

RISING STATE EXPECTATIONS
FOR HEALTHCARE
ORGANIZATIONS: MEETING
STANDARDS FOR COMPLIANCE,
QUALITY AND PAYMENT
HCCA
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DISCLAIMERS

- Personal opinions and ideas for collegial discussion, based upon 20 years of experience as healthcare lawyer and investigator
- Acknowledgement-ideas and some materials from many people-errors my own
- Presumption of good faith
- Interests you should know: 27 year US DOJ prosecutor; current New York State employee; Johnson & Johnson stockholder
- doing this presentation on personal time, no state expense

STATES ARE PRIMARY REGULATORS OF HEALTHCARE ORGANIZATIONS

- FACILITY LICENSING
- INSPECTION/SURVEY
- LICENSING/CERTIFICATION OF PROFESSIONAL STAFF
- RESPONSE TO COMPLAINTS
- MANDATORY REPORTING AND DISCLOSURE OF ADVERSE EVENTS
- MANAGED CARE REGULATION
- CONSUMER PROTECTION

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STATES HAVE SIGNIFICANT PURCHASING ROLE IN HEALTHCARE

- MEDICAID
- MEDICARE CONDITIONS OF PARTICIPATION AND INSPECTION ROLE
- WORKERS COMP
- AUTO INSURANCE
- STATE, LOCAL EMPLOYEE HEALTH INSURANCE
- PSYCH HOSPITALS, PRISONS, VETERANS HOMES, COUNTY AND LOCAL NURSING HOMES, HOSPITALS

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MEDICAID ALONE-

- 2007 spending:\$332 billion in US (\$142.6 billion state and \$190 billion federal),50 million enrollees. Source: CMS 2008 Actuarial Report on the Financial Outlook for Medicaid www.cms.hhs.gov/actuarial (OIG 2008 Report states \$350 billion for same period),*www.hhs.gov/afr/2008sectiii ("AFR Report")*
- 2008 spending: \$46 billion in New York
- 2009 and 2010 "enhanced federal share" for Medicaid as part of federal stimulus package
- Baucus Plan-\$37 billion increase in Medicaid spending as part of health reform bill

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PREVENTING AND DETECTING FRAUD AND ABUSE

- "ABUSE MEANS PRACTICES THAT ARE INCONSISTENT WITH SOUND . . . MEDICAL OR PROFESSIONAL PRACTICES AND WHICH RESULT IN UNNECESSARY COSTS. . . , PAYMENT FOR SERVICES NOT MEDICALLY NECESSARY, OR . . .WHICH FAIL TO MEET RECOGNIZED STANDARDS FOR HEALTH CARE." 18 NYCRR 515.1 (B) (1) (similar provisions in other states)

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LIMITED COORDINATION OF LICENSING, REGULATORY, PURCHASING FUNCTIONS IN PAST BY STATES (OR FEDS) BUT . . .

- DEBATE OVER CONDITIONS OF PARTICIPATION VS. CONDITIONS OF PAYMENT IN FALSE CLAIMS ACT CASES
- ARE STATES PAYING FOR OR ALLOWING POOR CARE THAT HARMS PEOPLE?
- IF WE ARE, WHY?
- ARE WE USING TOOLS THAT IMPROVE QUALITY AND OUTCOMES?
- ARE WE GETTING OUR MONEY'S WORTH?

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DEVELOPING DATA SOURCES HIGHLIGHT ISSUES, OPPORTUNITIES FOR STATES IN HEALTHCARE

- [U.S. News "Best Hospital"](#)
- [The Leapfrog Group](#)
- [NetDoc Hospital Ratings](#)
- [Healthgrades](#)
- [Medicare.gov - Hospital Compare](#)
- [Consumer Health Ratings - Hospital Quality Ratings & "Best Hospital"](#)

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HOW GOOD CAN QUALITY BE?

