

**Hospital Board Training Part 2:  
Laws Every Board Member Should Know**



Kim C. Stanger  
(6-16)

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This presentation is similar to any other legal education materials designed to provide general information on pertinent legal topics. The statements made as part of the presentation are provided for educational purposes only. They do not constitute legal advice nor do they necessarily reflect the views of Holland & Hart LLP or any of its attorneys other than the speaker. This presentation is not intended to create an attorney-client relationship between you and Holland & Hart LLP. If you have specific questions as to the application of law to your activities, you should seek the advice of your legal counsel.

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### Board Responsibilities

- Quality patient care
- Qualified practitioners
- Effective administration
- Hospital mission, vision and values
- Strategic planning
- Community relations
- Financial stability
- **Statutory and regulatory compliance**
- Board education and efficient processes

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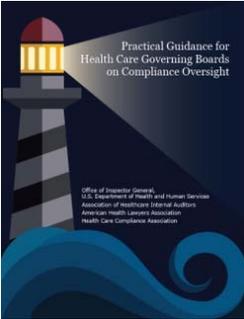
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### Board's Obligation for Compliance



- Published 4/20/15
- Available at <https://oig.hhs.gov/newsroom/news-releases/2015/guidance-release2015.asp>

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### Overview

- Laws every board member should know.
  - Fraud and Abuse Laws
    - False Claims Act
    - Anti-Kickback Statute
    - “Stark” Law
    - Civil Monetary Penalties
  - HIPAA
  - EMTALA
  - Antitrust
- Suggestions



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**Preliminaries**

- Written materials
  - Powerpoints
  - OIG, *Supplemental Compliance Program Guidance for Hospitals*, 70 FR 4858 (1/31/05)
  - OIG, *Practical Guidance for Health Care Governing Boards on Compliance Oversight* (4/20/15)
- Presentation will be recorded and available for download at [www.hhhealthlawblog.com](http://www.hhhealthlawblog.com).
- If you have questions, please submit them using chat line or e-mail me at [kcstanger@hollandhart.com](mailto:kcstanger@hollandhart.com).

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**CAUTION**

- This is an overview of some of the basic principles.
  - Focus on federal laws
- Check your own situation when it's time to apply:
  - Applicable laws, including state statutes and regulations
  - Hospital and medical staff bylaws
  - Contracts

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 **OIG** Office of Inspector General  
U.S. Department of State - Inspecting Board of Governors

**HELP FIGHT  
FRAUD.  
WASTE.  
ABUSE.**

If you suspect wrongdoing, contact:  
1-800-409-9926  
**OIG.state.gov/HOTLINE**

If you fear reprisal:  
Federal employees and employees of contractors, subcontractors, and grantees are protected by law from reprisal for reporting wrongdoing to a recipient authorized by law to receive such reports.

Contact the OIG Whistleblower Ombudsman to learn more about your rights:  
**OIGWPEAOmbuds@state.gov**

**Fraud and Abuse**



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*To make matters worse...*

***Now you must narc on yourself and others!***

- Affordable Care Act report and repay requirement.
- HIPAA breach notification rules.
- The Yates Memo

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**The Yates Memo**



- In September 2015, DOJ Deputy AG Sally Yates released a Memorandum addressing individual accountability for corporate wrongdoing.

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**The Yates Memo**

Primary message = The Government will hold individuals accountable who are found to be the responsible parties for corporate misconduct.

- Government is concerned that civil monetary penalties (no matter how large) do not alone deter noncompliant behavior in large organizations.
- The DOJ believes individual accountability is important to:
  - Deter future illegal activity.
  - Incentivize changes in corporate behavior.
  - Ensure that proper parties are held responsible for their actions.
  - Promote the public's confidence in the federal justice system.

