

**GENERAL SESSION: ENFORCEMENT:
QUALITY OF CARE ENFORCEMENT USED
IN THE FALSE CLAIMS ACT**

Health Care Compliance Association
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Presenters:

Laura Ellis, Senior Counsel, Office of Counsel to the
Inspector General
Cheryl Wagonhurst – Partner, Foley & Lardner LLP

Overview

- Background
- Use of the False Claims Act by whistleblowers and the government to address alleged quality of care failures
- Recent quality of care enforcement actions and settlements
- Proactive ideas for compliance officers

Why Quality Compliance?

- Mission
- Enforcement
- Payment

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Mission: Duty of Care and Quality

- Quality is an essential component of the mission of health care providers
- Quality and cost efficiency are complementary, not contradictory, elements of an effective health care system
- Unique opportunity for leadership and positive change

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Poor Quality = Fraud

- Failure of Care/Worthless Services
 - Services Not Provided as Claimed
 - Care so deficient it amounts to no care at all

- Medically Unnecessary Care
 - Fraudulent claims
 - Exposure to unnecessary risks

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Enforcement: Tools Available to Governments & Whistleblowers

- False Claims Act

- Criminal Statutes

- State False Claims Acts

- OIG's Civil Monetary Penalties Law

- OIG's Exclusion Statute

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OIG 2009 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.”

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Quality of Care Enforcement Actions & Settlements

- Tenet Healthcare Corporation
 - Multiple Settlements with DOJ & OIG
 - Forced Divestment of Redding Hospital
 - 5-year Corporate Integrity Agreement
 - Board Committee Reports to OIG on quality
 - IRO review of clinical quality management
 - Quality-of-Care Failure Reporting Requirement to OIG

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Recent Quality of Care Enforcement Actions & Settlements

- Quest Diagnostics Incorporated
 - \$302 million global settlement
 - 5-year Corporate Integrity Agreement
 - Compliance Expert to Board
 - IRO reviewing compliance with FDA Quality System Regulation

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Recent Quality of Care Enforcement Actions & Settlements (cont'd)

- Emmanuel Bernabe
 - Owner & President, Nursing Home Corporation
 - Permanent Exclusion from participation in Federal Health Care Programs
- Grant Park Nursing Home
 - \$2 million settlement
 - 5-year Corporate Integrity Agreement with Quality Monitor

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Payment Impact Regarding Quality of Care

- Rewarding for “good quality”
- Disincentives for poor quality

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Recommended Solutions

- Getting the Board on Board
- Assessing Quality
- Hospital/Physician integration strategies around quality of care
- Performance Improvement
- Training
 - Issue-Spotting and Issue-Responding
 - Competency-Based Training for Clinical Personnel

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Board of Directors

- Critical for providers to involve board of directors in order to
 - Set tone at the top
 - Provide guidance and leadership
 - Keep management in check
 - Keep physician leadership in check

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Board Fiduciary Duty and Quality in the Health Care Setting

- Duty of Care
 - Decision-making function (ex. medical staff credentialing)
 - Oversight function (ex. assessing emerging issues of quality of care, quality data reporting, reimbursement changes)
 - Compliance function (ex. demonstrating leadership's commitment to quality)

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Board Fiduciary Duty and Quality in the Health Care Setting (cont'd)

- Duty of Obedience
 - Quality is core to the corporate mission and purpose
 - Organization and function of medical staff is required by law. Legal requirements related to quality are increasing (Example: Adverse Events, COP compliance, etc.)

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Board Fiduciary Duty and Quality in the Health Care Setting (cont'd)

- Health care quality is a key component of mission
- Elevate quality to the same level of fiduciary obligation that financial viability and regulatory compliance currently constitute

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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?

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OIG Wants Boards To Ask (cont'd)

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?

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OIG Wants Boards To Ask (cont'd)

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, reported, and incorporated into performance improvement? How does the Board address these without increasing liability exposure?

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Resources for Boards

- “Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors” (OIG/AHLA)
- “Driving For Quality in Long-Term Care: A Board of Directors Dashboard” Government-Industry Roundtable (OIG/HCCA)
- “Driving for Quality in Acute Care: A Board of Directors Dashboard” Government-Industry Roundtable (OIG/HCCA)

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Recommendations

- Quality and Enforcement
 - Has there been a systemic failure by management and the Board to address quality issues?
 - Has the organization made false reports about quality, or failed to make mandated reports?
 - Has the organization profited from ignoring poor quality, or ignoring providers of poor quality?
 - Have patients been harmed by poor quality, or given false information?

