

Vol. 20 No. 32

July 15, 2005

IMPACT ON PATIENT CARE MUST BE FACTOR WHEN ASSESSING “GAINSHARING” ARRANGEMENTS

by

Bradley Merrill Thompson

In the ongoing debate over how to fix America's healthcare system, there are two notions on which most policymakers and stakeholders agree: healthcare costs must be reduced without compromising the quality of care, and the system contains significant inefficiencies and waste that must be addressed.

At the same time, we need to understand that some ideas for cost savings will indeed reduce the quality of care. One money-saving idea that is receiving increased attention is the use of “gainsharing.” While there is no fixed definition of gainsharing, the term typically refers to an arrangement in which a hospital gives physicians a share of any reduction in the hospital's costs attributable to the physicians' efforts, up to a certain limit. The goal of such programs is to give the physicians an incentive to (1) use fewer medical devices or supplies, or (2) switch to devices or supplies that are either less expensive or can be purchased more cost-effectively on a quantitative basis.

While the gainsharing idea seems to be growing in popularity, stakeholders and policymakers should step back and examine the practice through the eyes of the patient. This may take some time, because the issues are quite complex and require the development of data that must be collected over a substantial period of time. In studying the idea, it will be important to look at both the benefits and the possible burdens. This LEGAL BACKGROUNDER seeks to identify some of the unanswered questions in that analysis.

Benefits. The primary benefit, of course, is cost savings. While the amount of money gainsharing would save is the subject of some debate, some healthcare consultants claim hospitals can save millions of dollars. But despite these claims, it is unclear both how much these programs will reduce expenditures and how much they will cost to implement. Clearly the focus should be on net savings, but there simply is not enough data to estimate those savings.

Bradley Merrill Thompson is a partner with the law firm Baker & Daniels in its Indianapolis office. Mr. Thompson has broad experience representing food, drug and medical device companies with respect to the regulatory requirements of the U.S. Food and Drug Administration, the Centers for Medicare and Medicaid Services, and other federal and state agencies. *The views expressed here are those of the authors and do not necessarily reflect the views of the Washington Legal Foundation. This publication should not be construed as an attempt to aid or hinder the passage of legislation.*

Intuitively, when one looks at all of the conditions that are necessary to comply with the recent Department of Health & Human Services Office of Inspector General (“OIG”) advisory opinions,¹ the costs of operating a gainsharing program must be considerable. For example, in those programs, the hospitals must:

1. Analyze clinical information to ensure that credible medical support exists regarding a lack of adverse impact to patients from the gainsharing program.
2. Design the system to ensure that gainsharing payments are based on a hospital’s out-of-pocket costs, rather than accounting conventions.
3. Develop clinical guidelines to establish usage floors, below which physicians will not be rewarded for savings.

At this point, it is unclear what expenditure reductions can be achieved. It is also unclear whether the hospitals will be able to negotiate quantity discounts from manufacturers. For these types of products, the healthcare system is in uncharted waters.

In the same vein, if gainsharing does spark a price war, will the winning device maker change each time the bidding is conducted, and what costs will be associated with changing from one device to another each time? If the device requires different training and experience, switching from manufacturer to manufacturer will impose costs, and perhaps hurt patient outcomes as physicians must become accustomed to new devices.

More fundamentally, in each of the situations presented by different hospitals and therapeutic areas, will the potential savings be large enough — and thus will the payments to physicians be large enough — to motivate the physicians to do what gainsharing is trying to encourage them to do? This question has yet to be answered.

Burdens. What are the burdens that such a program might impose beyond the costs of the program?

Quality of care. At least one commentator suggests that quality will not really be an issue for gainsharing, asserting that clinical equivalency analysis will become standardized, thus allowing the physician to select less expensive options with confidence.² But this is counterintuitive, and indeed reveals a fundamental flaw with the concept of gainsharing.

Hospitals, like every business, are interested in reducing costs. If cutting costs associated with physician services in hospitals were easy, and if it did not require difficult clinical judgments to be exercised on a patient-by-patient basis, the hospital could simply take over the decision-making and order only the less expensive devices. But hospitals are not doing that, because in reality the savings *do* require the exercise of clinical judgment on a patient-by-patient basis. Instead, they are offering financial inducements to motivate the physicians in the direction the hospital favors.

Simply put, these gainsharing transactions necessarily involve (1) the exercise of clinical discretion and (2) an incentive to exercise that discretion in favor of cutting costs. This reveals the weakness of the whole approach, and creates the need for the many safeguards that the OIG has imposed.

How effectively can the OIG requirements protect the quality of patient care? The OIG relies heavily on the use of quality metrics, boards of review and monitoring to detect such developments such as whether difficult patients are shifted to other hospitals. In most cases, however, the effectiveness of those

¹OIG Advisory Opinions 05-01 – 05-06.

²*Gainsharing Feasibility Hinges on Developing Equivalency Criteria-Attorney*, MEDICAL DEVICES, DIAGNOSTICS & INSTRUMENTATION, May 30, 2005, at 13.

approaches has not been validated. In many cases the metrics will be quite debatable, and the board of review will conduct its analysis at quite a distance from the patient's bed and subject to potential conflicts of interest. Substantial questions therefore remain about the impact gainsharing would have on the quality of care.

