FOLEY

FOLEY & LARDNER LLP

Emerging Enforcement of Quality of Care and Compliance Solutions

HCCA Quality of Care Conference
September 30 – October 2, 2007
Philadelphia, PA

Panel Members

- James Sheehan, New York State Medicaid Inspector General
(518) 473-3782
JGS05@OMIG.State.NY.US
- Cheryl Wagonhurst, Foley & Lardner LLP, Los Angeles, CA,
(310) 975-7839
cwagonhurst@foley.com
- Neil Smithline, MD, Director of Clinical Quality, National Medical Audit Division, Mercer Health & Benefits
(415) 743-8704
neilsmithline@mercer.com

FOLEY
FOLEY & LARDNER LLP

Usual Disclaimers

- Personal opinions, not official New York State policy
- Limited to Public information
- Presumption of innocence

FOLEY
FOLEY & LARDNER LLP

Overview

- The Quality Revolution
- New Paradigm for Reimbursement
- The Government's Enforcement of Quality
- New Legal/Compliance Risks
- Compliance Safeguards
- Peer Review

FOLEY
FOLEY & LARDNER LLP

4

The Entire History of Health Care Payment and Fraud Enforcement – How We Got Here

- In Five Minutes!
- Paying to Hang Around (capitation)
- Paying for Inputs (cost reports)
- Paying for Processes (office visit, surgery and follow-up, lab tests)
- Paying for Disease Episodes (DRGs)
- Paying for Outcomes

FOLEY
FOLEY & LARDNER LLP

5

The Five Ways – Getting Paid in Health Care

- Capitation (per member/per month)
- Inputs-Cost Reports/Per Diems
- Process-Fee For Service
- Process-Name that Disease (Diagnosis Related Groups, RUGS)
- Outcomes and Data

FOLEY
FOLEY & LARDNER LLP

Each Method of Payment has Different Risks for Quality and for Fraud

6

- Need to examine quality and outcomes implications
- What are incentives to providers and insurers?
- How does method affect ability, willingness of providers to exercise professional judgment?
- What lies and false documents will occur?
- What are the risks of poor outcomes and adverse events to patients?

FOLEY
FOLEY & LARDNER LLP

Capitation and Managed Care Fraud

7

- AmeriHealth – trashing physician and hospital claims
- United States ex rel. Tyson v. AMERIGROUP (Illinois False Claims Act qui tam case)
- "Keep up the good work-not signing up any third trimester pregnant women"
- $334 million judgment, including penalties
- New York-obstetrical capitation payments requested for males

FOLEY
FOLEY & LARDNER LLP

The Next Way Paying for Data and Outcomes

8

- CMS/PREMIER P4P (Pay for Performance)
- Hospital Quality Incentive Demonstration (HQID) with PREMIER/CMS-Project Findings from Year Two (2005) report 5/07 "significant increase in quality of care across five clinical focus areas
- Bonus payments – top 20%=1%, top 10%=2%
- Pursuing Perfection Program-Institute for Healthcare Improvement and Robert Wood Johnson Foundation-13 hospital participants
- RHQDAPU
- Pay for Performance – HMOs, Employer Coalitions, States

FOLEY
FOLEY & LARDNER LLP

Premier Hospital Quality Incentive Demonstration

9

- WHAT IS QUALITY? (in pneumonia)
- Consensus standard-oxygenation assessment w/24 hours
- Consensus standard – Blood culture before antibiotic administration
- No error/adverse event measures
- No process measures (days in hospital, severity)
- No outcome measures!
- No cost measures

FOLEY
FOLEY & LARDNER LLP

Paying for Performance: The Administration Plan for Health Care

10

- "REFORMING HEALTH CARE FOR THE 21ST CENTURY" – National Economic Council 2/06
  - Consumer directed care (including Medicaid) subsidies, tax credits, HSAs-funding not control
  - Transparent information about quality and outcomes (e.g., Medicare Compare)
  - Health Information Technology systems
- "Pay for Performance: A Decision Guide for Purchasers" – AHRQ April 2006
- "Rewarding Provider Performance: Aligning Incentives in Medicare" Institute of Medicine 2007

FOLEY
FOLEY & LARDNER LLP

Governor Spitzer's Program for Quality Health Care

11

- Patient-centered care rather than institution centered care
- Coordination across systems of care
- Measurement of patient outcomes rather than inputs

FOLEY
FOLEY & LARDNER LLP

12

What is the Quality We Are Paying For?

