



Compliance TODAY

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Thank you
Roy Snell



ARTICLES

- 52 **Compliance program annual review: A game plan**
by **Margaret C. Scavotto**
Tips for essentials to include in a periodic evaluation of your compliance program effectiveness.
- 57 **Enterprise-wide PHI disclosure management: Closing the compliance gaps**
by **Rita Bowen**
An enterprise-wide strategy to protect patient privacy also protects the institution against breaches, financial risk, lawsuits, and reputational damage.
- 62 [CEU] **The diverse faces of telemedicine delivery and reimbursement**
by **John P. Benson**
Because state and federal rules are ambiguous and convoluted, navigating the ever-changing telemedicine landscape can be a recipe for risk, lost revenue, and fines.
- 67 **Getting your power brokers on board with compliance**
by **Cassandra A. Andrews Jackson**
Building momentum for the compliance program begins with enlisting the first C-suite executive as your ambassador for tone at the top.
- 70 [CEU] **Creating a culture of compliance**
by **Edye T. Edens**
You've been put in charge of Compliance, and you've shaken all the hands and kissed all the babies. Now what?
- 76 **Rethinking leadership: Are you "people smart"?**
by **Benjamin Martin**
Being perceived as a good leader or boss takes a lot more than just technical ability or management skills.
- 80 **That 'hot' research project may land your lab in hot water**
by **Michael J. Tuteur and Torrey K. Young**
A nonchalant approach to time-and-effort reporting on government grants can quickly lead to False Claims Act enforcement and reputational loss.

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by Edye T. Edens, JD, MA, CIP

Creating a culture of compliance

- » Implementing and/or maintaining a compliance program is a large and difficult task to undertake.
- » If the compliance program isn't implemented with enough employee support, the program could fail.
- » Obstacles will inevitably arise, but most can be resolved.
- » Documentation of your efforts is critical for continued resources, support, and mitigation during audits.
- » Setting realistic goals for yourself and your program can keep you from being too overwhelmed to succeed.

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[in bit.ly/in-TaylorEdens](https://bit.ly/in-TaylorEdens)

In my first decade as an attorney, I've had the unique privilege of being the "first" to hold several compliance-related positions, and even aided in the creation of an office dedicated to clinical research compliance at a major academic medical center. For



Edens

me, these positions were a blessing and, while overwhelming at times, provided the opportunity to mold the roles to fit my strengths and the needs of the organization. Whether you're being handed the keys to your dream job or taking over a position in a crunch, bringing a compliance plan that includes auditing and monitoring for a successful launch is no doubt daunting. I'm taking the opportunity to document my successes and failures below, so you can avoid any shortcomings and find success in your compliance efforts.

The true task at hand

First and foremost, you absolutely must embrace that you are not simply implementing or maintaining a compliance plan or a

program. Rather, you're establishing a culture of compliance throughout the area you oversee. Any failure to fully recognize and plan from this pivotal point is almost certain to result in weak implementation. Thus, you're building, establishing, or maintaining a culture shift, which requires a more global approach and demands an investment by your organization to be successful. Of course, some of this shift falls to your role and other pieces fall to organizational leadership, but that is a discussion for a different article.

Being first or turning a program around

Remember to view your perspective as influential and positive, despite feeling as if you're treading uphill, no matter how much culture shift and compliance wrangling you or your organization are hoping to accomplish. You have the privilege to establish a new and improved manner of conducting compliance that builds on the good, discards the bad, and strives to grow. You're present to impart your experiences and learn from those within, so don't lose sight of every networking opportunity, coffee with a colleague, and truly touring your new role. Whether you've moved in-house or arrived fresh on the grounds, how positively you approach the role from Day One

sets the tone loudly. One of the hardest moves I ever made was from one side of the table to the other within the same organization. Leaving previous bias outside the boardroom door is nearly impossible, and I challenge you to evaluate every step you make against any bias you believe you might possess. Knowing the pieces of any puzzle and how they interlock can make you an asset, but bias can and will cloud your judgment in tough situations when working with previous colleagues.

If you don't have buy-in, nothing will work

As foreshadowed, if you don't have organizational and employee "buy-in" to your shifting culture of compliance, you must work to build it. One hopes, given a role in compliance has been created and you're filling said role, that the organization has in essence made their commitment to a culture of compliance transparent. This, unfortunately, is not always true, but even when it exists, you as the face of this new or improved compliance program must still garner the respect of the existing employees if you hope to lead the charge successfully.