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Recommendations (cont'd)

- Hospital Peer Review and Quality Management
 - Historical process is retrospective and based on incidents
 - Peer review processes may be lengthy, biased (friends or competitors), and ineffective
 - Delays can lead to evidence of a pattern of poor quality or unnecessary care

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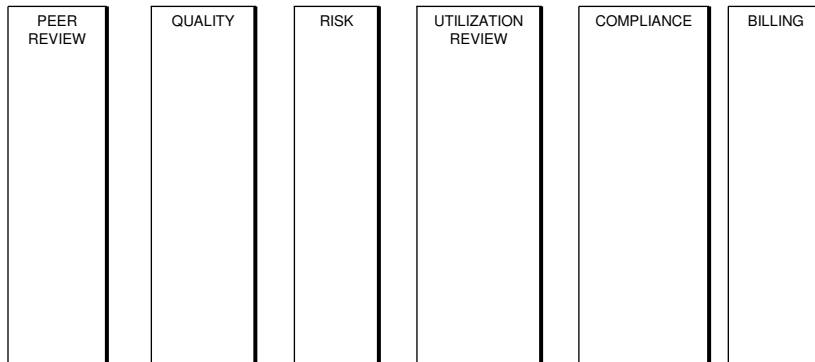
Recommendations (cont'd)

- What's Needed for the Future?
 - Move from case-by-case evaluation ("bad apples") to analysis and use of data
 - Structural change
 - Process change

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Recommendations (cont'd)

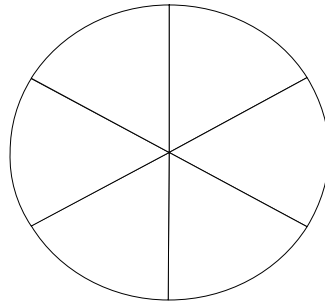
Old Structures – SILO Approach



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Recommendations (cont'd)

New Structure Needed



- Quality
- Risk
- Utilization Review
- Billing
- Compliance
- Peer Review

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Corporate Compliance Program

- Are quality of care and patient safety issues addressed in the organization's annual compliance risk assessment and related corrective action plans?
- Does the compliance officer collaborate with clinical leadership?

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Hospital/Physician Integration Strategies Involving Quality of Care

- Gainsharing
- Other Models
- OIG Advisory Opinion 08-16

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OIG Advisory Opinion 08-16

- What is “Pay for Quality”?
 - New legal entity to which medical staff members can join
 - Hospital pays the entity (*i.e.*, physician-owners) to meet quality targets. Includes a broad array of services necessary to achieve compliance
 - Pay for Performance dollars may provide funding source
 - Payments made based on achievement of targets (CMS quality indicators) set annually
 - Preamble to new proposed Stark exception recognizes benefits to be achieved through quality incentive program

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**Assessments to Enhance Quality and Compliance:
Why are Assessments Critical for Hospitals Today?**

- Quality is now the top compliance issue for hospitals today
- Many hospitals are unaware of their compliance vulnerabilities related to quality because they have not subjected their quality of care processes to the same scrutiny they devote to other compliance concerns (*i.e.*, billing/claims submission, physician financial relationships)

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**Assessments to Enhance Quality and Compliance:
Why are Assessments Critical for Hospitals Today? (cont'd)**

- OIG 2009 Work Plan emphasizes quality as an enforcement priority
- Data Mining, RAC Medical Integrity Program and other government initiatives increase the risk of enforcement based on quality failures
- Do you know where you may have risks?
- Evaluate your company's internal reporting structure

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Contact Information

Cheryl L. Wagonhurst

Partner
Foley & Lardner LLP
555 South Flower Street
Suite 3500
Los Angeles, CA 90071
213-972-4681
cwagonhurst@foley.com

Laura E. Ellis

Senior Counsel
Office of Inspector General
330 Independence Avenue
Room 5620
Washington, D.C. 20201
202-205-9366
Laura.ellis@oig.hhs.gov