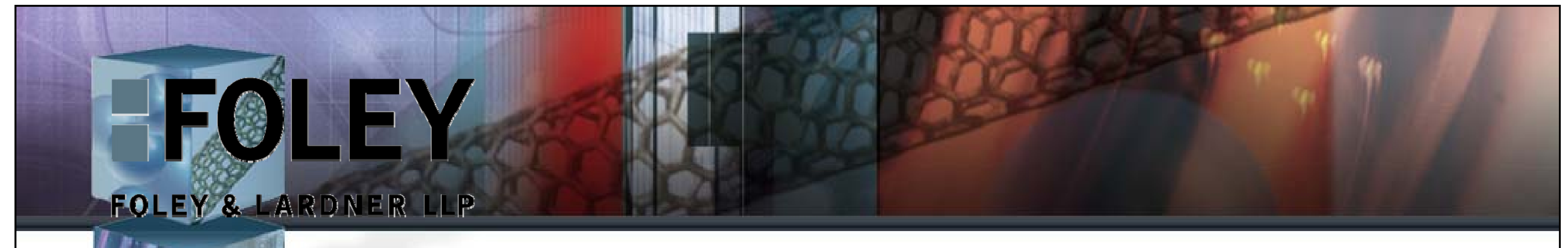

Advising Clients About Quality Of Care Legal/Compliance Risks

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State Bar of Michigan
Health Law Section
December 9, 2008

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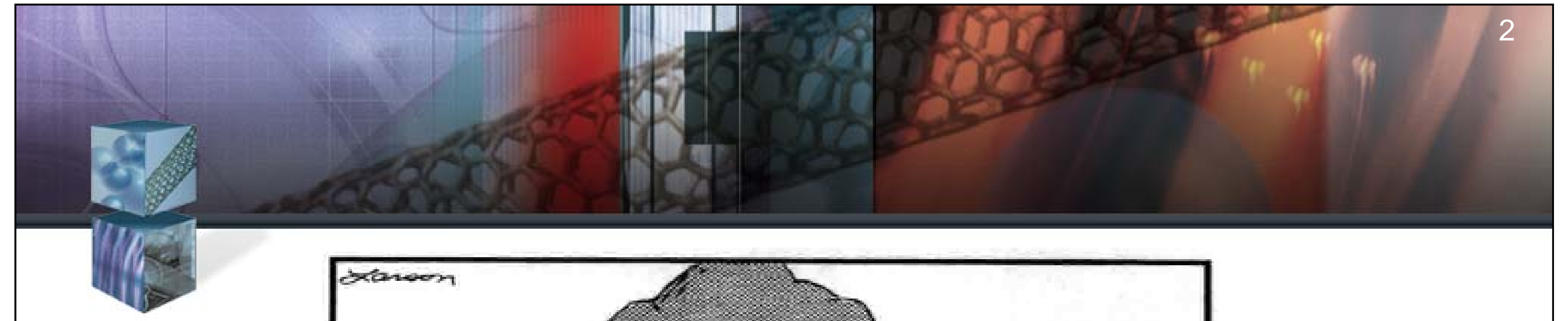

