

**GAINSHARING:
STRUCTURING INCENTIVE PAYMENT AND SHARED SAVINGS
PROGRAMS**

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I. INTRODUCTION & OVERVIEW

A. Why Discuss “Gainsharing” Now?

1. As the cost of health care continues to soar, stakeholders are concerned about addressing cost effectiveness while maintaining or improving quality.
2. Recently CMS proposed one or more new Stark exception(s) for shared savings and incentive payment programs.
3. AHA/AAMC has called on OIG to issue a parallel Anti-kickback safe harbor (2/17/09 letter).
4. These organizations also requested that OIG retract its Special Advisory Bulletin in light of 14 favorable Advisory Opinions.
5. CMS Demonstration Projects.
6. Managed Care pilot projects.

B. What is “Gainsharing”?

1. **Definition?:** There is no established definition of such programs. They vary considerably. CMS has solicited comments on defining types of “Shared Savings” and “Incentive Payment Programs” to be included in a proposed exception to the Stark statute, and on whether there should be a separate exception for each type of program. *See* the CMS 2009 final rule on the Medicare Physician Fee Schedule, discussed below in Section VI.
2. **“Gainsharing:”** Traditionally, “Gainsharing” has meant: sharing of cost savings attributable to physicians’ efforts in controlling the costs of providing patient care. Typically the share has been expressed as a percentage of cost savings. The OIG Advisory Opinions discussed below in Section V are traditional gainsharing programs.
3. **“Shared Savings Programs:”** CMS, in its proposed exception to Stark published in 2008, uses the term “Shared Savings Program”

to describe both a traditional gainsharing program and also hybrid programs that include elements of shared savings and incentive payment programs.

4. **“Incentive Payment Programs:”** In the proposed exception to Stark, CMS proposes to protect certain “P4P (Pay For Performance), also known as quality-based purchasing, and other quality-focused programs that do not involve sharing cost savings from the reduction of waste or changes in administrative or clinical practice” which it refers to as “Incentive Payment Programs.”

C. **Why Structure Such Programs?**

1. **Misaligned Incentives:** Currently, although the reimbursement methodology used for hospitals creates an incentive to provide services cost effectively, the reimbursement system for physicians creates an incentive for them to order more services: the greater the volume of services, the greater the reimbursement. Yet, hospital costs are driven in part by physician orders.
2. **Hospital Reimbursement Incentives:** Under the Inpatient Prospective Payment System (“IPPS”), Hospitals are essentially paid a set price *per case* for a bundled set of services to Medicare inpatients.
3. **Physician Reimbursement Incentives:** Physician services are excluded from the services reimbursed to a hospital under IPPS. Instead, Physicians are paid on a fee-for-service basis *per procedure or encounter* under the Medicare Physician Fee Schedule (“MPFS”).
4. **Other Physician Incentives** for Physicians to do more:
 - a. Public perception that “more” is better
 - b. Malpractice concerns
5. **Goals of “Gainsharing” Programs:** The goal of any gainsharing, shared savings or incentive payment program is to align financial incentives between hospitals, physicians, payors and patients in order to produce cost-effective, quality care.

II. FEDERAL LAWS

A number of federal laws constrain the ability of hospitals and physicians to cooperate in gainsharing programs. Below is a summary of key federal legal constraints that must be considered in structuring any gainsharing program.

A. Civil Monetary Penalty Law (“CMPL”)

1. **Statute:** Social Security Act § 1128A(b)(1)-(2); 42 U.S.C. § 1320a-7a(b)(1)-(2)
2. **Regulations:** 42 C.F.R. Part 1003
3. **Prohibited Activity:** Hospitals knowingly making a payment to a physician, directly or indirectly, to induce a reduction/limitation in services to Medicare or Medicaid fee-for-service beneficiaries
4. **Exceptions:** None specified in statute or regulation. The OIG takes the position that it cannot create a regulatory exception without a statutory change. *See* OIG Special Advisory Bulletin (July 8, 1999). However, the OIG has determined that the CMPL is not applicable to Medicare or Medicaid managed care plans and beneficiaries. *See* Section III(A).
5. **Penalty:** \$2,000 per violation
6. **Enforcement Agency:** HHS OIG
7. **Relationship to Gainsharing:** All traditional “gainsharing” programs applicable to Medicare and Medicaid FFS beneficiaries, which pay physicians for cost savings resulting from reducing or limiting services, implicate the CMPL. Nonetheless, the OIG has taken the policy position in a series of Advisory Opinions issued beginning in 2001 that it will not impose sanctions where there are sufficient safeguards in place to ensure that quality of care is not compromised. *See* discussion of OIG Advisory Opinions in Section V.

