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Healthcare fraud enforcement in federal programs

an interview with **Amy Berne**

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by Diana M. Fratto, Esq., Paulina M. Grabczak, Esq., and Gary W. Herschman, Esq.

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

- Providing patients with medically necessary care, determined on a patient-by-patient basis, is a primary focus in structuring gainsharing arrangements.
- Any proposed recommendations for physician behavior modifications must be medically appropriate and consistent with prevailing clinical standards.
- Ongoing monitoring and oversight of gainsharing arrangements is essential for transparency and mitigating risks.
- Gainsharing arrangements should include a mechanism for ensuring that payments are tied to actual, verifiable cost savings achieved, and physicians are not rewarded for prior achievements.
- Quality-of-care thresholds should be satisfied before providing physicians with any compensation relating to cost savings.

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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]

Fratto

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).

Grabczak

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.

Herschman

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]

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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.

In its legal analysis, OIG separately discussed important safeguards to protect against violations of the Gainsharing CMP and violations of the AKS.

OIG's legal analysis and determinations

In its legal analysis, OIG separately discussed important safeguards to protect against violations of the Gainsharing CMP and violations of the AKS. However, because there is some degree of overlap in the two categories of safeguards, it is crucial to blend both sets of safeguards in structuring a compliant gainsharing arrangement.

Interestingly, OIG declined to directly opine on whether the arrangement would reduce medically necessary services, but rather, it relied on the certifications made by the parties with respect to medical necessity. Further, OIG determined that the following features of the arrangement were all reasonable, including: (1) the methodology used to develop the cost-savings recommendations, (2) the monitoring and documentation safeguards implemented, and (3) the methodology used to calculate each performance year's savings. Thus, based on the certifications of the parties and the reasonableness of the

arrangement, OIG ultimately determined that it would not impose sanctions under the Gainsharing CMP.

Gainsharing CMP

Specifically, the arrangement contains key features for protecting against adverse effects on patient care and inappropriate reductions in clinical services.

Monitoring

Monitoring was handled by the program committee, which included the neurosurgeons, the medical center, the subsidiary, and a representative of the program administrator. The primary purpose was to confirm that the arrangement does not result in a reduction or limitation of medically necessary services. During the term of the arrangement, the program committee analyzed changes in costs and quality data and evaluated resource utilization. The program committee also monitored the neurosurgeons and was permitted to terminate neurosurgeons from the arrangement for breaches, such as not admitting "a historically consistent selection of patients" and materially violating clinical or administrative guidelines. Moreover, the neurosurgeons themselves were not permitted to enroll patients in or terminate patients from the arrangement in order to protect against selecting patients who were less costly or potentially driving away more costly patients.

Documentation

OIG determined that various documentation and notice measures were effective in maintaining the transparency of the arrangement. The parties provided written notice to patients of the arrangement (and the compensation relationship) and afforded patients an opportunity to learn how specific cost-savings measures impacted their own surgeries. The parties maintained detailed documentation regarding the nature and cost of services furnished under the arrangement.

Patient-Centeredness

The guidelines outlining the recommendations provided that the neurosurgeons must make a patient-by-patient determination of clinical appropriateness, and devices and supplies must be appropriate given a particular patient's needs. Further, although the goal of the arrangement was to streamline products and reduce costs associated with spinal surgeries, at no time would the neurosurgeons be restricted from using any products or taking any action that was clinically appropriate in a given surgery. Thus, clinical appropriateness is not viewed in terms of generalizations or what may be appropriate for most patients. Rather, it is a patient-by-patient determination that may not be restrained simply to achieve cost-savings.

Anti-Kickback Statute

With respect to AKS, OIG determined that the arrangement presents a sufficiently low risk that payments would be made in order to induce or reward referrals, because a variety of safeguards were in place.[4]

First, OIG noted that various safeguards reduce concerns that the arrangement worked to entice the neurosurgeons to increase referrals to the medical center. Specifically, OIG noted that: (1) the neurosurgeons were paid on a per capita basis; (2) savings were capped based on the number of surgeries performed by the neurosurgeons on federal program beneficiaries in the relevant base year; (3) the aggregate payment would not exceed 50% of the estimated cost savings calculated by the program administrator at the beginning of the term of the arrangement; and (4) patient data is reviewed

to confirm a historically consistent selection of patients.

