Is Gainsharing Finally Here to Stay? Recent Advisory Opinions and Proposed Stark Exception Appear to Pave the Way

Wednesday, August 26, 2009

After a rocky history with the agencies charged with enforcing the federal anti-kickback and self-referral statutes, we appear to have finally turned the corner toward acceptance of certain hospital-physician gainsharing arrangements. Based on a flurry of favorable advisory opinions and a proposed regulatory exception under the Stark II physician self-referral law, gainsharing arrangements may soon be available to hospitals and members of their medical staffs that are willing to take the time and trouble to carefully develop, execute and monitor detailed agreements that comply with the agencies’ requirements.

What is Gainsharing?

In a gainsharing program, a hospital, through a contractual arrangement, provides financial incentives to physicians on its medical staff to conserve hospital resources by sharing a portion, generally a percentage, of the savings in patient care costs attributable to the physicians’ use of cost-reduction measures. Gainsharing is an attempt by hospitals to control costs in light of the cost constraints of Medicare’s inpatient diagnosis-related group reimbursement system, which pays hospitals a fixed amount for each admission based upon the patient’s diagnosis, irrespective of the actual expense incurred in providing care to that patient.

Although hospitals are at risk for the cost of patient care and under financial pressure to reduce costs, physicians are paid separately for their professional services by third-party payors. Since physicians do not have the same incentive to save hospital costs, such programs are an attempt to align their incentives with those of the hospital by sharing cost savings with the physicians who produce those savings. Such measures are an acknowledgment by hospitals that it is often physicians, rather than non-physician hospital staff, who control many costs of patient care in the hospital setting, through their selection of supplies and devices.

Short History of the Positions of OIG and CMS on Gainsharing

The federal agencies have been inconsistent concerning their enforcement position on gainsharing arrangements. Gainsharing achieved some popularity among hospitals in the 1990’s, until the OIG issued a Special Advisory Bulletin on July 7, 1999, declaring that any incentive plan whereby a hospital compensated physicians directly or indirectly based on cost savings on items or services furnished to patients under the physicians’ care was prohibited by the civil monetary penalties statute, unless further legislation was adopted. The OIG noted that under the anti-kickback statute and civil monetary penalty law, gainsharing arrangements did not fall within any safe harbor or exception and involved a high risk of abuse. The OIG concluded that it had no authority under current law to allow such gainsharing arrangements and would not be issuing any more advisory opinions in this area. The Bulletin warned hospitals to unwind these programs expeditiously and concluded that hospitals should wait for legislative action before adopting such arrangements. Yet in 2001, within just two years of its Special Advisory Bulletin, the OIG softened its position by issuing an advisory opinion which approved a gainsharing arrangement.
Then, in its commentary to the Stark II, Phase II Interim Final Rules issued in 2004, CMS stated that there was no exception in the Stark law or regulations that would permit payments to physicians based on their utilization of designated health services, which include inpatient or outpatient hospital services, except for several Stark exceptions that permitted such payments only when made to enrollees of certain health plans. CMS reasoned that Congress intended to limit these kinds of incentives in accordance with the civil monetary penalty provision, and CMS could not create a regulatory exception for such activities. 69 Fed. Reg. 16054, 16088 (March 26, 2004).

The OIG renewed its earlier warning against the dangers of gainsharing in its Supplemental Compliance Program Guidance for Hospitals issued in January 2005. Later in 2005, however, the OIG changed course in six advisory opinions, Nos. 05-01 through 05-06. Those opinions concluded that the OIG would take no enforcement action under the anti-kickback statute against the gainsharing programs in question. The OIG indicated that hospitals may pay cardiologists and cardiac surgeons 50 percent of each hospital’s cost savings achieved through specific, verifiable cost-lowering measures during an initial one-year period. Such measures were designed to change the physician groups’ practice patterns by curbing the inappropriate use or waste of medical supplies, substituting less costly items, and standardizing certain cardiac devices and supplies where medically appropriate.

**Recent Advisory Opinions**

In five more recent advisory opinions issued over the past two years, the OIG has concluded that although each proposal would constitute an improper payment to induce the reduction of services under the civil monetary penalties statute and potentially violate the anti-kickback statute, the OIG would not impose administrative sanctions. On very similar sets of facts, the OIG approved the hospitals’ sharing of a percentage of their cost savings arising from the physicians’ implementation of a number of cost-reduction measures in certain designated hospital procedures through agreements with groups of cardiac surgeons, anesthesiologists, orthopedic surgeons and cardiologists. In each case, the hospital studied, and all parties agreed on, a fixed number of specific opportunities that would present substantial cost savings without adversely affecting the quality of care.

