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GAIN YOUR FAIR SHARE: GAINSHARING MAKES A COMEBACK

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Have you heard the news in connection with the “Rewarding Results” pay for performance study funded by The Robert Wood Johnson Foundation, the California HealthCare Foundation and the Commonwealth Fund?

No, it’s not that the three-year long study resulted in a finding that payment of financial incentives to physicians motivates change. Rather, it’s the fact that someone convinced these non-profits to throw money at a “study” of something so patently obvious. (If you close your eyes you might actually hear the sound of a newsboy on a corner near you shouting “Extra! Extra! People motivated by money!”) Aren’t the federal and state anti-kickback and self-referral laws based on studies that show that physicians’ practice patterns are affected by monetary gain?

All kidding aside (and, sorry if this article is a bit disjointed, as I'm simultaneously typing a $30 million grant proposal for a proposed study on whether mammals have hair), the anesthesia community should not look a gift horse in the mouth: The pay for performance movement (nicknamed "P4P"), supported by payors and pundits alike, together with the Department of Health and Human Services' Office of Inspector General's ("OIG") 2005 advisory opinions on gainsharing, signal that the time is ripe for anesthesia groups to negotiate for a share of the upside they can create.

What is Gainsharing?

Gainsharing is a pay for performance model particularly applicable to the anesthesia-hospital relationship. Let's take a step back and look at what gainsharing is, and isn't, on a larger scale.

First, gainsharing is not a healthcare industry-specific notion. In fact, it is a tool that has had general application across industry lines for many years. Roughly speaking, gainsharing is a compensation system that aims to involve workers in improving performance and that, by way of measurement, shares between labor and management the financial gains made.

Gainsharing is not a new concept either. One of the earliest cited examples in the United States is a system designed in the 1930's by a union official named Joseph Scanlon in order to save steel workers' jobs. The "Scanlon Plan" encouraged workers to adopt more efficient production methods by giving them half of the savings generated.

What differentiates gainsharing from other motivational type programs, such as quality circles, six sigma programs and total quality management is that those tools are not linked directly to compensation, while gainsharing is.

Gainsharing is not profit sharing; the system need not have anything to do with profitability, and is generally keyed to lowering costs. But, it can be linked to any number of factors, including quicker performance, exceeding quality baselines and the like. Finally, gainsharing is not individual-specific; rather, it is applied to groups of workers, the aim being to modify overall behavior and, therefore, output, however measured.

Although there is no one single type of gainsharing in healthcare, in general, the term has been used to describe programs to align physician incentives with those of hospitals by offering physicians a share of the hospital's variable cost savings. Or course, gainsharing can also include payment for measured quality improvement and for quicker case turnaround times, as well as for other cost savings or improvements.

Gainsharing and the OIG

The normally independent reimbursement mechanisms applied to hospitals, on the one hand, and physicians, on the other hand, are a hotbed for potential gainsharing arrangements. From the perspective of Medicare, hospitals are paid on the basis of DRGs; in other words, a fixed fee not tied to the actual cost of providing care, while physicians are paid on a fee for service basis. Under this system, in the absence of gainsharing, physicians are not affected by the actual cost

of hospital services, supplies and devices and, therefore, have no incentive to economize or standardize. Gainsharing conforms, to a certain extent, the otherwise differing incentives.

In the early 1990's, I designed what were then novel programs for anesthesia group clients, contracting with hospitals for a significant share of the savings resulting from changes in anesthesiologists' practice patterns. But by the end of the decade, the regulatory winds changed.

In July 1999, the Office of Inspector General ("OIG") of the Department of Health and Human Services released a Special Advisory Bulletin entitled "Gainsharing Arrangements and CMPs ["civil monetary penalties"] for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries." Special Advisory Bulletins are designed to warn of practices that potentially implicate the fraud and abuse laws subject to enforcement by the OIG.