- pay-for-performance hospitals showed greater improvement in all composite measures of quality, including measures of care for heart failure, acute myocardial infarction, and pneumonia and a composite of 10 measures. Baseline performance was inversely associated with improvement; in pay-for-performance hospitals, the improvement in the composite of all 10 measures was 16.1% for hospitals in the lowest quintile of baseline performance and 1.9% for those in the highest quintile ($P < 0.001$). After adjustments were made for differences in baseline performance and other hospital characteristics, pay for performance was associated with improvements ranging from 2.6 to 4.1% over the 2-year period.

Public Reporting and Pay for Performance in Hospital Quality Improvement

New England Journal of Medicine: **356:486-496 February 1, 2007** *Peter K. Lindenauer, M.D., M.Sc., et al.*

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HOW GOOD CAN QUALITY BE ?

- A project that links Medicare payments to quality of hospital care has led to the prevention of 4,700 heart attack deaths in four years, according to an analysis by the contractor, Premier Financial Services. (4th year data, Hospital Quality Improvement Project)

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2010 STATE ELECTION CYCLE- CA,FL,IL,PA,NY

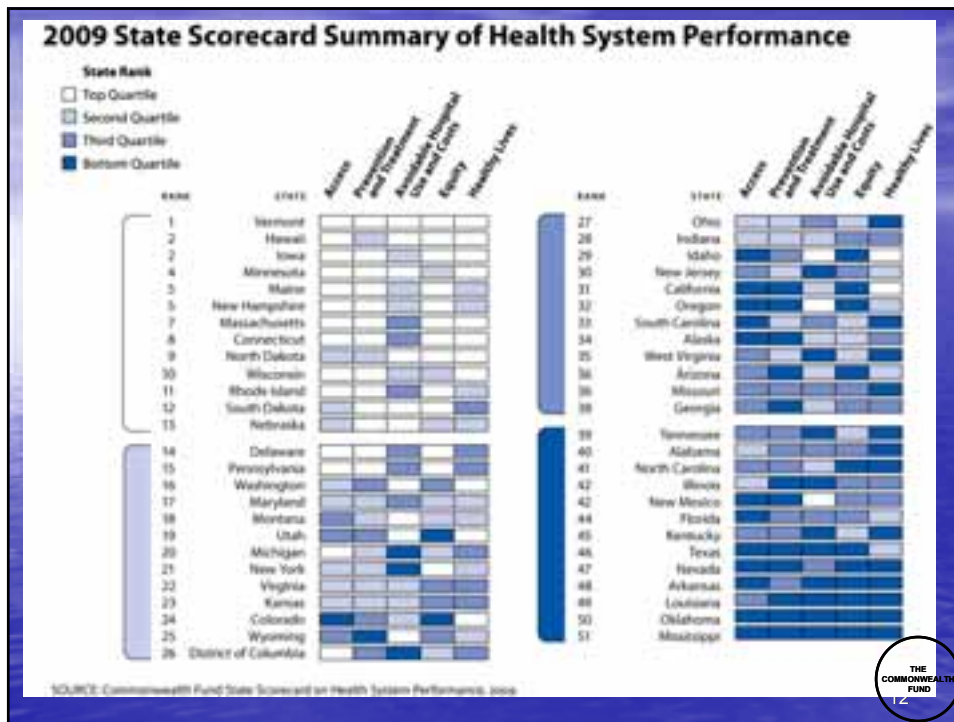
- BUDGET CRISES
- IMPENDING MEDICAID FEDERAL REDUCTION AFTER 2009-10 STIMULUS
- LIKELY FEDERAL HEALTH REFORM STARTING 2013
- OPPORTUNITIES FOR INNOVATORS
- DATA REVOLUTION SINCE LAST STATE ROUND

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HIGHLIGHTING STATE DIFFERENCES IN TREATMENT, AVOIDABLE HOSPITAL USE AND COSTS -COMMONWEALTH FUND STUDY-10/9/09

- WWW.COMMONWEALTH.ORG
- Medicare readmissions within 30 days
- In-patient stays by long-term nursing home residents
- Use of emergency services by asthma patients
- Use of in-patient for services treatable as outpatient

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USING "PRESENT ON ADMISSION," "NEVER EVENTS," AND READMISSION DATA TO IDENTIFY PROVIDER QUALITY ISSUES

