The Fourth National Pay for Performance Summit

Gainsharing with Physicians

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Overview

- Background – What is “gainsharing?”
- Statutory Obstacles
- 1999 Special Advisory Bulletin – Negative
- Recent Advisory Opinions – Offering Positive Guidance
- Good Facts
- Bad Facts
- Proposed Stark Exception

Background – What is “gainsharing?”

- Refers to programs through which hospitals reward physicians for cost-saving and/or quality improvement
- Hospitals paid for inpatient services on basis of DRGs – generally a fixed payment for the hospitalization, irrespective of cost
- Physicians have no direct economic incentive to contain costs
- Hospitals want to standardize procedures and contain costs without diminishing quality

Background -- What is “gainsharing?”

- Hospital program encourages changes in physician behavior
  - Product substitution
    - Routine use of less costly agents, medications, etc.
  - Product standardization
    - Routine use of specified devices and supplies, *e.g.*, stents, catheters, diagnostic devices, contrast agents, etc.
  - Elimination of routine use of specified products or services (“use as needed”)
- Hospital pays percentage of resulting savings to physicians

Statutory Obstacles

- Medicare Civil Monetary Penalty (“CMP”) Statute
- Anti-Kickback Law
- Stark Law

Medicare Civil Monetary Penalty Statute

Social Security Act §1128A(b)(1) prohibits a hospital from knowingly making a payment directly or indirectly to a physician as an inducement to reduce or limit services to Medicare or Medicaid beneficiaries under the physician's care

Broadly interpreted to apply to inducements not to provide any covered service; no exception for medical necessity or best practices

Anti-Kickback Law

Social Security Act § 1128B(b) makes a felon of anyone who knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

- to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
- to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program

Stark Law

Social Security Act § 1877 provides that (unless an exception exists) if a physician has a financial relationship with a hospital, then—

- the physician may not make a referral to the hospital for the furnishing of Medicare services, and
- The hospital may not make a claim under Medicare for hospital services furnished pursuant to a prohibited referral

  A gainsharing arrangement can be a financial relationship.

Stark Law

Exceptions:

- There is an exception for fair market value compensation for items or services (42 CFR § 411.357(l)).
- There is no explicit gainsharing exception
  - Proposed exception never finalized

"Properly structured [incentive payment or shared savings] arrangements may meet the requirements of one or more of the existing exceptions . . . ." Final 2009 Physician Fee Schedule Preamble

1999 Special Advisory Bulletin

"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."

1999 Special Advisory Bulletin

OIG concerned about:

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

Advisory Opinion 01-01 (2001)

- Cardiac surgery
- Program with single group to curb waste of medical supplies
  - Not opening supplies until needed
  - Substitution of less costly items
  - Limiting use of pre-op meds (Aprotinin) to at-risk patients
- Physicians paid 50% of cost savings for one year
- Safeguards
  - No savings below target “floor”
  - Objective, generally accepted clinical indicators
  - No payment for cases representing increased volume over base year
  - Case mix monitored to prevent steering
  - Arrangement disclosed to patient

Advisory Opinion 01-01 (2001)

OIG's concerns:

- stinting on patient care
- "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements
- payments in exchange for patient referrals
- unfair competition (a "race to the bottom") among hospitals offering cost sharing programs to foster physician loyalty and to attract more referrals

Advisory Opinion 01-01 (2001)

Nevertheless approved:

- The specific cost-saving actions and resulting savings are clearly and separately identified
- Credible medical support for the measures
- Payments based on all surgeries regardless of the patients' insurance coverage
- Baseline thresholds below which no savings accrue to the surgeon group
- Written disclosure to patients
- Limited duration and amount of financial incentives
- Savings distributed to surgeons per capita

2005 Advisory Opinions

- Opinions 05-01, 05-02, 05-04, 05-06
- Similar cardiac surgery and cardiac cath programs
  - Involved several cardiology groups
  - Open-as-needed items
  - Substitution If less costly items
  - Product standardization
    - substitution of less costly products with no clinical significance (and no floor)
    - but the full range of products remain available
- Relevant to the anti-kickback analysis
  - Limited to current medical staff members
  - Limited to prior year's volume

2007 & 2008 Advisory Opinions

- Following earlier analysis
- Similar programs
  - Cardiac catheterization
  - Anesthesia for cardiac surgery
  - Neurosurgery
- Product substitution, product standardization, use-as-needed products and services
- Also pay-for-performance program of private insurer involving quality and efficiency standards

Advisory Opinion 08-16 (2008)

