



OIG Issues Unfavorable Advisory Opinion on Service Arrangements

On September 25, 2023, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) published Advisory Opinion (AO) No. 23-06, evaluating a proposed purchase of the technical component of certain laboratories' anatomic pathology services.¹ In its opinion, the OIG concluded that the proposed arrangement may generate remuneration, which is prohibited under the federal Anti-Kickback Statute (AKS), and could result in the imposition of sanctions.²

The OIG typically releases several AOs each year regarding its opinion on certain business arrangements – either existing or proposed – on which a party (such as a healthcare organization) has requested an opinion. An AO is the OIG's position on whether a certain business arrangement is in conflict with the AKS, one of the laws the OIG is charged with enforcing.

The AKS makes it a felony for any person to “*knowingly and willfully*” solicit or receive, or to offer or pay, any “*remuneration*,” directly or indirectly, in exchange for the referral of a patient for a healthcare service paid for by a federal healthcare program.³ Criminal violations of the AKS are punishable by up to ten years in prison, criminal fines up to \$100,000, or both, and civil violations can result in administrative penalties, including exclusion from federal healthcare programs, and civil monetary penalties plus treble damages (or three times the illegal remuneration).⁴ Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited. Consequently, the law contains a number of exceptions, termed *safe harbors*,⁵ which set out regulatory criteria that, if met, shield an arrangement from liability, and are meant to protect transactions unlikely to result in fraud or abuse.⁶ However, failure to meet all of the requirements of a safe harbor does not necessarily render an arrangement illegal.⁷

The Requestor of the AO, an operator of anatomic pathology labs across the U.S., was motivated to develop the proposed arrangement after being approached by other laboratories seeking to enter into agreements for the provision of anatomic pathology services to commercially-insured patients. Under the proposed arrangement, the Requestor would purchase the technical component of anatomic pathology from the laboratory.⁸ In return, the Requestor would perform the professional component and bill commercial insurance providers for both the professional and technical components.⁹ The

Requestor would then pay the laboratory a per-specimen, fair market value fee for the technical component.¹⁰ The Requestor reasoned that it would bill both the professional and technical components because some of the laboratories either may not be able to bill certain payors for their services or may not be in-network.¹¹

The OIG concluded that the proposed arrangement would violate the AKS and based their conclusion on a number of concerns related to the arrangement. First, in most cases, the Requestor had the ability to perform both the professional and technical components itself, and doing so was much more cost-effective and efficient than utilizing (and paying) a third party to perform the technical component. Second, the proposed arrangement would have allowed other laboratories the chance to bill and receive payment for services they otherwise would not have been able to due to their out-of-network status. Third, because other laboratories did not have contracts allowing them to bill commercial insurers for anatomic pathology services, physician employees and owners of the other laboratories would more than likely refer anatomic pathology services to laboratories (such as the Requestor) that are in-network with commercial insurers. Fourth, entering into the proposed arrangement would likely result in referrals of federal healthcare program business to the Requestor, and if the Requestor did not enter into the proposed arrangement, it would not receive a significant amount of federal healthcare program referrals from the other laboratories.¹²

The OIG acknowledged that the AKS safe harbor for personal services and management contracts and outcomes-based payment arrangements may apply to the proposed arrangement, as the safe harbor allows payment to an agent (other laboratories) from a principal (the Requestor).¹³ However, the OIG concluded that the proposed arrangement did not satisfy requirements of 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,” i.e.:

“It is 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, in an arrangement that is

both less efficient and more costly—other than the possibility that such payment may induce referrals of patients.”¹⁴

In the advisory opinion, the OIG reiterated previous guidance from its “2014 Special Fraud Alert on Laboratory Payments to Referring Physicians”¹⁵ which states that “carve outs” for federal healthcare program beneficiaries or businesses 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.”¹⁶

According to legal experts, laboratories may be well-served to evaluate their service arrangements going forward and determine if they present a regulatory risk, based on the OIG’s determination, and ensure that any similar arrangements should be thoroughly documented as to its commercial reasonableness.¹⁷

- 1 “Re: OIG Advisory Opinion No. 23-06 (Unfavorable)” Office of Inspector General, Department of Health and Human Services, September 25, 2023, <https://oig.hhs.gov/documents/advisory-opinions/1131/AO-23-06.pdf> (Accessed 10/13/23).
- 2 “OIG Issues Advisory Opinion Nixing Purchased Services Arrangement Between Certain Anatomic Pathology Laboratories” By Samantha Kingsbury and Karen Lovitch, JD Supra, October 4, 2023, <https://www.jdsupra.com/legalnews/oig-issues-advisory-opinion-nixing-9785590/> (Accessed 10/13/23).
- 3 “Criminal Penalties for Acts Involving Federal Health Care Programs” 42 U.S.C. § 1320a-7b(b)(1).
- 4 “Criminal Penalties for Acts Involving Federal Health Care Programs” 42 USC § 1320a-7b(b)(1); “Civil Monetary Penalties” 42 USC § 1320a-7a(a).
- 5 “Re: OIG Advisory Opinion No. 15-10” By Gregory E. Demske, Chief counsel to the Inspector General, Letter to [Name Redacted], July 28, 2015, <http://oig.hhs.gov/fraud/docs/advisoryopinions/15/AdvOpn15-10.pdf> (Accessed 10/16/23), p. 5.
- 6 “Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute; Final Rule” federal Register, Vol. 64, No. 223 (November 19, 1999), p. 63518, 63520.
- 7 “Re: Malpractice Insurance Assistance” By Lewis Morris, Chief Counsel to the Inspector General, United States Department of Health and Human Services, Letter to [Name redacted], January 15, 2003, <http://oig.hhs.gov/fraud/docs/alertsandbulletins/MalpracticeProgram.pdf> (Accessed 10/16/23), p. 1.
- 8 “Re: OIG Advisory Opinion No. 23-06 (Unfavorable)” Office of Inspector General, Department of Health and Human Services, September 25, 2023, <https://oig.hhs.gov/documents/advisory-opinions/1131/AO-23-06.pdf> (Accessed 10/13/23); “OIG Issues Advisory Opinion Nixing Purchased Services Arrangement Between Certain Anatomic Pathology Laboratories” By Samantha Kingsbury and Karen Lovitch, JD Supra, October 4, 2023, <https://www.jdsupra.com/legalnews/oig-issues-advisory-opinion-nixing-9785590/> (Accessed 10/16/23).
- 9 *Ibid.*
- 10 *Ibid.*
- 11 *Ibid.*
- 12 *Ibid.*; “OIG Issues Advisory Opinion Nixing Purchased Services Arrangement Between Certain Anatomic Pathology Laboratories” By Samantha Kingsbury and Karen Lovitch, JD Supra, October 4, 2023, <https://www.jdsupra.com/legalnews/oig-issues-advisory-opinion-nixing-9785590/> (Accessed 10/18/23).
- 13 “HHS-OIG Says Anatomic Pathology Lab’s Purchased Service Arrangement Could Violate Anti-Kickback Statute” By Jason Schultz, Anne Compton-Brown, Mary Ford, Barnes & Thornburg LLP, October 9, 2023, <https://btlaw.com/en/insights/alerts/2023/anatomic-pathology-labs-purchased-service-arrangement-could-violate-anti-kickback-statute> (Accessed 10/18/23).
- 14 *Ibid.*
- 15 *Ibid.*
- 16 *Ibid.*
- 17 *Ibid.*

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