Gainsharing: How Do You Share Cost Savings with Your Physicians?

Health Care Compliance Association
13th Annual Compliance Institute
Las Vegas, NV -- April 27, 2009

Jana Kolarik Anderson
Epstein Becker & Green, P.C.

Lisa M. Ohrin
Sonnenschein Nath & Rosenthal, LLP

Overview of Today’s Presentation

• Definitions
• Legal and Compliance Considerations
• Common Shared Savings and Incentive Payment Models
• Practical Considerations
• What’s on the Horizon?
Definitions

Quality

• What does quality have to do with cost savings?
  – Foundation of value based purchasing initiatives
  – Underpinning of OIG gainsharing opinions
  – It is what you pay for in incentive payment programs; for example, pay-for-performance (P4P) programs
  – Ultimately, it will dictate reimbursement

• Cost savings without maintenance or improvement in quality are of little utility
Value-Based Purchasing (VBP)

- Broad category of health care initiatives that link payment to the quality and efficiency of care provided, not just the quantity of care
- CMS’s VBP “toolkit” includes:
  - Transparency and public reporting
  - Identification and promotion of the use of quality measures through pay for reporting
  - Pay for (quality) performance
  - Measures of physician and provider resource use
  - Pay for value – promote efficiency in resource use while providing high quality care
  - Alignment of financial incentives among providers
- Many of these tools are applicable to provider-sponsored programs as well

Gainsharing (Otherwise Known as “Shared Savings”)

- Generally speaking – an arrangement in which a hospital gives physicians a share of any reduction in the hospital’s costs for patient care attributable in part to the efforts of the physicians
- Variety of models – essential components are cost effectiveness and clinical quality
- Variety of financial mechanisms – bonuses, performance targets, percentages, fixed payments
Incentive Payment Programs (including Pay for Performance)

- Government/payor sponsored
  - One of the tools in CMS’s VBP toolkit
  - Pay for quality reporting and performance, efficiency, and (eventually) value

- Provider sponsored
  - Identify measures and goals
  - Pay for achievement of goals through changes in clinical and administrative practices of physicians

Gainsharing Programs

(also known as Shared Savings programs)
Gainsharing Is Important to Hospitals

• Medicare Part A DRGs – involve lump payments to hospitals for a bundle of services; put hospitals at financial risk for expenses incurred in furnishing care

• Physician Medicare Part B Payments – involve per-professional service basis payments to physicians; are not tied to the overall expenses incurred to treat a hospital patient

• Gainsharing programs are designed to ALIGN hospital and physician incentives

Pros and Cons of Gainsharing

Pros
• Engages hospital medical staff to improve quality, efficiency and patient safety
• Helps standardize resource use
• Treatment protocols may improve quality

Cons
• Potential to reduce access to services or new technology
• Homogenizes medicine and may stifle innovation
• May be a kickback or referral in disguise
• Cherry picking
• Quicker-sicker discharge
• Steering patients
Common Cost-saving Measures in Gainsharing Programs

- Product standardization
- Opening items as needed
- Substitution of less costly items and supplies
- Limiting use of certain pharmaceutical items and supplies
- Performing blood cross matching only as needed

Industry Support for Gainsharing

- NOT supported by device manufacturers
  - AdvaMed and MDMA cited concerns in their February 2009 comments to CMS’ proposed exception for incentive payment and shared savings programs
    - Risk to patient care – shift in incentives that can have a major effect
    - Failure to complete Congressionally-mandated gainsharing demonstration project and other 2 announced CMS gainsharing demonstrations
    - Legal concerns – risk of patient abuse and CMP violation
Industry Support for Gainsharing

- IS supported by AHA, FAH and AAMC
  - The three organizations jointly submitted comments requesting that CMS “go back to the drawing board”

Incentive Payment Programs
Common Performance Measures in Incentive Payment Programs

- Consensus-based measures
  - Continued development of quality measures and standards by CMS and its partners
- Examples of performance measures
  - Improvement in patient satisfaction
  - Compliance with treatment protocols (Coumadin, stroke, insulin, etc.)
  - Improving patient throughput
  - Decrease in re-admissions
  - Decrease in medication errors

Industry Support for Incentive Payment Programs

- Comments received in response to CMS’ proposed exception for incentive payment and shared savings programs express support for various types of incentive payment programs
- Payors support provider-sponsored P4P programs
CMS Initiatives and Demonstrations

• Payment reform
  – New bundled payment systems
  – Lower or no payments for certain hospital acquired conditions
• Pay for reporting quality data
  – Physicians, hospitals and HHAs
• Gainsharing demonstrations

Legal and Compliance Considerations
What’s stopping you?

