The Legal Context for Hospital Boards: Quality and Compliance Myths and Realities

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Why Do Boards Exist?

- To act in the stead of the owners
- Who owns a not for profit hospital?
  - *The community whom it serves.*
- Towards what end?
  - *It's viability and success in performing the function that qualifies it for tax exempt status*
- For profit boards have the same purposes, with their shareholders being the owners

Fiduciary Responsibilities: Post-Enron, Allegheny, Sarbanes-Oxley

- To act in the best interests of the company and no other interest
- Measured against the “Business Judgment Rule”
- Directors have a duty to protect the interest of shareholders, bondholders and the public
- Directors have a duty to stay informed
- Directors have a duty to act responsibly on information they receive

What Enron et al Did Wrong

- Board waived policies on conflicts of interest
- Interested directors were on the audit committee
- Board failed to understand or inquire into fundamental financial issues

More – what went wrong

- Board ignored warnings from auditors
- Lack of financial experience on audit committees
- Failure to attend meetings
  - *So what about not-for-profits?*

....Allegheny

- 123 Board members: 10 sued personally
- Minutes failed to document rationales for decision making
- Failure to question management and dissent
- Failure of obedience to charitable purpose
- Failure to focus on returning value to stakeholders
- Conflicts in form of inurement

Not-for-profit Governance Legal Issues Trends

- More and more ‘best practices’ guides
- Continued scrutiny of ‘community benefit’
- Derivative actions to remove ineffective boards
- State Attorneys General attention
- Caselaw regarding board obligation to oversee compliance

Best Practices – Composition and Compensation

- Independence of management
- Highly Qualified: Knowledgeable to deal with issues: how will you get there?
- Commitment: willingness to devote time and effort and attend 75% of meetings
- Directors should not take fees from the company
- Audit, Governance and Compensation committees should be made up of independent directors

Where does quality fit?

- Tax exempt non-profits have a higher standard
- Stewardship of public benefit resources
- It’s not just about the money

1. “Cure me”
2. “Heal me”
3. “Don’t hurt me”

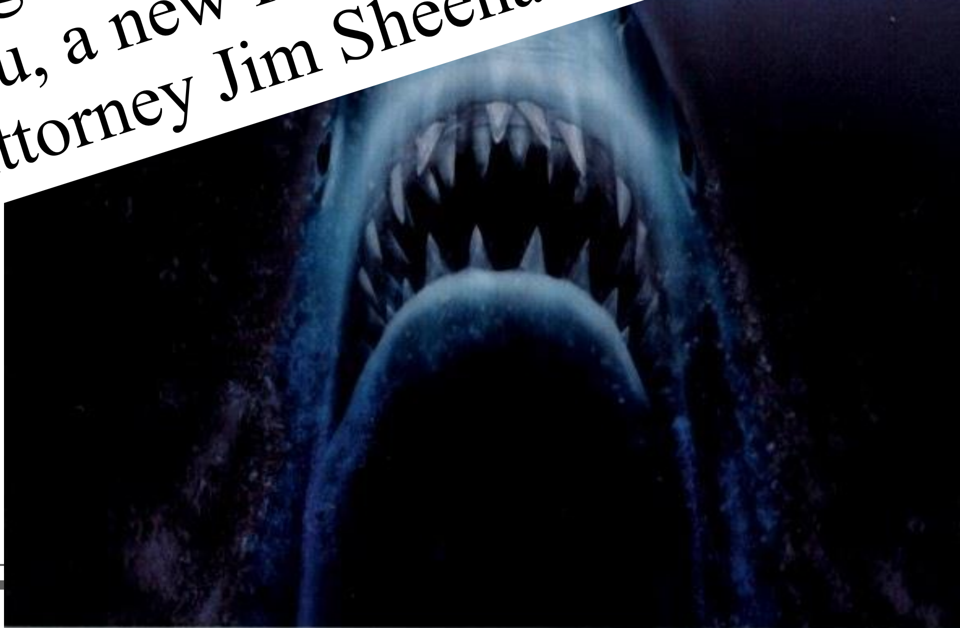
More -- P & P

- Boards should have comprehensive policies and procedures for governance
- Directors should hold executive sessions as a matter of course
- Directors should receive information at least a week in advance of Board meetings
- Directors should have independent access to management and outside professional advisors

More – Evaluation

- Boards should annually review performance including performance of committees of the board
- Board members should evaluate themselves and their own participation
- Opportunities for education should be made available

Coming soon to a Hospital near you, a new film by U.S. Attorney Jim Sheehan…



WHAT IS THE QUALITY WE ARE PAYING FOR?

- 1) Reduction of medical errors/adverse events
- 2) improvement in outcomes
- 3) compliance with practice guidelines or requirements
- 4) reduction in cost for same outcome

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?