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**False Claims Act**

- *Qui Tam* Suits: private entities (*e.g.*, employees, patients, providers, competitors, *etc.*) may sue the hospital under False Claims Act on behalf of the government.
  - Government may or may not intervene.
  - *Qui tam* relator.
    - Receives a percentage of any recovery.
    - Recovers their costs and attorneys fees.

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**False Claims Act**

- Claims for services that were not provided or were different than claimed.
- Failure to comply with quality of care.
  - Express or implied certification of quality.
  - Provision of “worthless” care.
- Failure to comply with regulations.
  - Express or implied certification of compliance when submit claims (see, *e.g.*, cost reports or claim forms).
  - *Universal Health Services v. Escobar* (Supreme Court 6/16/16)

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**Anti-Kickback Statute, Stark, & Civil Monetary Penalties Law**

 **WARNING**

Anytime you want to:

- Give anything to induce or reward referrals, or
- Do any deal with a referral source.

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**Anti-Kickback Statute (42 USC 1320a-7b; 42 CFR 1001.952)**



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**Anti-Kickback Statute**

- **Cannot knowingly and willfully offer, pay, solicit or receive remuneration to induce referrals for items or services covered by government program unless fit within regulatory safe harbor.**
  - Applies to anyone.
  - Applies to any form of remuneration, i.e., anything of value.
- Test: statute violated if “one purpose” is to induce improper referrals. (*U.S. v. Greber* (3d Cir. 1985))
- Ignorance of the law is no excuse.

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**Anti-Kickback Statute**

<ul style="list-style-type: none"> <li>• Penalties                     <ul style="list-style-type: none"> <li>– 5 years in prison</li> <li>– \$25,000 criminal fine</li> <li>– \$50,000 penalty</li> <li>– 3x damages</li> <li>– Exclusion from Medicare/Medicaid</li> </ul> </li> </ul> <p><small>(42 USC 1320a-7b(b); 42 CFR 1003.102)</small></p>	<ul style="list-style-type: none"> <li>• Anti-Kickback violation = False Claims Act violation                     <ul style="list-style-type: none"> <li>– Lower standard of proof</li> <li>– Subject to False Claims Act penalties</li> <li>– Subject to qui tam suit.</li> </ul> </li> </ul> <p><small>(42 USC 1320a-7a(a)(7))</small></p> <ul style="list-style-type: none"> <li>• OIG Self-Disclosure Protocol: minimum \$50,000 settlement.</li> </ul>
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**Anti-Kickback Statute**

HIRE THEM AS OVER-PAID CONSULTANTS AND DON'T ASK THEM FOR ANYTHING. THAT WAY, IT'S ALL LEGAL.



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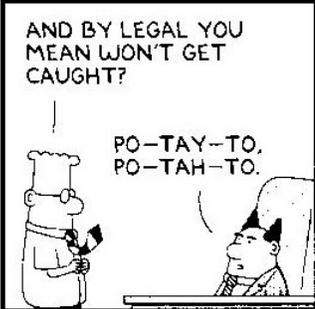
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**Anti-Kickback Statute**

AND BY LEGAL YOU MEAN WON'T GET CAUGHT?

PO-TAY-TO, PO-TAH-TO.



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**Anti-Kickback Statute**

- *United States v. Anderson* (10<sup>th</sup> Cir.).
  - Hospital paid two physicians who were substantial referral sources \$75,000/year to serve as co-directors and consultants for hospital geriatric department, but physicians performed few if any services.
  - Held:
    - Physician 1: 6 years + \$75,000 fine + \$142,000 restitution.
    - Physician 2: 3 years + \$25,000 fine.
    - Hospital CEO: 4 years + \$75,000 fine.
    - Hospital CFO: acquittal reversed.
    - Hospital attorney: acquitted.

