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Healthcare Alert

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OIG Advisory Opinion: Physician royalties under heightened scrutiny

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The advisory opinion found that an orthopedic medical device company's proposed consulting and royalty arrangements with physician consultants would violate the federal Anti-Kickback Statute if the requisite intent were present.



What's the impact?

- The OIG opinion provides important guidance on the boundaries of permissible physician consulting arrangements in the medical device industry, particularly when compensation includes royalty-based payments tied to product sales.
- It signals heightened OIG scrutiny of arrangements that combine consulting services with revenue-sharing components, even where the compensation constitutes fair market value.

The federal Anti-Kickback Statute prohibits the knowing and willful offer, payment, solicitation, or receipt of any remuneration to induce or reward referrals for, or the purchase of, items or services reimbursable by federal health care programs such as Medicare and Medicaid. In other words, violations expose parties to significant civil monetary penalties, program exclusion, and

potential criminal liability. To assist the healthcare industry in navigating these prohibitions, the US Department of Health and Human Services Office of Inspector General (OIG) issues Advisory Opinions in response to specific requests. While binding only on the requesting party with respect to the described facts, these opinions provide prospective guidance on whether an arrangement may implicate the Anti-Kickback Statute and offer broader insight into OIG's enforcement priorities.

OIG's recent Anti-Kickback Statute Advisory Opinion

On May 13, 2026, the OIG issued Advisory Opinion No. 26-10, finding that an orthopedic medical device company's proposal to compensate physician consultants through royalty payments on products sold by the company posed a heightened risk of prohibited remuneration under the Anti-Kickback Statute.

PROPOSED ARRANGEMENT

Under the proposed arrangement, an orthopedic medical device company that develops, manufactures, and distributes implant and replacement products would enter into agreements with physicians to serve as "product line consultants" to consult and advise on one of the company's full product lines. They would also provide teaching, training, and proctoring services related to the product line. The company certified that it did not consider the product line services to be marketing or promotional activities, but could not certify that none of the services performed by the product line consultants would contribute to the generation of revenue from the sale of products.

COMPENSATION STRUCTURE

The company would require product line consultants to provide consulting and advising services for a minimum number of hours per year and at a level satisfactory to the company. Those who did not meet such standards in a quarter would be paid an hourly rate for the services performed. Those who met the time and quality-of-work standards in a quarter would receive a royalty payment equal to a percentage of revenue from all products sold within the product line to which the product line consultants provided consulting and advising services. The company certified that it would engage a third-party valuator to ensure that the royalty payments would be consistent with fair market value and that the royalty payment methodology would exclude revenue from products personally used by a product line consultant or from products sold to a facility in which a product line consultant had an ownership interest or performed procedures.

Legal analysis

OIG concluded that the proposed arrangement may generate prohibited remuneration under the Anti-Kickback Statute if the requisite intent were present, citing longstanding concerns

about compensation paid by medical device companies to physicians who are in a position to influence the ordering of their products.

PERSONAL SERVICES AND MANAGEMENT CONTRACTS SAFE HARBOR

OIG determined that the proposed arrangement would not meet the Anti-Kickback Statute safe harbor for personal services and management contracts. Since the royalty payment methodology could include revenue attributable to product line consultants' recommendations of products, OIG concluded that such payment would be determined in a manner that takes into account the volume or value of referrals or other business generated between the parties. OIG reasoned that the royalty payment structure could provide a financial incentive for product line consultants to recommend the company's products and that their teaching, training, and proctoring activities heightened the risk of their recommending products to potential ordering providers.

RISKS OF FRAUD AND ABUSE IDENTIFIED BY OIG

OIG cited its longstanding concerns with compensation paid by medical device companies to physicians who are in a position to influence the ordering of the companies' products. To illustrate this point, OIG referenced studies suggesting that physicians are more likely to order a company's products when they receive compensation from that company, risking skewed clinical decision-making that favors financial interests over patients' best interests. OIG determined that the proposed arrangement posed such a risk, as well as the risks of patient steering, unfair competition, inappropriate utilization, and increased costs to federal healthcare programs. OIG described the proposed arrangement as potentially a "payment-for-referrals scheme" that would likely create a financial incentive for product line consultants to utilize and recommend the company's products over a competitor's.

RECOGNITION OF LEGITIMATE AND BENEFICIAL CONSULTING ARRANGEMENTS

Notwithstanding the opinion, OIG expressed that consulting arrangements involving physicians providing specialized clinical or technical expertise to contribute to companies' development of products can serve legitimate and beneficial purposes. OIG further noted that such arrangements, when structured in a compliant manner, can further innovation and patient care without presenting heightened risk under the Anti-Kickback Statute.

Compliance recommendations for physician consulting arrangements

Advisory Opinion 26-10 reinforces OIG's longstanding concern that financial relationships between medical device companies and physicians who are in a position to influence the purchasing of such companies' products can compromise clinical judgment and increase costs to federal healthcare programs. While OIG recognized that physician consulting arrangements can

be legitimate and contribute to better patient care, OIG's opinion signals that it will closely scrutinize compensation structures involving revenue-based royalties or other payments that appear to incentivize consultants to utilize or steer potential customers toward a company's products.

The themes raised in this Advisory Opinion reflect similar considerations raised in other common [physician-manufacturer relationships](#):

- / Fixed-fee consulting carries lower risk when compensation reflects fair market value for legitimate, documented services without volume- or value-based incentives.
- / IP royalty arrangements may be permissible for genuine contributions to product development if not tied to ongoing referrals.
- / [Speaker and training programs](#) may require fair market value compensation and careful monitoring to avoid the optics that the programs are disguised marketing or inducements for patient referrals.
- / Other arrangements, such as medical directorships and [equity interests](#), are options, each of which warrants separate consideration from Anti-Kickback Statute and Stark Law analysis.

To mitigate the risk of fraud and abuse scrutiny by OIG, medical device companies that maintain or are considering establishing physician consulting arrangements should continue to evaluate whether the related compensation structures create incentives for physician consultants to favor the company's products or recommend the company's products to other providers. Although the Advisory Opinion underscores the risks of revenue-sharing arrangements, these concerns can often be effectively addressed through thoughtful structuring and robust safeguards. For instance, compensation methodologies generally should exclude the consulting physician from any position to refer, order, or influence utilization of the company's products, such as by carving out sales related to the physician's own procedures or affiliated facilities, while limiting payments to fixed fair market value compensation for clearly documented, legitimate services. When properly implemented, such measures can help ensure that consulting relationships advance innovation and patient care, while presenting a low risk of fraud and abuse under the Anti-Kickback Statute.

Importantly, the most pragmatic approach is for industry stakeholders to also consider structuring arrangements to satisfy an applicable Anti-Kickback Statute safe harbor where possible.

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