Quality of Care Initiatives
Gaining Momentum

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Overview

- OIG/AHLA Guidance for Health Care Boards of Directors
- OIG/HCCA Roundtable
- Quality of Care Government Enforcement
- Recent Enforcement Actions and Settlements
- Developments in Quality of Care Corporate Integrity Agreements
- Gain sharing and Pay for Performance Initiatives
2008 OIG Work Plan

- “OIG will continue to examine quality-of-care issues for beneficiaries residing in nursing facilities and other care settings . . . We will expand our focus on these issues to additional institutions and community-based settings”

OIG/AHLA Guidance for Health Care Boards of Directors

- Released in September of 2007
- Third in a series of guides from OIG/AHLA
- Joint public sector/private sector effort
- Educational resource, not mandates
- Assists boards in exercising their fiduciary responsibilities
Defining Quality of Care

- “Crossing the Quality Chasm” Institute of Medicine’s six-part definition of health care quality
  - Safe
  - Effective
  - Patient-centered
  - Timely
  - Efficient
  - Equitable
- Public and private quality initiatives provide benchmarks
  - National Quality Forum, Joint Commission, Leapfrog, CMS Demonstrations

Duty of Care and Quality

- The “Bottom Line”
  - Quality is an essential component of the mission of health care providers.
  - Quality must receive the same level of Board attention as the corporation’s financial viability.
  - Quality and cost efficiency are complementary, not contradictory, elements of an effective health care system.
  - Unique opportunity for leadership and positive change.
OIG WANTS BOARDS TO ASK:

1. What are the goals of the quality program and benchmarks used? How is management accountable?

2. How is quality measured and by whom?

3. How is quality integrated into policies and operations, and how are they enforced? What controls are in place?

4. Is there an education program on quality for Board members, and do any members have quality expertise?

5. What is the essential information on quality, and how frequently is it received?

6. How do quality and compliance coordinate, and how are they addressed in the risk assessment and action plans?

7. What are the processes for reporting quality issues and preventing retaliation? What are the guidelines for Board reporting?

8. Are human and other resources adequate to support quality? Are systems in place to account for different patient needs?

9. Do competencies, training, credentialing and peer review adequately focus on quality?

10. How are adverse events identified, analyzed and reported and incorporated into performance improvement? How does Board address these without increasing liability exposure?
OIG/HCCA Roundtable

Driving for Quality in Long-Term Care: A Board of Directors Dashboard

- On December 6, 2007, OIG the HCCA co-sponsored a Government/Industry Roundtable for representatives from the long-term care industry.
- Provided representatives from the long-term care industry an opportunity to share experiences and inform OIG/HCCA of challenges surrounding boards of directors’ oversight of quality of care.

Purpose of Roundtable

- Discuss issues surrounding boards of directors’ oversight of quality of care
- Share ideas about how to improve boards of directors’ oversight of quality of care
- Generate ideas for a “Quality of Care Dashboard”
- Purpose was NOT to set forth any specific standard of care
Roundtable Breakout Discussions

Four Discussion Areas
- Commitment to quality
- Processes related to monitoring and improving quality of care
- Outcome measures for quality of care
- Challenges and opportunities in using a Quality of Care Dashboard

Roundtable – what did we learn?
- Commitment to Quality
  - Forum for quality issues
  - Regular reports to the Board
  - Active questioning
  - Mission statement
  - Board member training/education
  - Strategic and capital planning
  - Resources for staff training and retention
  - Culture of quality
  - Having necessary structures and processes
Roundtable – what did we learn?

- Process Measures
  - Quality data reports to the Board
  - Develop Board expertise and understanding of quality data and issues
  - Quality subcommittee
  - Validation of data/information
  - Free flow of information
  - Coordinated response to quality problems
  - Systemic corrective action
  - Staff retention, training, and competency

Roundtable – what did we learn?

- Outcome Measures
  - Use of quality outcomes
    - State surveys
    - Quality Indicators/Quality Measures
    - Events reporting
    - Employee, resident, and family surveys
    - Staff turnover
    - Complaints
  - Consistent and useful tracking of quality outcomes
  - Trend data and contrast and compare
  - Do not overwhelm with data; focus on key areas
Roundtable – what did we learn?

