

2001 HEALTH LAW UPDATE
HONIGMAN MILLER SCHWARTZ AND COHN LLP

A Legal Briefing on Gainsharing Programs

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I. Introduction

- Gainsharing is a plan to align the economic incentives of hospitals and physicians in an effort to provide cost effective care, maintain or improve quality of care and patient satisfaction, resulting in a sharing of the cost savings achieved through some combination of a percentage payment, hourly fee or fixed fee to the physician.
- Hospitals see gainsharing as a method to help reduce costs through standardization and economic efficiencies in operations.
- Physicians see gainsharing as an opportunity to share in an extra pool of money.
- Industry interest in gainsharing arrangements heightened as a result of a HCFA-sponsored demonstration project.
- In 1991 HCFA launched the Medicare Participating Heart Bypass Center Demonstration Project (to test the feasibility and costs savings potential of paying hospitals and physicians a single fee for all services related to coronary artery bypass graft procedures).
- In lieu of separate Part A and Part B payments to the hospital and physician, respectively, HCFA paid a global rate that was less than the sum of the applicable Part A and Part B payments. (The hospital and physicians were allowed to split the global payment under any agreed to methodology.)
- The demonstration project was a success. For a 4 yr period, in which 4 hospitals participated, savings to the Medicare program were estimated at 40 million dollars. Additionally, the mortality rates for these cases decreased at the participating hospitals.
- Better cost management of cases can lead to the delivery of higher quality care as well as economic efficiencies.
- Issuance of OIG Special Advisory Bulletin (the “SAB”) in July of 1999 had a chilling effect on gainsharing arrangements.
- Issuance of OIG Advisory Opinions Nos. 00-02 (April 2000) and 01-01 (January 2001) may lead to a renewed interest in gainsharing arrangements.

II. Defining “Gainsharing”

- Gainsharing programs seek to align incentives of physicians and hospitals by giving physicians a stake in hospital savings achieved by modifying physician behavior to control costs and increase margins on hospital business.

- Gainsharing programs typically include features to safeguard quality of care and control malpractice liability exposure.
- Typical gainsharing programs include a payment to physicians to develop, implement, assess and refine best practices in the physicians' specialty.
- Some program designs call for an incentive payment in the implementation phase only; others include both a fee for oversight and redesign functions as well as an incentive payment tied to achievement of the program's goals.
- Some gainsharing models:
 - (i) Cost management contracts – hospital contracts with physician to undertake defined responsibilities that relate to controlling facility costs;
 - (ii) Department management contracts – a physician group or individual physician is hired either to manage the overall operations of a given department or to provide more limited management services;
 - (iii) Cost per case – hospital defines its baseline costs per individual case and then contracts with specifically identified physicians to reduce costs; and
 - (iv) Joint ventures – physicians have an equity position in the entity responsible for delivering and/or managing the delivery of health care services.

III. Gainsharing for Tax-exempt Hospitals

- Of course any compensation arrangement between a tax-exempt hospital and a physician raises the issue of inurement/excess benefit transaction.
- To avoid problems, compensation must be based on the fair market value of services provided (does not prevent incentive compensation arrangements).
- Rev. Ruling 69-383 lists the following five factors to be considered in determining if compensation is at fair market value: (i) arm's length negotiations; (ii) real and discernible business purpose; (iii) accomplishment of objectives in furtherance of the organizations purpose; (iv) no evidence of an abusive arrangement (*i.e.*, safeguards in place); and (v) a reasonable ceiling or cap on the total amount of compensation possible under the arrangement related to the level of services provided.
- In early 1999, the IRS issued favorable private letter rulings (unreleased) regarding gainsharing programs for two three-year cardiovascular cost reduction and quality improvement programs which funded a physician incentive award pool from savings generated by reductions in the hospital's cost of certain cardiology services through meeting process improvement initiatives and quality/satisfaction criteria.

- The IRS relied on Rev. Rul. 69-383 and Rev. Rul. 97-21 in deciding that the programs provided valuable services needed by the hospital, would result in tangible cost savings, were limited by a fair market value cap and would not affect the hospital's tax-exempt status.
- Future IRS rulings may be limited and favorable rulings withdrawn in the wake of the OIG's SAB regarding gainsharing programs.