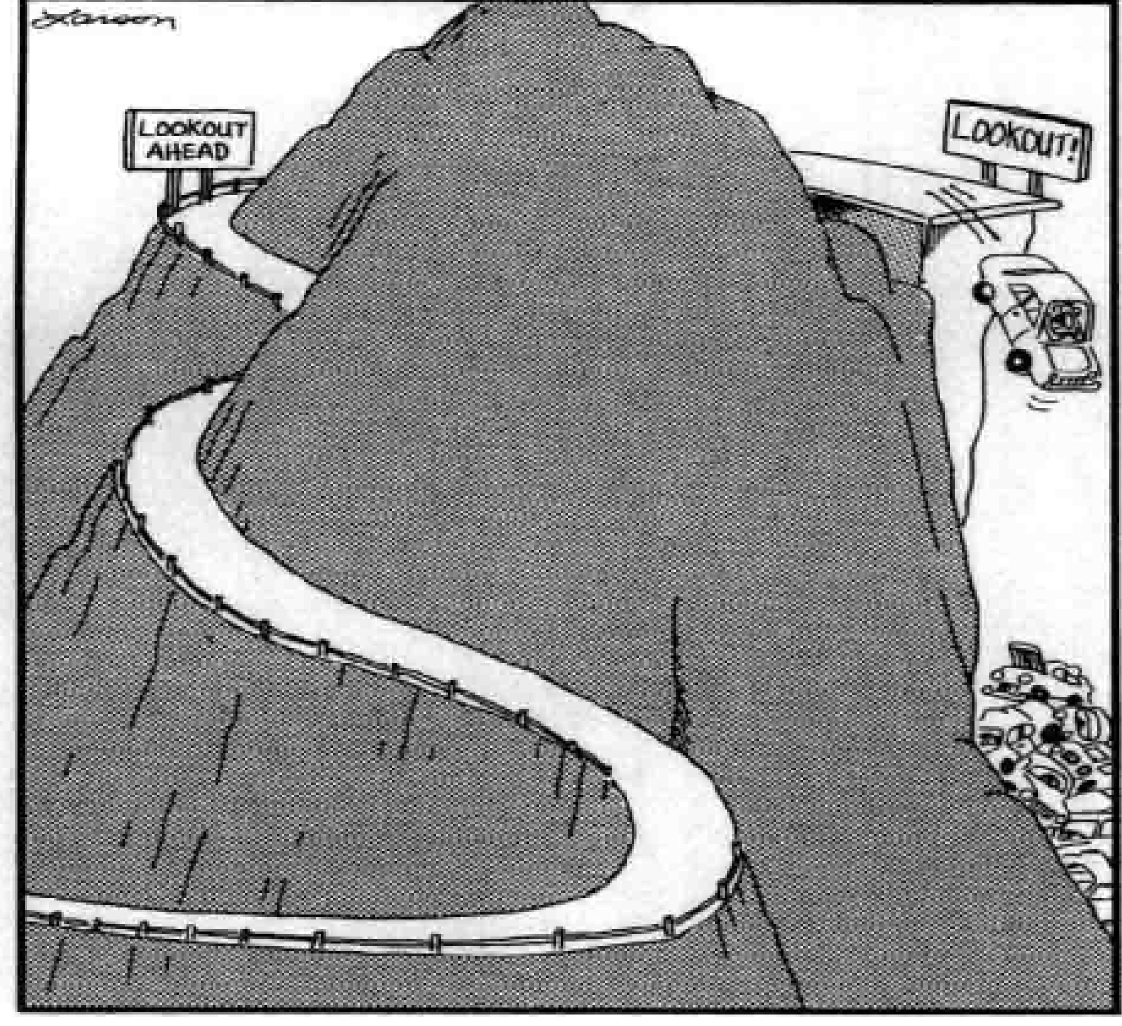

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BE AWARE OF NEW DEVELOPMENTS

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CMS' STRATEGIC DIRECTION

- Incentivizing Quality Care Through Payment Reform
- Driving Quality of Care Through Public Reporting
- Enforcing Quality of Care Through the False Claims Act

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- ***"I strongly support linking provider payment to quality care as a way to make Medicare a better purchaser of health care services. Today, Medicare rewards poor quality care. That is just plain wrong and we need to address this problem."***

  Sen. Chuck Grassley,

  Budget Hearing with Michael Leavitt

  February 7, 2007

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Pay For Performance

- Financial incentives for:
  - Adhering to recommended tasks or processes.
  - Adopting desired tools or infrastructure.
  - Meeting or improving measured outcomes.
- Sometimes includes cost savings or efficiency targets (aka “gainsharing”).

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Dramatic Increase in Pay for Performance Programs

- The number of private P4P programs is increasing exponentially.
- Blue Cross of Michigan has had a P4P program for several years.
- Wellpoint has hospital P4P programs in 12 states (California, Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri, New Hampshire, New York, Ohio and Virginia).
- Private payors have taken the lead in implementing P4P..