The Bulletin focused on the Social Security Act's provisions that permit the government to impose a civil monetary penalty, that is, a fine that can be levied administratively, if a hospital makes payment to a physician as an inducement to reduce or limit services to Medicare or Medicaid beneficiaries under the physician's care. CMPs can be tremendous: $2,000 per affected patient plus $50,000 per act plus up to three times the amount of the payment offered or made to the physicians as an inducement. Although the OIG conceded in the Bulletin that gainsharing may result in benefits without impacting the care received by Medicare or Medicaid patients, it held fast to the position that, nonetheless, gainsharing violated the CMP provision as the inducement itself violated the law. The OIG's position was that a change in the law was required in order for

an exception to be made permitting gainsharing. Furthermore, the OIG stated that it would not issue advisory opinions (that is, give sanction to a specific deal) regarding gainsharing programs.

Although focused on presenting the issues under the Social Security Act's civil monetary penalty provisions, the Bulletin mentioned that gainsharing also raises concerns under the federal antikickback statute, a statue that is also enforced by the OIG. The antikickback statute prohibits remuneration if at least one purpose of the remuneration is to induce referrals of items or services reimbursable under a federal healthcare program. It's easy to see that if the physician group receiving gainsharing payments also refers patients to the paying facility, there is a potential kickback.

A False Start?

Despite its 1999 position, in January 2001, the OIG issued Advisory Opinion No. 01-01 which addressed a situation in which a hospital proposed to share with a group of cardiac surgeons a percentage of the hospital's cost savings arising from the surgeons' use of specific supplies and medications during designated cardiac surgery procedures. Advisory opinions, although binding only on the parties to the specific transactions, give a useful glimpse into the considerations the government takes into account; that information helps guide the design of transactions.

Although the OIG concluded that the proposed arrangement violated both the CMP law and the antikickback law, it determined that it would not impose sanctions – this is the language of a favorable opinion.

The cardiac surgery group in the deal was the dominant such group practicing from the hospital. The hospital expected to include the other cardiac surgeons practicing at the hospital in similar gainsharing programs. The hospital engaged a third party to administer the gainsharing program. The program administrator conducted a study and identified nineteen specific cost saving opportunities, which were reviewed for medical appropriateness. The nineteen opportunities were broken down into three categories: (1) opening packaged items only as needed during a procedure; (2) the substitution, in whole or in part, of less costly items for the items currently being used by the surgeons; and (3) the use of a certain per-operative medication only in respect of high-risk patients.

The program included safeguards intended to protect against inappropriate reductions in services, including the use of historic practice patterns to establish floors below which no cost savings would be shared and the adoption of clinical indicators that had to be followed to assure that services and items would not inappropriately curtailed in an attempt to share in the gains.

The program tracked the savings on each of the nineteen categories and split the savings equally between the surgery group and the hospital. Patients would be given prior written notice of the gainsharing program.

Following the 2001 opinion, the OIG remained silent in terms of advisory opinions on gainsharing for four years. Despite the fact that Advisory Opinion 01-01 gave a green light to the specific deal, most hospitals remained concerned that the general scope of the 1999 Bulletin continued to

reflect the government's disapproval of gainsharing arrangements and, therefore, shied away from entering into such deals.

Change in the Tide: 2005

In January and February, 2005, the OIG broke its four year silence and issued six consecutive Advisory Opinions, numbered 05-01 through 05-06, on gainsharing arrangements, finding that all six were structured so as not to warrant either the imposition of Civil Monetary Penalties or prosecution for violation of the antikickback law.

Advisory Opinion No. 05-01 involved an agreement between a hospital and a cardiac surgery group. The hospital engaged an independent third party to study potential cost savings and to administer, for a fixed monthly fee, the gainsharing program. The surgeons were to share up to fifty percent of the hospital's savings resulting from the adoption of a number of recommendations to curb the inappropriate use or waste of medical supplies. The recommendations were grouped into four categories: (1) opening certain packaged items only as needed; (2) performing blood cross-matching only as needed; (3) substitution, in whole or in part, of less costly items for items currently being used; and (4) product standardization of certain cardiac devices where medically appropriate.