B. Anti-kickback Statute (“AKS”)

1. **Statute:** Social Security Act § 1128B(b); 42 U.S.C. § 1320a-7b(b)
2. **Regulations:** 42 C.F.R. § 1001.952 et. seq.
3. **Prohibited Activity:** Knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce referrals of items or services covered by Medicare, Medicaid or any other federally funded program

4. **Exceptions:**
 - a. Although some statutory and regulatory safe harbors exist, none are specific to shared savings or incentive payment programs. In a comment letter dated 2/17/09, the AHA, AAMC and Federation of American Hospitals requested that OIG issue a new safe harbor regulation specifically covering shared savings and incentive payment programs as a “companion” to the proposed new Stark exception, and that OIG and CMS provide “coordinated guidance” on such programs. <http://www.aha.org/aha/letter/2009/090217-cl-OIG-113-N.pdf>
 - b. Some gainsharing programs may be covered by the existing employment or personal services safe harbor. However, traditional gainsharing programs that express the amounts to be paid to physicians as a percentage of cost savings will not satisfy the safe harbor requirement that compensation be set in advance.
 - c. Non-compliance with a safe harbor does not necessarily indicate non-compliance with the statutory prohibition. Providers should structure any such program so that it will not reward or induce referrals.
5. **Penalty:** Up to 5 years in prison, fine up to \$25,000 under SSA § 1128A(a)(7), mandatory exclusion from participation in federal health care programs under SSA § 1128(b)(7)
6. **Enforcement Agency:** DOJ (criminal) & HHS OIG (exclusion authority)
7. **Relationship to Gainsharing:** Gainsharing programs violate the AKS if “remuneration is paid purposefully to induce referrals of items or services payable by a Federal health care program,” even if this is only one purpose of the program. Under Advisory Opinions issued to date, the OIG will not impose sanctions where the program includes certain design elements and safeguards that pose a low risk that the program can be used to disguise payments to induce referrals. *See* discussion of OIG Advisory Opinions in Section V.

C. **Physician Self-referral Law (“Stark”)**

1. **Statute:** Social Security Act § 1877; 42 U.S.C. § 1395nn
2. **Regulations:** 42 C.F.R. § 411.350 et. seq.
3. **Prohibited Activity:** Physicians referring Medicare and Medicaid patients for designated health services (including inpatient and outpatient services) to entities with which the physician has a financial relationship, unless the activity falls within a regulatory exception
4. **Exceptions:** Mandatory exceptions
 - a. **Currently:** Although there are exceptions applicable to Medicare and Medicaid managed care physician incentive plans that are risk-based (*see* Section III(A)(3)), there is no exception specific to hospital gainsharing plans. Some gainsharing programs may fall under exceptions for: bona fide employment relationships, personal services arrangements, arrangements involving fair market value, arrangements involving indirect compensation, or services provided by an academic medical center. Under the current law, compensation that is set out as a percentage or formula can meet the "set in advance" requirement if the method of calculating the compensation includes sufficient detail so that its application can be verified.
 - b. **Proposed Exception:** *See* discussion in Section VI.
5. **Penalty:** Fines, False Claims Act bootstrapping
6. **Enforcement Agency:** CMS; No advisory opinions, to date, on gainsharing arrangements
7. **Relationship to Gainsharing:** Most traditional gainsharing programs involve a financial relationship between a hospital and physicians, where the physicians refer *Medicare and Medicaid* patients to the hospital for inpatient or outpatient hospital services, which constitute designated health services. In these circumstances, a gainsharing program *must* meet a Stark exception. (Compliance with Stark is waived for gainsharing programs that are part of a CMS Demonstration Project, discussed in Section IV).

D. **Tax Exemption Laws**

1. **Statute:** Internal Revenue Code: § 501(c)(3); § 4958

2. **Prohibited Activity:** Private Inurement; Private Benefit; Excess Benefit Transactions
3. **IRS Guidance:** Revenue Ruling 69-383, 1969-2 C.B. 113; unreleased 1999 IRS ruling, available at 1999 TNT 128-39
4. **Relationship to Gainsharing:** In order to maintain tax-exempt status, no part of a hospital's net earnings may inure to the benefit of a private shareholder or individual. There were concerns that gainsharing with physicians might constitute such inurement, but an unreleased IRS ruling indicated that a properly structured program paying reasonable compensation will not threaten a hospital's tax exempt status. Gainsharing payments to certain physicians also need to comply with IRS excess benefit transaction requirements.

III. MANAGED CARE

A. Federal Law

1. **Not Applicable:** The CMPL does *not* apply to Medicare or Medicaid *managed care* beneficiaries. *See, e.g.*, OIG letter dated Aug. 19, 1999, available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/gletter.htm>. The CMPL initially prohibited payments by managed care plans. It was later amended to remove the reference to Medicare and Medicaid managed care plans. This permitted risk-based managed care plans to implement a variety of gainsharing and physician incentive programs, subject to the minimal limitations set forth in other statutes and regulations described below in section 3.
2. **Potentially Applicable:** Nonetheless, even in physician incentive arrangements involving managed care payors, a hospital should evaluate whether a proposed arrangement might induce physicians to reduce or limit services to Medicare or Medicaid *FFS* patients. In one Advisory Opinion, the OIG found the CMPL to be implicated by a payment from a *private insurer* to a hospital, and in turn to physicians, since it was determined on the basis of meeting targets applicable to *all* patients. *See* OIG Advisory Opinion No. 08-16 at page 6. In this opinion, the OIG further states in dicta that even if the quality targets were not so determined, the efforts of physicians to meet the quality targets “would, as a practical matter, necessarily be directed at all patients.” In fn 6 the OIG further notes: “Moreover, some patients insured by the Private Insurer may also be Federal health care program beneficiaries” (i.e. dual eligibles).

