OIG APPROVES PHARMACEUTICAL MANUFACTURER'S REPLACEMENT PROGRAM FOR SPOILED BIOLOGICS

On August 25, 2017, the Department of Health and Human Services Office of Inspector General ("OIG") posted Advisory Opinion 17-03 addressing a proposed arrangement whereby a pharmaceutical manufacturer of biologics and other products ("Supplier") would replace products that require specialized handling[1] that could not be administered to patients for certain reasons, at no additional charge to the purchaser ("Proposed Arrangement"). OIG concluded that the Proposed Arrangement could potentially constitute prohibited remuneration under the federal Anti-Kickback Statute ("AKS") but that OIG would not impose sanctions against the Supplier due to the low risk of the Proposed Arrangement. Hospitals, clinics and physicians that purchase biologics and other products for administration to patients should consider evaluating their purchasing arrangements with pharmaceutical manufacturers to ensure that product replacement programs comply with the guidance described below.

PROPOSED ARRANGEMENT

Under the Proposed Arrangement, the Supplier, under certain circumstances, would offer only a replacement product, without charge, for products purchased by physicians, clinics and hospitals if the products spoiled or otherwise became unusable after purchase. The circumstances that would qualify a purchaser for a replacement product include: (1) the product was mishandled, dropped or broken; (2) the product was inappropriately stored or refrigerated or was frozen; (3) there was an admixture error; or (4) the product was reconstituted but not administered due to an unforeseen patient condition or because the patient missed the appointment. The Supplier noted that replacement would not be available if a purchaser either administered the spoiled product or billed an insurer or patient for the spoiled product. Additionally, the Supplier would limit the replacement to single product claims unless the spoilage occurred due to a refrigeration failure (e.g., door left open or temperature issue), in which case replacement would be limited to no more than five products.

In order to receive a replacement product, the purchaser would be required to return the spoiled product (if possible) and submit documentation that described how the spoilage occurred. In the event the purchaser could not return the spoiled product, the purchaser would be required to provide a photograph of the spoiled product and attest to how it became unusable. Finally, purchasers would be required to sign an acknowledgement that neither the patient nor a third party payor was billed for the spoiled product.

ANALYSIS

The AKS makes it a criminal offense to knowingly and willfully offer or receive remuneration in an effort to induce or reward referrals of items or services reimbursable by federal health care programs. Under the AKS warranty safe harbor, remedial actions by suppliers to address products that fail to meet bargained-for requirements qualify for AKS safe harbor protection. In its analysis, OIG stated that the warranty safe harbor could potentially apply to the Proposed Arrangement. However, OIG further explained that the spoiled products as described in the Proposed Arrangement would fail to meet the definition of a "written warranty" under the warranty safe harbor because the spoiled products were neither defective nor substandard nor did the products "fail to meet the specifications set forth in the undertaking." Stated differently, because the products' labeling specified the required storage and handling requirements and, if applicable, limits on the amount of time that may elapse between when a product is reconstituted and when it is administered to a patient, had a purchaser correctly implemented the specifications set forth on the labeling, the product would not have spoiled. Thus, OIG concluded that the products subject to the Proposed Arrangement would not fail to meet the specifications, as characterized in the definition of "written warranty." As a result, OIG determined that the warranty safe harbor does not apply to the Proposed Arrangement.

Notably, OIG did state that while the products in the Proposed Arrangement did not fall within the definition of "written warranty," a product could "fail to meet the specifications in the undertaking" for many reasons, including failure to meet quality standards of failing to achieve patient clinical results specified as targets at the time of sale. In such circumstances, the warranty safe harbor could apply if other conditions of the safe harbor were met. This effectively broadens the types of warranties that may be protected by the Warranty Safe Harbor. Stated differently, this guidance seemingly allows manufacturers greater latitude when designing their warranty programs to link pricing to performance beyond product defects. However, it is important to note that while OIG expanded its guidance on the Warranty Safe Harbor, manufacturers may be faced with other challenges, such as FDA considerations related to labeling, which would require separate analysis.

Despite its failure to meet the warranty safe harbor, OIG found the Proposed Arrangement did not increase the risk to federal health care programs based on the totality of the facts and circumstances. OIG provided the following four reasons that supported its conclusion that the Proposed Arrangement was of sufficiently low risk under the AKS.

1. The replacement of spoiled products would be restricted to unplanned circumstances and could increase patient safety and quality of care (e.g., the availability of a replacement product would decrease the risk that a health care provider might administer a potentially spoiled product to avoid financial loss).
2. The risk is low that the Proposed Arrangement would lead to increased costs or overutilization because the Proposed Arrangement would only apply to products that were already selected and intended for use by a purchaser, but ultimately were not administered to a patient or billed to a third party payor.
3. The Proposed Arrangement would cover only individual claims of spoiled product, not large losses, and the purchaser would be limited to replacement of the same product. (OIG did acknowledge this type of model could potentially have an impact on competition but believed the risk was acceptably low that a purchaser would select the Supplier's products over a competitor's products on the basis of the Supplier's offer to replace a product that was inadvertently spoiled.)
4. It is unlikely that the Proposed Arrangement would cause a purchaser to change its behavior (e.g., a purchaser would be unlikely to reduce costs currently expended to maintain an environment that should prevent spoilage). Additionally, in order to receive a replacement product, the purchaser must complete an administrative process providing sufficient evidence of the spoilage, which further reduces the risk that the Proposed Arrangement would unduly influence the purchase of Products, or be abused, by purchasers.

PRACTICAL TAKEAWAYS

OIG's position on this Proposed Arrangement underscores the health care industry's continued search for value in all aspects of the delivery of care. Health care providers should consider the following when evaluating their supplier arrangements with pharmaceutical manufacturers.

- Assess organization policies and procedures that address product dispensing in an effort to limit spoilage;
- Evaluate available remedies for defective or spoiled products and document options in a written arrangement; and
- Ensure that all in-office dispensing and administration programs comply with applicable state scope of practice and pharmacy laws.

Further, manufacturers should consider evaluating the structure of their warranties to determine if tying pricing to performance is feasible given OIG's guidance. This Advisory Opinion is encouraging for both health care providers and manufacturers as they continue to navigate value-based opportunities and search for innovative partnerships.

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

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[1] Products requiring specialized handling include biologics and other products sensitive to temperature changes, direct sunlight or movement that may require reconstitution in a controlled environment.