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Structuring for Scrutiny: A Compliance and Risk Framework for Key Opinion Leader, Advisory Board, and Other Physician Consulting Arrangements with Life Sciences Companies

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Despite increasing government scrutiny of consulting arrangements between physicians and life sciences companies, these arrangements remain common. Manufacturers of pharmaceuticals, biologics, and medical devices rely on physicians with specialized clinical and experiential expertise that internal teams generally cannot fully replicate. Common examples of these arrangements include:

- **Key opinion leader agreements**, under which respected clinicians provide scientific expertise and lend credibility in connection with product development, clinical trial design, and therapeutic applications of products.
- **Advisory board agreements**, which provide companies with structured clinical input from physician experts, as well as input from clinical professionals with specific business or commercial strategy acumen.
- **Speaker program agreements**, under which physicians present on a company's products or disease states to peer audiences.

These arrangements are valuable to the life sciences industry, but because they are inherently situated at the intersection of clinical practice and commercial influence, they also carry meaningful legal and regulatory risks. Those risks should be managed proactively, particularly in the current environment of heightened regulatory scrutiny and enforcement.

Legal Framework

Key Legal Requirements. In the United States, three primary federal legal frameworks are relevant to the analysis of consulting arrangements between physicians and life sciences companies:

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- The Federal Anti-Kickback Statute (AKS),[1] which makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward referrals for, or arranging for, or recommending the purchases or orders of, items or services reimbursable under a federal health care program, is the primary law that applies to these consulting arrangements.
- The Physician Self-Referral Law (Stark Law),[2] which prohibits a physician from referring Medicare patients for designated health services (DHS) to an entity with which the physician has a financial relationship, absent an applicable exception, may be implicated in certain arrangements (e.g., a consulting arrangement with a clinical laboratory).
- The Physician Payments Sunshine Act,[3] which requires manufacturers to report payments and other transfers of value to covered recipients (such as physicians, teaching hospitals, and certain advanced practice professionals) for publication in the Open Payments database, can be used by regulators and plaintiffs' counsel to identify outlier physician compensation arrangements.

These laws are enforced alongside the civil False Claims Act, under which claims resulting from AKS violations are false (42 U.S.C. § 1320a-7b(g)), and various state laws.

OIG Guidance and Advisory Opinions. The U.S. Department of Health and Human Services Office of Inspector General (OIG) has consistently treated physician consulting arrangements as high risk when the physician can prescribe, refer, or influence product use. In its 2003 Compliance Program Guidance for Pharmaceutical Manufacturers, OIG cautioned that any transfer of value to a physician who might prescribe a company's products warrants scrutiny for improper inducement, and that a legitimate purpose or fair market value (FMV) payment does not immunize an arrangement where an illegal purpose also exists. That guidance flagged suspect practices, including switching arrangements—whereby physicians are incentivized to switch a patient from one product to another—and compensating physicians as passive "consultants" at conferences.

OIG's 2020 Special Fraud Alert on speaker programs questioned whether many such programs serve a legitimate educational purpose, citing red flags including the selection of high-prescribing physicians as speakers, lucrative deals conditioned on sales targets, repeat attendees, and lavish or entertainment-focused venues. More recently, OIG Advisory Opinion No. 26-10 (May 2026), an unfavorable opinion, addressed a proposed orthopedic implant manufacturer arrangement involving consulting payments and percentage-of-sales "royalty" payments made by the manufacturer to physician-users of its products. OIG concluded that the arrangement would generate prohibited remuneration under the AKS, if the requisite intent were present, because the royalty calculation took into account business generated by the consultants' own recommendations, incentivizing product loyalty. Additionally, OIG found that the consultants' teaching, training, and proctoring roles further positioned them to influence other providers, raising risks of skewed clinical decisions, patient steering, and increased federal program costs.

Enforcement Trends. Consistent with the government's historical scrutiny of consulting arrangements involving physicians and life sciences companies, the Department of Justice (DOJ) continues to prioritize enforcement actions involving these arrangements, frequently examining excessive advisory board and speaker fees. DOJ also increasingly uses data analytics—including Sunshine Act data contained in the Open Payments database and prescribing data—to correlate payments with prescribing trends and identify outliers. While the federal government ramps up its technology-enabled enforcement infrastructure, a significant proportion of enforcement actions continue to

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originate from qui tam or other whistleblower complaints. Common compliance gaps highlighted in these cases include the absence of a documented business need, repeated engagement of the same physicians without new justification, selection of consultants based on prescribing volume rather than expertise, lavish venues unrelated to program purpose, and blurred lines between promotional reach, education, and marketing. A recent settlement in which Veloxis Pharmaceuticals agreed to pay more than $46 million to resolve criminal and civil allegations of kickback schemes highlights the government's longstanding concerns about physician consulting arrangements. In its August 10, 2026 press release, DOJ stated that Veloxis paid kickbacks to transplant health care providers in the form of lavish meals, alcoholic beverages, expensive resort stays, personal gifts, and purported consulting fees, including consulting payments for work that was "not actually performed."[4]

Risk Mitigation Strategies in Structuring Consulting Arrangements

Given the legal requirements, OIG's views, and enforcement trends, the overarching principle is clear: consulting arrangements with physicians positioned to refer or influence the use of products offered by life sciences companies present a high risk of drawing fraud and abuse scrutiny. If a life sciences company cannot demonstrate a true business need, a defensible consultant selection methodology, compensation that is reasonable and based on an assessment of actual work efforts, and modest program spending, the risk that the arrangement will not withstand governmental scrutiny is high. The risk mitigation strategies outlined below can help build a defensible record supporting these arrangements and lower the overall risk profile.