1) Reduction of Medical Errors/Adverse Events

2) Improvement in Outcomes

3) Compliance with Practice Guidelines, Consensus Standards, or Requirements

4) Reduction in Cost for Same Outcome

FOLEY
FOLEY & LARDNER LLP

13

Core Question: Why (and When) Fraud Enforcement?

- Knowing Conduct by Institution/Gross and Systemic Leadership Failures (notice, warning, failure to act)
- Intentional Acts by Individuals
- False Reporting, Failure to Report
- Appalling Outcomes
- What Will be Consequences of Our Involvement?

FOLEY
FOLEY & LARDNER LLP

14

Model Cased for Outcomes Issues

- USA v. NHC (Nursing Home Civil Fraud Case - 2001)
- USA v. Martha Bell and Atrium I (WD PA)
- USA v. Robert Wachter and American Healthcare Management 2006 WL 2460790 (ED Mo.)
  - Knowledge about alleged worthless services by defendants
  - False statements and records concerning health care benefits of 5 specific individuals, in violation of 18 U.S.C. 1035

FOLEY
FOLEY & LARDNER LLP

15

Handling Historic Allegations of Systemic Leadership Failures Leading to Harm

- United Memorial Hospital – Michigan – Deferred Prosecution
- Redding Hospital – California – Sale of Hospital
- Putnam Hospital – West Virginia
- Edgewater Hospital – Illinois – Conviction of Management Company
- Central Montgomery Hospital – Pennsylvania – Oversight Changes

FOLEY
FOLEY & LARDNER LLP

United Memorial Hospital

- Dr. Jeffrey Askanazi-anesthesia and pain management
  - Nurse complaints (pace of practice, lack of sterile techniques, treatment of patients with no observable improvement)
  - Physician complaints (medical necessity, repeated procedures with no benefit)
  - Patient complaints (doctor admitted doing procedure solely for reimbursement)

FOLEY
FOLEY & LARDNER LLP

United Memorial Hospital – Response

- CEO to complaining – your complaints are not welcome
- CFO to Board after referral of doctor to Profession Activities Committee – Askanazi generates one-third of hospital income – hospital would not want to hurt him
- Medical expert to PAC – cannot do medical necessity review – lack of documentation – Askanazi counseled to improve paperwork

FOLEY
FOLEY & LARDNER LLP

United Memorial Hospital – 2003

- UMH, Dr. Seward (UMH chief of staff), and Dr. DeWys (chief of Emergency Medicine) indicted (Seward and DeWys had a joint venture with Askanazi, but sat on medical staff committees reviewing his practices)
- 2003 – hospital agrees to deferred prosecution agreement

FOLEY
FOLEY & LARDNER LLP

Redding Hospital – 2005 Unnecessary Cardiac Surgeries

- Physicians were major revenue sources
- Thirteen prior lawsuits – 1988-2002 (relevant?)
- Moon's privileges restricted at competing Redding hospital (lack of availability)
- Tenet spokesman states to New York Times, "we don't have an independent means of judging medical necessity" (November 2002)
- November, 2002 – Tenet hires Mercer national medical audit practice to review medical necessity after whistleblower suit, FBI search warrant, state medical board action

FOLEY
FOLEY & LARDNER LLP

Medical Errors and Care Failures Since "To Err Is Human"

- "The Long Road to Patient Safety: A Status Report on Patient Safety Systems" Daniel Longo, et al. 294 JAMA No. 22 (December 14, 2005)
  - "Data are consistent with recent reports that patient safety system progress is slow and is a cause for great concern . . ." the current status of patient safety system progress is not close to meeting IOM recommendations. . ." (based on 2002 and 2004 study of Missouri and Utah hospitals)
- At what point does the failure to have an effective safety system result in False Claims Act or other fraud liability?