The OIG stated that the proposed arrangement contains safeguards intended to protect against inappropriate reductions in services, including the use of floors below with no savings would

accrue to the surgical group, as well as the continued availability of the same selection of devices as before the gainsharing arrangements were implemented.

Advisory Opinion No. 05-02 involved an agreement between a hospital and five independent cardiology groups. The hospital engaged an independent third party to collect data and analyze and manage the gainsharing program in return for a fixed monthly fee. Under the program, the hospital will pay each group a share of the first year cost savings directly attributable to specific changes in the group's cardiac catheterization laboratory practices to curb inappropriate use or waste of medical supplies.

The eighteen recommendations developed by the third party program manager can be grouped into two categories: The first, standardization of the types of cardiac catheterization devices (stents, balloons, interventional guidewires and catheters, vascular closure devices, diagnostic devices, pacemakers, and defibrillators) used by the group, was to be safeguarded by a process in which the individual cardiologists will make a patient-by-patient determination of the most appropriate device; the full range of devices will continue to be available. The second, limiting the use of certain vascular closure devices to an "as needed" basis for inpatient coronary interventional procedures and diagnostic procedures, was to be safeguarded though the use of objective historical and clinical measures reasonably related to the practices and the patient population at the hospital to establish a "floor" beyond which no savings would accrue to the groups.

Advisory Opinion No. 05-03 involved an agreement between a hospital and a cardiac surgery group. Again, this would be a fifty-fifty split of the first year savings from the adoption of cost saving recommendations described as fitting within four categories, (1) open as needed items, including the disposable components of the cell-saver unit; (2) performing blood cross-matching only as needed; (3) substitution of less costly products with no appreciable clinical significance; and (4) product standardization of heart valves.

A floor beneath which no benefit would accrue to the surgical group was to apply in the case of the cell-saver and blood cross-matching recommendations. With respect to the product standardization recommendations for cardiac devices, the surgical group certified that the individual surgeons will make a patient-by-patient determination of the most appropriate device and that the full range of cardiac devices will continue to be available. The OIG found no appreciable clinical significance (and, therefore, no potential for violation of the CMP law) in the proposed open as needed policy for items other than the cell saver disposables and in the substitution of less costly items.

Advisory Opinion No. 05-04 involved a series of similar agreements between a hospital and a number of cardiology groups whereby each group would receive a share of the first year cost savings directly attributable to specific changes in the specific group's cardiac catheterization laboratory practices. The program administrator, to be paid a flat monthly fee, identified cost saving opportunities for each group after studying their practice patterns. In general, the recommendations involving changing practices to curb inappropriate use or waste of medical supplies. Specifically, there would be (i) standardization of cardiac catheterization devices (stents, balloons, interventional guidewires and catheters, vascular closure, diagnostic devices,

pacemakers, and defibrillators), where medically appropriate; (ii) limitation on the use of certain vascular closure devices to an "as needed" basis, with the devices being readily available in the procedure room (which the groups certified will not adversely affect patient care); and (iii) the substitution of less costly contrast agents.

With respect to the "as needed" use of vascular closure devices and the products substitution recommendations, the gainsharing deal would utilize objective historical and clinical measures to establish a "floor" beyond which no savings would accrue to any of the cardiology groups. With respect to the proposed product substitution recommendations, the administrator identified national averages and historic patterns of use and established quality thresholds beyond which no cost savings will be credited. In addition, the physicians would continue to have available the full range of products and will make a determination of substitution on a patient by patient basis.

Advisory Opinion No. 05-05 involved an arrangement between a hospital and a cardiology group whereby the group would receive a percentage of the first year cost savings resulting from adopting the recommendations developed by a program administrator engaged by the hospital for a fixed fee. As in Opinion No. 05-04, the subject is reducing cost in the cardiac catheterization lab.

Divided into two categories, the first category consists of product standardization where medically appropriate. The second consists of limiting the use of vascular closure devices to an "as needed" basis for inpatient coronary interventional procedures and diagnostic procedures.