3. **Applicable:** Instead of the CMPL, a different set of statutes and regulations are applicable to risk-based Medicare and Medicaid managed care programs which operate “physician incentive plans.” *See, e.g.,* OIG Advisory Op. No. 08-21 at fn 12. These impose far less stringent requirements than the CMPL, and only prohibit inducing the reduction of “*medically necessary*” services.
 - a. Under the original statute addressing Medicare Managed Care plans, SSA § 1876(i)(8), 42 U.S.C. § 1395mm(i)(8), Health Maintenance Organizations and Competitive Medical Plans may operate a “physician incentive plan” if:
 - i. “No specific payment is made directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit *medically necessary* services provided with respect to a specific individual enrolled with the organization,” and
 - ii. The organization conducts periodic surveys of enrollees and former enrollees to determine patient satisfaction with the quality of services and access.
 - iii. Also, if the plan puts physicians or physician groups at “substantial financial risk,” the organization must provide stop loss protection.
 - iv. A “physician incentive plan” is defined as: “any compensation arrangement between an eligible organization and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the organization.” SSA § 1876(i)(8), 42 U.S.C. § 1395mm(i)(8).
 - v. The regulations contain additional requirements. *See* 42 C.F.R. § 417.479.
 - b. A *Medicaid* managed care plan (as defined in SSA § 1903(m)(1)(A), 42 U.S.C. § 1396b(m)(1)(A)) must meet the requirements for physician incentive plans operated by Medicare managed care plans in SSA § 1876(i)(8), 42 U.S.C. § 1395mm(i)(8), summarized above. *See* SSA § 1903(m)(2)(A)(x), 42 U.S.C. § 1396b(m)(2)(A)(x); 42 C.F.R. § 438.6(h).
 - c. A Medicare Advantage Plan (formerly a Medicare + Choice Plan) may operate a physician incentive plan only if it meets the requirements set forth in SSA § 1852(j)(4), 42 U.S.C. §. 1395w-22(j)(4). These requirements are similar

to those required by SSA § 1876(i)(8), 42 U.S.C. § 1395mm(i)(8).

- d. *See also* the Medicare regulations at 42 C.F.R. §§ 417.479 and 422.208 which provide additional requirements for physician incentive plans operated by Medicare managed care organizations. Among these requirements is that “A private Medicare Advantage FFS plan may *not* operate a physician incentive plan.” 42 C.F.R. § 422.208(e). Accordingly, only *risk-based* MA plans may operate physician incentive plans. In addition, the MA regulations allow a physician incentive plan to pool Medicare, Medicaid and commercial patients if certain requirements are met. 42 C.F.R. § 422.208(g).

4. **Stark exceptions:**

- a. 42 C.F.R. § 411.355(c) - Protects the services provided by an organization or its subcontractors to enrollees of certain prepaid health plans, including Medicare and Medicaid managed care organizations, as well as entities operating under certain demonstration projects.
- b. 42 C.F.R. § 411.357(n) - Protects compensation arrangements between managed care organizations and physicians pursuant to certain risk-sharing arrangements.

B. **State Laws**

- 1. **Applicability:** State laws may apply to managed care beneficiaries, including those covered by Medicare and Medicaid managed care products.
- 2. **Example** - *See* discussion of New York law, below
 - a. **State Anti-Kickback Statute:** NY Social Services Law § 366-d
 - b. **State Physician Self-referral Law:** NY Public Health Law § 238 et seq. is called the “New York State Practitioner Self-Referral Law.” It is an all-payor statute modeled after Stark I, but with different exceptions from Stark.
 - c. **Relationship to Gainsharing:** Hospitals must evaluate State counterparts to Stark and AKS just as they would evaluate their compliance with the Federal rules. State laws add another level of analysis to the compliance evaluation of any gainsharing program. Nonetheless, *where a payor makes a payment directly to a physician or*

physician group, even state all-payor AKS and Stark type laws should not be implicated.