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Medicare Value Based Purchase Plan ("VBP")

- Hospitals are now reporting quality data to CMS under RHQDAPU program.
- The Deficit Reduction Act mandated CMS to develop a "Value Based Purchasing Plan" for hospitals, and CMS issued its final report to Congress on Hospital VBP November 21, 2007.
- The VBP will build on the RHQDAPU program.

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Quality FIRST Act (H.R. 7067)

- Introduced in the House Sept 25, 2008. The first and most substantive VBP proposal to date. The bill is a starting point to advance VBP legislation in 2009.
- VBP proposals were included in physician-based payment bills S. 3101, and S. 3118.
- The Quality FIRST Act would reward hospitals for their performance on process measures for the four specified conditions currently reported to CMS:
  - acute myocardial infarction;
  - heart failure;
  - pneumonia; and
  - surgical care improvement/surgical infection prevention.

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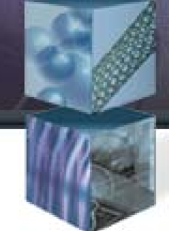

Quality FIRST Act (H.R. 7067)

- Under the Quality FIRST Act, the VBP program would begin FY 2011 with the benchmark levels announced in FY 2009 using hospital performance data from FY 2008. Hospitals' payments would be adjusted in FY 2011 based on performance on quality measures in FY 2010.

- A four-year, phased-in transition of Medicare payment bonuses would start with 0.5% for FY 2011, 1% for FY 2012, 1.5% for FY 2013, and 2% for FY 2014.

- Hospitals would have the opportunity to earn up to 2% of their reimbursement payments by meeting certain performance quality benchmarks. Bonus payments would be made to high-performing hospitals from the pool of funds made available by payment reductions to hospitals that do not meet the full-incentive benchmark level.

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Medicare Hospital Quality Improvement Act of 2008

- On November 12, 2008, Senators Grassley and Baucus released a discussion draft of Medicare Hospital Quality Improvement Act of 2008 to implement VBP plan for hospitals.
- Phased transition commencing in 2012 (1%) and be fully implemented by 2016 (2%).
- Same 4 conditions as Quality First.
- Comments due by December 15, 2008.

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Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)

- The transition to a VBP program for physicians and other professionals is required by MIPPA.
- By May 1, 2010, CMS is required to submit a report to Congress with recommendations for legislation and administrative action.
- “One possible approach would be to have multiple parallel tracks: a track appropriate for participation by virtually all physicians and other professionals, a track focused particularly on primary care for the management of beneficiaries with multiple chronic diseases, and a track focused on medical groups and entities that link professionals and institutional providers with the scope of practice broad enough to achieve cost savings,” according to a November 26, 2008 issue paper from CMS.
- Final PFS Rule expanded PQRI and signaled CMS intent to use PQRI as basis for professional VBP.

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Current VBP Initiative - No Payment for Poor Quality

- Effective October 1, 2007, hospitals must report all secondary diagnoses present on admission (POA).
- Effective October 1,2008, hospitals will not be paid for 11 “hospital acquired conditions” unless present on admission.
  - Object left in during surgery
  - Air embolism
  - Blood incompatibility
  - Catheter associated UTI
  - Pressure ulcers
  - Vascular catheter associated infection
  - Surgical site infection following CABG, certain orthopedic surgeries and bariatric surgery
  - Falls
  - DVT or PE following hip or knee replacement

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Evolving System

- HAC will continue to evolve and expand.
- CMS is considering ways to make HAC more precise, including risk-adjusting for a condition's prevalence and assessing rates of a condition's occurrence over time.
- CMS is also looking into expanding the policy to other payment settings, including outpatient hospitals, ambulatory surgery centers, physicians' offices, home health agencies, and skilled nursing facilities (“Healthcare Associated Conditions”).
- CMS proposed on December 2, 2008 three new NCDs to address certain “Never Events.”

