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Compliance Program Effectiveness

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Introduction



Compliance effectiveness, a buzzword in the industry, continues to be a focal point of compliance programs and governmental investigators. In September 2024, the United States Department of Justice (DOJ) Criminal Division again updated its guidance document, Evaluation of Corporate Compliance Programs. [1] This 4th update focuses on several critical areas including M&A due diligence as an ongoing process which requires compliance oversight before, during and after the transaction. Additionally, the update addresses the risks associated with emerging technologies and stresses the importance of continuously managing these risks, especially the rise of artificial intelligence, in order to mitigate potential compliance challenges posed by technological advances. The update also underscores the importance of learning from prior compliance issues within the industry and developing best practices to avoid the commitment of similar issues. The document also refers to anti-retaliation policies and the importance of providing protection for whistleblowers. This, coupled with the DOJ's recent launch of a pilot Corporate Whistleblower program signals the DOJ's support for individuals reporting misconduct without fear of reprisal. [2] Additionally, the update highlights the importance of maintaining a robust ongoing third-party risk management program to identify and address risks to ensure that compliance measures can be put in place.

Regrettably, despite such robust guidance, there continues to be significant compliance concerns across the healthcare industry, as evidenced by ongoing DOJ settlements, new corporate integrity agreements, and other findings and activity. Additionally, as consultants, too often, we see "paper programs" in place.

Although many organizations and providers adopt compliance policies and procedures, they neglect to operationalize them fully in their day-to-day operations. This inaction presents a significant problem and risk to these organizations/practices. So, what does it mean to be effective? It means it works. Just as it is evident that a weight loss pill works when the individual taking it loses weight, a compliance program is effective when the program is woven into the fabric of an organization's culture and operations resulting in the prevention, detection, and resolution of potential compliance concerns.

Federal Sentencing Guidelines, Chapter 8[3]

Initially published in 1991, the Federal Sentencing Guidelines Chapter 8 provides the fundamental framework for advising healthcare organizations/ practices on how to ensure an effective compliance program. Although the organizational guidelines are for judges to use in sentencing organizations for criminal conduct, every healthcare board member should review this document, as should every corporate executive/physician practice owner. Readers will understand the various components contributing to an effective compliance program and gain an appreciation for the relationship between an effective compliance program and the mitigation of fines and penalties.

An effective compliance program means the program does the following:



Prevents and detects noncompliance through the exercise of due diligence



Promotes an ethical and compliance-oriented culture that is committed to complying with the law



Is designed, implemented, and enforced so that it generally prevents and detects noncompliance [4]

The key to developing such an effective compliance program requires a purposeful intent to (a) create a robust structure for the compliance program, (b) operationalize the compliance program, and (c) follow-through with enforcing the policies and procedures surrounding compliance and creating a culture of compliance from the top down so that the program works.

The Federal Sentencing Guidelines then provide a listing of additional elements, deemed *minimal* standards, that reflect adequate due diligence and promotion of a compliance-oriented culture.

- Establish policies and procedures to prevent and detect noncompliance
- Ensure the following compliance leadership measures are established:
  - Educate the governing body on the contents of the organization's compliance program and their duty to oversee the implementation and effectiveness of the compliance program
  - Assign a high-level individual with responsibility for the compliance program and its effectiveness
  - Ensure the individual with compliance responsibility periodically reports on compliance to the governing body and is provided with proper authority, direct access to the governing body, and appropriate resources to carry out their duties
- Ensure through due diligence that any employee with substantial authority has not engaged in illegal or noncompliant activities
- Conduct effective education and training to employees regarding the compliance program and individual roles and responsibilities
- Ensure the compliance program is followed, including implementing ongoing monitoring and auditing
- *Periodically evaluate the compliance program's effectiveness*
- Establish an anonymous compliance reporting mechanism and implement a *no retaliation* policy
- Promote and consistently enforce the compliance program, including offering appropriate incentives and applying consistent disciplinary measures for those engaging in noncompliance and those who fail to take reasonable steps to prevent or detect noncompliance
- Respond appropriately to identified noncompliance and ensure that further similar noncompliant activity is prevented, including modifying the compliance program, as needed
- Periodically perform a risk assessment and take action to design, implement, or update the compliance program

The above guidelines seem reasonably straightforward, so why is there continued focus on compliance program effectiveness? What barriers are preventing the consistent application of the aforementioned *minimum standards* to ensure a *generally effective* compliance program?