Future Care. In health policy, whenever a major change is contemplated, policymakers should examine the change not just from how it might affect care today, but how it might affect care in the future. Americans have come to enjoy one of the best healthcare systems in the world, and one of the striking features of that system is its continuous improvement over time. The system improves, in part, because it structurally encourages that improvement. From a patient perspective, how gainsharing encourages future improvement must be ascertained. Unfortunately, the current gainsharing programs do not include any structural elements that would encourage future improvement. For example, there does not seem to be flexibility built into these programs which would allow physicians to adopt better technologies as they become available. Without that flexibility, patients will not experience the improvements they have enjoyed in the past.

Malpractice. When deciding health policy, the focus should clearly be on quality and cost. If quality can be ensured, malpractice will not be an issue. But as outlined above, there are a number of valid questions about whether quality is adequately protected. In the absence of clear answers to these questions, we can expect malpractice litigation to be an issue.

Gainsharing puts physicians and hospitals in a very weak position when it comes to malpractice. As already discussed, gainsharing specifically has as its purpose the financial inducement for physicians to exercise their clinical judgment in a manner that saves money. While we do not live in an ivory tower and money should be considered even as a counterweight to quality, one must question whether a physician's or hospital's response will be justifiable if a patient is harmed and malpractice is alleged.

One can imagine a scenario where a physician clearly changes his practice patterns in response to gainsharing. If a harmed patient brought suit against the physician, the physician would need to explain why he changed his practice patterns abruptly. In that position, the physician must be willing and able to say that his practices before gainsharing were unnecessarily wasteful and added no value. Because of his financial incentive, he will have an uphill battle to establish credibility. If there is any possible link between the change in practice and the injury sustained, a finding of malpractice seems likely.

Patient Rights. One of the cornerstones of the U.S. healthcare system is our respect for patient rights and informed consent. Given the very few instances in which gainsharing has been used, many issues remain concerning how the nature of gainsharing will be fully and transparently communicated to patients in a practical way.

Additionally, since most patients will be unlikely to receive the financial benefit of gainsharing, it is an open question as to whether they will consent. Therefore, it's fair to ask: what's in it for them? In every other instance where patients are asked to consent, there is arguably a benefit that they derive in exchange for increased risk. Gainsharing, on the other hand, quite simply does not offer any upside benefit directly to patients, and so they have little incentive to accept any downside risk.

The Tension. Gainsharing treats products as commodities even when they are not. In some of the areas that have been targeted for gainsharing — cardiology, cardiac surgery, and orthopedics — many of the products have a high degree of differentiation. Tremendous differences exist, for example, among orthopedic implants. Differences in the instrumentation used, metallurgy, design (including factors influencing patient fit, range of motion, and long-term stability), and durability reflect a wide variety of choices for surgeons and patients. The type of knee implant that might work best for a 45-year-old athlete as compared to a 70-year-old might be vastly different. Just as patients come in all different shapes, sizes and life-styles, so must orthopedic implants.

Gainsharing tends to treat these orthopedic implants as commodities and attempt to standardize usage into a smaller number of varieties. The cost of that reduced choice could be clinical effectiveness. Moreover, a challenge for those who want to experiment with gainsharing is the relatively long time that it takes to understand the outcomes in such fields. Reduced selection in orthopedic implants, if it in fact resulted in less than optimal implants being used, may not produce noticeable negative outcomes for a period of years.

The irony is that for devices and supplies that are indeed commodities, gainsharing is not needed. Hospitals can and already do consolidated purchasing of such items to obtain the quantity discounts they desire. Gainsharing was invented for instances where the items are *not* commodities, and where savings can only be obtained through the exercise of clinical judgment at the bedside. Policymakers cannot lose sight of that.

Going Forward. This paper has attempted to identify some of the outstanding issues that patients may consider in assessing the appropriateness of gainsharing. As discussed at the outset, though, policymakers need to look for any reasonable approach that could save money. No stone should remain unturned, including this one.

Demonstration Project. Gainsharing is essentially an idea, and a largely untested one at that. In these situations, policymakers normally would opt for a demonstration study through which the net savings can be more specifically assessed. Hopefully, that will be done with gainsharing. A demonstration project through the Medicare program may be the most effective approach. No matter who develops the project, however, it must be constructed to produce useful data on the pertinent issues. Careful attention to the program costs is necessary, as it is to the impacts on the quality of care and patient rights.

Freedom of Choice. Particularly in the early stages of exploring the consequences of gainsharing, it will be necessary to preserve freedom of choice for physicians so that they are not constrained to the point they must compromise patient care. Physicians must be allowed to exercise their judgment regarding the suitability of the medical product for a particular patient. While that discretion can be managed through oversight processes, it should never be removed.

Limits on Rewards. As the OIG has specified in its advisory opinions, it is prudent to impose limitations on gainsharing. For the foreseeable future, programs will need to recognize, for example, floors below which further savings will not be rewarded.

Transparency. As previously noted, ensuring transparency for patients will be quite difficult. Significant additional thought is required on how patients can be informed about gainsharing and its potential consequences. The tendency will be to downplay the consequences; as a result, the government must take extra care to protect patient rights.

Quality Assessed and Monitored. Of greatest concern is gainsharing's impact on patient care. Unfortunately, medicine is a combination of art and science, and as a result, in most cases it is simply not conducive to exact measurement. While there are a number of quality standards which can be utilized, policymakers certainly need to approach this topic understanding that these metrics will not capture all of the consequences of the program for patient care. At the same time, committees far from patients' bedside will not be able to detect every consequence either. Policymakers must therefore continue to look for additional safeguards.

Conclusion. While gainsharing is certainly an interesting idea worthy of further consideration, there are a number of outstanding issues that need to be identified and resolved. Hopefully, policymakers will thoughtfully consider these issues and look for ways to generate data through limited use of the program before allowing it to become more pervasive.