- Challenges
  - Enough information, but not too much
  - Legal liability concerns
  - One size does not fit all
  - Reliability of available quality data

- Opportunities
  - Setting quality as a priority
  - Quality tied to financial performance, overall success of organization, and staff satisfaction
  - Empower Board with a tool

Report of Roundtable available at:


- Hospital Quality of Care Roundtable
Federal Quality of Care Enforcement Authorities

- **Criminal**
  - 18 USC § 286, 287 (false certifications to the US)
  - 18 USC § 371 (conspiracy)
  - 18 USC § 1001 (false statements)
  - 18 USC § 1035 (false statements about health care matters)
  - 18 USC § 1341 (mail fraud)
  - 18 USC § 1343 (wire fraud)
  - 18 USC § 1347 (health care fraud)
  - 18 USC § 1518 (obstruction of criminal HC investigation)
  - 42 USC § 1320a-7b (false statements relating to fed. Health)

- **Civil**
  - the False Claims Act
    - Anyone who knowingly presents a false claim for payment to the federal government . . .
      - Actual knowledge, reckless disregard, or deliberate ignorance
    - shall be liable for treble damages and civil penalties from $5,500 to $11,000 per false claim. 31 U.S.C. 3729, et seq.
False Claims Act

- Legal theory = failure of care/worthless services
  - When a defendant knowingly bills the US for goods or services that were:
    - Not rendered
    - Medically or otherwise worthless
    - Violated a statutory, regulatory or contractual provision with a nexus to payment (also called false certification by us and “implied certification” cases by others)

What does this mean in plain English?

- Providers that knowingly render grossly substandard care or no care at all,
- That harms or kills patients, (not a required element, but usually present), and
- Bills Medicare or Medicaid for the alleged care,
- Can be pursued under the False Claims Act.
Federal Quality of Care Enforcement Authorities

- Key Administrative authorities
  - Mandatory exclusion: § 1128(a)(2) (Patient Abuse or Neglect Conviction)
  - Permissive exclusion: § 1128(b)(6)(B) (Failure of Care)
  - Duty to provide quality services that are medically necessary: § 1156

Exclusions

- **Purpose**
  - To protect Federal health care programs and their beneficiaries
  - Prospective
  - Remedial
  - Not punitive

- **Effect**
  - No payment will be made
  - For any item or service
  - Furnished
  - By an excluded individual or entity
State Quality of Care Enforcement

- Medicaid Fraud Control Units
  - Joint investigations with the Federal government
- State False Claims Acts
  - Incentive under Section 6031 of the DRA - ability of state to share in FCA recoveries
  - Growing number of states have enacted FCA statutes.

Recent Enforcement Actions

Ciena Healthcare Management

- Michigan nursing home chain (30+ facilities)
  - Allegations
    - resident-on-resident abuse,
    - excessive pressure sores, inadequate pain management, excessive contractures, etc.
  - Settled for $1.25 million
- 5-year CIA
  - Quality of care provisions including independent monitor selected by OIG, role of medical director

See 11 BNA’s Health Care Fraud Rep. 640 (Sept. 12, 2007)
Recent Enforcement Actions

- Nursing Homes: DOJ Intervenes in Whistleblower Lawsuit Against Five St. Louis-Area Nursing Homes, 11 BNA’s Health Care Fraud Rep. 474 (July 4, 2007).

Data Mining

- James Sheehan, New York’s Medicaid Inspector General, and a former Assistant U.S. Attorney for the Eastern District of Pennsylvania, has predicted that DOJ will begin bringing enforcement actions based on “data-mining” conducted by HHS-OIG and CMS.
Quality of Care Corporate Integrity Agreements

- 28 quality of care CIAs
- Different from other CIAs
  - Independent Monitor
  - Quality Assurance Monitoring Committee
  - Internal Audit Requirements
  - Extensive policies and procedures
  - Intensive training requirements
  - Reporting

Quality of Care CIA Purposes

- Purpose
  - CIA does not replace or duplicate CMS and state survey agency functions.
  - Focus on systemic issues, not individual problems.
  - Focus on provider’s internal system of quality assurance and improvement.
  - Cross state boundaries with chain-wide perspective.
CIA Independent Monitor

- Key provision in all quality of care CIAs.
- Provider pays for an outside monitor appointed by the OIG.
- Monitor has extensive powers of access to facilities, residents, staff, corporate management, and records.
- Monitor plays consultative role.