Legitimate Business Purpose. It is important to establish and document a legitimate business need for the consulting arrangement independent of any referral potential from the consulting physician. The documentation should reflect what expertise the company needs, why the particular physician is needed, what work is expected, and why the scope and number of engagements are reasonable. To help demonstrate a legitimate business purpose:

- Document the clinical and educational value of the physician's expertise to the company (e.g., specialty expertise critical for a new product launch) and link the services to a defined business objective.
- Engage only the number of physician consultants that the company's needs and purposes reasonably require.
- Require contemporaneous accounting of time and any contractually required deliverables as a condition of payment and ensure that payments are contingent on the actual performance of bona fide services.
- Do not engage in multiple arrangements with the same physician without performing both an aggregate review and an arrangement-by-arrangement review of the documented business purpose and legitimacy of each arrangement.
- Keep educational program design consistent with the stated educational purpose: use appropriate venues, provide modest meals, invite an appropriate and relevant audience, avoid luxury resorts and entertainment-driven settings, and do not include the physician's family as invitees.

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Reasonable Compensation. It is critical to ensure that compensation paid to the physician consultant is consistent with FMV for the services provided and that the arrangement is commercially reasonable. Risk mitigation steps to consider include:

- Obtain and document FMV support for the consultant's compensation that draws on market-driven benchmarks and Open Payments data while accounting for individual-specific intangibles (e.g., reputation, experience, track record), the scope of services, and performance indicators (e.g., publications and program feedback). Note that Open Payments data reflects what industry has paid rather than independent FMV evidence, so it shouldn't be the sole benchmark.
- Do not allow the FMV analysis, or any other compensation decision, to take into account the physician's referrals or referral potential.
- Use an hourly, daily, or project-based rate that is reasonable, consistent with FMV, and tied to the services actually expected and performed.
- Avoid high-risk compensation structures such as royalties, equity grants, stock options, and success- or milestone-based fees where possible, particularly where start-ups or novel technologies are involved and equity value may itself be shaped by the consulting physician's own influence over the company.
- Adopt and apply a uniform travel-expense policy that reimburses only reasonable, documented, and pre-approved expenses. Do not reimburse first-class travel, luxury hotels, or spouse or guest expenses.

Selection Criteria. Adopt, document, and consistently apply objective selection criteria for physician consultants. The documentation should evidence that the physician was selected on the basis of the physician's unique expertise and the program's legitimate need, and not because the physician could generate referrals, prescribe, or influence purchasing decisions. When selecting physician consultants:

- Do not base selection on referral potential, including high-prescribing or utilization history, referral volume, or expected product use.
- Consider objective factors such as length of time in practice, number of relevant publications, geographic location (to ensure diverse consultant representation and patient access), the stature of the institution where the physician practices, and the selected physician's role within the institution.
- Record how the criteria were applied, who approved the selection, and why the resulting group of consultants is reasonable.

Documentation. Document each physician consulting arrangement through a written agreement that incorporates the requirements of the AKS safe harbor for personal services and management contracts. The agreement should reflect the approved business purpose, and its terms should align with the services actually performed. Include safeguards such as:

- Prohibiting special product pricing for the consulting physician or any facility where the physician practices.
- Restricting the consulting physician from influencing other providers' purchasing decisions regarding the company's products through recusal from formulary, P&T, or purchasing decisions involving the company's products where the physician has a role.
- Requiring the consulting physician to represent or attest in writing that clinical decisions will be based solely on independent professional judgment and patients' clinical needs.

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- Requiring the consulting physician to represent or attest in writing that the arrangement does not violate the conflict-of-interest policies of the institution where the physician practices, or consider requiring disclosure to (and approval by, where the institution's policy requires it) the physician's institution.
- Requiring periodic written confirmation that the physician consultant's representations as stated in the agreement remain accurate, and retaining records of such confirmations.

Takeaways for In-House Counsel

Risk mitigation strategies can help consulting arrangements between physicians and life sciences companies withstand governmental scrutiny. Ultimately, however, lasting compliance depends on strong institutional infrastructure. Life sciences companies should maintain a consistent, enterprise-wide compliance program for physician consulting engagements and monitor for continued compliance with the implemented risk mitigation strategies. The enterprise value—including the potential financial value—of thoughtful, well-crafted compliance policies and programs with high levels of adherence cannot be overstated. In an enforcement environment increasingly driven by data analytics and whistleblower disclosures, these actions are not simply best practices but also defensive strategies against regulatory scrutiny.

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[1] 42 U.S.C. § 1320a-7b.

[2] 42 U.S.C. § 1395nn; 42 C.F.R. § 411.350.

[3] 42 U.S.C. § 1320a-7h.

[4] U.S. Attorney's Office, District of Massachusetts, Press Release, *Veloxis Pharmaceuticals Agrees to Pay $46 Million to Resolve Criminal and Civil Liability for Kickback Scheme, Press Release, U.S. Attorney's Office, District of Massachusetts* (Aug. 10, 2026), https://www.justice.gov/usao-ma/pr/veloxis-pharmaceuticals-agrees-pay-46-million-resolve-criminal-and-civil-liability.

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