The Department of Health and Human Services Office of the Inspector General (OIG) has issued an Advisory Opinion (Opinion) in connection with a hospital’s gainsharing arrangement (Arrangement) with a designated group of neurosurgeons who perform spinal fusion surgeries at the hospital. According to the Opinion, the OIG would not impose sanctions because the Arrangement, when viewed in its entirety, is not designed or likely to induce the neurosurgeons to (i) reduce or limit medically necessary services to their Medicare or Medicaid patients, or (ii) increase referrals to the hospital. This Opinion is the latest in a line of earlier advisory opinions to “bless” gainsharing arrangements that meet certain criteria for minimizing the risk of fraud and abuse.

The Arrangement

Overview

The Arrangement is structured as a three-year program designed to compensate the neurosurgeons, through a subsidiary, with up to 50% of the cost savings attributable to their selection of certain products utilized in spinal infusion surgeries. In order to identify the cost saving measures, a Program Administrator collected and analyzed data on spinal fusion surgeries by tracking supply costs, quality of care, and utilization on a national level and comparing the findings to the hospital’s historical data. The Program Administrator, working with a Program Committee consisting of the neurosurgeons, who are part of a large, multi-specialty practice group (Group), the hospital and its subsidiary, identified 34 cost saving measures that fall into two categories:

- reducing the use of Bone Morphogenetic Protein (BMP), previously used in 29% of spinal fusion surgeries, to use in no lower than 4% of spinal fusion surgeries (to prevent incentive to curtail completely), and
- using preferred products (based on clinical effectiveness and cost) where medically appropriate.

Compensation

To calculate the cost savings achieved in any performance year, the Program Committee looks at the actual costs incurred for the spinal fusion surgeries and compares them to the costs incurred during the “base year,” which is the 12-month period immediately prior to the applicable performance year. Procedures over and above the number performed during the base year are excluded from the savings calculation. Once the base year and performance year costs are determined, the hospital pays 50% of the total performance year savings to the Group after deducting the Program Administrator’s fee. The sum of the payments for all three years is capped at 50% of the total potential savings estimated by the Program Administrator at the outset. The Group then distributes the payments to the neurosurgeons per-capita after withholding a percentage for administrative expenses pursuant to the Group’s operating agreement.

Safeguards

In order to maintain quality of care and protect against inappropriate service reductions, the Arrangement includes the following safeguards:

- The neurosurgeons’ determination as to whether BMP is clinically indicated is made on a patient-by-patient basis;
- The Program Administrator is responsible for ongoing monitoring of the change in costs and quality measures and reports to the Committee on a quarterly basis;
- To prevent cherry-picking, the neurosurgeons are not permitted to select the patients participating in, or remove patients from, the Arrangement, and the Program Committee reviews patient data to ensure the appropriate and non-discriminatory selection of patients;
- The Group must provide patients with written notice of the Arrangement and the compensation relationship, and the patient can review the Arrangement and learn the specific cost-saving measures if requested.
OIG Analysis

The OIG analyzed the Arrangement under the Gainsharing Civil Monetary Penalty provisions (the Gainsharing CMP) in Section 1128A(B)(1) of the Social Security Act and its exclusion authority under the federal Anti-Kickback Statute (AKS). The Gainsharing CMP prohibits a hospital from paying a physician to reduce or limit medically necessary services to Medicare or Medicaid beneficiaries, and the AKS prohibits remuneration to induce referrals of services reimbursable by a Federal healthcare program.

The OIG determined that although the Arrangement implicates both the Gainsharing CMP and the AKS, it would not impose sanctions on the parties to the Arrangement. In analyzing the Arrangement under the Gainsharing CMP, the OIG concluded that the ongoing monitoring, consistent documentation and the reasonable methodology used to calculate the savings achieved in each performance year, when taken together, reduce the risk that the compensation to the neurosurgeons function as an inducement to reduce or limit medically necessary services to their Medicare or Medicaid patients.

From an AKS perspective, the OIG highlighted the following features of the Arrangement as mitigating the risk of increased referrals to the hospital:

- The incentive payments are made to the Group and passed on to the neurosurgeons on a per capita basis, reducing the incentive for a single neurosurgeon to generate disproportionate cost savings;
- The potential savings are capped;
- The Program Committee collects and reviews data to confirm a historically consistent selection of patients such that any patient steering would be noticed;
- The savings calculations are re-baselined every year to prevent “double-dipping” for saving already realized;
- The potential cost savings were identified in advance, minimizing the risk of the parties manipulating the system to show false savings; and
- Only the Group’s neurosurgeons participate, reducing the likelihood of the hospital using the Arrangement to recruit additional neurosurgeons.

The Opinion is consistent with the most recent line of advisory opinions on hospital gainsharing arrangements, which were issued between 2001 and 2008. These earlier arrangements (many with cardiac surgeons, cardiologists and anesthesiologists - see HERE, HERE and HERE for examples), reflect similar templates in both their cost saving opportunities (e.g., product standardization, limiting the use of certain products or devices on a patient by patient basis, product substitution, etc.) and programmatic frameworks (e.g., ongoing monitoring, quality reviews, documentation, etc.). Likewise, in concluding that it would not impose sanctions under any of the gainsharing arrangements, the OIG appears to hone in on two components:

- The monitoring and documentation required to protect against inappropriate reduction of services and cherry picking, and which ensure continued quality care; and
- The reasonableness of the compensation and whether it is structured to protect against the inducement of referrals.

In following the rubric used in past advisory opinions, the Opinion is helpful to hospitals looking to craft their own gainsharing arrangement. However, the OIG’s continued tolerance of such arrangements is clearly contingent on having the appropriate safeguards in place. As the OIG points out in each advisory opinion, its favorable conclusion is limited solely to the facts as certified by the parties requesting the opinion, and does not address the propriety of the Arrangement under the Federal physician self-referral (“Stark”) law. It is therefore critical for hospitals to be thoughtful in developing gainsharing arrangements and be sure to find experienced counsel for guidance.

Authors

Ryan Cuthbertson

Nili S. Yolin, Member

Nili S. Yolin helps Mintz’s health care clients understand and navigate regulations to maximize business opportunities. Nili helps clients structure transactions, develop and implement compliance programs, and reduce liability risks.