C. Example of a Managed Care Performance Based Incentive Program

1. **Goals of Program:** To align incentives of the physicians, hospital, patient and payor in producing cost-effective, quality care.
2. **Key Elements of Program:**
 - a. Payments to physicians are made by the *Health Plan*.
 - b. Patient Population used for measurement and payment *excludes* Medicare and Medicaid FFS patients
 - c. Performance is measured based on regionally developed “Best Practice Norms” relating to treatment of an entire case, which includes a severity of illness adjustment. A percentage of the savings achieved by using these norms is paid to physicians by Health Plan as an incentive to achieve the best practices. A cap on incentive payments discourages new/untried clinical practices. The Best Practice Norms include non-clinical savings opportunities.
 - d. Physicians can qualify for payments by (i) *maintaining* good practices as well as (ii) achieving improvement. (Note - OIG Advisory Opinions on programs relating to Medicare FFS beneficiaries require resetting the base in multi-year terms, failing to reward physicians for maintaining good practices. In the proposed Stark exception, discussed in Section VI, CMS solicits comments on whether to allow payments for maintaining a level of performance.)
 - e. Payments are made to individual physicians based on *individual performance per case*. (One outlier case doesn’t effect the achievements in other cases, and allows physicians to exercise sound professional judgment in each case without creating a financial incentive not to do so.)
 - f. To prevent steering, the number of admissions eligible for incentive payments is capped if the physician has privileges at another hospital.
 - g. Bonus only; no risk or penalties
 - h. Quality monitoring using established measures, plus patient satisfaction measured annually

- i. State Department of Health approves the payor/hospital contract. This adds a layer of protection, since a government agency is reviewing the terms of the contract.

IV. WAIVER AUTHORITY - DEMONSTRATION PROJECTS

A. CMS General Waiver Authority

1. **Statute:** 42 U.S.C. § 1395b-1(a)(1)(A). Section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92-603, enacted on October 30, 1972), as amended, and section 402 of the Social Security Amendments of 1967 (Pub. L. 90-248, enacted: January 2, 1968), as amended
2. **Limitations.** CMS' general waiver authority waives compliance with the requirements of Title XVIII (Medicare - codified at § 1395 U.S.C. *et seq.*) and Title XIX (Medicaid – codified at § 1396 *et seq.*), including Stark which is codified at § 1395nn. However, this general waiver authority does not authorize CMS to waive the AKS or CMPL. *See Robert Wood Johnson University Hospital v. Thompson*, 2004 U.S. Dist. LEXIS 8498 (D.N.J. Apr. 15, 2004): holding that a demonstration program approved by CMS in 2003 for 8 hospital members of the New Jersey Hospital Association did not implicate the AKS but did implicate the CMPL, and that CMS cannot use its general waiver authority to waive the CMPL. The court noted the distinction between the CMPL, which bars paying physicians to induce a reduction in services, and the managed care statute(s), which bar paying physicians to limit “medically necessary” services.

B. Statutorily Established Demonstration Projects on Gainsharing

1. **Purpose:** These Demonstration Projects provide an opportunity to evaluate different gainsharing program structures, determine whether programs achieve cost savings, and determine whether programs have a positive effect on the quality of patient care.
2. **Waiver of Stark, CMPL and AKS.** Each of the two statutory demonstration projects described below include an express statutory waiver of participants' compliance with Stark, CMPL and the AKS.
3. **Demonstration Projects:**
 - a. **Medicare Modernization Act of 2003 § 646 (P. L. 108-173) - “Physician-Hospital Collaboration Demo”**

- i. Will examine the effects of gainsharing on quality of care delivered within a health care system. Preference is given to a consortium of health care groups. No more than 72 hospitals (across all projects) may participate, for three year terms.
 - ii. Example: NJ Demo application 1/9/07 - Elements of this proposed demonstration project are described in the comments submitted by the New Jersey Hospital Association on August 25, 2008 to CMS on the Proposed Rule relating to a new Stark exception. *See* discussion in Section VI.
- b. **Deficit Reduction Act of 2005 § 5007 (P. L. 109-171)**
- i. Will examine the effects of gainsharing within one hospital. Up to six PPS hospitals may qualify, for three year terms
 - ii. Example: Beth Israel Medical Center, one of the hospitals in Continuum Health Partners, NY, NY

V. FEDERAL HHS OIG ADVISORY BULLETINS AND OPINIONS

- A. **Special Advisory Bulletin: “Gainsharing Arrangements and CMPs for Hospital Payments to Reduce or Limit Services to Beneficiaries” (July 8, 1999)** <http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm>
 Describes traditional gainsharing arrangements between hospitals and physicians as violating the CMPL. OIG takes the position that it cannot issue a regulation authorizing exceptions to the CMPL without a legislative change in that statute. OIG declined to issue favorable Advisory Opinions on arrangements proposed to date and indicated it was unlikely to issue any favorable Advisory Opinions in the future.

OIG Report “Recent Commentary Distorts HHS IG’s Gainsharing Bulletin” (Sept. 22, 1999)

<http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/bnagain.htm>

In this report, the OIG expressed reasons for declining to issue favorable Advisory Opinions thus far:

1. Insufficient safeguards against reductions in quality of care
2. Use of quality of care indicators that are subjective or of questionable validity
3. Patient volumes insufficient to yield statistically significant results
4. Insufficient independent verification of quality of care indicators, cost savings, or other essential aspects of the program

The AHA, AAMC and Federation of American Hospitals recently requested that OIG retract the 1999 Special Advisory Bulletin. *See* letter dated Feb. 17, 2009 at <http://www.aha.org/aha/letter/2009/090217-cl-OIG-113-N.pdf>