FOLEY
FOLEY & LARDNER LLP

Conditions of Payment? Physical and Chemical Restraints on Patients in Care Facilities

- *USA v. Kidspeace* E.D. Pa. – Settlement in excess of $1.8 million with Consent Decree – restraints (child psychiatric facility)
- Mercer County Geriatric Center (restraints, nutrition and hydration) – D-NJ (Civil Rights case)
- A. Holly Patterson, E.D. NY – restraints, nutrition, inadequate care (Civil Rights case)
- Hospital restraints, Medicare condition of participation, 42 C.F.R. 482.13
- *USA v. Central Montgomery Hospital*, July 25, 2005 - $200,000 settlement and consultant required to review restraint usage at the hospital, US Attorney Office, E.D. Pa.

FOLEY
FOLEY & LARDNER LLP

Section 501(b) 10 Quality Measures (RHQDAPU)

- Acute myocardial infraction
- Heart failure
- Pneumonia
- These are same measures collected by The Joint Commission for use in their certification program

FOLEY
FOLEY & LARDNER LLP

Section 501 Reporting and Payment

- CMS FAQ RESPONSE:
  - "Data from selected charts for each hospital that submits data will be audited; a successful audit is not required for the FY 2005 annual payment update. Additional requirements for data accuracy will likely be added for fiscal years 2006 and 2007."

FOLEY
FOLEY & LARDNER LLP

Multiple Sources and Reports

- RHQDAPU (reporting hospital quality data for annual payment update)
- The Joint Commission
- State reporting
- Mandated reports-errors, near misses
- Mandated apologies
- Quality improvement organizations
- Private Sector P4P Contracts
- Whistleblowers

FOLEY
FOLEY & LARDNER LLP

Compliance and Medical Errors Issues

- Section 501(b) of Medicare Modernization Act of 2003 – 0.4% reduction in reimbursement for each fiscal year (2005 and after) if the hospital fails to submit quality data on 10 quality measures
- During FY 2006, "approximately 96% of all eligible hospitals received their full annual payment. . ."

FOLEY
FOLEY & LARDNER LLP

26

Conditions of Participation
See, e.g., 11/28/06 revisions for hospitals

- Some courts have concluded that conditions of participation are not necessarily the same as conditions of payment
  - US ex rel. Mikes
  - US ex rel. Swan (E.D. Cal)
  - US ex rel. Cooper (W.D. Pa.)
- But a fraudulent representation or promise to comply with conditions of participation could make subsequent claims false
  - US ex rel. Swan
  - US ex re. Curtis (M.D. Fla.)
  - A fraudulent representation of compliance is a false claim

FOLEY
FOLEY & LARDNER LLP

27

Conditions of Participation/Payment Issues
HCFA Form 2552-96 (Express False Certification)

- Patients' Rights – 64 FR 36069 (1999) (includes right to freedom from physical and chemical restraint, with limited exceptions.) Deaths related to restraint must be reported by hospital 42 CFR 480.13(f)
- Quality Assessment/Performance Improvement – 68 FR 3435 (2003)
- Authentication of Verbal Orders – 42 CFR 482.24(c)(1) – dated, timed, authenticated
- Renal Dialysis Facilities – proposed 70 FR 6184-6254 (2005) – extensive changes to 42 CFR 494

FOLEY
FOLEY & LARDNER LLP

Medical Errors and Care Failures Move to Criminal Cases

28

- *USA v. Martha Bell and Atrium I* (W.D. Pa. 2005) Bell (nursing home administrator) convicted of health fraud and Atrium convicted of making false statements arising out of false records of care
- *USA v. American Healthcare Management* (W.D. Mo. November, 2005) – indictment charging violation of 18 U.S.C. § 1035 (False Statements concerning Health Care) because "the Defendants knew, at the time the claim was submitted, that the services were so inadequate, deficient and substandard as to constitute worthless services." guilty pleas 10/06
- http://www.usdoj.gov/usao/moe

FOLEY
FOLEY & LARDNER LLP

Medical Errors and Failures to Report – Exclusion

29

- *American Healthcare Management v. Inspector General* (www.hhs.gov/dab/decisionsCR1278) (February 15, 2005)
- Misdemeanor conviction of parent company of a snf for failure to report elder abuse is a conviction which relates to "neglect or abuse of patients in connection with delivery of a healthcare item or service."
- 5 year exclusion upheld

