

IN-FOCUS REVIEW OF OIG'S UNFAVORABLE ADVISORY OPINION REGARDING THIRD-PARTY PORTAL ACCESS FEES

Recently, the Department of Health and Human Services Office of Inspector General ("OIG") issued [Advisory Opinion 25-08](#) (the "Advisory Opinion"), which addressed whether a proposed arrangement involving a medical device manufacturer's payment of access fees to a third-party vendor's billing portal ("Proposed Arrangement") would violate the federal Anti-Kickback Statute ("AKS"). Based on the facts provided, the OIG declined to issue a favorable opinion and concluded that the Proposed Arrangement would pose a high risk of fraud and abuse if undertaken with the requisite intent.

BACKGROUND

In brief, the Requestor, a medical device manufacturer supplying bill-only surgical devices, was asked by certain hospital customers to use a third-party vendor's electronic billing portal. The vendor required the Requestor to pay hefty annual licensing fees for its representatives to access the portal, despite the portal offering little to no operational benefit. For additional background on the Proposed Arrangement, please refer to Hall Render's August 13 [alert](#) summarizing the Advisory Opinion.

OIG ANALYSIS

The AKS makes it a criminal offense to knowingly and willfully offer or receive remuneration to induce or reward referrals of items or services reimbursable by federal health care programs. If just one purpose of an arrangement is to induce or reward referrals, the arrangement violates the AKS. The AKS considers not only if remuneration will influence the selection of a particular provider, practitioner or supplier, but also whether it influences the selection of items or services reimbursable by federal health care programs. Because the Requestor would pay the vendor fees to use the Bill-Only Portal through which the vendor facilitates customers' purchases of the Requestor's bill-only items—some of which may be reimbursable by Federal health care programs—the OIG determined that the Proposed Arrangement would implicate the AKS.

Under the Proposed Arrangement, the Requestor would pay vendor fees to access the Bill-Only Portal, which facilitates customers' purchases of the Requestor's bill-only items, some of which are reimbursable by federal health care programs. Unlike arrangements where access has no independent value, the Bill-Only Portal provides customers with an independent economic benefit, namely, relief from costs they would otherwise incur, creating potential remuneration to referral sources. Moreover, the OIG determined that the arrangement is not commercially reasonable or necessary for a legitimate business purpose, failing to grant protection under the personal services and management contracts or outcomes-based payment safe harbor. The OIG also raised anti-competitive concerns, cautioning that the Proposed Arrangement could advantage manufacturers willing or able to absorb the costs, thereby distorting customer decision-making.

By contrast, prior OIG guidance, such as [Advisory Opinion 12-20](#), recognized that free access to an interface used solely to transmit orders and receive results has no independent value to the recipient and therefore does not implicate the AKS. In that context, the OIG emphasized that the lack of independent value to the recipient is dispositive: the recipient cannot derive benefit outside of the donor's services, distinguishing that scenario from the Proposed Arrangement.

PRACTICAL TAKEAWAYS

This Advisory Opinion provides important guidance for hospitals and health systems considering the use of third-party billing or ordering platforms that require vendor access fees. While such platforms may offer administrative efficiency, mandating their use and requiring manufacturers or suppliers to pay for access may raise concerns under the AKS, particularly where the fees provide a benefit to the customer and may not be commercially reasonable.

The Advisory Opinion also offers insight for manufacturers and suppliers considering similar arrangements. Payments made solely to maintain business relationships with customers, without a legitimate commercial rationale or fair market value support, are likely to draw scrutiny under the AKS.

Stakeholders considering similar models should consult with legal counsel in order to structure such arrangements in a compliant manner,

ensure all parties involved clearly document the business rationale for the arrangement and assess the regulatory implications before proceeding.

For help in understanding the impact of this Advisory Opinion or guidance assessing AKS risk under other similar arrangements, contact:

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