2013
Pay for Performance
Legal Issues

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DEFINING SUCCESS TOGETHER

Incentive Arrangements

- **Gainsharing:**
  - There is no definitive legal definition
  - Traditionally, "gainsharing" has meant the sharing of cost savings attributable to physicians' efforts in controlling the costs of providing patient care
- **Pay for Performance ("P4P"):**
  - Also no definitive legal definition
  - CMS has referred to P4P arrangements as "quality-based purchasing, and other quality-focused programs that do not involve cost savings from the reduction of waste or changes in administrative or clinical practice."

Legal Issues Triggered by Gainsharing & P4P

- Civil Money Penalty Law ("CMPL")
- Anti-Kickback Statute ("AKS")
- Physician Self-Referral Law ("Stark")
- Managed Care/Physician Incentive Plan ("PIP") Laws
- Non-Profit Tax Issues
- State Fraud and Abuse Laws

Civil Money Penalty Law ("CMPL")

- **Statute**: Social Security Act §1128A(b)(1)-(2)
- **Regulations**: 42 CFR Part 1003
- **Prohibited Activity**: Hospitals knowingly paying a physician, directly or indirectly, to reduce or limit services to Medicare/Medicaid fee-for-service beneficiaries
- **Exceptions**: None
- **Penalty**: $2,000 per violation, exclusion in some cases
- **Enforcement Agency**: Health and Human Services Office of Inspector General ("OIG")

CMPL: Relationship to P4P/Gainsharing

- Gainsharing and P4P programs that pay incentives to physicians for meeting quality or efficiency targets in connection with services furnished to Medicare or Medicaid FFS beneficiaries implicate the CMPL if the incentives could induce physicians to reduce or limit services to Medicare fee-for-service beneficiaries.
- OIG Advisory Opinions indicate that sanctions will not be imposed where there are sufficient safeguards in place to ensure that the gainsharing and P4P programs do not compromise quality.
- See discussion of OIG Advisory Opinions (starting at Slide #13)

Anti-Kickback Statute ("AKS")

- **Statute**: Social Security Act §1128B(b)
- **Regulations**: 42 CFR §1001.952 et seq.
- **Prohibited Activity**: Knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce referrals of items or services covered in whole or in part by Medicare, Medicaid or any other federally funded program.
- **Penalty**: Up to 5 years in prison, fine up to $25,000, mandatory exclusion, False Claim boostrapping
- **Enforcement Agency**: Department of Justice (criminal) and OIG (exclusion authority)

AKS: Relationship to Gainsharing/P4P

- Gainsharing and P4P programs violate the AKS if "remuneration is paid purposefully to induce referrals of items or services payable by a Federal health care program."
- In one purpose of an incentive program is to induce referrals, AKS is implicated.
- The OIG takes the position in Advisory Opinions that it will not impose sanctions where the program includes certain elements and safeguards that pose a low risk that gainsharing and P4P payments can be used to disguise payments to induce referrals.
- See discussion of OIG Advisory Opinions (Starting at Slide #13)

AKS: Safe Harbors

- Possible AKS Safe Harbors
  - Employment
  - Personal services
- No specific gainsharing/P4P safe harbor
- Associations have requested a new safe harbor regulation to protect incentive programs
- Non-compliance with a safe harbor does not necessarily indicate violation of AKS

OIG History on Gainsharing/P4P

- OIG Special Advisory Bulletin: "Gainsharing Arrangements and CMPs for Hospital Payments to Reduce or Limit Services to Beneficiaries" (July 8, 1999)
- OIG Report "Recent Commentary Distorts HHS IG's Gainsharing Bulletin" (Sept. 22, 1999)
- OIG Advisory Opinions

OIG Special Advisory Bulletin 1999

"While the OIG recognizes that appropriately structured gainsharing arrangements may offer significant benefits where there is no adverse impact on the quality of care received by patients, section 1128A(b)(1) of the Act clearly prohibits such arrangements. Moreover, regulatory relief from the CMP prohibition will require statutory authorization."

"Some hospitals and physicians may have already implemented programs that involve Medicare or Medicaid beneficiaries. In exercising its enforcement discretion, and in the absence of any evidence that a gainsharing arrangement has violated any other statutes or adversely affected patient care, the OIG will take into consideration whether a gainsharing arrangement was terminated expeditiously following publication of this Bulletin."