FOLEY
FOLEY & LARDNER LLP

Reporting Requirements for Hospitals (PA, IL, NY, RI, 20 other states)

30

- Act 13 of 2002, 40 P.S.A. 1303. – requires mandatory reporting to the Patient Safety Authority and the Department of Health by hospitals of "serious events" and "incidents" starting June 2004
- Requires designation of patient safety officer and patient safety committee, patient safety plan, reporting scheme
- Prohibits retaliation against employee for reporting serious event or incident
- Requires written notice to patients of certain events

FOLEY
FOLEY & LARDNER LLP

Conditions of Payment? Physical and Chemical Restraints on Patients in Care Facilities

31

- *USA v. Kidspeace* E.D. Pa. – Settlement in excess of $1.8 million with Consent Decree – restraints (child psychiatric facility)
- Mercer County Geriatric Center (restraints, nutrition and hydration) – D-NJ (Civil Rights case)
- A. Holly Patterson, E.D. NY – restraints, nutrition, inadequate care (Civil Rights case)
- Hospital restraints, Medicare condition of participation, 42 C.F.R. 482.13
- *USA v. Central Montgomery Hospital*, July 25, 2005 - $200,000 settlement and consultant required to review restraint usage at the hospital, US Attorney Office, E.D. Pa.

FOLEY
FOLEY & LARDNER LLP

Patient Safety and Quality Improvement Act of 2005 (42 U.S.C. 299c-21)

32

- "A provider may not take an adverse employment action. . .against an individual. . . Based upon good faith reported information. . . To the provider. . . Or to a patient safety organization."
- "Adverse employment action" includes credentialing and certification
- Equitable relief authorized "for any aggrieved individual" to enjoin any violation or for reinstatement and back pay

FOLEY
FOLEY & LARDNER LLP

Government Enforcement

33

- The Government prosecutions based on quality issues have grown exponentially in recent past
  - Example: United Memorial Hospital, Redding Medical Center, many others
- Themes present in cases
  - Unnecessary treatment/procedures
  - Kickbacks
  - Big admitters receiving special treatment
  - Poorly structured, or failure to follow, internal process
  - Underlying regulatory violations
- Cardiac procedures especially risky

FOLEY
FOLEY & LARDNER LLP

Government Enforcement (Cont'd)

- Sources of information leading to enforcement action
  - *Qui Tam* relators
  - Patient deaths
  - Malpractice suits
  - Data (new source – more to come)

FOLEY
FOLEY & LARDNER LLP

Fraud Enforcement – What Does it Require?

- False claim
- False statement in support of claim
- False statement in order to avoid repayment to government
- Requires notice and failure to act to be "knowing"

FOLEY
FOLEY & LARDNER LLP

Quality and Enforcement

- Prosecution Should be Limited to Egregious Cases, Systemic Failures to Respond
- Regulators and Prosecutors Should Support Voluntary Efforts, Compliance Programs, Whistleblowers Internal Remedies
- Peer Review Process Should Receive Needed Legal Protection – (Patient Safety Act, *Kibler v. Northern Inyo County Hospital*)

FOLEY
FOLEY & LARDNER LLP

The Board's Role in Overseeing Quality

- "Getting the Board on Board: Engaging Patient Boards in Quality and Patient Safety" in 32 Joint Commission Journal on Quality and Patient Safety 179-187 (April 2006)
- Interviews conducted with CEOs and Board Chairs at 30 hospitals in 14 states
- "The level of knowledge of landmark IOM quality reports among CEOs and board chairs was remarkably low. . . There were significant differences between the CEOs' perception of the knowledge of board chairs and the board chairs' self-perception

FOLEY
FOLEY & LARDNER LLP

The Board's Role in Overseeing Quality (Cont'd)

- Board education on compliance risks associated with quality
- Recruiting one or more board members with expertise on quality
- Frame an agenda for quality
- Quality planning needs to be a cooperative undertaking by board and medical staff
- Quality agenda approved by the Board and Board receives regular reports

FOLEY
FOLEY & LARDNER LLP

The Board's Role in Overseeing Quality (Cont'd)

- June, 2007 – OIG & ALHA releases joint white paper, "Corporate Responsibility & Health Care Quality: A Resource for Health Care Boards of Directors" which links the Boards' fiduciary obligations to oversee compliance with its obligation to oversee quality

