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HRx: Fair Warning: HHS OIG's New FAQs Caution that Fair Market Value and Stark-Compliant Arrangements Can Nonetheless Violate the Federal Anti-Kickback Statute

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Fair market value arrangements and those that satisfy an exception to the physician self-referral law (Stark Law) can nonetheless violate the federal Anti-Kickback Statute (AKS). That is the message of two recent updates the U.S. Department of Health and Human Services Office of Inspector General (OIG) made to its [Frequently Asked Questions \(FAQs\)](#) about fraud and abuse laws.

How Can a Financial Arrangement that Satisfies a Stark Law Exception Still Violate the AKS?

According to the OIG, a financial arrangement that satisfies the requirements of an applicable exception to the Stark Law could still violate the AKS if a party to the arrangement knowingly and willfully (1) solicits or receives any remuneration in return for federal healthcare program referrals or (2) offers or pays any remuneration to induce federal healthcare program referrals.

In FAQ 4, the OIG notes that the Stark Law's exceptions define terms differently than the AKS'

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safe harbors. And, importantly, intent is a critical element of the AKS, but the Stark Law is a strict liability statute that the parties can violate regardless of their intent.

As an example, the OIG explains that a hospital, lab, or other Medicare provider or supplier could offer physicians who refer federal healthcare program business tickets to a sporting or other entertainment event in a way that complies with the nonmonetary compensation exception to the Stark Law at 42 C.F.R. § 411.357(k). Yet, according to the OIG, such an arrangement would be unlikely to satisfy any safe harbor to the AKS and, depending upon the facts and circumstances, could violate the AKS if, for instance, the provision of the tickets is intended to induce or reward federal healthcare program referrals.

How Can Fair Market Value Arrangements Violate the AKS?

Although it is a best practice to ensure that remuneration between parties to a healthcare transaction is consistent with fair market value, the OIG explains in its answer to FAQ 17 that no AKS safe harbor protects remuneration based solely on whether it is fair market value. According to the OIG, protection under an AKS safe harbor requires each stream of remuneration to satisfy each condition of the applicable safe harbor. Fair market value remuneration is just one of several conditions that many safe harbors require. In sum, the OIG reiterates its consistent guidance that fair market value is not a dispositive defense under the AKS.

Takeaways

The upshot of the OIG's updated FAQs is that healthcare industry stakeholders engaging in financial arrangements with referral sources should be mindful that satisfying the conditions of a Stark Law exception alone does not ensure AKS compliance. Similarly, ensuring that remuneration is fair market value is not in and of itself enough for an arrangement to receive protection under the AKS'

safe harbors. Healthcare industry stakeholders should consult healthcare regulatory counsel before engaging in financial arrangements with referral sources. Akerman's Healthcare Practice Group is available to answer any questions you may have about such arrangements.

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