OIG Special Advisory Bulletin 1999

- OIG concerns regarding:
  - Dangers of abuse (hospitals competing for physician referrals using gainsharing arrangements)
  - Need for constant oversight to ensure that quality of care is not affected
  - Unsuitability of advisory opinion process
    - an area that needs clear, uniform and verifiable standards for all providers

1999 OIG Report

- OIG explains reasons for declining to issue favorable gainsharing/P4P Advisory Opinions:
  - Insufficient safeguards against reductions in quality of care
  - Use of quality of care indicators that are subjective or of questionable validity
  - Patient volumes insufficient to yield statistically significant results
  - Insufficient independent verification of quality of care indicators, cost savings, or other essential aspects of the program

OIG Advisory Opinions: Gainsharing/P4P

- OIG: Just Kidding . . .
- Beginning in 2001, OIG has Advisory Opinions evaluating 14 gainsharing and 2 P4P programs under CMPL and AKS (not Stark)
  - **CMPL**: OIG looking for safeguards to ensure that quality is not compromised
  - **AKS**: OIG analyzing whether one purpose of an incentive program is to induce referrals
- OIG issues a series of Advisory Opinions approving a variety of gainsharing arrangements focused on specialty practices

OIG Advisory Opinions: OIG's Gainsharing Concerns

- OIG's concerns expressed in Advisory Opinions
  - **CMPL**: Reduction or limitation of devices or supplies will adversely affect quality of patient care by
    - "Stinting" on patient care
    - "Cherry picking" healthy patients
    - "Steering" sicker patients to hospitals not in program
  - **AKS**:
    - Allowing hospitals to offer disguised payments for referrals
    - Promoting unfair competition (a "race to the bottom") to attract physician referrals

OIG Advisory Opinions: OIG's Gainsharing Safeguards

- The gainsharing programs that have received a favorable OIG opinion share characteristics:
  - **Written Contract.** There is a written contract between a hospital and one or more physician groups.
  - **Term of Program.** The duration of most of the programs is one year, but several are for three years. If the term of the arrangement is multi-year, the savings targets are "re-based" at the end of each year.

OIG Advisory Opinions: OIG's Gainsharing Safeguards

- **Hospital Privileges.** Each member of the physician group has medical staff privileges at the hospital.
- **Identification of Cost Savings.** The program administrator has 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.
- **Hospital Oversight.** Patients treated under the arrangement are monitored by a committee.
- **Patient Disclosure.** The hospitals provide written disclosure of the program to patients.

OIG Advisory Opinions: OIG's Gainsharing Safeguards

- **Efficiency Measures.** Recommendations relate to decreasing the inappropriate use or waste of medical supplies during surgery, such as:
  - product standardization,
  - product substitution, or
  - using a product only "as needed" (i.e. as medically necessary).

OIG Advisory Opinions: OIG's Gainsharing Safeguards

- **Safeguarding against Inappropriate Reductions:**
  - the full range of supplies and devices will be available to physicians if medically necessary for a particular patient,
  - physicians make patient decisions as to what supplies/devices are medically necessary for a particular patient, and
  - the program establishes a "floor" beyond which no savings accrue to the physicians

OIG Advisory Opinions: OIG's Gainsharing Safeguards

- **Payment Methodology:**
  - The hospital pays physicians a percentage of the cost savings achieved by subtracting current costs from historical costs.
  - The hospital may adjust current costs if there has been an inappropriate reduction in use below targets.
  - The hospital calculates the cost savings separately for each group (if there are multiple groups) and separately for each cost savings recommendation.
  - Hospital pays group, and the group pays each physician on a per capita basis.

OIG Advisory Opinions: P4P

- OIG has issued four Advisory Opinions addressing P4P programs
  - Only two pertain to hospital/physician P4P programs
  - The other two apply to unique arrangements with payors
  - First Opinion published in 2008
  - Second Opinion published this year

OIG Advisory Opinions: P4P Advisory Opinion (Oct. 14, 2008)

- **Background.** P4P program implemented by private insurer that pays hospital a 4% bonus for achieving two data reporting and four quality standards related to patients admitted for one of six specific conditions or procedures.
- **Significance of Advisory Opinion:** Demonstrates the OIG's willingness to embrace emerging types of gainsharing arrangements, such as programs involving third-party commercial insurers using quality standards, where they are based on credible medical standards and contain appropriate safeguards against fraud and abuse.

OIG Advisory Opinions: P4P Advisory Opinion (Oct. 14, 2008) (cont.)

- **OIG's AKS Analysis.** OIG declined to impose sanctions under the AKS due to the following safeguards:
  - Participation open to all physicians who have been on medical staff for at least one year (not just high referrers);
  - Physician incentive is subject to a cap tied to the base compensation paid by the private insurer to the hospital in the base year (avoids rewarding for volume of referrals);
  - Distribution of incentive payments to physicians is made on a per capita basis within groups;
  - Quality standards derived from The Joint Commission with input from CMS; and
  - Program limited to a three-year term, and payments in subsequent terms are not be based on prior year performance.