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### Anti-Kickback: Safe Harbors

- Anti-Kickback Statute contains regulatory safe harbors.
  - To be safe, must comply with all elements.
  - Not required to fit within safe harbor.
- Safe harbors include:
  - Bona fide employment contracts
  - Personal services contracts
  - Leases for space or equipment
  - Acquisition of physician practices
  - Investments
  - Recruitment

**Common elements:**

- Written contract
- Fair market value
- Not based on volume or value of referrals
- Commercially reasonable

• *Structure deals to comply with AKS!*

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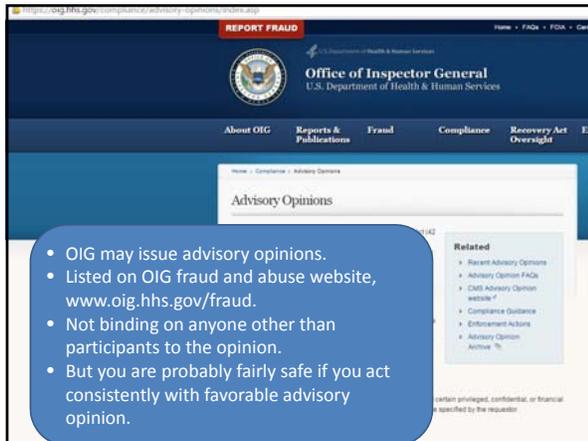
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**REPORT FRAUD**

Office of Inspector General  
U.S. Department of Health & Human Services

Home | Compliance | Advisory Opinions

Advisory Opinions

- OIG may issue advisory opinions.
- Listed on OIG fraud and abuse website, [www.oig.hhs.gov/fraud](http://www.oig.hhs.gov/fraud).
- Not binding on anyone other than participants to the opinion.
- But you are probably fairly safe if you act consistently with favorable advisory opinion.

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### Ethics in Patient Referrals Act ("Stark") (42 USC 1395nn)



REP. FORTNEY PETE STARK  
(D) California

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### Stark Self-Referral Law

- If a physician (or their family member) has a financial relationship with an entity:
  - The physician may not refer patients to that entity for designated health services (“DHS”), and
  - The entity may not bill Medicare for such designated health services
 unless arrangement structured to fit within a regulatory exception.

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### Stark Self-Referral Law

- Penalties
  - No payment for services provided per improper referral.
  - Repayment of payments improperly received within 60 days.
  - Civil penalties.
    - \$15,000 per improper referral/claim
    - \$100,000 per scheme
- Stark violation is also likely a False Claims Act violation
  - Penalty of \$5,500 to \$11,000 per claim
  - Exclusion from Medicare and Medicaid
  - Qui tam lawsuit

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Stark =  
 False Claim;  
 3x damages +  
 penalties  
 under FCA

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### Stark Safe Harbors

- Stark contains regulatory safe harbors.
  - To receive benefit, must comply with all elements.
- Safe harbors include:
  - Ownership or investment in rural providers
  - Bona fide employment contracts
  - Services contracts
  - Leases for space or equipment
  - Acquisition of physician practices
  - Medical staff incidental benefits
  - Professional courtesy
  - Recruitment

**Common elements**

- Written contract
- Fair market value
- Not based on volume or value of referrals
- Commercially reasonable

• *Structure physician transactions to comply with Stark!*

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### Stark Analysis

- Is there a financial relationship with the physician or their family member?
  - Direct or indirect financial relationship.
  - Anything of value.
- If so, does the physician refer designated health services payable by Medicare to the hospital?
- If so, has the relationship been structured to fit within a regulatory safe harbor?
- If not, prepare to repay \$.