Independent Monitor Activities

- Facility visits
- Corporate & regional office visits
- Meetings with corporate boards
- Periodic reports to the OIG and provider
Board-Level Obligations in CIAs

In hospital CIA
- Board-level Quality, Compliance, and Ethics Committee:
  - Review and oversee performance of the compliance staff
  - Annually review the effectiveness of the compliance program
  - Engage an independent compliance consultant to assist board in review and oversight
  - Submit to OIG a resolution summarizing its review of provider’s compliance with CIA

Board-Level Obligations in CIAs

In nursing home CIAs
- Board-level Quality Assurance Monitoring Committee:
  - Review system of internal controls, quality assurance monitoring, and patient care
  - Ensure adequate response to reports of quality of care issues
  - Ensure that there are policies and procedures directed at providing quality resident care
Developments in Nursing Home Quality of Care CIAs

- Policy and Procedure defining role of Medical Directors
- Training must be competency-based
- Reportable events include insolvency
- Certification from President/CEO/Board of Directors
- Meeting with OIG after each annual report

Comments from Nursing Homes under CIAs

- CEOs of nursing home chains under Quality of Care CIAs have reported to the OIG that providing good quality:
  - Improved reputation
  - Decreased exposure to liability
  - Increase staff retention
Compliance Guidance

- Draft Supplemental OIG Nursing Home Compliance Guidance
  - April 16, 2008 Notice with Draft CPG
  - Expanded discussion of risk areas
  - Comments due by June 2, 2008

Gainsharing & Pay-for-Performance

- What does gainsharing and pay-for-performance have to do with quality of care?
  - Underlying premise
    - Money drives performance
  - Common elements
    - Developing performance targets or criteria
    - Utilizing objective standards and performance measures
    - Creating or aligning financial incentives
What is Gainsharing?

- Covers a host of different approaches
- Typically involves payments from hospital to physician for designing and/or implementing programs
  - To improve the quality of care; and
  - To control hospital costs.
- Gainsharing is designed to try to align the financial interests of hospitals and physicians.
- Gainsharing is a subset of pay-for-performance

Criteria for Evaluating Pay-for-Performance Systems

- Additional Cost
- Over, Under, and Mis-Utilization
- Quality of Care
- Access to Care
- Patients’ Freedom of Choice
- Competition
- Exercise of Professional Judgment
Applicable Statutes

- Anti-kickback statute
- Stark physician self-referral law
- Civil money penalty against hospital payments to reduce or limit services

Anti-Kickback Statute

- Prohibited Conduct
  - Knowing & willful
  - Solicitation or receipt or
  - Offer or payment of
  - Remuneration
  - In return for referring a Federal health care program patient, or
  - To induce the purchasing, leasing, or arranging for or recommending purchasing or leasing items or services paid by a Federal health care program.
Anti-Kickback Statute

- Penalties
  - Criminal fines & imprisonment
  - Civil money penalty of $50,000 plus 3X the amount of the remuneration
  - Exclusion
  - False Claims Act liability?

Stark Physician Self-Referral Prohibition

- Physician may not refer:
  - Medicare [or Medicaid] patients
  - For “designated health services”
  - to an entity with which the physician or
  - an immediate family member has
  - a “financial relationship”
    - Ownership interest through equity or debt
    - Compensation arrangement
Stark (cont.)

- Unless an exception applies:
  - Employment
  - Personal services arrangement
  - Fair market value
  - Indirect compensation arrangement

Stark (cont.)

- Penalties
  - Denial of Payment (from anyone)
  - $15,000 per service
  - 2X damages
  - Exclusion
  - False Claims Act liability?
Civil Monetary Penalty  
– Reduce or Limit Services  

- Prohibited Conduct  
  - Hospital knowingly making payments, *directly or indirectly*, to physician as an inducement to reduce or limit services to Federal health care program patient under the physician’s care.  

- Penalties  
  - Civil Money Penalty of $2,000 per patient covered by the improper payment  
  - Both Hospital and Physician liable  

Special Advisory Bulletin on Gainsharing  

- 64 Fed. Reg. 37,985 (July 14, 1999)  
- OIG said: “appropriately structured gainsharing arrangements may offer significant benefits.”  
- OIG seemed to say all gainsharing arrangements between hospitals and physicians were impermissible  
  - Violated CMP against hospital payments to reduce or limit services  
- OIG said it could not provide “any regulatory relief ... absent further authorizing legislation.”
Gainsharing Advisory Opinions

