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OIG Reaffirms Its Concern About "Carving Out" Federal Health Care Program Business

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Last month, the Office of Inspector General (OIG) for the U.S. Department of Health and Human Services reaffirmed its longstanding position that an arrangement that "carves out" Federal health care program (FHCP) business is not dispositive with respect to whether such arrangement implicates the Federal Anti-Kickback Statute (AKS). Specifically, OIG issued an unfavorable advisory opinion (AO 23-06), explaining that the Requestor's proposed purchase of the technical component (TC) of anatomic pathology services payable by commercial health plans "could give rise to a significant incentive" for physicians being paid such TC by the Requestor to refer patients, including FHCP beneficiaries, to the Requestor.

The Proposed Arrangement

Under the Proposed Arrangement, the Requestor (which operates anatomic pathology laboratories across the U.S.) would enter into agreements with other laboratories (that may or may not be owned by or employ referring physicians) to perform the TC of referred commercial tests to the Requestor. Because the other laboratories were out-of-network for the commercial health plans, the Requestor would bill globally for the TC and professional component (PC) of the tests and then remit a fair market value (FMV), per-specimen fee to the other laboratories for performing the TC of the referred test. The Requestor certified to OIG that its agreements with these other laboratories would satisfy the conditions set forth in the "personal services and management contracts and outcomes-based payment arrangements" safe harbor (42 C.F.R. § 1001.952(d)) except the requirement that the aggregate services contracted for would not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services. It is upon this unmet requirement that OIG appeared to have hung its prosecutorial discretion hat when issuing AO 23-06.

OIG's Analysis

First, OIG began its analysis of the Proposed Arrangement with the premise that arrangements that "carve out" FHCP business could be suspect under the AKS. Consistent with and as has been elaborated in its 2014 Special Fraud Alert, OIG reasoned that such arrangements may implicate and potentially violate the AKS by "disguising" remuneration for FHCP business through the payment of amounts purportedly related to non-FHCP (e.g., commercial) business.

Such was the potential of the Proposed Arrangement, per OIG: "[T]he remuneration paid from Requestor to [the other laboratories] may increase the likelihood that these entities or their affiliated Referring Physicians would order services from Requestor that are billable to [FHCPs]. We cannot conclude that there would be no nexus between the remuneration paid as part of the Proposed Arrangement and potential referrals to Requestor for services reimbursable by [FHCPs]."

Second, the Requestor certified that its agreements with the other laboratories would not squarely fit within a safe harbor. Thus, OIG was left with the task of evaluating the Proposed Arrangement under its "totality of the facts and circumstances" rubric. For such analysis, OIG relied upon the Requestor's certifications that (1) the Proposed Arrangement was likely to result in referrals of FHCP business from the other laboratories, (2) the Requestor, itself, was already equipped to perform both the TC and PC of most of the anatomic pathology services, and (3) the Requestor's performance of both components was more efficient and cost-effective than paying another laboratory to do the same, in whole or in part.

Thus, OIG concluded that it was "difficult to discern any commercially reasonable business purpose for Requestor to enter into the Proposed Arrangement—forgoing the opportunity to bill and retain payment for both components of the anatomic pathology services [(the TC and PC)], in an arrangement that is both less efficient and more costly—other than the possibility that such payment may induce referrals of patients, including FHCP beneficiaries."

Lastly, although the Requestor certified that it would remit an FMV, per-specimen fee to the other laboratories for performing the TC of the referred test, and despite OIG being statutorily prohibited, pursuant to 42 U.S.C. § 1320a-7d(b)(3)(A) of the Social Security Act, from opining on the aspects of FMV, OIG explained that such FMV fee would not protect the Proposed Arrangement from implicating and potentially violating the AKS. On this point, OIG, again, relied on its 2014 Special Fraud Alert, reasoning that the AKS is implicated when a clinical laboratory pays a physician for services and that whether an actual violation of the AKS occurs depends on the intent, irrespective of whether such payment is FMV for services rendered.

Takeaways

OIG's position in AO 23-06, despite being unfavorable, provides helpful guidance for the industry:

- Arrangements involving non-FHCP business only may still implicate and potentially violate the AKS. "Carve outs" do not provide absolute protection from AKS enforcement.
- The intent of the parties to such arrangements matters.
- FMV is not an end-all be-all for regulatory compliance.
- Commercial reasonableness is still very much important as it is not only a requirement for protection under certain safe harbors, but also can become part of OIG's story for demonstrating the requisite intent under the AKS.

Proskauer is available to assist providers and suppliers desiring to evaluate its arrangements for purposes of regulatory compliance with the AKS and other laws, rules, and regulations.

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