Navigating Successfully (and Compliantly) Vendor Contracts

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The scope and complexity of arrangements being presented by device vendors to hospitals is expanding, making compliance with federal health care program rules increasingly more challenging. While at first blush the rules related to discounts and warranties seem fairly straightforward, many manufacturers offer complex, multi-prong arrangements that can be difficult to evaluate against the rules. For example, some vendors offer discounts and/or warranties on a bundle of products or on a bundle of products and services. In some cases, a device is offered with free equipment. To help hospital representatives evaluate the legitimacy of these types of arrangements, this article will provide an overview of the key compliance principals to consider when presented with a proposal.

The Anti-Kickback Statute and Safe Harbors for Vendor Relationships. While commonly accepted business arrangements, discounts and warranties on products and services reimbursable by federal health care programs may implicate and potentially violate the Anti-Kickback Statute (the "AKS") and other regulations governing health care providers. The news on federal enforcement from the 1990s and 2000s was filled with reports of mega settlements with pharmaceutical companies who purportedly violated the AKS related to a variety of financial relationships with health care providers, including discounts. Now, a similar storyline is evolving related to device manufacturers. And, more recently, the Office the Inspector General has focused on how hospitals account for refunds or cost adjustments provided under warranties. All this points to the need for hospitals to be able to understand the regulatory framework surrounding these vendor relationships.

As a starting place, the AKS broadly prohibits either giving or receiving remuneration that is intended to induce or reward the referral of patients or the generation of business involving any item or service payable by federal health care programs. The term "remuneration" is defined broadly by the AKS to include *anything* of value – including discounts or payments made pursuant to a warranty. While such an arrangement may have a legitimate purpose, if it is determined *one* purpose of the arrangement is to induce or reward referrals, the government may contend that there is a violation of the AKS.

Because the scope of the AKS is broad and potentially implicates arrangements that provide legitimate benefits to health care providers, the Office of the Inspector General for the Department of Health and Human Services (the "OIG") has created a number of "safe harbors" that protect certain financial arrangements from violating the AKS. Two of those safe harbors applicable to hospital relationships with vendors are the discount safe harbor and the warranty safe harbor. Having at least a basic understanding of both safe harbors can help hospitals spot problematic relationships proposed by vendors.

Discounts. The safe harbor for discounts[1] is relatively straight forward on its face, requiring only that the discount (1) be appropriately accounted for between the parties and (2) disclosed to federal health care programs. However, the definition of "discount" is fairly nuanced. A discount includes a commercially reasonable reduction in the amount a buyer is charged for an item or service and while it includes rebates and credits, it does not include so-called "pre-bate" payments. Fully complying with the reporting provisions of the discount safe harbor can also be fairly complex. For example, a buyer that is an entity that files cost reports must earn the discount based on purchases of the same good or service bought within a single year and the discount must be reported in the year it was earned or the following year. Additionally, parties to a discount arrangement must be mindful that, while the safe harbor allows bundled discounts that cover multiple products or a combination of goods and services, such bundled discounts are only allowed in limited circumstances, such as where the goods or services are reimbursable under the same federal health care program using the same methodology of reimbursement so that they can be accurately reported.

Warranties. Since a warranty typically involves the refund of a payment or the replacement of equipment, it also implicates the AKS. Similar to the discount safe harbor, the safe harbor that protects warranties simply requires that (1) the buyer accurately reports any item of reduced price (including a free item received through a warranty) on the applicable cost report, and (2) the seller of the item accurately reports any item of reduced price provided to a buyer on an invoice or statement submitted to the buyer and informs the buyer of its reporting obligation.[2] The warranty safe harbor was also recently expanded by the OIG in 2020 to protect warranties that cover a bundle of items and services (coving services for the first time). However, similar to the discount safe harbor, the updated provisions make clear that, in order for a bundled warranty to be covered by the safe harbor, the items and services must be reimbursed by the same federal health care program and in the same FHCP payment.

Reporting Device Credits on Medicare Claims: Hospitals need to be separately mindful that federal regulations also require that Medicare reduce payments to hospitals when certain types of implanted devices are replaced without cost, the hospital receives a full credit for the device, or the hospital receives a credit of 50% or more of the device cost. An audit report published by the Office of the Inspector in November 2020[3] found that nearly 50% of the claims it reviewed related to cardiac devices failed to appropriately report credits given by manufacturers.

Conclusion. While discounts and warranties can provide needed cost savings to hospitals, those programs present a variety of compliance considerations. The safest course is to utilize vendor arrangements that fall squarely within one of the safe harbors and to have strong systems around reporting any discount or refund. However, proposed arrangements that do not fit into a safe harbor do not necessarily violate the AKS. In such cases where the requirements of a safe harbor cannot be met, the arrangement requires careful consideration to ensure that it contains sufficient safe guards so to avoid violating the AKS. It is truly a case of "buyer beware!"

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[1] 42 C.F.R. § 1001.952(h)

[2] 42 C.F.R. § 1001.952(g)

[3] "Hospitals Did Not Comply with Medicare Requirements for Reporting Cardiac Device Credits," A-01-18-00502 (November 2020).

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