

## OIG APPROVES GAINSHARING ARRANGEMENT FOR SURGICAL PROCEDURES

The Department of Health and Human Services Office of Inspector General ("OIG") recently issued [Advisory Opinion 17-09](#), which approved an arrangement between a hospital and physician group in which neurosurgeons and the hospital implemented a cost-savings program where the hospital agreed to share a percentage of its cost savings resulting from the program ("Proposed Arrangement"). OIG stated that it would not impose sanctions against the parties for violations of the Anti-Kickback Statute ("AKS") or the Civil Monetary Penalties law ("CMP") because the arrangement promotes access to care and poses a low risk of harm to federal health care programs.

### BACKGROUND

#### *Relevant Parties*

The requesting hospital ("Hospital"), which provides various inpatient and outpatient services including spinal fusion surgeries, implemented a program to achieve cost reduction for its spinal fusion surgeries. The physician group ("Group") is a multi-specialty group that has several practicing neurosurgeons ("Neurosurgeons"). The Hospital also wholly owns a subsidiary management company ("Subsidiary") that provides administrative and management services pursuant to the Proposed Arrangement.

#### *Proposed Arrangement*

In seeking the Advisory Opinion, the Hospital proposed it would pay the Group (via the Subsidiary) a share of the three-year cost savings attributable to the Neurosurgeons' selection and use of various products during spinal fusion surgeries. The parties also agreed that a "Program Administrator" would help monitor and implement various aspects of the Proposed Arrangement.

In order to identify the cost-savings opportunities, the Program Administrator performed a study of the historical practices of spinal fusion surgeries performed at the Hospital. The Hospital, Subsidiary and Group had the opportunity to review and approve the metrics developed by the Program Administrator, which were divided into two categories.

1. Use of Bone Morphogenetic Protein on an As-Needed Basis. Using national survey data, the Program Administrator determined that a reduction in the Neurosurgeons' use of bone morphogenetic protein ("BMP") would be clinically appropriate and in line with national data regarding the use of BMP. The Program Administrator established a floor to the reduction in use so that the Neurosurgeons would not share in any cost savings resulting in a decrease in BMP use lower than four percent of spinal fusion surgeries.
2. Product Standardization. The Neurosurgeons, in collaboration with the Hospital, considered various vendors and products and selected preferred products utilizing the following considerations: i) whether the products were clinically safe and effective; ii) whether the proposed standardization measures were clinically appropriate; and iii) the prices available to the Hospital. The Hospital and Group certified that none of the Neurosurgeons have an ownership interest in any of the products that were deemed to be preferred.

As part of the Proposed Arrangement, guidelines were developed to safeguard against reducing or limiting medically necessary services for patients. Stated differently, for both categories, the Neurosurgeons had the same devices and supplies available for spinal fusion surgeries performed while the Proposed Arrangement was in place as they did prior to the Proposed Arrangement. This framework ensured the economies gained through the Proposed Arrangement resulted from the clinical and fiscal value of using BMP on an as-needed basis or product standardization, rather than from limiting the availability of the products.

Additionally, Hospital, Subsidiary and Group developed an oversight committee to monitor the implementation and operation of the Proposed Arrangement. The oversight committee gathers data and analyzes changes in costs to spinal fusion surgery products and evaluates the utilization of resources for patients whose surgeries are subject to the Proposed Arrangement.

At the end of every year in the three-year period of the Proposed Arrangement, the cost savings will be calculated separately for each metric. The historical cost for each product will be calculated ("Base Year Cost"). The Base Year Cost will be calculated for the year prior to the current performance year and will be reset each year so that all savings from previous years will be excluded from the accounting. Next, the total cost for the applicable performance year will be calculated ("Performance Year Cost"). Then, the Performance Year Cost will be

compared to the Base Year Cost to determine the savings for the applicable performance year.

Once the total cost savings for the year has been calculated, the Hospital transfers half of the savings, less the Program Administrator's fee, to the Subsidiary, who then makes separate payments to the Group. The Group will then distribute the funds to the Neurosurgeons on a per capita basis pursuant to the Group's operating agreement.

## OIG ANALYSIS

### *Civil Monetary Penalties Law*

The CMP prohibits hospitals from directly or indirectly making payments to physicians in order to induce the physician to reduce or limit medically necessary services to Medicare and/or Medicaid beneficiaries under the physicians' care.