B. OIG Advisory Opinions on Gainsharing Programs:

1. **Scope:** The OIG evaluates gainsharing programs for their compliance with the CMPL and the AKS. Because the OIG does not enforce the Stark Law, the OIG opinions do not evaluate gainsharing programs' compliance with the Stark Law.
2. **Legal Analysis:**
 - a. **CMPL:** Because traditional gainsharing programs are predicated on paying physicians to induce them to implement cost savings measures by standardizing or substituting devices or supplies or using them only as needed, the OIG advisory opinions conclude that they always have the potential to induce physicians to limit or reduce care; therefore, the OIG always finds that these programs implicate the CMPL, the important consideration is whether the OIG, "given the safeguards in place, exercises its discretion not to impose sanctions." The OIG notes that, unlike the managed care statutes, the CMPL prohibits all reduction or limitation of services, regardless of whether current practices exceed what is medically necessary.
 - b. **AKS:** The OIG analyses whether the structure is likely to induce referrals or contains safeguards to eliminate the risk that it will induce referrals.
3. **Concerns Expressed by OIG** in its advisory opinion analysis:
 - a. **CMPL:** Reduction or limitation of devices or supplies will adversely impact patient care quality by leading to
 - i. "Stinting" on patient care
 - ii. "Cherry picking" healthy patients
 - iii. "Steering" sicker patients to hospitals not in program
 - b. **Stark/AKS:** The program will
 - i. allow hospitals to offer disguised payments for referrals
 - ii. promote unfair competition (a 'race to the bottom') to attract physician referrals

4. **Common Program Elements in OIG Advisory Opinions:**
To date, the OIG has issued favorable advisory opinions on 13 traditional gainsharing programs and one incentive payment program structured as a pay for performance program. All of the gainsharing programs that have received a favorable OIG opinion are similarly structured. These programs share the following characteristics:

- a. There is a written contract between a hospital and one or more physician groups (typically cardiology groups).
- b. Each member of the physician group currently has medical staff privileges at the hospital.
- c. For each arrangement, a program administrator identified a number of specific cost-savings opportunities after reviewing the physician's historical practices and developed recommendations on how to increase cost savings based on these opportunities; each of these recommended practices was reviewed for medical appropriateness.
- d. The recommendations for most of the programs related to decreasing the inappropriate use or waste of medical supplies during surgery, especially cardiac catheterization procedures. These recommendations generally fall into the following three categories:
 - i. product standardization,
 - ii. product substitution, or
 - iii. using a product only "as needed" (i.e. as medically necessary).
- e. Each program contained significant safeguards to protect against inappropriate reductions/limitations in services, including:
 - i. a full range of supplies and devices will be available to physicians if medically necessary for a particular patient,
 - ii. physicians make patient decisions as to what supplies/devices are needed to treat a particular patient, and
 - iii. where the recommendation is to use a supply/device only "as needed" or to make a substitution from a more expensive supply/device, the program establishes a "floor" beyond which no savings accrue to the physician groups, since the more

expensive supply/device may be needed in certain cases.

- f. The duration of most of the programs is one year, but several are for three years.
- g. If the term of the arrangement is multi-year, the savings targets are “re-based” at the end of each year (allegedly to avoid “duplicate” payments for having already achieved a level of performance).
- h. The hospital pays each physician group 50% of the cost savings achieved - by subtracting actual, current costs from historical, base year costs, and adjusting current costs if there has been an inappropriate reduction in use below targets.
- i. The hospital calculates the cost savings separately for each group (if there are multiple groups) and separately for each cost savings recommendation.
- j. Each Hospital makes an aggregate payment to a physician group, and the group pays each physician on a per capita basis.
- k. Patients treated under the arrangement are monitored by a committee.
- l. The hospitals provide written disclosure of the program to patients.

5. **Citations to OIG Advisory Opinions on Traditional Gainsharing:**

<http://www.oig.hhs.gov/fraud/advisoryopinions/opinions.asp>

- a. **No. 01-1 (Jan. 18, 2001)** - Arrangement with cardiology group shared 50% of cost savings achieved through 19 cost savings opportunities. One year term.
- b. **No. 05-01 (Jan. 28, 2005)** - Arrangement with cardiology group shared up to 50% of cost savings achieved through 24 cost savings opportunities. One year term.
- c. **No. 05-02 (Feb. 10, 2005)** - Arrangement with five cardiology groups shared up to 50% of cost savings achieved through 18 cost savings opportunities. One year term.
- d. **No. 05-03 (Feb. 10, 2005)** - Arrangement with cardiology group shared up to 50% of cost savings achieved through 29 cost savings opportunities. One year term.
- e. **No. 05-04 (Feb. 10, 2005)** - Arrangement with eight cardiology groups shared up to 50% of cost savings

achieved through 17 cost savings opportunities. One year term.