IV. OIG Special Advisory Bulletin

- In light of the IRS guidance, many in the industry were expecting the issuance of a favorable advisory opinion by the OIG.
- On July 8, 1999, the OIG released a Special Advisory Bulletin entitled "*Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries*" in which it concluded that gainsharing arrangements involving payments to physicians to induce a reduction or limitation of services to Medicare or Medicaid patients are "flatly prohibited" by the civil money penalty provisions of the Social Security Act (the "CMP Law").
- The CMP Law (Section 1128A(b)(1) of the Social Security Act) prohibits a hospital from knowingly making a payment, directly or indirectly, to induce a physician to reduce or limit services to federal health care beneficiaries under the physician's direct care. A hospital that makes, and any physician who accepts, such payments is subject to civil money penalties of up to \$ 2,000 for each patient covered by the improper payments.
- The OIG adopts the position that the prohibitions under the CMP Law apply to any reduction in medical services rather than a reduction in medically necessary services.
- In contrast, the OIG is generally fond of reminding providers that the Medicare program covers only "medically necessary" services – why would Congress be interested in a reduction of non-necessary services if the overall quality of care is not impacted?
- According to OIG, a violation may also occur if the hospital knows the payments may induce physicians to reduce or limit services to patients, even if no actual reduction in care occurs. (Arguably the OIG ignores the specific intent standard of the statutory language.)
- The OIG bases its interpretation of the CMP Law, in part, on a report by the General Accounting Office (the "GAO Report") which concluded that hospital physician incentive plans designed to reduce the length of stay and service intensity for Medicare hospital patients may be subject to abuse.

- According to the OIG, it is still possible to structure gainsharing arrangements without violating the CMP Law, but any such arrangements must still satisfy the requirements of the Anti-Kickback Statute.
- An example of such an arrangement would be a personal services contract where a hospital pays a physician based on a fixed fee (or hourly rate) that is fair market value for services rendered rather than a percentage of cost savings (*i.e.*, potentially avoiding payments intended to induce a limitation in services provided).
- The OIG expressly declined to issue advisory opinions on gainsharing because:
 - (i) the OIG, to date, has only exercised its discretion to protect arrangements which pose a minimal risk of fraud and abuse, as compared to gainsharing arrangements which pose a serious risk of fraud and abuse in OIG's view, such that it would be "imprudent and inappropriate" to immunize such arrangements from sanctions;
 - (ii) the amount of ongoing oversight required for gainsharing programs as to both quality of care and fraud and abuse is not available through the Advisory Opinion process; and
 - (iii) case by case determinations by Advisory Opinions are an "inadequate and inequitable" substitute for comprehensive and uniform regulation in this area.

V. OIG Reasoning Under Siege

- In response to the SAB, commentators cited possible flaws in the OIG's reasoning for relying on the GAO Report as pushing a ban on gainsharing arrangements when the GAO Report only recommended adopting safeguards.
- The GAO report also recognized that many well designed gainsharing programs included safeguards to protect against a diminution in patient care.
- The commentators noted that the OIG's interpretation ignores the plain meaning of the term "inducement" and imports a "may influence" rule into the CMP statute.
- The commentators asserted that OIG ignored its legal duty to issue advisory opinions interpreting the CMP Law in an attempt to ban all gainsharing programs because of lack of staff to review numerous opinion requests.
- In response, the OIG argued that the CMP Law only requires an intent to induce (not actual reduction or limitation of services), the principal evil being the potential for financial considerations to influence a physician's medical judgment.

Moreover, OIG indicated in the SAB that simply adding the “medically necessary” qualification to the CMP Law would not be sufficient to protect certain incentive programs and that a negotiated rule making process would be more appropriate (if authorized by Congress).

- OIG also indicated its belief that the SAB provided efficient and timely general guidance on a common gainsharing model. OIG’s quality of care concerns with these programs are in the measures of quality which are subjective and have no established mechanism for independent verification, as well as the fact that in most programs, volume would be insufficient to be statistically significant.
- OIG did indicate it will consider revised advisory opinion requests, and providers should ignore the SAB only at their own risk.
- SAB does not have the force of law, however, as an agency’s interpretation of a statute the SAB would likely be afforded deference by a court.

