

OIG Advisory Opinion 26-12 Approves Concierge Program Warranty for Surgical Outcomes

September 9, 2026
By George W. Bodenger



On May 22, 2026, the Office of Inspector General ("OIG") issued Advisory Opinion 26-12, concluding that a proposed warranty program offered by an orthopedic surgery provider would not generate prohibited remuneration under either the Federal Anti-Kickback Statute ("AKS") or the Beneficiary Inducements Civil Monetary Penalty ("CMP") provisions. Accordingly, OIG stated that it would not impose administrative sanctions in connection with the arrangement. The opinion provides important guidance regarding the application of the AKS warranty safe harbor to innovative service delivery models.

The Proposed Arrangement

The Requestor, an orthopedic surgery provider, offers patients an optional concierge program that includes post-operative recovery support services and products for one (1) year following surgery. These services include wellness coaching, educational support, nutritional programs, digital health monitoring tools, and recovery-related products. The provider certified that none of these concierge services are reimbursable by Medicare, Medicaid, or commercial insurance, although the underlying surgical procedures may be covered by Federal health care programs.

Patients who elect to participate pay a separate concierge fee and execute a membership agreement before surgery. Under the proposed arrangement, the provider would warrant that a patient's substantial compliance with the concierge program would result in the patient not requiring revision surgery within two (2) years of the initial procedure. If the patient nevertheless required revision surgery during that period, the provider would refund the concierge fees paid in connection with the original surgery. The provider would not refund medical expenses, cover revision surgery costs, or provide any additional remuneration. Nor would the patient be required to return to the provider for the revision procedure.

Anti-Kickback Statute Analysis

OIG recognized that the arrangement potentially implicates the AKS because the offer of a refund could make the provider more attractive to prospective patients seeking surgeries that are reimbursable by Federal health care programs. As a result, OIG examined whether the arrangement satisfied the regulatory safe harbor for warranties found at 42 C.F.R. § 1001.952(g).

The warranty safe harbor protects certain written undertakings to refund, repair, replace, or provide other remedial action when an item, bundle of items, or related services fail to meet specified performance standards. OIG concluded that the proposed concierge fee refund met the regulatory definition of a warranty because:

- The commitment was memorialized in a written membership agreement
- The warranty formed part of the bargain between the provider and the patient

- The provider agreed to take remedial action in the form of a refund
- The refund would be triggered by the failure of the concierge program and related services to achieve the promised outcome of avoiding revision surgery within two years

OIG further determined that the arrangement satisfied the applicable conditions of the warranty safe harbor. Among other things, the provider certified that it would accurately disclose and document any refund, require patients to provide information to government authorities upon request, and refrain from conditioning the warranty on exclusive use of the provider or minimum purchase requirements.

Because the arrangement fit squarely within the warranty safe harbor, OIG concluded that it would not constitute prohibited remuneration under the AKS.

Beneficiary Inducements Civil Monetary Penalties Analysis

OIG likewise found no violation of the Beneficiary Inducements Civil Monetary Penalties (CMP). Although the refund offer could arguably influence a Medicare or Medicaid beneficiary's selection of a provider, the CMP's definition of remuneration excludes practices that are permissible under an AKS safe harbor. Having determined that the proposed arrangement qualified for protection under the warranty safe harbor, OIG concluded that the arrangement likewise posed no risk under the Beneficiary Inducements CMP.

Key Compliance Considerations

Several facts were central to OIG's favorable determination:

- The concierge services were separately purchased at fair market value
- The refund applied only to the concierge fees paid by the patient and not to medical, hospital, or surgical expenses
- Patients were not required to use the provider for any future procedure, including revision surgery
- The provider did not condition the warranty on exclusive use arrangements or minimum purchasing commitments
- Appropriate reporting, documentation, and disclosure requirements were incorporated into the membership agreement

Conclusions

Advisory Opinion 26-12 demonstrates OIG's willingness to recognize properly structured outcome-based warranty programs tied to non-covered services that satisfy the warranty safe harbor. The opinion may be particularly relevant to providers developing concierge, care coordination, recovery support, or other value-added patient programs.

At the same time, OIG emphasized that its approval was limited to the specific facts presented. Notably, the agency distinguished the proposed arrangement from the provision of free concierge services or other free benefits to patients. OIG reiterated its longstanding concerns that free items or services connected to federally reimbursable care may present significant fraud and abuse risks and would not necessarily qualify for safe harbor protection.

While advisory opinions bind only the requesting party, Advisory Opinion 26-12 offers a useful roadmap for providers seeking to design patient-centered warranty programs that reward outcomes without running afoul of the AKS or Beneficiary Inducements CMP. Proper structuring, fair market value pricing, careful documentation, and strict adherence to the warranty safe harbor remain essential to achieving a favorable compliance result.