HLB's Fraud & Abuse Blog

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OIG Rejects Physician Royalty Structure in Orthopedic Device Consulting Arrangement

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.

OIG Issues Favorable Opinion on Free Precision Oncology Reports

On May 20, HHS-OIG posted Advisory Opinion 26-11 (Favorable), issued May 15, a favorable opinion addressing a precision oncology company's practice of providing consenting patients a free Supplemental Report expressing multi-cancer detection results in connection with an FDA-approved blood-based CRC screening test. The multi-cancer detection algorithm, which holds FDA Breakthrough Device designation, is run on the same blood sample collected for the CRC screening test and screens for 11 cancer types, 6 of which have no USPSTF-recommended screening modality. The algorithm is not yet FDA-approved as a standalone device and is not separately reimbursable. OIG analyzed the arrangement under both the Anti-Kickback Statute and the Beneficiary Inducements CMP, concluding that it generates prohibited remuneration under each, but that the risk of fraud and abuse was sufficiently low that OIG would not impose sanctions. No safe harbor applied, and the Preventive Care Exception was unavailable because neither test is listed in the USPSTF Guide. OIG credited three categories of low risk: (1) the arrangement is unlikely to cause overutilization, because the Supplemental Report requires no additional procedure, the

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underlying test is reimbursable only once every three years, the MCD Test is not itself reimbursable, and any follow up ; (2) it is unlikely to skew clinical decision-making, because physicians are not compensated for ordering or opting in, there is no targeted or direct-to-consumer marketing of the Supplemental Report, and the company actively monitors and removes third-party social media promotion; and (3) it is unlikely to cause steering or unfair competition, in part because the company's laboratory is the sole performer of the CRC screening test and 6 of the detected cancers lack any alternative screening option. The arrangement is time-limited, ending upon FDA approval or Medicare coverage of the MCD Test. The opinion offers a compliance framework for diagnostics companies seeking to deliver investigational, non-reimbursable test outputs to patients during the pre-approval period, but its favorable outcome is tightly tethered to the specific requester and facts presented.

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