VI. Application of Special Advisory Bulletin to Managed Care

- On August 19, 1999, the OIG released a follow-up letter to the SAB to clarify that hospital-based physician incentive plans limited to Medicare or Medicaid beneficiaries enrolled in risk-based managed care are not subject to the CMP Law.

VII. Post-SAB: OIG Issues Advisory Opinions regarding Gainsharing Arrangements

OIG Advisory Opinion No. 00-02 (2000)

- The OIG favorably reviewed a proposed cost savings program pursuant to which a hospital would reward its **non-physician** employees for submitting cost saving suggestions implemented by the hospital.
- Participation limited to non-physician employees of the hospital, although some of the participating employees would be in a position to make referrals for, or arrange for the referral or provision of, items or services reimbursable by federal health care programs.
- Non-physician employees would submit written cost saving suggestions to the HR department of the hospital. If the hospital determined that the cost saving suggestions were feasible, the employee would be paid a percentage of the cost savings generated by the suggestion.
- For suggestions resulting in quantifiable and measurable financial savings, the hospital would pay the employee a set percentage of the cost savings derived during **the first year** the suggestion was implemented. For cost saving suggestions that could not be measured or quantified, the hospital would estimate

its savings and pay the employee an amount based upon a predetermined, sliding scale, subject to a predetermined threshold cap.

- The hospital certified that (i) no payments would be made under the program, either directly or indirectly, to physicians; (ii) the program would not reward or implement suggestions that would reduce or limit health care services provided to patients or impair the quality of care delivered to its patients; (iii) the program would not reward suggestions that identify specific vendors, directly or indirectly; and (iv) the program would not reward or implement suggestions that would shift costs to a federal health care program.
- The OIG noted that the program would not implicate the CMP prohibition set forth in Section 1128A(b)(1) of the Act because physicians were prohibited from participating, either directly or indirectly, in the program.
- The OIG concluded that the program was unlikely to implicate the Anti-Kickback Statute. Further, even if the Anti-Kickback Statute was implicated, payments to bona fide hospital employees may be protected by the employment safe harbor set forth at 42 CFR §1001.952(i).
- The following factors were identified by the OIG as relevant to its conclusion that the proposed program would not likely implicate the Anti-Kickback Statute:
 - (i) the non-physician employee who would receive payment under the program would not have the decision-making authority necessary to implement the suggestion;
 - (ii) the program would not reward suggestions that specify, directly or indirectly, a particular vendor, thus, although some non-physician employees could be in a position to make referrals for, or recommend, items or services within the meaning of the Anti-Kickback Statute, the program does not create an inducement for such non-physician employees to steer patients to one provider over another; and,
 - (iii) the risk that a proposed suggestion could result in costs for, or overutilization of items or services reimbursable by, federal health care programs is minimized because the proposed arrangement (a) will only reward suggestions that increase efficiency or reduce cost, and (b) will not reward or implement suggestions that shift costs to any federal health care program.
- Thus, the OIG concluded that the hospital's proposed program: (i) would not violate the CMP law (which prohibit financial incentives to reduce or limit items or services); and (ii) could potentially generate prohibited remuneration under the Anti-Kickback Statute, if the requisite intent to induce referrals were present, but that the OIG would not subject the hospital to sanctions arising under the

Anti-Kickback Statute in connection with the establishment of the program itself; provided, however, that the OIG's conclusion does not apply to specific payments made by the hospital for specific suggestions. (Please note that the OIG has often used the Advisory Opinion process to protect arrangements that "technically" violate the Anti-Kickback Statute or other provisions of the Social Security Act.)

OIG Advisory Opinion No. 01-01 (2001)

- In OIG Advisory Opinion No. 01-1, the OIG favorably reviewed a proposed gainsharing program in which a hospital would share with a group of cardiac surgeons a percentage of the hospital's cost savings arising from the surgeons' implementation of a number of cost reduction measures in certain surgical procedures.
- Under the proposed program, the hospital would pay the surgeon group a share of the **first year cost savings** directly attributable to specific changes in the surgeon group's operating room practices designed to curb the inappropriate use or waste of medical supplies.
- Although the program included nineteen specific changes to the group's OR practices, all nineteen changes were grouped into three categories:
 - (i) The first category involved opening packaged items only as needed during a procedure. Most of these "open as needed" items are surgical tray or comparable supplies that will be readily available, albeit unopened, in the operating room during surgical procedures. One "open as needed" item included disposable components of a cell saver unit which, under the program, would not be opened until a patient experienced excessive bleeding. The hospital certified that the resulting delay in cell saver readiness would not exceed two to five minutes and would not adversely affect patient care.
 - (ii) The second category of recommendations consisted of the substitution, in whole or in part, of less costly items for items currently being used by the surgeons.
 - (iii) The third category consisted of a recommendation to limit use of Aprotinin – a medication currently given to many surgical patients pre-operatively to prevent hemorrhaging – to patients that are at higher risk of perioperative hemorrhages indicated by objective clinical standards.
- The proposed program contained several **safeguards** intended to protect against inappropriate reductions in services:
 - (i) With respect to the cell saver and the substitution recommendations, the program would utilize objective historical and clinical measures

