Healthcare Compliance: Ideas for Protecting and Preparing for Success

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Fletcher Brown
Partner Healthcare Compliance and Operations
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- Recognized by *Chambers USA* as a leader in Texas health law
- Assistance with operational and regulatory issues ranging from contract negotiations to Stark and anti-kickback compliance
- Precedent-setting work with the Texas Medicaid 1115 Waiver
- Provides governmental and tax-exempt entities guidance on:
  - policies and procedures
  - physician contracting
  - board governance
  - HIPAA and HITECH patient privacy issues
About Waller

- Recognized as one of the top five healthcare law firms in the nation by Modern Healthcare and the American Health Lawyers Association
- More than 200 attorneys – 100 of which focus majority of their time on healthcare
- Represent independent hospitals and hospital companies that operate more than 450 facilities and 500 ASCs

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Today’s Agenda

1) 2017 - Top 10 Health Care Trends
2) Why Compliance is Important
3) General Duties of Directors
4) Lessons for a Compliance Response
Top 10 Health Care Trends - 2017
1. Uncertain reimbursement future

“Noreen, have they added a reimbursement code for kale and yoga yet?”
2. Payment moves to value
3. Cost reduction pressure
4. Move to collaborate/system
Top 10 Health Care Trends - 2017

5. More consumerism
6. Widely Accessible Care Delivery
Top 10 Health Care Trends - 2017

7. Optimizing Analytics and Digital Uses
8. Focusing on cost drivers (behavioral health)
9. Adapting to and using Clinical advances
Top 10 Health Care Trends - 2017

10. Changing workforce needs
Why Compliance is Important
Oversight of the Healthcare Industry

- Congress
- Federal Circuit Courts
- Departmental Appeals
- State Level:
  - Survey & Certification
  - Courts
  - Attorneys General
  - Medicaid Health Boards
  - Medical Boards
  - Local Governments
  - Licensure
  - Oversight Departments

- CMS
  - PRRB
  - OIG
  - QIOs
  - Carriers
  - Intermediaries
  - Regional Offices
  - DME Regional Contractors
  - Regional Home Health Intermediaries
  - Medicare Integrity Program Contractors

- DEA
- FAA
- OPOs
- SEC
- GSA
- IRS
- EPA
- FTC
- FCC
- ERISA
- CLIA
- OCR
- HHS / HRSA
- HHS / NIOSH
- Other accreditation agencies

- FDA
- DOT
- OSHA
- DOJ
- TREASURY
- FBI
- DOL
- NRC
- TJC
Annual Healthcare Spending

- According to CMS, annual healthcare spending for 2025 is projected to exceed $5.63 trillion, and account for 20.1% of the GDP.
- For 2015-25, health spending is projected to grow at an average rate of 5.8% per year.
- Federal, state and local government share of health expenditures to increase to 47% by 2025.
The Cost of Regulation

- If the 2015 U.S. regulatory costs of $1.885 trillion were a country, it would be the world's 9th largest economy behind India and ahead of Russia

- The 2015 Federal Register had 80,260 pages, third highest in history, behind 2010 and 2011

- Fact: The ACA regulations alone are eight times longer than the Gutenberg Bible

Source: Competitive Enterprise Institute, 2016 report
Recent Government Action

**Effective 2011 but only recently enforced**

- Payment Suspensions on Credible Allegations of Fraud

**May 2014**

- New York hospital pays record $4.8 million HIPAA settlement
- OIG proposed rules to expand exclusion authority and its penalty authority
Recent Government Action

May 2014

- Proposed Rule for failure to report and return a known overpayment within 60 days; interprets the penalty as a per-day penalty, up to $10,000 for each day a person fails to report and return each overpayment

September 2014

- U.S. Department of Justice (DOJ) Criminal Division Assistant Attorney General Leslie R. Caldwell announced the formal adoption of a DOJ policy initiative in furtherance of bringing a greater number of criminal prosecutions
Recent Government Action

**September 2015**
- Adventist Health System agreed to $118.7 million settlement over physician compensation arrangement and claim coding

**October 2015**
- Toumey Healthcare System in Sumter, SC reached a $72.4 million settlement and agreed to sell itself to larger system
Why is Compliance Important?

