COMPLIANCE IS THE GOLD STANDARD—WITH OR WITHOUT A FEDERAL MANDATE

by Kelly O'Neill and Karla Dreisbach

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As compliance officers in the aging services field, we understand the significance of an organization operating legally, with integrity, and in line with industry regulations and best practices. But what if an organization isn't mandated federally or at the state level to have a compliance program? How can you persuade your board and executive teams that it remains essential?

Over the past decade, one thing has become clear: healthcare organizations are facing increased scrutiny from payers, patients, partners, and the media. In this environment, proactively implementing and maintaining a comprehensive compliance program—regardless of federal or state mandates—is a strategic advantage that will set your organization apart and establish a solid foundation for long-term success.

At its core, a strong compliance practice acts as an insurance policy, helping to manage risks and showcase your organization's commitment to best practices.

More importantly, the U.S. Department of Justice (DOJ) continues to look at new ways to assess compliance efforts. This includes implementing a code of conduct, applying confidential reporting structures, and developing thorough investigation processes. Implementing a compliance program is a commitment and not just an endeavor to check off the boxes. Compliance standards should be practiced to show that your organization is sincere in creating a culture of compliance.

Although not every healthcare organization is federally mandated to implement the seven elements of an effective compliance program, every organization has risks for potential exposure to state and federal agencies and regulatory bodies such as the U.S. Department of Labor.

Why now is the time to refresh your compliance program

The healthcare sector is constantly evolving, making it necessary to adjust to the changes. In November 2023, the U.S. Department of Health and Human Services Office of the Inspector General (OIG) released its *General Compliance Program Guidance* (*GCPG*), reflecting best practices for healthcare providers.[1] The *GCPG* is a broad document for "all healthcare providers and entities," with new industry-specific guidances expected this year.

Even if your organization has a robust compliance program in

place, now is a good time to make sure you're up to speed with best practices.

New areas of focus for leadership teams and boards

In the *GCPG*, OIG identified new areas of focus that warrant immediate attention and implementation by executive leadership teams and boards of directors.

One key change is the heightened focus on holistic oversight and governance, emphasizing board education, engagement, and involvement. With compliance officers often reporting directly to the board, board members must be able to understand risks, have knowledge of the regulatory environment, and have a grasp on compliance practices to accurately provide insights and guidance—more so than in years past.

There's also a growing emphasis on comprehensive compliance training throughout the organization, including board members, and an expectation that certain positions will receive additional specialized instruction. Are your training programs digestible, understandable, and relevant to everyone's job? For instance, certain roles, like marketing and admission, may require more specialized education on topics such as anti-kickback policies and gifting.

Another enhanced focus area is on the importance of conducting thorough risk assessments. These assessments should be designed to refine an organization's focus on critical areas by incorporating insights from past experiences and identifying current and future concerns. These should then be incorporated into their compliance conversations and annual work plans.

Increased consumer focus on a company's values

Younger team members and patients have different perspectives and expectations when it comes to an organization's stance on social issues; therefore, it is imperative that your compliance program reflects your organizational values.

Is your company's code of ethics easily accessible to potential patients, vendors, team members, and other stakeholders? Do you practice transparency in other areas of your communication? With the increasing overlap of business with politics and social issues, the line continues to blur between what was traditionally considered appropriate and what is needed or desired today. Without proper policies in place, you may be opening your organization up to risk.[2]

Implementing a strong compliance program

In the long run, fostering a culture of ethical behavior and investing in the resources needed to have an effective compliance team and program will always pay off. When the DOJ is looking at concerns within a business organization, they are looking at all organizations—not just those federally funded healthcare organizations. As part of their investigation, they are directed to review the organization's compliance program. Many of the elements that DOJ would be reviewing highlight the significance of a compliance program in all organizations.[3] The following compliance elements apply to any organization—not just those that are government-funded.

- **Risk assessment**—This is a tool used to evaluate the organization's risks. It can include reviewing changes and updates that may have occurred within the organization within the past year. The risk assessment is then used to create a work plan to direct the organization's work for the upcoming year.
- **Policies and procedures and code of conduct (integrity)**—This documentation should be in place to guide the program and help all stakeholders understand the organization's goals.
- **Training and communications**—Educating staff and all involved with the organization on the program helps build a "culture of compliance" throughout. This education goes beyond just following government requirements and extends into the principle of doing the right thing.

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- **Confidential reporting structure and investigation process**—There should be a hotline for staff to report when they might have concerns, whether they want to report without fear of retaliation or are

just concerned about reporting items without management knowing who reported them. The reported concerns need to be tracked and investigated.

- **Third-party management**—Your organization should have a process for reviewing all contracts and business relationships, including sanction screening of individuals and companies. This process ensures there are no individuals the organization does not want to do business with (if the government doesn't want its money going to those individuals, then neither does the organization).
- **Commitment by management**—Compliance officers with access to the board or owners allow for these parties to have oversight of the program and the operations. Operational information that the compliance committee is overseeing should be shared so that the board or owners are able to track progress and commit to the forward growth of the organization through compliance dashboards.
- **Consequences management and investigation of misconduct**—Your organization should have a formal outline of disciplinary actions for those who do not follow the rules so that if things go wrong, there is a set of policies for how things will be handled.
- **Continuous improvement, testing, and review**—It's crucial to have audits and monitoring to ensure systems are in place. This makes certain that the needs of residents or patients are being met and helps identify risks before they become larger issues. When opportunities are identified, compliance allows a system for items to be tracked for follow-up.[4]

Fundamental questions familiar to compliance officers

To assess the effectiveness of the compliance program, DOJ has provided fundamental questions that should be familiar to every compliance officer. When talking about compliance, these questions should be regularly reviewed with your board of directors and leadership team.

