



Navigating Compliance Following the OIG Advisory Opinion on Purchased Service Agreements

For specialty physician practices that own or operate a lab, an OIG Advisory Opinion issued late last year questions the legality of purchased service arrangements that may exist between independent pathology labs and specialty physician-owned labs. **Clinical Pathology Associates understands specialists' compliance concerns resulting from the Opinion and brings our consultative approach to specialty pathology to working through the implications of the Opinion and ensuring compliant pathology lab arrangements.**

OIG Advisory Opinion 23-06

In response to a request for an advisory opinion from a lab regarding the permissibility of a proposed purchase of the technical component of anatomic pathology services from other laboratories, the Office of Inspector General for the U.S. Department of Health and Human Services issued AO 23-06 in September 2023.* The OIG concluded that the proposed arrangement between laboratories for the purchase of the technical component of anatomic pathology could trigger the federal Anti-Kickback Statute and create grounds for the imposition of financial sanctions.

The Opinion focused on purchased service arrangements where:

1. A treating specialist, such as gastroenterologist or dermatologist, orders an anatomic pathology service for patient.
2. The lab of the specialist who ordered the service performs the technical component of the pathology service.
3. The independent lab performs the professional component.
4. The independent lab bills the patient's third-party payor for both the technical and professional components.
5. The independent lab pays the referring, specialist-owned lab a fair market value per-specimen fee for performing the technical component.

The OIG concluded the proposed arrangement, "would implicate the Federal anti-kickback statute because it would involve the payment of remuneration by Requestor to a party that is in a position to make referrals to Requestor for items and services that may be paid for, in whole or in part, by a Federal health care program."

*The information provided does not, and is not intended to, constitute legal advice. Readers should contact their attorney to obtain advice with respect to any particular legal matter.

A Partner You Can Trust

In a regulatory environment with increased scrutiny of pathology lab relationships and arrangements, having a compliant pathology partner you can trust is essential.

For more than 75 years, Clinical Pathology Associates has served our hospital, physician practice, and surgery center clients with integrity, delivering clinical excellence and accuracy for every specimen and consultation.



Contact us to learn more about our collaborative approach to partnering with physician practices for patient care excellence and compliance.