The CMP is implicated by the Proposed Arrangement as a result of the payments flowing from the Hospital to the Neurosurgeons. Because the parties certified that none of the metrics will reduce or limit medically necessary care for patients and includes appropriate safeguards, OIG determined that it would not impose sanctions on Hospital, Subsidiary, Group or Neurosurgeons as a result of the Proposed Arrangement's implication of the CMP. However, it is important to note that OIG would not opine on whether or not the specific metrics would only reduce services that were not medically necessary.

### *Anti-Kickback Statute*

The federal 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.

AKS implications are often a concern for arrangements similar to the Proposed Arrangement due to the fact that the cost-savings payments could actually be payments to induce or reward referrals. Although OIG acknowledged that gainsharing arrangements encourage physicians to refer to a particular hospital in order to receive a share of the reimbursement due to the safeguards implemented by the parties, OIG determined that it would not impose sanctions on Hospital, Subsidiary, Group or Neurosurgeons as a result of the Proposed Arrangement's implication of the AKS. Even though the Group retains a portion of the cost savings before disbursing the sum to the Neurosurgeons, this amount is only used for administrative expenses and thus would not influence referrals from the Group's non-participating physicians.

### *Safeguards*

In making its determinations regarding the Proposed Arrangement, OIG enumerated the many safeguards that the parties implemented in order to reduce the risk of the arrangement. The following safeguards were relied upon by OIG and should be implemented where possible in any similar arrangements.

- Recommendations for cost savings will not reduce or limit medically necessary care provided to patients.
- The implementation of the Proposed Arrangement and the corresponding cost savings will be monitored and documented in order to uphold quality of care standards and safeguard against inappropriate reductions in services.
- Neurosurgeons are prohibited from selecting patients to participate in the Proposed Arrangement, which reduces the risk of "cherry-picking" lower cost patients. The oversight committee also monitors patient data regarding age, case severity and payor. If the oversight committee determines that a Neurosurgeon is changing admitting practices, the Neurosurgeon may be removed from the Proposed Arrangement.
- Neurosurgeons must make determinations regarding the use of BMP on a case-by-case basis.
- Neurosurgeons must select the most appropriate device or supply for each patient.
- Neurosurgeons have the same devices and supplies available for patients as they did prior to the implementation of the Proposed Arrangement.
- Neurosurgeons reviewed FDA guidelines and medical literature when developing criteria for when to use BMP.
- Patients are provided with written notice of the Proposed Arrangement and the compensation structure between the Subsidiary and

Group upon the patient's admittance to the Hospital or prior to the patient's consent to surgery.

- Incentive payments will be distributed on a per capita basis.
- Savings are capped based on the number of spinal fusion surgeries performed by the Neurosurgeons in the relevant base year.
- The Payment made to the Group will not exceed 50 percent of the projected cost savings estimated by the Program Administrator at the beginning of the Proposed Arrangement term.
- Rebased on an annual basis prevents prior performance year savings from being calculated in multiple measurement periods.
- No neurosurgeons from other groups are eligible to participate in the Proposed Arrangement, which limits the risk that the Proposed Arrangement will influence surgeons to perform procedures at the Hospital.

Of note, OIG has opined on gainsharing arrangements in the past, including in Advisory Opinion 12-22, where a hospital paid a cardiology physician group based on certain quality and cost-savings metrics. In Advisory Opinion 12-22, OIG approved the arrangement due to the safeguards that were implemented into the arrangement's structure, many of which were similar to the safeguards addressed in the Proposed Arrangement.

## **PRACTICAL TAKEAWAYS**

Gainsharing arrangements, while popular among hospitals and physicians, are not without risk of violating the CMP and AKS. As such, it is imperative that any hospitals considering such arrangements consult with legal counsel in order to ensure that the arrangement is appropriately structured and does not incentivize the reduction or limitation of medically necessary services or induce or reward referrals. Hospitals and physicians should take care to ensure that appropriate safeguards are in place so that any potential gainsharing arrangements cannot be misconstrued as reducing medically necessary services or incentivizing referrals from physicians.

Additionally, supply chain departments capture significant amounts of data such as pricing, quantity and cost drivers in their everyday operations. Collaboration between hospital supply chain departments and physicians is a contemporary approach to achieve cost savings while maintaining or improving overall quality of patient care. In this value-based era, it is now more important than ever to re-examine current processes. Hospitals and physicians should assess their overall supply chain strategies as it relates to their patient care initiatives and consider consulting with legal counsel. Legal counsel is often in the best position to facilitate further discussions since they are familiar with and involved in both supply chain agreements and their associated risks as well physician service line strategies.

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

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