Patient Safety Audio Conference on Legal Issues in Quality of Care January 26, 2009

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PATIENT-CENTERED CARE

- BENCHMARKNG, MEASUREMENT, REPORTING
- CONTINUOUS IMPROVEMENT
- ALLOWING PATIENTS AND THEIR FAMILIES TO PARTICIPATE IN HEALTH CARE DECISIONS
- Information/Data
  - Accuracy
  - Availability
  - Transparency
  - Ease of use

The new model of Patient-centered-you can look it up

- http://www.hospitalcompare.hhs.gov/Hospital
- http: www.healthgrades.com
- http://hospitals.nyhealth.gov
- http://www.consumerhealthratings.com
- www.talkingquality.gov (ahrq index of 221 quality measurement websites)

CMS as a "Person-Centered" Health Agency-(a CMS quality slide by Dr. Barry Straube)

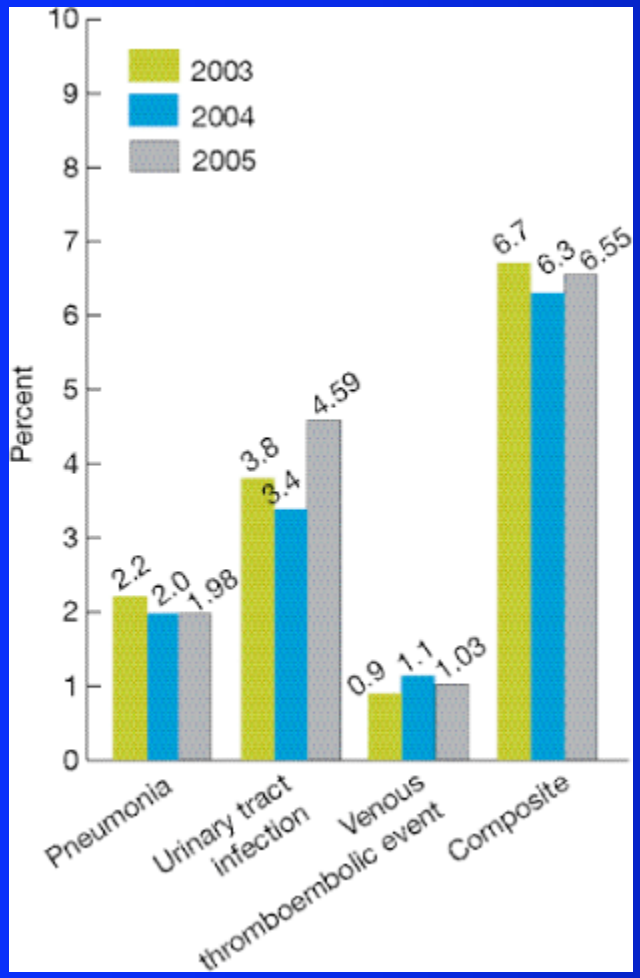
- Using CMS influence and financial leverage, in partnership with other healthcare stakeholders, to transform American healthcare system
- Focusing on not just Medicare & Medicaid, but also Commercial, uninsured, etc.
- Quality, Value, Efficiency, Cost-effectiveness
- Person-centeredness
- Assisting patients and providers in receiving evidence-based, technologically-advanced care while reducing avoidable complications & unnecessary costs

CHANGE IN CMS MODEL

- OLD CMS MODEL-QIOs, quality separate from payment-professional standards, aspirational
- False Claims act defense-different issues, different remedies
- NEW CMS MODEL-express performance and quality representations for payment, conditions requiring non-billing
- BUT "Participants received 54.9 percent (95 percent confidence interval, 54.3 to 55.5) of recommended care." **The Quality of Health Care Delivered to Adults in the United States**, McGlynn, et al. NEJM **Volume 348:2635-2645 June 26, 2003**

National Healthcare Quality Report, 2007 (AHRQ)

- **Medicare surgical patients with postoperative pneumonia, urinary tract infection, and venous thromboembolic event and composite, 2003-2005**
- **See next slide**


10
9
8
7
6
5
4
3
2
1
0
Percent
2003
2004
2005
2.2
2.0
1.98
3.8
3.4
4.59
0.9
1.1
1.03
6.7
6.3
6.55
Pneumonia
Urinary tract infection
Venous thromboembolic event
Composite

WHERE DOES INSPECTOR GENERAL FIT IN QUALITY ?

