# PUBLICATION

## OIG Advisory Opinion 17-03 Approves Pharmaceutical Manufacturer's Product Spoilage/Replacement Program

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**A pharmaceutical manufacturer proposing to offer customers – at no additional cost – replacements for certain spoiled products that can no longer be administered to patients (Replacement Program) has been granted approval by the U.S. Department of Health & Human Services, Office of the Inspector General (OIG). The OIG reviewed the Replacement Program in Advisory Opinion 17-03, issued August 25, 2017, and determined that the Replacement Program does not fit within the safe harbor for warranties (42 C.F.R. § 1001.952(g)), but nonetheless presents an "acceptably low" risk of fraud and abuse. While finding the Replacement Program could potentially generate prohibited remuneration, the OIG concluded it would not constitute grounds for the imposition of sanctions under the civil monetary penalty prohibition against inducements to beneficiaries (CMP) or the Anti-Kickback Statute (AKS).**

The manufacturer sells biologics and other products, some of which are sensitive to environmental conditions (temperature changes, sunlight, movement) and some of which require reconstitution in a controlled environment prior to administering the product to patients. The product labeling includes specific handling and storage instructions, as well as directions regarding safe reconstitution practices. Failure to meet these instructions can result in product spoilage.

The manufacturer's Replacement Program provides that, with certain limitations and a written set of conditions provided to the customer, the manufacturer will replace, free of charge, spoiled or otherwise unusable products (such as reconstituted products that can no longer be administered to a patient). A product is eligible for replacement only if it has not been administered to the patient after it was rendered unusable after purchase because either:

- the product was mishandled, dropped or broken;
- the product was inappropriately stored, refrigerated or was frozen;
- there was an admixture error; or
- the product was reconstituted but not administered due to an unforeseen patient condition or because the patient missed an appointment.

Further, the customer must not have billed an insurer or patient for the spoiled product. The customer cannot receive credit for the product nor replacements for free samples, and the replacements apply only to single-product claims, not multi-unit losses. The customer must submit documentation detailing how the spoilage occurred and return the product (if returnable), or attest to how it became unusable and include photo evidence when appropriate.

Analyzing the Replacement Program under the safe harbor for warranties (42 C.F.R. § 1001.952(g)), the OIG found that it failed to meet the first and second definitions of a *written warranty*. The safe harbor defines *warranty*, in relevant part, as "an agreement made in accordance with the provisions of 15 U.S.C. § 2301(6)." *Written warranty* is defined in 15 U.S.C. § 2301(6) as:

(A) any written affirmation of fact or written promise made in connection with the sale of a consumer product by a supplier to a buyer which relates to the nature of the material or workmanship and affirms or promises that

such material or workmanship is defect free or will meet a specified level of performance over a specified period of time, or

(B) any undertaking in writing in connection with the sale by a supplier of a consumer product to refund, repair, replace, or take such other remedial action with respect to such product in the event that such product fails to meet the specifications set forth in the undertaking, which written affirmation, promise, or undertaking becomes part of the basis of the bargain between a supplier and a buyer for purposes other than resale of such product.

Here, because the spoiled products that the manufacturer replaces are not defective or substandard, but rather spoiled due to post-manufacturer conduct or customer error, the remedial actions do not address deficiencies in the bargained-for-requirements of the product that customers purchase, nor otherwise address any failure to meet product specifications as with a typical warranty scenario. In other words, if the customer had implemented the specifications that were part of the undertaking, the product would not have spoiled.

In the absence of a safe harbor, the OIG next analyzed the Replacement Program using its case-by-case approach, finding a low risk of fraud and abuse under the specific facts and circumstances here, for four primary reasons.

First, the OIG explained that the replacement of spoiled products could increase patient safety and quality of care, and decrease the risk that a customer might administer a spoiled product to avoid financial loss. Second, there is low risk of overutilization because the customer is not permitted to bill a patient or a payor, nor actually administer the spoiled product, when applying for a replacement product.

Third, the OIG recognized that while the program has some impact on competition because customers may choose the manufacturer over other manufacturers without such replacement programs, the risk is "acceptably low" because the Replacement Program covers only individual claims, not large losses, and replaces the spoiled product with the same product that a customer already intended to use.

Finally, the OIG likened the Replacement Program to an insurance policy, noting that just as "an insured driver or homeowner is unlikely to act recklessly in reliance on a vehicle or homeowner's insurance policy," a customer is unlikely to change its behavior and reduce the spend associated with maintaining its storage environment due to the Replacement Program. Relatedly, the added burden of filing detailed claims for replacements through the manufacturer's administrative processes further reduces the risk that customers will abuse the process.

### Baker Donelson's Comments

Advisory Opinion 17-03 highlights the limitations of the warranty safe harbor. The definition of *warranty* used by the OIG significantly limits the potential reach of the safe harbor. Nonetheless, the OIG showed a willingness to move beyond the limits of the safe harbor to protect a particular arrangement.

Another aspect of Advisory Opinion 17-03 that is worth noting is the OIG's use of the phrase *acceptably low* in describing the fraud and abuse risk. This is not a phrase we have seen used by the OIG in the past. Time will tell whether this new phrase suggests a new – potentially more lenient – standard for evaluating the fraud and abuse risk of arrangements.