TO: HEALTH CARE CLIENTS
DATE: March 17, 2005
RE: Recent Developments Regarding Hospital-Physician “Gainsharing”

I. INTRODUCTION

The Office of Inspector General (the “OIG”) of the U.S. Department of Health and Human Services (“HHS”) recently issued a series of six favorable Advisory Opinions (the “Advisory Opinions”) relating to so-called “gainsharing” arrangements between hospitals and physicians.1 In addition, in its March 2005 report on physician-owned specialty hospitals, the Medicare Payment Advisory Commission (“MedPAC”) recommended that Congress grant the Secretary of HHS the authority to allow certain gainsharing arrangements.2 These developments are likely to restore the interest of hospitals and physicians in exploring gainsharing arrangements, which was stifled when the OIG issued a 1999 Special Advisory Bulletin warning that gainsharing arrangements could violate various federal laws.

This Client Memorandum provides background information and a summary of previous guidance issued by the OIG concerning gainsharing arrangements; discusses the recent Advisory Opinions, including the specific facts and analysis they contain, the safeguards identified by the OIG to support its decision not to impose sanctions on these arrangements; and describes MedPAC’s recent recommendations to Congress concerning gainsharing. In general, although these developments signal increasing recognition of the potential benefits of properly-structured gainsharing arrangements, we

1 The six advisory opinions are designated Advisory Opinions 05-01 through 05-06, and are available through the OIG website at: http://oig.hhs.gov/fraud/advisoryopinions/opinions.html.

recommend a careful and cautious approach to any new gainsharing arrangements since the OIG has explicitly said that significant elements of the arrangements covered by the Advisory Opinions would violate federal law in the absence of a favorable advisory opinion applicable to the parties involved.

II. BACKGROUND

A. General

Gainsharing is a term used to refer to a variety of financial arrangements between physicians and hospitals to encourage physicians to deliver care in a more cost-effective manner. Under the Medicare hospital inpatient and outpatient reimbursement systems and many managed care and commercial insurance payment arrangements, hospitals are at risk for the costs of the care that they provide to patients. For some hospital services, physician behavior, including the protocols followed by a physician when performing a procedure and a physician’s selection of supplies and devices, can significantly affect hospital costs in treating the physician’s patients. However, physicians often do not have the same incentives to reduce hospital costs, since they are typically separately reimbursed for their professional services under Medicare and other payment systems. By offering physicians a portion of the hospital’s costs savings in exchange for implementing cost-saving strategies, gainsharing arrangements are designed to encourage physicians to alter their behavior so as to help contain hospital costs.

The OIG has acknowledged that appropriately structured gainsharing arrangements may offer significant benefits where there is no adverse affect on the quality of care provided to patients. Nevertheless, many gainsharing arrangements do violate the plain language of the Civil Monetary Penalty statute,3 which prohibits any hospital or critical access hospital from knowingly making a payment directly or indirectly to a physician as an inducement to reduce or limit services to Medicare or Medicaid beneficiaries (the “CMP”). The CMP imposes civil money penalties of up to $2,000 per patient on hospitals that make and physicians who receive such payments.

Gainsharing arrangements may also implicate the federal anti-kickback statute, which makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by any federal health care program.4 In addition, absent an

3  Sections 1128A(b)(1) & (2) of the Social Security Act, 42 U.S.C. § 1320a-7a(b)(1) & (2).
4  Section 1128B of the Social Security Act, 42 U.S.C. § 1320a-7b(b).
applicable exception, the federal Stark Law\(^5\) can prohibit referrals from physicians to hospitals involved in a gainsharing arrangement if the arrangement creates a financial relationship between the hospital and the physicians. Finally, gainsharing arrangements can raise issues of private benefit or inurement for hospitals that are exempt from federal income taxation.

In the Advisory Opinions, the OIG stated that the proposed gainsharing arrangements would violate the CMP and would potentially violate the anti-kickback statute. However, the OIG concluded that it would not impose sanctions on the requestors under either law. Although the OIG reiterated its concerns regarding the potential adverse affects of gainsharing on patient care and its potential for disguising payments for referrals, it permitted the hospitals and physicians to enter into the carefully structured cost-sharing arrangements proposed by the requestors. The Advisory Opinions do not address the Stark Law or federal tax exemption issues.

