

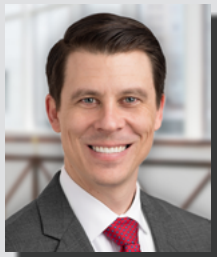
January 2018

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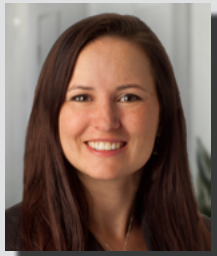
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## Gainsharing Guidance: Clarification on Cost-Savings Arrangements Between Hospitals and Physicians

by Paul Gomez, Gabriel Scott and Marissa Urban

The Office of Inspector General of the U.S. Department of Health and Human Services (OIG) recently posted its first advisory opinion interpreting a gainsharing arrangement – that is, a financial relationship under which providers share in cost-savings – since passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The opinion, Advisory Opinion 17-09 (the “Opinion”), marks the OIG’s first interpretation of the Civil Monetary Penalties Law (CMP) since MACRA amended the law to limit the prohibition on gainsharing arrangements to those involving reductions or limits in medically necessary services, as opposed to all services, including medically *unnecessary* services.

**The OIG concluded that it would not impose sanctions on the arrangement. The Opinion provides potentially valuable insight into how the OIG may address gainsharing arrangements going forward, which hospitals and providers may want to consider as many move into value-based and alternative payment arrangements, particularly arrangements including cost saving distributions.**

### The Arrangement

The Opinion, which was posted Jan. 8, addresses a gainsharing arrangement (the “Arrangement”) between a non-profit hospital (“Hospital”) and spinal surgeons (“Neurosurgeons”) in a multi-specialty physician practice (“Group”) under which Hospital pays Group a share of cost savings associated with adhering to guidelines on the proper use, and associated reduction in unnecessary use, of bone morphogenetic protein and the use of other standardized products during spinal fusion surgeries. To prevent reductions in medically necessary services, Group only shares in cost-savings tied to use reduction supported by appropriate clinical data and evidence. Group then distributes such amounts to Neurosurgeons on a per capita basis. In its advisory opinion request, Hospital certified that it instituted a number oversight measures to mitigate the potential risk of Neurosurgeons cherry-picking or steering certain patients, including establishing a Hospital committee, conducting periodic data reviews and requiring specific documentation and patient disclosure regarding the Arrangement.

A wholly-owned subsidiary of the Hospital will provide all administrative and managerial support for the Arrangement (“Subsidiary”) and will coordinate with a program administrator (“Program Administrator”) regarding calculation of any incentive payments to Neurosurgeons who participate in the Arrangement. The Subsidiary facilitates formation of the program committee (composed of representatives of the Subsidiary, Hospital and Program Administrator, as well as



the Neurosurgeons) that oversees the monitors the Arrangement (“Program Committee”). The Program Administrator is paid a fixed monthly fee by the Hospital for services rendered in support of the Arrangement which is not tied to cost savings or to the compensation paid to the Group under the Arrangement.

Under the Arrangement, cost-savings are calculated by comparing historic out-of-pocket costs incurred prior to each year of the Arrangement for each product (“Base Year”) to costs in the relevant Arrangement year.<sup>1</sup> In order to remove savings from the prior year, the Base Year is reset annually, so that the first year of the Arrangement becomes the base year for the second performance year, the second year of the Arrangement becomes the base year for the third performance year, and so on. Group receives fifty percent of cost-savings achieved. Hospital pays the Program Administrator a fixed monthly fee that is not tied to cost savings or compensation paid to Group under the Arrangement.

### OIG Guidance

**Gainsharing CMP** – The OIG notes that the Arrangement implicates the Gainsharing CMP given that Neurosurgeons are incentivized to potentially reduce or limit medically necessary services to Medicare and Medicaid patients. The OIG states that, although it cannot opine on whether the Arrangement will in fact limit or reduce medically necessary services, Hospital monitoring and associated reporting of cost, resource utilization, and quality of patient care reduces the risk of such unlawful reduction or limitation. The OIG also places emphasis on Hospital’s certification that use and product recommendations under the arrangement will not reduce or limit medically necessary services. Thus, the OIG states that it would not impose sanctions under the Gainsharing CMP based on the Arrangement.

