

Good morning Madam Chairman and Members of the Subcommittee. I am Lewis Morris, Chief Counsel at the U.S. Department of Health and Human Services' Office of Inspector General (OIG). I appreciate the opportunity to discuss OIG's views on gainsharing programs offered by hospitals.

While gainsharing promotes hospital cost reductions by aligning physician incentives with those of the hospital, these arrangements also implicate the fraud and abuse laws. When evaluating the risks posed by a gainsharing program, OIG looks for three types of safeguards: measures that promote accountability, adequate quality controls, and controls on payments that may change referral patterns. Properly structured, gainsharing arrangements may offer opportunities for hospitals to reduce costs without causing inappropriate reductions in medical services or rewarding referrals of Federal health care program patients. In a number of specific cases, OIG has concluded that the arrangement presents a low risk of abuse and, therefore, exercised its prosecutorial discretion not to impose sanctions. However, absent a change in law, it is not currently possible for gainsharing arrangements to be structured without implicating the fraud and abuse laws.

My testimony begins with a brief overview of gainsharing and a discussion of the Federal laws that are implicated by these types of arrangements. I will then describe some useful considerations in evaluating the risk of fraud and abuse posed by gainsharing arrangements.

### **BACKGROUND ON GAINSHARING ARRANGEMENTS**

While there is no fixed definition of gainsharing, the term has typically referred to an arrangement in which a hospital gives physicians a share of any reduction in the hospital's costs attributable in part to the physicians' efforts. Gainsharing can take several forms. Some arrangements are narrowly targeted, giving the physician a financial incentive to reduce the use of specific medical devices and supplies, to switch to specific products that are less expensive, or to adopt specific clinical practices or protocols that reduce costs. Other more problematic arrangements are not targeted at utilization of specific supplies or specific clinical practices, but instead offer the physician payments to reduce total average costs per case below target amounts.

A purpose of gainsharing is to align physician incentives with those of the hospital and thereby promote hospital cost reductions. Under Medicare's prospective payment system, hospitals have a strong incentive to reduce per patient admission costs, because they receive a fixed amount for inpatient services without regard to actual costs. Physicians, on the other hand, are reimbursed separately based upon a fee schedule and may have little or no incentive to choose less costly supplies or devices, or to support hospital efforts to negotiate lower prices from suppliers of physician-chosen items and supplies, such as stents and cardiac and prosthetic devices. In fact, there are reports of medical device manufacturers having financial relationships with some physicians that

create conflicts of interest and potentially reward the physician for loyalty to the device manufacturer at the expense of the hospital and the health care system in general.

Gainsharing arrangements are an attempt to bridge the gap between the hospital and physician payment systems. By giving the physician a share of any reduction in the hospital's costs attributable to his or her efforts, hospitals anticipate that the physician will practice more cost effective medicine. For example, gainsharing programs that include product standardization may provide a physician with an incentive to choose clinically equivalent and medically appropriate devices that are also less expensive. The hospital then shares with the physician a portion of the hospital's savings resulting from the physician's use of the standardized product.

### **PERSPECTIVE ON GAINSHARING**

OIG recognizes the potential benefits of gainsharing arrangements and that hospitals have a legitimate interest in enlisting physicians in efforts to reduce and eliminate unnecessary costs. Nonetheless, OIG has historically been very wary of gainsharing arrangements, because these arrangements implicate the Civil Monetary Penalty (CMP) and Federal anti-kickback statutes. There may also be physician self-referral or "Stark" law implications. However, the physician self-referral issues are more appropriately addressed by the Centers for Medicare & Medicaid Services (CMS) because the "Stark" law falls under the purview of that agency.

With respect to the CMP, the major concern is the impact of gainsharing on the quality of care provided to Medicare and Medicaid beneficiaries. The CMP, sections 1128A(b)(1) and (b)(2) of the Social Security Act, prohibits a hospital from knowingly making a payment directly or indirectly to a physician as an inducement to reduce or limit items or services furnished to Medicare or Medicaid beneficiaries under a physician's direct care. The CMP is an intentionally broad prohibition, reflecting Congressional concern that under the inpatient prospective payment system hospitals would have an economic incentive to pay physicians to discharge patients too soon—quicker and sicker—or otherwise truncate patient care.

Any hospital gainsharing plan that encourages physicians, through direct or indirect payments, to reduce or limit clinical services violates the CMP. The payment need not be tied to an actual reduction in care or to a reduction in medically necessary services, so long as the hospital knows that the payment may influence the physician to reduce services to his or her patients. There may be limited cost-saving measures that do not have the potential to reduce services, such as not opening certain supplies until needed. Even then, the circumstances must be closely scrutinized to ensure that the delay in opening the supplies does not have the potential to cause a reduction in services.

Gainsharing arrangements may also implicate the Federal anti-kickback statute, section 1128B(b) of the Social Security Act, if one purpose of the cost-saving payments is to influence referrals of Federal health care program business. Examples of gainsharing arrangements that give rise to concerns under the anti-kickback statute include, without limitation: an arrangement intended to encourage physicians to "cherry pick" healthier patients for hospitals offering gainsharing while sending the sicker, more costly patients

to other hospitals not offering gainsharing; an arrangement intended to foster loyalty and attract more physician referrals to the hospital; or an arrangement that allows a physician to continue for an extended period of time to reap the benefits of previously-achieved savings or to receive cost-saving payments unrelated to anything done by the physician. Moreover, OIG is concerned that gainsharing arrangements may lead to unfair competition among hospitals competing for physician-generated business.

