



Vol. 20 No. 27

July 1, 2005

“GAINSHARING” ARRANGEMENTS PRESENT CHALLENGING ISSUES FOR POLICYMAKERS & PARTICIPANTS

by

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Pressure to allow broader gainsharing is growing throughout the hospital and physician communities and is spreading to Washington, D.C. Last year, a gainsharing demonstration project sponsored by the Center for Medicare and Medicaid Services (CMS) was progressing in New Jersey until a federal court blocked it. In February 2005, the Department of Health and Human Services Office of the Inspector General (OIG) issued six advisory opinions permitting limited cardiology gainsharing arrangements. See *OIG Advisory Opinions 01-01, 05-01, 05-02, 05-03, 05-04, 05-05, and 05-06*. In March 2005, the Medicare Payment Advisory Commission (MedPAC) recommended that Congress approve broader gainsharing.¹ On May 11, 2005, Senators Charles Grassley and Max Baucus introduced legislation to eliminate legal obstacles to broader gainsharing or “coordinated care incentive arrangements.” *Hospital Fair Competition Act of 2005*, S. 1002, 109th Cong. (2005).

This LEGAL BACKGROUNDER explains what constitutes gainsharing and why the hospital and physician communities are pushing to expand gainsharing. Next, it explores the legal obstacles to gainsharing and how the government might address these obstacles. Finally, it considers whether broader gainsharing will accomplish its intended goals — namely, improving quality of care and reducing costs — and how the law of unintended consequences may play into the debate.

Background. As the saying goes, “when you’ve seen one gainsharing arrangement, you’ve seen one gainsharing arrangement.” In fact, gainsharing covers a range of financial arrangements between hospitals and physicians designed to encourage physicians to use more cost-effective methods while improving the quality of care provided in hospitals. Typically, gainsharing involves payments from a hospital to a physician for designing and/or implementing programs to improve the quality of care and to control hospital costs. The payments can take a number of forms, from hourly payments for tasks completed by physicians to a percentage of the cost savings generated by the program.

¹One of the recommendations in the MedPAC report on specialty hospitals was to permit gainsharing arrangements. While MedPAC recognized the value of aligning the financial incentives of physicians and hospitals, it warned that physician ownership of hospitals fully aligns such incentives, which raises concerns about self-referrals. MedPAC proposed gainsharing as an alternative to physician ownership of hospitals. Ultimately, MedPAC concluded that “[s]tructured properly, gainsharing arrangements could garner the benefits of aligning incentives while allaying legitimate concerns.”

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Traditionally, physicians decide what care should be provided to patients in hospitals, and the hospitals must provide such care. Under the Medicare prospective payment systems, hospitals are reimbursed fixed amounts depending on patients' diagnoses without taking into account the hospitals' actual costs. Physicians are reimbursed separately based on fee schedules for the services they provide. Consequently, most physicians have little interest in minimizing hospital costs and certainly no financial incentive to do so.

Interest in gainsharing first developed in the late 1990s. However, in July 1999, the OIG issued a Special Advisory Bulletin taking the position that gainsharing between hospitals and physicians violated federal law. OIG, Special Advisory Bulletin, *Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries* (July 1999) reprinted in 64 Fed. Reg. 37,985 (July 14, 1999). Specifically, the OIG concluded that hospitals sharing cost savings with physicians violated the civil monetary penalty prohibition on hospitals making payments to physicians to induce reductions or limitations in services to Medicare or Medicaid beneficiaries under the physicians' direct care. 42 U.S.C. § 1320a-7a(b)(1) & (2) (the CMP). In fact, the OIG stated that it could not provide "any regulatory relief absent further authorizing legislation." The OIG also cautioned that gainsharing potentially raises concerns under the anti-kickback law. 42 U.S.C. § 1320a-7b(b).

In January 2001, the OIG retreated somewhat from the position it took in the Special Advisory Bulletin. Specifically, the OIG issued an advisory opinion permitting limited gainsharing. OIG Advisory Opinion 01-01. In February 2005, the OIG issued six more favorable gainsharing advisory opinions. While these advisory opinions suggest a possible renaissance in gainsharing, caution is still warranted given that the OIG found that virtually all of the elements of these gainsharing arrangements implicated federal law.

Legal Obstacles to Gainsharing. Gainsharing arrangements must be analyzed carefully under three separate federal laws — the civil monetary penalty law, the anti-kickback law, and the Stark physician self-referral law, 42 U.S.C. § 1395nn. The obstacles raised under each law are explored below.