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### Civil Monetary Penalties Law (42 USC 1320a-7a)



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### Civil Monetary Penalties Law

Prohibits specified conduct, e.g.,

- Submitting false or fraudulent claims, or claims for unnecessary services.
- Offering inducements to govt program beneficiaries to get them to purchase items or services.
  - Waivers or copays
  - Free or discounted items or services
- Offering incentives to physicians to reduce services payable by govt programs.
  - Gainsharing programs
  - Share of profits of department
- Contract with excluded entity.
  - Employees, providers, contractors

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### Civil Monetary Penalties Law

- Penalties generally include:
  - \$2,000 to \$50,000 fines
  - 3x amount claimed
  - Exclusion from government programs
- CMPL violations may also violate:
  - False Claims Act
  - Anti-Kickback Statute
  - Stark

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### Repay Overpayments (18 USC 1347)



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**Report and Repay Overpayments**

- “Overpayment” = funds a person receives or retains to which person is not entitled after reconciliation.
- **Providers and suppliers must:**
  - Report and return overpayments to HHS, the state, or contractor by the later of:
    - 60 days after the date the overpayment was identified, or
    - The date the corresponding cost report is due.
  - Provide written explanation of reason for overpayment.

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**Report and Repay Overpayments**

- “Knowing” failure to report and return overpayments by the date due may result in penalties under:
  - False Claims Act
    - Additional \$5,500 to \$11,000 per violation
    - 3x damages
    - Exclusion from Medicare and Medicaid
    - Qui tam lawsuit
  - Civil Monetary Penalties Law
    - \$10,000 per violation

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**Report and Repay Overpayments**

- CMS Report and Repay Rules
  - Proposed rule for reporting and repaying overpayments.
- Stark Self-Referral Disclosure Protocol (“SRDP”)
  - For confirmed Stark violations.
  - Suspends obligation to repay under ACA rules.
  - Government may reduce repayment.
- OIG Self-Disclosure Protocol (“SDP”)
  - For violations of AKS or CMPL.
  - Suspends obligation to repay under ACA rules.
  - Government may reduce repayment.
- *No guarantee that government will go easier on you.*

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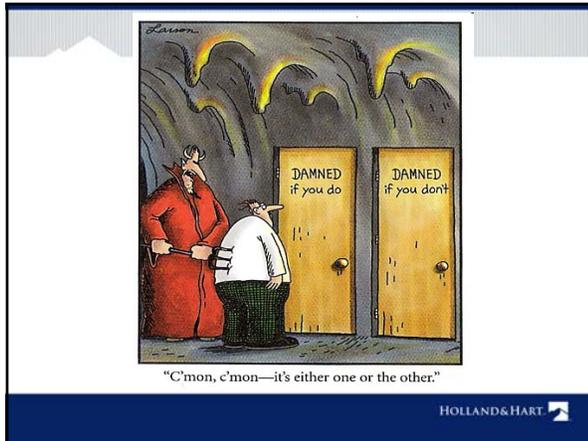
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### Best defense is good offense

- **Ensure you comply!**
- Ensure arrangements with physicians, patients, and other referral sources comply with applicable laws.
  - Beware free or discounted items to referring physicians.
  - Make sure you have written contracts with referring physicians.
  - Make sure you pay fair market value.
  - Do not condition payments on referrals.
- Ensure marketing initiatives comply with applicable laws.
- Require reports and respond immediately to suspected problems.
- Report and repay as necessary.
- **Don't forget about state laws!**

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### State Fraud and Abuse Laws

- Many states have their own fraud and abuse laws.
  - Anti-kickback
  - Self-referral prohibitions
  - Fee splitting
  - Repayment
  - Insurance fraud
  - Others?
- May vary from federal laws.
  - May apply to private payers as well as govt payers.



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**Health Insurance Portability and Accountability Act (“HIPAA”) (42 CFR part 164)**



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**HIPAA Privacy and Security Rules**

- Health care providers and their business associates must:
  - Protect the privacy of protected health info (“PHI”).
  - Secure patient’s electronic PHI by adopting specified safeguards.
  - Give patients certain rights concerning their PHI.
  - Report breaches of unsecured info within 60 days to:
    - The affected individual.
    - HHS.
    - Local media if breach involves > 500 persons.

