

## Client Alert

*A report for clients and friends of the firm*

February 2001

### Gainsharing: It's Back

#### *OIG Issues Opinion Accepting Certain Gainsharing Relationships*

In a remarkable advisory opinion, the Office of the Inspector General (OIG) has indicated acceptance of certain "Gainsharing" relationships that do not present a material risk of reduction in services to patients. The complex arrangement reviewed and approved in Advisory Opinion No. 01-1 is certain to be emulated by many other hospitals that have avoided Gainsharing out of concern that such arrangements would violate the Civil Monetary Penalties (CMP) Law, the Anti-Kickback Law or the Stark Law.

In July, 1999 OIG issued a special advisory bulletin (the SAB) on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries." In the SAB, OIG indicated that it would look unfavorably upon virtually any Gainsharing structure that rewarded physicians for reducing services -- including "substituting one type of good or service for another good or service" -- to patients (essentially without regard to whether the service was medically necessary or appropriate). OIG, citing the "clear statutory prohibition on hospital-physician incentive plans" suggested that those seeking to protect Gainsharing arrangements should seek legislative relief. The new advisory opinion appears to reflect a complete rethinking on the part of the OIG.

#### **The Proposed Arrangement**

The proposed arrangement at issue in Advisory Opinion No. 01-1 (the Arrangement) involves a hospital (the Hospital) entering into a contract with a group of surgeons (the Group) that provides 85% of the Hospital's cardiac surgery. (The remaining cardiac surgeons initially will not participate in the proposed arrangement. However, the Hospital expected to include them in future cost saving sharing initiatives on terms

and conditions substantially comparable to those offered to the Group.) In addition, the Hospital is employing a program administrator. (The program administrator is to be paid a monthly fixed fee that is presumably fair market value. The fee is not tied to cost savings or to the Group's compensation under the Arrangement.) Under the Arrangement the Hospital will pay the Group a share of the cost savings directly attributable to specific changes in the Group's operating room practices. The proposed changes consist of nineteen specific cost savings opportunities identified in a study conducted by the program administrator. Both the Hospital and the Group reviewed and agreed on the medical appropriateness of each of the recommended changes. OIG divided the 19 recommendations into three categories. The first consisted of 14 recommendations that involve opening packaged items only if needed during a procedure. (These generally include surgical trays or comparable supplies.) One of these 14 items consists of not opening the disposable components of the cell saver unit until a patient experiences excessive bleeding. The OIG noted that this will result in a delay in cell saver readiness of not to exceed 2-5 minutes but that the requestor of the opinion had certified that the delay would not "adversely affect patient care." The second category of savings recommendations related to the substitution of less costly items for the items currently used by the surgeons. The final category consists of limiting the use of a particular medication, Aprotinin, that is given routinely to many surgical patients preoperatively to reduce the risk of hemorrhaging, but which, according to "objective, generally-accepted clinical indicators" identified by the requestors, is only indicated for certain patients that are at a higher risk of hemorrhage during surgery. (Seventy-five percent of the total cost savings identified would come from the

reduction in the use of Aprotinin, and an additional ten percent would come from not routinely opening the package containing the disposable components of the cell saver unit.)

The Arrangement contains several safeguards intended to protect against inappropriate reductions of services. For example, data on historical utilization and objective clinical measures that are related to the practices and the patient population at the Hospital were used to establish a floor of procedures below which no savings would accrue to the Group. Specifically, if the cell saver is currently used in approximately 50% of the cardiac procedures specified in the Arrangement (based on historical data) the Group would receive no savings resulting from any reduction in cell saver use below that floor. Other examples include getting savings from using less expensive forms of sutures only in not more than the percentage of cases where an objective historical review indicates such a change could be made without an impact on patient care. Similar limits are applied to the savings obtainable from reduction in the use of Aprotinin.

