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OIG gives the green light to another innovative warranty

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Last week, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) published Advisory Opinion No. 18-10, advising that the OIG would not pursue an enforcement action under the Anti-Kickback Statute (AKS) based on a warranty offered by the manufacturer of a suite of products used in joint replacement surgeries. Together with Advisory Opinion No. 17-03, issued last August, the new advisory opinion seems to signal that the OIG will not stand in the way of value-based pricing arrangements that offer clear benefits to both patients and the health care system. For manufacturers considering innovative warranties or similar outcomes-based arrangements, these opinions offer a window into the OIG's thinking about what factors distinguish acceptable from unacceptable arrangements. The advisory opinions also are consistent with statements from OIG leadership at the American Health Lawyers Association (AHLA) annual meeting in June and with the OIG's recent request for information (RFI) asking stakeholders how to protect value-based arrangements from enforcement under the AKS and other fraud and abuse laws, which we summarized here. Manufacturers exploring such arrangements should consider commenting on the RFI.

The latest OIG-approved warranty: Advisory Opinion 18-10

The requestor, a manufacturer of surgical devices and wound care products, proposed to refund hospitals for the aggregate purchase price of three of the manufacturer's products, offered and used together as a "product suite": a total knee or total hip implant, a wound therapy system, and an antimicrobial dressing. To qualify for the refund, the hospital must have purchased all three of the products, must have performed an inpatient joint replacement surgery on a patient who was subsequently readmitted to the hospital within 90 days due to a surgical site infection or for a revision of the implanted knee or hip system, and must have certified to the requestor that the patient's readmission resulted from the failure of one or more of the products to perform as expected.

The OIG concluded that the proposed arrangement did not satisfy the warranty safe harbor under the AKS because that safe harbor, by its terms, does not apply to bundled items. However, the OIG concluded that it would exercise enforcement discretion because the proposed arrangement contained safeguards that resulted in a sufficiently low risk of fraud and abuse.

Specifically, the OIG highlighted the following safeguards as the basis for its favorable opinion.

- **Products are not separately reimbursable**. Medicare would reimburse the hospital for each product in the bundled suite through the pre-set diagnosis-related group (DRG) payment for the replacement surgery, and the patient would not be required to continue using any of the products after leaving the hospital. The hospital therefore would have no opportunity to bill separately for any product as a result of the warranty, which reduces the risk that the availability of the warranty will lead to overutilization or inappropriate use of any of the covered products.

- **Seller will comply with warranty safe harbor obligations.** The requestor certified that it will meet all the obligations of a seller under the warranty safe harbor, including notifying the hospital that it must report any refund obtained through the warranty program. The requestor also expects hospitals to comply with the Medicare rules requiring reduced payment for procedures using replacement devices for which the hospital received a full credit. The OIG reasoned that these safeguards would reduce the risk of increased costs to the Medicare program.

- **Physician is responsible for assessing medical necessity and clinical appropriateness.** Each hospital is required under the warranty program to certify that the physicians performing joint replacement surgeries at the hospital would remain responsible for determining whether a specific medical device is medically necessary and clinically appropriate for a particular patient, and the hospital is required to certify for each refund that the products were used in a manner consistent with each product's instructions and labeling. These safeguards reduce the risk that the warranty might result in the products being used in a clinically inappropriate or medically unnecessary manner.

- **May reduce patient readmissions; discernible connection between performance of product and clinical outcome.** The requestor asserted that the products, used in combination, are designed to reduce the incidence of infection-related readmissions and required revisions. In the OIG's view, the manufacturer effectively warranted "that an undesirable result, namely, readmission after a joint replacement surgery, will not occur." The OIG acknowledged that "it may not be possible to state with medical certainty that a readmission due either to a surgical site infection or to a revision of the implanted knee or hip system was caused by one or more of the Products," but went on to state that the warranty was "reasonably related to the use of the Product Suite and that, in the absence of other obvious causes of an infection or required revision," a hospital could reasonably claim that the revision surgery resulted from the failure of the product suite to perform "as expected." The OIG concluded that, under these circumstances, it is "reluctant to chill innovative and potentially beneficial arrangements."

- **Hospitals have flexibility to shop around.** The proposed arrangement does not require hospitals to recommend or require the use of the warranted products to physicians, nor does the arrangement include exclusivity provisions, quotas, minimums, or other eligibility criteria tied to the volume or value of referrals, meaning that hospitals have the flexibility to purchase and offer various joint replacement and wound care products and still take advantage of the warranty.

A growing trend: Advisory Opinion 17-03 and Advisory Opinion 01-08

Opinion 18-10 follows on last year's Advisory Opinion 17-03, which also approved a kind of warranty arrangement that permits tying pricing to overall performance. The requestor in Advisory Opinion 17-03 was a manufacturer of biologics that are sensitive to temperature changes, direct sunlight, or movement, and that require reconstitution in a controlled environment. Under the arrangement, the requestor would replace products if the products

spoiled or otherwise became unusable after purchase, including products that are mishandled, dropped, or broken; are inappropriately stored, refrigerated, or frozen; experienced an admixture error; or were reconstituted but not administered due to an unforeseen patient condition or because the patient missed the appointment.