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**Civil Penalties (45 CFR 160.400)**

Conduct	Penalty
Did not know and should not have known of violation	<ul style="list-style-type: none"> <li>• \$100 to \$50,000 per violation</li> <li>• Up to \$1.5 million per type per year</li> <li>• No penalty if correct w/in 30 days</li> <li>• OCR may waive or reduce penalty</li> </ul>
Violation due to reasonable cause	<ul style="list-style-type: none"> <li>• \$1000 to \$50,000 per violation</li> <li>• Up to \$1.5 million per type per year</li> <li>• No penalty if correct w/in 30 days</li> <li>• OCR may waive or reduce penalty</li> </ul>
Willful neglect, but correct w/in 30 days	<ul style="list-style-type: none"> <li>• \$10,000 to \$50,000 per violation</li> <li>• Up to \$1.5 million per type per year</li> <li>• Penalty is mandatory</li> </ul>
Willful neglect, but do not correct w/in 30 days	<ul style="list-style-type: none"> <li>• At least \$50,000 per violation</li> <li>• Up to \$1.5 million per type per year</li> <li>• Penalty is mandatory</li> </ul>

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**NBC News (February 13, 2016)**

- Healthcare related hacking up 11,000% since last year.
- 1/3 of Americans have had their health records compromised.
- Health records receive premium on “dark web”
  - ✓ Credit cards: \$1 to \$3
  - ✓ SSNs: \$15
  - ✓ Complete health records: \$60

**Hacking of Health Care Records Skyrockets**  
by TOM COSTELLO

For John Kuhn, a simple X-ray after a snowboarding accident turned into an accounting nightmare when the hospital billed him \$20,000 for a surgery he

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**Anthem's big data breach is already sparking lawsuits**  
by Tom Huddleston, Jr. @jhuddle

MedStar Georgetown University Hospital

HACKERS PARALYZED HOSPITAL CHAIN

Anthem

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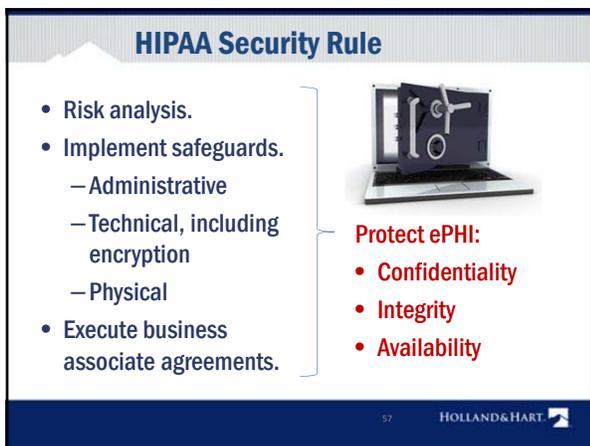
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**HIPAA Security Rule**

- Risk analysis.
- Implement safeguards.
  - Administrative
  - Technical, including encryption
  - Physical
- Execute business associate agreements.

**Protect ePHI:**

- Confidentiality
- Integrity
- Availability

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### Avoiding HIPAA Penalties

For hospitals:

- Ensure you have required safeguards in place.
  - Privacy Rule
  - Security Rule
- Train and retrain your personnel and document training.
- If there is violation:
  - Respond immediately.
    - Required to mitigate.
    - May avoid breach notification requirement.
    - May avoid penalties if correct w/in 30 days.
  - Impose appropriate sanctions.
  - Report breach, if necessary.

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### Avoiding HIPAA Penalties

For board members (and others):

- Limit your access, use or disclosure of protected health info to the minimum necessary.
- If you don't have need to know, don't access the protected health info.
- Don't snoop...

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### Emergency Treatment and Active Labor Act ("EMTALA") (42 USC 1395dd)



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### Legal Duty to Provide Care

Provider-Patient Relationship Created

No duty to provide care

Duty of Care

- Liable for breach of duty of care.
  - Malpractice
- Liable for violations of laws applicable to treating patients.
  - Medicare Conditions of Participation
  - State regulations governing treatment of hospital patients.