The Group is to receive 50% of the savings achieved over the course of one year and the savings are to be calculated separately for each of the nineteen proposed changes. In addition, the Group distributes profits to its members on a per capita basis (not on any basis related to savings accrual, for example). Payments by the Hospital to the Group will also be subject to other limitations: (1) if the volume of procedures payable by a federal health care program in the current year exceeds the volume of like procedures payable in the base year, there is no sharing of cost savings for the additional procedures; (2) if there is a significant change in historical measures of patient illness intensity with respect to any of the surgeons, any surgeon who is admitting those presumably less ill patients will be terminated from participation in the Arrangement; and (3) the aggregate payment to the Group will not exceed 50% of the projected cost savings identified in the program administrator's study. Further (although it is not really clear how this could be done), the requesters have certified that the payment methodology will generate payments to the Group that will be consistent with fair market value for services rendered to the Hospital in arms-length transactions. Moreover, the Hospital and the Group will document the activities and the payment methodology and make the data available to HHS upon request. Perhaps most importantly the Group will disclose the Arrangement to the patient, including the fact that the Group's compensation is based on a percentage of the Hospital's cost savings.

### **The CMP Law**

In analyzing the proposal under the CMP Law the OIG first noted that all but the unopened surgical tray item implicated the civil monetary penalties prohibition because the proposed arrangement constituted an inducement to reduce or limit the current medical practice at the Hospital. (The OIG notes, "we recognize that the current medical practice may involve care that exceeds the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP." The OIG also notes that the open-as-needed surgery tray item does not reflect a reduction in services to patients and therefore would be outside the CMP.) Nevertheless, the OIG concluded that despite the fact that a technical violation of CMP is presented by the proposed arrangement, it would not seek sanctions for the following reasons: (1) the specific cost saving actions and resulting savings are each clearly and separately identified which will facilitate accountability in the event of any adverse effects; (2) the requesters have proffered credible medical support for the position that implementation of the recommendations, including the reduction of the routine use of Aprotinin, will not adversely effect patient care; (3) the Arrangement will periodically be reviewed to confirm that it is not having an adverse impact on clinical care. (In this regard it is noteworthy that the OIG had the Arrangement reviewed by both a government medical expert and independent medical expert and both concluded that the proposed cost saving measures should not adversely effect patient care); (4) the payments under the Arrangement are based on all surgeries regardless of the patients' insurance coverage (subject to the cap on payment for federal health care program procedures); and moreover, the surgical procedures to which the Arrangement applies are not disproportionately performed on federal health care program beneficiaries; (5) the cost savings are calculated on the Hospital's actual out-of-pocket acquisition costs, "not an accounting convention;" (6) the Arrangement protects against inappropriate reduction in services by using objective historical and clinical measures to establish baseline thresholds below which no savings accrue to the Group; (7) the Hospital and the Group would provide written disclosure of the Arrangement to patients; (8) the Arrangement's financial incentives are reasonably limited in duration and amount (OIG notes that the Arrangement is proposed for only one year and that its opinion does not apply to any future renewal or extension, but it also notes that any renewal or extension should incorporate updated base year costs, which suggests the OIG would accept the Arrangement on a going forward basis; on the other hand the limited duration was clearly a significant factor in the

OIG's approval of the plan, and it is not clear that it would approve a plan that was longer than a year. Thus it would seem that such programs should be one year in length and then reviewed and renewed as the term ends); and (9) the incentive for a surgeon to generate disproportionate cost savings is limited because the Group's profits are distributed to its members on a per capita basis.

The OIG argues that this exercise of discretion not to impose sanctions is consistent with the SAB mentioned above. However, given the unusually strong language of the SAB, the SAB and Advisory Opinion No. 01-1 are difficult to reconcile. OIG notes that the Arrangement is markedly different from many "Gainsharing" plans, particularly those that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable, cost-lowering activities. OIG states, "Importantly, the Proposed Arrangement sets out the specific action to be taken and ties the remuneration to the actual verifiable costs savings attributable to those actions. This transparency allows an assessment of the likely effect of the Proposed Arrangement on quality of care and assures that the identified actions will be the cause of the savings."