Second, even though the physician group keeps a portion of the savings under the arrangement, OIG noted that the arrangement's structure would not induce referrals from the group's physicians who are not participating, because the retained portion must exclusively be used for the physician group's recruitment and administrative expenses. OIG cautioned that they may have reached a different conclusion if this money were not exclusively used for administrative expenses or "if the formula were not a pre-existing feature of the group's compensation structure."

Third, although this is a three-year arrangement, OIG's typical concerns regarding the potential for duplicate payments in multi-year arrangements were assuaged because the arrangement includes annual rebasing methods that protect against paying the neurosurgeons for previously earned savings in the prior performance year.

Fourth, for the BMP, there was an evidence-based medical review of relevant literature to develop the clinical guidelines. For the product standardization, an evaluation and review took place to determine that the products were effective and clinically safe.

Fifth, incentives are tied to actual, verifiable cost savings attributable to changes implemented during spinal surgeries.

Sixth, during the surgeries, the neurosurgeons have available to them all of the products they had prior to the arrangement, and the neurosurgeons make patient-by-patient determinations as to the most appropriate device or supply to use in a given case.

Lastly, no neurosurgeons from other physician groups were eligible to participate in the arrangement, which protects against the parties using the arrangement to attract physicians to the medical center.

Practical recommendations for hospital-physician gainsharing arrangements

Hospitals have long wondered about the permissible limits in offering physicians incentive compensation based on achieving quality and cost-savings measures. Advisory Opinion 17-09 is insightful in setting forth post-MACRA safeguards to ensure that the primary focus remains on providing the most clinically appropriate, medically necessary, and patient-centered care possible, despite any ancillary quality or cost goals the parties may have in mind. So long as these safeguards are present in an otherwise compliant gainsharing arrangement, there may be opportunities to create incentives in areas previously viewed as unfavorable, for example, creating medically appropriate length-of-stay incentives involving a patient-by-patient assessment and various other targeted safeguards to prevent any premature (improper) discharges.

As evidenced by OIG's gainsharing advisory opinions in prior years and in Advisory Opinion 17-09, the parties to any financial arrangement involving quality and cost-savings components must heed the various safeguards that were integral in OIG's conclusions that such arrangements would not violate the Gainsharing CMP and AKS.

The following is an overview of the key historical safeguards, including the safeguards highlighted in Advisory Opinion 17-09.

Quality-of-care safeguards

- A gainsharing arrangement should not adversely affect patient care, and there must be no inappropriate reduction or limitation in patient care or services.
- Physicians should have the flexibility to use the most cost-effective, clinically appropriate products.
- Medical necessity must be assessed on a patient-by-patient basis and documented by physicians in every case.

- Physicians and hospital personnel should work together to determine medically appropriate cost-savings opportunities that are consistent with national standards of care.
- Cost-savings opportunities must be tied to quality achievements and quality metrics.

Other safeguards

- Financial incentives must be reasonably limited in amount and duration.
- Avoid cherry picking patients, increasing referrals, or inappropriately accelerating patient discharges.
- Compensation must be fair market value for services provided.
- Compensation must not vary with the number of patients treated.
- Arrangements can't be used as incentives to refer business.
- There can be no rewards for prior achievements, and payments should be tied to actual, verifiable cost savings achieved.
- The arrangements should be transparent through notices to patients.
- The parties must make efforts to monitor the arrangement on an ongoing basis to protect against potential violations of law.
- Appropriate remedial actions should be taken in the event improprieties are discovered.

Conclusion

Although each gainsharing arrangement is unique, OIG's guidance is valuable in understanding the parameters in which gainsharing arrangements may operate as well as what types of safeguards can mitigate regulatory risks. Given Advisory Opinion 17-09, implementing robust safeguards around patient-centered care is undoubtedly a key element in structuring a compliant gainsharing arrangement.

1. HHS OIG: Advisory Opinion 17-09, January 5, 2018. Available at http://bit.ly/2Jk5IYC
2. 42 U.S.C 1320a-7a(b)(1)&(2) (Civil monetary penalties). Available at http://bit.ly/2HKYRdF
3. 42 USC § 1320a-7a et seq.
4. HHS OIG: Advisory Opinion 17-09, January 5, 2018. Available at http://bit.ly/2Jk5IYC

501 Ideas for Your Compliance and Ethics Program:

Lessons from 30 Years of Practice

Anyone working in the compliance field knows that the best ideas for building an effective program come from other compliance and ethics professionals. Author Joe Murphy has spent years not only collecting such ideas, but also using them and networking with others who use them.

He shares 501 of them here—ideas big and small—to help others find new ways to improve their compliance and ethics programs.

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