- Practice patterns and issues
- Where did this patient come from before admission? Where did they go after discharge?
- Track records of individual physicians-both for ambulatory and for in-patient care
- HHS/OIG 2010 WORK PLAN-Office of Evaluation and Inspections-"State Medicaid Agency Policies to Deny Payment for Hospital-Acquired Conditions" (p. 42)

State Learning from Medicaid Integrity Contractors (MICS)

- 100% reviews
- Sharing targets, results with states
- Readmissions
- Ambulatory/in-patient
- Not Present on admission

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CONWAY'S LAW

- Conway's Law:
- **Any organization that designs a system (defined broadly) will produce a design whose structure is a copy of the organization's communication structure.**

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CONWAY'S LAW-SHEEHAN'S COROLLARY

- Sheehan's Corollary: Boards which oversee compliance systems produce oversight systems which are copies of the communication structures of the Board
- What does this mean? If compliance efforts and results are assigned to different board committees, compliance oversight will vary based on committee membership and subject matter.
- Is quality oversight a democratic or a leadership process?
- Is the model of an organized, self-governing medical staff of a hospital realistic?

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Joint Commission Sentinel Event Alert-August 27,2009

- TJC-health care leadership is responsible for failure to "achieve the zero-defect safety interventions seen other industries"
- Call for renewed commitment to developing "safety culture"

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WHY DOES CONWAY'S LAW MATTER IN QUALITY AND COMPLIANCE?

- Would you allow managers to have different accounting systems for each department?
- Would you allow managers to use different operating software systems in each department? (do your clinical systems integrate with your financial systems?)
- Would you allow managers to use different internal audit standards in each department?

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ENTERPRISE INFORMATION SYSTEMS-ENTERPRISE RISK

- Accounting
- Revenue cycle
- Audit
- Information/Operating Systems
- Compliance Systems
- External Reporting Systems
- Credentialing
- QA/QR

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FUNCTIONS IN QUALITY

- Peer review
- Mandatory reporting
- Utilization review/quality assurance
- Patient safety
- Quality improvement
- Compliance
- Counsel/risk management
- Audit/internal controls

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NEW ENTERPRISE RISKS FOR HOSPITALS IN COMPLIANCE

- MANDATORY COMPLIANCE PROGRAMS-here or coming
- New York Medicaid:18 NYCRR § 521. This rule is effective on July 1, 2009 and covered providers must have compliance programs in place satisfying the requirements of the rule by October 1, 2009.
- Federal contracting-December 2008
- HHS/OIG –testimony of OIG-considering mandatory compliance program-June 2009

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COMPLIANCE AS ENTERPRISE RISK

- JUNE 19,2009 HOUSE HEALTH CARE DISCUSSION DRAFT-
 - 10 point mandatory compliance plan for certain health providers and suppliers-similar to New York regulation
 - Section 1641 of discussion draft-Medicare provider must return overpayment, provide statement in writing of reason for overpayment
- Baucus DRAFT-REFUNDS, OVERSIGHT

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HOW DOES CONWAY'S LAW WORK IN COMPLIANCE?

- DESIGN A COMPLIANCE SYSTEM-
 - General Counsel
 - CFO/Internal Audit
 - Billing Department
 - Credentialing/Peer Review
 - Adverse events/ patient safety reporting
 - Risk/Loss prevention
 - Quality Improvement

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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)

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DEVELOPING BOARD/MANAGEMENT RESPONSIBILITIES-

- IRS -FORM 990 and STANDARDS FOR NON-PROFITS
- NY DEPARTMENT OF HEALTH-ENTITY CONDITIONS OF PARTICIPATION
- HHS/OIG-GUIDANCE FOR BOARDS ON GOVERNANCE
- REVISED JCAHO STANDARDS

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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

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CONGRESS AND CMS:QUALITY CAN BE BETTER, AND WE WILL PAY LESS FOR POOR QUALITY

- **2005 Deficit Reduction Act Requires Development of Value-Based Payment Plan for hospitals and physicians**
- **REPORT TO CONGRESS:Plan to Implement a Medicare Hospital Value-Based Purchasing Program (November 21, 2007)**

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CONGRESS AND CMS:QUALITY CAN BE BETTER, AND WE WILL PAY LESS FOR POOR QUALITY

- “CMS recommends replacing the current quality reporting program with a new program that would include both public reporting and financial incentives for better performance as tools to drive improvements in clinical quality, patient-centeredness, and efficiency. A Medicare Hospital VBP Program should be implemented in a manner that does not increase Medicare spending.”

