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OIG Issues Guidance on Flexible Bundled Discount Arrangements

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On December 15, 2025, the U.S. Department of Health and Human Services Office of the Inspector General (OIG) issued Advisory Opinion No. 25-11, a favorable advisory opinion that discusses a vaccine discount arrangement. The Advisory Opinion involved a biopharmaceutical company that manufactured three different vaccines (Vaccine A, Vaccine B, and Vaccine C). The company offered four different discount arrangements to customers that purchased these vaccines:

1. **Upfront discounts**, which were discounts applied to Vaccine A that were: (i) calculated based on a certain percentage of Vaccine A's list price or contract price, and (ii) known and applied at the time of purchase.

2. **Upfront discounts with a purchase requirement**, which were upfront discounts applied to Vaccine A that were: (i) contingent on the purchaser satisfying certain purchase requirements (i.e., market share requirements or volume purchase requirements) during a prior measurement period, and (ii) known and applied at the time of purchase.

3. **Bundled upfront discounts with a purchase requirement**, which were upfront discounts applied to Vaccine A, Vaccine B, and/or Vaccine C that were: (i) contingent on the purchaser satisfying certain purchase requirements during a prior measurement period for multiple vaccines and (ii) were known and applied at the time of purchase. This discount arrangement included both bundles of products that were reimbursed by the same federal health care program using the same methodology (i.e., bundles with both Vaccine A and Vaccine C, both of which were reimbursed under Medicare Part B) and bundles of products that were reimbursed by the same federal health care program using different methodologies (i.e., bundles with that included Vaccine A and/or Vaccine C, which were reimbursed under Medicare Part B, and Vaccine B, which was reimbursed under Medicare Part D).

4. **Bundled rebates**, which were rebates offered that were: (i) calculated based on a percentage of the purchase price or list price of Vaccine A, Vaccine B, and/or Vaccine C; (ii) contingent on the purchaser satisfying certain purchase requirements during a measurement period; (iii) disclosed to the customer at the time of purchase; and (iv) provided for units of vaccines purchased during the measurement period. Some of the requestor's agreements with customers related to this rebate arrangement provided the requestor with the ability to modify the terms of the rebate during the contract term (e.g., increasing the rebate offered, lowering the market share requirements, lowering the purchase requirements, and/or adjusting the contract term, in some cases to promote competition).

Each Vaccine was reimbursed by a federal health care program. Vaccine A and Vaccine C were reimbursable via Medicare Part B, and Vaccine B was reimbursable via Medicare Part D. The OIG explained that the arrangement would implicate the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (AKS) because (i) the company would offer discounts and rebates to customers in exchange for customers' agreement to purchase vaccines and (ii) some of the vaccines would be reimbursed by federal health care programs. Due to

this, the OIG analyzed the arrangement to evaluate whether it would satisfy the elements of the discount safe harbor, 42 C.F.R. § 1001.952(h).

Based on the requestor's certifications, the OIG concluded that the requestor satisfied the obligations of a seller under the safe harbor because:

- The requestor provided customers with the necessary information (i.e., discount terms) and notification of their reporting obligations (via written agreements and invoices), to ensure that customers could properly disclose and appropriately reflect the discounts and rebates on applicable cost reports and claims submitted to federal health care programs.

- For upfront discounts that were contingent on a purchase requirement, both before the discount period begins and at the end of each performance period, the requestor sent customers an explanation of the discount program tier for which the customer had qualified and the total discount to which they were entitled.

- For rebates, at the end of each performance period, the requestor certified that it sent each participating customer a report that includes the customer's total qualifying purchases for a rebate and a calculation of the total rebate to which the customer was entitled.

- The requestor certified that it complies with all price reporting requirements for pharmaceutical manufacturers under all federal and state health care programs.

- The requestor certified that it would refrain from doing anything that would impede the customers' reporting obligations.

The OIG, however, also explained that only two of the four discount arrangements would satisfy the definition of a "discount" set forth in the safe harbor regulations. In relevant part, the safe harbor defines a discount as "a reduction in the amount a buyer ... is charged for an item or service based on an arms-length transaction." 42 C.F.R. § 1001.952(h)(5). Similarly, a rebate is defined as "any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale." 42 C.F.R. § 1001.952(h)(4).

