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OIG Approves Warranty Program for Surgical Devices and Wound Care Products in Advisory Opinion 18-10

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In Advisory Opinion 18-10, issued September 10, 2018, the OIG permitted a manufacturer of surgical devices and wound care products to implement a warranty program under which the manufacturer's hospital customers could receive refunds should a suite of products used in joint replacement fail to perform as expected. Observing that the warranty program would involve offering hospitals something of value in exchange for using the manufacturer's products, the OIG analyzed the arrangement under the Anti-Kickback Statute (AKS) and the safe harbor for warranties. In outlining its determination, the OIG emphasized that although the warranty safe harbor was not satisfied, the manufacturer made efforts to meet the reporting requirements of the safe harbor and several factual characteristics of the arrangement reduced the risk of overutilization and limited the impact on clinical decision-making.

Factual Background

Under the proposed arrangement, the manufacturer's hospital customers would be offered a warranty on three of the manufacturer's products (a total knee or hip implant, a wound therapy system and an anti-microbial dressing) when all three are used together as part of an inpatient joint replacement surgery. The manufacturer would refund the aggregate purchase price for all three products to the hospital if a patient is readmitted for a surgical site infection or revision of the joint replacement within 90 days after surgery. To qualify for a refund under the program, the hospital would have to certify that each product was used consistently with its instructions and that the readmission resulted from failure of one or more of the manufacturer's three products.

The manufacturer would execute an agreement with hospitals participating in the warranty program that would obligate the hospitals to meet several requirements, including:

- fully and accurately reporting any refunds to federal health care programs;
- certifying that the treating physicians will remain responsible for determining what medical device and products are medically necessary and appropriate for a particular patient; and
- allowing the manufacturer to perform audits to confirm that refunds requested or received meet program qualifications.

The manufacturer confirmed that the program would be offered regardless of a patient's insurance or status as a federal health care program beneficiary. The program would not include any exclusivity provisions or otherwise tie eligibility for the warranty program to use of a certain volume of the manufacturer's products.

Payment methodology, as well as several safeguards put in place by the manufacturer, contributed to the OIG's conclusion that the arrangement posed a low risk of fraud and abuse. Noting that the products included in the warranty program are not separately billable by the hospital under Medicare during an inpatient stay, the OIG determined there was minimal risk that the warranty program would incentivize hospitals to engage in overutilization or improper decision-making. The OIG reasoned that the bundled payment rate instead encouraged hospitals to choose products based on value and clinical outcomes.

The requirement that hospitals certify that physicians would remain independent to choose the appropriate medical device for each particular patient also contributed to the OIG's determination. The OIG cited the certification requirement, as well as the lack of quotas or exclusivity requirements, as evidence that the warranty program was unlikely to lead to clinically inappropriate use of the products.

The OIG also looked favorably on the manufacturer's efforts to comply with elements of the warranty safe harbor. Because the warranty safe harbor is inapplicable to bundled items, the OIG determined that the arrangement did not qualify for protection under the safe harbor. However, the OIG determined that the manufacturer's compliance with the seller requirements of the safe harbor would make hospitals aware of their obligation to report refunds received, which would in turn increase transparency and reduce risk of increased federal health care program costs.

Finally, the OIG noted the beneficial purpose of the program as an additional consideration in its analysis. The OIG observed that the intended result of the warranty program was reduction of readmissions after joint replacement surgery, which would benefit patients and the federal health care programs. The OIG indicated it was open to innovative arrangements that create the potential for such benefits.

AO 18-11 provides insight into the ability of manufacturers to develop innovative programs, particularly in the inpatient setting where hospitals have incentives to reduce costs.