- f. **No. 05-05 (Feb. 10, 2005)** - Arrangement with cardiology group shared up to 50% of cost savings achieved through 12 cost savings opportunities. One year term.
- g. **No. 05-06 (Feb. 10, 2005)** - Arrangement with cardiology group shared up to 50% of cost savings achieved through 27 cost savings opportunities. One year term.
- h. **No. 06-22 (Nov. 9, 2006)** - Arrangement with cardiology group shared 50% of cost savings achieved through 24 cost savings opportunities. One year term.
- i. **No. 07-21 (Dec. 28, 2007)** - Arrangement with cardiology group shared 50% of cost savings achieved by through 25 cost savings opportunities. One year term.
- j. **No. 07-22 (Dec. 28, 2007)** - Arrangement with *anesthesiology* group shared 50% of cost savings achieved through 5 cost savings opportunities. One year term.
- k. **No. 08-09B (Aug. 7, 2008)** – Arrangement with *orthopedic* surgery groups and a *neurosurgery* group; hospital shared 50% of 36 cost savings opportunities from standardizing use of spine fusion devices/supplies; One year term.
- l. **No. 08-15 (Oct. 14, 2008)** - Arrangement with two cardiology groups shared 50% of cost savings achieved through 30 cost savings opportunities, including standardized use of devices/supplies. Three year term.
- m. **No. 08-21 (Nov. 25, 2008)** - Arrangement with four cardiology and one *radiology* group shared 50% of cost savings achieved in cardiac catheterization practices through 27 cost savings recommendations. Third party was hired to collect data, analyze, and manage the program. Two year term, with rebasing at the end of the first year.

6. **OIG Advisory Opinion on Pay for Performance Program**

No. 08-16 (Oct. 14, 2008) - *Pay for performance* program implemented by a private insurer allows a hospital to receive a 4% bonus for achieving 2 data reporting standards and 4 quality standards (“quality targets”) based on the CMS Specifications Manual for National Hospital Quality Measures. Any physician who is a member of the hospital’s medical staff may participate. Three year term. This advisory opinion is available at: <http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-16A.pdf>

C. Structuring Arrangements Likely to Lead to OIG Approval

1. Broad Principles Likely to Lead to Approval:

- a. Credible medical support that the program does not adversely affect the quality of patient care, including periodic review
- b. Safeguards to ensure physicians' treatment options are not limited by the program
- c. Cost saving actions and resulting savings are clearly identified and measured separately (transparency)
- d. Use of objective historical and clinical measures to establish baselines
- e. Payments do not take into account the type of insurance held by the patient and are calculated based on actual costs
- f. Disclosure of the program to hospital patients
- g. Limitations on duration and amount of financial incentives

2. Specific Design Features Likely to Lead to Approval:

- a. Available only to physicians who are currently members of the hospital medical staff
- b. Participation by a pool/group of at least five physicians
- c. Payment by hospital to the pool/group on an aggregate basis, and payment by the pool/group to each physician on a *per capita* basis.
- d. Program includes objective measures by which to judge changes in quality
 - i. Quality targets should use the CMS Specification Manual for National Hospital Quality Measures
 - ii. If a multi-year program, cost-savings baselines should be reset each year to avoid "duplicate" payments for performance levels already achieved
- e. Programs should have an independent reviewer/auditor review the program prior to commencement and at least annually
- f. Cost savings programs should cap sharing at no more than 50% of cost savings
- g. The duration of the arrangement should not be longer than three years
- h. Written notice to patients before admission or before the relevant procedure

VI. PROPOSED EXCEPTION(S) TO STARK REGULATIONS

A. Citations:

1. Proposed 2009 Medicare Physician Fee Schedule
73 Fed. Reg. 38502, 38548 (July 7, 2008); Proposes one exception for both “shared savings” and “incentive payment” programs § 411.357(x) at 73 Fed. Reg. 38502, 38604.
2. Final 2009 Medicare Physician Fee Schedule (“MPFS”)
73 Fed. Reg. 69726 (Nov. 19, 2008)

B. Concerns To Be Addressed: (73 FR 69795):

1. “Stinting” – “limiting the use of quality improving but more costly devices, tests or treatments”
2. “Cherry-picking” – “treating only healthier patients as part of the ...program”
3. “Steering” patients – “avoiding sicker patients at the hospital sponsoring the ...program”
4. “Quicker-sicker” discharges – “discharging patients earlier than clinically indicated either to home or to post-acute settings”

C. Design Features of the CMS Proposed Exception:

Many of the design features in the CMS proposed exception to Stark are drawn from the design elements discussed in the OIG Advisory Opinions discussed above in Section V.

