PUBLICATION

OIG Advisory Opinion 25-08: Unfavorable DME – Vendor Payment Arrangement

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On July 1, 2025, the U.S. Department of Health and Human Services Office of Inspector General (OIG) issued Advisory Opinion 25-08, an unfavorable opinion discussing a proposed arrangement in which a medical device company would pay fees to a third-party billing software vendor in order to receive access to the billing software vendor's customers.

In this Advisory Opinion, the Requestor was a medical device company that supplies, among other items, certain "bill-only" medical devices to hospitals, health systems, and ambulatory surgery centers. Bill-only medical devices are medical devices that are not part of a health care facility's regular inventory, but instead are purchased by the facility close to the date of a patient's procedure.

The Requestor certified that its typical process for selling bill-only items to health care facilities involves:

(i) a representative of the Requestor delivering a selection of bill-only items to a facility;

(ii) a surgeon at the facility selecting bill-only items for use in the facility's procedures;

(iii) a member of the facility's staff generating a purchase order for such bill-only items;

(iv) the Requestor generating an invoice based on the purchase order; and

(v) the facility paying the Requestor for the invoiced items.

The Proposed Arrangement

The Requestor certified that some of its health care facility customers had begun requesting or requiring the Requestor to use the services of a particular third-party billing software vendor to facilitate the purchase and sale of bill-only items (the Proposed Arrangement).

Under the Proposed Arrangement, the Requestor would pay the third-party billing software vendor approximately $395.00 per year per device representative to access the billing software vendor's portal. The Requestor estimated that its total annual cost for all of its representatives to obtain access to the billing vendor's software would be approximately $1.2 million.

In exchange for this compensation, the billing vendor would permit the Requestor to use the software portal to facilitate the purchase of bill-only items by health care facility customers that also use the software. In particular, the software portal would capture purchasing data for bill-only services selected by health facility customers, confirm the accuracy of such data, generate a bill and deliver it to the appropriate facility personnel for approval, and then issue a purchase order to the Requestor's applicable representative.

Importantly, however, the Requestor certified that the billing vendor's software portal was "redundant to Requestor's existing operations," that it had not identified any "appreciable benefits or services" that it would receive by using the billing vendor's software portal, and that, as a result, it could not certify that the fees it would pay in the Proposed Arrangement were commercially reasonable. In this regard, the Requestor also certified that the only reason that it would pay the fees and enter into the Proposed Arrangement would be to access the billing vendor's software portal in order to sell medical devices to health care facilities that also use the portal and request or require, as a condition of doing business, that the Requestor use the portal.

The Requestor certified that the billing software vendor's website included advertisements to health care facilities stating that use of the software portal could result in benefits, including potential cost savings. The Requestor also certified that some of the bill-only items purchased by the health care facilities would be reimbursable by Federal health care programs.

Analysis

The OIG explained that the Proposed Arrangement would implicate the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (the AKS), because:

(i) the Requestor would pay fees to the billing vendor for access to its software portal, which the billing vendor would then use to arrange for health care facilities to purchase bill-only items – some of which may be reimbursable by Federal health care programs; and

(ii) the Requestor's use of the portal and corresponding payments to the vendor might result in cost savings for the health care facilities, which means that, ultimately, the Requestor's payments to the vendor could constitute remuneration to the facilities to induce the purchase of bill-only items – some of which may be reimbursable by a Federal health care program.

Based on the Requestor's inability to certify that the Proposed Arrangement was commercially reasonable, the OIG explained that the Proposed Arrangement could not satisfy the personal services and management contracts and outcomes-based payment arrangements safe harbor to the AKS, 42 C.F.R. § 1001.952(d). Due to this, the OIG examined the Proposed Arrangement based on the totality of the facts and circumstances and issued an unfavorable opinion because:

(i) the Proposed Arrangement would involve the Requestor paying substantial fees to access a billing software portal that was redundant to its existing billing and collection infrastructure for the sole purpose of maintaining and potentially expanding business from certain health care facilities that use the billing software vendor's services; and

(ii) the Proposed Arrangement presents anti-competitive risks and patient steering risks because the payments that the Requestor would make to the billing software vendor could inappropriately steer health care facilities to the Requestor over the Requestor's competitors that do not pay for access to such billing portal services.

Important Takeaways

There are two important takeaways from this advisory opinion. First, the OIG's analysis is guided by the specific factual certifications submitted by a requestor, including those that are "unfavorable," as part of the advisory opinion process. As described above, the OIG relied on several unfavorable certifications that the Requestor made regarding the Proposed Arrangement (e.g., the billing software portal was redundant to its existing billing infrastructure; the only reason that the Requestor would pay for the software would be to access certain health care facility customers; the Requestor could not identify any appreciable benefits or services that it would receive by using the software portal). Specifically, because the Requestor could not certify that the aggregate services contracted for would not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the service, the OIG did not undertake further analysis of the personal services, management contracts, and outcomes-based payment arrangements safe harbor. The Requestor had already conceded the issue and certified accordingly, with knowledge of the penalties for false statements under 18 U.S.C. 1001. As a result, the safe harbor did not apply to the Proposed Arrangement because all required elements could not be met.

Second, the Proposed Arrangement raises pay-to-play concerns. According to the Requestor's certifications, the Requestor would pay the billing software vendor approximately $1.2 million just for the opportunity to sell its medical devices to certain health care facilities that prefer to contract through the vendor. In return, those facilities may opt to purchase the Requestor's devices over those of competitors that are unable or unwilling to pay such fees – raising risks of inappropriate steering and anti-competitive effects, both of which are harms the AKS was designed to prevent.

This opinion serves as a reminder that such arrangements warrant careful scrutiny. Notably, the OIG made clear that parties have a variety of permissible options for structuring business relationships to allocate responsibilities (e.g., billing support) in ways that do not raise significant fraud and abuse concerns.

For more information or assistance on this topic, please contact Amanda W. Copsey, Bernard Miller, or any member of Baker Donelson's Health Law Team.