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# Navigating Enforcement Actions, Investigations and Settlements

HCCA Compliance Institute

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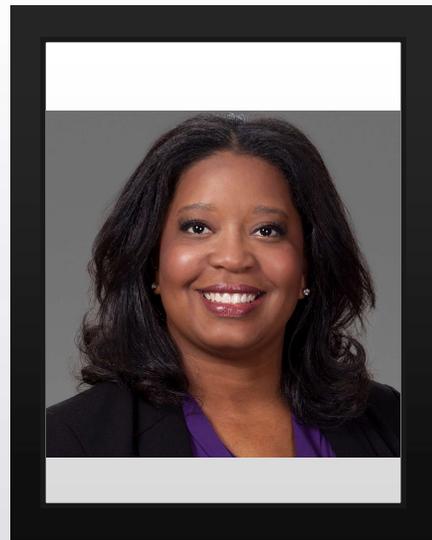
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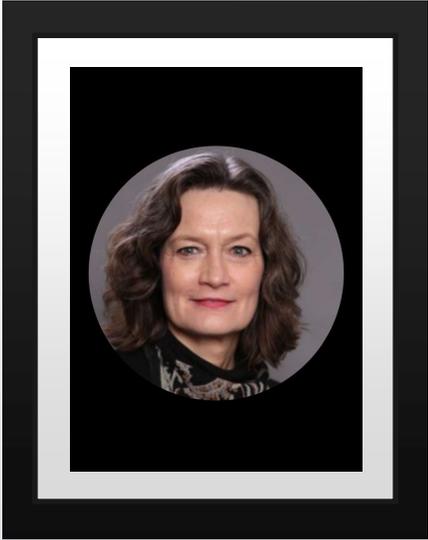


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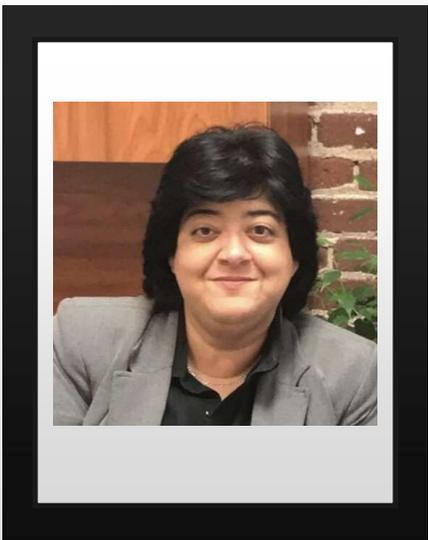


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## Objectives

- Case Studies: How adverse events and other triggers can lead organizations down the path toward enforcement actions, investigations and settlements.
- Compliance Role: How the compliance team can facilitate the best results possible (for everyone) in all three actions.
- Tools and Methods: We will share tales from the front lines, as well as processes, tools and other considerations learned from both the worst and best scenarios.

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## Case Study #1 – A Tale of Two Hospitals

- Evolution from a rural hospital in the early 20<sup>th</sup> Century to a regional medical facility tackling economic issues in the early 21<sup>st</sup> Century.
- Growing Pains and Distractions
- When Bad Things Happen to Good People
- One Thing Leads to Another
- “Big Brother” in the House
- Happily Ever After (maybe)

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## Cha cha cha changes!

- Community grew to 100,000 + people
- Busting at the (building) Seams
- Larger Hospitals and Health Systems were “gobbling up” stand alone hospitals
- Nurse shortages and union disagreements
- Long time “family docs” were beginning to “age out”
- New docs had bigger resumes, bigger needs, bigger student loans, etc
- No more handshake arrangements



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## The Devil's in the Details

- Building Issues
- Focus on Finance – Not Quality
- Nursing Shortages and Union Disputes
- Contract Upheaval
- Airing Dirty Laundry
- Board Crisis
- Leadership Crisis
- Heavy Handed Finance (Part II)
- Bad Stuff
- Regulatory Investigations
- Criminal Investigations
- Loss of Deemed Status (Conditional)
- Enforcement Action
- Handcuffs
- More shakeups
- Statement of Deficiency



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## “Twin City Hospital”

- This organization had a VERY similar history as CTC (in fact, they were just down the highway and competitors).
- Rather than wanting to remain a stand alone, their Board was positioning for affiliation (also stressing finance over quality).
- This time, the CEO and a VP actually were walked out in handcuffs (and the Board thought they were next).
- Everything all over again, only this time:
  - There was a formal SIA rather than a Statement of Deficiency.
  - Both CTC and Twin City had CMS deemed status at risk, but this one included a loooooooooong list of 195 items to fix.
  - BUT, that list positioned them better for long term success.



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## Case Study #2 – Big Little Hospital

- Small hospital in a big city.
- Significant growth in a short period of time.
- Early Beginnings – neighborhood hospital, family like atmosphere.
- Growth – economic and physical growth occurred rapidly and led to serving patients across the country, not just across a neighborhood.
- Rapid Development of Technology and Services
- Character of Compliance (What did it look like to them? What did they need?)

