



Navigating Enforcement Actions, Investigations and Settlements

Healthcare Enforcement Compliance Conference

November 3, 2019

Washington, D.C.

1

1



Christina M. Villa

Adventist Health (Marysville, California)

Compliance and Audit Coordinator



2

2



Anne S. Daly

Children's Hospital of Chicago Medical Center
(Chicago, Illinois)

Chief Compliance and Integrity Officer



3

3



Ana-Cristina "Cris" Navarro

Shasta Community Health Center (Redding,
California)

Chief Compliance Officer



4

4



Objectives

- Case Study: 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.

5

5



Case Study #1 – “College Town Community Hospital” (CTC)

- Evolution from a rural hospital in the early 20th Century to a regional medical facility tackling economic issues in the early 21st 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)

6

6

CTC History

- Beginnings
- Leadership
- How “Business” was transacted



7

7

Cha cha cha changes!

- Community grew to 100,000 + people
- Busting at the 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



8

8

Trigger Events



- New Economic Focus
- New Administrators
- New Board Members
- Contracting Challenges
- Compliance Culture
- Quality Issues
- Physician and Community Support
- Adverse Events

9

9

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



10

10

Case Study #2 – “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 looooooong list of 195 items to fix.
 - BUT, that list positioned them better for long term success.

11

11

Options for Organizations

WRECKING BALL



Level it and start over.



Find a really great disguise and sneak out of town.



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



Hire a tough, sexy (or at least charming), dynamic Compliance Officer (who does not require sleep)

....and then do pretty much whatever the CO and the government tells you to do.

12

12

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 wa.....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

13

13

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.

14

14

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.)

15

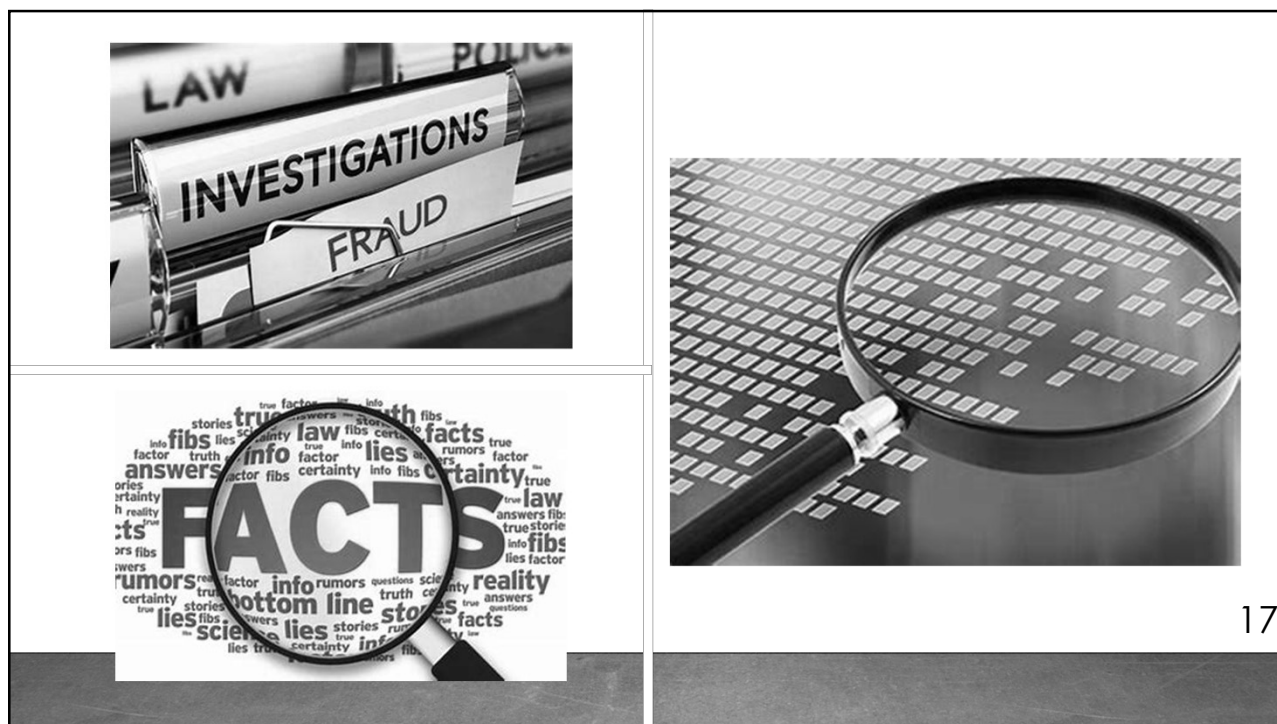
15

Investigations



16

16



17

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!

