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OIG Approves Value-Based Warranty Program, Signals Potential Trend

On Sept. 10, 2018, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) issued Advisory Opinion No. 18-10 (Opinion), in which the OIG concluded that an outcomes-based warranty arrangement would not result in prohibited remuneration under the federal Anti-Kickback Statute (AKS). In light of Advisory Opinion No. 17-03, issued Aug. 18, 2017, and discussed in more detail below, the Opinion indicates a possible trend in the OIG declining to act as a barrier to value-based arrangements, so long as appropriate safeguards are in place.

The Opinion was requested by a manufacturer seeking to offer its hospital customers a warranty arrangement covering a suite of three products (Product Suite) – a total knee or total hip implant, a wound therapy system, and an antimicrobial dressing – which, when used together, purportedly reduce the incidence of readmission following inpatient joint replacement procedures. In order for a hospital to qualify for a refund under the proposed warranty arrangement, the following conditions must be satisfied: (i) the full Product Suite must be used as part of an inpatient joint replacement surgery; (ii) within 90 days of the initial procedure, the patient who received the Product Suite must be readmitted to the same hospital where the joint replacement was performed for a surgical site infection or a second surgery, known as a revision; and (iii) each portion of the Product Suite must have been used in accordance with its instructions for use and other labeling, and the hospital must certify that the patient's readmission resulted from a failure of one or more of the products in the Product Suite. The manufacturer certified that the individual elements of the Product Suite are not separately reimbursable under the Medicare Inpatient Prospective Payment System. Instead, all three products are reimbursed through a bundled payment as part of severity diagnosis-related groups in connection with an inpatient stay.

As a threshold matter, the OIG considered whether the proposed arrangement, which involves a bundle of three products, qualified for protection under the warranties safe harbor at 42 C.F.R. § 1001.952(g). According to the OIG, the regulatory text makes clear that the safe harbor protects only single-product arrangements. Furthermore, the OIG distinguished the warranties safe harbor from the discount safe harbor at 42 C.F.R. § 1001.952(h), which permits bundled discounts as long as the bundled goods or services are reimbursed using the same methodology and other requirements are met. In contrast, neither the regulatory text nor the preamble to the warranties safe harbor addresses the permissibility of bundled warranties or any associated safeguards. Accordingly, the OIG determined that the proposed arrangement did not qualify for protection under the warranties safe harbor.

Arrangements that do not fit in a safe harbor must be analyzed on a case-by-case basis, based on the totality of the facts and circumstances. For the following reasons, the OIG concluded that the proposed arrangement posed a sufficiently low risk of fraud and abuse under the AKS:

1. The individual elements of the Product Suite are not separately reimbursable under Medicare, meaning that a hospital making use of the warranty could not bill Medicare separately for any one of the three products, thereby reducing the risk of improper of overutilization of the Product Suite.

2. Although the proposed warranty does not fall squarely within the warranties safe harbor, the manufacturer certified that it would comply with all warranties safe harbor obligations of a seller, including reporting the existence of the warranty program on the invoice or statement it would furnish to hospital customers and providing the hospital with documentation of the refund calculation. By notifying the hospital of its obligation to appropriately report any refund obtained under the program, the arrangement would mitigate concern over increased costs to federal health care programs. Moreover, the warranty arrangement would require that any hospital claiming a refund must comply with the all legal obligations related to Medicare cost reporting.

3. As part of the proposed warranty program, each hospital would be required to certify that the physicians performing the applicable joint replacement surgeries would retain all responsibility for decisions related to medical necessity, thereby further reducing overutilization of the Product Suite.

4. The proposed warranty is intended to reduce hospital readmissions and provide improved clinical outcomes, thus furthering the overall quality and policy goals of federal health care programs. Here, the OIG noted that the proposed warranty program would essentially "warrant that an undesirable result, namely readmission after a joint replacement surgery, will not occur." The program would rely on the hospital to certify that all program requirements were satisfied, including that the products in the Product Suite were used in a manner consistent with their instructions for use and other labeling, and that the patient's readmission resulted from at least one of the products in the Product Suite failing to perform as expected. The OIG noted that, while it may be impossible to state with medical certainty that a readmission due to infection or required revision was caused by one or more of the products in the Product Suite, the manufacturer asserted that the products, when used together, are designed to reduce such readmissions. As a result, the OIG "believe[s] that the [warranty program] is 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 make a valid claim that the infection or required revision resulted from failure of the Product Suite to perform as expected." Furthermore, the OIG stated that it is "reluctant to chill innovative and potentially beneficial arrangements."

5. Because the proposed warranty would not be an exclusive arrangement between the hospital and the manufacturer, nor does it require any minimums or quotas, hospitals retain the ability to "shop around" for and compare the best joint replacement products while potentially reaping the benefits of a successful Product Suite.

The circumstances and reasoning set forth in the Opinion echo the analysis set forth in Advisory Opinion 17-03. In that opinion, a manufacturer of biologic products that spoil unless kept in a controlled environment proposed a replacement program for product that had spoiled due to unintentional, unplanned circumstances. The OIG also found the arrangement permissible based on safeguards that reduced the risk of overutilization, increased costs, and use of spoiled products.

While it may be too early to consider these opinions to be a trend, they do indicate that the OIG is taking into consideration industry concerns about the AKS stifling the development of value-based arrangements that offer the potential of increased quality of clinical outcomes to patients and payors.

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