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In Another Unfavorable Advisory Opinion, OIG KOs Lab Deal; Requester Again Wanted a No

By Nina Youngstrom

For the second time in about six weeks, the HHS Office of Inspector General (OIG) posted an unfavorable advisory opinion, this time about a plan by one lab to buy the technical component of anatomic pathology services from other labs to help them get paid.[1] Again, the requestor obviously wanted OIG to say no way to the proposed arrangement, an attorney said, and it obliged on the grounds that the risk of violating the Anti-Kickback Statute (AKS) "is not sufficiently low." OIG explained that, among other things, paying fair market value to the labs and carving out federal health care program business "would not protect the Proposed Arrangement from implicating, and potentially violating, the Federal anti-kickback statute," according to the advisory opinion, which was posted Sept. 28.

Like last time, the requestor described what a competitor plans to do in the hope of warning it off, said attorney Larry Vernaglia, with Foley & Lardner LLP in Boston.[2] But "this is even worse than the last one" in terms of the "particulars of the transaction," he said. "The requestor is a competitor unhappy with the way the competition is doing business. They could have explained bona fide reasons why this model made sense, but they didn't."

According to the advisory opinion, the requestor runs anatomic pathology laboratories across the country and is reimbursed for technical and professional services by commercial payers. The technical component is the physical preparation of specimens and the professional component is the analysis of the specimen by a pathologist, with the outcomes reported to referring physicians.

The requestor explained that certain labs have proposed to enter into arrangements around anatomic pathology services performed for patients insured by commercial payers. The labs that approached the requestor are either owned by referring physicians or employ them or not. Both types of labs could refer business to the requestor, including lab services billable to federal health care programs.

Under the proposed arrangement, the requestor must buy the technical component of certain anatomic pathology tests from the physician and nonphysician labs for patients with commercial insurance. The requestor would perform the professional component and bill commercial payers for both components as an in-network provider and then pay the referring labs a fair-market, per-specimen fee for the technical component of the referred tests.

The requestor noted that it can do both components itself—in fact, that's more "efficient and cost-effective" and would allow the requestor to keep all the reimbursement. But the physician and nonphysician labs want to enter into the proposed arrangement because they're unable to bill some commercial payers for anatomic pathology services or aren't in-network with them.

"In addition, Requestor certified that, because Physician Laboratories and Non-Physician Laboratories currently lack contracts that would give them the ability to bill certain commercial insurers for anatomic pathology services as in-network providers, Referring Physicians would be more likely to refer anatomic pathology services

to other laboratories—including Requestor—that maintain contracts with commercial insurers to bill for those services," OIG explained.

The requestor noted that the labs wouldn't be required to refer federal health care program business to the requester and could send patients to other labs, although there are no guarantees.

So why did OIG shoot down the proposed arrangement? OIG concluded it implicates the AKS because of the requestor's potential remuneration to the physician and nonphysician labs, which could refer business paid by federal health care programs to the requestor. Although there would be a carve-out, "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 Federal health care programs," OIG said.

Where Was the Commercially Reasonable Purpose?

It also was hard to find a commercially reasonable purpose for the requester to do the deal. It looks like the proposed arrangement is designed to influence the labs' referrals of specimens to the requestor for testing, OIG said. Even if the requestor paid fair market value to the labs and they weren't required to refer federal health care program business to the requestor, the arrangement wouldn't be protected from implicating the AKS, OIG said.

"Here, the Proposed Arrangement could give rise to a significant incentive for the Physician Laboratories and Non-Physician Laboratories to refer patients, including Federal health care program beneficiaries, to Requestor. The Proposed Arrangement could result in the selection of a laboratory that offers the most remuneration to the Physician Laboratories and Non-Physician Laboratories—remuneration they otherwise would not have been able to realize—rather than the highest quality and most appropriate laboratory for patients," OIG said.

Lawyer: OIG's Hands Are Tied

Vernaglia noted that the requestor made it impossible for OIG to give the proposed arrangement a green light. For example, OIG stated that "The Proposed Arrangement would not be protected by the safe harbor for personal services and management contracts and outcomes-based payment arrangements. In particular, 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."

That's another piece of evidence the requestor wanted a negative answer. "There are reasonable, non-kickback reasons you might want to purchase those services and they didn't choose to do that," Vernaglia explained. "I don't think the industry should necessarily look at this advisory opinion and say this business model is fundamentally flawed and I don't think OIG said so either." He doesn't blame OIG for issuing the opinion. If the requester certified it would do the deal in the event of a favorable opinion, OIG's hands are tied.

Unfavorable advisory opinions are rare, but OIG posted another one Aug. 18, also requested to get bad news, Vernaglia said. OIG frowned on a proposed arrangement in which a company that provides intraoperative neuromonitoring during surgeries would help its surgeon clients set up a turnkey physician-owned entity to provide the same services. OIG said the arrangement would implicate the AKS for several reasons, including the risk the arrangement would induce referrals of federal health care program business—even if it were carved out.

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1 U.S. Department of Health and Human Services, Office of Inspector General, "Re: OIG Advisory Opinion No. 23-06 (Unfavorable)," memorandum, September 25, 2023, https://bit.ly/3EZzYa9.
2 Nina Youngstrom, "Advisory Opinion Says No to Turnkey Entity, the Answer the Requester Wanted, Lawyers

Say," *Report on Medicare Compliance* 32, no. 31 (August 28, 2023), https://bit.ly/3PCnnyj.