Early last year, the Office of Inspector General of the Department of Health and Human Services issued six advisory opinions approving hospital-physician gainsharing arrangements—arrangements between a hospital and physicians under which the hospital proposes to pay the physicians a share of any reductions in the hospital’s costs that are attributable in part to the physicians’ efforts. These advisory opinions are significant because they represent a relaxation of the OIG’s prior position of an absolute bar on such gainsharing arrangements. The opinions have contributed to the revival of the national debate on these types of arrangements.

Rationale and Background

Gainsharing between employers and employees in some form has existed for many years in various industries, and for a time, hospitals also were exploring this option. Hospitals found gainsharing arrangements with physicians attractive because, in addition to promoting physician loyalty, they provide an opportunity to align the disparate economic interests of hospitals and physicians. Under Medicare, hospitals are reimbursed on a fixed-fee basis without regard to their actual costs, while physicians are separately reimbursed on a fee-schedule basis and thus have no incentive to reduce hospital costs.

Hospital-physician gainsharing came to a crashing halt in 1999, however, when the OIG issued a Special Advisory Bulletin in which it concluded that these arrangements violate the civil monetary penalty provisions of the Social Security Act, which prohibit payments by hospitals to physicians that may induce a reduction or limitation of items or services to Medicare or Medicaid patients. In the bulletin, the OIG stated that, absent further authorizing legislation, it would not afford regulatory relief through the issuance of advisory opinions on gainsharing arrangements.

Then, in January 2001, the OIG somewhat retreated from this absolute position by issuing an advisory opinion in which it approved a gainsharing arrangement between a hospital and a group of cardiac surgeons under which the group would receive a percentage of the savings generated by their implementation of certain cost-saving measures when performing surgery at the hospital. The 2005 gainsharing opinions expand on the 2001 opinion by, among other things, adding a new product standardization measure to the list of permissible cost savings measures.

The 2005 Opinions

In each of the 2005 advisory opinions, a hospital proposed to enter into one-year contracts with cardiologists or cardiac surgeons on its medical staff to pay 50 percent of the cost savings directly attributable to specific changes in their practices. Using historic utilization data, a consultant identified certain specific cost-saving opportunities to improve operating room practices and curb the inappropriate use or waste of medical supplies, and made recommendations, which involved:

- Standardizing products for certain cardiac devices (e.g., stents, balloons, valves, catheters, pacemakers, and defibrillators)
- Limiting the use of certain vascular closure devices
- Opening items only as needed
- Performing blood cross matching only as needed
- Substituting certain existing items with less costly items

For a while, it seemed that the OIG was predisposed to disapprove of hospital-physician gainsharing. Now, the OIG appears to be more open to such arrangements.
The January 2001 opinion involved a similar cost-savings arrangement, in which items were opened only as needed and less costly items were substituted for items currently in use. It also involved a measure requiring that the use of Aprotinin, an antihemorrhaging drug, be limited only to patients at a higher risk of pre-operative hemorrhage. The primary difference between this arrangement and those addressed in the 2005 opinions is that the latter introduced a new category of cost savings, product standardization, and that the OIG describes in detail the product standardization measures that are permissible, involving certain medical devices.

Under the arrangements addressed in the 2005 opinions, the contracts would specify historic costs, base year costs, and projected cost-savings opportunities. At the end of the year, cost savings (compared with a base year consisting of the 12 months immediately preceding implementation of the gainsharing program) would be calculated separately for each of the cost recommendations, and 50 percent would be distributed to the physicians on a per capita basis.

The arrangements also contained several safeguards:

- Certain floors and thresholds were established beyond which no cost savings would accrue to the physicians. For example, historically, blood cross matching was performed in all cases, with fewer than 30 percent resulting in actual transfusions; thus, the physicians would not receive a share of any savings from reductions in the blood cross matching below the 30 percent floor. With regard to product standardization, physicians would continue to be able to make patient-by-patient determinations of the appropriate device and continue to have the same selection of devices as before the implementation of the gainsharing protocol.
- If the volume of procedures payable by federal healthcare programs in the current year were to exceed the volume of like procedures performed in the base year, the physicians would not receive a portion of the cost savings for the additional procedures.
- To limit the physicians’ incentive to steer more costly patients to other hospitals, the case severity, age, and payer mix would be monitored by the hospital, and if a particular physician were responsible for a significant change from historical measures, he would be terminated from the arrangement.
- Both the hospital and the physicians would provide written disclosures of their involvement in the arrangement to patients.

As it did in its 2001 opinion, the OIG concluded that all of the recommendations in the proposed arrangements implicate the CMP Law (except for the open-as-needed and substitution recommendations). However, the OIG stated it would not impose sanctions because the proposed arrangements did not involve paying physicians a percentage of “generalized” cost savings, but were tied to specific, identifiable cost-lowering activities. The OIG noted that because the arrangements set out the specific actions to be taken and tied the remuneration to the actual, verifiable cost savings attributable to those actions, this transparency permits an assessment of the effect of the cost savings measures on patient quality of care and ensures that the identified actions will be the cause of the savings.

