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

Kim C. Stanger
(6-16)

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.
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

Board's Obligation for Compliance

- Published 4/20/15

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
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.
• If you have questions, please submit them using chat line or e-mail me at kcstanger@hollandhart.com.

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
For every $1 spent in enforcement, the government recovers $7.70.

$3.3 billion recovered in FY2014
$27.8 billion recovered to date

Ohio-Based Health System Pays United States $10 Million to Settle False Claims Act Allegations

March 31, 2015
WASHINGTON – Robinson Health System Inc. has agreed to pay $10 million to settle claims that it violated the False Claims Act, the Anti-Kickback Statute and the Stark Statute by engaging in improper financial relationships with referring physicians, the Justice Department announced today. Robinson is a nonprofit corporation based in Ohio that operates a number of health care facilities in Portage County, Ohio, including Robinson Memorial Hospital.

"The Department of Justice has longstanding concerns about improper financial relationships between health care providers and their referral sources, because such relationships can alter a physician's judgment about the patient's true health care needs and drive up health care costs for everybody," said Acting Assistant Attorney General Benjamin C. Mizer of the Justice Department's Civil Division. "In addition to yielding a recovery for taxpayers, this settlement should deter similar conduct in the future and help make health care more affordable."

The settlement announced today involved Robinson's financial relationships with a number of referring physicians that allegedly violated the Anti-Kickback Statute and the Stark Statute, both of which restrict the financial relationships that hospitals may have with doctors who refer patients to them. These relationships included management agreements that Robinson had with two physician groups. These physicians allegedly failed to provide sufficient bona fide management services to have justified the payments that they received. Robinson disclosed these issues to the government.

Adventist Health System Agrees to Pay $115 Million to Settle False Claims Act Allegations

Adventist Health System has agreed to pay the United States $115 million to settle allegations that it violated the False Claims Act by maintaining improper compensation arrangements with referring physicians and by miscoding claims, the Justice Department announced today. Adventist is a non-profit healthcare organization that operates hospitals and other health care facilities.

Fraud and Abuse Laws

- False Claims Act
- Anti-Kickback Statute
- Ethics in Patient Referrals Act ("Stark")
- Civil Monetary Penalties Law
- State laws
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

The Yates Memo

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

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.
The Yates Memo – 6 Key Factors

1. Companies will have to turn over information on individual involvement in order to get cooperation credits.

2. All wrongdoers—both individuals and staff who aid or abet—will be held to the same standard, requiring both to be personally involved in the wrongdoing.

3. Employees and others will work in lockstep on corporate cases, sharing information freely.

4. Use provisions used when approving a plea or a cooperation agreement to get a cooperation credit.

5. Individual and corporate action to be treated for purposes of exclusion and/or civil monetary penalties.

6. Civil actions will be pursued against corporate entities, either under existing laws or through new criminal penalties for individual conduct.

False Claims Act (18 USC 1347)

- Cannot knowingly submit a false claim for payment to the federal government.
- Must report and repay a false claim within 60 days.
- Penalties:
  - Repayment plus interest
  - Civil monetary penalties of $5,500 to $11,000 per claim
  - 3x damages
  - Exclusion from Medicare/Medicaid
**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.

**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)

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

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.

Anti-Kickback Statute

• Penalties
  — 5 years in prison
  — $25,000 criminal fine
  — $50,000 penalty
  — 3x damages
  — Exclusion from Medicare/Medicaid *(42 USC 1320a-7b(b); 42 CFR 1001.102)*
• Anti-Kickback violation = False Claims Act violation
  — Lower standard of proof
  — Subject to False Claims Act penalties
  — Subject to qui tam suit. *(42 USC 1320a-7a(j)(7))*
• OIG Self-Disclosure Protocol: minimum $50,000 settlement.
Anti-Kickback Statute

- Applies to any form of remuneration, i.e., anything of value.
  - Money
  - Free or discounted items, services, gifts, perks or subsidies (e.g., free use of hospital services, equipment, space)
  - Contract compensation based on referrals
  - Business opportunities
  - Waivers of copays or deductibles
  - Overpayments or underpayments (paying more or less than fair market value)
United States v. Anderson (10th 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.
**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
- Structure deals to comply with AKS!

**Common elements:**
- Written contract
- Fair market value
- Not based on volume or value of referrals
- Commercially reasonable

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

- OIG may issue advisory opinions.
- Not binding on anyone other than participants to the opinion.
- But you are probably fairly safe if you act consistently with favorable advisory opinion.
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.

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

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

- **Structure physician transactions to comply with Stark!**

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 $.

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

Prohibits specified conduct, e.g.,
• Submitting false or fraudulent claims, or claims for unnecessary services.
• Offering inducements to government 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 government programs.
  – Gainsharing programs
  – Share of profits of department
• Contract with excluded entity.
  – Employees, providers, contractors

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

Repay Overpayments

(18 USC 1347)
**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.

**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

**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.**
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!**

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.
Health Insurance Portability and Accountability Act ("HIPAA") (42 CFR part 164)

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.