**Tuomey Healthcare System Settlement:**

- Announced October 16, 2015
- Related to physician employment and outpatient procedures
- Began with disgruntled orthopedic surgeon
- $72.4 million paid from $237 million awarded. (of which 18.1 million will go to relator)
- Five Year Corporate Integrity Agreement
- Requires hospital to be sold
- Sumter, South Carolina
Recent Government Action

October 2016

- Tenet Healthcare Corporation and two Atlanta, GA subsidiaries pay $513 million to resolve DOT criminal divisions corporate healthcare fraud strike force charges of kickbacks and bribes
- Tenet also agreed to retain independent compliance monitor to reduce risks of recurrent AKS violations
Recent Government Action

October 2016

- 50 year old owner of Detroit home health agency sentenced to 30 years in prison and $40.4 million restitution
- Paid cash kickbacks to patient recruiters
- Falsified records to appear as if patients qualified for and received medicare services
- Laundered ill-gotten money through shell corporation
January 2017

- 43 year old Detroit neurosurgeon sentenced to 235 months (19.6 years) in prison for performing unnecessary spinal surgeries and falsely claiming to have performed certain surgeries and bill for implants

- Was an investor in devices he convinced his hospital to buy – concealed ownership for financial gain with surgeries
February 2017

- Children’s Medical Center of Dallas fined $3.2 million over patient privacy breaches dating back to 2007.
- Voluntary reported potential disclosures in 2010 of a Blackberry lost at DFW allowed unencrypted, non-password access to 3,800 patients’ information.
- Security analysis performed in 2007 had reported this gap to management, as did a separate report in 2008. No action taken.
Between 2009 and 2014, federal healthcare fraud-related convictions increased by over 25% (from 583 to 734)

During 2014, DOJ prosecutors:

- Opened 924 new criminal healthcare fraud investigations
- Filed 496 criminal cases against 805 defendants;
- Obtained convictions of 734 defendants charged with healthcare fraud-related crimes
Why is Compliance Important?

Aggressive Government Enforcement Continues

• Vigorous enforcement of healthcare fraud and abuse laws remains a top priority of HHS-OIG

• For 2015, the OIG reported:
  – 983 new criminal healthcare fraud investigations
  – 463 criminal cases
  – 808 new civil actions; and
  – 4,112 exclusion actions

• *Health Care Fraud and Abuse Control Program (HCFAC)* has “returned” over $29.4 billion to the Medicare since 1997, with $16.2 billion since 2009.
2015 — The Results:

- DOJ recovered $4.7 billion in FY 2016 from False Claims Act enforcement efforts
  - Fifth consecutive year that DOJ recovered more than $3.5 billion under the FCA
  - $2.5 billion was related to cases involving the health care industry
  - Total health care recoveries from January 2009 to end of FY 2016 is $19.3 billion
  - 702 qui tams were filed in FY 2016 (13.5 per week)
  - Whistleblowers received $519 million - a big incentive to report!
Federal Sentencing Guidelines for Organizations

“These guidelines offer incentives to organizations to reduce and ultimately eliminate criminal conduct by providing a structural foundation from which an organization may self-police its own conduct through an effective compliance and ethics program. The prevention and detection of criminal conduct, as facilitated by an effective compliance program, will assist an organization in encouraging ethical conduct and in complying fully with all applicable laws.”

– U.S.S.G., Ch. 8, Sentencing of Organizations, Introductory Commentary (November 1, 2010)
2004 Amendments — Expanded Role of Boards

• Initially, the Guidelines were silent on the board’s role

• In 2004, the revised Guidelines made governing boards responsible for:
  – being knowledgeable about the organization’s compliance/ethics program
  – exercising “reasonable oversight” of the compliance program’s effectiveness

• To achieve this, governing boards should receive direct reports from individuals with “day-to-day operational responsibility” for the compliance program
September 2015

- Yates Memorandum reveals a renewed focus on individual prosecutions for corporate wrongdoing.

