

Health Law Alert: Favorable OIG Advisory Opinion and Recent Increase in Civil Monetary Penalties Impact Fraud and Abuse Enforcement

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The first several months of 2018 have seen no shortage of developments in the world of health care enforcement. One positive development comes in the form of Advisory Opinion 17-09 from the Office of Inspector General (OIG). This opinion approved a gainsharing arrangement between a multi-specialty physician group (the "Group") and a hospital (the "Hospital"). At the same time, however, providers are facing even larger financial penalties for fraud and abuse. This is due to the Bipartisan Budget Act of 2018 (BBA), which significantly increased civil monetary penalties for health care fraud. The BBA also amended the federal Ethics in Patient Referrals Act (aka the "Stark Law") to include in the statute several changes made by the Centers for Medicare and Medicaid Services (CMS) to the Stark Law regulations in 2016. This is a positive development for providers because it means that liberalization of certain Stark Law exceptions are now included in the statute and therefore cannot easily be changed, including how to document agreements "in writing," satisfy signature requirements, and how to "holdover" certain arrangements that have expired.

I. Favorable OIG Advisory Opinion Concerning a Gainsharing Arrangement

The Arrangement

Advisory Opinion 17-09 involved a cost-reduction arrangement between the Hospital and four neurosurgeons (the "Neurosurgeons") who belong to the Group (the "Arrangement"). The Hospital wanted to pay the Neurosurgeons a share of three years of cost savings attributable to changes the Neurosurgeons make when selecting and using products during spinal fusion surgeries.

The parties identified numerous opportunities to save costs, which fell into two categories: (1) use of bone morphogenetic protein (BMP) on an as-needed basis; and (2) product standardization. The Neurosurgeons would share in any savings that result from reducing the use of BMP; but would not receive any shared savings that result from reducing the use of BMP beyond a specified level. In addition, the Neurosurgeons would receive savings that result from product standardization.

"Shared savings" or "gainsharing" arrangements implicate the section of the Social Security Act that prohibits payments to reduce medically necessary services (often referred to as the "Gainsharing CMP") and the Anti-Kickback Statute (AKS). 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 or Medicaid beneficiaries who are under the physician's direct care. The AKS 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.

General Features of the Arrangement that Provided Helpful Safeguards

In approving the Arrangement, the OIG highlighted several features that the agency felt reduced risks under the Gainsharing CMP and AKS:

1. An oversight committee (the "Program Committee") would monitor documentation and reporting requirements for the entire time the Arrangement is in operation (three years) to ensure the Neurosurgeons do not reduce any medically necessary services.
2. The Neurosurgeons would disclose the Arrangement to patients in advance. The patient must be given an opportunity to review the details of the Arrangement and to learn the specific cost-saving measures applicable to his or her surgery.
3. The Neurosurgeons must make a patient-by-patient determination as to which device to use and whether BMP is warranted.
4. The Hospital would not restrict the availability of products; rather, the Neurosurgeons have the same devices and supplies available for the spinal fusion surgeries they will perform as they had prior to the Arrangement.

Safeguards Specific to the Gainsharing CMP

In addition to these general features, the OIG recognized three key features of the Arrangement that, when taken together, reduced the risk of violating the Gainsharing CMP:



1. The parties certified that none of the recommendations would reduce or limit medically necessary services;
2. The program administrator would continually monitor and report quarterly to the Program Committee regarding any changes in cost, resource utilization and quality of patient care; and
3. The methodology used to develop the cost-saving recommendations, monitoring and documentation safeguards, and calculation of each performance year's savings appeared reasonable to the OIG.

Safeguards Specific to the AKS

Because the savings from cost reduction would be shared with the Group and Neurosurgeons, the OIG analyzed whether payments would incentivize referrals to the Hospital. The OIG concluded that a number of factors suggested that there was little risk of this happening. These included:

1. The payments would be dispersed to the Neurosurgeons on a per capita basis, reducing the incentive for any particular Neurosurgeon to generate disproportionate cost savings.
2. The amount the Neurosurgeons can make is capped each year by the number of procedures that was performed in the baseline year.
3. The parties certified they would not earn more than fifty percent of the projected cost-savings.
4. The Program Committee collects and reviews patient data to prevent cherry-picking of healthier patients.
5. The Group (rather than individual physicians) retains a percentage of the cost-savings. Importantly, pursuant to the Group's pre-existing compensation structure, the savings must be used exclusively for the Group's administrative and recruitment expenses, reducing the risk that it would be used to reward particular physicians.

6. The annual rebasing process removes any savings from prior years and ensures the performance year savings are calculated only as compared to the most recent year.
7. The individualized nature of each cost-saving opportunity reduced the risk that the parties may manipulate the data and create "phantom savings."

OIG advisory opinions of course do not address the Stark Law. Given how closely the OIG and CMS work together, however, it is unlikely that OIG would have approved of the Arrangement if CMS thought that it presented significant Stark Law concerns.

II. Bipartisan Budget Act Increases Civil Monetary Penalties for Health Care Fraud and Amends Stark Law

Congress passed the BBA on February 9, 2018, which increased both monetary and criminal penalties for fraud and abuse violations. Many penalties were doubled and others were increased even more. Notably, Congress increased the financial penalty for violating the AKS from \$25,000 per violation to \$100,000 per violation, and increased the maximum prison sentence from five years to 10 years. Congress also increased the civil monetary penalty for illegal gainsharing arrangements from \$2,000 to \$5,000 per patient. Violations of the beneficiary anti-inducement prohibition will now result in penalties of \$20,000 (as opposed to \$10,000).

The BBA also amended the Stark Law to add to the statute certain changes made by CMS to the Stark Law regulations in 2016. These changes include allowing the "writing" requirement necessary to meet many Stark Law compensation exceptions to be satisfied through any means established by HHS, including a "collection of documents" and through "contemporaneous documents evidencing the course of conduct of the parties involved." Prior to the regulatory change in 2016, many providers faced challenges in documenting their financial relationship in one formal contract. Other changes made to the Stark Law by the BBA include:

- The statute now provides that the Stark Law's signature requirement needed to meet many exceptions can be satisfied by obtaining signatures within 90 consecutive calendar days after the arrangement became noncompliant (as long as the other requirements of the exception are met).
- Expired equipment and space leases and personal service arrangements can continue as long as the holdover arrangement is on the same terms as the preceding arrangement.



Although these changes were already in the regulations, adding them to the statute is helpful for providers because it makes it much more difficult for CMS to change these rules in the future. This is because CMS cannot change the statute itself.

If you are interested in learning more about the top ten enforcement trends for 2018, and how these developments could impact your organization, please join the Gray Plant Mooty Health Law Team for a roundtable breakfast and webinar on April 12. Attorneys Jesse Berg and Julia Reiland will provide an overview of recent enforcement efforts by the Department of Justice, Office for Civil Rights, and OIG.

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