The OIG concluded that the arrangement did not meet the warranty safe harbor, because the warranty would not apply to products that are defective or substandard at the time of sale. However, the OIG concluded that the proposed arrangement nevertheless posed a sufficiently low risk of fraud and abuse under the AKS because

- the replacement was restricted to unintentional and unplanned circumstances and could increase patient safety and quality of care by decreasing the risk that a customer might administer a potentially spoiled product to avoid financial loss;
- the replacement would only be available for products that customers had already selected and intended to use, reducing the risk that the proposed arrangement would lead to increased costs or overutilization;
- the proposed arrangement allowed only the replacement of the same product that the customer had intended to use, thus reducing the risk that the customer would be incentivized to pick the requestor's product over a competitor; and
- the proposed arrangement resembled an insurance policy in that a customer was unlikely to recklessly allow spoilage simply because the warranty arrangement was available, particularly because the customer would be required to complete an administrative process providing proof of the spoilage.

Opinion 18-10 also echoes and reinforces an older OIG advisory opinion, Advisory Opinion 01-08, which approved a proposal by a manufacturer of therapeutic mattresses to reimburse nursing facilities for a portion of deductibles owed under their liability insurance policies as a result of claims made by residents related to skin or wound care deficiencies. As the OIG characterized that arrangement, "the Program is designed to show potential customers that the Company is willing to put its money at risk if its therapeutic mattresses do not perform as intended by reducing substantially the incidence of pressure ulcers." The OIG concluded that the warranty very nearly met the terms of the warranty safe harbor, that the warranty would produce benefits for patients and federal programs if it worked as intended, and lacked "any identifiable opportunity for abuse."

Looking beyond the usual factors

These advisory opinions seem to indicate that the OIG is willing to consider a broader approach to certain innovative manufacturer arrangements, looking beyond the safe harbors and even beyond the usual factors that the OIG typically considers when weighing a non-safe-harbored arrangement. Although the opinions address those usual factors (including the risk of overutilization, increased program costs, and ensuring patient and provider choice), the opinions also emphasize the following considerations.

- **The arrangement offers the potential for a clinical benefit to patients.** In Advisory Opinion 18-10, the OIG suggested that the warranty program might improve the outcomes of patient surgeries. In Advisory Opinion 17-03, the OIG highlighted the reduced likelihood that patients would receive spoiled drug product. In Advisory Opinion 01-08, the OIG suggested the warranty could reduce the incidence of pressure ulcers, thereby improving patient well-being and avoiding significant treatment costs.

- **There is a reasonable connection between the manufacturer's offer and the clinical benefit.** In Opinion 18-10, the OIG appears to have reasoned that the warranty offer would encourage hospitals to choose a product suite that, as warranted by the manufacturer, will reduce infections and revisions: "[I]f the proposed Warranty Program works as intended and reduces the incidence of readmissions following joint replacement surgery due either to a surgical site infection or to a revision of the implanted knee or hip system, patients and Federal health care programs would benefit." (Opinion 01-08 used nearly identical language.) In Advisory Opinion 17-03, the manufacturer's offer to replace spoiled product removed the financial incentive for providers to use the spoiled product.
- **There is a benefit to warranties based on clinical outcomes.** The OIG appears to be open to allowing warranties or similar offers even when the loss warranted against is not clearly the result of a defect in the design or construction of the product.
    - In Advisory Opinion 18-10, the OIG was willing to approve a warranty relying on the hospital's assertion that the patient's readmission was because the product failed to work "as expected" to reduce infections and revisions. This gets closer to an outcomes-based arrangement or a performance guarantee, i.e., a replacement offer that turns on clinical outcomes rather than a clear product malfunction, though it does not quite endorse such an arrangement. However, the OIG's reasoning in Advisory Opinion 18-10 continues to rely on the assumption that a hospital could reasonably connect the patient's readmission to the failure of the product to prevent the infection or revision, and not to "other obvious causes of an infection or required revision."
    - In Advisory Opinion 17-03, the offer of replacement product would be available even if the spoilage was not the fault of the manufacturer, thus shifting the focus of the arrangement from a defect to a sharing of performance risks.
    - In Advisory Opinion 01-08, the manufacturer stood behind its claim that the product would reduce pressure ulcers by agreeing to offset some cost of medical treatment if the product did not perform as promised.

The OIG's inclination to approve certain innovative arrangements soon may extend beyond the type of warranty arrangements addressed in these advisory opinions. The agency recently released an RFI requesting input on new AKS safe harbors and other new paths to compliance for value-based arrangements, which could be another important step toward a more permissive approach toward such arrangements in the future. Although it is too soon to tell what regulatory changes the OIG may propose or finalize in the future, the agency continues to signal its willingness to allow more flexibility for certain innovative arrangements that benefit patients and the Medicare program and offer adequate safeguards against abuse. Indeed, speaking at the AHLA annual meeting, Rob DeConti, assistant inspector general for legal affairs, pointed to the OIG's advisory opinions as evidence that the agency did not intend to be an obstacle to reasonably calibrated risk-sharing arrangements.

If you have questions about the import of these advisory opinions or you are considering similar arrangements, please contact any of the authors of this alert or the Hogan Lovells lawyer with whom you regularly work.

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