OIG Advisory Opinions: P4P Advisory Opinion (Oct. 14, 2008) (cont.)

- **OIG's CMPL Analysis.** OIG declined to impose sanctions due to the presence of the following safeguards:
  - Quality targets based on credible medical evidence that they improve patient care;
  - Incentive not reduced if a quality standard is contraindicated;
  - Quality targets are reasonably related to the practices and patient population of the hospital; and
  - The hospital will monitor program to avoid inappropriate reductions in care.

OIG Advisory Opinions: P4P Advisory Opinion 12-22 (Jan. 7, 2013)

- **Background.** A hospital and cardiology group entered into a co-management agreement that includes a performance bonus for implementing patient service, quality, and cost-savings measures at the hospital's cardiac cath labs. In exchange for management and medical direction services, group receives a fixed fee and a performance-based payment (subject to a cap). Each performance measure involves three achievement levels. Performance measures involve:
  - Patient satisfaction,
  - Employee satisfaction,
  - National quality improvement measures, and
  - Cost savings (standardization and device limitation).
- **Significance:** Expansion to co-management agreements.

OIG Advisory Opinions: P4P Advisory Opinion 12-22 (Jan. 7, 2013)

- **OIG's CMPL Analysis.** OIG determined the cost-savings component implicates the CMPL, as cost-saving measures may induce physicians to reduce services. OIG found that the fixed fee, employee satisfaction, patient satisfaction, and quality components did not implicate the CMPL. OIG concluded that although the cost-saving component implicated the CMPL, sufficient safeguards existed to avoid sanctions:
  - Hospital monitors for inappropriate reductions in care;
  - Physicians may access medically necessary devices or supplies;
  - Incentive payment is based on aggregate performance;
  - Incentive fee is capped; and
  - Incentive fee is conditioned upon the group not: (1) stinting on care; (2) increasing referrals to hospital; (3) "cherry-picking" healthy or insured patients; or (4) accelerating patient discharges.

OIG Advisory Opinions: P4P Advisory Opinion 12-22 (Jan. 7, 2013)

- **OIG's AKS Analysis**. OIG determined the program did not fit any AKS safe harbors because aggregate payments to group were not set in advance. Thus, the arrangement could result in illegal remuneration if intent to induce referrals was present. OIG did not impose sanctions, however, because:
  - Compensation was fair market value:
  - The group provided substantial services, minimizing the risk of payments for referrals;
  - Compensation did not vary with the number of patients or referrals;
  - Group used hospital's labs for all its cardiac cath procedures; and
  - The measures and the baseline achievement levels ensured that the purpose was to improve quality, not reward referrals.

Physician Self-Referral Law ("Stark" Law)

- **Statute**: Social Security Act §1877
- **Regulations**: 42 CFR 411.350 et. seq.
- **Prohibited Activity**: Physicians referring Medicare patients for designated health services (including inpatient and outpatient hospital services) to entities with which the physician has a financial relationship that does not fit within an exception
- **Penalty**: Fines, False Claims Act bootstrapping
- **Enforcement Agency**: CMS

Stark Law: Relationship to Gainsharing

- Most traditional gainsharing programs create a financial relationship between a hospital and physicians, where the physicians already refer Medicare 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.
- Unlike AKS, there is no "facts and circumstances" or intent analysis under Stark.
- No CMS Advisory Opinions to date on gainsharing or P4P

Stark Law: Exceptions

- Available exceptions
  - Bona fide employment relationships
  - Personal service arrangements (physician incentive plan)
  - Fair market value compensation
  - Academic medical centers
- These exceptions require
  - Payment to be “set in advance”
  - CMS has suggested that the exceptions are only available to protect P4P incentives, not gainsharing
- Other exceptions
  - Proposed gainsharing exception
  - Indirect Compensation Arrangement
  - Risk Sharing exception

Stark Law: Indirect Compensation Arrangement Exception

- Indirect Compensation Arrangement Exception
- Key is whether the compensation to the physician is based on volume or value of DHS referrals
- Special rules on compensation provide that per service per unit compensation not based on volume or value
- No requirement that compensation must be "set in advance"

Stark Law: Proposed Gainsharing Exception

- Proposed gainsharing exception in 2009 proposed Medicare Physician Fee Schedule (July 7, 2008)
- Many of the features of the CMS proposed gainsharing exception come from the OIG Advisory Opinions
- Where are we now?
  - Final 2009 Medicare Physician Fee Schedule (Nov. 19, 2008)
  - CMS reopens comment period, indicates it will respond to 55 specific comments
  - It seems unlikely that a final rule establishing one or more exceptions to Stark will be published in the near future.