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### Sercye v. Ravenswood Hospital

- May 16, 1998, 15-year old Sercye was shot twice while playing basketball.
- Taken to Ravenswood Hospital, but staff refused to come out to treat him. Sercye eventually died.

*Hospital and staff had no common law duty to treat Sercye because no provider-patient relationship established.*



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### EMTALA

Applies to hospitals that participate in Medicare.

- If hospital has an emergency dept, hospital must provide emergency care appropriate to patient's condition regardless of patient's ability to pay.
- Must maintain list of on-call physicians to provide emergency care.
- If hospital has specialized capabilities, hospital must accept transfer of unstabilized person.
- Cannot delay exam or treatment to inquire about payment.
- Must post signage and retain required documents.

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### EMTALA Penalties

- Termination of Medicare provider agreement and exclusion from Medicare and Medicaid.
- Civil penalties
  - Hospital:
    - Less than 100 beds: \$25,000 per violation
    - 100+ beds: \$50,000 per violation
  - Physicians: \$50,000 per violation.
- Hospital may be sued for damages.
  - Individuals who suffer personal harm.
  - Medical facilities that suffer financial loss.

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### EMTALA

If person comes to hospital seeking emergency care:

Medical screening exam

- Appropriate to condition
- by qualified medical personnel
- Within hospital's capabilities

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    graph TD
      A[Medical screening exam] --> B[No  
Emergency medical condition  
or admit patient]
      A --> C[Yes  
emergency medical condition]
      B --> D[EMTALA ends;  
may transfer or discharge,  
but beware malpractice and COPs]
      C --> E[Stabilizing treatment within  
hospital's capabilities]
      C --> F[Appropriate Transfer to  
another facility]
    
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### Avoiding EMTALA Penalties

- Ensure staff are trained on EMTALA and document training.
- Board identified "qualified medical personnel."
- Document, document, document.
  - Appropriate medical screening exam.
  - Patient is stabilized before transfer or discharge.
- Do not refuse inbound patients unless on divert status.
- Ensure proper on-call list is maintained and physicians comply with call requirements.
- Respond promptly to suspected EMTALA violations.
  - Investigate and document as necessary.
  - Take corrective action.

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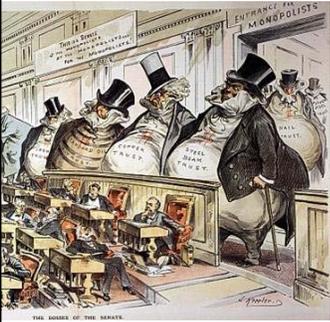
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### Antitrust



- In late 1800's, large corporate conglomerates ("trusts") held monopolies, e.g.,
  - Standard Oil
  - Steel
  - Railroads
  - Copper
  - Sugar
  - Others
- Their power allowed them to:
  - Control prices.
  - Restrict competition

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### Antitrust



- Federal antitrust laws
  - Sherman Act
  - Clayton Act
  - Federal Trade Comm'n Act
  - Robinson-Patman Act
  - Hart-Scott-Rodino Antitrust Improvements Act
- State antitrust laws

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### Enforcement

- Criminal penalties
  - Significant fines
  - Prison
- Civil penalties
  - Action by state or federal government
    - Treble (3x) damages
    - Injunctive relief, e.g. divestiture, break up corporation, requirements for contracting, etc.
    - Attorneys fees
  - Private lawsuit
    - Treble damages
    - Injunctive relief
    - Attorneys fees

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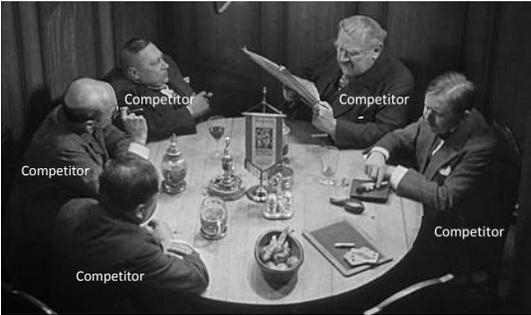
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### Sherman Act § 1



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### Sherman Act § 1

- “Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade ... is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding \$100,000,000 if a corporation, or, if any other person, \$1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.”