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CONGRESS AND CMS:QUALITY CAN BE BETTER, AND WE WILL PAY LESS FOR POOR QUALITY

- CMS Value Based Purchasing components:
- (1) a potential Performance Assessment Model that incorporates measures from different quality “domains” (clinical process of care, patient perspective of care, outcomes, etc.) to calculate a hospital’s Total Performance Score;
- (2) options to translate of that score into an incentive payment that makes a portion of the base DRG payment contingent on performance;
- (3) options for criteria to select performance measures for the financial incentive and candidate measures for FY 2009 and beyond;
- (4) a potential phased approach to transitioning from RHQDAPU to VBP;
- (5) a redesign of current data transmission and validation infrastructure to support VBP Program requirements;
- (6) potential enhancements to the Hospital Compare website to support expanded public reporting; and
- (7) an approach to monitoring VBP impacts.

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BOARD OF DIRECTORS

- GOVERNANCE ROLE:
- What compliance systems are 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 medical staff (or others) without adequate oversight?
- What is the Board doing to assure accurate measurement and reporting of outcomes and quality and reduce avoidable adverse events ("errors")

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NEW YORK MEDICAID INSPECTOR GENERAL WORK PLAN 2009-2010

- "governing body . . . Must assure "that processes and systems are in place to provide a reasonable assurance of compliance. . . And for exercising reasonable oversight over information and reporting systems on an ongoing basis . . ."

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NEW YORK MEDICAID INSPECTOR GENERAL WORK PLAN 2009-2010

- “When OMIG identifies a significant compliance or control weakness. . . In the course of an audit, investigation, or match project . . .OMIG will inquire into the board’s actions . . .”
- -to assure compliance processes and systems are in place
- That board members have exercised reasonable oversight over information and reporting systems . . .”

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NEW YORK MEDICAID INSPECTOR GENERAL WORK PLAN 2009-2010

- “In appropriate circumstances, OMIG will consider sanctions. . .against individual members of the governing body for significant failures to comply with their duties with respect to compliance and oversight. . .”

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THE NEXT PAYMENT REFORM WILL BE QUALITY AND OUTCOMES BASED

- PREDICTION: THE SHIFT TO QUALITY BASED REPORTING AND PAYMENT WILL HAVE INDUSTRY EFFECTS GREATER THAN THE SHIFT FROM COST REIMBURSEMENT TO DRGs.

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Business processes in compliance

- Reporting lines
- Audit, review, risk identification
- Medical staff, audit, counsel, quality assurance, patient safety officer, risk management, patient advocate/case manager-do they talk? do they know each other?
- Listening to patients and employees
- Evaluation, measurement, communication
- role for compliance officer

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How common are harms to patients resulting from physician failures?

- Physician performance failures are not rare and pose substantial threats to patient welfare and safety. Few hospitals respond to such failures promptly or effectively. Failure to ensure the quality and safety of the performance of colleagues is a breach of medicine's fiduciary responsibility to the public. A major reason for this deficiency is the hospitals' lack of formal systems to monitor physician performance and to identify and correct shortcomings. Dr. Lucian Leape "Problem Physicians; Is There a System Solution?" *Annals of Internal Medicine* **17 January 2006 | Volume 144 Issue 2 | Pages 107-115**
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"Hospitals Drop the Ball on Physician Oversight"-Nader Group-May 2009

- 49 percent of U.S. hospitals (2,845 of 5,823) have never submitted a clinical privilege sanction report on a physician; at the end of CY 2007, the NPDB contained only 11,221 adverse hospital clinical privilege reports, [(Health Research Group Publication #1873)]

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“Dead by Mistake: Hospital patients exposed to world of avoidable risk”

