fraud and abuse the Proposed Arrangement would present. As a threshold matter, we state our longstanding and continuing concerns regarding payments by device manufacturers to physicians in a position to influence the purchases of their products. We have previously pointed to studies that have shown that physicians who receive remuneration from a company are more likely to prescribe or order that company's products and that such remuneration to physicians may skew their clinical decision making in favor of their own and the company's financial interests rather than the

patient’s best interests.¹⁴ We conclude that the Proposed Arrangement presents not only this risk of skewed clinical decision making, but a host of other risks, including patient steering, unfair competition, inappropriate utilization, and increased costs to Federal health care programs. We believe there is a heightened risk that the Product Line Consultants may utilize—and steer other providers to utilize—Requestor’s Products for the financial gain they would realize via the Product Line Royalty payments even when the products of a competitor may be more clinically appropriate. The presence of these risks leads us to conclude that that the Product Line Royalty payments may actually be a payment-for-referrals scheme and consequently, the Proposed Arrangement would not be sufficiently low risk under the Federal anti-kickback statute to provide prospective immunity through a favorable advisory opinion. Notwithstanding the foregoing, we recognize that consulting arrangements can serve legitimate and beneficial purposes when physicians provide specialized clinical or technical expertise to assist medical technology companies in the development, evaluation, and refinement of their products. When structured in a manner that does not induce or reward referrals, such arrangements may support innovation and enhance patient care without posing undue risk under the Federal anti-kickback statute.

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 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.

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.

¹⁴ See, e.g., Special Fraud Alert: Speaker Programs, 87 Fed. Reg. 51,683, 51,684 (Aug. 23, 2022), <https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/SpecialFraudAlertSpeakerPrograms.pdf> (citing Amarnath Annappureddy et al., Association Between Industry Payments to Physicians and Device Selection in ICD Implantation, 324 JAMA 1759, 1762–63 (2020); William Fleischman et al., Association Between Payments From Manufacturers of Pharmaceuticals to Physicians and Regional Prescribing: Cross Sectional Ecological Study, 354 BMJ i4189, 4–7 (2016); James P. Orłowski & Leon Wateska, The Effects of Pharmaceutical Firm Enticements on Physician Prescribing Patterns: There’s No Such Thing as a Free Lunch, 102 Chest 270 (1992)).

- 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 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,

/Spencer K. Turnbull/

Spencer K. Turnbull
Acting Assistant Inspector General for
Legal Affairs