Civil Monetary Penalty Law. The CMP imposes civil monetary penalties "if a hospital . . . knowingly makes a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided with respect to [Medicare and Medicaid patients] . . . who are under the direct care of the physician." 42 U.S.C. § 1320a-7a(b)(1) & (2).

In the Special Advisory Bulletin, the OIG concluded that gainsharing arrangements that involve paying physicians a percentage of the hospitals' cost savings violate the CMP. The CMP provision has been broadly interpreted to mean that the payments do not have to be tied to an actual diminution in care, as long as the hospital knows that the payments may influence the physicians, directly or indirectly, to reduce or limit the provision of clinical services. The OIG has pointed out in recent gainsharing advisory opinions that the CMP is violated even if the care that is reduced or limited is medically unnecessary. Thus, any change in current hospital procedures for which a physician is compensated by the hospital may violate the CMP.

In the advisory opinions, the OIG found sufficient safeguards so that sanctions need not be imposed. The specific safeguards were as follows:

- **Identified Cost Saving.** Specific cost-saving actions and resulting savings were clearly and separately identified to allow public scrutiny and individual physician accountability.
- **Credible Medical Support.** Credible medical support existed for the position that the cost savings recommendations would not adversely affect patient care. In addition, periodic reviews of any impact on clinical care would be conducted.
- **Limited Impact on Federal Health Care Programs.** Payments would be based on all surgeries regardless of payor. Additionally, federal health care program procedures would be subject to a cap which would limit any disproportionate impact on federal health care program beneficiaries. Cost savings would be based on actual, out-of-pocket acquisition costs.
- **Protections against Inappropriate Reductions in Service.** Baseline thresholds would be established through the use of objective measures to protect against inappropriate reductions in services.

- **Savings from Inherent Clinical and Fiscal Value.** Savings from product standardization would be obtained from “inherent clinical and fiscal value.” Individual physicians would continue to have access to the same selection of devices.
- **Patient Disclosure.** The hospital and the physician groups would provide patients with written disclosures about the arrangements.
- **Limits on Incentives.** Financial incentives would be reasonably limited in duration and amount.
- **Protections against Disproportionate Cost Savings.** The physician groups distribute profits, and thus, any gainsharing payments, on a per capita basis, which should limit any incentive for individual physicians to generate disproportionate cost savings.

In the advisory opinions, the OIG found that certain recommendations did not implicate the CMP. Specifically, the OIG found that opening packaged items or substituting less costly items would have no appreciable clinical significance and thus would not implicate the CMP. The OIG’s finding that certain cost savings recommendations would not have an appreciable clinical significance suggests that hospitals may have greater flexibility in implementing gainsharing arrangements that focus on such savings. Nevertheless, the ability to operate gainsharing arrangements under the CMP remains fairly narrow.

The Grassley/Baucus legislation would address the CMP issue by mandating that the OIG develop regulations. Without clear legislative guidance, the OIG may end up with regulations similar to the factors identified in the recent advisory opinions. Proponents of gainsharing may find such an approach to be too narrow.

Anti-kickback Law. The anti-kickback law generally prohibits the provision of any remuneration in exchange for past or future referrals of patients or business reimbursed under any federal health care program. 42 U.S.C. § 1320a-7b(b). The law is a “two-way street,” meaning that it is just as illegal to *solicit* or *accept* payments for referrals, as it is to *offer* or *make* such payments. In analyzing the implications of gainsharing under the anti-kickback law, the OIG warned that gainsharing could be used to disguise illegal remuneration from hospitals by encouraging physicians to admit more federal health care program beneficiaries to such hospitals.

Despite the risk of illegal remuneration, the OIG declined to impose administrative sanctions in the advisory opinions based on certain aspects of the gainsharing arrangements that the OIG felt reduced the risk.

- The circumstances and safeguards associated with the gainsharing arrangements reduce the likelihood that the arrangements would be used to attract referring physicians or to increase referrals from existing physicians: (1) the arrangements are limited to physicians on the medical staffs of the hospitals; (2) savings derived from procedures for federal health care program beneficiaries are capped based on the prior year’s admissions; and (3) the arrangements are limited to one year.
- The structure of the proposed arrangements eliminates the risk that they would be used to reward non-surgeons for referring patients to the surgeon groups. Profits within the groups are distributed on a per capita basis, which minimizes any incentive for an individual physician to inappropriately reduce services to achieve savings.
- The arrangements describe the particular actions that would generate the cost savings on which the payments are based. The physicians may have some increased malpractice liability risk from making the cost-saving changes for which it is reasonable to compensate them. Payments are limited in amount, duration, and scope.