- Protecting patients
- Mandatory compliance plans
- Model Compliance Guidance
- Enforcement of Conditions of Participation as basis for payment
- Clinical team to evaluate poor care
- Exclusion/penalty authority-individual, entity
- Collaboration with DOH, IPRO, licensing
- Integrity plans
- Dollar recoveries

NOT EVERYTHING BAD IS FRAUD-BUT ENFORCEMENT NOT LIMITED TO FRAUD

- Fraud is intentional breach of standard of good faith and fair dealing as understood in the community involving deception or breach of trust, for money
- fraud can involve criminal prosecution
- An improper payment is a payment we should not have made under program rules-we want it back (no inference of fraud, no requirement of intent)
- An improper practice is a violation which need not be intentional (but can result in exclusion)

The Medicaid Challenge

- Historic investigative focus-smaller individual or small entity providers
- Historic prosecutive focus-criminal enforcement
- Historic audit focus-random claims sampling and projection, and rate audits for hospitals and nursing homes-elaborate audit standards
- Pay quickly and chase slowly

THE MEDICAID CHALLENGE- WHERE ARE WE GOING?

- FOCUS ON LARGER PROVIDERS
- MOST OF THE CARE, MOST OF THE MONEY
- SYSTEMS ISSUES, NOT INDIVIDUAL INTENT
- MEET STANDARDS FOR PATIENT CARE
- EMPHASIZE INTEGRITY STANDARDS BUILT INTO SYSTEM, NOT PUNISHMENT AFTER THE FACT
- NEVER EVENTS
- "PRESENT ON ADMISSION"

How is New York addressing this challenge?-mandated compliance programs

- "Every provider of medical assistance program items and services" (subject to IG regulatory inclusion) "shall adopt and implement a compliance program" including "the following elements. . ." Section 363-d of the Social Services Law.
- Quality is integral part of compliance process

QUALITY AND OUTCOMES ARE THE FUTURE OF FRAUD ENFORCEMENT

- State ex rel. Raymer v. University of Chicago 2006 WL 2987118(10/6/06)(Illinois Circuit Court)
- Exceeding the licensed capacity of neonatal unit(by doublebunking) can be a false claim
- claims based on certification of compliance
- Inspection defect and notice to University-knowing and intentional disregard of licensing regulations, while continuing to submit claims

DEVELOPING BOARD LEGAL RESPONSIBILITIES

- Board Duty to undertake reasonable efforts to assure that compliance programs are in place and effective (In Re Caremark-Delaware)-
- Board Duty to undertake reasonable efforts to become aware of signals of system weaknesses-"systematic failure of the board to exercise oversight" (Abbott Laboratories-7th Circuit)
- General Counsel Duty to advise Board of its monitoring obligations and its structural inability to satisfy them. (Pereira v. Cogan SDNY)

DEVELOPING BOARD/MANAGEMENT RESPONSIBILITIES-NON-PROFIT/CHARITABLE ORGANIZATIONS

- IRS -FORM 990 and STANDARDS FOR NON-PROFITS
- NY DEPARTMENT OF HEALTH-ENTITY CONDITIONS OF PARTICIPATION
- HHS/OIG-GUIDANCE FOR BOARDS ON GOVERNANCE
- NY OMIG-MANDATORY COMPLIANCE PLANS FOR HOSPITALS AND OTHERS;COMPLIANCE GUIDANCE EARLY 2008

The Board's Role in Overseeing Quality

- 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 (available at HHS/OIG website –oig.hhs.gov and at American Health Lawyers website-healthlawyers.org)

HOW DOES BOARD'S ROLE EVOLVE WITH NEW FOCUS ON QUALITY AND OUTCOMES?

- Need to assure business processes to measure and report quality
- Increased role for compliance
- Integration of risk management, utilization review, peer review, mandatory reporting, quality improvement
- What are "system failures," "signals," "monitoring," and "systemic inability to satisfy" in the quality area?

