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OIG APPROVES RISK-SHARING ARRANGEMENT FURTHERING SHIFT TOWARD VALUE-BASED PURCHASING

In the era of value-based care, health care providers and manufacturers are increasingly examining risk sharing opportunities in the treatment of patients. On September 17, the Department of Health and Human Services Office of Inspector General ("OIG") published Advisory Opinion 18-10 whereby it approved a proposed risk sharing initiative with defined guardrails. Advisory Opinion 18-10 builds on the guidance offered in Advisory Opinion 17-03 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." In the era of value-based care, this type of warranty program is increasingly appealing. This model could serve as a road map for these kinds of risk sharing arrangements.

Advisory Opinion 18-10 involved an arrangement in which a product manufacturer and seller (the "Requestor") would refund hospitals for the aggregate purchase price of certain product bundles manufactured by the Requestor under certain circumstances (the "Proposed Arrangement"). OIG concluded that although the Proposed Arrangement does not meet the warranty safe harbor to the AKS, OIG would not impose sanctions because the Proposed Arrangement presented a sufficiently low risk of fraud and abuse based on the totality of the facts and circumstances.

PROPOSED ARRANGEMENT

The Requestor manufactures and sells surgical devices and wound care products. Under the Proposed Arrangement, the Requestor would, under certain circumstances, refund hospitals for the aggregate purchase price of three of the Requestor's products (the "Warranty Program"). The following conditions must be satisfied for a hospital purchaser to qualify for a refund under the Warranty Program:

- A patient **must** have had joint replacement surgery, as an **inpatient**, at the hospital and **must** have received each of the following Requestor-manufactured products: (i) a total knee or total hip implant; (ii) a wound therapy system; and (iii) an antimicrobial dressing (each, a "Product" and collectively, the "Product Suite").
- A patient who received the Product Suite **must** have been readmitted to the **same hospital** where the joint replacement surgery was performed, as an **inpatient**, within **90 days** following the patient's joint replacement surgery due to a surgical site infection or for a revision of the implanted knee or hip system.
- Each Product **must** have been used in a manner consistent with its instructions for use and other labeling ("Documentation"), and the hospital **must** certify that the patient's readmission resulted from the failure of one or more of the Products to perform as expected.

If the above requirements are satisfied, the Requestor would refund the hospital its aggregate purchase price for all three Products in the Product Suite, regardless of which, or how many, of the Products actually failed to perform as expected. The Requestor would provide a refund without regard to the patient's insurance status and, if the patient is insured, without regard to the third-party payor that covered the patient's joint replacement surgery or the third-party payor's payment methodology. the Requestor stated that when hospitals use the Product Suite as indicated, the Requestor expected the Product Suite would reduce the likelihood of a surgical site infection or required revision of the implanted knee or hip system.

Significantly, the Requestor certified that the Products in the Product Suite are not separately reimbursable under the Medicare Inpatient Prospective Payment System ("IPPS"). In particular, the Requestor certified that the payments for the Products in the Product Suite are bundled into the payments for the MS-DRGs associated with the inpatient joint replacement surgeries. In addition, the Requestor certified that the Warranty Program would not require the patient, or any subsequent providers or suppliers, to purchase the Requestor's wound therapy system or antimicrobial dressing after the hospital discharges the patient. Accordingly, any refund under the Warranty Program related to a Medicare beneficiary's joint replacement surgery would only be for Products used during an inpatient stay and reimbursed through a bundled payment.

The Requestor further certified that it would fully and accurately report the existence of the Warranty Program on the invoice or statement it

furnishes to a hospital when it purchases the Product Suite. The Requestor also explained that it expects that hospitals participating in the Warranty Program would continue to comply with all legal obligations associated with Medicare cost reporting. The Requestor certified that it would not pay any remuneration to a hospital under the Proposed Arrangement **other than** the hospital's aggregate purchase price for the entire Product Suite in accordance with the Warranty Program. In other words, there would be no sharing of other types of payments, just the purchase price of the Product Suite.

