

OIG Issues Favorable Advisory Opinion Addressing Gainsharing CMP Arrangement

January 22, 2018 – *Dorsey Health Law*
by Claire H. Topp and Nicole Burgmeier

On January 5, 2018, the Office of the Inspector General of the United States Department of Health and Human Services (“OIG”) released a favorable Advisory Opinion 17-09 that addresses Section 1128A(b)(1) of the Social Security Act (the “Gainsharing CMP”) and Section 1128B(b) of the Social Security Act (the “Anti-Kickback Statute”) with respect to a cost-reduction arrangement (the “Arrangement”) between a medical center (“Medical Center”) and designated surgeons. The Arrangement called for the Medical Center to share with the designated surgeons a percentage of the Medical Center’s cost savings as a result of the cost-reduction measures agreed to by the parties.

This advisory opinion is the first gainsharing advisory opinion issued since the passage of the Medicare Access and CHIP Reauthorization Act (“MACRA”) in 2015. MACRA clarified that the Gainsharing CMP was only violated if the payment to the physician is for the purpose of reducing *medically necessary* services. However, the clarification under MACRA does not appear to have changed the OIG’s analysis significantly. Gainsharing arrangements have long been considered suspicious by the OIG; although numerous gainsharing arrangements had been reviewed in OIG Advisory Opinions, and have been found to contain enough mitigating factors to not warrant sanctions. The OIG has analyzed these arrangements under the Gainsharing CMP and the Anti-kickback Statute, and has expressed concern that gainsharing arrangements could result in: (i) stinting on patient care; (ii) cherry picking healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments to induce patient referrals; and (iv) unfair competition among hospitals that offer incentive compensation programs in order to foster physician loyalty to attract more referrals. This advisory opinion joins the list of previous advisory opinions in which the OIG has analyzed detailed facts and circumstances about a proposed gainsharing arrangement with physicians, and has approved the arrangement because it included certain criteria for minimizing the risk of fraud and abuse. Advisory Opinion 17-09 is helpful to hospitals and physicians that are interesting in entering into gainsharing arrangements because it provides recent insight into the OIG’s perspective on the important factors to include in these arrangements.

Related People

- Claire H. Topp

Related Capabilities

- Healthcare & Life Sciences
- Healthcare Transactions & Regulations
- Healthcare Litigation
- Medical Devices

The Gainsharing CMP prohibits a hospital from knowingly making payments, directly or indirectly, to a physician to induce the physician to reduce or limit medically necessary services to Medicare and Medicaid beneficiaries who are under the physician's direct care. The Anti-Kickback Statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program.

Here, Advisory Opinion 17-09 addresses an Arrangement between a Medical Center and spine surgeons ("Neurosurgeons") who are part of a larger multi-specialty physician group ("Group"). In order to participate in the Arrangement, physicians have to be in the Group and be a Neurosurgeon. In total, four physicians were identified as eligible for participation in the Arrangement. All of the Neurosurgeons have medical staff privileges at the Medical Center and all of the Medical Center's spinal surgeries are performed by the Neurosurgeons.

In an effort to reduce costs, a subsidiary of the Medical Center (the "Program Administrator") conducted a historical practices study of spinal fusion surgeries performed by the Neurosurgeons and identified 34 cost-saving opportunities; including things such as using product standardization. Under the Arrangement, the Medical Center will pay the Neurosurgeons a share of the three-years of cost-savings attributed to the changes the Neurosurgeons make when selecting products to use during the spinal fusion surgeries, among other cost-savings measures. The payment will be distributed to the Neurosurgeons on a per capita basis and the amount allocated to each Neurosurgeon will be subject to a long-standing, pre-existing provision in the Group's operating agreement that requires the Group to withhold a percentage of collections earned by all physicians for their personally performed services to fund the Group's administrative and recruitment expenses. The Arrangement includes safeguards such as monitoring and documentation requirements, which are intended to maintain quality of care and protect against inappropriate reduction in services to patients. The parties certified that the cost-savings recommendations will not reduce or limit medically necessary services for patients.

Anti-Kickback Analysis:

In reaching a favorable opinion, the OIG specifically noted the following safeguards are present in the Arrangement which limit the risk under the Anti-Kickback Statute that the payments to the Neurosurgeons would induce or reward referrals or attract referring physicians:

(1) the payment of the cost savings on a per capita (as opposed to an individual) basis reduces the risk the Arrangement creates for any one Neurosurgeon to generate disproportionate cost savings;

(2) the potential savings are capped based on the number of spinal fusion surgeries performed by the Neurosurgeons on Federal health care program beneficiaries in the relevant base year, thus limiting the Neurosurgeons' incentives to increase their referrals

to the Medical Center;

(3) the aggregate payment to the Neurosurgeons will not exceed 50 percent of the projected cost savings estimated at the beginning of the term of the Arrangement, which reduces the risk of incentivizing referrals;

(4) the Program Administrator collects and reviews data on patient severity, age, and payor of the spinal surgeries to confirm historically consistent selection of patients, to prevent data-skewing based on selecting healthier patients;

(5) the group of Neurosurgeons retains the portion of the savings, rather than the individual physicians, and the amount retained must be used exclusively for the group's long-standing formula set forth in their governance documents related to payment of administrative and recruitment expenses, which reduces the risk of inducing or rewarding referrals from non-participating physicians or any particular physician;

(6) an annual rebasing method removes savings from prior years and ensures that the performance year savings are calculated only as compared to the most recent base year therefore preventing improper duplicate payments that could constitute unlawful kickbacks;

(7) evidence-based medical reviews were completed in order to establish clinical guidelines and evaluations related to the recommended cost-saving measures. Following these reviews, the Requester certified that the recommendations may require additional training for the Neurosurgeons, or changes in their clinical practices/processes, which provided support for the compensation to the Neurosurgeons;

(8) the Arrangement ties the incentives to the actual, verifiable cost savings attributable to each recommendation implemented during spinal fusion surgeries, which creates transparency that reduces the risk of the Medical Center accounts being manipulated to "game the system";

(9) Neurosurgeons continue to make patient-by-patient determinations as to the most appropriate device or supply and continue to have access to the same selection of devices and supplies that they had prior to the Arrangement; and

(10) no neurosurgeons from other physician groups participate in the Arrangement, thus the risk is reduced that the Medical Center would use the Arrangement to attract others from competitor hospitals to perform surgeries at the Medical Center.

Gainsharing CMP:

With respect to its analysis of the Arrangement under the Gainsharing CMP, the OIG stated that it relied on the truthfulness of the Requestor's certification that none of the cost-saving recommendations in the Arrangement will reduce or limit medically necessary services for patients, and that the Program Administrator monitors any changes in cost, resource utilization or quality of patient care; and reports quarterly to a

Program Oversight Committee, which is comprised of representatives from the Medical Center, an administrative subsidiary of the Medical Center, the Program Administrator and the Neurosurgeons. The OIG would not opine on whether the recommended cost-saving measures would reduce only non-medically necessary services, but the OIG did evaluate the Requestor's methodology for developing the recommendations, monitoring safeguards and calculating the savings, and the OIG concluded the methodology was reasonable. The OIG concluded that together, the reasonableness of the methodology and the certifications from the Requestor reduced the risk appropriately that the payments to the Neurosurgeons would limit/reduce medically necessary services to Medicare and Medicaid patients.

For more information about gainsharing arrangements, contact your Dorsey & Whitney attorney.