**AKS** – The OIG also states that the Arrangement implicates the Anti-Kickback Statute (“AKS”) because remuneration flows indirectly from Hospital to Neurosurgeons under the Arrangement, and the OIG generally is concerned that payments under gainsharing arrangements are payments to induce or reward referrals. However, the OIG finds that the Arrangement contains a number of safeguards that mitigate Neurosurgeons incentive to increase referrals to Hospital, including:

1. Shared cost-saving amounts are capped based on the number of spinal fusion surgeries performed by Neurosurgeons on Federal health care program beneficiaries in the relevant Base Year and are distributed by Group to Neurosurgeons on a per capita basis, reducing the incentive for any particular neurosurgeon to generate disproportionate cost savings.

2. Cost-saving amounts considered in shared cost-saving amounts may not exceed fifty percent of projected cost savings estimated by Hospital at the beginning of the term of the Arrangement;
3. Patient severity, age, and payor will be monitored to ensure historically-consistent patient selection.
4. Shared cost-savings amounts retained by Group are calculated based on Group’s pre-existing compensation structure for all physicians and must be used exclusively for Group’s administrative and recruitment expenses, lowering the risk that Group could use such amounts to reward particular physicians for referrals.
5. Hospital annually rebases cost calculations to remove prior-year savings, preventing duplicate compensation for savings.
6. The Arrangement’s guidelines for use and product selection are based on U.S. Food and Drug Administration guidelines and Neurosurgeon evidence-based medical review to assure that product standardization recommendations were clinically safe and effective.
7. The arrangement ties Neurosurgeons’ incentives to actual, verifiable cost savings attributable to each recommendation implemented during spinal fusion surgeries, reducing the risk that false savings will be calculated to generate income for Neurosurgeons.
8. Neurosurgeons continue to make patient-by-patient determinations as to the most appropriate device or supply and the same devices and supplies available prior to the Arrangement remain available to Neurosurgeons, preserving Neurosurgeons’ ability to use the most clinically-appropriate product for their patient.
9. Only Group Neurosurgeons participate in the Arrangement, reducing the likelihood that Hospital uses the Arrangement to attract referral sources from competitor hospitals.

### New Considerations

The Arrangement includes a number of facts not addressed in prior gainsharing arrangements approved by the OIG:

- **First**, unlike previous gainsharing arrangements addressed in OIG Advisory Opinions, the Arrangement does not prohibit

<sup>1</sup> The Arrangement had a three-year term.





participants from increasing referrals to Hospital.<sup>2</sup> Rather, referral increases are capped at amounts in the relevant Base Year.

- **Second**, Hospital, Subsidiary, and Group are required to provide patients with written notice of the Arrangement and compensation relationship prior to the patient’s admission (unless not possible) and give patients an opportunity to review the Arrangement details, if desired. It is unclear whether this feature affected the OIG’s decision or would affect future decisions, given that the OIG did not specifically identify patient notice requirements in identifying factors that reduced the risk of fraud and abuse, and that the OIG has not addressed this factor in other advisory opinions (e.g., Advisory Opinion 12-22).
- **Third**, while the Opinion does not state that Hospital’s cost-saving opportunities specifically affect medically unnecessary items or services only, the OIG notes that the recommendations are reasonable and cited to Hospital’s certification. Thus, entities engaging in or considering gainsharing arrangements should consider whether (1) medically necessary items or services will be reduced or limited and whether the parties could certify that they will not, if necessary; and (2) safeguards to mitigate incentives to reduce or limit such services or reward referrals.

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<sup>2</sup> See Advisory Opinion 12-22 (in which a physician’s receipt of any part of the performance-based payment under the arrangement is conditioned upon the physician not increasing referrals to hospital). There are, however, several safeguards in place under the Arrangement to lower the risk that Neurosurgeons will be improperly incentivized to do so, as discussed above.

## Conclusion

The Opinion marks the first OIG guidance on gainsharing arrangements since MACRA amended the Gainsharing CMP in 2015. **It is unclear whether the industry can expect additional advisory opinions regarding gainsharing arrangements, particularly given the limited amount of advisory opinions issued by the OIG in the last year. Although limited to the Arrangement, the Opinion provides potentially valuable (and rare) guidance for entities engaging or looking to engage in gainsharing arrangements.**<sup>3</sup>

If you would like advice or counsel regarding the Opinion, gainsharing arrangements, or ideas presented in this article, please contact one of the authors of this e-alert or your Polsinelli attorney. To learn more about our Health Care Services practice, [click here](#).

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<sup>3</sup> As noted by the OIG, the Advisory Opinion does not address the Physician Self-Referral Law and potentially liability thereunder associated with remuneration under gainsharing arrangements, which industry players should also consider in structuring such arrangements.





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