- Hearst newspapers-August 9-16, 2009
- “A national investigation by Hearst newspapers found that the medical community . . .have failed to take the effective steps (outlined in To Err Is Human). . . Consequently, as many as 2 million Americans have died needlessly of preventable medical mistakes.”
- “HOSPITALS: ‘We’re better than we were’ ”
- Errors/Solutions page(handout at conference)

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MEDICAL ERROR IN HOSPITALS

- [Secrecy shields medical mishaps from public view](#) San Francisco Chronicle August 2009
- Lincoln Hospital specializes in hiding fatal errors New York Daily News, August 2009
- [Note to Parents of Hospitalized Kids: Be Vigilant](#) Wall Street Journal Blogs
- **Nurses offer tips for surviving a hospital stay- CNN.com**
 - If you think something is wrong, don't back down

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Media Focus in Health Care Debate

- Nearly 400 patients died during low-risk surgeries, 89 patients had foreign objects left in their bodies after surgery and five patients received transfusions of the wrong blood type in New York hospitals. – Albany Times-Union June 2009

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Public Reviews of Hospital Performance-Example: Niagara Health Quality Coalition

- Hospital received poor marks for stroke mortality and accidental punctures during surgery, but the hospital had a lower incidence of postoperative respiratory failure than most New York hospitals.
- A statement from the hospital said, "We will be reviewing the Niagara data to determine why their numbers differ from the other reports we have received."
- The full report card is available online at <http://www.myhealthfinder.com>

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LARGE RISK FOR QUALITY- Credentialing and Peer Review Process

- Hospital law and structure-function of medical staff
- Incident driven
- Focus on one or a few physicians
- Rely on physicians donating time
- Results highly variable
 - Subjective
 - Reluctance to evaluate peers

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Media and Academic Focus-Quality

- "Performance problems are more widespread than people recognize; it's not just the small number of doctors disciplined annually by state medical boards. . . Up to one-third of doctors may have a condition that impairs their performance at some time during their career, and most of them get little help for it." Dr. Lucian Leape "Problem Physicians; Is There a System Solution?" **Annals of Internal Medicine** **17 January 2006 | Volume 144 Issue 2 | Pages 107-115**

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Identifying High – Risk Physicians

- Poor performing physicians at your hospital
- the quality and utilization staff already know who they are
- So do the nurses
- documentation and verification
 - Incident reports
 - Malpractice claims
 - Nurses, ancillary personnel
 - Credentialing
 - Behavioral issues/anger management
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QUALITY REVIEW/ PEER REVIEW ARE NOT OPTIONAL

- Mandated as conditions of participation
- Reporting, electronic medical records, and mining of large-scale databases (e.g., EMEDNY, New York's database) are going to identify significant outliers on results
- Medicare exclusion of payments for mistakes will identify participants in mistakes
- Payment for outcomes will identify poorer outcomes

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LARGE ENTITY RISKS FOR QUALITY

- Never events payment
- Hospital-acquired conditions
- Discharge and readmission
- Failure to report adverse events (Pa. model)

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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)

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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

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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

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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'

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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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CONCLUSION

- "VALUE-BASED PURCHASING" IS THE FUTURE
- PUBLIC DISCLOSURE OF ERRORS AND OUTCOMES
- RANKING AND RATING OF HOSPITALS AND PHYSICIANS BY PAYORS, RATING AGENCIES, CONSUMERS
- HOSPITAL BOARDS NEED A GOVERNANCE PLAN TO ASSURE QUALITY ISSUES
- HOSPITAL NEED GOVERNANCE ATTENTION AND FOLLOWUP TO ASSURE QUALITY ISSUES ARE ADDRESSED
- ZERO IS NEVER A GOOD NUMBER

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FREE STUFF FROM New York- OMIG website- WWW.OMIG.State.ny.us

- Model compliance programs-hospitals, managed care (coming soon)
- Over 100 provider audit reports, detailing findings in specific industry
- 70 page work plan issued 4/24/09-shared with other states and CMS, OIG
- Listserv
- New York excluded provider list
- Disclosure protocol

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THANK YOU

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