B. 1999 Special Advisory Bulletin

On July 8, 1999, the OIG issued a Special Advisory Bulletin (the “Bulletin”) in which it concluded that many gainsharing arrangements between hospitals and physicians clearly violate the CMP.\(^6\) In the Bulletin, the OIG acknowledged hospitals’ legitimate interest in enlisting physicians to help eliminate unnecessary hospital costs, but concluded that it had no authority under current law to allow such gainsharing arrangements.\(^7\) The OIG observed that this statutory proscription is “very broad,” and that it can be violated even where a payment is not tied to an actual diminution in care. Additionally, according to the OIG, the CMP will be violated even where a payment is not made with respect to a specific patient, and where the payment does not reduce medically necessary care.


\(^6\) See also January 2005 Supplemental Compliance Program Guidance for Hospitals, available on the OIG website at [http://www.oig.hhs.gov/fraud/complianceguidance.html](http://www.oig.hhs.gov/fraud/complianceguidance.html) (noting that gainsharing arrangements violate the CMP and can implicate the anti-kickback statute); Robert Wood Johnson Univ. Hosp. v. Thompson, 2004 U.S. Dist. LEXIS 8498 (D.N.J. 2004) (holding that an HHS Demonstration Project in gainsharing violated the CMP and that the Secretary of HHS should have required the participants to secure Advisory Opinions to assure forbearance from sanctions).

\(^7\) The text of the guidance is available on the OIG Internet home page ([http://www.hhs.gov/progorg/oig/frdalrt/gainsh.htm](http://www.hhs.gov/progorg/oig/frdalrt/gainsh.htm)), and in the Federal Register (64 Fed. Reg. 37985 (July 14, 1999)). Our Client Memorandum entitled, “OIG Issues Special Advisory Bulletin on Hospital-Physician ‘Gainsharing’” is available on the Reed Smith website, [www.reedsmith.com](http://www.reedsmith.com).
Rather than issue separate advisory opinions regarding specific factual scenarios, the OIG at that time elected to issue a broad and general pronouncement that all gainsharing programs in which hospitals share cost savings with physicians are prohibited. The OIG also encouraged the expeditious termination of all gainsharing programs following the publication of the Bulletin in the Federal Register. In justifying the decision not to analyze individual gainsharing programs through the advisory opinion process, the OIG stated that (1) gainsharing arrangements involved a high risk of abuse; (2) gainsharing arrangements would require ongoing oversight that was not available through the advisory opinion process; and (3) case-by-case determinations on gainsharing programs would be an inadequate substitute for comprehensive regulation in this area. However, notwithstanding the statutory proscription and the definitive statements in the Bulletin, the OIG did acknowledge that some gainsharing arrangements could be implemented without violating the CMP. Moreover, the OIG approved a gainsharing arrangement in Advisory Opinion 01-1, issued just one year later.

III. RECENT OIG ADVISORY OPINIONS

A. Description of Gainsharing Arrangements

The Advisory Opinions evaluate proposed gainsharing arrangements between hospitals and physician groups that implicate the CMP. Since the facts of these opinions are virtually identical, we will summarize the common facts here, and highlight the differences in more detail below.

Each of the Advisory Opinions involves a hospital that participates in the Medicare and Medicaid programs (the “Hospital”), and a physician group (either a Cardiac Surgeon Group or a Cardiology Group) with active medical staff privileges at the Hospital (the “Physician Group”). In each of the Advisory Opinions, the Hospital proposed to share with the Physician Group a percentage of the Hospital’s cost savings arising from the Physician Group’s implementation of a number of specified cost reduction measures. In each case, a Program Administrator engaged by the Hospital conducted a study of the past practices at the Hospital’s cardiac surgery department or cardiac catheterization laboratory. Each study resulted in several recommended cost saving actions—summarized in a “Practice Patterns Report”—in cardiac surgery or cardiac catheterization laboratory practices to curb the inappropriate use

8. The Program Administrator was paid a monthly fixed fee that the Requestors of the Advisory Opinions certified was a fair market value in an arm’s-length transaction. The monthly fee was not tied in any way to the cost savings.
or waste of medical supplies. The recommendations addressed in each Advisory Opinion fall into the following categories:

- **Open as Needed.** Several recommended actions involved opening *only as needed* certain packaged items potentially useful during a surgical procedure. Specifically, the recommendations in Advisory Opinions 05-01, 05-03 and 05-06 included opening surgical tray supplies only as needed, and the recommendations in each of Advisory Opinions 05-01 and 05-03 involved not opening disposable components of the cell saver unit until a patient experiences excessive bleeding. According to the requestors, the resulting delay in opening surgical tray items and cell saver readiness would not adversely affect patient care.

