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# OIG Provides Regulatory Considerations for Gainsharing Agreements in Advisory Opinion 17-09

***New guidance helps healthcare providers balance fraud and abuse risks with the cost savings that gainsharing offers.***

**Key Points**:

- Gainsharing arrangements allow providers, such as physicians and hospitals, to share in cost savings achieved from implementing quality improvements and achieving efficiencies.
- Regulatory authorities are primarily concerned with two regulatory risks associated with these programs: (1) improper incentives paid to physicians to refer patients to the hospital with which the physicians have a gainsharing arrangement, and (2) denial of medically necessary services.[1]
- The OIG Advisory Opinion No. 17-09[2] (AO 17-09) includes guardrails that can help providers mitigate these risks.

The federal government has been slow in providing a compliance pathway for providers to adopt gainsharing programs while avoiding regulatory landmines, despite the growing concern and public interest in controlling healthcare costs. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) was a critical development that cleared the way for gainsharing arrangements by limiting Civil Monetary Penalties (CMPs) to denial of "medically necessary" services. The first US Health & Human Services (HHS) Office of Inspector General (OIG) Advisory Opinion issued since MACRA, AO 17-09 highlights the importance of appropriately structuring gainsharing arrangements to reduce regulatory risk. This *Client Alert* provides a brief discussion of the historical context of gainsharing arrangements and the trends that have led to the current guidance, analyzes the OIG's most recent guidance on gainsharing arrangements in AO 17-09, and provides an overview of regulatory considerations for hospitals and physicians that are interested in setting up gainsharing arrangements.

## Gainsharing Arrangements

Gainsharing arrangements include a potentially wide range of arrangements in which healthcare providers (*e.g.*, physicians or a physician group and a medical center) agree to work together to reduce healthcare costs and then share in savings generated. While the OIG continues to express concern that gainsharing arrangements could result in a reduction of medical necessary care, it also recognizes that "appropriately structured gainsharing arrangements may offer significant benefits."[3] While gainsharing arrangements may differ in name[4] and structure, they generally aim to reduce healthcare expenses through adoption of clinical protocols and guidelines. These programs need to strike a careful balance to mitigate the potential regulatory risks that payments may induce physicians to refer patients to a hospital

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with which the physicians have a gainsharing arrangement, or to inappropriately choose products based on price rather than quality and patient needs.

### Overview of the Regulatory Laws Analyzed Under AO 17-09

Providers need to navigate the regulatory constraints imposed by the gainsharing CMP, Anti-Kickback Statute (AKS), and Physician Self-Referral Law (Stark Law). MACRA provided for more flexibility, allowing hospitals and physicians to partner to provide high-quality care while reducing or managing costs. Prior to MACRA, as evident in a 1999 Special Advisory Opinion on Gainsharing Agreements, the OIG took the position that the gainsharing CMP prohibited any physician incentive plan that induced the reduction of services, even if those services were medically unnecessary.[5] This historical view had a chilling effect on hospitals' and providers' appetites to develop innovative models to manage healthcare expenses. MACRA narrowed the gainsharing CMP prohibition to arrangements that would limit medically necessary services, signaling to hospitals that they could develop gainsharing arrangements that would appropriately improve care while managing costs. The current gainsharing CMP states that if a 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 federal healthcare program beneficiaries under the direct care of the physician, then the hospital and each physician who receives a payment are subject to CMPs.[6] AO 17-09 is a notable advisory opinion because it is the first advisory opinion issued on gainsharing arrangements since MACRA.

In addition to the gainsharing CMP, gainsharing arrangements must comply with the AKS and Stark Law, because gainsharing arrangements often involve payments to physicians for implementing cost-saving and quality measures. Providers need to be mindful of the AKS and the Stark Law when structuring these arrangements. While AO 17-09 addresses the AKS, it does not provide any guidance on the Stark Law, which is overseen by the Centers for Medicare and Medicaid Services (CMS).