• What’s the big deal?
• Why can’t you just share cost savings with physicians?
  – Legal barriers
  – Practical barriers
• What can you do within the laws as they exist today?

Relevant Law

• Civil Monetary Penalty Statute (CMP)
  42 U.S.C. §1320a-7a(b) (42 CFR §1003.101-1003.135)

• Federal Anti-kickback Statute
  42 U.S.C. §1320a-7b(b) (42 CFR §1001.951-1001.952)

• Physician Self-Referral Law (commonly known as the “Stark Law”)

• Other laws to consider
  – State “all payor” laws
  – Exempt organization laws and regulations
Civil Monetary Penalty (CMP) Statute

- Generally, the CMP statute prohibits a hospital from knowingly paying a physician to induce reductions or limitations of patient care services to Medicare or Medicaid beneficiaries under the physician’s direct care.
- **Penalty**: $2,000 per violation

Federal Anti-kickback Statute

- Prohibits “knowing” and “willful” offer, payment, solicitation or receipt of remuneration for the referral of federal health care program patients or business.
- “Remuneration” defined broadly.
- Penalties include fines, imprisonment, potential Medicare/Medicaid exclusion, potential “bootstrapped” False Claims Act claims.
- Covers ALL Federal health care programs.
- “Safe Harbors” are “voluntary.”
Federal Anti-kickback Statute

- P4P and gainsharing concerns
  - Cherry picking healthier patients
  - Fostering physician loyalty
  - Providing portion of hospital’s Part A payment
    - classic kickback
  - Payment varies with volume or value of services, such as percentage-based payment formula
  - Aggregate payment not set in advance
  - Quality of care concerns

OIG Guidance: CMP and Anti-kickback Statutes

- July 1999 Special Advisory Bulletin
- Numerous favorable OIG advisory opinions (including one P4P)
- OIG’s analysis focuses on:
  - Accountability
  - Quality controls
  - Protection against payments for referrals

NOTE: Congress is also suspicious of gainsharing
Physician Self-Referral Law

• Prohibits a physician from referring Medicare patients for designated health services (DHS) to entities with which the physician has a financial relationship
• Strict liability – statute is violated unless an exception is met
• No specific exception has yet been issued that squarely protects gainsharing or incentive payment programs

Physician Self-Referral Law

• Penalties include repayment, fines; potential “bootstrapped” False Claims Act claims
• Proposed exception(s) for “incentive payment” and “shared savings” programs have been published for public comment, but not yet finalized
• To date, no published CMS advisory opinions under the physician self-referral law addressing gainsharing programs
  – None requested as of January 1, 2009
CMS Guidance: Physician Self-Referral Law

“We believe that properly structured arrangements involving physician participation in an incentive payment or shared savings program may meet the requirements of one or more of the existing physician self-referral exceptions for compensation arrangements.”
- 73 FR 69798

Physician Self-Referral Law Issues

- Most likely available exceptions:
  - *Bona fide* employment relationships
  - Personal service arrangements
  - Fair market value compensation
  - Indirect compensation arrangements
- Biggest hurdle:
  - Fair market value for identifiable services actually provided
Common Incentive Payment and Shared Savings Program Models

Hospital contracts directly with individual participating physicians

Hospital contracts directly with Group Practice, which distributes payments to individual participating physicians

Common Payor-Based Incentive Payment Program Models

Third-Party Payor P4P Program

• Third-Party Payor contracts with Hospital
• Hospital contracts directly with individual participating physicians

Third-Party Payor P4P Program

• Third-Party Payor contracts with Hospital
• Hospital contracts directly with Group Practice, which distributes payments to individual participating physicians
Physician Self-Referral Law Analysis of Hospital-Physician Arrangements

- Four (4) separate analyses may be required
  1. Direct compensation arrangement
  2. Indirect compensation arrangement
  3. “Stand in the shoes” direct compensation arrangement
  4. “Stand in the shoes” indirect compensation arrangement

Direct Compensation Arrangement
Physician Self-Referral Law - Direct Compensation Analysis

- Any payment made directly by the hospital to an individual physician (or to a physician who stands in the shoes of his or her physician organization)

- Hurdles
  - Identifiable services?
  - Fair market value?
  - Related to the volume or value of referrals or other business generated between the parties?
  - Legitimate business purpose?
  - Commercially reasonable?
  - Promotion of a business arrangement that violates a Federal or State law (e.g., CMP statute)?