HANDLING HISTORIC ALLEGATIONS OF SYSTEMIC LEADERSHIP FAILURES LEADING TO HARM

- UNITED METHODIST HOSPITAL-MICHIGAN-DEFERRED PROSECUTION
- REDDING HOSPITAL-CALIFORNIA-SALE OF HOSPITAL
- EDGEWATER HOSPITAL-ILLINOIS-CONVICTION OF MANAGEMENT COMPANY
- CENTRAL MONTGOMERY HOSPITAL- Pa.-SETTLEMENT AGREEMENT FOR OVERSIGHT CHANGES

UNITED METHODIST 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 METHODIST 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 Methodist 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

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?

Lions and Tigers and Bears, Oh My!

- What can you – hospitals and physicians -- do to help each other?
- How the Board can do better at stewardship of quality comes after lunch

The Legal Myths: Stark

- "Stark and antikickback are the same"
- "Everything that benefits physicians financially is prohibited by Stark"
  - No intent necessary;
  - Referrals are everything – not just directing a patient to a source; all hospital services are implicated
- "Fair market value is a number"
  - The new definitions for hourly payments

The Legal Myths: Anti-kickback, Antitrust

- No intent is necessary
  - Requires bad intent
- The safety zones are so narrow
  - There is safety in management services, personal services, bona fide employment, IT safe harbors
- Anything not in a safe harbor is illegal
  - Safe harbors are not the only legitimate relationships
- Antitrust prevents collaboration between hospitals and physicians and among physicians
  - Not so, remember clinical integration?

What can you pay for and how much?

- Time is money
- Pay for some things: FMV under Stark
- Doing the work on the quality initiatives
- Medical staff service may be on the list
- Gainsharing: who is helping whom?
- On-call coverage
- Avoiding LaHue-type messes

Exclusions Based on Quality Failures

- Items or services to patients (whether or not eligible for benefits under Medicare or Medicaid) substantially <u>in excess of the patient's needs</u> (42 USC 1320a-7(b)(6)(B))

- Of a <u>quality</u> which fails to meet professionally recognized standards of health care

Civil Money Penalties for Quality

- Claims for a pattern of medical items or services that a person knows or should know are <u>not medically necessary</u> (42 USC 1320a-7a(a)(1)(E))
- Provides false or misleading information that could be expected to lead to <u>premature discharge</u> (42 USC 1320a-7a(a)(3))
- Hospital payments to physicians <u>to reduce services</u> (42 USC 1320a-7-a(b))

CMPs and More (continued)

- Physician incentive plans that put physicians at substantial financial risk
- Stark and Kickback violations
- OIG Model Compliance Guidances all mention quality
- OIG Work Plans 2003-2007 increasingly deal with quality issues and medical necessity

Where Does Compliance Come From?

- Federal sentencing guidelines
- HIPAA impacts: “knew or should know”
  - Acts in deliberate ignorance of the truth or falsity of the claim
  - Acts in reckless disregard of the truth
  - No proof of specific intent is required
- Case law on intent
- Not everything is even an overpayment

How do they decide false claims liability?

- Notice to the provider?
- Clarity of the rule
- Pervasiveness and magnitude of the claims
- <u>Is there a compliance plan</u>
- Have they taken previous steps to rectify
- Has there been agency or program guidance
- Have there been prior audits
- Other information

The Quality/Compliance Nexus

- The point of compliance:
  - 1. Do it right.
  - 2. If you make a mess clean it up.
- Where compliance is today:
  - 1. eternal internal self-inspection and reporting
  - 2. ‘gotcha’
- Shifting the focus of compliance to reflect quality concerns with programmatic integration strengthens both (see AGG Note)

Principles of Compliance

- Be the little red hen
- Walk the walk: Don’t spawn whistleblowers
- Prioritize using the three questions:
  - What makes us think we are doing it right or wrong?
  - What will it take to fix it?
  - How will we know it stays fixed?

Seven Elements

- Standards and procedures (but it's not what you write; it's what you do)
- Specific individuals, high up, have responsibility: write in the active voice
- Use due care not to engage with those 'with a propensity" to bad behavior: due diligence
- Communication and training

The Rest

- Monitor and audit over time and provide mechanisms to report (hot lines)
- Disciplinary mechanisms: the lipid nurse
- If 'an offense' is detected take steps to

Can compliance really help you?

- Quality is job 1
- Even false claims issues relate to risk management which includes clinical risk management
- Integrate compliance and quality principles
- Related issues: utilization (med nec); antitrust (clin integration); privacy

Making a New Reality

- Review quality relevant enforcement challenges and get them into the compliance program
- Make use of Stark provision: 42 CFR 411.357(o)
- Think about the new ‘gainsharing’
- Focus on medical necessity

Keep in mind

- Do you want it on the front page of the paper?
- What kind of snapshot will a prosecutor make of this in 30 seconds to a jury of people who haven’t graduated high school?
- What would your Mom say?
- Not asking doesn’t make it right
- Everyone does it doesn’t count
- Can you do better?

“Choose your own adventure”

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