PUBLICATION

OIG Offers Additional Guidance on Gainsharing Arrangement in Advisory Opinion 17-09

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A non-profit acute care hospital may share cost savings for certain spinal surgeries with neurosurgeons in a multi-specialty physician group following approval by the U.S. Department of Health & Human Services, Office of Inspector General (OIG). In Advisory Opinion 17-09, the OIG determined that the parties had incorporated sufficient safeguards in the gainsharing arrangement to avoid sanctions under both the civil monetary penalty prohibiting a hospital's payment to a physician to induce the reduction or limitation of medically necessary services to Medicare or Medicaid beneficiaries (the Gainsharing CMP) and the Anti-Kickback Statute (AKS).

The advisory opinion is notable for two firsts. It is the first advisory opinion to address gainsharing since the passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), which modified the Gainsharing CMP to prohibit only inducements made to reduce or limit medically necessary services under Medicare or Medicaid. Furthermore, it is the first gainsharing advisory opinion involving a large multi-specialty physician group.

Development of the Arrangement

Under the arrangement, the hospital, through a wholly owned subsidiary, intends to share certain cost savings with the neurosurgeons in a large multi-specialty physician group over a three-year period. The hospital engaged a program administrator to administer and manage the cost-savings program. The program administrator conducted a historical study of the neurosurgeons' spinal fusion surgeries, comparing supply costs, quality of care, and utilization on a national level. Ultimately, the program administrator was able to identify 34 cost-saving opportunities. These cost-savings opportunities could be grouped into two main categories: (1) use of Bone Morphogenetic Protein (BMP) in surgeries and (2) product standardization. The historical study revealed that the neurosurgeons could reasonably reduce their use of BMP from their current usage in 29 percent of surgeries to around four percent. The arrangement set a floor at four percent, below which the neurosurgeons would not receive a share of cost-savings for BMP usage. The product standardization measures focused around standardizing medical devices and supplies for spinal fusion surgeries. The neurosurgeons developed a process to evaluate and clinically review medical device vendors and products and agreed to use preferred products where clinically appropriate.

Features of the Arrangement

The hospital and neurosurgeons implemented several safeguards to avoid a reduction of medically necessary services and established documentation requirements to increase transparency. In particular:

- A program committee monitors and tracks the arrangement.
- To avoid cherry-picking patients, the neurosurgeons are prohibited from selecting patients to participate in or removing patients from the arrangement. The program committee reviews data to ensure appropriate patient selection.
- Any neurosurgeon from the arrangement who is found to be actively steering patients or in violation of the arrangement's clinical or administrative guidelines will be removed from the arrangement.
- Both the hospital and neurosurgeons will maintain all documentation detailing services and costs provided under the arrangement.

- Any patient seen as part of the arrangement must be given written notice of the arrangement before the patient is admitted to the hospital.

Compensation Under the Arrangement

To determine the cost savings achieved in a performance year, the program administrator determines the base year cost, a historical cost for each product covered by the arrangement, and then compares it to a performance year cost to calculate the total savings. The base year is reset annually, so the cost from the first performance year becomes the base cost for the second performance year and so on. This effectively removes any earlier-accomplished savings from the accounting. Once the total performance savings is determined, the hospital will pass up to 50 percent of the total cost savings to the subsidiary for distribution to the physician group. Before transferring payment to the physician group, the subsidiary will deduct a fee to compensate the program administrator for managing the arrangement. Any cost savings distributed to the neurosurgeons will be on a per capita basis. Before distribution to the neurosurgeons, the physician group will extract a fee for administrative expenses and a recruitment fee for efforts in helping recruit other physicians to the physician group.

OIG Analysis

Gainsharing CMP

As originally drafted, the Gainsharing CMP prohibited payments to physicians to induce them to reduce or limit any services to Medicare or Medicaid beneficiaries under their direct care. MACRA amended the Gainsharing CMP to limit it to inducements to reduce or limit "medically necessary" care. Despite the change, the OIG concluded that the Gainsharing CMP was potentially implicated since payments flow from the hospital to the neurosurgeons and could potentially encourage them to reduce or limit medically necessary services. In their advisory opinion request, however, the parties certified that none of the cost-savings measures will reduce or limit medically necessary services and that the program administrator tracks any changes in cost, resource utilization, or quality of patient care. The OIG expressly stated that it was not able to opine on whether the gainsharing program would only reduce services that are not medically necessary. The OIG then relied on the parties' certification to conclude that the methodology used to calculate the cost savings and the safeguards in place reduced the risk of a gainsharing violation.

AKS

The OIG noted that, under gainsharing arrangements, there is a concern that payments made to physicians for implementing cost-saving measures are an inducement or reward for referrals and, as such, constitute illegal remuneration under the AKS. While recognizing the potential for prohibited referrals, the OIG found sufficient safeguards present in the current arrangement to conclude there is a relatively low risk of fraud and abuse. The OIG analyzed the following safeguards:

- Incentive payments are distributed on a per capita basis, reducing the incentive for any particular neurosurgeon to generate disproportionate cost savings.
- Incentive payments to the physician group are capped and will not exceed 50 percent of the projected cost savings.
- The program committee reviews data on patient severity, age, and payor to confirm consistent patient selection for the arrangement.
- The fee retained by the physician group is used exclusively for administrative and recruitment expenses, lowering the risk that it would be used to reward particular physicians.
- Annually rebasing the base year cost to remove prior year savings is sufficient to prevent duplicate payments.

- For the product standardization recommendations, the neurosurgeons used evidence-based medical review and consulted U.S. Food and Drug Administration guidelines to ensure that selected medical devices and supplies were clinically safe and effective.
- The arrangement ties the neurosurgeons' incentives to actual, verifiable cost savings attributable to each recommendation implemented during the spinal fusion surgeries.
- Neurosurgeons will continue to make a patient-by-patient determination as to the most clinically appropriate medical device or supply to be used for surgery.
- Only the neurosurgeons from the physician group are allowed to participate in the arrangement, reducing the likelihood the arrangement will influence other neurosurgeons outside of the physician group to perform surgeries at the hospital.

Baker Donelson's Comments

Advisory Opinion 17-09 is the first OIG advisory opinion focused on gainsharing arrangements issued after MACRA modified the Gainsharing CMP to add a "medically necessary" condition. Nevertheless, the OIG applied a similar analysis to prior gainsharing opinions. The OIG effectively assumed away the main issue by stating that they were unable to opine on whether the gainsharing program would only reduce services that were not medically necessary and then relying on the parties' certification. Advisory Opinion 17-09 is also the first arrangement involving a gainsharing arrangement with a large, multi-specialty physician group. While the gainsharing payments are primarily to the neurosurgeons, there will be some payment to the group. The OIG stressed that the payment to the group was only for administrative expenses and was part of a pre-existing arrangement. Although not expressly stated, it appears that the OIG was concerned that gainsharing payments not be shared with members of the physician group who did not perform procedures but were only potential referral sources to the neurosurgeons.

The bottom line is that hospitals and physicians should work with experienced health care regulatory counsel when developing gainsharing arrangements, particularly when they will involve sharing cost savings. Appropriate safeguards must be in place to avoid penalties under the Gainsharing CMP and AKS.