Those wishing to pursue gainsharing in the face of the anti-kickback law might argue that hospitals involved in such a practice have no intent to induce referrals (the government must prove intent in anti-kickback cases). One difficulty with such an approach is the risk, at least in those Circuits that have adopted a “one-purpose test,”² that a court would find that while gainsharing is primarily designed to improve the quality of care and reduce costs, another purpose of such arrangements is to induce referrals. The

²Some federal courts have interpreted the anti-kickback law as covering any arrangement where one purpose of the remuneration was to obtain money for the referral of past services or to induce future referrals. *See United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir.), *cert. denied*, 474 U.S. 988 (1985).

Grassley/Baucus legislation would create a statutory exception for gainsharing arrangements that satisfy the CMP regulations.

Stark Physician Self-Referral Law. The federal Stark physician self-referral law generally prohibits a physician from making referrals to an entity for any of eleven (11) designated health services if the physician (or an immediate family member) has a “financial relationship” with the entity. The “financial relationship” may be either (i) an ownership or investment interest or (ii) a compensation arrangement. Unless a financial relationship qualifies for an exception, the referral and submission of claims for services provided to a Medicare or Medicaid beneficiary pursuant to the referral is prohibited. Gainsharing generally implicates the Stark law as it involves hospital-physician financial relationships where the physicians make referrals to the hospitals for designated health services, namely inpatient and outpatient hospital services. Nevertheless, there has been virtually no guidance from CMS on gainsharing under the Stark law to date.³

The Stark law exceptions that are most likely to apply to gainsharing are the personal services, fair market value, and indirect compensation exceptions. The applicability of the personal services and fair market value exceptions seem to require that the physicians provide identifiable services for which they may be compensated at fair market value rates. The difficulty with this approach is that it focuses on paying physicians for their efforts rather than for the results. Under many gainsharing models, physicians do not provide identifiable services, but rather follow protocols or use items that generate savings for the hospitals.

The indirect compensation exception may also apply to gainsharing. The difficulty with relying on this exception is that it ultimately may only provide a partial solution. Among others, physicians who are in solo practices will not qualify for protection under the indirect compensation exception. The Grassley/Baucus legislation includes an exception to the Stark law for gainsharing arrangements that satisfy the CMP regulations.

Future of Gainsharing. The goals of gainsharing are simple in theory — improve the quality of care in hospitals while reducing the costs of such care. However, these simple goals have proven elusive to the health care industry. For example, high technology supply costs have increased dramatically in the past several years. Aligning the financial incentives of hospitals and physicians could possibly improve the bargaining position of hospitals with respect to certain vendors in the short term. Depending on the solution fashioned by Congress and/or the Administration, it may be difficult to sustain any benefits derived from gainsharing over the long term.

Key issues include how long hospitals will be permitted to share savings with physicians and how those savings will be calculated. The recent advisory opinions were limited to one year, and the OIG cautioned that the baselines upon which the savings were calculated would have to be updated if the gainsharing was to extend beyond one year. Thus, any payments beyond one year would have to reflect new savings. While one year may seem short, some time limit would seem appropriate to prevent hospitals from paying physicians in perpetuity for changes in hospital practices.

Health care providers should carefully consider whether, and how, to pursue gainsharing in light of the relatively narrow scope of permissible gainsharing under the advisory opinions and existing law. If Congress or the Administration chooses to step in and permit the broader use of gainsharing, there are a number of difficult issues that need to be addressed for gainsharing to have long-term viability.

³Based on a comment in the preamble to the Stark regulations, an argument can be made that gainsharing is not permitted outside the managed care context. Specifically, the preamble states: “To the extent that a payment gives a physician an incentive to reduce the volume or value of [designated health services], it must be a qualified physician incentive plan payment under the personal service arrangements exception or fit in the prepaid plans or risk-sharing arrangements exceptions.” 69 Fed. Reg. 16054, 16088 (Mar. 26, 2004). It seems unlikely that such a brief comment would be viewed as reflecting CMS’s position on gainsharing.