1. Is the corporation's compliance program well-designed?
2. Is the program being applied earnestly and in good faith? In other words, is the program adequately resourced and empowered to function effectively?
3. Does the corporation's compliance program work in practice?[5]

Creating a culture of collaboration

As a healthcare compliance officer, one of your biggest challenges is often a lack of buy-in from leadership. Many have experienced the conundrum of an organization that isn't fully committed to taking the steps needed to mitigate risk.

Without the belief that this is a necessary business function or the perception that it's simply another "to-do" on an exhaustive list of expectations, it's difficult to wield the influence necessary to implement an effective compliance program. Fostering a collaborative culture between leadership and compliance officers is vital to making progress.

As a compliance officer, you might find that staff view you as more of a police figure rather than a partner. Your role is often misunderstood as obstructing progress, adding unnecessary bureaucracy, or being overly dogmatic.

To overcome this, aligning with leadership and securing their support is critical. When leadership buys into the compliance program, it fosters a culture that not only accepts but values the role of compliance officers. This support helps in creating a compliant organization. It will also be important to work with staff so that they see the value of compliance. For example, when a staff member brings concerns forward, they should get a response to how they were handled.

Demonstrating that compliance supports organizational goals, aligns with best practices valued by investigators, mitigates negative publicity, and is increasingly significant to patients and stakeholders can help you secure the necessary resources.

Building a strong compliance program before it's needed

The goal of a compliance program is to be proactive and bring concerns forward before they become a larger issue. When audits and internal monitoring systems are implemented, an organization can become aware of an issue prior to the licensing agencies bringing it to their attention with deficiencies, fines, and penalties.

For non-Medicare organizations, these can be issues that can have a huge effect on resident comfort and safety. This could be something as simple as having monitoring systems in place to ensure water temperatures don't exceed the maximum temperatures prescribed by the state regulations or having audits of medications residents are self-administering to ensure that residents remain cognitively able

to continue to self-administer their medications without supervision.

Although these duties may seem a natural course of business, monitoring these tasks will ensure they continue as changes occur within the organization. This oversight can be a small but noteworthy assignment of the compliance program in organizations that want to do the right thing but are not necessarily mandated to have the program in place.

Adaptations for smaller healthcare organizations' compliance officers

As a healthcare compliance officer in a smaller organization, such as a non-Medicare certified nursing home or assisted living facility, OIG provides several adaptations that can guide you in building a strong compliance program regardless of human or financial resources. Here are some key recommendations:

- **Designate a compliance contact** within your organization. Organizations should look to who can best provide leadership to the compliance effort and have the needed authority to function in that role.
- **Utilize existing resources** from management firms or online sources for policies, procedures, and training.
- **Implement user-friendly methods** for team members to report potential issues or concerns and ensure appropriate investigation and resolution processes are in place.
- **Assess compliance risks annually** using available online tools. The compliance committee, leadership, and the board should engage in conversation to determine potential risks, which can then be incorporated into compliance auditing and monitoring activities.
- **Establish a flexible mechanism** for enforcing disciplinary actions that allow staff to bring issues forward in a nonretaliatory environment.

When stepping into a role in a small organization, the compliance officer should carefully review these recommended steps and resources and assess how their organization can best implement a program.[6]

Seeking the gold standard of compliance

A robust compliance program will help detect potential issues before they reach a level of being reportable to state or federal agencies and subject to potential public scrutiny. However, if they do reach the level of investigation, being prepared can help reduce legal and reputational risks.

The number one reason organizations that are not mandated by regulation should implement a strong compliance program is to build a culture of integrity and accountability that supports and enhances their values. CT

Endnotes

1. U.S. Department of Health and Human Services, Office of Inspector General, *General Compliance Program Guidance,* November 2023, https://oig.hhs.gov/documents/compliance-guidance/1135/HHS-OIG-GCPG-2023.pdf.
2. Alison Taylor, "Corporate Advocacy in a Time of Social Outrage," *Harvard Business Review*, February 6, 2024, https://hbr.org/2024/02/corporate-advocacy-in-a-time-of-social-outrage.
3. U.S. Department of Justice, Criminal Division, *Evaluation of Corporate Compliance Programs*, updated September 2024, https://www.justice.gov/criminal/criminal-fraud/page/file/937501/dl?inline.
4. U.S. Department of Health and Human Services, Office of Inspector General, *General Compliance Program Guidance*.
5. U.S. Department of Justice, Criminal Division, *Evaluation of Corporate Compliance Programs*.
6. U.S. Department of Health and Human Services, Office of Inspector General, *General Compliance Program Guidance*.

Takeaways

- Compliance programs offer a strategic advantage. Regardless of federal or state mandates, proactively implementing a comprehensive compliance program can set an organization apart, manage risks, and establish a foundation for long-term success.
- Compliance standards evolve with the industry. The healthcare sector continuously changes, necessitating regular compliance program updates. Recent guidance by the U.S. Department of Health and Services Office of Inspector General highlights new areas of focus, including enhanced board involvement.
- Lack of compliance can lead to reputational and legal risks. Compliance failures can result in significant legal and reputation damage.
- Compliance programs need collaboration. It's critical to foster a culture where leadership and staff see the value of compliance programs, ensuring progress and buy-in from all levels.
- The primary goal of a compliance program remains the same. Above all else, the primary goal of a strong compliance program is to foster a culture of integrity within an organization.