reasonably related to the practices and patient population at the hospital to establish a “floor” below which no savings would accrue to the surgeon group.

- (ii) Similarly, for each of the proposed substitution recommendations, the program administrator identified historic patterns of use at the hospital or at hospitals with comparable practices and patient populations and established thresholds below which no cost savings would be credited to the surgeon group.
- (iii) With respect to Aprotinin, the program set forth specific, objective, generally accepted clinical indicators reasonably related to the practices to the hospital and its patient population to determine medical appropriateness. The program administrator determined that a certain percentage of patients to whom Aprotinin is administered meet these objective clinical indicators and under the cost savings program, savings from reduced use of Aprotinin would not be credited to the surgeon group if the savings result from utilization of Aprotinin in less than that certain percentage of cases or if the savings result from failure to use Aprotinin in a case that meets the clinical indicators.

- According to the program administrator, the cost savings recommendations would present substantial cost savings opportunities for the hospital without adversely impacting the quality of patient care.
- The program included appropriate **limitations** on the potential compensation payable to the group.
- As proposed, the surgeon group is to receive 50% of the cost savings achieved by implementing the recommendations for a period of one year. At the end of the year, cost savings will be calculated separately for each recommendation; this will preclude shifting of cost savings and ensure that savings generated by utilization below the set targets will not be credited to the surgeon group. The payment from the hospital will be made on an aggregate basis to the surgeon group which will then distribute its profits to each of its members on a per capita basis.
- In addition, payments to the surgeon group will be subject to the following limitations:
 - (i) if the volume of procedures payable by a federal health care program in the current year exceeds the volume of like procedures payable by a federal health care program performed in the base year, there will be no sharing of cost savings for the additional procedures;
 - (ii) to minimize the surgeons’ financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient

population treated under the program will be monitored by a committee composed of representatives of the hospital, the surgeon group and the program administrator, using generally accepted standards. If there are significant changes from historical measures, the surgeon at issue will be terminated from participation in the program;

- (iii) the aggregate payment to the surgeon group will not exceed 50% of the projected cost savings;
 - (iv) the payment methodology will generate payments to the surgeon group that will be consistent with fair market value for services tendered to the hospital in an arm's length transaction; and
 - (v) the hospital and the surgeon group will document the activities and the payment methodology under the program and will make this documentation available to HHS upon request. In addition, the hospital and the surgeon group will disclose the program to the patient, including the fact that the surgeon group's compensation is based on a percentage of the hospital's cost savings.
- In reviewing the proposed program, the OIG noted that hospital cost savings programs in general, and the proposed program in particular, may implicate at least three legal authorities:
 - (i) the CMP Law (for reductions or limitations of direct patient care services provided to federal health care program beneficiaries)
 - (ii) the Anti-Kickback Statute; and
 - (iii) the Stark Law (noting that the prohibitions imposed by the Stark Law fall outside the scope of the OIG's Advisory Opinion authority).
 - The OIG concluded that except for the unopened surgical tray items, the recommendations set forth in the program implicate the CMP in that the program constitutes an inducement to reduce or limit the current medical practice at the hospital.
 - With respect to the recommendations regarding "open as needed" surgical tray items, the OIG concluded that to the extent that the sole delay in providing items or services is the insubstantial time it takes to open a package of supplies readily available in the operating room, there would be no perceptible reduction or limitation in the provision of items or services to patients sufficient to trigger the CMP Law.
 - The OIG did not extend the above conclusion to the disposable cell saver components. Because the components must be attached to the machine and the machine must be started up, there will be an additional delay in the cell saver's

availability beyond merely opening the disposable components and thus there is a greater potential for harm. Accordingly, the OIG concluded that the cell saver incentive is subject to the statutory proscription of the CMP Law.

