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Advisory Opinion Deals Another Blow to Clinical Labs

On April 18, 2022, the *Department of Health and Human Services* (HHS) *Office of Inspector General* (OIG) published *Advisory Opinion* (AO) No. 22-09 analyzing a proposed business arrangement involving a testing laboratory contracting with hospitals for specimen collection and testing. This AO is an extension on earlier opinions and guidance, and is yet another blow for laboratory arrangements.

The OIG typically releases several AOs each year regarding their opinions on certain business arrangements – either existing or proposed – on which a party (such as a healthcare organization) has requested an opinion. In short, an AO is the OIG's position on whether a certain business arrangement is in conflict with the federal Anti-Kickback Statute (AKS), the law that 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.[1] Violations of the AKS are punishable by up to five years in prison, criminal fines up to $25,000, or both.[2] Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[3] Consequently, the law has a number of exceptions, termed *safe harbors*,[4] which set out regulatory criteria that, if met, shield an arrangement from liability, and are meant to protect transactional arrangements unlikely to result in fraud or abuse.[5] However, failure to meet all of the requirements of a safe harbor does not necessarily render an arrangement illegal.[6] Notably, for the purposes of this AO, one of the common safe harbors utilized by healthcare providers is the Personal Services and Management Contracts and Outcomes-Based Payment safe harbor. Under this safe harbor, compensation is allowed to be made "by a principal to an agent as compensation for the services of the agent, as long as all of the following standards are met":

(1) The agreement "is set out in writing and signed by the parties;"
(2) The agreement identifies the all of services to be provided to the agreement during the term;
(3) The agreement term must be at least one year;
(4) The methodology for determining the compensation to be paid to the agent "is set in advance, is consistent with fair market value in arm's-length transactions, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part" by federal healthcare programs;
(5) The services to be performed "do not involve the counseling or promotion of a business arrangement;" and,
(6) "The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services."[7]

Under the proposed arrangement proposed to the OIG, the requestor of the AO, a group of clinical laboratories, would compensate hospitals on a per-patient-encounter basis for the collection, processing, and handling of those specimens sent to the labs for testing.[8] The labs would bill the payor (including Medicare, Medicaid, and commercial payors) and phlebotomists employed or contracted by the hospital would conduct the collection, processing, and handling services.[9] While the hospitals were free to choose a lab other than the requestor, if a physician's order did not specify the testing laboratory, the hospital could select the lab to which it would send the specimen.[10]

The OIG determined that such an arrangement "would generate prohibited remuneration under the [AKS], if the requisite intent were present"[11] because a fee would be paid, ultimately, for each patient encounter, which could incentivize the improper steering of patients to the labs. This is despite the labs certifying that the arrangement:

(1) Would be set out in writing and signed by the parties;
(2) Would be for a term of at least one year;
(3) Would cover all of the services to be provided, but would not exceed those reasonable and necessary to accomplish a reasonable business purpose;
(4) Fee would be consistent with Fair Market Value in an arm's-length transaction;
(5) Would prohibit double billing (i.e., the contracting hospitals could not separately bill any payors or patients for the services);

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(6) Would prohibit the hospitals from requiring referrals to the labs from paying physicians based on their referrals to the labs; and,

(7) Would require the hospitals to certify that none of their employed or contracted physicians or affiliated parties would be required to refer to the labs and consequently the labs would not receive payments from the hospitals for any referrals.[12]

Further, the OIG noted that lab services are "particularly susceptible to the risk of steering under" the AKS. Additionally, the agency was concerned that the "per-click" fee structure, even if consistent with Fair Market Value, nonetheless fluctuates (i.e., reflects) the volume or value of referrals or other business sent to the labs, and thus does not fall under the Personal Services and Management Contracts and Outcomes-Based Payment safe harbor.[13]

