



ALERTS

HHS-OIG Says Anatomic Pathology Lab's Purchased Service Arrangement Could Violate Anti-Kickback Statute

October 9, 2023

Highlights

U.S. Department of Health and Human Services issued an unfavorable opinion addressing an anatomic pathology laboratory that purchases services at fair market value from other labs, and bills commercial payors for such services

Even though the proposed arrangement carved out services reimbursed by Federal healthcare programs, the agency determined the arrangement posed a risk of fraud and abuse under the Anti-Kickback Statute

The opinion reiterates the HHS-OIG's long-standing position against arrangements that "carve out" Federal healthcare program business, but still result in increased referrals of Federal healthcare program business outside of the arrangement

The Office of Inspector General of the U.S. Department of Health and Human Services (HHS-OIG) issued [Advisory Opinion No. 23-06](#) on Sept. 25, 2023, after reviewing a proposed arrangement whereby an anatomic

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pathology laboratory operator would purchase certain anatomic pathology services from other laboratories and then bill third-party commercial payors for those services.

The HHS-OIG concluded the proposed arrangement, if it had been entered into with the requisite intent, would generate illegal remuneration under the Federal Anti-Kickback Statute (AKS) and constitute grounds for sanctions under the agency's exclusion authority and the civil monetary penalty provisions of the Social Security Act.

Reimbursement for anatomic pathology laboratory services involves two components: a "technical" component, involving the physical preparation of the specimen for pathologist review, and a "professional" component, involving analysis of the slide by the pathologist.

Under the proposed arrangement, the anatomic pathology laboratory operator (Requestor) would enter into agreements with other third-party laboratories, including laboratories that are owned by and/or employ physicians (Physician Laboratories) and laboratories that are not owned by and do not employ physicians (Non-Physician Laboratories). Pursuant to these agreements:

- The third-party laboratory would complete the technical component of the anatomic pathology service for certain commercially insured patients
- The laboratory would then refer the prepared specimen(s) to the Requestor for completion of the professional component of the service
- Once complete, the Requestor would then bill third-party commercial payors as an in-network provider for both the professional component and technical component of the laboratory services
- Finally, the Requestor would pay the referring laboratory a fair market value, per-specimen fee for such laboratory's completion of the technical component of the anatomic pathology service

The Requestor further certified the following facts:

- The third-party laboratories with whom the Requestor would contract under the proposed arrangement may have the ability to complete both the technical component and professional components on their own, but are not able to bill (and/or are not in-network with) certain commercial payors for their anatomic pathology services
- In most instances, the Requestor has the ability to perform both the professional component and technical component without use of a third-party laboratory, and in a manner that is more cost effective and efficient
- As a result of the proposed arrangement, Physician Laboratories and Non-Physician Laboratories would be more likely to contract with laboratory operators, like the Requestor, that can bill and receive reimbursement from commercial insurers for anatomic pathology services

- The commercial insurers with whom the Requestor contracts as an in-network provider permit the Requestor to bill for both the professional component and technical components as proposed under this arrangement
- Physician Laboratories and Non-Physician Laboratories would not be required to refer any Federal healthcare program business as a condition of the proposed arrangement, and they could still refer patients to other third-party laboratories
- Nevertheless, the proposed arrangement would likely result in Federal healthcare program business referrals from Non-Physician Laboratories and Physician Laboratories to the Requestor

The HHS-OIG concluded that, even if the proposed compensation between the Requestor and the Physician Laboratories and Non-Physician Laboratories was assumed to be fair market value for the purchase of the technical component of the anatomic pathology services under the proposed arrangement, because 1) the Requestor could perform both the professional component and technical component on its own, and 2) it would be more efficient and cost effective for the Requestor to conduct the professional component and technical component, there was no commercially reasonable business purpose for the proposed arrangement.

Therefore, the HHS-OIG concluded that the goal of the proposed arrangement was likely to induce referrals from Physician Laboratories and Non-Physician Laboratories.

Key Takeaways

The HHS-OIG's opinion reiterates the guidance from its [2014 Special Fraud Alert on Laboratory Payments to Referring Physicians](#), specifically that "carve outs" for Federal healthcare program beneficiaries or business in otherwise questionable arrangements may still violate the AKS by "disguising remuneration for Federal healthcare program business through the payment of amounts purportedly related to non-Federal healthcare program business."

It is also important to note that the safe harbor for personal services and management contracts and outcomes-based payment arrangements was potentially applicable to this proposed arrangement. This safe harbor allows payment to an agent (the Physician Laboratories and Non-Physician Laboratories) from a principal (the Requestor).

The safe harbor requires 1) a signed lawful agreement "set out in writing" that covers services that the "agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent;" 2) an agreement term of at least one year; 3) a payment methodology for the agent's services that is "consistent with fair market value" and "not determined in a manner that takes into account the volume or value of any referrals or business" from Federal healthcare programs; and 4) and the total amount of services provided by the agent in the agreement must "not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services."

The HHS-OIG determined that the proposed arrangement would not be protected by the safe harbor because the Requestor "was unable to

certify that the aggregate services contracted for would not exceed those which are reasonably necessary to accomplish the reasonable business purpose of the services.”

The advisory opinion also explained that, absent protection by a safe harbor, the proposed arrangement must be evaluated under the AKS on a case-by-case basis by examining the totality of the facts and circumstances in order to determine whether a “nexus” exists between the proposed arrangement and potential referrals for services reimbursable by Federal healthcare programs. The HHS-OIG determined a nexus likely exists between the proposed arrangement and potential referrals for services reimbursable by Federal healthcare programs because there was no commercially reasonable business purpose for the arrangement and the Requestor would likely receive more referrals of Federal healthcare program business from Physician Laboratories and Non-Physician Laboratories involved in the arrangement with the Requestor.

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