- Provides six key steps “to most effectively pursue the individuals responsible for corporate wrongs.” Basically:
  - The strong DOJ presumption is one of individual prosecution in every case;
  - There will be much more coordination between civil/criminal; and
  - Internal investigations will be more scrutinized that ever and therefore will need to be more thorough and independent.
  - FY 2016 at least ten executives held personally liable ranging from $10.3 million to $250,000 in individual fines
General Duties of Directors
Duty of Care

- Care that an ordinarily prudent person in a similar position would exercise under similar circumstances

- Discharge duties in good faith and ordinary care as the director reasonably believes to be in the best interest of the entity
Duty of Care

• May rely on information, opinions, reports or statements by officers, employees, or a committee of the board

• May rely on information or opinions from legal counsel, public accountants or other professional experts

• Not relying “in good faith” if director knows reliance on information is unwarranted
Duty of Care

• Not liable if complied with the standards

• To establish liability, must prove that the director has *not* acted in good faith, with ordinary care and in a manner the director reasonably believes to be in the best interest of the corporation
Duty of Loyalty

• Pursue the interests of the organization rather than the interests of the director, another person or another organization

• Duty of undivided loyalty to the interests of the organization’s mission and basic well-being
Duty of Loyalty

- Director must not use his/her position to advance conflicting interests, including the interests of other entities which may have an interest the particular matter the entity is considering.
Duty of Obedience

• Act in accordance with the organization’s mission as expressed in its Governing Documents

• To see that an organization operates in such a way as to further its stated goals

• Directors are ultimately responsible for ensuring that the organization substantially holds to its purposes
Basic Board Processes

• Set Direction and Goals
  – Financial
  – Patient Experience
  – Access/scope of services
  – Clinical Care
• Approve strategies to reach the goals
• Review progress against strategies and targets
• Ensure compliance
• Hire and fire the CEO
Why Boards and CEOs get into trouble...

- Failure to ask questions
- Failure to set and understand performance expectations
- Failure to choose the right CEO or take action
- Failure to achieve a shared vision between the board, medical staff and management
- Failure to balance community responsibility with fiduciary responsibility
- Failure to implement appropriate board processes and structures
- Forgetting your Mission
- Managing vs. Governing
- Individual interests/COI
- The Chair as Czar
Why is Compliance Important?

Aggressive Government Enforcement Continues

- Vigorous enforcement of healthcare fraud and abuse laws remains a top priority of HHS-OIG

- For FY 2014, the OIG reported:
  - Recovery of $2.3 billion
  - 924 new criminal investigations
  - 782 new civil actions; and
  - 4,017 exclusion actions

* The Health Care Fraud and Abuse Control Program (HCFAC) has returned over $27.8 billion to the Medicare Trust Fund since the inception of the Program in 1997.
We intend to “alter the cost-benefit calculus of the corporate executives who run these companies. By excluding the individuals who are responsible for the fraud, either directly or because of their positions of responsibility in the company”

We have “the authority to exclude every officer and managing employee of a sanctioned entity.”

—OIG
Personal Accountability

• Board members and officers of healthcare organizations are responsible for:
  – Knowing and adhering to laws and regulations that affect the Organization
  – Supervising the Compliance Program and policies and procedures
  – Devoting sufficient resources to compliance
  – Taking appropriate action when compliance problems are identified in the Organization
FBI Raided the Residence of a Nursing Home CEO

Individuals from the FBI, IRS and the OIG raided the home of nursing home chain American Senior Communities’ CEO in September of 2015 as part of their investigation into criminal activities.
Quality of Care is the Board’s Responsibility

- The Boards of Directors of healthcare companies have a “duty to make reasonable inquiry regarding the emerging legal and compliance issues associated with quality of care initiatives, and to direct executive leadership to address those issues.”
  - Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors, HHS-OIG and AHLA publication (Sept. 13, 2007)
Quality of Care Has Become a Fraud and Abuse Issue