18

18

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.

19

19

What do THEIR investigations look like?



20

20



Agency Investigations

- They are in charge (and defense is not as "comfortable" as offense).
- Services are disrupted.
- If an Immediate Jeopardy is called, services are STOPPED (until things are fixed)
- Legal stuff starts happening Demands, Subpoenas, Discovery, "Unscheduled Evidence Retrieval."
- But, in some cases, the very WORST thing that can happen is.....
- NOTHING (What?!)

21

21



Settlements

- System Improvement Agreements
- Corporate Integrity Agreements
- Civil Penalties
- Criminal Penalties



22

22

Systems Improvement Agreements (SIA)

- An SIA is a time-limited contractual arrangement between a Medicare-accredited healthcare organization and CMS.
- SIAs and CIAs have many common elements, but each one addresses the specific facts at issue and often attempts to accommodate and recognize many of the elements of preexisting voluntary compliance programs. A comprehensive CIA typically lasts 5 years and includes certain elements; whereas, SIAs are designed to be completed in 18 months or less, typically.

23

23

SIA Elements

The SIA reads much like a legal document and stipulates the terms under which your organization agrees to:

- ☐ Obtain independent consultative review (your expense)
- ☐ Submit the names of proposed consultants or consulting firms (and their experience)
- ☐ Acquire expertise in the development and implementation of an effective quality assessment and performance improvement program. (Example: CMS → ECRI)
- ☐ Engage the services of an independent, full-time, on-site compliance officer for the duration of the agreement
- ☐ Other terms specified by CMS, including re-survey by CMS or their designee.



24

24

Corporate Integrity Agreements (CIAs)

- “The OIG negotiates corporate integrity agreements (CIA) with health care providers and other entities as part of the settlement of Federal health care program investigations arising under a variety of civil false claims statutes. Providers or entities agree to the obligations, and in exchange, OIG agrees not to seek their exclusion from participation in Medicare, Medicaid, or other Federal health care programs.”

-- United States Health and Human Services, Office of the Inspector General

25

25

CIA Elements

- hire a compliance officer/appoint a compliance committee;
- develop written standards and policies;
- implement a comprehensive employee training program;
- retain an independent review organization to conduct annual reviews;
- establish a confidential disclosure program;
- restrict employment of ineligible persons;
- report overpayments, reportable events, and ongoing investigations/legal proceedings; and
- provide an implementation report and annual reports to OIG on the status of the entity's compliance activities.

-- United States Health and Human Services, Office of the Inspector General

26

26

CIA Consequences

- "CIAs include breach and default provisions that allow OIG to impose certain monetary penalties (referred to as Stipulated Penalties) for the failure to comply with certain obligations set forth in the CIA. In addition, a material breach of the CIA constitutes an independent basis for the provider's exclusion from participation in the Federal health care programs."

-- United States Health and Human Services, Office of the Inspector General

27

27

Civil Money Penalties & More

- The Office of Inspector General (OIG) has the authority to seek civil money penalties (CMPs), assessments, and exclusion against an individual or entity based on a wide variety of prohibited conduct. (See Civil Money Penalties Rule and periodic adjustments to rates.)
- In addition to CMPs, the OIG has the authority to issue:
 - Provider Self-Disclosure Settlements
 - Reportable Event Settlements
 - Grantee Self-Disclosure Settlements

28

28



Criminal Penalties

- The criminal penalties for knowingly submitting false Medicare claims, giving kickbacks or accepting kickbacks can be significant. If a person is convicted of making fraudulent claims as described in the False Claims Act, he or she may face up to five years in prison and criminal fines as high as \$250,000. People who are convicted of violating the Anti-Kickback Statute may face criminal fines of up to \$25,000 and a five-year period of incarceration. HOWEVER, the United States
- Sentencing Guidelines (USSG) take into consideration the value of fraud cases and other factors, such as the number of incidents. As a result, a number of recent cases have involved more egregious sentence terms and restitution/criminal fines. (There are some creative criminal cases utilizing RICO statutes.)

29

29



The Role of Compliance

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



30

30



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)

31

31



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)

32

32

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)

33

33

Policy Management

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

34

34



Contract Management

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

35

35



Incident Management

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

36

36

Regulatory Focus and Governance

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

37

37

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!



38

38



Questions?

39