- **Use as Needed.** The recommended actions in this category relate to the use of certain devices only on an “as needed” basis. For example, Advisory Opinions 05-01 and 05-03 involved the performance of blood matching by the Cardiac Surgeons only as needed, and Advisory Opinions 05-02, 05-04 and 05-05 involved the use of certain vascular closure devices by the Cardiologists only as needed. The OIG stated that the “use as needed” recommendations are similar in many ways to the “open as needed” recommendations. In each case, the requestors certified that the use as needed recommendations would not adversely affect patient care.

- **Product Substitution.** Some recommendations consisted of the substitution of less costly items for the items currently being used by the physicians in connection with surgical or cardiac catheterization laboratory procedures. For example, in Advisory Opinion 05-03, the product substitutions included items such as slush drapes, wrist splints, armboards, aortic punches, and suture boots used by Cardiac Surgeons, and in Advisory Opinion 05-04, the product substitutions involved contrast agents used by Cardiologists. In several of the Advisory Opinions, the OIG stated that the identified substitutions would have no appreciable clinical significance.

- **Product Standardization.** This category consists of product standardization of certain cardiac devices where medically appropriate. For example, the Practice Patterns Report in Advisory Opinion 05-02 and 05-04 recommended product standardization of cardiac catheterization devices, such as stents, balloons, interventional guidewires and catheters, vascular closure devices, diagnostic devices, pacemakers, and defibrillators used by Cardiologists, and the Practice Patterns Report in Advisory Opinion 05-03 recommended product standardization of certain cardiac heart valves used by Cardiac Surgeons. In each case, the Physician Group would work with the Hospital to evaluate and clinically review vendors and products. Additionally, the Physician Group would agree to use the selected products, where medically appropriate, which may require additional training or changes in clinical practice.

All six proposed gainsharing arrangements contained the same safeguards to protect against inappropriate reductions in services. With respect to the cell saver “open as needed” recommendation and the “use as needed” and the product substitution recommendations, the proposed arrangements would utilize objective historical and clinical measures to establish a “floor” beyond which no savings
would accrue to the Physician Group. Moreover, with respect to the product standardization recommendations for certain devices, the requestors certified that the individual physicians/surgeons would make a patient-by-patient determination of the most appropriate device and the full range of devices would still be available for patient use.

All six arrangements specify that the Hospital would pay the Physician Group 50% of the cost savings attributable to the specific recommendations for a period of one year. In order to determine the payments to the Physician Group, each arrangement subtracts the actual costs incurred for the items specified in the recommendations when used by the physicians/surgeons during procedures (the “current year costs”) from the historic costs for the same items when used during comparable surgical procedures in the base year (the “base year costs”). The payment to the Physician Group would be 50% of the difference, if any, between the adjusted current year costs and the base year costs. Each Physician Group, in turn, would distribute its profits on a per capita basis to each of its member physicians.

Finally, each of the proposed gainsharing arrangements would be subject to the following limitations:

- No additional sharing of cost savings would accrue if the volume of procedures payable by a federal health care program in the year covered by the gainsharing program exceeds the volume of procedures payable by a federal health care program in the base year.

- To minimize the financial incentives to steer more costly patients to other hospitals, a committee would monitor the case severity, ages and payors of the patient population, and could terminate a surgeon from participation in the arrangements for significant changes from historical measures.

- The aggregate payment to the Physician Group will not exceed 50% of the projected cost savings identified in the study.

In addition to these safeguards, the Hospital and the Physician Group would disclose the arrangement to the patient. The written disclosure would be made to the patient before Hospital admission, or before the patient consents to the surgical or medical procedure. Patients also would have an opportunity to review the details of the arrangement, including the specific cost savings measures applicable to the patient’s procedure.