FOLEY
FOLEY & LARDNER LLP

1) *What are the goals of the organization's quality improvement program? What metrics and benchmarks are used to measure progress towards each of these performance goals? How is each goal specifically linked to management accountability?*

2) *How does the organization measure and improve the quality of patient/resident care? Who are the key management and clinical leaders responsible for these quality and safety programs?*

FOLEY
FOLEY & LARDNER LLP

3) *How are the organization's quality assessment and improvement processes integrated into overall corporate policies and operations? Are clinical quality standards supported by operational policies? How does management implement and enforce these policies? What internal controls exist to monitor and report on quality metrics?*

4) *Does the board have a formal orientation and continuing education process that helps members appreciate external quality and patient safety requirements? Does the board include members with expertise in patient safety and quality improvement issues?*

FOLEY
FOLEY & LARDNER LLP

5) *What information is essential to the board's ability to understand and evaluate the organization's quality assessment and performance improvement programs? Once these performance metrics and benchmarks are established, how frequently does the board receive reports about the quality improvement efforts?*

6) *How are the organization's quality assessment and improvement processes coordinated with its corporate compliance program? How are quality of care and patient safety issues addressed in the organization's risk assessment and corrective action plans?*

FOLEY
FOLEY & LARDNER LLP

7) *What processes are in place to promote the reporting of quality concerns and medical errors and to protect those who ask questions and report problems? What guidelines exist for reporting quality and patient safety concerns to the board?*

8) *Are human and other resources adequate to support patient safety and clinical quality? How are proposed changes in resource allocation evaluated from the perspective of clinical quality and patient care? Are systems in place to provide adequate resources to account for differences in patient acuity and care needs?*

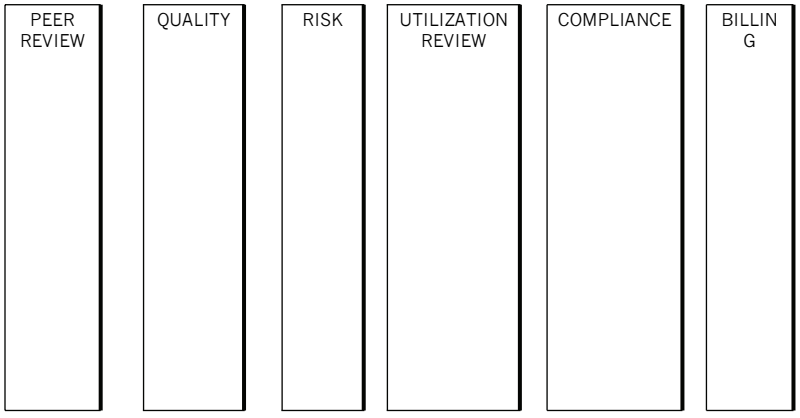
FOLEY
FOLEY & LARDNER LLP

9) *Do the organization's competency assessment and training, credentialing, and peer review processes adequately recognize the necessary focus on clinical quality and patient safety issues?*

10) *How are "adverse patient events" and other medical errors identified, analyzed, reported, and incorporated into the organization's performance improvement activities? How do management and the board address quality deficiencies without unnecessarily increasing the organization's liability exposure?*

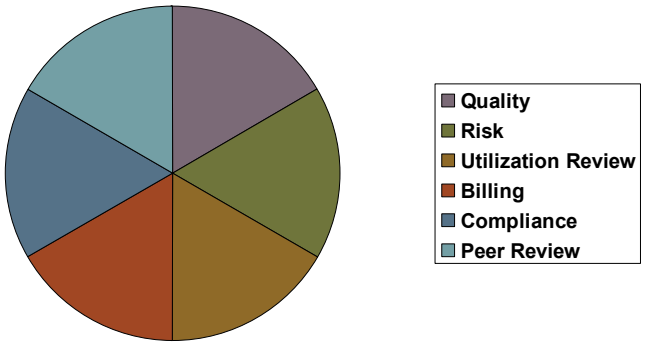
FOLEY
FOLEY & LARDNER LLP

Old Structures – SILO Approach



FOLEY
FOLEY & LARDNER LLP

Structure Needed



Be careful to keep the Privilege!

