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OIG Rejects Physician Royalty Structure in Orthopedic Device Consulting Arrangement

Fraud & Abuse

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On May 18, HHS-OIG posted Advisory Opinion 26-10 (Unfavorable), issued on May 13, addressing an orthopedic device manufacturer's proposal to pay physician consultants a "royalty" equal to a percentage of net sales across an entire product line in exchange for product-line-level consulting services, including teaching, training, and proctoring. The arrangement featured compliance-oriented guardrails: an evaluation panel to assess consultant performance, minimum-hours requirements, an FMV hourly fallback rate for consultants who did not qualify for royalties, and exclusions for certain sales attributable to the consultant's own procedures, affiliated facilities, or products already subject to separate royalty agreements. OIG was unpersuaded. According to the OIG, the arrangement failed the personal services safe harbor at 42 C.F.R. § 1001.952(d) because the royalty methodology took into account the volume or value of business generated between the parties. OIG gave particular weight to the requestor's inability to certify that none of the consulting services would contribute to revenue generation, the fact that a consultant could earn royalties without contributing to the development of any specific product in the line, and the risk that teaching and training duties would motivate consultants to steer other ordering physicians toward the manufacturer's products. OIG concluded the arrangement presented risks of skewed clinical decision-making, patient steering, unfair competition, inappropriate utilization, increased federal health care program costs, and could amount to a payment-for-referrals scheme. The opinion reinforces that FMV compensation, referral-exclusion carve-outs, and creative compliance structures do not necessarily insulate product-line royalty arrangements from AKS risk when the consultant is positioned to recommend or arrange for downstream purchasing.