- Two main criminal and civil fraud theories:
  - **Medically unnecessary services**
    - “When medically unnecessary services are provided, the patient is unnecessarily exposed to risks of a medical procedure and the federal health care programs incur needless costs”
  - “**Failure of Care**”
    - “Involves the provision of care that is so deficient that it amounts to no care at all” (and therefore is tantamount to billing for “services that were not actually rendered”)
The OIG’s Seven Essential Elements of A Compliance Plan

1. Establish compliance standards and procedures.
2. Assign responsibility for the compliance program.
3. Develop effective lines of communication.
4. Develop a method to educate all employees on the standards of conduct, the compliance program, and the procedures under the program.
5. Develop a monitoring and auditing system reasonably designed to detect improper conduct.
6. Develop a method to investigate and take action designed to correct identified problems.
7. Enforce standards through well-publicized disciplinary guidelines.
The Rise of the Whistleblower

Health care whistle-blowers

<table>
<thead>
<tr>
<th>Year</th>
<th>Cases</th>
<th>Total amount recovered</th>
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<tbody>
<tr>
<td>2000</td>
<td></td>
<td></td>
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<tr>
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<td>2009</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>417</td>
<td>$2.3</td>
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A fiscal year runs from Oct. 1 through Sept. 30
Source: Civil Division, U.S. Department of Justice
By Julie Snider, USA TODAY

“Remember the good old days when it was a suggestion box?”
The Rise (and Risk) of Whistleblowers

Number of FCA New Matters, Including Qui Tam Actions

Source: DOJ "Fraud Statistics – Overview" (December 23, 2013)
Why Are There More Whistleblowers Than Ever?

- Expansion of whistleblower provisions under federal law
- Case law expanding protected activity and making retaliation claims more difficult to defend
- Government increasingly relying on whistleblowers as source for new cases
- False Claims Act creates a “bounty” for whistleblowers to recover a percentage of recovery
  - Bounty can be up to 30% of recovery based on value of information provided
Do Not Strive to Take Unnecessary Risks or Be a Market Leader in Creative Compliance

• Due to the technical nature of many of the healthcare laws and regulations (Stark Law and Anti-Kickback), it is wise to be conservative in your approach to compliance
  - Even small technical violations can potentially lead to large penalties and fines
  - Consider use of the self-disclosure protocol if violations are detected and to increase your potential to minimize liability exposure especially for minor technical violations
Lessons and Concepts for Response
“You can't control the cards you're dealt just how you play the hand.”

The Last Lecture

— Randy Pausch (1960-2008)

Professor, Carnegie Mellon University
Lesson # 1: Be Prepared for Government Inquiry

- Establish credibility early
  - First do no harm: ensure that employees understand the risks
  - Unequivocal requirement that contact with enforcement agencies be communicated immediately
  - Clear prohibition on information destruction
  - Cooperation as an established policy
  - Have the litigation hold ready to go
  - Present the government with details of the organization’s operations and information storage from the outset
Lesson # 1: Be Prepared for Government Inquiry

- Identify tangible evidence of “systemic success”
  - Concrete examples showing that the program is not only in place, but actually works
    - Specific instances where the organization has elevated compliance over profits
- Having in place clear policies which demonstrate authenticity of commitment
  - Whistleblower
  - Internal investigations
Lesson #1: Be Prepared for Government Inquiry

- Reducing the burden of responding to the document request
  - Reduce the size of the haystack
    - Document retention and destruction policies
  - Decrease the number of needles to be searched for
    - Be in a position to provide quickly those items the government will want at the outset
    - Be able to provide government with specifics about the impact of a full-scale response
  - The virtues of an incremental approach
Lesson #2: Tone at the Top is Important

• Repeat the compliance “sound bite” frequently
• Show support for the Compliance Officer
• Emphasize obligation to report concerns
• Emphasize non-retaliation policy
• Report activity to the Board (KPI)
Lesson #3: Conduct Timely Investigations

- Timely/objective investigations
  - Get started!
  - Ensure senior management is subject to same investigation rules
  - Seek outside assistance if objectivity might be questioned
Lesson #4: Develop Effective Action Plans

- Specific/achievable action plans
  - Assign responsibility and timelines
  - Include discipline as appropriate and tie to performance review

- Report open and completed items to the Board
Lesson #5: Know Your Data!

