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Post-MACRA gainsharing OIG advisory opinion focuses on patient-centered care

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On January 5, 2018, the Office of Inspector General of the U.S. Department of Health and Human Services (OIG) released its first guidance on gainsharing in five years, Advisory Opinion 17-09, in which it approved a gainsharing arrangement between neurosurgeons and a medical center concerning spinal fusion surgeries.[1]

Gainsharing arrangements typically refer to an arrangement in which a hospital pays a group of physicians a share in the hospital's cost savings that is earned as a direct result of specific actions taken by those physicians. Gainsharing aligns the financial incentives of physicians and hospitals by promoting hospital cost reductions and gives physicians an incentive to help the hospital achieve these cost reductions. Although gainsharing arrangements have many worthy aims, they implicate both the gainsharing prohibitions contained in the Civil Monetary Penalties (Gainsharing CMP) law[2] and the payment prohibitions in the Anti-Kickback Statute (AKS).

Advisory Opinion 17-09's significance lies in the fact that it is the first advisory opinion dealing with gainsharing since the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) amendments to the Gainsharing CMP.

Prior to MACRA, the Gainsharing CMP prohibited hospitals from knowingly making a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided to federal program patients.[3] However, following MACRA, the Gainsharing CMP now only prohibits reductions or limitations in medically necessary services. "Medically necessary" is not defined in MACRA, and it was unclear how the amendment impacted the structuring of gainsharing arrangements. Specifically, the language states:

> If a hospital or a critical access hospital knowingly makes a payment, directly or indirectly, to a physician as an inducement to reduce or limit medically necessary services provided with respect to individuals who — (A) are entitled to benefits under part A or part B of title XVIII [42 USCS §§ 1395c et seq., 1395j et seq] or to medical assistance under a State plan approved under title XIX [42 USCS §§ 1396 et seq.], and (B) are under the direct care of the physician, the hospital or a critical access hospital shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $5,000 for each such individual with respect to whom the payment is made.

Thus, OIG's latest Advisory Opinion provides helpful guidance as to how OIG views gainsharing arrangements

following MACRA's amendment, and sheds light on important safeguards to include against reducing or limiting medically necessary services. Further, Advisory Opinion 17-09 reinforces much of OIG's prior guidance on gainsharing arrangements and safeguards to protect against violations of the Gainsharing CMP and AKS.

Summary of key aspects of Advisory Opinion 17-09

In the three-year arrangement, four neurosurgeons were given the opportunity to be paid a share of a hospital's cost savings that resulted from changes in neurosurgeons' operating room practices for spinal fusion surgeries.

The parties to the arrangement are:

- A non-profit acute care hospital (medical center) that provides a range of inpatient and outpatient hospital services, including spinal fusion surgeries;
- Three shareholder neurosurgeons of a multi-specialty physician group and one neurosurgeon employed by the physician group (collectively, neurosurgeons), who are the only four physicians participating in the arrangement from the physician group. The neurosurgeons perform the majority of their spinal surgeries at the medical center. The employed neurosurgeon will be eligible to share in incentive payments only in the third performance year (PY) of the arrangement;
- A program administrator engaged by the medical center for a fixed monthly fee to administer and manage the arrangement; and
- A wholly owned subsidiary of the medical center (subsidiary), which provides administrative and managerial infrastructure for the arrangement, supports a committee that monitors the arrangement (program committee), and coordinates with the program administrator regarding the calculation of any incentive payments to the neurosurgeons.

Prior to the commencement of the arrangement, the program administrator studied the historical practices in spinal fusion surgeries and identified 34 cost saving opportunities, and subsequently collaborated with the subsidiary, the physician group, and the medical center to co-develop clinically appropriate and evidence-based recommendations for making changes to the neurosurgeons' operating room practices for spinal fusion surgeries, which fell into two main categories (recommendations):

1. Using bone morphogenetic protein (BMP) on an "as-needed" basis, because it was determined by the parties that it would be reasonable for the neurosurgeons to reduce the use of BMP to no lower than 4% of the neurosurgeons' surgeries; and
2. Standardizing certain devices and supplies (while not restraining the neurosurgeons' use of any devices and supplies available to them prior to the arrangement).

At the end of each performance year of the arrangement, the program administrator calculates the cost savings attributable to the neurosurgeons' implementation of the recommendations. To determine the performance year savings, the total cost for each product used in spinal surgeries in the relevant performance year is divided by the total number of products used in surgeries during the year, and this amount is then compared to product costs in the prior 12-month period. This removes any duplicate payments to the neurosurgeons for savings previously earned in the prior performance year. The cost savings calculation is adjusted to remove savings for: (1) increased procedures performed on federal healthcare program patients as compared to the base year; and (2) inappropriate uses of the recommendations. Savings related to each recommendation are calculated separately to protect against inappropriate shifting of cost savings.

Before distributing cost savings to the neurosurgeons, the program administrator is paid a fee for its services. Then, 50% of the total performance year savings is transferred from the medical center to its subsidiary. The subsidiary then makes three separate payments to the physician group (representing the first, second, and third performance years). In the aggregate, these three payments are the sum of what is paid to the physician group under the arrangement. It was noted that this aggregate payment (after deducting the program administrator's fee) would not be more than 50% of the total potential cost savings that was estimated by the program administrator at the beginning of the arrangement. The physician group retains a percentage of the fee for various administrative expenses in accordance with the physician group's historic operating practices. Lastly, the physician group pays the neurosurgeons their share on a per capita basis.