### **GUIDANCE ON GAINSHARING ARRANGEMENTS**

OIG has expressed significant concerns about the risks posed by gainsharing. In 1999, OIG issued a Special Advisory Bulletin on Gainsharing outlining its analysis of arrangements call “black box” gainsharing. Black box gainsharing refers to arrangements that give physicians money for overall cost-savings without knowing what specific actions the physicians are taking to generate those savings. Under these types of arrangements, there is little accountability, insufficient safeguards against improper referral payments, and a lack of objective performance measures to ensure that quality of care is not adversely affected. For example, the drive for savings could motivate the physician to discharge a patient prematurely or otherwise inappropriately influence length of stay decisions, the very abuses that led to the enactment of the CMP law.

OIG also has issued seven favorable advisory opinions on gainsharing arrangements that are significantly different from the black box arrangements discussed in the 1999 Special Advisory Bulletin. The cost-saving measures in the approved arrangements generally fall into one of the following categories: product standardization; product substitution; opening packaged items only as needed; or limiting the use of certain supplies or devices. While each advisory opinion is limited to the specific facts presented by the requestor and cannot be relied upon by any other party, the considerations identified in the opinions are relevant when assessing gainsharing arrangements.

When evaluating a particular gainsharing program, OIG has generally focused on three aspects: accountability; quality controls; and safeguards against payments for referrals. With respect to accountability, a transparent arrangement that clearly and separately identifies the actions that will result in the cost-savings promotes accountability in several ways. First, it allows for a meaningful, objective assessment of the arrangement’s potential effects on quality of care. By contrast, black box gainsharing involves payments based on overall cost-savings, without any way to identify what specific and measurable actions the physician has taken to generate the cost-savings. Second, full disclosure to the patient of his or her physician’s participation in the gainsharing program promotes accountability. Finally, transparency permits scrutiny of the actions of physicians that are attributable to gainsharing payments, thus allowing the medical malpractice liability system to act as a further safeguard against inappropriate care.

Quality controls are a second key aspect OIG looks at when evaluating a gainsharing arrangement under the advisory opinion process. It is critical that the cost-saving measures for which gainsharing payments are made do not adversely affect patients. Accordingly, OIG looks for features that protect quality care. For example, OIG believes it is important to have a qualified, outside, independent party perform a medical expert review of each cost-savings measure to assess the potential impact on patient care. The

hospitals that obtained favorable advisory opinions established baseline thresholds based upon historic utilization and national data to protect against inappropriate reductions in services and to ensure that physicians would not receive any money for savings that accrued beyond the baseline thresholds. This structure helped protect against the physicians receiving payments for savings resulting from limiting necessary items and services. The arrangements OIG approved also include ongoing monitoring of quality of care and compliance with the gainsharing program. This oversight allows for the detection and appropriate handling of any inappropriate variation in treatment or uses of supplies or devices.

A third category of safeguards is directed at preventing gainsharing payments from being used to reward or induce patient referrals in violation of the anti-kickback statute. In this regard, OIG focuses on how payments are calculated and distributed to the physicians. Examples of safeguards that minimize the risk of abuse include, but are not limited to: calculating savings based on the hospital's actual acquisition costs; limiting participation to physicians already on the hospital's medical staff (to prevent enticing other physicians to change referral patterns); limiting the amount, duration, and scope of the payments (there is less incentive for a physician to switch referral patterns for short-term dollars); and distributing the gainsharing profits on a *per capita* basis to all physicians in a single-specialty group practice (reducing the incentive for individual physicians to generate disproportionate cost-savings). In short, there need to be safeguards that minimize the physician's incentives to change referral patterns or cherry pick healthier patients for the hospitals offering gainsharing payments, while steering sicker, more costly patients to other facilities.

It must be stressed that any evaluation of the risks presented by a gainsharing arrangement is highly fact specific. For example, with respect to the product standardization cost-saving measures approved in the favorable advisory opinions, OIG knew the specific vendors and products at issue and were able to have a medical expert evaluate the impact on quality of care. Furthermore, the physicians participating in the gainsharing arrangements could make patient-by-patient determinations of the appropriate supply or device, because the hospital continued to stock the full range of supplies and devices, not just those that would result in cost-saving payments. It is important to note that OIG did not approve every cost-saving measure proposed by the requestors of the opinions. As noted in the opinions, some measures were rejected and withdrawn from the arrangements. As such, any broad reading of the opinions should be done with caution. Different cost-saving measures or different payment structures could have produced different results.

## CONCLUSION

Gainsharing arrangements may help reduce hospital costs by aligning the economic interests of the hospital and its physicians. However, gainsharing arrangements violate the CMP and, improperly structured, pose substantial risk under the Federal anti-kickback statute. OIG has approved several arrangements that had been structured very carefully in order to minimize the risk to quality of care and the abuses associated with kickbacks. These arrangements incorporated a number of safeguards to promote accountability, quality, and protections against payments for referrals.