Indirect Compensation Arrangements

- Group Practice
  - Doctor 1
  - Doctor 2
  - Doctor 3
Physician Self-Referral Law - Indirect Compensation Analysis

• Do you have an indirect compensation arrangement between the hospital and the referring physician?
  – Unbroken chain of persons or organizations with financial relationships
  – Referring physician receives aggregate compensation from group practice that varies with or takes into account the volume or value of referrals or other business generated by the referring physician for the hospital
  – Hospital has actual knowledge of the referring physician’s compensation from the group practice

Physician Self-Referral Law - Indirect Compensation Analysis

• If so, does the arrangement satisfy §411.357(p)?
  – Compensation received by the referring physician from the group practice is
    • fair market value
    • not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician to the hospital
  – Compensation arrangement between the group practice and the physician is for identifiable services
Physician Self-Referral Law - “Stand in the Shoes” (SITS) Direct Compensation Analysis

§411.354(c)(1)(ii)

- Physician is deemed to SITS of group practice and have direct compensation arrangement with hospital if
  - Only intervening entity between the physician and the hospital is the physician organization, e.g., group practice
  - Physician has an ownership or investment interest in the group practice

- Hospital is deemed to have a direct compensation arrangement with the Physician Owner
  - Back to direct compensation analysis

Physician Self-Referral Law - “Stand in the Shoes” (SITS) Direct Compensation Analysis

§411.354(c)(1)(ii)

- If the group practice is not the only intervening entity between the Physician Owner and the Hospital, then
  - No “SITS” direct compensation arrangement
  - No “regular” direct compensation arrangement
  - Must still consider indirect compensation arrangement analysis

- CMS is likely to address this issue
Physician Self-Referral Law - “Stand in the Shoes” (SITS)  
Indirect Compensation Analysis

§411.354(c)(2)(iv)

- Physician is deemed to SITS of group practice and have indirect compensation arrangement with hospital if:
  - Physician has an ownership or investment interest in the physician organization, e.g., group practice
- The Physician Owner has an (indirect) ownership interest in the physician organization
- For purposes of determining whether the Physician Owner has an indirect compensation arrangement with the Hospital:
  - Physician Owner stands in the shoes of the Physician Organization
  - Unbroken chain between Physician Owner (standing in the shoes of the Physician Organization) and Hospital of not less than one person or entity with financial relationships? NO.
- No indirect compensation arrangement

Management of a Service Line Model

- Management Company is owned by Hospital and Physicians
- Management Company contracts with Hospital to manage a service line, such as cardiology
- Management Company is compensated using a percentage of savings methodology (usually 100 percent of cost savings)
- Management Company disburses compensation received from Hospital (if any), which represents the cost savings for the service line, to the owners of the Management Company
Practical Considerations: Getting Started

- Access to good data on clinical quality, usage and cost
  - Physician level data
- Historical practices
  - Identify areas for improvement
  - Set benchmarks and goals
- Identify recognized standards and/or quality benchmarks
- Executive support
  - Leadership buy-in
- Active physician participation

Practical Considerations: Establishing the Hospital-Physician Relationship

- Structure the program to comply with the federal Physician Self-Referral Law and the federal Anti-kickback Statute
- Build in sufficient safeguards and quality monitoring to limit risk under the CMP statute
- Safeguards against cherry picking, overutilization, and payments for referrals
Practical Considerations: Ongoing Monitoring

- Establish quality oversight committees
  - New or expand existing systems
- Review data to ensure performance does not fall below established thresholds
- Ensure proper systems are in place to identify and address quality of care issues
- Maintain documentation

Practical Considerations: Payment Matters

- Per-capita, all payors
- Multi-year arrangements
  - Rebasing
  - Decreased share of savings
- Federal health care program procedures subject to a cap
  - Limit any disproportionate impact on federal health care program beneficiaries
- Proper accounting system
What’s on the Horizon?

• Proposed exception for incentive payment and shared savings programs
  – Finalize the exception (or two separate exceptions)?
  – Propose new exception (or exceptions)?
  – Comment period closed February 20, 2009
• Safe harbor to the federal Anti-kickback Statute
  – Suggested by commenter to 2008 annual solicitation for new safe harbors
• Legislative landscape

Resources

• Centers for Medicare and Medicaid Services (CMS) (oversees the Physician Self-Referral Law)
  – www.cms.hhs.gov/physicianselfreferral/
  – www.cms.hhs.gov/QualityInitiativesGenInfo/
• Office of Inspector General (OIG) (oversees the CMP and Anti-kickback Statutes)
  – www.oig.hhs.gov
Contact Information

• Jana Kolarik Anderson
  Epstein Becker & Green, PC
  jkolarik@ebglaw.com
  (202) 861-1804

• Lisa M. Ohrin
  Sonnenschein Nath & Rosenthal, LLP
  lohrin@sonnenschein.com
  (202) 408-9129