## OIG AO 17-09

### The Arrangement

In the gainsharing arrangement the OIG examined in AO 17-09 (the Arrangement), a hospital (the Hospital) contracted with a multi-specialty physician group (the Group), in which all physicians are either shareholders or employees, and that includes four neurosurgeons. All of the Hospital's spinal fusion surgeries were provided by these Group neurosurgeons. The Hospital established a three-year gainsharing arrangement with the Group, and the arrangement is administered by a wholly owned subsidiary (the Subsidiary) of the Hospital. The Subsidiary coordinates with a program administrator (the Administrator) regarding the calculation of any incentive payments made under the agreement. The Administrator facilitated the formation of a committee (the Committee) that oversees the Arrangement. The Committee included representatives of the Subsidiary, Hospital, and the neurosurgeons as well as an advisory representative from the Administrator who worked to identify cost savings, including limiting the use of Bone Morphogenic Protein (BMP) and standardization of the default equipment and supplies used in the neurosurgeons' spinal fusion surgeries. Under the Arrangement, the Hospital pays the Administrator a fixed flat monthly fee that the Hospital, Administrator, Subsidiary, and Group certified as fair market value (FMV) for the services the Administrator provides, and which is not tied in any way to cost savings or to the compensation paid to the Group under the Arrangement. According to the Arrangement, the Subsidiary will pay the Group neurosurgeons half of the cost savings attributable to the neurosurgeons' implementation of the cost-saving measures.

### Development of Cost-Saving Measures

The Administrator analyzed data on the neurosurgeons' spinal fusion surgeries at the Hospital using internally developed software that tracked supply cost, quality of patient care, and national utilization levels. Based on its review of the data, cost-savings options were identified. The Hospital, Subsidiary, and Group reviewed and approved these options, which fall into the following two categories, for medical appropriateness.

- *BMP on an As-Needed Basis*: The neurosurgeons considered guidelines published by the US Food and Drug Administration (FDA) and conducted an evidence-based medical review of literature to develop clinical guidelines. Based on this review, the parties determined that BMP was appropriate when performed on three specific regions of the spine. The Administrator also analyzed national data regarding use of BMP, adjusted that data to the Hospital's patient population, and determined that it was reasonable to reduce the use of BMP to not less than 4% of Hospital patients. No payments will be made to the Group for reductions in BMP utilization below the 4% floor. The neurosurgeons had to adopt new clinical processes to carry out these recommendations.

- *Product Standardization*: Savings from standardization of devices and supplies used in surgery were also identified using a three-step process. The neurosurgeons and the Hospital evaluated vendors and products, and as a threshold question, the parties determined whether the products were clinically safe and effective. Next they determined if product standardization measures were clinically appropriate. Finally, from these safe, effective, and clinically appropriate products, the neurosurgeons selected products based on the prices available to the Hospital. Use of these preferred products, when medically appropriate, may require the neurosurgeons to undergo training or change clinical practice.

## OIG's Analysis of the Arrangement Under the Gainsharing CMP and AKS

The OIG's analysis of the Arrangement focused on the following topics.

- *Gainsharing*: The gainsharing CMP prohibits a hospital from knowingly making payments to a physician to induce the physician to reduce or limit medically necessary services to Medicare and Medicaid beneficiaries. This Arrangement implicates the gainsharing CMP because the Group received compensation based on reducing its use of BMP. A threshold question is whether the Arrangement induces the physicians to curtail medically necessary services, which is prohibited, or only medically unnecessary services. The OIG focused on the fact that the same selection of devices and supplies were available in the program, and that the physicians would continue to make patient-by-patient determinations as to what was the most appropriate device or supply. The OIG was careful not to opine on whether the processes in the Arrangement would reduce only medically unnecessary services but stated that the OIG considered the methodology, including the monitoring and documentation safeguards, to be reasonable. Ultimately, however, the OIG relied on the requestors' certification that no medically necessary services would be limited.

- *AKS*: The AKS prohibits the knowing and willful payment of any remuneration to induce or reward referrals of items or services reimbursable by a federal healthcare program. Because the Group was receiving payments to implement cost-saving measures, the OIG was concerned that the payments could induce the physicians to perform surgeries at the Hospital. The OIG stated it would not impose AKS penalties based on certain safeguards contained in the Arrangement.

- *Distribution Payments*: In particular, the OIG focused on per capita distributions of the savings to the neurosurgeons, as reducing the risk that the Arrangement would incentivize any particular neurosurgeon to generate disproportionate cost savings. The Arrangement also capped total shared

savings using a baseline number from the prior year of the Hospital's spinal fusion surgeries. The Arrangement also required a Committee to monitor the patient mix, ensuring that the payments are related to true savings achieved based on a similar patient mix historically served by the Hospital. While the OIG generally disfavors multi-year gainsharing arrangements because they can result in duplicate payments to physicians, the OIG viewed the Arrangement's annual baseline methodology, as reducing this risk and requiring the physicians to achieve more savings each year compared to the prior year in order to receive payments.