BOARDS

- GOVERNANCE ROLE:
- What compliance systems do you have in place to address quality, errors, and outcomes? To whom do they report?
- What expertise does the Board have on clinical quality, outcomes, and errors? What formal orientation?
- What responsibilities for quality, errors, and outcomes have been delegated to the staff (or others) without adequate oversight? (peer review by medical staff)
- What is the Board doing to assure measurement and improve outcomes and quality and reduce avoidable adverse events (“errors”)

QUALITY REVIEW/ PEER REVIEW ARE NOT OPTIONAL

- Mandated as conditions of participation for many health care facilities, including diagnosis and treatment centers
- Reporting, electronic medical records, and mining of large-scale databases (e.g., EMEDNY, New York's Medicaid database) are going to identify significant outliers on results
- Medicare and Medicaid exclusion of payments for mistakes and never events(e.g., decubiti developed in the inpatient setting) will identify participants in mistakes
- Payment for outcomes will identify poorer outcomes

QUALITY AND PEER REVIEW ARE NOT OPTIONAL

- Physician appraisals every two years
- -board certification is not alone enough
- Quality initiatives are required 42 CFR 481

Paying for Performance: The Federal Plan for Health Care

- "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
- Value-Based Purchasing Proposal-November 2007

CONDITIONS OF PARTICIPATION

- 42 U.S.C. 1395x(k), 42 CFR 482.30- utilization review requirements for hospitals
- Review of durations of stay
- Review of medical necessity of services, drugs
- Every outlier case; sampling of other cases

BAD CASES MAKE HARD LAW

- 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

CORE QUESTION:WHY (AND WHEN) ENFORCEMENT-AND AGAINST WHOM?

- 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?

HANDLING HISTORIC ALLEGATIONS OF SYSTEMIC LEADERSHIP FAILURES LEADING TO HARM

- UNITED MEMORIAL HOSPITAL-MICHIGAN-DEFERRED PROSECUTION
- PUTNAM HOSPITAL-WEST VIRGINIA
- CENTRAL MONTGOMERY HOSPITAL- Pa.-SETTLEMENT AGREEMENT FOR OVERSIGHT CHANGES

UNITED MEMORIAL HOSPITAL

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

UNITED MEMORIAL HOSPITAL-RESPONSE

- CEO to complaining physician-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

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 Askenazi, but sat on medical staff committees reviewing his practices
- 2003-hospital agrees to deferred prosecution agreement

PUTNAM (wva) HOSPITAL(HCA)

- Dr. John King-orthopedic physician, hired 11/02-6/03
- 100 malpractice suits
- Peer reviewer, brought in by hospital –Dr. King is a "snake-oil salesman" "not competent to practice medicine."(Wall Street Journal, 9/21/05 citing federal court suit.)
- Issue-failure of credentialing to discover prior malpractice suits, history of drop-out in residency programs, prior suspension.(JCAHO found Putnam's credentialing deficient in 2002, before King was hired)
- Problem- need for additional orthopedic surgeon –what should hospital have done?
- Mark Foust,HCA: neither HCA nor Putnam responsible for any harm to patients (per WSJ)-once issues identified by consultant, privileges suspended

CENTRAL MONTGOMERY MEDICAL CENTER-2005

- USE OF PATIENT RESTRAINTS WITHOUT APPROPRIATE ORDERS
- JCAHO-Must fix
- Pa. Inspectors-must fix
- Hospital to Pa.-we did fix
- Death from failure to fix
- NEED FOR SYSTEMIC SOLUTION IN COMPLIANCE WITH CONDITIONS OF PARTICIPATION

Medical Errors and Care Failures Since "To Err Is Human"-Board Role

- "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?

Medical Errors and Failures to Report – Exclusion

- 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

Compliance Safeguards Hospital Boards in Quality and Patient Safety

- "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"

Compliance Safeguards Hospital Boards in Quality and Patient Safety

- Increasing education on quality-part of orientation and reporting (errors, outcomes)
- Recruiting one or more board members with expertise on quality
- Frame an agenda for quality-100,000 lives campaign, JCAHO quality measures
- Quality planning, cooperation between board and medical staff
- Governance responsibility for quality-measures and goals
- JCAHO -2007 Ongoing Professional Practice Evaluation requirements

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?