In addition to the positive, unbiased attitude you must put forth, you must learn the infrastructure inside and out, in the most non-threatening fashion possible, to move a culture forward. Although admittedly ominous, this means your first few months absolutely must revolve around attending every stakeholders' functional meeting, small or large, and committing to as many coffee and lunch dates internally as possible. If you don't learn about the actual individuals you're working with and for, the infrastructure simply will not matter. Learning peoples' opinions, fears, ideas, and experiences sets the stage for how you will not only form your auditing and monitoring plan, but also how best to implement it. You may find allies and even volunteers in the most unlikely of circumstances.

Start at the pure and basic structural foundations

I promise to revisit this topic only this one, last time: structural foundations to compliance. If you haven't had the opportunity to review it in a while, you should visit the Office of Inspector General (OIG) website¹ on the pillars of a compliance program. As I teach my students, you should look here, no matter your specific industry, to see how the federal government views compliance programs. The external federal compliance authorities are tossing you a softball here, so please, please knock it out of the park as such.

Hint: Mitigation directed at these exact pillars plays a huge role in resources and decisions in your program, as well as how you'll fare in a federal agency audit.

At this juncture, whether you're interviewing or already waist deep in the position, is also when you will strongly evaluate your organization's infrastructure and willingness to change. This analysis is multi-faceted, and while you might not find your organization as dedicated to change or compliance as you'd dreamed, hope is not lost. You use this information only to determine next steps, expectations, and your personal cost-benefit analysis. Factor what you find into your resource analysis and proposal, as well as the depth of your program and, if interviewing, your proposed compensation. Only you can decide how to best proceed in any given fact-finding mission, but remember, information is knowledge and thus power.

Concrete steps

Okay, so you've kissed all the babies and shaken all the hands, now what? At every one of these meetings, you should be taking copious notes about both subject matter and institutional knowledge, even personal impressions or points of focus. The more you immediately understand your "constituents,"

the sooner you can form a successful, working program. If appropriate, be forthcoming and ask the room what they want to see come from your program and changes or improvements they feel strongly about, but whatever you do, do not scare anyone about their job security or proceed in an off-putting manner. You are here to observe everyone in their native environment and find where your role and program fit best.

Assessing what's happening and forming a plan

Now that you possess the correct frame of mind for success, the time has come to begin moving thoughts to actions. Your notes are your personal catalog of issues that must be addressed, above and beyond the basic and industry-appropriate framework of a compliance plan. This most elementary-level, skeleton plan already exists in your unique sector, I assure you, so do not overcomplicate this step. Borrow from previous experiences, finally put that MBA to work, or even perform armchair research to gather a slim outline that you can use to input your organization-focused data.

This step is a personal explication, your whiteboard, an Excel spreadsheet—however you best input and analyze data for a comprehensive output. It is, in fact, your algorithm to your program. You will want to include:

- ▶ Corrective and Prevention Actions (CAPAs) on a broad level for current deficiencies;
- ▶ Ongoing education for staff;
- ▶ Regularly scheduled evaluation of all quality measures broken into a rotating

format so all the areas your plan covers are audited and monitored as frequently as is reasonable, given size and anticipated resources;

- ▶ Opportunities to present findings both specifically to small groups or in aggregate to mold continued change;
- ▶ Workflow enhancement measures for staff as it relates to efficiency; and
- ▶ Performance improvement for staff as it relates to personnel issues.

How you obtain the information you want to synthesize may vary throughout the many areas you're responsible for. Using already existing staff meetings to literally map out

certain workflows works just as well as Lean Six Sigma² principles, but again, remember to ensure your approach stimulates positive change and makes employees feel included. If your method instead stifles communication or pushes staff beyond their absorbable limits, you will do more damage than good.

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Implementation

As with many compliance efforts, implementation is likely the key component in bringing the plan to fruition.

Your staff on board as editors

Ever so quietly, you need to select your direct reports who will act as a vetting group for different areas or your entire proposed plan. Perhaps you have a small-but-mighty crew of mid-level managers, and it makes sense to have them all be present for proposed ideas and changes, or maybe you do it by department. Either way, you need to walk through your formula for change with those who will

be assisting you with implementation via their role at the organization. We aren't talking "present it with perfection" or even all in one sitting, because change happens when and where it is needed most in a moment's notice. However, the ideas should be more than cloud bubbles above a cartoon-inflated head. Be transparent about your rationale, and be open to criticism and questions. Ensure your staff knows this is a respectfully critical brainstorming session whereby you're working as a group to hone the proposed concept.