As previously stated, in September 2024, the DOJ again updated its 2017 guidance on evaluating corporate compliance programs to provide greater depth on what principles are consistent with an effective compliance program in the view of the federal prosecutors.

DOJ Evaluation of Corporate Compliance Programs



Just as judges use the Federal Sentencing Guidelines in determining whether an organization is entitled to mitigation credit for having an effective compliance program in place, prosecutors use the DOJ guidance to decide whether to bring charges or negotiate pleas or other agreements when investigating an organization. Specifically, the "adequacy and effectiveness of the corporation's compliance program at the time of the offense as well as at the time of the charging decision" [5] and the organization's remedial efforts "to implement an adequate and effective compliance program or to improve an existing one" [6] are factors assessed.

The updated guidance poses **three fundamental questions** to guide its review, noting that there is no rigid formula or checklist that is followed:

- Is the corporation's compliance program well-designed?
- Is the program being applied earnestly and in good faith?
- Does the corporation's compliance program work in practice?

What Constitutes a Well-Designed Compliance Program?

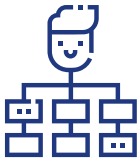
According to the DOJ, a well-designed compliance program is **comprehensive**, thereby maximizing the effectiveness of the program in preventing and detecting misconduct, sending a clear message of **zero tolerance** for misconduct regardless of position within the company, and is **well-integrated** into day-to-day operations.

Risk Assessment



The foundation of a well-designed compliance program is the company's performance of a periodic risk assessment, identifying the company and industry-specific risk areas, including emerging risks as the business evolves, and using the risk assessment results to tailor the compliance work plan around high-risk areas. One such emerging risk area of note relates to the evaluation of risk associated with the use of new technologies with specific reference being made to the use of artificial intelligence (AI). In addition, the guidance clarifies that an organization that focuses on high-risk areas will not be faulted for missing a low-risk violation so long as the company revises its compliance program as a result of the lessons learned from the identified low-risk violation.

Policies and Procedures



Key to operationalizing a compliance program is developing and implementing comprehensive compliance policies and procedures, including a Code of Conduct that sets out the organization's commitment to compliance and expectation of adherence to the compliance program and compliance with the law. Consideration should be given to the process in place to develop and implement policies and procedures, responsibility for operational integration of the policies and procedures, and training of the gatekeepers to understand the potential misconduct to look for. Further, policies and procedures should reinforce the culture of compliance within the organization and be easily accessible to all employees.

Training and Communications



Training also plays a critical role in designing a compliance program and in determining its effectiveness. As an indicator of how well an organization's policies and procedures have been integrated into operations, prosecutors will expect to see training and certification of training by all directors, managers, employees and key business partners. In addition to general training, employees should receive training based upon risks and actual compliance issues identified throughout the prior year and associated lessons learned. Employees should be tested on their comprehension and certify they understand the compliance policies and procedures and acknowledge their duty to report known or suspected compliance concerns as a condition of employment. Additionally, senior leadership should message employees and providers about their zero-tolerance position on misconduct. The guidance goes so far as to suggest that communication to employees should occur about why the conduct resulted in termination when it relates to a compliance issue.

Hotline and Investigation Process



Most organizations/practices establish a hotline mechanism and believe that in doing so, they have "checked the box." The key to ensuring this element is met and demonstrating effectiveness is ensuring that the confidential/anonymous reporting system is well-publicized to all employees such that they feel they have a mechanism to report concerns or seek guidance without the fear of retaliation. Further, the DOJ guidance indicates that having such an established reporting mechanism in place is "highly probative" of whether or not the organization/practice can prevent and detect misconduct in an effective manner. [7]

An obvious next step in the process is ensuring an appropriate investigation is conducted by appropriate personnel, and in a way that is objective, independent, timely, and provides accountability for follow-through with recommendations. [8] Often, organizations/practices permit the leader over the particular area where the misconduct occurred to conduct an investigation and recommend corrective action. It is easy to see the conflict that results from such a practice.