FOLEY
FOLEY & LARDNER LLP

Compliance Safeguards

- Sorting out responsibilities – Quality officer, patient safety compliance officer
- Quality of care as an element of compliance program
  - code of conduct
  - policy & procedures
  - training
  - reporting – hotline, etc.
  - monitoring
  - auditing

FOLEY
FOLEY & LARDNER LLP

Compliance Processes and Safeguards

- Quality Assurance
- Utilization programs
  - Plans
  - Policies
  - Training
  - Monitoring of utilization processes
- Peer review processes/conflicts

FOLEY
FOLEY & LARDNER LLP

Deficit Reduction Act Impact

- 2005 Deficit Reduction Act requirement effective (January, 2007) – advise employees of Federal and State False Claims Acts and whistleblower statutes – likely to generate additional government enforcement activity

FOLEY
FOLEY & LARDNER LLP

Peer Review

- Historically the purview of the medical staff
- Incident driven
- Focus on one or a few physicians–accusations of witch hunt
- Rely on physicians donating time
- Results highly variable
  - Subjective
  - Reluctance to evaluate peers
- 1986 Health Care Quality Improvement Act (HCQIA)
  - Gave immunity to physicians acting in good faith

FOLEY
FOLEY & LARDNER LLP

Identifying High – Risk Physicians

- Smithline's Axiom – If there are high risk physicians at your hospital, the quality and utilization staff already know who they are!
- So the problem is not one of identification, but one of documentation and verification
  - Incident reports
  - Malpractice claims
  - Nurses, ancillary personnel
- Chances are, your hospital has already reviewed charts of some high risk physicians, however …no action has been taken, because your peer review system is broken

FOLEY
FOLEY & LARDNER LLP

How Peer Review Works – Not

- Peer review is conducted by a medical staff committee to identify *inappropriate practices and incompetent practitioners*
- Peer review questions:
  - Whether a service is medically necessary
  - Was the service performed at the standard of care
- Often little oversight from QM
- Takes a great deal of time to review a case – often many hours
  - Physicians not trained
- Reviews typically unstructured → high degree of variability
- Conflicts of interest – partners or competitors, friends
- Cognitive dissonance

FOLEY
FOLEY & LARDNER LLP

What's Needed to Fix Peer Review

- Structural changes
- Process changes
- Culture Changes

FOLEY
FOLEY & LARDNER LLP

54

Difficult to Fix Peer Review: Process Change

- Requires organized effort by quality and risk departments
  - Quality staff must actively participate in peer review process
  - Provide structured review tools to reduce variability
  - Provide training
- Requires good faith action by medical staff
  - Need to eliminate as many conflicts of interest as possible
- These actions will improve peer review
- Some circumstances demand external Peer Review

FOLEY
FOLEY & LARDNER LLP

55

Expectations from Outside Peer Review

- Step 1. Work hand-in-hand with medical staff attorney to develop medical record review strategy
  - Which types of cases
  - Clearly stated review objectives
  - What to review—what not to review
- Step 2. Perform review
- Step 3. Senior physician develops report in conjunction with expert reviewer suitable for fair hearing challenge
  - Clear, concise, authoritative custom report
  - Synthesize, organize, summarize issues

FOLEY
FOLEY & LARDNER LLP

56

Physician-Based Quality Control — Reports That Make a Difference

- Train each physician reviewer
  - Terminology
  - Accuracy and consistency
  - Secure online review process
- Provide reviewers state-of-the-art tools:
  - *Explicit* review tools
  - Make it easy: secure Internet reviews
- Unbiased, independent professional judgment
  - Objective, qualitative and quantitative validation
  - Comprehensive, substantiated analysis

FOLEY
FOLEY & LARDNER LLP

57

When to Use Outside Peer Guidance

- When the potential risk is sufficiently great that the cost of outside review is justified
- When conflicts or other factors prevent candid internal reviews
- After internal peer review has demonstrated a potential high-risk problem
  - Unnecessary stents
  - Unnecessary spine surgery
  - Frequent adverse outcomes
  - The inexcusable: unnecessary service with bad outcomes
- When MEC needs support and guidance

FOLEY
FOLEY & LARDNER LLP