Civil Penalties (45 CFR 160.400)

<table>
<thead>
<tr>
<th>Conduct</th>
<th>Penalty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did not know and should not have known of violation</td>
<td>$100 to $50,000 per violation</td>
</tr>
<tr>
<td></td>
<td>Up to $1.5 million per type per year</td>
</tr>
<tr>
<td></td>
<td>No penalty if correct w/in 30 days</td>
</tr>
<tr>
<td></td>
<td>OCR may waive or reduce penalty</td>
</tr>
<tr>
<td>Violation due to reasonable cause</td>
<td>$1000 to $50,000 per violation</td>
</tr>
<tr>
<td></td>
<td>Up to $1.5 million per type per year</td>
</tr>
<tr>
<td></td>
<td>No penalty if correct w/in 30 days</td>
</tr>
<tr>
<td></td>
<td>OCR may waive or reduce penalty</td>
</tr>
<tr>
<td>Willful neglect, but correct w/in 30 days</td>
<td>$10,000 to $50,000 per violation</td>
</tr>
<tr>
<td></td>
<td>Up to $1.5 million per type per year</td>
</tr>
<tr>
<td></td>
<td>Penalty is mandatory</td>
</tr>
<tr>
<td>Willful neglect, but do not correct w/in 30 days</td>
<td>At least $50,000 per violation</td>
</tr>
<tr>
<td></td>
<td>Up to $1.5 million per type per year</td>
</tr>
<tr>
<td></td>
<td>Penalty is mandatory</td>
</tr>
</tbody>
</table>
### Civil Penalties

#### 42 USC 1320d-6(a)

- Applies if employees or others obtain or disclose protected health info from covered entity without authorization.

<table>
<thead>
<tr>
<th>Conduct</th>
<th>Penalties</th>
</tr>
</thead>
</table>
| Knowingly obtain info in violation of the law | • $50,000 fine  
• 1 year in prison |
| Committed under false pretenses              | • $100,000 fine  
• 5 years in prison |
| Intent to sell, transfer, or use for commercial gain, personal gain, or malicious harm | • $250,000 fine  
• 10 years in prison |

### Criminal Penalties

Criminal Penalties

- Applies if employees or others obtain or disclose protected health info from covered entity without authorization.

<table>
<thead>
<tr>
<th>Conduct</th>
<th>Penalties</th>
</tr>
</thead>
</table>
| Knowingly obtain info in violation of the law | • $50,000 fine  
• 1 year in prison |
| Committed under false pretenses              | • $100,000 fine  
• 5 years in prison |
| Intent to sell, transfer, or use for commercial gain, personal gain, or malicious harm | • $250,000 fine  
• 10 years in prison |
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

Anthem’s big data breach is already sparking lawsuits

HIPAA Security Rule
• Risk analysis.
• Implement safeguards.
  — Administrative
  — Technical, including encryption
  — Physical
• Execute business associate agreements.

Protect ePHI:
• Confidentiality
• Integrity
• Availability
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 within 30 days.
  — Impose appropriate sanctions.
  — Report breach, if necessary.

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...

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

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.

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.
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.

EMTALA

If person comes to hospital seeking emergency care:

Medical screening exam
- Appropriate to condition
- by qualified medical personnel
- Within hospital’s capabilities

EMTALA ends; may transfer or discharge, but beware malpractice and COPs

No Emergency medical condition or admit patient

Yes emergency medical condition

Stabilizing treatment within hospital’s capabilities

Appropriate Transfer to another facility

Avoiding EMTALA Penalties

- Ensure staff are trained on EMTALA and document training.
- Board identified “qualified medical personnel.”
  - 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.
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

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

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.
    • Attorney fees
  – Private lawsuit
    • Treble damages
    • Injunctive relief
    • Attorney fees
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)
Sherman Act § 2

• “Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, 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 § 2)

Clayton Act § 7

• “No person ... shall acquire the whole or any part of the assets of another person engaged also in commerce or in any activity affecting commerce, where ... the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly.”

(15 USC § 18)
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.

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.

What can/should the Board do?
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.

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...

Don’t do this!
Protections for Board Members

Liability Defenses and Protections

• Business Judgement Rule
• Statutory immunity.
  – Health Care Quality Improvement Act, 42 USC 11101
  – Volunteer Protection Act, 42 USC 14501
  – State Tort Claims Act (e.g., Idaho Code 6-901 et seq.)
  – State Peer Review Privilege (e.g., Idaho Code 39-1392 et seq.)
• Indemnification agreements.
• Directors and officers liability insurance.
• Risk management actions.

Additional Resources
Board Compliance Resources

- OIG Compliance Program Guidance for Hospitals
  - Original, 63 FR 8897 (2/23/98)
  - Supplemental, 70 FR 4058 (1/27/05)  
  - [OIG Compliance Guidance](http://oig.hhs.gov/fraud/complianceguidance.asp)
No More Talking!

Kim C. Stanger
Holland & Hart LLP
(208) 383-3913
kcstanger@hollandhart.com

We don't want to hear it!

Kim C. Stanger
208-383-3913
csstanger@hollandhart.com
www.hollandhart.com
www.hhhealthlawblog.com