Vendor Management



The use of third parties is prevalent and necessary for the functioning of many organizations/practices. A well-designed compliance program will ensure the performance of due diligence around the selection of vendors, including reputational and relationship diligence, particularly when used for interacting with foreign officials where concerns of bribes in international business transactions arise.

Particularly in larger organizations where third parties may be used, but really for all third-party relationships, it is important to have a clear business rationale for using a third party. It is equally critical to ensure the services to be provided are clearly articulated in the agreement, along with associated appropriate compensation. Where utilized, proper controls should be established to ensure the contracted work was performed and that the compensation is reasonable for the services rendered. Moreover, in terms of managing vendor relationships, organizations must monitor their vendors and ensure they have a contractual right to audit books and records, and further, to take appropriate action if misconduct is identified.

Mergers and Acquisitions



With mergers and acquisitions in healthcare continuing to be an important business strategy, how and to what extent an organization subjects a target to compliance diligence reflects on how well-designed its compliance program is. Failure to identify wrongdoing in diligence may permit misconduct to continue at the acquiring organization undetected and may subject the acquiring organization to civil and criminal liability, business losses, and reputational harm.

Finally, post-acquisition activity is equally important. How is the remediation of identified compliance issues tracked, and what is the routine for follow-through? Employing a solid post-acquisition integration plan can ensure that acquiring organizations successfully address compliance concerns identified in the diligence process and provide a roadmap for continued success.

Is the Program Being Applied Earnestly and in Good Faith?



Even the most robust structured compliance program may fail when implementation is ineffective, absent, or lax. As alluded to earlier, too often, organizations/practices develop a soundly written compliance program but then allow it to sit on the shelf. The DOJ coins these programs as “paper programs.”

Another barrier to effective implementation surrounds the compliance officer’s stature and authority within the organization/practice. Without the proper authority and a “seat at the table,” resources may be limited, and ineffective or corrective action inconsistently applied. Each of the areas discussed in this section is directly related to the organizational culture and “tone-at-the-top” set by senior leaders.

Commitment by Senior and Middle Management



The DOJ reiterates that an effective compliance program requires a high-level commitment by senior leadership. Here, you must see leaders messaging employees about the importance of compliance and that misconduct will not be tolerated, regardless of your position, including the CEO or other executives. Too often, leadership is speaking all of the right words but then having difficulty following through when misconduct involves an executive, physician, or some other highly regarded employee. Disparate treatment in action sets a low tone about compliance within the organization and sends a message that compliance is important for some but not all.

The Board and senior leadership are responsible for setting the tone at the top. Further, the governing body is responsible for ensuring senior executives set the correct tone including holding them accountable for doing so. [9] Given this expectation, consideration is given to the types of compliance guidance that has been provided to the Board. In evaluating an organization's commitment to compliance, the DOJ guidance instructs its prosecutors to look for "rigorous adherence by example" of senior leaders when investigating misconduct and concrete examples of modeling proper behavior to subordinates. [10]

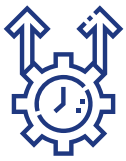
Autonomy and Resources



The authority and stature of the compliance officer are often closely connected with the tone at the top. In some smaller organizations, it may make sense based upon size and resources to assign compliance operations to a lower-level employee who reports to a high-level employee. In larger organizations, the compliance officer must have the same authority and stature as other senior leaders. [11] For example, a compliance officer should be involved in strategic and operational discussions on matters within the organization and be able to offer opinions and recommendations that are considered in the same manner as any other executive. [12]

Too often, we see the compliance officer uninvolved in these key discussions and decisions due to not being of the same stature as other leaders. This tone at the top issue directly impacts the compliance officer's ability to adequately and effectively act on behalf of the organization it serves. It also harms the organization by losing valuable compliance advice and direction to other leaders as they pursue new programs and services. A key consideration when evaluating the structure of the compliance program is the resources, including personnel, available to the compliance officer to perform the requisite auditing, monitoring, documentation and analysis required to operate an effective compliance program. Of utmost importance, regardless of the level of the compliance officer, the compliance officer must have direct access to the board and be allowed to function independently. ". . . [I]f a compliance program is to be truly effective, compliance personnel must be empowered within the company." [13]

