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OIG Clarifies AKS Liability Beyond FMV and Stark

On April 23, 2026, the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) updated its *General Questions Regarding Certain Fraud and Abuse Authorities* Frequently Asked Questions (FAQ) page for the first time since July 2024.[1] The update revised one existing FAQ and added another, addressing what the OIG describes as persistent misconceptions about the federal Anti-Kickback Statute (AKS), its relationship to the physician self-referral law (Stark Law), and the role of Fair Market Value (FMV) in evaluating financial arrangements with referral sources. This Health Capital Topics article discusses the OIG's updated guidance and its implications for parties that rely on FMV opinions in structuring healthcare arrangements.

The two statutes at issue – AKS and the Stark Law – operate on fundamentally different premises. The AKS is a criminal statute that prohibits the knowing and willful offer, payment, solicitation, or receipt of any remuneration to induce or reward referrals or other business reimbursable by a federal healthcare program.[2] Arrangements that do not fit within a regulatory safe harbor are evaluated under a totality-of-the-circumstances test that turns on the parties' intent.[3] The Stark Law, by contrast, is a strict liability civil statute that prohibits a physician from referring designated health services to an entity with which the physician (or an immediate family member) has a financial relationship, unless the relationship satisfies an enumerated exception.[4] Many AKS safe harbors and Stark exceptions contain similar elements, most notably that the remuneration must be consistent with and not exceed FMV, and some cross-reference one another. The OIG's updated FAQs are aimed at clarifying how the two laws relate and at correcting positions some healthcare industry stakeholders have taken regarding the role of FMV.[5]

In revised FAQ No. 4, the OIG addressed the first of those misconceptions, answering affirmatively that a financial arrangement satisfying a Stark Law exception can still violate the AKS where the requisite knowing and willful intent is present.[6] The OIG explained that the two statutes "exist for different purposes, differ in what they prohibit," and "are subject to separate legal and regulatory frameworks and analyses."[7] The OIG illustrated the point with an example involving the provision of tickets to sporting events and other entertainment to physician referral sources. Such items may, depending on the facts, fall within the Stark nonmonetary compensation exception,[8] which for 2026 caps the protected amount at $535 per physician per calendar year.[9] However, the AKS has no analogous safe harbor, and the OIG observed that the same items "would be unlikely to receive protection under any safe harbor" to the AKS.[10] The arrangement would therefore remain subject to a case-by-case AKS assessment based on the totality of facts and circumstances, including the intent of the parties.

New FAQ No. 17 addresses the second misconception: the position of "some health care industry stakeholders" that compensation consistent with FMV cannot, by definition, give rise to unlawful remuneration under the AKS.[11] The OIG rejected that interpretation as inconsistent with the text of the AKS, the regulatory safe harbors, and "prior and enduring OIG guidance."[12] The OIG emphasized three points. First, the AKS itself does not use the term "FMV," and the statute contains no exception or safe harbor protecting remuneration based solely on FMV. Second, while certain regulatory safe harbors, including those for space rental, equipment rental, and personal services and management contracts, include an FMV element, FMV is "only one of several conditions" required for safe harbor protection.[13] Third, the OIG cited a series of prior pronouncements (including the 2003 Compliance Program Guidance for Pharmaceutical Manufacturers, the 2005 Supplemental Compliance Program Guidance for Hospitals, the 2014 Special Fraud Alert on laboratory payments to referring physicians, and Advisory Opinions 22-09 and 23-06) for the proposition that "fair market value is not a dispositive defense" under the AKS.[14]

Notwithstanding that conclusion, the OIG acknowledged that ensuring FMV remuneration "is a best practice and may reduce the risk of fraud and abuse."[15] While the FAQ does not name any judicial decisions, courts addressing AKS allegations have at times treated FMV as central to the remuneration inquiry. For example, in 2019, the Eleventh Circuit held in *Bingham v. HCA, Inc.* that a relator failed to establish AKS remuneration because he had not shown that physician tenants received anything of value in excess of FMV.[16]

For parties that rely on FMV opinions in structuring healthcare arrangements, the FAQ updates do not diminish the importance of such analyses; the OIG expressly confirmed that ensuring FMV remuneration is

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a "best practice."[17] However, the FAQs underscore that FMV opinions are one component of an AKS compliance posture rather than a standalone defense. Where an arrangement can be structured to satisfy each element of an applicable AKS safe harbor, the OIG noted that compliance must be evaluated for each "stream of remuneration" separately.[18] For arrangements that fall outside a safe harbor, the intent inquiry and the surrounding facts and circumstances govern, and FMV remuneration is one of several relevant facts rather than a complete defense.

Taken together, the April 2026 FAQ updates do not change the underlying law, but they restate two principles the OIG views as recurring sources of industry confusion. The practical effect of the OIG's reaffirmed position on judicial treatment of FMV in AKS cases, particularly in jurisdictions following *Bingham*, will likely become clearer as future enforcement actions and litigation test how the OIG's emphasis on intent operates alongside contrary precedent.

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1 "General Questions Regarding Certain Fraud and Abuse Authorities" U.S. Department of Health and Human Services Office of Inspector General, updated April 23, 2026, https://oig.hhs.gov/faqs/general-questions-regarding-certain-fraud-and-abuse-authorities/ (Accessed 5/15/26).
2 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b).
3 "Exceptions" 42 C.F.R. § 1001.952.
4 "Limitation on Certain Physician Referrals" 42 U.S.C. § 1395nn.
5 U.S. Department of Health and Human Services Office of Inspector General, updated April 23, 2026.
6 *Ibid.*
7 *Ibid.*
8 "Exceptions Relating to Other Compensation Arrangements" 42 C.F.R. § 411.357(k).
9 "CPI-U Updates" Centers for Medicare & Medicaid Services, page last modified February 19, 2026, https://www.cms.gov/medicare/regulations-guidance/physician-self-referral/cpi-u-updates (Accessed 5/15/26).
10 U.S. Department of Health and Human Services Office of Inspector General, updated April 23, 2026.
11 *Ibid.*
12 *Ibid.*
13 *Ibid.*
14 *Ibid.*
15 *Ibid.*
16 "Bingham v. HCA, Inc." 783 F. App'x 868 (11th Cir. 2019).
17 U.S. Department of Health and Human Services Office of Inspector General, updated April 23, 2026.
18 *Ibid.*

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