OIG Approves Two Existing Gainsharing Arrangements Related To Cardiac Surgery and Anesthesiology Services

The U.S. Department of Health and Human Services Office of Inspector General ("OIG") has issued two new favorable gainsharing advisory opinions – OIG Advisory Opinion Nos. 07-21 and 07-22, available on the OIG website at http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-21A.pdf and http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-22A.pdf. These opinions raise the number of favorable gainsharing advisory opinions issued by the OIG to 10, an indication that gainsharing continues to be a viable option for hospitals looking to reduce costs and align their economic incentives with physicians. Similar to previously issued opinions, Advisory Opinion 07-21 approves a gainsharing arrangement between a hospital and a group of cardiac surgeons. Advisory Opinion 07-22 approves a gainsharing arrangement between a hospital and a group of anesthesiologists for services provided during cardiac surgical procedures, signaling the OIG’s willingness to approve gainsharing outside of cardiac surgery and cardiology specialties.

Gainsharing is a term that is used to describe arrangements between hospitals and physicians whereby the hospital agrees to share with the physicians any reduction in the hospital’s costs for patient care attributable in part to the efforts of the physician. Typically, these payments are structured in a variety of ways, including hourly payments for services performed by the physician or as a percentage of the cost savings realized under the arrangement. While gainsharing has gained increasing acceptance in the past years, the road traveled has not been an easy one.

Background on Gainsharing

Historically, the OIG has been extremely suspicious of gainsharing programs. In 1999, the OIG issued a Special Advisory Bulletin outlining its concerns with generalized gainsharing (payments tied to overall cost savings rather than payments tied to specific, identifiable cost savings) and took the position that gainsharing arrangements between hospitals and physicians violated current federal law. Specifically, the OIG said that gainsharing violated the civil monetary penalty ("CMP") provision that prohibits a hospital from paying a physician to induce reductions or limitations of patient care services to Medicare or Medicaid beneficiaries under the physician’s direct care. Additionally, the OIG noted that gainsharing arrangements

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1  OIG Special Advisory Bulletin: Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries (July 1999), available on the OIG website at: http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm.
2  42 U.S.C. § 1320a-7a(b)(1) and (2).
may also raise concerns under the federal anti-kickback law. The 1999 OIG issuance was viewed by many as signaling the end to gainsharing. Nevertheless, in 2001, gainsharing was given new life when the OIG approved the first of many gainsharing programs under the OIG advisory opinion process. In the advisory opinion, the OIG, consistent with its historical position on gainsharing, stated that while gainsharing violates the CMP, the OIG would exercise its discretion not to seek administrative sanctions against the requestors of the opinion. In addition, the OIG stated that the arrangement contained sufficient safeguards to pose a low risk of fraud or abuse under the anti-kickback statute. Since the issuance of the 2001 opinion, the OIG has approved nine additional gainsharing programs, bringing the total number of OIG-approved gainsharing programs to 10.

Beyond these OIG issuances, gainsharing has garnered attention in a number of other ways. In 2004, the Centers for Medicare and Medicaid Services (“CMS”) approved a gainsharing demonstration project (the “Hospital Performance-Based Incentives Demonstration”), developed by the New Jersey Hospital Association, that would have permitted the eight New Jersey hospital participants to make incentive payments to physicians as rewards for providing high quality and efficient care. However, a federal court permanently enjoined CMS from pursuing the project when three New Jersey hospitals not chosen to participate in the project brought suit seeking to expand the project to other state hospitals and doctors. Since then, the Medicare Payment Advisory Commission (“MedPAC”) has recommended that gainsharing be made legal. Specifically, in its March 2005 report to Congress on physician-owned specialty hospitals, MedPAC urged Congress to grant the Secretary of Health and Human Services the authority to allow gainsharing arrangements between physicians and hospitals and to regulate such arrangements with respect to concerns about quality of care and physician referrals. Along similar lines, the Joint Commission has issued principles for the construct of pay for performance initiatives that are yet another tool being implemented to improve health care quality and patient safety.

Despite the fate of its 2004 gainsharing demonstration, CMS has initiated two new gainsharing demonstration projects over the past three years. One of these projects, the “DRA 5007 Medicare Hospital Gainsharing Demonstration,” responds to a mandate in the Deficit Reduction Act of 2005 to study whether gainsharing can improve quality and efficiency of inpatient care and also improve hospital operational and financial performance. This project, which is currently ongoing, is designed to review the short-term impact of gainsharing programs in six hospitals nationwide (including two rural hospitals). In addition, the Medicare Modernization Act (“MMA”) authorized a CMS demonstration project, the “MMA Section 646 Physician

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3 42 U.S.C. § 1320a-7b(b).

4 MedPAC, Physician-Owned Specialty Hospitals (March 2005), available at http://www.medpac.gov/documents/Mar05_SpecHospitals.pdf. In explaining its recommendation, MedPAC indicated that, “Gainsharing could capture some of the incentives that are animating the move to physician-owned specialty hospitals while minimizing some of the concerns that direct physician ownership raises. Permitting gainsharing opportunities and lessening the current inaccuracies in the Medicare payment system will provide an alternative to starting physician-owned specialty hospitals. At the same time, these actions should maintain incentives for improved hospital performance.” Id. at ix.

5 The Joint Commission is an independent, not-for-profit organization that evaluates and accredits health care organizations and programs in the United States. The Joint Commission is the nation's predominant standards-setting and accrediting body in health care.