There are several exceptions to the definition of a discount. A discount does not include "services provided in accordance with a personal or management services contract." 42 C.F.R. § 1001.952(h)(vi). In addition, a discount does not include supplying one good or service without charge or at a reduced charge in order to induce the purchase of a different good or service, unless the goods and services are: (i) reimbursed by the same federal health care program using the same methodology and (ii) the reduced charge is fully disclosed to the federal health care program and accurately reflected, as appropriate, to the reimbursement methodology. *See* 42 C.F.R. § 1001.952(h)(5)(ii).

Here, the OIG concluded that the upfront discount and the upfront discount with purchase requirement arrangements would satisfy the definition of "discount" under the safe harbor. Both arrangements involved reductions in price applied at the time of sale and, with respect to the upfront discounts with purchase requirements, the OIG relied on the requestor's certification that customers were not required to provide services (e.g., marketing of products or switching patients from one product to another) in order to obtain discounts.

On the other hand, the OIG determined that the bundled upfront discount with a purchase requirement and the bundled rebate arrangements did not satisfy the definition of a discount under the safe harbor. Nonetheless,

the OIG explained that each arrangement involved sufficiently low risk such that a favorable advisory opinion was appropriate.

The bundled upfront discount with purchase requirement arrangements did not satisfy the definition of a discount because a customer was required to reach certain market share or volume requirements for multiple vaccine types in order to obtain an upfront discount on any of the vaccines. Despite this, however, the OIG concluded that these arrangements involved low risk because: (i) the discounts were structured in a manner that were easily attributable to each separately billable item, (ii) each Medicare reimbursement system (i.e., Medicare Part B and Medicare Part D) would benefit equally from the discount, (iii) the discounts were applied to each vaccine in the bundle, and (iv) each vaccine had at least one competing vaccine with a list price similar to the requestor's vaccine, which lowered the risk that the bundling arrangement could obfuscate the pricing of any vaccine in the requestor's bundle.

The bundled rebate arrangements did not satisfy the definition of a discount because, as discussed above, some of the customer agreements authorized the requestor to revise the terms of the rebate agreement during the contract's term. Nonetheless, the OIG determined that these arrangements involved low risk because, in addition to the rationale discussed for bundled upfront discount with a purchase requirement arrangements above, (i) the customers were aware at the time of the initial purchase that adjustments might be made to the terms of the rebate, and (ii) allowing requestor to change the terms of a discount to promote competition could promote patient choice by making it more likely that a customer maintains an inventory of both the requestor's vaccines and a competitor's vaccines.

Practical Takeaways

There are several practical takeaways from the Advisory Opinion. First, this Advisory Opinion suggests that individuals and entities that offer or sell bundled items or services reimbursable by a federal health care program at a discount can mitigate their risk by incorporating various structural safeguards, even when they do not satisfy the AKS discount safe harbor. For example, such individuals and entities should consider structuring discounts in a manner that is easily attributable to each separately billable item in the bundle and applying a discount to each item within the bundle. In addition, to the extent applicable, individuals and entities should also be prepared to demonstrate that bundled discount arrangements would involve a low risk of harm to federal health care programs by maintaining evidence that other items or services have a list price that is similar to items or services included in the bundle.

Also, this Advisory Opinion suggests that, according to the OIG, under the right circumstances, a variable rebate arrangement could potentially present a low risk of fraud and abuse if there is a reasonable argument that the variable rebate arrangement structure would promote competition and increase patient choice. This is a key insight because, though the Advisory Opinion's scope is technically limited to this particular bundled vaccine arrangement, the OIG's analysis in this Advisory Opinion (which focuses on the specific language of the discount safe harbor) could be considered more broadly for other types of arrangements that involve discounts for items and services reimbursable by a federal health care program. There is no reason to suggest that this analysis would be limited to just discounts for vaccines.

Finally, it is important to note that though this Advisory Opinion focuses on the conduct of a seller of discounted items and services reimbursable by a federal health care program, the analysis is still relevant to the other party to the arrangement (i.e., the buyer). This analysis is useful to a buyer of discounted items and services because, if the seller has structured the discount arrangement to satisfy the seller's obligations under the discount safe harbor, then the buyer would be subject to less risk under the AKS for accepting such discounts. Please note that the buyer should still satisfy its applicable obligations under the discount safe harbor in order to mitigate its risk.

Pharmaceutical manufacturers, medical device manufacturers, distributors, group purchasing organizations, pharmacies, and other related health care industry stakeholders should review their bundled discount arrangements and variable discount arrangements to ensure compliance with applicable health care fraud and abuse laws.

For more information or additional guidance, please contact Robert Anthony Wells, Bernard Miller, or any member of Baker Donelson's Health Law Group.