Prior to participating in the Warranty Program, each hospital must execute an agreement with the Requestor that requires the hospital to:

- Fully and accurately report any Warranty Program refunds to federal health care programs, in accordance with the rules governing the applicable federal health care program;
- Upon request by the Secretary or a state agency, provide information regarding the Warranty Program provided by the Requestor;
- Certify that physicians performing joint replacement surgeries at the hospital would at all times remain responsible for determining whether a specific medical device, including any of the Products, is medically necessary and clinically appropriate for a particular patient; and
- Provide the Requestor with the right to audit the hospital's eligibility with respect to any patient for whom the hospital claimed or received a Warranty Program refund.

Further, to obtain a refund through the Warranty Program, a hospital would be required to submit certain documentation, including: (i) a summary of the claimed refund amount; and (ii) a certification by the hospital that all of the Warranty Program's requirements were satisfied, including that the Products were used in a manner consistent with their Documentation and that the patient's readmission resulted from a failure of at least one of the Products. When providing a refund to a hospital for the Product Suite, the Requestor would provide the hospital with documentation detailing the refund calculation.

OIG ANALYSIS - WARRANTY SAFE HARBOR

The AKS makes it a criminal offense to knowingly and willfully offer or receive remuneration to induce or reward referrals of items or services reimbursable by federal health care programs. If just one purpose of an arrangement is to induce or reward referrals, the arrangement violates the AKS. OIG has promulgated safe harbor regulations that define practices that are not subject to the AKS because such practices would be unlikely to result in fraud or abuse. However, safe harbor protection is only offered to arrangements that squarely meet all of the conditions set forth in the applicable safe harbor.

The Warranty Safe Harbor to the AKS protects remedial actions by manufacturers and suppliers intended to address products that fail to meet bargained-for requirements. The Warranty Safe Harbor to the AKS allows the refund of the cost of certain items under a warranty provided by a manufacturer or supplier of an item to the buyer (such as a health care provider or beneficiary) of the item, as long as all of the following standards are met:

- The buyer must fully and accurately report any price reduction of the item (including a free item), which was obtained as part of the warranty, in the applicable cost-reporting mechanism or claim for payment filed with HHS or a state agency;
- The buyer must provide, upon request by the Secretary or a state agency, information provided by the manufacturer or supplier;
- The manufacturer or supplier must either:
  - Fully and accurately report the price reduction of the item (including a free item), which was obtained as part of the warranty, on the invoice or statement submitted to the buyer, and inform the buyer of its obligations under the warranty safe harbor; or
  - Where the amount of the price reduction is not known at the time of sale, fully and accurately report the existence of a warranty on the invoice or statement, inform the buyer of its obligations under the warranty safe harbor, and, when the price reduction becomes known, provide the buyer with documentation of the calculation of the price reduction resulting from the warranty; and
- The manufacturer or supplier must not pay remuneration to any individual (other than a beneficiary) or entity for any medical, surgical or hospital expense incurred by a beneficiary other than for the cost of the item itself.

Since the Requestor sought to offer hospitals something of value in exchange for the purchase of the Product Suite, which could be

reimbursable by a federal health care program, the Proposed Arrangement implicates the AKS. OIG concluded that the Warranty Program, which involves a bundle of the three Products in the Product Suite, does not qualify for protection under the warranty safe harbor, as the warranty safe harbor does not apply to bundled items, only to the particular item that might be defective.

Discount Safe Harbor Comparison. OIG compared the text of the Warranty Safe Harbor to the Discount Safe Harbor of the AKS.[1] The text and preamble of the Discount Safe Harbor expressly support the concept of allowing bundled discounts when the goods or services are reimbursed by the same payment methodology. In contrast, the Warranty Safe Harbor does not address these protections for a bundle of items. Unlike the Discount Safe Harbor, the Warranty Safe Harbor does not include conditions that mitigate the fraud and abuse risk of warranty arrangements involving bundled items.