6 For more information, see http://www.jointcommission.org/PublicPolicy/pay.htm.

7 For more information, see http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/Itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=3&sortOrder=ascending&itemID=1186805&intNumPerPage=10.
Hospital Collaboration Demonstration. This project is open to up to 72 hospitals nationwide (including consortia of health care groups — with a maximum of 12 hospitals per consortium) and is designed to assess quality improvements and cost reductions in health delivery systems by tracking patients long term for entire episodes of care.

Following on these efforts by CMS and MedPAC to reconsider the potential benefits of gainsharing, the OIG has recently issued two new advisory opinions that treat gainsharing arrangements favorably. While similar to what we have seen before from the OIG and following the same model as previously approved gainsharing programs, the newly issued opinions do provide some new features and additional insight into the OIG’s analysis of gainsharing arrangements. Significantly, the two opinions are for “existing” arrangements rather than “proposed” arrangements. Under OIG authority, the OIG is permitted to issue an advisory opinion for an existing arrangement or a proposed arrangement that the requestors in good faith intend to undertake. All of the prior OIG-approved gainsharing arrangements were proposed — meaning the programs could not begin until the OIG advisory opinion process was complete and a favorable opinion was issued. In the recent opinions, the requestors implemented the gainsharing arrangements and began performing the specific changes in the operating room practices prior to requesting an opinion from the OIG. The hospital withheld any payments under the arrangement, however, pending the outcome of the advisory opinion request. While the OIG ultimately approved and issued favorable opinions, the OIG makes clear in the opinions that “nonpayment of amounts owed pursuant to a contractual agreement does not, by itself, absolve parties from liability under the fraud and abuse laws,” a statement that should not be taken lightly by anyone involved in the development and implementation of gainsharing arrangements.

Advisory Opinion 07-21

Advisory Opinion 07-21 approves a one-year gainsharing arrangement between a hospital and a group of cardiac surgeons, whereby the group would share a maximum of 50 percent of the hospital’s savings arising from the surgeons’ implementation of specific cost-saving measures. The analysis of this arrangement is consistent with the previously approved gainsharing opinions and focuses heavily on the quality of care safeguards present in the arrangement, including the data utilized by the program administrator in designing, implementing and monitoring the gainsharing program. The approved cost-savings measures fall within the following categories:

- Use as Needed — Disposable Cell Saver Components and Supplies: the surgeons agreed to open the disposable cell saver component only when needed (the patient experiences excessive bleeding) and the surgeons agreed to use specific surgical supplies on an as-needed basis, which included limiting the use of Aprotinin and eliminating the use of both vancomycin and triple antibiotic ointment where medically appropriate;

- Product Substitution: the surgeons agreed to substitute less costly items for those currently being used by the surgeons which include substitutions deemed to have no appreciable clinical significance.

8 For more information, see http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=none&filterByDID=-9&sortByDID=3&sortOrder=ascending&itemID=1186653&intNumPerPage=10.

9 42 C.F.R. § 1008.11.
(elbow pads, wrist splints, or skin staplers) and other items such as pharmacy items and supplies that may have had an appreciable clinical significance with all items and supplies remaining available to the surgeons;

- Product Standardization: the surgeons agreed to standardize specific cardiac devices and supplies where medically appropriate with all devices and supplies remaining available to the surgeons.

**Advisory Opinion 07-22**

As noted above, Advisory Opinion 07-22 approves a one-year gainsharing arrangement between a hospital and an anesthesiology group, expanding gainsharing into a new medical specialty — anesthesiology services provided during cardiac surgery. Under the arrangement, the group would share a maximum of 50 percent of the hospital’s savings arising from the anesthesiologists' implementation of specific cost-saving measures. Advisory Opinion 07-22 provides similar analysis to the previously approved cardiology and cardiac surgery opinions and focuses heavily on the quality of care safeguards present in the arrangement, including the data utilized by the program administrator in designing, implementing and monitoring the gainsharing program. The approved cost-saving measures fall within the following categories:

- Use as Needed: the anesthesiologists agreed to eliminate the routine use of a specific drug and a brain function monitoring device where medically appropriate with the drug and monitoring device remaining available to the anesthesiologists;

- Product Substitution: the anesthesiologists agreed to utilize less costly items, specifically the use of a specific catheter and the substitution of a less expensive nasogastric tube with both items remaining available to the anesthesiologists; and

- Product Standardization: the anesthesiologists agreed to standardize the use of certain fluid warming hot lines where medically appropriate with all fluid warming hot lines remaining available to the anesthesiologists.

While the cost-saving measures fall generally within the same categories previously approved by the OIG, Advisory Opinion 07-22 represents a willingness by the OIG to extend gainsharing to other practice areas. Such expansion provides hospitals, physicians and counsel additional means by which to address escalating cost and quality of care issues.

**Conclusion**

While the OIG’s continued willingness to approve gainsharing arrangements and expand into new specialties is promising, caution is still warranted. The OIG’s analysis of each approved program is highly fact-specific and should not be viewed as an overarching approval of gainsharing. In addition, the OIG opinions do not analyze the gainsharing arrangements for compliance with the physician self-referral law (“Stark”), which falls under the purview of CMS. Unfortunately, whether and how gainsharing programs comply with Stark remains an open issue. Nevertheless, with the initiation of the CMS demonstration projects, the support from MedPAC, the OIG’s continued willingness to approve gainsharing arrangements through the OIG advisory opinion process, and the current focus on initiatives aimed at improving quality of care and patient safety, gainsharing continues to gain momentum.
If you have any questions or would like additional information, please contact your Alston & Bird attorney or a member of our Health Care Group.

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