Most recently, the OIG, in Advisory Opinion No. 08-15, issued on October 6, 2008, found that although a gainsharing arrangement with two cardiology groups could constitute an improper payment to induce the reduction or limitation of services in violation of the civil monetary penalties law and potentially violate the anti-kickback statute, the OIG would not impose administrative sanctions based on the facts as presented. The OIG reviewed a hospital’s arrangement with the two physician groups, both made up of cardiologists who had active privileges at the Hospital and who together performed nearly all the cardiac catheterization laboratory services at the Hospital. As in the facts in the earlier Advisory Opinion No. 07-22, the Hospital had commenced the program, but no payment had been made to the cardiology groups pending the outcome of the advisory opinion process. The Hospital had hired a program administrator who would be paid a monthly fixed fee not tied in any way to the cost savings and representing fair market compensation.

To develop the arrangement, the Hospital studied the cardiology groups’ practices at the Hospital’s cardiac catheterization laboratory and identified 30 specific cost-saving opportunities, which were adopted by both the Hospital and the cardiology groups for medical appropriateness. Designed to change the current laboratory practices to standardize the use of medical devices and supplies and curb the inappropriate use or waste of devices and supplies, the 30 recommendations fell into three major categories:

- **Product Standardization.** Twenty-five recommendations would standardize the types of cardiac catheterization devices used by the Cardiology Groups, such as stents, balloons, interventional guide wires and catheters, vascular closure devices, diagnostic devices, pacemakers and defibrillators. The cardiology groups were required to work with the Hospital to evaluate vendors and products based on clinical safety and effectiveness, whether standardization was clinically appropriate, and finally cost.

- **“Use as Needed” Devices.** Four recommendations would limit the use of specific vascular closure devices to an “as needed” basis for coronary and peripheral interventional procedures and diagnostic procedures. The cardiology groups would make patient-by-patient determinations as to whether the devices were clinically indicated, and these devices would remain readily available in the procedure room.

- **Product Substitution.** One final recommendation was to substitute, as appropriate, less costly antithrombotic medication for other products being used by the cardiologists, which the Hospital certified would not adversely impact patient care.

Similar to the other favorable advisory opinions referenced above, the arrangement included many safeguards to protect against inappropriate reductions in services. For product standardization, the cardiologists would make an individual determination for each patient of the most appropriate device or supply, and the physicians would have available the same selection of devices and medications as before the arrangement was instituted. For
“use as needed” recommendations for vascular closing devices, objective historical and clinical measures would be used to establish floors beyond which no savings would accrue to the cardiologists.

The covered cardiac procedures would be tracked against quality indicators established by the American College of Cardiology which reflect objective hospital baselines. The cardiologists would receive no cost-sharing amounts for procedures involving reductions in these historical quality indicators. The program administrator predicted that implementation of the 30 recommendations in accordance with these guidelines would result in substantial cost-savings opportunities for the Hospital without adversely impacting the quality of patient care.

Over the three-year period of the arrangement, the hospital would pay each of the Cardiology Groups separately on an annual basis for 50 percent of the savings achieved in the prior year by the particular group’s implementation of the recommendations. To calculate the amount of the payment for the first year, the actual costs incurred for the items included in the 30 recommendations and used in the current year would be subtracted from the costs for similar items used for comparable procedures in the prior base year. At the beginning of the second and third years, however, the hospital would “rebase” the arrangement to remove the prior year’s savings from the accounting so that the cardiologists would not receive payments for savings achieved in prior years.

Further safeguards would prohibit a physician from receiving cost savings if his or her volume of the affected procedures payable by a federal health care program in the current year exceeded the volume of similar procedures performed in the prior base year. In addition, a committee would monitor the case severity, patient age and payors of the patient population treated under the arrangement. If there were significant changes indicating that a cardiologist had altered his referral patterns to steer less costly patients to the Hospital, that physician’s participation in the arrangement would be terminated. Finally, a cap would be imposed on payments to each group so that the group could be paid no more than 50 percent of the projected cost savings in the initial base year. Each group would be compensated solely for its own savings.

Documentation of the arrangement by the hospital and the cardiologists would be made available to the secretary of DHHS upon request. Patients would be informed in writing prior to admission or giving their consent that the cardiology groups are compensated based on a portion of the hospital’s cost savings, and patients would be provided with detailed information upon request. Payments would be distributed by each cardiology group to its physician members on a per capita basis to reduce the incentive for an individual physician to generate disproportionate cost savings.