- OIG has issued 10 advisory opinions on gainsharing
  - 01-01, 05-01, 05-02, 05-03, 05-04, 05-05, 05-06, 06-22, 07-21, and 07-22
- Facts and analysis are virtually identical in each advisory opinion.
  - Typically involve cardiac surgery
  - Series of cost saving recommendations

Gainsharing Advisory Opinions
  – CMP Analysis

- Virtually all cost savings recommendations could induce physicians to reduce or limit current medical practices at the hospital.
- Ignored whether current medical practices at hospital were consistent with what is medically necessary
- OIG identified safeguards:
  - Identified Cost Savings. Specific cost-saving actions and resulting savings were clearly and separately identified to allow public scrutiny and individual physician accountability.
  - Credible Medical Support. Credible medical support that cost savings recommendations would not adversely affect patient care. Plus, periodic reviews of impact on clinical care.
Gainsharing Advisory Opinions
– CMP Analysis

- Limited Impact on Federal Health Care Programs. Payments based on surgeries regardless of payor. Federal health care program procedures subject to cap. Cost savings based on actual acquisition costs.
- Protections Against Inappropriate Reductions in Service. Baseline thresholds established through the use of objective historical and clinical measures to protect against inappropriate reductions in service.
- Savings from Inherent Clinical and Fiscal Value. Savings from product standardization based on “inherent clinical and fiscal value.” Physicians would have access to the same selection of devices.
- Patient Disclosure. Hospital and the physician groups provide patients with written disclosures about the arrangements.
- Limits on Incentives. Financial incentives reasonably limited in duration and amount.
- Protections Against Disproportionate Cost Savings. Physician groups distribute profits on a per capita basis, thus limiting any incentive for individual physicians to generate disproportionate cost savings.

Gainsharing Advisory Opinions
– AKS Analysis

- No Safe Harbor protection because percentage-based compensation not set in advance
- OIG warned payments could be used to disguise illegal remuneration encouraging physicians to admit more federal health care program patients to hospital
- OIG approval based on low risk of fraud and abuse
  - Reduced likelihood arrangement would be used to attract referring physicians or to increase referrals from existing physicians:
    - arrangements are limited to physicians on hospital’s medical staff;
    - savings derived from procedures for federal health care program patients are capped based on prior year’s admissions; and
    - arrangements are limited to one year.
Gainsharing Advisory Opinions
– AKS Analysis

- Profits within group are distributed on per capita basis
  - Eliminates risk arrangements would be used to reward non-surgeons for referring patients to the surgeon groups
  - Minimizes incentive for individual physicians to inappropriately reduce services because
- Payments are limited in amount, duration, and scope.
  - Particular actions that would generate cost savings are described.
  - Physicians may have some increased malpractice liability risk from making cost-saving changes and it is reasonable to compensate them.

Gainsharing Advisory Opinions
– Stark Analysis

- Outside OIG’s Authority
  - No position
- Position of CMS unclear
  - Preamble to Phase III raised concerns
    - In discussing proposed change to “set in advance” definition, CMS stated: “Percentage–based compensation, other than compensation based on revenues directly resulting from personally performed physician services…is not considered set in advance.”
    - Arguably would prohibit gainsharing
  - Preamble to Proposed Hospital IPPS regulation seeks comments about need for gainsharing exception
Analytical Framework for Pay-for-Performance

- Structural Issues
  - Implicate anti-kickback law
  - Stark exception

- Incentive design
  - Implicates CMP
  - Depends on who is paying the incentive

Incentive Design

- Clearly permissible benchmarks
  - Patient satisfaction levels
  - On-time surgery starts
  - Low complication rates
  - Timeliness of drug orders
  - Timeliness of paperwork (e.g., H&P)
  - Mortality/Morbidity Measures
Incentive Design

- Clearly problematic criteria
  - Shortened length of stay
  - Levels of ancillary testing
  - Costs associated with patient care

- Open issues
  - Following treatment protocols
  - Meeting aggregate budget goals

Pay-for-Performance – Current Initiatives

- Private sector
  - Bridges to Excellence
  - Leapfrog
  - Prometheus

- Government initiatives
  - Premier Hospital Quality Incentive Demonstration
  - Physician Demonstration
  - Hospital/Physician Gainsharing Demonstration
The Future of Gainsharing & Pay-for-Performance

- Continued growth
  - Recognition of the value in aligning the interests of hospitals and physicians
- MedPAC has endorsed gainsharing
- Need more clarity/flexibility about fraud and abuse implications
  - CMP
  - Stark

Questions?

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