As noted above, this AO builds upon previous agency guidance related to laboratory arrangements. In 1994, OIG published a Special Fraud Alert regarding joint venture arrangements, such as those for the provision of clinical lab services, that may violate the AKS.[14] In this alert, the OIG stated that labs could station phlebotomists in physician offices, so long as the phlebotomists did not render any additional services to the office.[15] In 2014, the OIG published another Special Fraud Alert addressing "compensation paid by laboratories to referring physicians and physician group practices…for blood specimen collection, processing, and packaging, and for submitting patient data to a registry or database."[16] The agency noted its concern with patient steering, stating that "the choice of laboratory, as well as the decision to order laboratory tests, typically is made or strongly influenced by the physician, with little or no input from patients."[17] An AO published that same year reviewed an arrangement wherein a lab would pay an electronic health record (EHR) vendor a fee of $1 per order to transmit orders to a lab (so that the physicians did not have to do so); the OIG found that there seemed to be "no reason" for the lab to pay these fees "other than to secure referrals."[18]

As noted by some legal experts, this AO may serve to effectively chill all arrangements for specimen collection between hospitals and laboratories, unless "the laboratory is certain that the hospital could not and would not refer, or influence referrals, to the laboratory."[19] This could make specimen collection particularly difficult going forward, as laboratories rely on hospitals and other providers to collect the specimens and provide them to the laboratories, which tasks providers understandably do not want to undertake for free.[20] How these issues will bear out long term remains to be seen.

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1 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b)(1).
2 *Ibid.*
3 "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 2/11/22), p. 5.
4 *Ibid.*
5 "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.
6 "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 2/11/22), p. 1.
7 "Personal Services and management contracts and outcomes-based payment arrangements" 42 CFR § 1001.952(d).
8 "Re: OIG Advisory Opinion No. 22-09" By Robert K. DeConti, Assistant Inspector General for Legal Affairs, Letter to [Name Redacted], April 25, 2022, https://oig.hhs.gov/documents/advisory-opinions/1031/AO-22-09.pdf (Accessed 5/23/22), p. 1.
9 *Ibid.*
10 *Ibid.*
11 Notably, because the AKS is a criminal law, *mens rea*, or intent, is required in order to be found guilty. *Ibid.*
12 *Ibid*, p. 2; "Laboratory Specimen Collection Arrangements with Contract Hospitals - OIG Advisory Opinion 22-09" By Kathryn Hickner and Kevin Cripe, May 19, 2022, Brennan, Manna & Diamond, https://www.bmdllc.com/resources/blog/laboratory-specimen-collection-arrangements-with-contract-hospitals-oig-advisory-opinion-22-09/ (Accessed 5/23/22); "OIG Declines to Approve Lab's Payment of Specimen Collection Fees to Hospitals" Bass Berry Sims, May 5, 2022, https://www.bassberry.com/news/oig-declines-to-approve-labs-payment-of-specimen-collection-fees-to-hospitals/ (Accessed 5/23/22).
13 Bass Berry Sims, May 5, 2022.
14 "Publication of OIG Special Fraud Alerts" Federal Register 94-31157 (December 19, 1994), https://oig.hhs.gov/documents/special-fraud-alerts/876/121994.html (Accessed 5/23/22).
15 *Ibid*; "OIG Expresses Concern about Laboratory Specimen Collection Payments to Hospitals in AO 22-09" By Karen S. Lovitch and Sara Beth S. Kuyers, Mintz, National Law Review, May 5, 2022, https://www.natlawreview.com/article/oig-expresses-concern-about-laboratory-specimen-collection-payments-to-hospitals-ao#:~:text=Legal%20Analysis%20of%20AO%2022%2D09&text=The%20OIG%20ultimately%20concluded%20that%20the%20per%2Dpatient%2Dencounter%20fee,a%20federal%20health%20care%20program (Accessed 5/24/22).
16 "Special Fraud Alert: Laboratory Payments to Referring Physicians" Office of Inspector General, June 25, 2014, https://oig.hhs.gov/documents/special-fraud-alerts/866/OIG_SFA_Laboratory_Payments_06252014.pdf (Accessed 5/23/22).
17 *Ibid.*
18 Demske, April 1, 2014, p. 6.
19 National Law Review, May 5, 2022.
20 *Ibid.*

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