(15 USC § 1)

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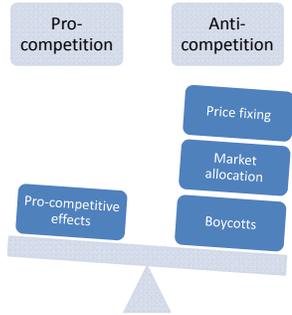
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### Sherman Act § 1



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### Antitrust Defenses

- State action immunity
  - Applies to state actors.
- Local Govt Antitrust Act
  - Applies to state and local government entities.
- Health Care Quality Improvement Act (“HCQIA”)
  - Applies to credentialing decisions.
- *Noerr-Pennington Doctrine*
  - Allows competitors to seek state action.

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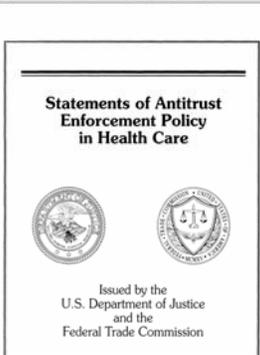
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### DOJ/FTC Statements of Antitrust Enforcement Policy in Health Care



- Outlines DOJ/FTC enforcement policy for specific situations, e.g.
  - Mergers
  - Joint ventures
  - Networks
  - Sharing price info
- Includes “safety zones” in which DOJ/FTC will not challenge action absent extraordinary circumstances.

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### What can/should the Board do?



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**Board's Role in Compliance**

- Gain basic understanding of key compliance issues.
- Accept compliance as a board responsibility.
- Endorse a culture of integrity and compliance.
- Ensure hospital has an effective compliance plan.
  - See elements in *OIG Compliance Program Guidance for Hospitals*
    - Competent compliance officer + committee
    - Educate hospital staff
    - Review and monitor compliance
    - Process for reporting violations
    - Investigate and respond to problems
  - It will be mandatory soon...
- Make compliance a regular part of the board agenda.

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**Board's Role in Compliance**

- Ensure hospital has polices and procedures that are required by regulations.
- Ensure hospital trains and retrains staff concerning compliance issues.
- Require reports of significant compliance issues.
- Authorize compliance officer to report directly to board.
- Follow up regarding compliance problems, including potential repayment obligations.
- Beware high risk compliance issues.
  - Transactions with physicians and other referral sources.
  - Billing and coding.
- Consult with competent counsel as needed.
- If there's a problem...

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**Don't do this!**



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## Holland & Hart Resources

- [www.hollandhart.com/healthcare](http://www.hollandhart.com/healthcare)
  - Webinar recordings
  - Articles
  - Forms
  - Checklists



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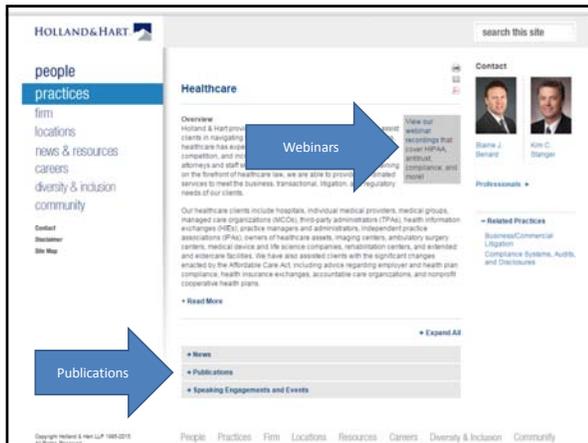
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