That said, arrangements that do not fit in a safe harbor must be evaluated on a case-by-case basis, based on the totality of the facts and circumstances. OIG concluded that the Proposed Arrangement posed a sufficiently low risk of fraud and abuse under the AKS for the following reasons:

1. Medicare reimburses hospitals through one bundled payment for all of the items and services the hospitals furnish in connection with an inpatient stay for a joint replacement surgery. None of the Products in the Product Suite are separately reimbursable under the IPPS. The Warranty Program would not require the patient to continue to use the Requestor's wound therapy system or antimicrobial dressing after the hospital discharges the patient. Consequently, all of the Products in the Product Suite would be covered by one Medicare payment to the hospital, so the hospital's inability to separately bill for each Product should encourage the hospital to closely examine available products and select a combination that results in the best value and clinical outcomes for patients, thus reducing the risk of overutilization of the Products.
2. The Requestor certified that it would meet all of the obligations of a seller under the Warranty Safe Harbor, including notifying hospitals of their obligation to appropriately report any refund they obtained through the Warranty Program. The Requestor also expects that hospitals participating in the Warranty Program would comply with all applicable cost reporting requirements, including the Medicare policy that requires a reduced payment to a hospital when a hospital received full credit for the cost of a device.
3. The Requestor would require each hospital to certify that the physicians performing joint replacement surgeries at the hospital would remain responsible for determining whether a specific medical device, including each of the Products, is medically necessary and clinically appropriate for a particular patient. Further, the Requestor would require hospitals seeking a refund to certify that each Product in the Product Suite was used in a manner consistent with each Product's Documentation. The combination of these requirements by the Requestor would decrease the risk that the Products would be used in a clinically inappropriate or medically unnecessary manner.
4. Patients and federal health care programs would benefit if the 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. OIG found 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 the failure of the Product Suite to perform as expected.
5. The Requestor certified that the Warranty Program would contain no exclusivity requirements, quotas, minimum purchases or other eligibility criteria tied to the volume or value of referrals. The Requestor also would not require hospitals participating in the Warranty Program to make any specific communications to physicians performing surgeries in the hospital that encourages or requires the use of the Requestor's Products. Therefore, the Warranty Program would neither: (1) impede the hospitals' ability to make purchasing decisions that result in both the best value and clinical outcomes for their patients, as they would maintain the flexibility to purchase a variety of joint replacement and wound care products; nor (2) require coercive communications from a hospital to physicians regarding the Products.

Although the Proposed Arrangement would not be protected by the warranty safe harbor, OIG concluded based on the totality of the facts and circumstances that the Proposed Arrangement posed an acceptably low risk of fraud and abuse under the AKS, noting its reluctance to "chill innovative and potentially beneficial arrangements" such as these.

PRACTICAL TAKEAWAYS

Advisory Opinions 17-03 and 18-10 highlight that value-based contracting and risk sharing models continue to gain traction, and there are

potential business models approved by OIG for consideration.

When models deviate from a safe harbor, there is no bright line test and the variation of the elements of the arrangement as well as the level of risk differs from case to case. Nonetheless, when providers and suppliers evaluate these types of arrangements, consideration should be given to the following:

- *Ensuring both parties understand and agree upon all elements of a program or arrangement*. Specifically, providers should assess eligibility criteria for patients and establish proper clinical protocols.
- *Analyzing whether volume commitments are tied to additional reimbursement, whether the in-patient procedure was performed at the hospital receiving the readmission and whether the products being reimbursed are being reimbursed under the same payment methodology*. Transparency into the arrangement is paramount, so all terms should be expressly laid out in a written agreement.
- *Analyzing whether the parties contemplate additional remuneration outside of the product costs, which could cause considerable risk analysis.*
- *Structuring arrangements in a manner that attempts to meet the Warranty Safe Harbor*. Providers must perform a careful analysis of risk sharing proposals to ensure they are comfortable with the level or risk associated with the arrangement to the extent it does not comply with the safe harbor. Where there is a legitimate business case coupled with strong clinical support for a program, a provider might be more willing to pursue a risk sharing arrangement even if the safe harbor is not met.
- *Creating an appropriate workflow for providers to track warranty claims and reimbursements so claims submitted to payors are adjusted appropriately*. Suppliers should continue to provide sufficient information regarding the initial purchase value and subsequent information regarding warranty claims so that providers are able to meet their cost-reporting obligations and can seek reimbursement or other available remedies from suppliers when appropriate.

If you have any questions or would like additional information about this topic, please contact:

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[1] 42 C.F.R. § 1001.952(h).