
1. Background
A recent Advisory Opinion issued by the Office of the Inspector General (OIG) provides helpful guidance on the application of the discount safe harbor for pharmaceutical and device companies. In Advisory Opinion 13-07, published on July 1, 2013, the OIG provided additional clarity on the definition of a “bundle” under the discount safe harbor, and clarified a seller’s obligations as well, while determining that the Requestor’s proposed Global Rebate Program would not generate prohibited remuneration under the anti-kickback statute.

According to the Advisory Opinion, the Requestor manufactures and sells items reimbursed either directly or indirectly by federal health care programs, as well as items that are not reimbursed by federal health care programs. Id. The proposed discount program would provide a tiered rebate based on the total dollar volume of purchases made by a customer of the Requestor’s surgical products. Id. The program would include all of the devices and supplies in the Requestor’s surgical line, excluding only capital equipment. Id. The rebate would be calculated as a percentage of the customer’s total purchases of all surgical products, and would increase as a percentage of total volume as certain volume thresholds were reached. Id. Thus, as the dollar volume of a customer’s purchases increased, the customer could qualify for a higher-tiered rebate percentage, which would apply to all of the customer’s purchases during the year. Id. In other words, the proposed arrangement involved a volume discount.

Notably, the Requestor certified that the rebate would be determined based on total purchases of all products, and would not vary in any way “regardless of whether all of those surgical products were reimbursable by Federal health care programs, half were reimbursable by Federal health care programs, or none were.” Id. The Requestor also certified that it would provide information on 3 different occasions to participants in the rebate program about their potential obligations to report the discount. First, as a precondition for participating in the program, the customers would sign a contract which would identify the items included in the program, the methodology that would be used to determine the discount, an explanation of how to apportion the final rebate to each individual item purchased, and a notification to the participant of its potential obligation to report the rebate to Federal health care programs. Id. at 3. Second, the invoices received by the participants would state that items included may be subject to a later rebate, and trigger reporting obligations. Id. Finally, “at the end of each calendar year, the Requestor
would give 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.” *Id.* (This third disclosure comports with the discount safe harbor requirement to provide a reconciliation statement for rebate transactions.) Finally, the Requestor would refrain from doing anything that would impede a buyer from meeting its obligations under the discount safe harbor.

2. Legal Analysis and Conclusion
The OIG concluded that the proposed arrangement fits within the regulatory safe harbor for discounts found at 1001.952(h). The OIG conducted a two-prong analysis to reach this conclusion. First, it stated that the proposed rebate program would meet the regulatory definition of discount; second, it found that the Requestor’s proposed steps satisfy a seller’s obligations under the discount safe harbor.

With respect to the definition of a discount, the OIG first recited its traditional disfavor of “discounts on bundled items” that tend to shift the costs among reimbursement systems, but make it difficult to “determine the net price of any item for reporting purposes.” *Id.* However, citing earlier guidance in the preamble to the 1999 Final Rule, the OIG acknowledged that “discounts offered on one good or service to induce the purchase of a different good or service where the net value can be properly reported do not pose a risk of program abuse and may benefit the programs through lower costs or charges achieved through volume purchasing and other economies of scale.” *Id.* (citing 64 Fed. Reg. 63518, 63530 (Nov. 19, 1999)). In analyzing the proposed program, the OIG noted that, “[a]ll purchases of Surgical Products – whether or not reimbursable by Federal health care programs – would be aggregated to determine the percentage amount of the rebate.” *Id.* Contrasting the proposed arrangement to a prohibited arrangement where free surgical packs would be given for the purchase of surgical devices reimbursed under a different payment methodology, the OIG stated that while the proposed arrangement applied to products reimbursed under different payment methodologies, it “does not involve a ‘bundle,’” because “[n]ot only would a discount on one product not be contingent on purchase of another product, the discount also would be readily attributable to each item.” *Id.* at 6. Further, the OIG determined that the proposed program fit squarely within the definition of a “rebate” for purposes of safe harbor protection. *Id.*