The OIG found there were multiple safeguards in place, including the fact that the vascular closure devices subject to limitation would remain readily available and that the reduction in use will not adversely affect patient care; and the fact that, with respect to the product standardization recommendation, the individual cardiologists will make a patient-by-patient determination of the most appropriate device and the availability of the full range of devices will not be compromised by the product standardization. Additionally, the OIG was satisfied with the fact that the proposed arrangement would utilize objective historical and clinical measures reasonably tp establish a “floor” beyond which no savings would accrue to the cardiology group.

Advisory Opinion No. 05-06 involved a hospital’s proposal to share with a group of cardiac surgeons the first year cost savings to result from the implementation of cost reduction measures. The program administrator engaged by the hospital to implement and oversee the gainsharing program studied historical practices and identified twenty seven recommendations to curb inappropriate and wasteful use of medical supplies. Grouped into four categories, recommendations concerned (i) adopting an open as needed policy for packaged items; (ii) limiting the use of certain supplies to those cases for which they are needed; (iii) substituting less costly items; and (iv) product standardization of certain cardiac devices and supplies where medically appropriate.

In respect of the open as needed policy, the OIG found that the insubstantial time it takes to open a package of supplies is not a perceptible reduction or limitation in the provision of items or services to patients sufficient to trigger the CMP. With respect to the specific product substitution recommendations, the OIG determined that the substitutions will have no appreciable clinical

significance and therefore do not constitute a perceptible reduction or limitation in the provision of items or services to patients sufficient to trigger the CMP.

Even though the remaining recommendations involving limitations on use of certain surgical supplies and product standardization would trigger the CMP, the OIG concluded that it would not seek to impose sanctions, as the proposed arrangement protect against inappropriate reductions in services by ensuring that individual physicians will still have available the same selection of cardiac devices.

A Stark Contrast?

On the basis of the six gainsharing OIG opinions, it's obvious that a gainsharing programs can be legally structured – at least as concerns the statutes within the OIG's purview. The problem, of course, is that "Stark," the federal "self-referral" prohibition, is *outside* of the OIG's range of authority.

For Stark to be triggered, a physician must make a referral, in respect of a Medicare beneficiary, for certain designated health services. The referral must be to an entity in which the physician, or certain family members, has a direct or indirect financial relationship.

For many physician groups, notably the cardiology and cardiac surgery groups which received the favorable OIG opinions discussed above, Stark is a significant problem, as those physicians clearly refer patients to the gainsharing-paying hospitals.

On the other hand, for anesthesia groups that provide perioperative services only, the chance of a Stark issue is slight, as it is unlikely that the group's physicians will make referrals – a necessary element of a Stark violation. However, for groups providing, whether alone or in addition to perioperative services, chronic pain management services that refer patients to the gainsharing facility, the Stark issue requires detailed analysis.

It should also be noted that state law may contain similar, or different, antikickback and self-referral prohibitions. If so, solving the Stark and federal antikickback/CMP issues is only part of the compliance analysis that must be performed before any deal is implemented.

What Gain to Share?

Assuming that the relationship between the anesthesia group and the hospital does not present unsolvable compliance issues, possible subjects for gainsharing are very much tied to facts of your specific hospital or surgery center and warrant serious thought and investigation.

For example, possible gainsharing deals might focus on drug cost savings, procedures to split bottles of drugs, or increased O.R. productivity based on case turn-around times. In fact, let me

turn this around on you, the reader: Send me your suggestions on other possible gainsharing "targets" for a follow up article and, if you're the first to make a specific suggestion, I'll send you a copy of my book on anesthesia employment agreements.

It's clear that both the regulatory trends and the willingness of payors to adopt performance-linked payment make this the right time to consider possible gainsharing deals. As with most other economic arrangements with facilities, one of the key factors in negotiating a successful gainsharing program is to implement a long term strategy to make the facility well aware of the benefits that the group provides, as well as of the potential additional value that it can help create.

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