1. Medical Evidence and Independent Review

- a. Program should contain quality measures derived from CMS Specifications Manual for National Hospital Quality Measures
- b. Independent review *prior to* implementation and *annually*
- c. Reviewer must have clinical expertise and may not participate in the program

2. Physician Participation and Payment

- a. Pools of five or more physicians who are current medical staff
- b. Payment on per capita basis, with a cap on amount and/or duration (1-3 years)

3. **Cost Savings for Shared Savings Programs**

- a. Capped at 50% of cost savings
- b. Savings measured from baseline standards
- c. Annual rebasing of quality standards
- d. Sharing of global savings: comments solicited

4. **Protecting Quality of Care**

- a. Must show actual improvement from baseline standard
- b. No payment if quality of patient care is diminished
- c. Open as to individual or global quality measures

5. **Documentation**

- a. Must be made available to Secretary upon request

6. **Disclosure / Notice to Patients**

7. **Usual Stark Criteria**

- a. In writing
- b. Criteria and compensation formula set in advance
- c. Not based on volume/value of referrals
- d. Minimum term of 1 year

D. **CMS Reopens Comment Period** - - In the preamble to the final rule on the MPFS for 2009, CMS concluded that it had not received sufficient comments on the proposed exception to adopt a final rule. The comment period was reopened from Nov. 19, 2008 - Feb. 17, 2009. 73 Fed. Reg. 69726 (Nov. 19, 2008). CMS indicated it will respond to all comments received during the initial and reopened comment periods when it issues a final rule adopting one or more exceptions. CMS noted the difficulty of crafting an exception due to the variety and complexity of incentive payment and shared savings programs. CMS expressed a desire to allow flexibility and innovation, while meeting the twin goals of preventing (a) “program abuse” (i.e. inducing referrals) and (b) patient abuse. CMS solicited comments on 55 discrete questions, with comments due Feb. 17, 2009.

E. **Selected Comments on CMS Proposed Exception to Stark:**

- 1. **CMS Authority to Issue Exception:** Some comments asserted that creating any exceptions of this type would exceed CMS authority since all such programs would impose a risk of program or patient abuse; CMS disagrees.

2. **Two Exceptions vs. One:** Most comments favored creating two exceptions: one for incentive payment programs and a separate one for shared savings programs.
3. **AHA/AAMC/&Federation of American Hospitals Comments:**

In a comment letter dated 2/17/09, these organizations jointly requested that OIG issue two separate exceptions covering shared savings and incentive payment programs, and criticized the proposed regulations as too narrow, complex (containing 16 sections and over 40 requirements), burdensome, and inflexible. The letter recommends that the exceptions address broad principles in order to allow flexibility and innovation, as well as to lessen the burden of compliance and the risk of non-compliance. <http://www.aha.org/aha/letter/2009/090217-cl-CMS-1403-FC.pdf>. The letter suggests specific language for two separate exceptions, with five core requirements for each of these exceptions:

 - a. *Credible medical evidence* supports all patient care or cost savings practices
 - b. *Monitoring* exists to protect against inappropriate reductions or limitations in patient care services; the monitoring could be by the hospital using existing quality assurance processes
 - c. Payments should reflect an *individual physician's contributions*; the exception should *not* require payment to a pool with per capita distributions
 - d. *Legally binding written agreement*
 - e. *Maintain documentation* on program design, amount, and calculation of payments
4. **New Jersey Hospital Association (“NJHA”) comments:**

In letters sent on August 25, 2008 and February 17, 2009, the NJHA noted that the CMS proposed exception does not present a workable framework for shared savings or hybrid programs that attempt to address non-clinical, patient management issues which can lead to significant cost savings without endangering quality. (A copy of these two letters is attached to this outline.) The NJHA comments include the following key points.

 - a. **Type of Program**
 - i. CMS Proposed Exception: is designed mostly to address programs providing incentives to save costs by changing the usage of devices/supplies (typical of OIG Advisory Opinion fact patterns)

- ii. Alternative (J Demo): The exception should also address programs designed to reduce operational bottlenecks that add to the length and cost of an inpatient stay, such as:
 - (a) Decreasing time between admission and attending physician note
 - (b) Reducing the time between when tests are ordered and results received;
 - (c) Improving operating room scheduling and usage
 - (d) Improving discharge planning to increase weekend discharges
- b. **Cost-finding system**
 - i. CMS Proposed Exception: Difference between current year actual cost and base year acquisition cost. This works for cost savings programs focusing on devices/supplies used, but not for other types of programs.
 - ii. Alternative (NJ Demo): Use All Patient Refined DRGs (“APR DRGs”) and ratio of cost to charges (“RCC”) -
- c. **Severity of Illness Adjustment**
 - i. CMS Proposed Exception: None
 - ii. Alternative (NJ Demo): Adjusts for severity of illness to be fair and equitable and to address regulatory concerns relating to “cherry picking,” “steering,” and “quicker-sicker” discharge.
- d. **The Responsible Physician**
 - i. CMS Proposed Exception: Requires *pooling* at least 5 physicians and allocating payments *per capita*
 - ii. Alternative (NJ Demo): Identifies the physician responsible for managing the patient in each case (attending physician if medical case and surgeon if surgical case) and rewards individual physician behavior

- e. **Improvement vs. Performance** - whether/when to rebase:
 - i. CMS Proposed Exception: Requires re-basing after year 1 (due to concern that otherwise would make “duplicative payment” which might be a disguised payment for referrals)
 - ii. Alternative (NJ Demo): Makes payments initially for performance and improvement, recognizing that inducing behavior changes takes time and that maintaining changes should be rewarded because the changes may lead to loss of physician income (due to the need to spend non-billable time on patient management issues such as discharge planning)
 - (a) Performance - Measuring the physician vs. his/her peers
 - (b) Improvement - Measuring the change in the physician’s own behavior over time, adjusted for case mix and severity of illness

- f. **Physician Incentives**
 - i. CMS Proposed Exception: Cash or cash equivalent payments only; threshold above/below which no payments accrue based on baseline and target levels established using hospital’s patient population compared to regional or national
 - ii. Alternative (NJ Demo): At CMS direction they are limited to 25% of Part B fees and no more than a specified amount per APR DRG.

