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OIG Reiterates the Need for Full Safe Harbor Compliance and Reminds the Health Care Industry that Arrangements Relying on Fair Market Value Alone May Be Violative

Physician groups, hospital administrators, and health care investors all navigate the complexities of health care fraud and abuse statutes, including compliance with the Anti-Kickback Statute[1] (AKS). The AKS is a criminal statute that makes it a crime to knowingly and willfully offer, pay, solicit, or receive any form of remuneration (cash, gifts, rent, fees, etc.) to induce patient referrals for services paid by federal healthcare programs like Medicare or Medicaid. Individuals who violate the AKS (as recipients or payers of such remuneration) risk jail time and significant financial penalties. While application of the AKS is broad, a specific intent to violate the statute is required. In addition, the AKS offers numerous safe harbor provisions that provide protection from prosecution for arrangements that meet the rigorous Safe Harbor requirements. Safe Harbor compliance is completely voluntary and the failure to satisfy a Safe Harbor does not mean that an arrangement is illegal.

However, because all of the requirements of a Safe Harbor must be met in order for an arrangement to be protected, many arrangements fall outside the Safe Harbors. These unprotected arrangements often rely on ensuring their arrangements are compensated at fair market value (FMV) to show that the requisite intent is not present. Just pay the other side at market rate for the goods or services, the thinking goes, and you cannot also have the requisite intent to receive remuneration for referrals because the remuneration is FMV for the goods or services provided – there is no overage to allocate as remuneration for referrals.

Not so. On April 23, the U.S. Department of Health and Human Services Office of Inspector General (OIG) added a new FAQ to its "General Questions Regarding Certain Fraud and Abuse Authorities" FAQ page reiterating past guidance and further clarifying that an arrangement may violate the AKS even if it is FMV. The OIG occasionally updates their FAQ pages with relevant and applicable sub-regulatory guidance on how to apply the more nuanced laws and regulations based on current market trends and the OIG's evolving enforcement focus. Specifically, in the recent update the OIG states:

> ". . . some health care industry stakeholders have taken the position that, so long as the remuneration offered, paid, solicited, or received in an arrangement is consistent with fair market value, there is no unlawful remuneration under the Federal antikickback statute, and consequently, there can be no liability under the Federal anti-kickback statute. . . OIG's guidance has been consistent and unwavering that fair market value is not a dispositive defense under the Federal anti-kickback statute."

The recent guidance emphasizes that there is more to complying with the AKS than ensuring the compensation arrangements are FMV, and this position is supported by the fact that the AKS does not use the term "fair market value" even once. Rather, FMV is a foundational condition that each stream of remuneration must meet to be compliant with the applicable Safe Harbor requirements. The OIG is reiterating its view that while all payments related to referrals paid for by federal healthcare funds should always be FMV, the OIG looks at many more factors when considering if an arrangement is violative and the market should recalibrate its reliance on FMV accordingly.

Anticipated Impact

We expect to see the Commercial Reasonableness and Bona Fide Business Purpose tests play a much larger role in the OIG's facts and circumstances analysis of arrangements that fall outside Safe Harbor protections. Commercial Reasonableness asks why a payment is happening. Does the arrangement make sense independent of any referrals? An arrangement is Commercially Reasonable if it is sensible for well-informed parties to enter into it, even if they are not in a position to generate business for one another. The Bona Fide Business Purpose test, looks at

whether the services are necessary, real, and actually provided. These tests require a much more detailed analysis than the FMV analysis which only looks at how much is being paid and whether the amount is consistent with the market.

Accordingly, an arrangement that is compensated at FMV but is not Commercially Reasonable or fulfilling a Bona Fide Business Purpose will likely be found to violate the AKS. For example, leasing more space than is commercially reasonable at FMV; paying multiple medical directors FMV compensation when only one medical director needed; and paying a referring physician at FMV for 50 hours of consulting when five hours is needed to meet the business need, are all arrangements with FMV compensation that would fail one or both of the commercially reasonable and bona fide business purpose tests and likely violate the AKS.

In addition to more applications of the Commercial Reasonableness and Bona Fide Business Purpose tests, we expect to see greater reliance on the "One Purpose Rule." The One Purpose Rule states that "[i]f one purpose of the payment is to induce referrals, the entire arrangement is illegal." In application this means that where an arrangement is at FMV, is Commercially Reasonable and for a Bona Fide Business purpose, if one underlying purpose of the arrangement is to induce referrals, the entire arrangement, regardless of multiple legitimate business purposes, is illegal. Accordingly, if the OIG can show that any part of the motivation for the arrangement was to secure referrals (e.g. an email stating that the arrangement may improve referrals), FMV, Commercially Reasonable, and a Bona Fide Business will not prevent a conviction.

Finally, we expect greater scrutiny of percentage-based fees that fluctuate based on the volume or value of referrals. As the OIG focuses on intent, percentage-based fee models may more frequently be viewed as circumstantial evidence of an intent to influence referrals and thereby increase the share in referral profits.

Conclusion

Legal counsel can assist in navigating physician referral laws to reduce the risk of arrangements being out of compliance. Providers, administrators, and investors with concerns about their financial arrangements may benefit from a review of how their compensation structure fits into a safe harbor.

This article was written by June S. Santiago and Kaleb Rasmussen, attorneys on the Spencer Fane health care team. For more information, visit spencerfane.com.

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1 (42 U.S.C. § 1320a-7b)

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