Compensation Structures and Consequence Management



Considered another hallmark of an effectively *implemented* compliance program is the establishment and the consistent implementation of incentives for compliance and disincentives for non-compliance. Incentives and discipline motivate employees to promote compliance and avoid misconduct; however, they must be meaningful and consistently applied. Incentives often range from a merit increase based upon compliance as an element of a performance evaluation or a factor considered when giving promotions. Organizations that offer bonus programs to management or employees should consider adding compliance program adherence as a trigger for receiving a bonus. Doing so reinforces the importance of compliance within the organization and incentivizes such behavior from all levels.

Additionally, well-publicized disciplinary measures that are consistently enforced are equally important. As mentioned previously, consistent application of disciplinary actions, regardless of the stature of the individual involved in the misconduct, is imperative. Failing to do so sets a low tone within the organization regarding the tolerance level of misconduct. Thus, organizations should evaluate who determines which disciplinary actions are implemented to permit consistent application and ensure the compliance function is an active participant in this process.

The design and implementation of compensation systems, policies and procedures is considered an important mechanism in fostering a culture of compliance and managing the consequences of noncompliant conduct. An effective process might design compensation models that escrow or defer certain compensation tied to behavior that is consistent with the organization's values and policies or there may be contractual provisions that permit or require an organization to recoup previously distributed compensation when an individual is deemed responsible for a compliance violation.

Does the Corporation's Compliance Program Work in Practice?

Prosecutors will review the compliance program's effectiveness at the time of the misconduct and again at the time of the charging decision. In the first instance, the DOJ articulates an understanding that all misconduct cannot be prevented even with the best compliance program in place. Key to its evaluation, if the organization did not detect the misconduct immediately, is whether it had appropriately focused its activities on high-risk behaviors and whether the compliance program was revised or modified in response to the misconduct by the time of the charging decision. On the other hand, if the compliance program did detect the misconduct, halt the noncompliance, and effectively remediate and self-report the issue, then prosecutors would likely view the organization as having an effective compliance program in place.



One additional hallmark of an effective compliance program is its capacity to evolve and improve over time in response to the changing business environment, prior incidents and lessons learned. The 2017 and subsequently updated guidance documents each discuss the importance of performing a root-cause analysis when noncompliance occurs. Through this process, an organization can identify where controls failed or were missing, what compliance culture issues may be presently impacting compliance effectiveness and put in place improved controls to prevent a similar problem in the future. This process permits employees and departments involved in the misconduct to understand the concerns and the importance of their role in preventing noncompliance.

Finally, an effective compliance program must continuously evaluate its program by periodically updating its risk assessment, reviewing and updating policies and procedures, surveying all levels of employees on the culture of compliance and in particular the commitment of senior and middle management to compliance, and testing that established controls are working. In its 2024 update, the DOJ guidance provides that periodic measurement of the success and the effectiveness of its compliance program is a measure of how well a compliance program is functioning. The updated guidance also recommends that consideration be given to utilizing available data to gain insights and identify outliers in the program to help drive the commitment to compliance.