For example, in Advisory Opinion 05-01, the cell saver units were set up and available in 100% of the procedures but ultimately only used in 30% of the cases. Thus, 30% was set as the floor beyond which the Physician Group would receive no share of any hospital cost savings.
B. Analysis

1. Applicability of the CMP to Specific Recommendations

The OIG concluded that most, but not all, of the recommendations identified above implicate the CMP since they involve a payment to a physician as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries. Specifically, the OIG concluded that the “open as needed” recommendations regarding surgical tray items do not implicate the CMP because the time it takes to open a package of readily available supplies would create no perceptible reduction or limitation in the provision of items or services to patients. Similarly, with regard to the product substitution recommendations, the OIG determined that if the product to be substituted had no appreciable clinical significance, then the CMP is not violated. For example, in Advisory Opinions 05-03 and 05-06, the OIG concluded that the substitution of wrist splints, armboards, aortic punches, suture boots, head supports, blankets, etc., would have no appreciable clinical significance and therefore would not run afoul of the CMP.

In contrast, the OIG concluded that the “open as needed” recommendation regarding the cell saver units violate the CMP. The OIG reasoned that because the cell saver units must be attached to a machine and that the machine must be started up, the additional delay beyond merely opening a package would trigger the CMP. In addition, the OIG also found that all of the “use as needed” recommendations, some of the product substitution recommendations and all of the product standardization recommendations violate the CMP. Similar to the recommendations regarding the cell saver units, the OIG presumably believes that these recommendations would constitute an inappropriate inducement to reduce or limit services provided to beneficiaries at the Hospital.

2. Safeguards in Approved Gainsharing Arrangements

Despite their violation of the CMP, the OIG stated that it would exercise its discretion not to impose sanctions under the CMP because sufficient safeguards were included in all of the proposed arrangements. In general, the OIG stated that it would not impose sanctions on the requestors because the proposed gainsharing arrangements included the following:

- The specific cost-saving actions and resulting savings are clearly and separately identified, permitting public scrutiny and individual physician accountability.
- The requestors presented credible data to support their contention that the specific cost-saving actions would not adversely affect patient care.
- The payments under the arrangements are based on all surgeries or medical procedures regardless of the patients’ insurance coverage, and are subject to a cap on payment for federal health care programs. In addition, the procedures to which the arrangement applies are not disproportionately performed on federal health care program beneficiaries.
Objective historical and clinical measures establish the baseline thresholds ("floors") to protect against inappropriate reductions in service. No savings will accrue to the physicians beyond these thresholds.

Patients will not experience inappropriate reductions in services, since physicians and surgeons will still have available the same selection of cardiac devices after implementation of the proposed arrangement as before.

Patients receive written disclosure of the arrangement which “offer some protection against possible abuses of patient trust.”

The financial incentives are limited in duration and amount.

The Physician Groups distribute profits to their members on a per capita basis, which mitigates any incentive for an individual physician or surgeon to generate disproportionate cost savings.

The OIG stated that the Advisory Opinions at issue here are markedly different from the gainsharing plans that were the subject of the OIG’s warning in the Special Advisory Bulletin. In particular, the OIG noted that the factual scenarios addressed in the Advisory Opinions set out specific actions to be taken and tie the remuneration to actual, verifiable cost savings attributable to those actions. The features of these arrangements, and their safeguards, provide useful guidance for the structuring of other hospital-physician gainsharing agreements without sanction under the CMP.

By contrast, the OIG also identified features of gainsharing plans that would heighten the risk that payments will lead to inappropriate reductions or limitations of services. In particular, the OIG identified the following elements as potentially raising concern if present:

- No demonstrable direct connection between individual actions and any reduction in the hospital’s out-of-pocket costs (and any corresponding gainsharing payment).
- No specific identification of the individual cost saving actions.
- Insufficient safeguards against the risk that other unidentified actions, such as premature hospital discharges, might actually account for any “savings.”
- Questionable validity and statistical significance of quality of care indicators.
- No independent verification of cost savings, quality of care indicators, or other essential aspects of the arrangement.

3. Applicability of Anti-Kickback Statute to Specific Recommendations

The OIG also stated that the proposed gainsharing arrangements can implicate the federal anti-kickback statute. The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by any federal health care program. The OIG noted that the proposed gainsharing arrangements would not
qualify for safe harbor protection under the anti-kickback statute. In particular, the personal services and management contracts safe harbor would not apply because the aggregate compensation to the Physician Groups would not be set in advance since the payments are paid on a percentage basis.