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Driving Quality of Care Through Public Reporting

- ***"We are reviewing assorted sources of quality information on your facility to see what it says and if it is consistent. You should be doing the same."***

  James G. Sheehan,

  Medicaid Inspector General, New York

  February 6, 2007

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Driving Quality of Care Through Public Reporting

Data Mining

- Defined:
- Data mining is a ***technology*** that facilitates the ability to ***sort*** through masses of information through database exploration, extract specific information in accordance with defined criteria, and then ***identify patterns of interest*** to its user.
- Goals
  - Correct inappropriate behavior
  - Identify overpayments
  - Deny payment

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RAC Audits

- Section 302 of the Tax Relief and Health Care Act of 2006 required a permanent RAC Program and requires the Secretary to expand the program to all 50 states by no later than 2010.
- By 2010, CMS plans to have 4 RACs in place. Each RAC will be responsible for identifying overpayment and underpayment in approximately ¼ of the country. The new RAC jurisdictions match the DME MAC jurisdictions.

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RAC Audits

- The goal of the RAC program is to identify improper payments (overpayments and underpayments) made on claims of health care services provided to Medicare beneficiaries.
- Overpayments can occur when health care providers submit claims that do not meet Medicare's coding or medical necessity policies. Providers that might be reviewed include hospitals, physician practices, nursing homes, HHAs, DME suppliers and any other provider or supplier that bills Medicare Parts A and B.

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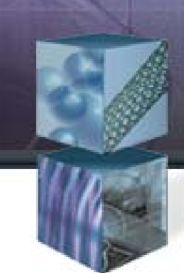
Patient Safety and Quality Improvements Act



- November 21, 2008 HHS final rule (effective January 19, 2009) created a system of voluntary reporting to Patient Safety Organizations (PSOs)
- Designed to complement the 2005 PSQIA (Pub. L. No. 109-41; S. 544).
- Final Rule has 4 Sections:
  - General Provisions
  - PSO Requirements and Agency Procedure
  - Confidentiality and Privilege
  - Enforcement

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- A PSO can be a public or private entity or component thereof, including hospitals.
- Incentive = Confidentiality and Privilege Protections for Patient Safety Work Product (PSWP)

- MHA has developed a Michigan PSO and has introduced legislation to (1) extend state privilege/confidentiality protections to PSOs and (2) require reporting of adverse events to PSOs.

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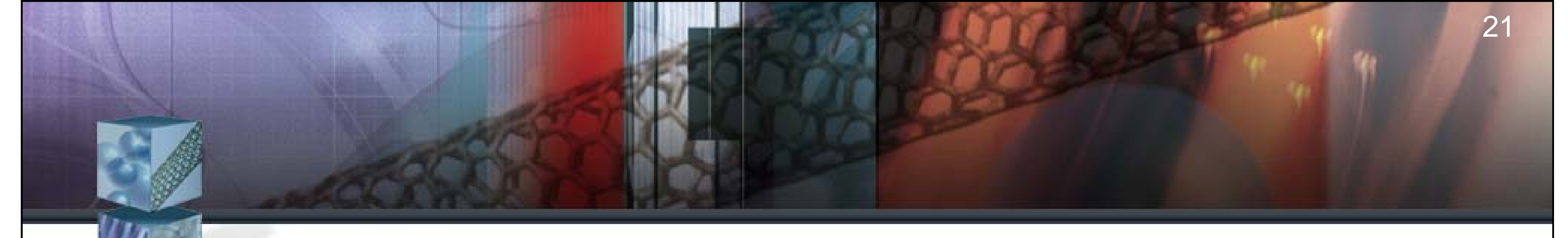

UNDERSTAND THE ENFORCEMENT RISKS

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Enforcement of Quality of Care

- The government uses a variety of legal theories under the FCA to attach quality failures, but all follow the same principle: **the government will not pay for medically unnecessary or substandard care**.
- Physicians, executives, and board members face *real risks* for poor quality of care.