Managed Care: Gainsharing/P4P

- "Managed Care" means gainsharing/P4P programs offered through
  - Health Maintenance Organizations ("HMOs")
  - Competitive Medical Plans ("CMPs")
  - Medicaid Managed Care Plans
  - Medicare Advantage Organizations ("MAOs")
- Fraud and abuse laws (CMPL, AKS and Stark) apply differently to gainsharing/P4P plans offered by Managed Care

Managed Care & Gainsharing/P4P: CMPL

- **CMPL**
  - Does not apply to Medicare or Medicaid managed care beneficiaries (OIG Letter dated August 19, 1999)
  - Potentially applicable if the managed care arrangement might affect physicians' behavior towards fee-for-service patients (e.g., "spillover" and Medicare secondary patients)
- Instead of CMPL, Physician Incentive Plan ("PIP") law applies directly to managed care gainsharing/P4P arrangements

Managed Care & Gainsharing/P4P: Physician Incentive Plan ("PIP") Law

- PIP Law is far less stringent than CMPL
- Gainsharing/P4P programs offered through Medicare or Medicaid Managed Care Plans will comply with PIP laws if:
  - No payment is made to a physician "as an inducement to reduce or limit medically necessary services"
  - The plan conducts periodic surveys to determine patient satisfaction with the quality of services and access
  - If the plan puts physicians compensation at "substantial financial risk," the plan must provide stop loss insurance
  - Additional requirements at See 42 CFR §417.479 (Medicare) and 42 CFR §438.6 (Medicaid)

Managed Care & Gainsharing/P4P: Stark Law

- Stark exceptions available for incentive payments related to care provided to Managed Care patients
  - **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.
  - **42 C.F.R.§ 411.357(n)** - Protects compensation arrangements between managed care organizations and physicians pursuant to certain risk-sharing arrangements.

Managed Care & Gainsharing/P4P: Stark Law

- Risk Sharing Exception
  - Potential coverage of enrollees is broad
  - Health plan is broadly defined
  - CMS guidance suggests broad applicability of risk sharing exception

CMS Waiver Authority

- **CMS general waiver authority:** Federal statute gives CMS authority to waive compliance with Medicare and Medicaid Acts
  - Stark waivable
  - AKS and CMPL are not waivable
- **CMS specific waiver authority**: CMS may waive fraud and abuse laws related to specific demonstration projects when authorized by Congress
  - Physician-Hospital Collaboration Demonstration
  - ACE Demonstration Project

CMS Waiver Authority

- **ACOs**: Protect distributions to ACO participants if conveyed as compensation for activities related to ACO
  - Pre-participation waiver
  - Participation waiver
  - Shared savings distribution waiver
  - Compliance with Stark law waiver
  - Patient incentive waiver
- **Bundled Payment**: All 4 bundled payment models contemplate a waiver, but scope of waiver will be individual to each awardee.
- **CMMI?**

State Fraud and Abuse Laws: Gainsharing P4P

- Some state fraud and abuse statutes apply to all payors
  - E.g., California (Bus. & Prof. Code 650; 650.01; 650.02)
  - Includes commercial and self pay patients
  - Includes Medicare and Medicaid managed care payors/patients
- Some state fraud and abuse statutes contain exceptions that are different than Stark Law

Gainsharing/P4P: What Gainsharing/P4P Programs Can Hospitals Offer?

- ACOs
- Bundled Payment
  - Contingent of scope of waiver granted
  - Watch out for state law
- Participate in a demonstration project
- Other CMMI proposal

Gainsharing/P4P: What Gainsharing/P4P Programs Can Hospitals Offer?

- If Medicare/Medicaid FFS Beneficiaries are included:
  - Adopt safeguards from OIG Advisory Opinions
  - Comply with a Stark Exception
  - Gainsharing is riskier
- If Medicare/Medicaid FFS Beneficiaries are carved out:
  - Incentives cannot induce physicians to change behavior relating to fee-for-service patients
  - Carve-out method may be difficult to apply
  - Watch out for state law

Gainsharing/P4P: What Gainsharing/P4P Programs Can Hospitals Offer?

- Offer gainsharing/P4P program in conjunction with a managed care plan
  - Comply with PIP Laws
  - Fit within Stark managed care exceptions
  - Be aware of “spillover” and “pull through” concerns
  - Watch out for state law

Gainsharing/P4P: The Future

- Stark
  - Will the proposed gainsharing exception ever be finalized?
- AKS:
  - Could OIG adopt a new safe harbor?
  - Would OIG ever revoke 1999 Advisory Bulletin?
- CMPL
  - Modify statute to allow for exceptions?
- More Health Care Reform?
- State law?

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