Rolling out the plan

Following the session above, you must codify the plan. This step is always delicate, because you don't want to spend so much time creating the program on the page, when you're fully aware more edits are potentially to come from upper management as well as staff. Of course, the timing of all the implementation steps somewhat relies on your specific organizational model, but without at least having the outline and supporting data for your plan at a high level, you certainly can't bring it to your superiors for approval. Your organization may work smoothly, and you can vet to larger and larger groups of management before then beginning to seek feedback from the staff at large. Other organizations prefer grander presentations of such issues at board meetings and the like. Only you know your organization, but this step and the next do, in fact, rely heavily on knowing the organization, so ensure you've thoroughly completed that step above for maximum success.

Asking for resources

In this step, you're using traditional bargaining techniques no different from a salesperson on a car lot. You absolutely will not receive all the resources you want, but you can certainly aim high so the end result is at least what you need. No rocket science

needed here—you will determine the size of the desired "ask," prioritize what you can and can't lack in resources moving forward, attach a price to each step, and then proceed to how best to present, given your audience. No one method exists to lay out the "ask" in any given industry or organization, and I implore you to know your audience, because you should already know them, given the aforementioned steps. The time has come to consult your notes and decide whether you should offer multiple options transparently (i.e., the amount of resources correlated to the amount of progress you can provide). Perhaps everyone in the room prefers beautiful pie charts and PowerPoint slides, or only has the time to review a one-page executive summary, but prefers a full report of justification to be attached. Again, know your audience. Don't be afraid to seek out a trusted colleague who knows the room or will be present to test your final work product before the meeting—just ensure you leave time for edits, because inevitably, you will have more work to complete post-review. These helpful tips are also readily usable for the section above on how to best lay out your plan to executive management, and often these two meetings are held concurrently.

More buy-in from the group at large

Before you place anything in poured cement, I would strongly advise that you bring bargaining chips to your metaphorical all-staff table, no matter the organizational model in existence. Whatever the appropriate venue, if you haven't been updating staff at large as to wholesale decisions and changes, you should start immediately. Further, hold forums where interested staff can weigh in, and you can bounce ideas off them in the most appropriate process available. The more you push the positive and open opportunity to be a focal and vocal part of change, the more employees will

likely respond. You may not always love what you hear, or even be able to effect the changes employees request of you. But, if you're honest with what you can and can't do, as well as appreciative, you'll find staff likely respects your honesty more than grandiose promises.

Completing the task

Don't forget to benchmark as you put the plan and improvements into motion. Nothing extinguishes the fires of evolution faster than progress you can't prove, particularly when your organization is filled with clinicians and scientists who operate in data. Further, documentation is key during these efforts, both internally and externally. Auditing and monitoring notes should be kept, and the final compliance plan should be codified and broken into standard operating procedures for staff use and agency review. At the end of the day, your compliance efforts are only as great as what you've documented. This step is often overlooked in the interest of time, and it always recoils into a negative issue for those managing compliance.

Remember

The more you're willing to take ownership of successes as well as failures, the quicker all your perceived roadblocks become speed bumps.

Obstacles across the board

Let me start by saying, I am the inventor of unrealistic expectations—I live and die by

them in my own mind. It has pros and cons, but please, please learn from the consensus at large and be reasonable in your outcome evaluation assessments of your progress. As someone recently pointed out to me, evaluating your efforts by actual effort and not outcome is exceedingly difficult, yet possibly best. Although you should “never say die” nor relent, you are but one person and can only accomplish that which you're fully supported to complete. Give your organization all you can offer within the healthy benefits of yourself, and then stop. Period. I maintain you are absolutely no good to your organization if you don't take good care of yourself. Data supports this stance, despite the fact you may have to place the boundaries for your employer. Find a way and, if your current role doesn't allow for it, that realization has another set of implications ripe for discussion.

Conclusion

I am in no way attempting to oversimplify what is often a formidable task. Rather, I am attempting to remove paralysis by over analysis, as my father used to diagnose with me. If you have an outright checklist of the major categories, including endpoints and benchmarking suggestions, you have a starting point. As a law professor once taught our class, “It's a marathon, not a sprint.” 🍷

1. Office of Inspector General: Compliance Guidance. Available at <https://bit.ly/2kZMqx1>
2. Chuck Mills, Mike Carnell, and Barbara Wheat: *Leaning into Six Sigma: The path to integration of Lean Enterprise and Six Sigma*. Boulder City, Colorado. 2001. ISBN 978.097.1249103.