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## Options for Organizations

### WRECKING BALL



Level it and start over.



Find a really great disguise and sneak out of town.



Pay off....well...  
everybody.



Make sure you have a solid CO and compliance team who can motivate and support the organization.

**HINT: Only one of these is a good option.**

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## Actually, it's not quite that simple.....

- Risk Assessments
  - START with whatever is most obviously on fire. (In CTC's case...CONTRACTS...no, wait, QUALITY.....no, wait, LEADERSHIP....no wait.....oh, you get the picture)
  - See where it leads you. Ultimately anything and everything can (and, likely, will) impact quality.
- OR – if the Government has already pulled the alarm
  - Be part of the leadership team to work with them (and/or their intermediaries)
  - Know when Compliance should take the lead (facilitate, doing the work, doing the check)
  - SET THE TONE! (Then set it again. And again.)
- Do the fixes – but work SUSTAINABILITY INTO THE MIX FROM THE GET GO!
  - Policies
  - Training
  - Monitoring/Auditing

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## If you have the chance.....

- If you are lucky (or unlucky) enough to show up before (or just before) everything breaks loose, here are a couple of ways to be prepared:
  - Conduct a comprehensive risk assessment using a tried and true tool (or bring someone in to do it if you do not have the time but do have the resources).
  - Make sure to include a review of Quality in that assessment (there are really 8 pillars). Know WHICH standards apply (Conditions of Participation, HRSA, etc.)
  - Don't reinvent the wheel. Use the resources the government uses (or that they WANT you to use).
  - Don't do it ALONE. If you haven't done so before, learn to make the Quality team your closest friends. They need to learn your lingo – AND YOU NEED TO LEARN THEIRS!
  - Oh...and...same thing with Clinical Operations.
  - Start rounding. Start earning some "cred." Start evaluating and leading the culture.

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## Still have some lead time? COOL!

- **Policies:** Figure out what management system they have and how it works (IF it works).
- **Contracts:** How are they managing these? ARE they being managed? Are they compliant? Do they have quality provisions? Is anyone doing anything with those provisions? Who audits them? How often and how?
- **Incidents:** How are these reported? Do people feel safe reporting? What do they do with them (the reports – not the people; well....maybe the people, too)? What do they look like (any trends)? Is Administration and the Board in the loop? If so, how do they REACT to them?
- **Investigations:** (Really a part of incidents.....but a whole lotta work.)

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## Find Something? Okay, now what?

- Preliminary assessment (how big, or little, is this – potentially?)
- Resource check
- Culture check
- Pulse check (do you have what it takes?)
- Consequences
  - Reporting to Enforcement Agencies, Regulatory Bodies
  - Managing the Message (internally and externally)
  - Determining the resolution (Risk Ratings, Corrective Action Plans, etc)
  - Anticipating
    - Enforcement
    - Settlement

**Psst – You might not get to do this! The government might beat you to it!**

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## Enforcement Actions and Agencies

- State and Regional Licensing Offices
- Office of the Inspector General
- Office of Civil Rights
- Department of Justice
- Drug Enforcement Agency
- Attorney General
- Federal Bureau of Investigation
- ETC.

*Some could take your license or deemed status away.*

*Others can take your money away.*

*Still others can take your freedom away.*

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## The Role of Compliance

- Culture and Team Building
- Policy Management
- Contract Management
- Incident Management
- Other Regulatory Focus
  - 340B
  - Quality
  - Governance



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## Culture and Team Building

- Set the tone at the top
- Know your organization
- Know your people
- Develop/Update Your Code of Conduct
- Identify Key Stakeholders for Risk Areas
- Develop Consensus (but offer your experience and skills to facilitate)

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# Policy Management

- Consensus (C-Suite, the Board, Operations)
- Settle on a Policy Management System and a Driver (or Drivers)
- Create an Interdisciplinary Work Group/Decision Making Body
  - Review
  - Revise
  - Verify/Critique
  - Approve (vet before it goes to oversight committees)

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# Policy Management

- Develop Standards (Policy on Policies)
  - Standard Templates
  - Approval Chain Processes
  - Identify Necessary Education Elements
  - Identify Related Forms
  - Up-to-Date References
  - Review periods (know relevant requirements)

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# Policy Management

- Accountability
  - Document Owners
  - Approvers (Department, C-Suite, the Board)
- Utilization and Monitoring
  - Training of Staff
  - Risk Designations (protect against "slippage")
  - Monitoring/Auditing

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# Contract Management

- Baselines
- Herding Cats
- Management Systems
- Auditing/Monitoring
- Responding to Findings
- The Tricky Stuff



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## Incident Management

- Historical Trending
- Management Systems
- Processes
- Training
- Responding
- Reporting

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## Regulatory Focus and Governance

- 340B
- Quality
- Governance
- Developments Over Last Five Years (Highlights)

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## Tool Box

- Compliance Program Effectiveness Dashboard
- Risk Assessments and Compliance Work Plan Development
- Root Cause Analysis/Corrective Action Plans
- Management Systems
  - What to look for
  - Who to involve
  - How to implement
  - How to sustain!



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# Questions?

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