The OIG expressed concern that the gainsharing arrangements could be used to disguise remuneration from the Hospital to reward or induce referrals by the Physician Group. The Physician Group could potentially admit federal health care program patients to the Hospital to receive both their professional fee and a share of the Hospital’s payment, depending on cost savings. Although the OIG indicated that these arrangements could result in illegal remuneration if the requisite intent to induce referrals were present, the OIG stated that it would not impose sanctions because of the existence of the following safeguards that reduce the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians:

- Limitation of participation in the arrangement to surgeons/physicians already on the Hospital’s medical staff, thus limiting the likelihood that the arrangement would attract other physicians.
- Capping the potential savings to be derived from procedures for federal health care program beneficiaries.
- Limiting the contract term to one year to reduce any incentive to switch facilities.
- Monitoring admissions for changes in severity, age, or payor.
- Lack of risk that the arrangement will be used to reward other physicians who refer patients to the Physician Group or its physicians/surgeons, because the Physician Group is the sole participant and is composed entirely of cardiologists/cardiac surgeons.
- Setting out with specificity the actions that will generate the cost savings on which payments will be based.
- Limitation of the amount, duration, and scope of the payments to the Physician Group.

IV. **MedPAC GAINSHARING RECOMMENDATION**

The March 2005 MedPAC Report to Congress on Physician-Owned Specialty Hospitals recommended allowing certain gainsharing arrangements between physicians and hospitals. Specifically, MedPAC recommended that Congress grant the Secretary of HHS the authority to allow gainsharing arrangements between physicians and hospitals and to regulate those arrangements to protect the quality of care and minimize financial incentives that could affect physician referrals. MedPAC’s recommendation was based on its belief that gainsharing arrangements have the potential to encourage physician and hospital cooperation to lower costs and improve care.
However, like the OIG, MedPAC believes that gainsharing arrangements should contain a number of safeguards to ensure that cost-saving measures do not reduce quality or inappropriately influence physician referrals. In the Report, MedPAC discussed a recent OIG Advisory Opinion that contained a number of safeguards to protect the quality of care and minimize incentives that could affect physician referral patterns. Some of these key features noted approvingly by MedPAC are: clearly identified, specific actions that would produce cost savings, such as curbing the use of inappropriate supplies; plan transparency and disclosure of its elements to patients to promote physician accountability and deter abusive behavior; periodic quality reviews by an independent agent; the creation of set thresholds beyond which savings could not accrue to physicians; and the limited scope and duration of the plan.

MedPAC recommended that the Secretary consult with physicians, hospitals, and beneficiaries to determine whether these arrangements would be feasible from a quality perspective. In addition, MedPAC commented that the Secretary may want to develop model arrangements, or create another safe harbor to the anti-kickback statute, that incorporate all or some of the safeguards noted above. Gainsharing arrangements that meet any such safe harbor would be protected from prosecution under the CMP provision and the anti-kickback statute.

V. CONCLUSION

The recently-issued Advisory Opinions suggest that it is now possible for hospitals and physicians to pursue certain limited types of gainsharing arrangements. While these programs may implicate the CMP and the federal anti-kickback statute, the OIG now appears willing to authorize gainsharing agreements.

Significantly, however, the Advisory Opinions conclude that many elements of the proposed gainsharing arrangements would violate the CMP and would potentially violate the anti-kickback statute. Since the Advisory Opinions protect only requesting party(s), they do not provide legal protection for others, and any hospital or physician group that is contemplating a gainsharing arrangement should proceed cautiously and consider seeking an advisory opinion for any gainsharing arrangement that it wants to implement.

In any event, any gainsharing arrangements should be narrowly structured for legitimate business and medical purposes, and should incorporate, to the extent appropriate, the safeguards identified by the OIG in the Advisory Opinions.
Finally, because of the limited scope of the OIG’s advisory opinion authority, the Advisory Opinions did not address the application of the Stark Law or the prohibitions on private inurement by tax-exempt hospital organizations. These laws comprise additional legal constraints on gainsharing which should also be evaluated by hospital and/or physician counsel before proceeding.

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