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OIG's Expanded Interpretation of Warranty Safe Harbor Portends Well for Value-Based Health Care

In a new advisory opinion, the U.S. Department of Health and Human Services Office of Inspector General ("OIG") clarified the scope of the Anti-Kickback Statute ("AKS") warranty safe harbor (the "Warranty Safe Harbor").[1] In brief, the opinion recognizes that the Warranty Safe Harbor can provide protection for a warranty offered for "many reasons, including failure to meet quality standards or failing to achieve patient clinical results specified as targets at the time of sale."[2] This confirms the long-standing view of many in the drug and medical device industry that the Warranty Safe Harbor applies more broadly than the traditional product defect settings described in previous OIG guidance. This broadening of OIG's previous guidance on the Warranty Safe Harbor may facilitate many of the outcomes-based risk-sharing arrangements that drug and device sellers have been contemplating (and pursuing) as part of the movement towards value-based health care.

Background on Warranty Safe Harbor

The AKS prohibits the knowing and willful solicitation, receipt, offer or payment of any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for either referrals of federal health care program patients or arranging, recommending, leasing or ordering any item or service reimbursed by a federal health care program.[3] The Warranty Safe Harbor, adopted in regulations under the AKS, shields warranty arrangements that meet each of its elements.[4] The Warranty Safe Harbor adopts, by reference, the statutory definition of a warranty set forth at 15 U.S.C. § 2301(6), which defines a "written warranty" 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 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.[5]

A 2001 OIG advisory opinion, originally issued in the preamble to the final rule adopting the Warranty Safe Harbor, indicated that manufacturer indemnification of health care providers for liabilities incurred in connection with product defects may fall within the Warranty Safe Harbor, focusing on the first of the two warranty definitions.[6] However, a 2002 OIG advisory opinion had suggested that, in order to qualify under the Warranty Safe Harbor, "the

[1] OIG Advisory Op. No. 17-03 (Aug. 18, 2017).
[2] *Id.* at 5 n.3.
[3] 42 U.S.C. § 1320a-7b(b).
[4] 42 C.F.R. § 1001.952(g).
[5] 15 .S.C. § 2301(6).
[6] OIG Advisory Op. No. 01-8 at 7-8 (Jul. 3, 2001); 56 Fed. Reg. 35952, 35977 (Jul. 29, 1991).

warranty must be related to a product failure."[7] Until the new advisory opinion in August 2017, OIG guidance had not addressed a number of other warranty types that might satisfy the second definition, which depends not on product defect, but rather upon the product's not living up to any "specifications" that the manufacturer might set forth as the basis for obtaining payment under the warranty.

Significance of New Advisory Opinion for Drug and Device Manufacturers in the Era of Value-Based Health Care

The new OIG advisory opinion thus expands the number of warranty types for which the OIG has recognized the availability of the Warranty Safe Harbor. This is significant because the advisory opinion expressly sanctions reliance on the Warranty Safe Harbor for manufacturer warranties granted for "many reasons" beyond product defects, including failure to meet quality standards or to achieve patient clinical results when those standards or results are specified as targets at the time of sale.[8] This affords manufacturers greater flexibility to tie product pricing to performance. Such sale arrangements are increasingly important to the provider customers of drug and device makers, as their own health insurance payments are more and more tied to patient outcomes under various value-based payment initiatives. Providers thus have been and will continue to be particularly incentivized to deal with product sellers who are willing to stand behind the performance of their products by sharing the risk on outcomes.

Further, the OIG advisory opinion is significant because clarifying the circumstances in which the Warranty Safe Harbor is available was not necessary to the reasoning of the advisory opinion, suggesting that OIG intentionally sought an opportunity to expand its guidance on the Warranty Safe Harbor in an attempt to clarify the state of existing law. In the advisory opinion, OIG determined that the warranty in question did not satisfy the statutory definition of a warranty because it would indemnify providers for certain product spoilage arising out of the purchaser's failure to follow the product's handling instructions, which OIG characterized as the "specifications set forth in the undertaking."[9]

This may indicate that, in designing safe harbor-compliant warranties, manufacturers may be constrained by the FDA label for their product, at least if the label imposes handling instructions. It is unclear, for example, whether OIG would consider a provider's use of a product off-label to violate the "specifications" that define the warranty (and a separate analysis under the Food, Drug and Cosmetic Act of course would be required for a warranty that veers off-label). However, there would seem to be a broad array of warranty possibilities for patient outcomes that could be offered that would not be defeated by mishandling under the label.

Conclusion and Next Steps

The new OIG advisory opinion addressing the Warranty Safe Harbor provides an important clarification regarding the safe harbor's reach that will be helpful to drug and device manufacturers selling products to health care providers engaged in value-based health care initiatives. If you would like to discuss the implications of a specific warranty proposal in light of the new advisory opinion, please contact your usual Ropes & Gray attorney.

[7] OIG Advisory Op. No. 02-6 at 5 (May 14, 2002).
[8] Note that, under the plain language of the regulation, the Warranty Safe Harbor remains restricted to warranties on items. 42 C.F.R. § 1001.952(g). The Warranty Safe Harbor is unavailable for warranties on services, as expressly noted in a prior OIG advisory opinion. OIG Advisory Op. No. 01-8 at 6 ("Since the Warranty Safe Harbor only protects warranties on 'items', a warranty on a combination of items and services does not technically qualify for protection").
[9] OIG Advisory Op. No. 17-03 at 5 (Aug. 18, 2017).