OIG Legal Analysis in Recent Advisory Opinions

Civil Monetary Penalty Law. The civil monetary penalty law prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to Medicare and Medicaid patients. Although many of the provisions of the proposed arrangements implicated this law, the OIG found that certain specific cost-saving actions could alleviate the agency’s concerns. Favorable factors permitting the arrangements despite the provisions of the civil monetary penalty law included the following common elements:

- The cost savings were clearly and separately identified, and there was transparency and individual physician accountability for any adverse effects of the arrangement.
- The parties provided credible medical support that the recommendations would not adversely affect patient care, and this was confirmed by periodic review of the arrangement.
- The payments under the arrangement were calculated based on actual out-of-pocket costs for all procedures, regardless of the source of reimbursement, and were not disproportionately performed on federal health care program beneficiaries.
- To protect against inappropriate reductions in services, the arrangement used objective historical and clinical measures to establish a “floor” or baseline thresholds beyond which no savings accrued to the physicians.
- In the product standardization area, the availability of devices was not restricted, and the physicians still had available the same selection of devices as prior to the arrangement.
- The hospital and physician groups provided written disclosures about their involvement in the arrangement to patients who could have been affected and provided patients with the opportunity to review this documentation prior to admission to the hospital.
- The financial incentives under the arrangement were reasonably limited in duration and amount.
- Payments were made to the physician group, with profits distributed to members on a per capita basis.

Anti-Kickback Statute. The anti-kickback statute renders it a felony to offer payment, solicitation or receipt of remuneration intended to induce or reward referrals of items or services reimbursable by a federal health care program. Although such arrangements could disguise remuneration intended to reward or induce referrals, the
A number of protections were put into place to ensure that the arrangement did not have a disproportionate effect on federal health care program beneficiaries. The protections included the facts that the physicians were already on the medical staff; there was a cap on potential savings derived from federal program beneficiaries; the contract was for only a limited number of years; and patient admissions were monitored for any changes in referral patterns based on severity, age or payor.

The structure of the arrangement included features to ensure that payments were not used to reward physician referrals. The physician groups distributed profits to their members on a per capita basis, mitigating any incentive for one physician to generate disproportionate cost savings, and in the case of the anesthesiologists, were not in a position to refer federal program business to the hospital.

The OIG indicated that it had particular concern about multiyear arrangements. One year’s worth of cost savings was subject to an aggregate cap on the amount of payment, limited to a term of between one and three years, and limited in scope by appropriate utilization levels. Annual rebasing would remove previously accomplished savings from the accounting and thus avoid improper duplication of physician payments.

CMS’s Proposed Exception to the Stark II Law for Gainsharing Programs

Unless an exception applies, the Stark II statute prohibits (1) a physician or his immediate family member, who has any kind of “financial relationship” with an entity, from making a referral to that entity to furnish one or more of 11 categories of “designated health services” payable by the Medicare program, and (2) the entity from presenting a claim for reimbursement for a designated health service resulting from a prohibited referral. 42 USC § 1395nn(a). This is a “bright line” statute; if a physician makes a referral for such a service to an entity with which he has a financial relationship, then presenting that item or service to Medicare or Medicaid for payment would be illegal in the absence of an applicable exception. The Stark law has been an ongoing concern of commentators with respect to gainsharing, because the OIG advisory opinion process does not address the lawfulness of the proposed facts under Stark.

On July 7, 2008, CMS for the first time issued a proposed regulatory exception to the Stark II law for incentive payment and shared savings programs, which includes certain pay-for-performance and gainsharing arrangements. Specifically, the new proposed rule excepts from the Stark law remuneration paid by a hospital to a physician as part of certain documented incentive payments or shared savings programs designed to achieve (1) improvement of the quality of hospital patient care services by changing physician clinical or administrative practices, and/or (2) actual cost savings for the hospital resulting from the reduction of waste or changes in a physician’s clinical or administrative practices, without an adverse effect on or diminution in the quality of hospital patient care services. 73 Fed. Reg. 38502, 38604-05. The proposed rule incorporates the standard established by the advisory opinions issued by the OIG under the anti-kickback statute, including Advisory Opinion No. 08-15, to codify those requirements into the new Stark II exception.

The first category addresses “pay for performance” (P4P) programs, whereby hospitals provide a bonus payment to physicians for improving quality and outcomes and may also address improvements to efficiency. These programs are subject to a legal analysis similar to that for gainsharing arrangements.

