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OIG Issues Advisory Opinion Nixing Purchased Services Arrangement Between Certain Anatomic Pathology Laboratories

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Last week the Office of Inspector General for the U.S. Department of Health and Human Services (OIG) issued Advisory Opinion 23-06 (AO), which advised that a proposed arrangement between certain laboratories for the purchase of the technical component (TC) of anatomic pathology (AP) services (Proposed Arrangement) could generate prohibited remuneration under the federal Anti-Kickback Statute (AKS) and thus be grounds for the imposition of sanctions. As we discuss below, this AO was notable because the OIG's decision seems to be driven by its views on the (lack of) commercial reasonableness of the arrangement and its skepticism regarding arrangements that "carve out" federal health care program business.

The Proposed Arrangement is a variation on an arrangement known as "client billing," which is typical among AP laboratories and physician practices. In these arrangements, the treating physician orders an AP service, the laboratory performs one component of the AP service, the ordering physician's practice performs the other component, and the treating physician buys the component performed by the laboratory and bills the third party payor for both components of the AP service. The parties enter into these arrangements for a variety of commercially reasonable reasons, which may include the fact that the physician practice client lacks

the infrastructure, personnel, and equipment necessary to perform the TC, but it prefers to interpret its own slides (i.e., perform the professional component, or PC).

In this AO, other laboratories (the Other Labs) had approached the Requestor, an independent laboratory, about entering into written agreements that would require the Requestor to purchase the TC from the Other Labs (some of which employed and/or were owned by physicians who might refer patients to the Requestor). The Requestor, in turn, would perform the PC and bill commercial insurers as an in-network provider for both the TC and PC, and pay the Other Lab a fair market value per-specimen fee for performing the TC. The Other Labs wanted to enter into the Proposed Arrangement because they were unable to bill certain commercial insurers for AP services or because they were out of network with certain commercial insurers. This type of arrangement is known as a "purchased services" arrangement and is less common in the laboratory industry than client billing.

The OIG ultimately concluded that the Proposed Arrangement implicated the AKS and did not satisfy the safe harbor for personal services and management contracts, noting that the "Requestor was unable to certify that the aggregate services contracted for would not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services."

In explaining this conclusion, the OIG highlights several facts:

- The Proposed Arrangement would allow the Requestor to give the Other Labs the opportunity to bill and receive payment for services they would otherwise not be able to bill due to their out-of-network status.
- In most instances, the Requestor had the ability to perform the TC and PC itself and doing so was generally more efficient and cost-effective than paying a third party to perform the TC.
- Because the Other Labs did not have contracts that allowed them to bill commercial insurers for AP services, the physician owners/employees of the Other Labs would be more likely to refer AP

services to laboratories (including the Requestor) that are in-network with commercial insurers.
- Entering into the Proposed Arrangement would likely result in referrals of federal health care program business to the Requestor and, conversely, if the Requestor did not enter into the Proposed Arrangement, it likely would not receive a significant volume of referrals, including federal health care program business, from the Other Labs.

Not surprisingly, the OIG noted that the "carve out" of federal health care program business to minimize risk under the AKS did not save the Proposed Arrangement. For years, the OIG has viewed "carve out" arrangements skeptically and has characterized them as potentially "disguising remuneration for Federal health care program business through the payment of amounts purportedly related to non-Federal health care program business." While the OIG commented that the carve out of federal health care program business was "not dispositive with respect to whether the Proposed Arrangement implicates" the AKS, the OIG usually view carve outs with suspicion.

The result here is not surprising for at least two reasons. First, the Requestor presumably sought an unfavorable advisory opinion to prevent competitors from engaging in this business practice, which may have colored the OIG's views of the Proposed Arrangement. Second, the OIG often views laboratory industry arrangements critically (see, e.g., previous posts addressing OIG AO 15-04 and OIG AO 22-09). We note that, while the OIG issued an unfavorable opinion of a client billing arrangement in OIG AO 99-13, laboratories across the country continue to enter into such arrangements, with appropriate compliance safeguards in place. Going forward, laboratories should evaluate their purchased services arrangements and decide whether they present health care regulatory risks in light of the AO.

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