The OIG also analyzed the proposed arrangements under the federal anti-kickback statute, which prohibits any person from knowingly offering, paying, soliciting, or receiving any remuneration to induce referrals of items or services that are reimbursable by a federal healthcare program. The OIG noted that the safe harbor for personal services and management contracts would not be met because the aggregate compensation paid to the physicians would be on a percentage basis and not set in advance. Nevertheless, the OIG concluded that, although the proposed arrangements could involve illegal remuneration, it would not impose sanctions because sufficient safeguards were in place.

The OIG found that the likelihood that the proposed arrangements would be used to attract referring physicians or to increase referrals from existing physicians was low because participation in the gainsharing program was limited to physicians already on the hospitals’ medical staffs, thereby limiting the risk that the program would attract other physicians. In addition, the potential cost savings from federal healthcare programs would be capped, and the terms of the arrangements would be limited to one year, thereby reducing the incentive to switch facilities. Also, admissions data would be monitored for changes in case severity, age, or payer mix. The incentive to reward referrals from other sources would also be reduced because cost savings would be distributed on a per capita basis, thereby mitigating the incentive for an individual physician to generate disproportionate cost savings.

Last, the OIG noted that the physicians would, in some cases, be subject to increased exposure to liability (e.g., from medical malpractice claims), and it is not unreasonable to compensate them for assuming this increased risk. The OIG found that the payments under the proposed arrangements do not appear to be unreasonable because they are limited in amount (50 percent cap), duration (one year only), and scope (the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels).

A Word of Caution
The 2005 advisory opinions do not suggest that the OIG has opened the floodgates to all gainsharing arrangements. In fact, in the opinions, the OIG cautions that payments of 50 percent of cost savings in other arrangements, including multiyear arrangements or arrangements with generalized cost savings formulas, could lead it to draw a different conclusion. What has changed with the 2005 opinions is that the OIG has now drawn a clearer distinction between “generalized,” or what it calls “black box,” gainsharing arrangements, which are tied to overall cost savings and which the OIG does not support, and limited gainsharing arrangements, which are tied to specific, identifiable, and verifiable actions and cost savings, which the OIG is willing to approve on a case-by-case basis. In short, according to the OIG’s chief counsel,
Lewis Morris, the OIG is looking for three safeguards in a gainsharing arrangement:

> Accountability
> Quality controls
> Controls on referral patterns

**Impact of Other Laws**

The 2005 opinions analyze the effect of only the CMP law and the anti-kickback statute on the gainsharing programs described in the opinions because these laws are the only ones strictly within the OIG’s jurisdictional purview. Yet aside from these two laws, gainsharing arrangements face other legal hurdles. For example, most hospital-physician gainsharing arrangements would also implicate the federal Stark law, which prohibits a physician from making referrals of certain types of services (including inpatient hospital services) to an entity with which the physician has a direct or indirect financial relationship. Most gainsharing arrangements, including the ones proposed in the 2005 advisory opinions, would trigger the Stark law because they involve paying physicians who refer covered services to a hospital.

Unlike the anti-kickback statute, which includes an "intent" element, the Stark law is a strict liability law—which means that the gainsharing arrangements must meet a Stark law exception to comply with the law. Depending on the nature of the relationship between the physician and hospital, there are a few potentially relevant exceptions, such as the fair market value exception, the personal service arrangements exception, and the indirect compensation arrangements exception. Although each of these exceptions contains various different requirements, one element common to all of them is that the gainsharing payments must reflect fair market value for the services provided by the physicians.

Further, if the hospital is a tax-exempt organization under Section 501(c)(3) of the Internal Revenue Code, then the gainsharing payments may raise other issues. In 1999, the IRS issued two private letter rulings in which it reached favorable conclusions regarding hospital-physician gainsharing programs. The IRS concluded that the gainsharing arrangements were consistent with prior IRS guidance regarding incentive compensation plans and recruitment incentives.

The IRS found that the physicians were providing valuable services needed by the hospitals that would result in tangible cost savings. A third-party appraisal provided an important fair market value cap on the compensation to the physicians.

