

OIG APPROVES A TIERED REBATE PURCHASING PROGRAM

EXECUTIVE SUMMARY

On July 1, 2013, the Department of Health and Human Services Office of Inspector General ("OIG") posted Advisory Opinion 13-07, addressing a proposed arrangement whereby a medical products manufacturer would offer tiered rebates to customers on a combination of products, some of which are reimbursable under the Federal health care programs ("Proposed Arrangement"). The OIG concluded that the Proposed Arrangement would not generate prohibited remuneration under the Anti-Kickback Statute ("AKS"), and thus, it would not impose administrative sanctions.

PROPOSED ARRANGEMENT

Under the Proposed Arrangement, a manufacturer of pharmaceutical products and surgical equipment would establish a rebate program offering a tiered, percentage rebate based on a customer's total annual purchases of surgical supplies and devices. The manufacturer certified that the rebate amount would not vary based on the number of Federally reimbursable products purchased by the customer, and it would inform all customers receiving rebates of their obligation to report any discounts received from sales of Federally reimbursable items through three different notifications. The manufacturer also certified that it would refrain from any action that would impede any customer from meeting its obligations under the AKS discount safe harbor ("Safe Harbor").

ANALYSIS

First, the OIG established that definitions of "discount" and "rebate" under the Safe Harbor would be applicable to the Proposed Arrangement. The OIG has previously expressed concern about bundling arrangements (i.e., an arrangement where a customer might receive a free surgical pack if the customer purchased five surgical devices), in part, because such arrangements can lead to shifting costs and may obscure the true cost of an item, leading to the inability to report costs accurately, as required by the Safe Harbor. However, under the Proposed Arrangement, the OIG concluded that it was distinguishable from a bundled discount because the discount would apply based on the total annual purchase amount and would not be, in any way, contingent upon the purchase of other products.

The OIG also concluded that the Proposed Arrangement satisfied the Safe Harbor's definition of a "rebate" because the discount would be fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, though not realized until after the sale. That is to say, the manufacturer would provide customers with a contract explaining the terms of the program, the types of products involved and the volume required to reach each rebate tier. The OIG also distinguished this volume purchasing arrangement from unlawful rewards programs offering valuable goods, such as trips, travel vouchers and computers in exchange for a customer's business.

Finally, the OIG concluded that the manufacturer would satisfy its notification obligations under the Safe Harbor because once the actual rebate amount was calculated and known, the manufacturer would send each participating customer a year-end report that would include a summary of the customer's total qualifying purchases, an explanation of the rebate program tier for which the customer qualified and a calculation of the total rebate to which the customer is entitled.

PRACTICAL TAKEAWAYS

The OIG did not express particular concern for the proposed arrangement because it involved a tiered rebate that would apply to the aggregate amount of purchased supplies, regardless of whether the supplies are reimbursable by a Federal health care program. Providers considering entering into an agreement containing similar rebate programs should pay particular attention to the concerns the OIG has expressed regarding the structure of the rebate, its applicability to goods and services reimbursed under separate payment methodologies and the manufacturer's compliance with the Safe Harbor's notification requirements. In particular, providers should:

- Analyze any proposed rebate programs offered by vendors to ensure compliance under the Safe Harbor, including a requirement that the rebate is fixed and disclosed in writing at the time of the sale;
- In the event of a bundled discount, ensure that such discount is limited to items that are reimbursable under the same payment methodology; and

- Prior to entering into purchase agreements, ensure that manufacturers are required to fully and accurately report discounts on invoices, by report or in the contract at the time of purchase. The manufacturer must be required to inform the customer of its obligations to report the discount and to refrain from any action that would impede the customer from meeting its reporting obligations.

If you have any questions regarding existing or proposed arrangements that may have AKS implications, please contact:

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