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What's In a Name? New OIG Advisory Opinion Highlights When a Price Reduction is Not Remuneration

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On June 29, 2021, the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) released Advisory Opinion No. 21-06 (Opinion 21-06), a favorable opinion regarding a medical device manufacturer offering reduced prices to hospitals if the hospitals assume the duties usually performed by third parties that are compensated by the manufacturer (Proposed Arrangement). In this opinion, the OIG said it would not impose sanctions on the Proposed Arrangement because it neither violated the Gainsharing CMP nor generated prohibited remuneration under the Anti-Kickback Statute.

The Proposed Arrangement

Opinion 21-06 involves a manufacturer of spinal implants and devices, which sells its products through its traditional distribution system, including sales representatives and / or distributors ("Intermediaries"). Typically, the Intermediaries also perform a number of services, before, during, and after surgeries wherein the manufacturer's products are used, and the manufacturer compensates the Intermediaries for their services. This compensation is factored into prices that the manufacturer charges hospitals for the products.

Under the Proposed Arrangement, hospitals would have the option to purchase the products directly from the manufacturer with no Intermediary assistance or involvement. Hospitals that participate in the Proposed Arrangement ("Participating Hospitals") would assume the Intermediaries' duties (e.g., training all appropriate surgical staff on how to use the products in the product kits and receiving / restocking replacement parts so that they are ready to be packed into kits for future surgeries). In exchange for a Participating Hospital assuming the Intermediaries' duties, the manufacturer would offer its products to the Participating Hospital at a reduced price approximately equal to the compensation otherwise paid to the Intermediaries. After an initial three -year term, any renewal agreement would be based on manufacturer's own assessment and discretion.

Legal Implications of the Proposed Arrangement

Sections 1128A(b)(1)–(2) of the Social Security Act (the "Gainsharing CMP") prohibits a hospital or critical access hospital from knowingly making payments, directly or indirectly, to a physician to induce the physician to reduce or limit medically necessary services to Medicare or Medicaid beneficiaries who are under the physician's direct care. Hospitals and physicians who violate the Gainsharing CMP

provisions are liable for civil money penalties of up to $5,000 for each patient for which the prohibited payment was made. Here, the OIG determined that the Gainsharing CMP did not apply because the Proposed Arrangement does not involve any payments from a hospital or critical access hospital to physicians.

The Anti-Kickback Statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an individual to a person for the furnishing of, or arranging for the furnishing of, any item or service reimbursable under a Federal health care program. A "safe harbor" to the Anti-Kickback Statute exists for discounts or rebates (Discount Safe Harbor), but only if the discounts or rebates meet the conditions enumerated at 42 C.F.R. § 1001.952(h).

OIG's Approach to Analyzing Arrangements

In reviewing substance over form, the OIG found that the Proposed Arrangement did not involve a "discount" that should be analyzed under the Discount Safe Harbor despite language suggesting "reduced" or "lower" prices. The agency concluded that, rather than providing something of value, the manufacturer's price reduction under the Proposed Arrangement merely reflected the reduction in services the Participating Hospital would be purchasing. Accordingly, the lower price offered to Participating Hospitals for the products under the Proposed Arrangement would not constitute remuneration within the meaning of the Anti-Kickback Statute. It appears that, conversely, if an arrangement involved a discount yet omitted language that described it as such, the OIG would still analyze the arrangement through the lens of the Discount Safe Harbor.

Even if the Proposed Arrangement were analyzed under the Discount Safe Harbor and failed to satisfy its requirements, it would not necessarily be fatal to the arrangement. The OIG evaluates arrangements that do not fit in a safe harbor on a case-by-case basis, based on the totality of the facts and circumstances. For example, in Advisory Opinion 02-10, a device manufacturer's proposal to offer discounts to customers based on their purchases of dialysis equipment and supplies did not meet the requirements of the Discount Safe Harbor. Nonetheless, one of the manufacturer's proposed discounts contained sufficient safeguards for the OIG to determine that it did not present a substantial risk of program abuse and the OIG stated that it would not impose administrative sanctions against the manufacturer in relation to this arrangement. Ultimately, it is the substance of an arrangement that faces the OIG's scrutiny.

Conclusion

With continued scrutiny surrounding discounts and rebates offered to customers, manufacturers must continue to ensure that their arrangements comply with the Anti-Kickback Statute and other administrative regulations. Importantly, manufacturers must remember that, notwithstanding the language used to describe the terms of arrangements, the OIG will continue to assess whether an arrangement constitutes a substantial risk of fraud and abuse based upon the substance of the arrangement itself.

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