GAINSHARING: A Good Concept Getting A Bad Name?

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Background Information
Wither Gainsharing?

• Here, Gone, Back Again
• OIG Flip-Flops
• IRS Position
• Legislative Solution?
Gainsharing

• Gainsharing is being tested per the OIG, but in a limited number of hospitals and with a limited scope

• No real results yet

• Congress authorized a limited trial

• Potential for cost savings and improving “quality” and outcomes

  ➢ Finding common agreement on defining “quality is the challenge"
Gainsharing Defined

- Gainsharing is generally used to describe arrangements in which a hospital gives physicians a portion of cost savings that result from the physicians’ efforts with the hospital.
- Economic incentive to change certain behaviors, for example:
  - Waste (“open as needed”)
  - Appropriate utilization (“only as needed”)
  - Standardization
  - Substitution
Gainsharing -

The process by which a hospital and its medical staff identify clinical practices that increase hospital operating costs without improving quality of care, develop initiatives to reduce or eliminate such practices, and share the resulting cost savings directly attributable to the clinical initiatives.

Max Reynolds
Healthcare Financial Management
November 2005
Impetus Behind Gainsharing – The Provider’s Perspective

- Economics – Rising costs and narrow margins
- Medicare Part A reimbursement
- Physician control over preference with no financial responsibility for decision
- Complex subject matter
- Decisions are not “purely objective”
- Competition between and among providers
Legal Implications of Gainsharing

A. Federal civil monetary penalties law
B. Federal anti-kickback statute
C. Federal physician self-referral law
D. Private inurement and private benefit law restrictions under federal tax law
Legal Implications of Gainsharing (cont’d)

A. Federal Civil Monetary Penalties: Hospitals are prohibited from knowingly making payments to a physician, either directly or indirectly, to induce the physician to reduce or limit services provided to Medicare/Medicaid patients under the physicians “direct care.”

1. Physicians are prohibited from knowingly accepting such a payment

2. Penalties
   - Civil penalty of $2,000 for each individual for whom payment is made
   - Exclusion from federal programs
Legal Implications of Gainsharing (cont’d)

B. Federal Anti-Kickback Statute:
   1. Broadly worded statute
   2. Interpreted broadly
   3. Applies if one purpose of a payment to a provider is to induce referrals of federal health care program business
   4. Penalties
      - Criminal – Felony (maximum 5 years in prison)
      - Civil - $25,000 (maximum)
      - Exclusion from federal health care programs
Legal Implications of Gainsharing (cont’d)

C. **Federal Physician Self-Referral Statute:**
   1. Prohibits physicians from making a referral to an entity with which the physician has a “financial relationship” for “designated health services.”
   2. Penalties
      - Cannot bill Medicare for a prohibited referral
      - If Medicare is billed, physician subject to claim repayment, civil penalties up to $15,000 per service and liability for filing a false claim
   3. OIG Business Advisory Opinions do not address Stark Law implications
   4. CMS has jurisdiction over Stark Law violations
D. Private Inurement and Private Benefit:
   1. Private Benefit
   2. Private Inurement
Historical Perspective on Gainsharing (from a Regulatory Perspective)

- 1980: Hospital Prospective Payment System Implemented
- 1986: Civil Monetary Penalties Enacted
- 1996: "Black Box" Gainsharing
- 1999: Special Advisory Bulletin
- 2001: OIG Advisory Opinion No. 01-01
- 2003: NJ Gainsharing Demonstration Project Overturned by U.S. District Court
- 2005: OIG Advisory Opinions 05-01 through 05-06
Gainsharing

February 2005

• OIG Issues – 6 Advisory Opinions
• Cardiology and Cardiovascular Services at 4 Hospitals
• Importance of Incorporated Safeguards
Gainsharing 2006 - 2009

- September 2006: CMS announces Gainsharing Project
- December 2007: 2 OIG Approvals Involving Anesthesia
- July 2008: CMS Stark Exception Guidelines for Gainsharing
- August 2008: OIG Approval Spine Surgery
- Oct - Dec 2008: 2 and 3 Years Gainsharing
- June - April 2009: ACE Demo
Legal Safeguards (as Stipulated by OIG)

A. **CMP Safeguards**
   1. Transparency
   2. Credible medical support
   3. Guards and caps to prevent cherry picking and referral increases
   4. Protection against inappropriate Reductions (the floor below which no savings count)
Legal Safeguards (as Stipulated by OIG) (cont’d)

5. Written disclosure
6. Reasonableness in amount
7. Reasonableness in duration
8. Distribution on a per capita basis
B. Federal Anti-Kickback Statute Safeguards

1. Safeguards prevent use of gainsharing as a recruitment tool
2. Safeguards eliminate risk that gainsharing will be used to reward referrals
3. Safeguards ensure specific action will generate savings
4. Gainsharing exposes physicians to liability risk and acts as a control on decisions based purely on economics
Legal Safeguards (as Stipulated by OIG) (cont’d)

5. Reasonableness of compensation
6. Limited duration
7. Appropriate utilization caps
OIG-Approved Gainsharing Safeguards

1. Programs will be transparent, with clearly identified cost-saving actions and resulting savings that allow for public scrutiny and individual physician accountability.