• Enforcement agencies expect that you know your own data

• They know your data:
  – Software capable of analyzing large volume of electronic billing information, remotely
  – Data is shared between agencies
  – Agencies are getting experienced at evaluation
  – They had a head start in looking at your data
Lesson #6: Be Supportive Yet Wary of Evolving Payment Systems

- Payment systems continue to evolve
  - CMS Innovation Center seems interested in trying almost anything and seeing what sticks but there are regulatory issues that remain to be addressed

- Don’t let the tail wag the dog
  - Don’t be lured into risky or unwise arrangements
  - Consider hard questions on how does this improve quality (or maintain quality at a lower cost)?
  - If quality isn’t improved, what’s the point?
Lesson #7: Prepare for Increased Focus on Individual Liability

We have “the authority to exclude every officer and managing employee of a sanctioned entity.”

We intend to “alter the cost-benefit calculus of the corporate executives who run these companies by excluding the individuals who are responsible for the fraud, either directly or because of their positions of responsibility in the company”

—OIG
Lesson #7: Prepare for Increased Focus on Individual Liability
Lesson #7: Prepare for Increased Focus on Individual Liability

- Responsible Corporate Officer Doctrine/The Park Doctrine: *United States v. Park* (1975)
  - Criminal Liability under Food, Drug & Cosmetic Act
    - “Responsible Corporate Officer”
    - Power to prevent improper conduct
    - Failure to prevent
    - Neither knowledge or negligence needed
    - Assumption that misconduct cannot occur without individual involvement
Lesson #8: Educate Board on Increased Responsibility

- Case law
- Federal sentencing guidelines
- Settlements/Corporate Integrity Agreements
- Healthcare reform (“ACA”)
  - Mandatory compliance programs including board requirements
- OIG resources
- IRS guidelines
Lesson #8: Educate Board on Increased Responsibility

OIG’s “Toolkit for Health Care Boards” (February 2012)

- Establish a board quality committee and make quality of care a standing board agenda item
- Ensure that board has access to sufficient clinical expertise
- Understand how management assesses the credentials of the medical staff and stays current on best practices
- Use dashboards and benchmarks to measure and track outcomes and utilization
- Track how organization compares to its peers on quality indicators
Lesson #8: Educate Board on Increased Responsibility

- Certification that the Board has made reasonable inquiry into the operations of the compliance program and that the compliance program is effective (CIAs)

- Board to remain informed about:
  - Outcomes
  - Notices of non-compliance
  - Results of internal and external audits
  - Open/closed corrective action plans
  - Corrective action appropriately and timely implemented and tested for effectiveness (CMS Mandatory Compliance Programs)
Lesson #9: Provide Tools to Assist Board Members in Meeting Obligations

- Develop key performance indicators
- Summary of investigation action plans/progress
- Compliance training for boards
- Develop a compliance library
  - OIG Toolkit for Health Care Boards
  - Entity Compliance Program
  - AHLA / OIG Joint Compliance Publications
  - Articles
  - Relevant CIAs/DPAs
Lesson #9: Provide Tools to Assist Board Members in Meeting Obligations

- Develop Board Dashboards that Address each of the OIG’s Seven Elements of an Effective Compliance Program
- Implement written policies, procedures and standard of conduct
- Designate a compliance officer and compliance committee
- Conduct effective training and education
- Develop effective lines of communication
- Enforce standards through well-publicized disciplinary guidelines
- Conduct internal monitoring and auditing
- Respond promptly to detected offenses and developing corrective action
Lesson #10: Be Willing to Consider Litigation-Settlement vs. Defense Cost

Litigation Expense: Settlement vs. Defense Cost

Settlement Cost = 2x damages + penalties + counsel fees

Defence Cost
Lesson #10: Be Willing to Consider Litigation - Settlement vs. Defense Cost

**Keys to Successful FCA Defense**

- FCA trial experience – The experience and judgment necessary to analyze an FCA case through an **evidentiary** lens.

- Reputation for ability and willingness to test claims through fact and expert discovery, summary judgment and trial