The OIG also notes a number of features in older Gainsharing plans that "heighten the risk that payments will lead to inappropriate reductions or limitations of services." These include: (1) no demonstrable direct connection between individual action and any reduction in a hospital's out-of-pocket costs; (2) the individual actions that would give rise to savings are not identified with specificity; (3) inadequate safeguards against the risk that other unidentified actions such as premature hospital discharges might account for savings; (4) questionable quality of care indicators are used; and (5) no independent verification of costs savings, quality of care indicators or other essential aspects of the arrangement is obtained. Finally, the OIG notes that arrangements that are "longer in duration or more expansive in scope than the Proposed Arrangement" approved in Advisory Opinion No. 01-1 are likely to require additional or different safeguards. (Note that OIG did not state that such other arrangements would necessarily be prohibited).

### **The Anti-Kickback Law**

Turning to the Anti-Kickback Law, the OIG noted that the Arrangement could result in a illegal remuneration if the requi-

site intent to induce referrals is present. Although noting that no safe harbor applies, the OIG nevertheless determined that it would not impose sanctions. It did so because: (1) the circumstances and safeguards of the proposed arrangement reduced the likelihood that the arrangement would be used to attract referring physicians or to increase referrals from existing physicians (new physicians are barred from participation in the Arrangement), and any increase in federally-funded admissions would be excluded from the savings). In this regard the fact that the contract term was limited to a year was an important factor as was the review of admissions for case mix intensity; (2) the structure of the proposed arrangement eliminated the risk that the proposed arrangement would reward cardiologists or other physicians who refer patients to the surgeon group. The surgeon group is the sole participant in the Arrangement and is composed entirely of cardiac surgeons, thus no outside physician referring patients to the Group could share in the benefits. Further, within the Group, the distribution of profits is done on a per capita basis, which reduces the possibility that any individual surgeon would realize disproportionate benefits from any cost savings; (3) some of the changes proposed are consistent with "common sense," but may nevertheless, place the surgeon at some minimal increased risk of a malpractice claim, particularly as it relates to the delay in utilizing the cell saver and in the less frequent prophylactic administration of Aprotinin, and therefore it is appropriate to compensate the surgeon for the increased risk from this change of practice. This presents an interesting paradox: how can it be that the surgeon is at greater risk of malpractice liability if the reduction in use of Aprotinin is consistent with the proper standard of care. Finally, the OIG noted that there is a cap (50% of total savings) on total remuneration potential to the Group.<sup>1</sup>

### **Conclusion**

Having thus opened the floodgates for "Gainsharing," the OIG in its conclusion sounds a clear warning. The OIG writes, "Improperly designed or implemented arrangements risk adversely affecting patient care and could be a vehicle to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall costs savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened risk of

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<sup>1</sup> Advisory Opinion No. 01-1 does not address the Stark Law, as the OIG is not authorized to issue advisory opinions on that law. (The Health Care Financing Administration ("HCFA") renders opinions in the Stark Law; it is not known whether a request for such an opinion was made to HCFA regarding the Gainsharing arrangement at issue in Advisory Opinion No. 01-1.) In any event, Stark Law compliance is complicated, although it should be possible to structure most Gainsharing arrangements to comply. (Another February 2001 Client Alert discusses the recently adopted final regulations on certain aspects of the Stark law.)

potential patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement proposed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result."

It does appear that the OIG is cautioning hospitals to avoid too much reliance on its opinion and is suggesting that each hospital should seek its own advisory opinion regarding its own plans. For now this may be the best advice, but one wonders whether this is really functional in the long run. Broader and less specific guidance would be very helpful. In any event, it is clear that the structuring of Gainsharing arrangements is once again viable. In this time of fiscal stress hospitals continue to reduce unnecessary expenses, and Gainsharing has long been recognized to be an effective vehicle to do so. Structuring these arrangements will require close consultation with counsel and communication with the OIG.

## Has Your Address Changed?

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