2. The physicians will offer credible medical support for the position that the cost-saving recommendations would not adversely affect patient care.

3. Payments will be based on all procedures, regardless of payer, and savings that result from procedures related to federal health care programs are subject to a cap.
OIG-Approved Gainsharing Safeguards

4. Procedures to which the cost-saving program applies will not be performed disproportionately on federal health care program beneficiaries or a generally healthier mix of patients.

5. Each cost-saving mechanism will be tracked separately to preclude shifting cost savings.

6. Objective historical and clinical measures will be used as benchmarks to protect against inappropriate service reductions.
OIG-Approved Gainsharing Safeguards

7. After the arrangement is implemented, individual physicians will have discretionary judgment to select cardiac devices to use for specific patients.

8. The program is of a limited, one-year duration (It is unclear as to whether the OIG will approve multi-year programs. In a footnote to the advisory opinions, the OIG indicated that “any renewal or extension of the Proposed Arrangement should incorporate updated base year costs.”)
OIG-Approved Gainsharing Safeguards

9. The hospital and the physician groups involved in the gainsharing program will provide written disclosures of their participation in the cost saving measures about arrangements for patients whose care may be affected.

10. Financial incentives will be limited to a reasonable duration and monetary amount.
OIG-Approved Gainsharing Safeguards

11. Participating physician groups will distribute their profits on a per capita basis, thus restricting the incentive for individual physicians to generate disproportionate cost savings through these programs

12. Outside independent program administrator
OIG – Approved Cost-Saving Measures

• Opening packaged items only as needed during a procedure
• Cross-matching blood only as needed
• Substituting less costly items with equivalent clinical effectiveness
• Product standardization where appropriate
• Limiting the use of certain vascular closure devices to an “as needed” basis
MedPAC
Physician-Owned Specialty Hospitals ~ Report to Congress ~ March 2005

Recommendation:
The Congress should grant the authority to allow gainsharing arrangements between physicians and hospitals and to regulate those arrangements to protect the quality of care and minimize financial incentives that could affect physician referrals.
MedPAC
Physician-Owned Specialty Hospitals ~ Report to Congress ~ March 2005

Rationale:
Properly structured, gainsharing arrangements have the potential to encourage physician and hospital cooperation to lower costs and improve care, but there should be safeguards to ensure that cost-saving measures do not reduce quality or inappropriately influence physician referrals. These arrangements could serve as an alternative to physician-owned specialty hospitals.
Example of Gainsharing Agreement
Physician Owned Specialty Hospitals ~ Report to Congress ~ March 2005

Key Features:

• The plan clearly identified specific actions that would produce savings, such as curbing the inappropriate use of supplies. For example, the agreement encouraged surgeons to forego the use of preoperative medication unless indicated by clinical standards.

• The plan was transparent and disclosed to patients, which promoted physician accountability and deterred abusive behavior.
Example of Gainsharing Agreement

Key Features (cont’d):

• Periodic reviews of quality of care by an independent agent would take place.

• The agreement set thresholds of appropriate use of supplies based on clinical standards and historic patterns. Surgeons could not receive a share of savings if use fell below this baseline.

• The plan was of limited scope and duration (only one year).
Example of Gainsharing Agreement

Key Features (cont’d):

The advisory opinion also found that several of the plan’s features made it unlikely to be used to financially reward physician for referring patients to the hospital, a potential violation of the anti-kickback statute:

• Participation in the arrangement was limited to surgeons already on the medical staff, thus minimizing its potential to attract new surgeons.
Example of Gainsharing Agreement

• The potential savings would be capped based on the number of prior year admissions by the surgeons; thus, little incentive would exist to increase the number of admissions.

• To minimize the incentive to steer less costly patients to the hospital, the severity, age, and insurance coverage of patients admitted by physicians to the hospital would be monitored.
Legislative Outlook

• Grassley-Baucus gainsharing provision was not included in the Medicare-Medicaid budget bill passed by the Senate
• Johnson gainsharing bill was not included in the budget bill that passed the House
• Final DRA law includes a limited Medicare gainsharing demo project = six “sites”
Gainsharing

May be a useful tool

Regulatory process complex and time consuming

Legislation likely needed
Beyond Legal: Gainsharing Issues

• Goals beyond high cost devices
• Applicability to a broader range of specialties
• Links to patient safety and quality
• Links to PFP
• Links to chronic disease management
• Sustainability over time
Other Approaches

- Medical Director stipends
- Part A/B bundling
- Competitive bidding
- Cost effectiveness profiling
- Episode of care analysis
- Disease management organizations
- Medicare advantage
- Consumer empowerment
Other Approaches

• Employment
• Group practice/PHO incentives
• Integrated delivery models
• Innovative reimbursement models