**How to Structure Gainsharing Arrangements**

When structuring a hospital-physician gainsharing arrangement, the following points should be kept in mind:

> Any financial incentives should be reasonably limited in duration (e.g., one year) and amount (e.g., 50 percent of savings).
> Savings to physicians should be distributed on a per capita basis, and patient admissions should be monitored before, during, and after implementation for changes in severity, age, or payer mix.
> Cost saving measures should be based on hospitals’ actual out-of-pocket costs, and any resulting savings should be clearly and separately identified.
> Objective and verifiable historical and national clinical data should be used to establish thresholds and floors beyond which no savings accrue to physicians. (For example, if a less expensive catheter could be used in 90 percent of the cases without having an adverse impact on patient care, then the physicians should not receive any benefit for using the less expensive catheter in more than 90 percent of cases).
> Credible medical evidence should exist demonstrating that the cost saving recommendations will not adversely affect patient care.
> Any cost savings should be uniformly applied, regardless of insurance coverage, and should be subject to a cap on payments for patients enrolled in federal healthcare programs.
> Product standardization measures should ensure that the same selection of medical devices continue to be available to physicians.
> Advance written disclosures of the arrangement should be provided to patients.
> The impact of other laws and regulations, such as the Stark law and the IRS’s regulations should be evaluated. (For example, consider obtaining an opinion from a third-party appraiser with respect to the fair market value of the cost savings payments to the physicians.)

**What to Avoid**

Four types of arrangements should be avoided in any case:

> Arrangements that encourage cherry-picking healthy patients and steering sicker and more costly patients to hospitals without gainsharing arrangements.
> Arrangements that do not identify specifically both the individual actions to be taken and the direct connection between those actions and any reductions in the hospital’s actual out-of-pocket costs.
> Arrangements that do not provide for independent verification of the essential aspects of the arrangement (e.g., the cost savings and the quality-of-care indicators) or where the quality-of-care indicators have questionable validity and statistical significance.
> Arrangements that stint on patient care and include insufficient safeguards against the risk that other, unidentified factors (e.g., premature hospital discharges) might actually account for any "savings."

**Practical Benefits**

Gainsharing provides an opportunity for hospitals and physicians to align their economic interests, and offers hospitals a means to improve operational efficiencies and quality of patient care through the development of certain standardized procedures and protocols, or best practices. It also opens an avenue for virtual joint ventures with physicians. Gainsharing can potentially be extended to specialties, such as orthopedics, that involve a high degree of supply costs and physician preference items (i.e., medical supplies and devices), and possibly even to internists through the use of best practices to reduce unnecessary services.
Limitations
Gainsharing still faces limitations. Success largely depends on changing physician behavior, not only during the term of the gainsharing program, but also after any economic incentives are gone. Hospitals also should be mindful of the investment needed to implement a gainsharing program, including the costs of engaging consultants and attorneys and acquiring sophisticated (and often expensive) accounting systems designed to track appropriately structured cost savings.

In addition, if a product standardization measure is included, hospitals still must stock the same costly selection of devices as before. Further, absent legislative changes, arrangements should be patterned after those described in the OIG opinions, and it may be necessary to seek favorable regulatory guidance from the appropriate agencies.

The Future of Gainsharing
Conceptually, the 2005 gainsharing opinions demonstrate a major shift in the OIG’s policy from that expressed in its 1999 Special Advisory Bulletin. Practically, because gainsharing implicates various legal authorities within the enforcement jurisdiction of different agencies, its effectiveness and successful use in the future depends on congressional action in the form of legislation providing unified practical guidance that can be broadly relied upon.

Progress in that direction came first in March 2005, when the Medicare Payment Advisory Council made recommendations to Congress to pass legislation supporting gainsharing as an alternative to physician-owned specialty hospitals (which then were under substantial restrictions). Then, in May 2005, Sens. Chuck Grassly and Max Baucus introduced a new bill, The Hospital Fair Competition Act of 2005, based largely on MedPAC’s recommendations. This bill, which is currently in the Committee on Finance, would further clear the way for hospital-physician gainsharing arrangements by creating exemptions under the CMP law, the Stark law and the anti-kickback statute.

Whether further congressional action on the Hospital Fair Competition Act of 2005 will occur remains to be seen. A more cautious approach was proposed in another congressional measure that was eventually signed into law by President Bush on Feb. 8, 2005, as part of the Deficit Reduction Act of 2005. The DRA requires the HHS secretary to establish up to six gainsharing demonstration programs (of which at least two must be in a rural area), with two objectives:
- To test and evaluate methodologies and arrangements between hospitals and physicians designed to govern the utilization of inpatient hospital resources and physician work to improve the quality and efficiency of care to Medicare beneficiaries
- To develop improved operational and financial hospital performance with sharing of remuneration as specified in the projects

The secretary is required to approve the projects no later than Nov. 1, 2006. Each project will be operational for two years starting on Jan. 1, 2007. During the two-year term, the secretary is required to provide Congress with periodic updates, and a final report is to be issued no later than May 1, 2010.

The DRA’s demonstration projects will allow Congress to more fully and better study hospital-physician gainsharing. Although the act is a positive first step, substantive gainsharing legislative changes may be slow to come, if at all, depending on the results from the projects. At a minimum, these efforts demonstrate that the national debate on gainsharing is alive and that there is widespread recognition of the noticeable shift in public policy to recognize gainsharing as a useful tool to control hospital costs and ultimately, federal healthcare program costs.

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The views and opinions expressed in this article are those of the author and do not necessarily reflect those of Sills Cummis Epstein & Gross PC.