**Case Study 2: Navigating Enforcement Action, Investigations, and Settlements**

**“Big Little Hospital”**

In a major city, a small hospital grew into a major academic research hospital in a very short time period. The hospital’s location, size, and focus changed in what many would consider “overnight”. As expected with rapid growth and change, there are some areas that do not develop at the necessary pace, for example, when reliance on old habits is more comfortable than adapting to the new demands and requirements of the “new” business.

“The Hospital” was founded in a home in the late 1800s to serve the public need for medical care. For years, The Hospital was located in a residential neighborhood and met the needs of the local community. While providing excellent care, the hospital developed a family like atmosphere for patients, their families, and the staff. More than one hundred years after opening, “The Hospital” relocated into a state-of-the-art facility located in the center of the city’s downtown. That move transformed the hospital into a three hundred plus bed facility into a specialty facility that became known for caring for complex patients and academic research. The once local hospital was now serving patients throughout the United States as well as patients from more than fifty countries.

The Hospital had acquired many of the necessary elements to run a major hospital of this nature. Staff, technology, and resources were enhanced to meet the new demands. There was necessary focus on enhancing clinical practices, procedures, and resources to ensure excellent quality of care. Development of non-clinical areas was not as rapid, and there was a reliance on established practices and procedures that no longer met the needs of the “new” environment.

One of the areas that required development to meet the new demands was the compliance program. The compliance program existed, but did not function in the manner that it should considering how complex the organization had become. Some common themes were:

* We come to compliance when we need to or have a question

How would people KNOW that there was a compliance question or issue?

Is the compliance program/team big enough and skilled enough to infiltrate the organization, regularly spot issues, and consistently train staff to have a compliance awareness?

* We have always done it this way and it worked

It’s hard to let go of that “small community” culture even when facing the facts of a large organization/facility.

And, isn’t that human nature?

* What does [Neighboring Hospital 1], [Peer Hospital 2] do - without recognition that Neighbor or Peer might be unaware of, or struggling with, the issue, too.
* What’s the likelihood “that” would happen?

Again…human nature. We have almost a voyeuristic attitude – more so now. Look at how people are reacting to the pandemic.

The truth is “that” happens all the time somewhere. There’s a reason why “compliance” is an industry. The government nurtured it to be so because they recognized it was inevitable (ENRON) so we need to find ways to encourage people to prevent it. (Incentivize)

* What are the possible fines? *and* Will they investigate?

More so now then ever – yes…they will investigate. And I think that culture is finally shifting to understand that. Consider how the government (OCR) had to take the steps to assure the industry that they will temporarily alter their enforcement discretion during the pandemic to facilitate rapid deployment of telehealth and telemedicine.

Nonmonetary risks must be considered - Reputation can truly be priceless. And can absolutely be lost in one incident and not regained for years.

* There just isn’t enough time for compliance on the agenda

Unfortunately, it can be hard to convince people otherwise until they “see” it. SIAs, CIAs, even basic investigations are very time consuming. They DEVOUR resources. We have a bit of a “I’ll believe it when I see it attitude across the country.” Again, the response to the pandemic illustrate that yet again.

Some questions to consider are:

1. What are the potential pitfalls of some of the above behaviors?
* People will die. I’m not going to play that down. Unfortunately, I have seen it.
* It will cause more resources to be spent than if we took a more proactive approach. That’s true about everything, isn’t it?
1. What is the role of compliance in addressing necessary cultural and operational adjustments?
* We certainly cannot have an “us versus them” approach.
* Understand your organization and the people and services within it.
* Find ways to be a part of developing ideas, planning and implementing.
* Educate and support. Be a resource, not a nag. Sometimes that can be in the eye of the beholder. Recognize that. We have to adapt to different types of attitudes and behaviors.
* Assess, assess, assess, assess (dashboard)
* Then educate and problem solve. Don’t just tell them it’s broken. Find ways to help them fix it. KEY: You need THEM to be a part of this. They know the nuances better. (We’ll talk about that in a bit.)
* Make it EASIER for them to reach out to you. (Incident Management) AND, respond well so that they will come to you again and again.
1. What role does the Compliance Officer play in responding to and working with enforcement agencies?
* You are not the LAWYER for the organization. It’s not about defending. By the time the agency is there, it’s too late for that. It’s about facilitating. Communicating to them well everything the organization HAS been doing. Even if those safeguards failed, you want to show due diligence in trying to prevent. And if due diligence was lacking, convince them that the organization is taking this seriously. AND THEN DELIVER!
1. What can a Compliance Officer do to help prevent an organization from going down the path of significant enforcement action(s)?
* Start with that Dashboard. No kidding. And the items on that Dashboard can be addressed by looking closely at some key areas, such as Risk Assessment processes, Incident Management, Policies, etc.

Let’s talk about that now in more detail.