As permitted by the terms of the proposed exception, an incentive payment or shared savings program must identify patient care quality measures or cost-saving measures, or both. It must use an objective methodology that is verifiable and supported by credible medical evidence. The measures must be individually tracked and reasonably related to the hospital’s practices and patient population. The arrangement must be monitored throughout its term to protect against inappropriate reductions or limitations in patient care services.

The incentive payment or shared savings program must establish baseline levels for the performance measures subject to the program, using the hospital’s historical and clinical data. Target levels for the performance measures must be developed by comparing historical data for the hospital’s practices and patient population with national or regional data for comparable hospitals, and there must be thresholds above or below which no payments will accrue to the physicians.

At least five physicians must participate in each performance measure. All participating physicians must already be on the medical staff at the commencement of the program and may not be selected in a manner that takes into account the volume or value of the physician’s referrals or business generated for the hospital. The hospital must offer the opportunity to participate in the program to all physicians in the department or specialty on the same terms and conditions.

There must be independent medical review of the program’s impact on the quality of patient care services by an individual or organization that is neither affiliated with the hospital or physicians in the program nor participating in any shared savings under the program. The arrangement must utilize corrective action if that review indicates a diminution in the quality of patient care. The independent review must be completed prior to the
Physicians must have access to the same selection of items, supplies or devices as was available at the hospital prior to the commencement of the program and must not be restricted from making medically appropriate decisions for their patients concerning the full range of tests, procedures and supplies. An individual physician may not have an investment interest or compensation arrangement with the manufacturer or distributor that arranges for the purchase of the items, supplies or devices tracked by the program. The hospital may not limit the availability of new technology that is linked to improved outcomes, is clinically appropriate for a particular patient and meets regulatory standards.

Patients must be given effective prior notice of their physicians’ participation in the program, describing the paid incentives and the performance measures under the arrangement. The program must be set out in writing and in sufficient detail to be independently verified, must be signed by both parties, and must identify each specific performance measure and the formula for calculating the resulting payment.

The term of the arrangement must be for no less than one year and no more than three years. The program must take into account previous payments made for performance measures already achieved to ensure that physicians do not receive duplicative payment for such cost savings. Cost savings must be paid based on (1) the hospital’s actual costs of either acquiring the items and supplies or providing the services that are subject to the gainsharing program, as compared with (2) the hospital’s costs for the same items, supplies or services during the one-year period immediately prior to the commencement of the program.

The formula for the calculation of payments over the term of the arrangement must be set in advance, not vary during the term of the arrangement, and not be determined in a manner that takes into consideration the volume or value of the physicians’ referrals or business generated between the parties. Payments may not be based in whole or in part on a reduction in the length of stay for one or all patients at the hospital. They must be distributed to each set of physicians participating in each performance measure (or to each physician organization consisting of at least five participating physicians) and ultimately distributed to individual physicians on a per capita basis with respect to each performance measure. There may be no increased payment based on the physicians’ treatment of a greater volume of federally reimbursed patient services than during the prior payment period. 72 Fed. Reg. 38606.

The hospital must maintain accurate and contemporaneous documentation of the program and make such documentation available to the Secretary of HHS upon request. These records should include the following: (a) the written agreement between the parties; (b) how the performance measures were selected; (c) the selection and qualifications of the independent medical reviewer; (d) the written findings of the reviewer; (e) any corrective actions taken by the hospital based on the reviewer’s written findings; (f) the amount and calculation of payments made under the program, including the hospital’s projected and actual product acquisition costs; (g) the rebasing of performance measures; and (h) the written notification given to hospital patients.

Finally, the arrangement may not violate the anti-kickback statute or any federal or state law or regulation governing billing or claims submission. 72 Fed. Reg. 38606.

**Conclusion**

In its recent advisory opinions, the OIG has indicated that carefully structured arrangements can meet hospitals’ goals of incentivizing efficiencies through monetary rewards to physicians under the anti-kickback statute. However, every advisory opinion includes the express limitation that it has no application to, and cannot be relied upon by, any individual or entity other than the parties to the particular arrangement. Moreover, the advisory opinions provide no protection from violations of the Stark law.

With the advent of the proposed Stark exception, hospitals and physicians can anticipate that there will soon be a mechanism that clearly permits such arrangements without having to go through the expensive and time-consuming advisory opinion process. The new Stark exception is proposed but not yet final or effective, and it may be revised when issued in final form. Upon adoption as a final rule, however, it should effectively protect the parties against a federal enforcement challenge under any applicable statute if the arrangement is carefully tailored to meet the myriad requirements of the new rule.

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