- The OIG noted that although the program would generally be subject to the CMP Law, several program features together provided sufficient safeguards such that the OIG would not seek sanctions against the parties under the CMP Law.
- These safeguards are as follows:
 - (i) the specific cost savings actions and resulting savings are clearly and separately identified and the transparency of the program will allow for public scrutiny and individual physician accountability for any adverse effects of the program on patient care;
 - (ii) the parties proffered credible medical support for the position that implementation of the recommendations would not adversely affect patient care;
 - (iii) the payments under the program are based on all surgeries regardless of the patient's insurance coverage, subject to the cap on payment for federal health care program procedures;
 - (iv) the surgical procedures to which the program applies are not disproportionately performed on federal health care program beneficiaries and the cost savings are calculated on the hospital's actual out of pocket acquisition costs, not on accounting conventions;
 - (v) the program protects against inappropriate reductions in services by utilizing objective and historical and clinical measures to establish baseline thresholds below which no savings will accrue to the surgeon group – further these baseline measures are reasonably related to the hospital's or comparable hospital's practices and patient populations, are action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in operating room practices;
 - (vi) the hospital and the surgeon group will provide written disclosures of their involvement in the program to patient's whose care may be affected by the program and will provide patients an opportunity to review the cost savings recommendations prior to admission to the hospital;
 - (vii) the financial incentives under the program are reasonably limited in duration and amount; and,
 - (viii) because the surgeon group's profits are distributed to its members on a per capita basis, any incentive for an individual surgeon to generate disproportionate cost savings is mitigated.

- The OIG noted that its decision not to impose sanctions in connection with the program was an exercise of its discretion and its position was consistent with that set forth in the SAB.
- The OIG further stated that the proposed program was “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.”
- The OIG proceeded to list features of many gainsharing programs **that heighten the risk** that payments will lead to inappropriate reductions or limitations of services including the following:
 - (i) there is no demonstrable direct connection between individual actions and any reduction in the hospital’s out of pocket costs and any corresponding gainsharing payment;
 - (ii) the individual actions that would give rise to the savings are not identified with specificity;
 - (iii) there are insufficient safeguards against the risk that the other, unidentified actions, such as premature hospital discharges, might actually account for any “savings;”
 - (iv) the quality of care indicators are of questionable validity and statistical significance;
 - (v) there is no independent verification of cost savings, quality of care indicators or other essential aspects of the arrangement.
- Anti-Kickback Statute concerns:
- The OIG noted that like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, it is concerned that the proposed program could be used to disguise remuneration from the hospital to reward or induce referrals by the surgeon group. Specifically, the proposed program could encourage the surgeons to admit federal health care program patients to the hospital, since the surgeons would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the hospital’s payment, dependent on cost savings.
- The OIG then stated that while the proposed program could result in illegal remuneration if the requisite intent to induce referrals were present, it would not impose sanctions in the particular circumstances presented by the proposed arrangement because:

- (i) the circumstances and safeguards of the proposed program reduce the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians;
 - (ii) the program eliminates the risk that it will be used to reward cardiologists or other physicians who refer patients to the surgeon group because the surgeon group is the sole participant in the program and is composed entirely of cardiac surgeons;
 - (iii) within the surgeon group, profits are distributed to its members on a per capita basis, mitigating any incentive for an individual surgeon to generate disproportionate cost savings;
 - (iv) the program specifies particular actions that will generate the costs savings on which the payments are based, which actions represent a change in operating room practice for which the surgeon is responsible and will have liability exposure;
 - (v) the payments will represent a portion of one year's worth of cost savings and will be limited in amount (*i.e.*, the aggregate cap), duration (*i.e.*, the limited contract term), and scope (*i.e.*, the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels).
 - (vi) Thus, the program payments do not appear unreasonable.
- The OIG concluded that:
 - (i) Program payments from the hospital to the surgeon group would constitute improper payments to induce reduction or limitation of services pursuant to the CMP Law, but the OIG would not impose sanctions in connection with the proposed program,
 - (ii) the proposed program would potentially generate prohibited remuneration under the Anti-Kickback Statute, if the requisite intent to induce referrals was present, but, that based on the totality of the facts present in the proposed program, the OIG would not request or seek sanctions for violation of the Anti-Kickback Statute.