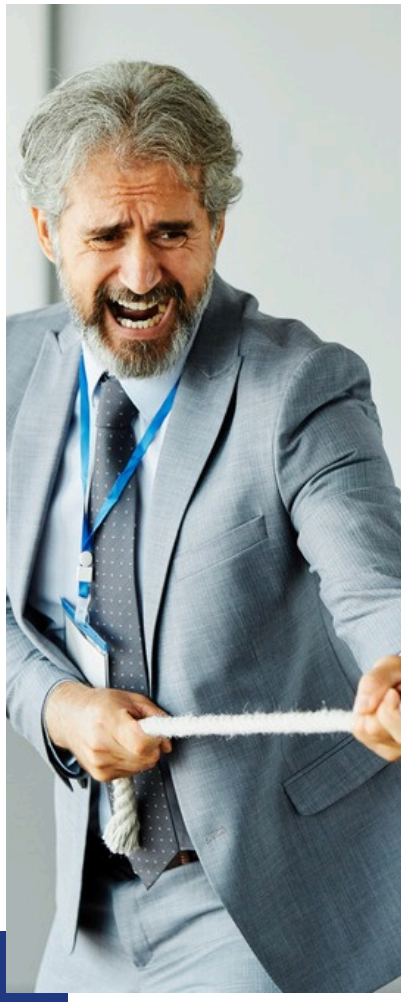
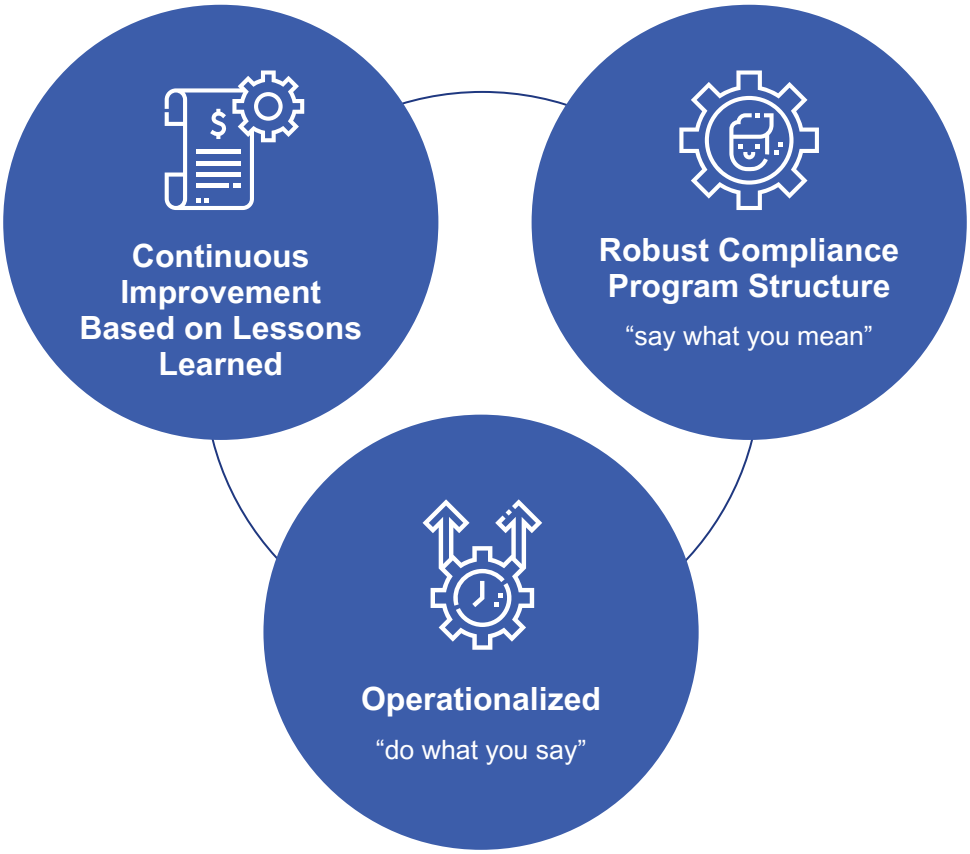


Figure 1. Checklist for Red Flags that Compromise Compliance Effectiveness

- My organization does not have a compliance program in place
- My organization has a compliance program in place, but it has not been operationalized
- My organization does not have compliance policies and procedures in place
- My organization does not have an anonymous reporting mechanism
- A structured root-cause analysis has never been performed
- My organization does not have an audit work plan
- My organization has not performed a compliance risk assessment
- My organization has not surveyed the culture of compliance
- My organization does not survey all levels of employees regarding the culture of compliance and commitment of middle and senior management towards compliance
- There are no meaningful incentives offered to employees for compliance
- There is an inconsistent application of disciplinary action depending on the person involved
- Consequences management policies and procedures do not exist
- Compensation models do not include requirements for recoupment or deferring of compensation to incentivize and/or disincentive a lack of compliance
- The compliance officer in my organization is not a senior leader, equal in status to other senior leaders (CFO, CIO, CLO)
- The Board is not familiar with the compliance program operations in my organization
- The compliance officer does not have direct access to the Board
- The compliance officer does not report in person to the Board on at least a quarterly basis
- The Board does not periodically go into closed session with the compliance officer with no other executives present
- The compliance officer is not involved in performing due diligence for practice acquisitions
- The compliance officer is not engaged in strategic/operational discussions/decisions
- An objective third party has not evaluated my organization’s compliance program

Figure 2. Sustaining Compliance Effectiveness

What should an effective compliance plan encompass for long-term effectiveness? Figure 2 illustrates the characteristics of an effective compliance program.



