

March 3, 2026

**KEY TAKEAWAYS FROM FAVORABLE OIG ADVISORY OPINION 26-02: MSO-AFFILIATED LABORATORY ARRANGEMENTS STRUCTURED TO AVOID AKS LIABILITY**

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On February 18, 2026, the Office of Inspector General (OIG) issued [Advisory Opinion No. 26-02](#), analyzing a proposed arrangement in which a management services organization (MSO) would operate an independent clinical laboratory serving urgent care centers it manages and favorably concluded that the arrangement would not generate prohibited remuneration under the Federal Anti-Kickback Statute (AKS) (the Proposed Arrangement).

The requestor, an MSO, is affiliated with four urgent care centers which are operated through several management companies and one affiliated professional corporation. Due to state corporate practice of medicine restrictions, the requestor does not own the professional corporation but does hold ownership interests in the related management companies furnishing management and oversight services for the centers.

Under the Proposed Arrangement, the requestor would create a separate legal entity to own and operate an offsite clinical laboratory designed to meet the clinical testing needs of the affiliated urgent care centers. The laboratory would enroll with and bill payors directly, including federal health care programs, and would not bill the urgent care centers or other providers for services. The requestor certified that no individual or entity in a position to refer testing to the laboratory would hold any ownership or operational interest in it and that the laboratory would accept specimens only in accordance with applicable payor contracts and each patient's insurance coverage. Neither the requestor nor the centers would require, steer or track referrals.

Compensation design and operational safeguards were central to the OIG's analysis. Provider compensation would not vary based on the volume or value of laboratory services, no remuneration would flow between the laboratory and referral sources, and the laboratory would not share revenue or provide any other payments, benefits, or items of value connected to referrals. The Proposed Arrangement also incorporated multiple safeguards to promote

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transparency, preserve clinical independence, and prevent improper financial incentives, including written notice of the laboratory affiliation and meaningful patient choice, neutral electronic health record functionality allowing providers to direct orders without preference, offsite laboratory operations, no embedded laboratory personnel at referring sites, specimen collection by existing clinical staff, direct billing to payors, and strict adherence to payor contracts and patient coverage. Based on these factors, the OIG concluded that the Proposed Arrangement would not generate prohibited remuneration under the AKS.

Although the OIG reached a favorable determination on the certified facts, it cautioned that similar laboratory affiliation models may present substantial risk where any transfer of value to referral sources is present. The OIG reiterated its longstanding concern with arrangements in which management entities or affiliated laboratories provide revenue sharing, investment opportunities, consulting fees, free personnel, equipment, or other financial benefits that, in substance, are designed to generate or reward referrals. In the OIG's view, such structures implicate the core concerns underlying the AKS, including overutilization, inappropriate steering, medically unnecessary services, and distortion of fair competition. The favorable outcome in this opinion was directly tied to the absence of these features and to the safeguards embedded in the Proposed Arrangement.

This advisory opinion underscores the importance of maintaining clear operational and financial separation between clinical services and affiliated laboratory operations and ensuring that the economics of any arrangement do not depend on transferring value to referring providers. The OIG emphasized that common ownership alone is not determinative; rather, the analysis focuses on whether the structure involves referral-linked financial incentives and whether meaningful safeguards function effectively in practice.

As with all advisory opinions, this determination is limited to the specific facts certified and binds only the requestor. It addresses potential administrative sanctions under the AKS and does not resolve exposure under other federal or state laws, including physician self-referral prohibitions, the False Claims Act, or corporate practice of medicine restrictions, which should be evaluated separately with legal counsel.

For more information on this OIG advisory opinion or other health care legal matters, please contact Christina Principe, Esq., at [cp@spsk.com](mailto:cp@spsk.com).

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