VIII. Stark Law Issues

- All financial relationships with physicians, including gainsharing programs, must fit within a specific Stark Law exception regardless of the parties' intent.
- For Medicare or Medicaid patient referrals by a physician for designated health services, the gainsharing program must comply with a Stark Law exception.

- Many gainsharing arrangements will have difficulties complying with a Stark Law exception. For example, both the personal services exception and the fair market value exception require that the compensation payable under the arrangement be “set in advance.” Gainsharing arrangements in which the compensation paid to a physician is based on a percentage of savings basis is not likely to be deemed to be “set in advance.”
- Payments to physicians under both exceptions must be consistent with fair market value.
- HCFA has not yet issued any guidance regarding the application of the Stark Law to gainsharing programs; however, OIG did note in its SAB that such programs may implicate the Stark Law.

IX. Anti-Kickback Statute Issues

- Both Advisory Opinion No. 00-02 and Advisory Opinion No. 01-01 note that gainsharing programs may generate prohibited remuneration within the meaning of the Anti-Kickback Statute.
- Almost all incentive and gainsharing arrangements might be construed as payments for referrals under the Anti-Kickback Statute.
- Any incentive or gainsharing arrangement analysis must focus on the Anti-Kickback Statute exceptions, regulatory safe harbors and the intent of the parties. The question to be answered is whether the arrangement is intended to induce referrals (*i.e.*, the failure to comply with an exception or a safe harbor is not fatal).

X. Overlap between Anti-Kickback Statute and CMP Law

- The GAO Report indicates that incentive payments to physicians could be viewed as analogous but not identical to kickbacks.
- Not only do gainsharing programs incentivize reduced services after the referral decision has been made, these programs also may influence the physician’s initial decision as to where to refer.
- Another way to distinguish the Anti-Kickback Statute issues regarding gainsharing from the CMP Law issues is in timing – at the time of deciding where to refer a patient versus after the referral has been made and the physician is incentivized to reduce or limit care.
- To reduce Anti-Kickback Statute concerns, the entity should avoid referral requirements, measure cost savings in a volume neutral manner and exclude outliers or high cost cases from cost saving calculations. The arrangement should

focus primarily on quality and efficiency measures as the basis for compensation and should include a cap on total incentive payments.

- Pending clear, favorable guidance from OIG or legislative change, and bearing in mind that the Anti-Kickback Statute is a criminal statute, the risks of proceeding with many gainsharing programs may be prohibitive.
- Possible exceptions may be plans that pay at a reasonable hourly rate for actual consulting services for their design, and programs where the cost savings fund program development at the hospital but do not benefit or compensate the participating physicians in their private practice.
- The CMP Law is an intent-based statute with no safe harbors of its own. Compliance with an Anti-Kickback Statute safe harbor does not protect programs from violating the CMP Law. The CMP Law prohibition applies to physicians who have direct patient care responsibilities, and extends to inducements to limit any care, not just medically necessary care.
- Examples of potentially prohibited incentives include incentives designed to limit or reduce services a hospital would normally provide to a patient, and plans that encourage admission of likely low-cost cases to the hospital while excluding higher-cost patients.

XI. Alternative Gainsharing Arrangements

- It is possible to restructure gainsharing arrangements so as not to violate the CMP Law or the Anti-Kickback Statute.
- Consider non-hospital programs, programs that exclude Medicare and Medicaid patients, programs that apply to non-physicians (or only to physicians who do not have responsibility for direct patient care).
- Consider programs that reward physicians based on quality or patient satisfaction (*i.e.*, programs not relating to the quantity or cost of clinical services).
- Consider programs that are based on a fixed-fee or hourly rate compensation methodology.

XII. Current Status of Gainsharing Arrangements

- Providers should avoid entering into any gainsharing program of the type proscribed by the OIG in the SAB unless it receives a favorable Advisory Opinion.
- Be aware of the hurdles raised by Stark.

- Providers should use the guidance set forth in both Advisory Opinion No. 00-02 and Advisory Opinion No. 01-01 in structuring gainsharing arrangements.
- Providers also should evaluate their existing arrangements.

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