Barriers to Implementing an Effective Compliance Program

Much more is involved than initially meets the eye in ensuring the effectiveness of a corporate compliance program. However, the one area organizations and Boards can address that would most greatly improve the effectiveness of a compliance program centers around the tone-at-the-top. The stature and authority of the compliance officer have to be equivalent to the other senior leaders. For example, they must:



have a seat at the table around strategic and operational decisions



be valued as an important member of the senior leadership team



have the necessary resources, including ongoing continuing education



be empowered to make decisions independently



hold the authority to address all levels of employees in not addressing compliance concerns that have been brought to management's attention

Although some organizations have this right, many others do not. Compliance officers, senior executives, and board members each have an obligation and a duty to ensure an effective compliance program is in place. There is tremendous guidance available on this topic. Each of these essential groups should study the available guidance and do their part in moving the needle towards the greater effectiveness of their programs.

Conclusion

Compliance is a crucial matter that calls for consideration of specific guidance established by the Office of Inspector General (OIG) and the United States Department of Justice (DOJ) Criminal Division, as published in *Evaluation of Corporate Compliance Programs*. Penalties are onerous and, in some cases, devastating. A compliance program must be more than a paper document or a one-time exercise. The program must be enacted throughout the organization, closely administered, and continually maintained and updated. The leadership must come from the top to be implemented through all levels of the enterprise.

Acuvance Coker has a full menu of compliance services available that we are happy to discuss with you in more detail. These include:



Compliance effectiveness assessments



Compliance program development



Compliance advisory services, including assistance with operationalizing your compliance program, performance of risk assessments, and facilitation of compliance culture surveys



Governance education and advisory services



Root cause analysis facilitation



Virtual Compliance Officer services



Physician Compensation Governance procedure development



Physician arrangements compliance audits



Physician payment reconciliation audits



Mergers and Acquisitions compliance diligence



Development of a provider documentation and coding compliance plan

Sources & Endnotes

1. U.S. Department of Justice Criminal Division. "Evaluation of Corporate Compliance Programs" (Updated September 2024). Guidance Document. https://www.justice.gov/criminal-fraud/page/file/937501/download. Accessed October 10, 2024.

2. U.S. Department of Justice Criminal Division. "Corporate Whistleblower Awards Pilot Program." https://www.justice.gov/criminal/criminal-division-corporate-whistleblower-awards-pilot-program. Accessed October 10, 2024.

3. United States Sentencing Commission. "2018 Chapter 8, Sentencing of Organizations." https://www.ussc.gov/guidelines/2018-guidelines-manual/2018-chapter-8. Accessed June 30, 2021.

4. Both the Federal Sentencing Guidelines and the DOJ Evaluation of Compliance Programs guidance understand that it is not possible to completely avoid noncompliance and that the failure to prevent and detect noncompliance does not necessarily mean the program is not generally effective.

5. See en 1, citing JM 9-28.800.

6. See en 1, citing JM 9-29.1000.

7. See en 1, p. 7.

8. The DOJ guidance recommends setting timing standards and metrics and measuring and reporting on these metrics.

9. To that end, governing bodies should reflect on how they are ensuring the correct tone is being set within the organization. As a best practice, Boards should periodically meet in closed session with their compliance officer and talk about how the program is running.

10. See en 1, p. 11.

11. "How does the compliance function compare with other strategic functions in the company in terms of stature, compensation levels, rank/title, reporting line, resources, and access to key decision-makers?" Ibid, p. 12.

12. "How has the company responded to specific instances where compliance has raised concerns? Have there been transactions or deals that were stopped, modified, or further scrutinized as a result of compliance concerns?" Ibid, p. 13.

13. Ibid, p. 12.



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