- g. **Patient Protections/Safeguards relating to Quality**
 - i. CMS Proposed Exception: Multiple requirements that limit flexibility and stifle innovation
 - ii. Alternative (NJ Demo):
 - (a) Severity of Illness adjustment
 - (b) Best Practice Norms based on community practice and regional data base
 - (c) Incentives are capped at meaningful but not excessive amounts, are limited in duration, and there is no additional payment if exceed Best Practice Norms.
 - (d) Two committees: (i) Consortium wide and (ii) individual hospital (with at least 50%

physician participation and consumer participation) that will prescribe and monitor quality standards; Also, hospitals participate in national and statewide quality initiatives.

- (e) Committee will identify and remove any physician who is an outlier, based on semi-annual audits designed to identify any unusual changes;
- (f) Disclosure notice to patients

h. Self-Referral Protections

- i. CMS Proposed Exception: Indirect protections
- ii. Alternative (NJ Demo): Direct protections
 - (a) To be eligible to participate: Physicians must have at least 10 admissions to the participating hospital; No new physicians;
 - (b) Dual Privileged Physicians: Incentives are capped at prior year patient volume at the participating hospital, with adjustments for natural practice growth
 - (c) Administered by independent third party

F. FUTURE OF PROPOSED STARK EXCEPTION

Because CMS invited additional comments on 55 specific issues in late 2008, and just received significant comments on February 17, 2009, it is unlikely that a final rule establishing one or more exceptions to Stark will be published in the near future. Moreover, AHA, AAMC and the Federation of American Hospitals recently called on OIG to coordinate with CMS and to issue a parallel AKS safe harbor. To the extent that the two agencies seek to coordinate before finalizing rulemaking on a Stark exception and an AKS safe harbor, this would also likely delay the publication of any such final rules.

VII. CONCLUSION

A. Currently: What can a hospital do currently, given the existing legal constraints?

- 1. **If No Medicare/Medicaid FFS Beneficiaries:** If a hospital designs its program to involve *no* Medicare or Medicaid FFS beneficiaries, and to induce no changes in behavior relating to such patients, then it will have more flexibility in program design due to fewer legal constraints. Nonetheless, the hospital will need pay

attention to the legal constraints listed above in section III if its program involves Medicare or Medicaid managed care beneficiaries or if it is in a state with an all-payor AKS or Stark statute. There are advantages to working with a risk-based managed care payor, with the payor making the payments to the physicians, since such arrangements are protected by federal statutes and regulations that have minimal requirements.

2. **If Medicare or Medicaid FFS Beneficiaries:** If the hospital's program will involve or induce behavior relating to Medicare or Medicaid FFS beneficiaries, then:
 - a. Use existing safe harbors/exceptions for AKS/Stark
 - b. Follow design features approved in OIG Advisory Opinions relating to CMPL and AKS (*see* Section V) or seek an OIG Advisory Opinion
 - i. Note – each opinion states it cannot serve as precedent for other hospital programs. Nonetheless, most of these opinions offer similar guidance as to arrangements that will not lead to sanctions by OIG.
 - ii. The OIG Advisory Opinions provide no protection under Stark, but there has been no Stark enforcement to date against programs approved by the OIG. Also, the proposed CMS exception to Stark gives guidance on what CMS views as not abusive, which in many cases follows elements the OIG found to be favorable.
 - c. Participate in CMS Demonstration Project

B. **Future**

1. **Stark:**
 - a. New Stark exception(s) may be adopted covering “shared savings” and/or “performance incentive” programs.
 - b. Existing Stark exceptions may be modified, since CMS solicited comments on modifying existing exceptions as an alternative to adopting one or more new exceptions
2. **AKS:** Will HHS heed the call of the AHA/AAMC to issue a regulatory exception?
3. **CMPL:** This statute presents the most significant problem. Query – will there be any legislative efforts a) to modify the statutory language so that it only prohibits reducing or limiting “medically

necessary” services or b) to allow CMS to adopt regulatory exceptions?

4. **Demonstration Projects:** Reports on statutory demonstration programs are due to Congress, and could lead to additional statutory demonstration projects or statutory changes.
5. **Health Care Reform:** Given the soaring costs of health care and the misaligned incentives of the current reimbursement system, will Congress and CMS revise the reimbursement methodologies (as well as the legal constraints listed above) so that hospitals and physicians are no longer in separate silos and can effectively coordinate in providing cost-effective, quality care?