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- ***"You will see more and more physicians going to jail."***
  - Kirk Ogrosky, Deputy Chief for Health Care Fraud, Department of Justice, Criminal Division (Dec. 4, 2007)

- ***"We're holding those individuals accountable." "You may not go to jail ... but we will take your money."***
  - Lewis Morris, Chief Counsel to the Office of Inspector General, U.S. Department of Health and Human Services (Dec. 4, 2007)

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- Six themes present in cases:
  - Unnecessary treatment/procedures
  - Kickbacks
  - Big admitters receiving special treatment
  - Fraudulent documentation
  - Poorly structured, or failure to follow, internal process
  - Underlying regulatory violations

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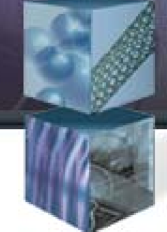

Elements of a False Claim

- Submit or cause to be submitted, a claim for payment;
- Claim is false or fraudulent (false statement); and
- Scienter: “Knew or should have known” or “reckless disregard” for the truth or falsity of the claim.
  - *No specific intent needed*

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Traditional Theories

- Claims for services not rendered
- Unbundling
- Claims for services not covered
- Duplicate payments

Quality of Care Theories

- Express False Certification
- Implied False Certification
- Worthless Services
- Criminal Statutes

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Examples of Quality of Care Enforcement Cases

- *United Memorial*
- *Redding Hospital*
- *Baptist Memorial Health Care Corp.*
  - Distinguished between Conditions of Participation and Conditions of Payment. Violation of Conditions of Participation insufficient to trigger FCA liability.

- ***Exercise caution!***

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What Does This Mean?

- New legal/compliance risks to consider:
  - Knowledge arising from data reporting.
  - Work force encouragement to "whistleblow."
  - Processes and structures are not effective in identifying quality failures.
- May lead to:
  - False Claims Act liability
  - Corporate liability
  - Liability of board members, owners and high-ranking officers

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KNOW THE PROBLEMS HOSPITALS AND PHYSICIANS FACE UNDER THE CURRENT STRUCTURE

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Hospital Peer Review and Quality Management are Not Structured to Proactively Drive Quality of Care

- Historical process is retrospective and based on incidents.
- Processes may be lengthy, biased (friends or competitors), and ineffective.
- Delays can lead to evidence of a pattern of poor quality or unnecessary care.
- Is evidence based medicine now the standard of care?
- According to “Survey on Medical Professionalism” by the Institute of Medicine as a Profession, *Annuals of Internal Medicine* (December 4, 2007), nearly ***half*** of physicians do not report medical incompetence by peers.

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Traditional Medical Staff Structure is Not Designed For New Paradigm

- Blurring of specialty lines (ex. Interventional radiology / cardiology / neurology).
- Increasing number of hospital based physicians (ex. Hospitalists intensivists, OB hospitalists, Peds hospitalists).
- Growing number of outpatient based physicians, reducing collegiality with specialists and hospital-based physicians and impacting credentialing.
- Regulators mandating change (i.e. competency based credentialing, standardization of care processes, and increased medical staff oversight of quality).

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Siloing

- ***"When looking at some of these very large [health care] corporations, there is a siloing of responsibility, which has the effect of inadequate cross of information between the peer review/quality people and the compliance people. The different components of a health care organization need to communicate and exchange information with each other and boards of directors can encourage this process."***

Lewis Morris,
Chief Counsel to the Office of Inspector General,
U.S. Department of Health and Human Services
September 25, 2007

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PEER REVIEW	QUALITY	RISK	UTILIZATION REVIEW	COMPLIANCE	BILLING

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Lack of Board Education and Oversight

- "Getting the Board on Board: Engaging Patient Boards in Quality and Patient Safety," 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.
- "We are beginning to look to boards to ensure fiscal integrity and CIA oversight." Lewis Morris, September 25, 2007.
- OIG/AHLA publication,September, 2007.
- "Driving for Quality in Long-Term Care: A Board of Directors Dashboard," HHS and HCCA joint report (January 2008). Round-table for Hospitals held November 10, 2008.

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Lack of Effective Physician-Hospital Collaboration Strategies

- Hospitals need to enlist physician support to meet quality targets and earn the pay for performance incentive payments.
  - It is often difficult to enlist physician support by simply coaxing, cajoling, scolding, etc.
  - Particularly true if you do not (or cannot) employ physicians.
- Physicians need to enlist hospitals to help with systems to drive quality across the continuum of care.
- New structures are needed to align physicians and hospitals around quality of care (See OIG Advisory Opinion 08-16)

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Questions?

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