- Hospital participated in private insurer's pay-for-performance program
- Insurer pays hospital bonus compensation to extent hospital meets quality and efficiency standards for 6 conditions or procedures
- Quality Targets in Joint Commission's Specifications Manual for National Hospital Quality Measures
- Hospital pays 50% of bonus compensation to contracting physician group – group distributes to physicians per capita

Advisory Opinion 08-16 (2008)

- OIG's concerns – same as before
- Nevertheless approved
- Relevant factors for CMP analysis:
  - Credible medical support that arrangement has potential to improve patient care and adverse effects are unlikely
  - No incentive for physician to apply a standard in medically inappropriate circumstances
  - Quality targets reasonably related to Hospital's practices and patient population
  - Disclosure to patients, transparency, public scrutiny, physician accountability for adverse effects
  - Hospital will monitor quality and take action if problems arise

Advisory Opinion 08-16 (2008)

- Relevant factors for Anti-Kickback analysis:
  - Participation limited to physicians on active medical staff for at least 1 year
  - Payment to physician group capped to avoid encouraging referrals to hospital
  - Hospital will monitor changes in referral patterns
  - Per capita distribution
  - Transparency
  - Oversight by private insurer with no incentive to overcompensate hospital
  - Program limited to 3 years

Good Facts

- Objective and transparent documentation
- Specific, clearly identified actions and resulting savings
- Credible clinical support for the measures
- Payments based on all procedures regardless of the patients' insurance coverage
- Baseline thresholds below which no savings accrue
- Written disclosure to patients
- Limited duration and amount of financial incentives
- Controls on shifting volume and high-cost cases
- Savings distributed per capita
- Not targeted at referring physicians
- Monitoring, particularly by objective party

Bad Facts

- No demonstrable direct connection between individual actions and any reduction in costs
- The individual actions that would give rise to the savings are not identified with specificity
- Insufficient safeguards against the risk that other, unidentified actions, such as premature hospital discharges, might account for “savings”
- The quality of care indicators are of questionable validity and statistical significance
- No independent verification of cost savings, quality of care indicators, or other essential aspects of the arrangement
- Longer duration or more expansive in scope

Proposed Stark Exception
for
"Incentive Payment and Shared Savings Programs"

- Proposed rule long and detailed
- Program designed to achieve improvement of quality through changes in physician clinical or administrative practices and/or actual cost savings without adverse effect on patient care
- Performance measures that
  - Use objective methodology, are verifiable, supported by credible medical evidence, individually tracked
  - Are reasonably related to hospital's practices and patient population
  - Are listed in CMS's Specification Manual for National Hospital Quality Measures (if applicable)
  - Are monitored to protect against inappropriate reductions or limitations on patient care

Proposed Stark Exception
for
"Incentive Payment and Shared Savings Programs"

- Baseline levels based on hospital's historical and clinical data
- Targets determined by comparison to national or regional data
- Floors and ceilings upon physician payments
- Participating physicians
  - Pool for each measure of at least 5; must be on medical staff at beginning, may not be selected based on value or volume of referrals or other business generated
  - If pool is a hospital department, opportunity to participate must be offered to all equally
- Independent medical review of impact on quality and corrective action
  - Conducted before commencement and at least annually thereafter
  - "Independent" means not affiliated with hospital or participating physician or their organization, and not participating in any other incentive/sharing program

Proposed Stark Exception
for
"Incentive Payment and Shared Savings Programs"

- Physicians have access to same selection of supplies, etc. as before Program; decision-making not restricted
- No payment for a device, etc. made/supplied by party with which participating physician has a financial interest
- Hospital may not limit availability of new clinically appropriate technology linked by objective evidence to improved outcomes that meets same federal regulatory standards
- Notice of Program to patients that discloses participants and performance measures
- Arrangement in writing in detail sufficient to be independently verified
- May not promote unlawful arrangement or other violation of law; in the aggregate, reasonable and necessary for legitimate business purposes

Proposed Stark Exception
for
"Incentive Payment and Shared Savings Programs"

- Term of arrangement 1 to 3 years
- No compensation for improvements achieved in prior period
- Remuneration set in advance, does not vary during term, not determined by value or volume of referrals or business generated, not based on reductions on length of stay, distributed directly to physicians or organization per capita
- Remuneration may not take into account increases in hospital's volume of Medicare business
- Hospital documents conduct of program

Final 2009 Physician Fee Schedule Rule

- No final rule; further comments requested:
  - Incentive payment vs shared savings programs
  - Avoiding program or patient abuse through reduction of services
  - The need for independent medical review (and alternatives)
  - Minimum no. of physician participants, specialty mix, medical staff membership
  - Term of program
  - Avoiding excessive payments
  - Payments for global improvements in quality
  - Payments for global reductions in cost
  - Quality improvement measurements
  - Documentation requirements