The OIG also found that the proposed method of notifying the program participants of the program’s existence and parameters, as well as the participants’ obligations under the safe harbor, were sufficient to meet a seller’s obligations under the discount safe harbor. The OIG explained that the safe harbor requires a seller to provide a buyer with sufficient information to meet the buyer’s reporting requirements. By providing the buyer with: (1) a program description that describes the terms of the rebate program and notifies a customer of its obligations to report a portion of the rebate applicable to Federally reimbursed products; (2) invoices that would state that items included on the invoice may be subject to a later rebate and thus may trigger reporting obligations; and (3) a year-end report that includes a summary of the customer’s total qualifying purchases, an explanation of the rebate tier for which the customer qualified, a calculation of the total rebate for which the customer qualified, and a calculation of the total rebate to which the customer is entitled, the Requestor would meet the seller’s obligation under the safe harbor.

3. Implications for Future Discount Programs
Advisory Opinion 13-07 is an important development in the OIG’s guidance on discount programs. In recent years, the government has made clear, especially in the pharmaceutical and device industries, that it views performance-based discounts (that is, discounts conditioned on market share or volume requirements) critically and will pursue enforcement action when it believes that the letter or the spirit of the discount safe harbor is not met. *See U.S. ex rel. Lisitza v. Johnson & Johnson*, 765 F.Supp.2d 112 (2011). Advisory opinions also reflect a concern in connection with bundling products for discounting purposes, rarely finding that such arrangements fit within the safe-harbor, and only
under the most specific of circumstances indicating that it would not seek sanctions against a Requestor proposing such a program.

Advisory Opinion 13-07, however, focuses on two key elements that appear to form the basis of the OIG’s approval: (1) transparency in the amount of the discount and (2) assurance that federal health programs participate fully in the discount program. Specifically, the OIG noted that traditional bundled discounts reflect inherent difficulties in accurately allocating and reporting discounts, thereby limiting the protection of such bundled discounts to items reimbursed under the same methodology. The Global Rebate program proposed by the Requestor, however, does not present such difficulties, as it is not a “bundle” where a discount on one product is contingent on the purchase of another product. (Note, however, that it would be a bundled discount under Medicaid rebate bundling rules.) In addition, the OIG’s reference to the language in the preamble to its 1999 Final Rule reaffirms its commitment to approve of discounts that can be properly reported so that the federal programs may benefit through lower costs. In its analysis, the OIG found that Requestor’s program met this criterion as well.

In summary, there are several helpful lessons to draw from Advisory Opinion 13-07. First, a discount or rebate program may take into consideration the purchases of a variety of different items, even those reimbursed under different payment methodologies, so long as the items are identified in advance, the discount is based on the total volume of all items purchased, and the discount can be apportioned to each individual item purchased, such that accurate reporting of the discount on each product is possible. Second, the OIG will take a more favorable view of discount or rebate programs which tend to provide for an easy allocation of discount value between bundled items as a result of a high level of visibility as to how the discount is calculated and apportioned. Third, a volume-based discount earned and apportioned equally to multiple products will not be considered a bundle for discount safe harbor purposes, regardless of what products are included or how they are reimbursed. Finally, and most significantly, the OIG, for the first time, has clearly spelled out in an advisory opinion the requirements of a seller under the discount safe harbor. The OIG has stated that a seller who offers a performance-based discount nevertheless complies with the discount safe harbor if it informs the buyer of its duty to disclose the net effective discounted price and otherwise complies with the requirements of the discount safe harbor.

If you have any questions about any of the topics discussed in this advisory, please contact your Arnold & Porter attorney or any of the following attorneys:

Jeffrey L. Handwerker  
+1 202.942.6103  
Jeffrey.Handwerker@aporter.com

Alan E. Reider  
+1 202.942.6496  
Alan.Reider@aporter.com

Allison W. Shuren  
+1 202.942.6525  
Allison.Shuren@aporter.com

Rosemary Maxwell  
+1 202.942.6040  
Rosemary.Maxwell@aporter.com

Anthony J. Burba  
+1 202.942.5013  
Anthony.Burba@aporter.com

© 2013 Arnold & Porter LLP. This Advisory is intended to be a general summary of the law and does not constitute legal advice. You should consult with counsel to determine applicable legal requirements in a specific fact situation.