- *Evidence-Based Criteria*: As noted above, the neurosurgeons led the development of the program using evidence-based criteria that involved several stages. The program required changes to the neurosurgeons' clinical practice and training, which the OIG viewed as a reasonable basis for compensating the physicians during the term of the agreement. The OIG also found comfort in the evidence-based approach the parties took to find cost savings, and that each measure had a documented associated cost savings. The OIG viewed this approach as protection against "phantom savings."[7] As in its CMP analysis, the OIG highlighted the importance of preserving the physicians' judgment and that the physicians would continue to make patient-specific clinical decisions. The final consideration highlighted in the opinion was that only neurosurgeons in the existing Group that provided all of the Hospital's spinal fusion surgeries participated, which prevented the Hospital using the payments to attract new neurosurgeons and new business.

- *Monitoring and Transparency*: The OIG focused on the monitoring and documentation aspects of the Program as reducing potential fraud and abuse (F&A) risk, including tracking clinical quality measures, resource utilization, and patient/payor mix. Patients would also receive written notification of the program in advance to being admitted to the hospital, or to having the surgery.

## Considerations for Structuring Gainsharing Programs

Gainsharing programs should be carefully structured and implemented to reduce regulatory risks associated with these types of programs. When developing these programs, providers should keep in mind the following guidelines.

- *Clinical Evidence and Objective Criteria*: Any program should be developed using clinical data and evidence-based medical review of literature, including guidance published by the FDA and specialty societies. Physicians should review and approve any product standardization programs to ensure that all products are clinically safe and effective, and that measures are appropriate on the basis of clinical criteria.

- *Individualized Care*: Physicians must make patient-specific decisions as to whether a procedure is clinically indicated, and whether standardized equipment and supplies are medically appropriate for each patient.

- *Oversight and Monitoring*: An oversight committee can serve an important function in ensuring that the program maintains quality of care and does not result in a reduction or limitation of medically necessary services. The program should evaluate and maintain records of the cost savings the parties achieve, including tracking changes in cost, evaluating resource utilization, and documenting the quality of patient care and quality measures. Periodic monitoring of quality measures is critical.[8] In addition, patient severity, age, and payor mix should be reviewed to confirm a historically consistent selection of patients.[9]

- *Cost Saving Distributions*: Payments should be carefully structured to comply with the Stark Law and the AKS. Shared savings payments distributed to the neurosurgeons per capita reduce any incentive that may exist for physicians to directly increase their payments by performing more surgeries at the hospital or by more aggressively cutting costs. Cost savings should be calculated without regard to payor, to prevent discrimination against federal healthcare program beneficiaries, or gaming based on payor reimbursement rates. In addition, capping payments based on the number of procedures performed in the prior year can help reduce any incentive to increase utilization.

- *Duration and Rebasing*: The OIG has expressed concern regarding multi-year programs because such programs can inappropriately carry over savings from previous performance years, resulting in unearned duplicate payments. Incorporating an annual baseline methodology helps address this concern and reduces any risk that physicians could receive multiple payments for finding savings once.

- *Transparency*: Another important safeguard is providing patients with appropriate written disclosure about the program in advance of surgery. The disclosure should inform the patient of the physician's participation in the program and financial incentive of sharing in costs savings. Patients also should be given the opportunity to review the specific cost savings to be implemented in their surgeries.

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**Endnotes**

1 42 U.S.C. § 1320a–7a(b)(1).

2 OIG Advisory Opinion No. 17-09 (Jan. 5, 2018).

3 OIG Special Advisory Bulletin, "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries," (July 14, 1999).

4 OIG Advisory Opinion No. 12-22 (Jan. 7, 2013).

5 OIG Special Advisory Bulletin, "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries," (July 14, 1999).

6 42 U.S.C. § 1320a–7a(b)(3).

[7] OIG Advisory Opinion No. 17-09.

[8] OIG Advisory Opinion No. 17-09; OIG Advisory Opinion No. 12-22.

[9] *Id.*