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To the Spoiler Go the Spoils: OIG Approves Limited Product Replacement Program

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A perennial question for manufacturers of drugs and biologicals that require specialized handling, storage, or reconstitution is how to handle circumstances in which the product is spoiled, breaks, or otherwise becomes unusable after purchase by physicians, clinics, and hospitals. Many manufacturers have designed product replacement programs intended to strike a balance between assuring patient safety and the risk that replacing product in those circumstances can be seen as removing a business risk or subsidizing a provider's business expense in a way that implicates the federal healthcare program anti-kickback statute. In a recently issued Advisory Opinion, the U.S. Department of Health and Human Services Office of Inspector General (OIG) approved a manufacturer-proposed program to replace at no additional charge to the provider certain "spoiled products" that cannot be administered to a patient.[1] OIG concluded that although the program cannot fit under the regulatory warranty safe harbor,[2] the proposed program poses a low risk of fraud and abuse under the anti-kickback statute, and it would not be subject to administrative sanctions by OIG.

The Proposed Replacement Program for Spoiled Products

The Advisory Opinion addresses a proposed program by the manufacturer of biological and other similar products, some of which are sensitive to temperature, sunlight, and movement. The products' labeling contains detailed instructions for storage and handling. In addition, some products require providers to reconstitute the products in a controlled environment and administer them to patients within a narrow time window after reconstitution. The manufacturer certified to OIG that failure to meet these storage and handling requirements would result in product spoilage.

The proposed program would replace, at no charge, products that become spoiled or otherwise unusable after purchase by customers, subject to the following limitations and conditions:[3]

1. The product was not administered to a patient after it was spoiled or rendered unusable.

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1 OIG, Ad. Op. 17-03 (Aug. 25, 2017), available at https://oig.hhs.gov/compliance/advisory-opinions/index.asp#advisory.

2 42 C.F.R. § 1001.952(g).

3 The Advisory Opinion notes that, for purposes of the opinion, the scope of "customers" was limited to a single location, such as a hospital, clinic, or physician office. A customer did not include an individual physician within a group practice.

2. The product must have been spoiled or rendered unusable after purchase due to one of the following events:
    - the product was mishandled, dropped, or broken;
    - the product was inappropriately stored, refrigerated, or frozen;
    - the product was reconstituted but not administered due to an unforeseen patient condition or the patient missed the appointment; or
    - an admixture error occurred.
3. The manufacturer has a written policy describing the terms and conditions the customer must satisfy to qualify for product replacement, and the manufacturer notifies customers of the policy prior to purchase.
4. The manufacturer only replaces purchased spoiled products; customers could not receive a credit for purchased products or replacement for samples.
5. A customer that bills a payor or patient for the spoiled product cannot be eligible for product replacement.
6. The proposed program would apply only to single product claims by a customer, regardless of the number of units actually spoiled, with an exception allowing up to five claims due to refrigeration errors (regardless of the how many products were spoiled).

Customers could obtain replacement products under the proposed program only after returning the spoiled product, submitting required documentation explaining how the spoilage occurred, and certifying that no patient or payor was billed for the spoiled product.

OIG's Analysis

OIG first explores whether the warranty safe harbor applies, and concludes that the proposed program fails to meet both definitions of "written warranty" under the safe harbor. First, the "spoiled products" the program would replace are not defective or substandard upon purchase. Second, the spoiled products would not fail "to meet the specifications set forth in the undertaking" because they would be spoiled or become unusable after delivery to the customer due to a customer error or some other unforeseen inability to administer the product because of patient circumstances.[4] In other words, the safe harbor protects warranties addressing defective products, not products that become unusable without any fault on the part of the manufacturer.

OIG next turns to review the totality of the facts and circumstances of the proposed program to determine the risk of fraud and abuse under the anti-kickback statute. Based on the specific structure of the proposed program, OIG concludes that it will not impose sanctions under the anti-kickback statute.

Patient Safety

A key consideration for OIG appears to be that the proposed program could increase patient safety and quality of care. The availability of replacement product decreases the likelihood that a customer would administer a spoiled product to avoid financial loss.

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4 Interestingly, although the proposed program did not qualify for safe harbor protection, OIG suggests in a footnote that the warranty safe harbor might be available to protect a value-based purchasing arrangement that replaced products based on outcomes measures such as "failure to meet quality standards or failing to achieve patient clinical results specified as targets at the time of sale . . . if other conditions of the safe harbor were met." Advisory Op. at 5, note 3.

Low Risk of Overutilization

OIG also concludes that the proposed program has a low risk of overutilization and increased costs because the program would apply only to products customers already selected (and purchased) for administration. Moreover, OIG emphasizes that the risks of increased costs or overutilization are low because a customer that administers the spoiled product to a patient, or bills the patient or any third-party payor (including federal health care programs), would not be eligible for replacement product.

Low Impact on Competition

OIG acknowledges that the proposed program could affect competition by giving customers an incentive to select the manufacturer's products over competitor products based on the availability of replacement product. Nevertheless, OIG concludes that the potential impact would be low because the program would cover only individual claims and not large losses of product. Moreover, OIG notes that the proposed program only replaces the product the customer had intended to use prior to it being spoiled.

Akin to Insurance Policy

Finally, OIG concludes that the manufacturer's program "would bear some similarity to an insurance policy, the cost of which [the manufacturer] certified would be bundled into the price" of the products.[5] According to OIG, the program would no more give customers an incentive to change their behavior and act carelessly than a car insurance policy creates an incentive for reckless driving. OIG also concludes that the administrative burden of obtaining replacement product under the program, including providing proof or attestation of the spoilage, returning the product when possible, and attesting to not billing patients or payors tempers any undue influence the program would otherwise have in inducing product purchases.

Conclusion

Advisory Opinion 17-03 offers a framework for analyzing the risks of manufacturer replacement product programs under the federal health care program anti-kickback statute. OIG confirmed that it does not view such programs as generally protected under a safe harbor or statutory exception, but noted a number of factors that caused it to view the proposed program favorably. Securing patient safety and quality of care appears to have been a key consideration in OIG's facts and circumstances analysis. OIG also appears to place significant weight on the safeguards the program imposes related to billing of patients and payors, as well as limiting replacement product to individual claims and not for large losses.

Beyond these structural safeguards, manufacturers considering adopting a replacement program need to consider the risks such programs may raise operationally. For example, is there a threshold at which point repeat claims for replacement product from a single customer would seem effectively to eliminate the prohibition against replacement for large losses? Enforcement of the program's terms and conditions and in particular the requirements that customers submit appropriate proof of spoilage or related attestations also may present some operational challenges. Manufacturers should separately consider other relevant laws when structuring product replacement programs, including without

[5] Advisory Op. at 6.

limitation, laws relevant to government price reporting, financial accounting, and drug product distribution. In the absence of safe harbor protection, manufacturers should continue to be careful structuring and monitoring the execution of programs offering replacement product to customers to minimize potential anti-kickback statute risks raised by these programs.

If you have any questions related to the new OIG advisory opinion, please contact one of the lawyers listed in this client alert, or the Hogan Lovells lawyer with whom you normally work.

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