

Publications

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New OIG FAQ Warns Fair Market Value Alone Does Not Shield AKS Liability

Key Takeaways

- OIG's new FAQ #17 reiterates that fair market value alone does not eliminate risk under the Federal Anti-Kickback Statute and emphasizes that AKS compliance depends on the full facts and circumstances, including intent.
- The FAQ reinforces that health care organizations cannot rely solely on FMV analyses or commercial reasonableness opinions when structuring arrangements involving referral sources. OIG stated that safe harbor protection requires compliance with all applicable conditions, not just FMV requirements.

The U.S. Department of Health and Human Services Office of Inspector General (OIG) updated its General Questions Regarding Certain Fraud and Abuse Authorities FAQ page on April 23, reinforcing a point that OIG has articulated in prior rulemaking, advisory opinions, compliance guidance and enforcement actions: compliance with fair market value (FMV) principles alone does not insulate an arrangement from scrutiny under the Federal Anti-Kickback Statute (AKS). Although the position articulated by OIG is not new, the new FAQ guidance serves as an important reminder that reliance on remuneration that is FMV is not sufficient on its own to eliminate AKS risk.

OIG Reaffirms That FMV Alone Does Not Eliminate AKS Risk

The new FAQ #17 is meant to address what OIG describes as some health care industry stakeholders' position that so long as remuneration is consistent with FMV, there is no unlawful remuneration under the AKS, and consequently, there can be no liability under the AKS. And there are at least a handful of court decisions that support this position, such as the 11th Circuit's decision in *Bingham v. HCA, Inc.*, 783 F. App'x 868 (11th Cir. 2019) (unpublished), which held that the relator in that case failed to establish AKS remuneration because he did not show that physician tenants received anything of value in excess of FMV.

In contrast, OIG's FAQ emphasizes that the AKS does not contain exceptions or safe harbors that protect remuneration based solely on the FMV of the remuneration and that the legality of an arrangement continues to depend on the totality of the facts and

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circumstances, including the parties' intent.

Key Takeaways from FAQ #17

- Ensuring remuneration is consistent with FMV is a “best practice” and may reduce fraud and abuse risk.
- An arrangement nevertheless may violate the AKS even if the compensation is consistent with FMV.
- The AKS does not contain a standalone FMV exception.
- Safe harbors that contain FMV requirements require compliance with all safe harbor elements — not only the FMV component.
- AKS analysis remains dependent on the facts and circumstances of the arrangement, including intent.

Why the FAQ Matters

Many healthcare organizations appropriately focus on obtaining FMV analyses and commercial reasonableness opinions for arrangements involving physicians or referral sources. The FAQ confirms that OIG continues to view FMV as only one component of AKS compliance. The FAQ is especially important because stakeholders sometimes conflate Physician Self-Referral Law (PSL, often called Stark Law) concepts with AKS compliance principles. While FMV and commercial reasonableness are central to many PSL exceptions, the AKS is an intent-based criminal statute. Accordingly, even compensation that falls within FMV parameters may create AKS risk if one purpose of the remuneration is to induce referrals or generate Federal healthcare program business.

Practical Compliance Considerations for Health Care Organizations

The FAQ suggests that OIG will continue to evaluate the intent and structure of arrangements for factors including the purpose and rationale for the arrangement, how compensation is structured and whether the arrangement reflects legitimate operational objectives.

The FAQ also reiterates several important compliance considerations:

- **Safe harbor protection requires strict compliance with all applicable safe harbor conditions.** If an arrangement meets a safe harbor, of which FMV is an important element of many safe harbors, that arrangement is shielded from AKS liability.
- **If no safe harbor applies, OIG will evaluate all the facts and circumstances to determine intent.** In that situation, if there is clear evidence of intent, then the presence of FMV remuneration is irrelevant for determining AKS liability.
- **If no safe harbor applies and no clear evidence of intent exists, but the government can demonstrate bad intent from the facts of the arrangement,** then having FMV remuneration for that arrangement alone may not protect that arrangement from AKS liability.
- **FMV remuneration may still be a highly persuasive and important element for determining AKS liability.** Notably, the OIG stated that “ensuring that remuneration in an arrangement is consistent with fair market value is a best practice and may reduce the risk of fraud and abuse under the federal anti-kickback statute.”
 - For example: in instances where the government — after evaluating the facts and circumstances of an arrangement — cannot point to evidence of express intent, and the remuneration paid under the arrangement is FMV and under a commercially reasonable relationship in exchange for identifiable and legally permitted purpose(s), it would be challenging to identify other facts that could convincingly support an inference of bad intent.

Conclusion: FMV Support Remains Important, Not Dispositive

While the OIG's new FAQ #17 reinforces a longstanding but important principle FMV alone does not determine whether an arrangement complies with the AKS, FMV remuneration in arrangements continues to be a relevant factor when assessing AKS liability.

As such, organizations should review arrangements subject to the AKS to ensure that compensation arrangements either fit a safe harbor or are structured, implemented and documented in a manner consistent with the AKS, given all of the applicable facts and circumstances (including the presence of FMV).

If you have questions regarding the implications of FAQ #17 or would like assistance reviewing your compensation arrangements, please contact your Polsinelli attorney or a member of our Health Care team.