

The Effectiveness of Your Compliance Program

Combine DOJ guidance with data and metrics

By Joseph Zielinski, JD, CHC, CHRC

Are you looking for a structure and format to audit and document your organization's compliance program and gain valuable insight for your organization? Your audit goal can be achieved by answering the three fundamental questions posed by the Department of Justice guidance to determine the effectiveness of your compliance program. A spreadsheet-based tool can facilitate your review and provide a way to display your results.

Healthcare compliance is “an ongoing process of meeting or exceeding the legal, ethical, and professional standards applicable to a health care organization or provider,” according to [Richard Kusserow](#), the former Inspector General of Health and Human Services. The definition provides a foundation for evaluating what compliance should look like.

The Department of Justice (DOJ) initially released its [Evaluation of Corporate Compliance Programs](#) in 2017, with subsequent revisions in 2019 and 2020. In 2019, Assistant Attorney General Brian Benczkowski said one of the goals of the updated guidance was to provide additional transparency in how the DOJ will analyze an organization's compliance program. Specifically, [he added](#), DOJ “hope[s] this updated version provides additional insight to both prosecutors and companies with respect to evaluation of compliance programs.”

The [new guidance](#) “provides a framework for our prosecutors to use to evaluate whether a corporation's compliance program was adequate and effective at the time of suspected misconduct, as well as at the time of a resolution or charging decision.” This statement is important because it provides insight into how prosecutors evaluate a program.

Prosecutors take an organization's compliance program into account in three ways. They:

- Assess a program to determine whether they should decline to bring a case, or if a resolution is appropriate, what the resolution should be.

- Consider compliance programs in determining the organization's culpability score as part of calculating the range of fines under the United States Sentencing Commission [Guidelines Manual](#) and whether the organization is eligible for a reduction of the lowest potential fine.
- Look at the organization's compliance program at the time of the resolution to determine whether an independent compliance monitor is necessary to prevent the recurrence of misconduct, or whether the compliance program is sufficiently effective to permit the organization to self-monitor.

Three fundamental questions

The largest change to the guidance from the 2019 updates was the introduction of the three fundamental questions:

- Is the compliance program well designed?
- Is the program being applied earnestly and in good faith—is it adequately resourced and empowered to function effectively?
- Does the compliance program work in practice?

With the introduction of the three fundamental questions, the shift towards needing to demonstrate effectiveness (rather than showing that policies and procedures exist) continues. As part of this shift, a greater emphasis is placed on analyzing your program (and failures of your program to use tools such as a root cause analysis) and the use of data and metrics.

Data and metrics are where you need to focus now. Your organization will need to be able to show how data and

metrics have informed the compliance program's priorities and work. Additionally, your compliance program should be designed with the government's focus on measuring and testing in mind. Finally, if a violation occurred, your organization's compliance program will need to be able to provide months, if not years, of data to demonstrate the effectiveness of the program.

To apply the three fundamental questions, you must understand what they require.

Question 1 – Is the compliance program well designed?

Address six areas in answering the design question:

1. Risk assessment
2. Policies and procedures
3. Training and communication
4. Confidential reporting and investigative process
5. Third-party management
6. Mergers and acquisitions

Risk assessment

Risk assessment is made up of the risk management process, risk-tailored resource allocation, ongoing program improvement, and lessons learned (added in 2020). When you are performing an assessment, begin by identifying your risks and prioritizing them. Prosecutors may give credit to a program that devotes appropriate attention and resources to high-risk transactions and activities, even if the program fails to prevent an infraction in a low-risk area.

Policies and procedures

Policies and procedures should:

- Provide clear guidance
- Comprehensively cover topics of significant regulatory risk
- Be accessible to anyone affected
- Identify responsibility for operational integration
- Have an ethical foundation

Keep these areas in mind when you are developing or evaluating policies and procedures. Ensure that the content is appropriate, accessible and coherent to your employees. Additionally, you need to understand how the policy or procedure fits into operations and you should have evidence indicating that leaders will champion that policy or procedure.

Training and communication

Your significant compliance risks should carry through to the content in your organization's training. Additionally, you should ensure that the form and content are conducive to your goals. Finally, you should confirm that the educational guidance is available, and individuals know how to access it.

Confidential reporting and investigative process

Confidential reporting and investigative processes include an effective reporting mechanism, a properly scoped investigation by qualified personnel, a completed investigation and response, appropriate resources and monitoring. An appropriate reporting platform is the most important element in this area. Determine that issues are thoroughly investigated and handled consistently. Make sure appropriate resources are in place for monitoring. Verify that reporting and investigations are properly funded, and that the program collects, tracks, analyzes and uses the information collected through its reporting mechanism.

Third-party management

Third-party management should have a risk-based and integrated process and appropriate controls. Responsibility within your organization for the management of relationships should be clearly articulated, and the failure of third parties to meet their compliance obligations should have appropriate consequences. Again, note the use of a risk-based approach. The risk analysis will be the foundation for the program's approach and how reviews of third parties are managed.

Your organization's program will need to have appropriate monitoring controls in place, which is an area that compliance and internal audit can work together to design, implement and manage.

The compliance department must have sufficient independence and the appropriate resources.

DOJ has said an organization’s third-party due diligence practices are a factor that prosecutors should assess. Due diligence practices determine whether a [compliance program](#) can “detect the particular types of misconduct most likely to occur in a particular line of business.”

Mergers and acquisitions

Ensuring compliance in mergers and acquisitions requires a due diligence process, integrating ethics and compliance into the mergers and acquisition process, and another process connecting due diligence to implementation. The biggest takeaway from this area is that compliance must be involved in the due diligence process leading up to the merger or acquisition and in the transition.

The compliance department should verify that management has taken appropriate steps to implement policies post-closing. Further, the extent to which your organization subjects its acquisition targets to appropriate scrutiny indicates whether its compliance program is able to effectively enforce its internal controls and remediate misconduct at all levels of the organization.

Question 2 – Is the program adequately resourced and empowered?

You must address three areas to answer this question:

- Commitment by senior and middle management (ethical leadership)
- Autonomy and resources (organizational structure and accountability)
- Incentives and disciplinary measures

Commitment by management

Commitment of management includes conduct at the top, shared commitment (solve problems together), and oversight. Ethical buy-in at the top of the organization is essential, as well as a demonstration from senior management of their commitment to compliance. A shared commitment should exist to solve problems together.

Verify that the board of directors provides oversight, and that appropriate expertise is available to the board. Examine the extent that senior management has clearly articulated the company’s ethical standards, conveyed and disseminated them in unambiguous terms, and demonstrated rigorous adherence by example. Additionally, consider how middle management has reinforced these standards and encouraged employees to abide by them.

Autonomy and resources

Autonomy and resources for the compliance function require evaluation of organizational structure, seniority and stature, experience and qualifications, funding and human resources, data and access (added in 2020), autonomy (accountability), and outsourced compliance functions. The compliance department must have sufficient independence and appropriate resources.

Data and access include access to the data the compliance function needs to carry out its mission. If any portion of compliance is going to be outsourced, the need should be documented, and ongoing effectiveness evaluations should be performed.

Incentives and disciplinary measures

Incentives and discipline measures include human resource process (transparency), consistent application, and an incentive system. Important factors include who participates in making decisions and who determines whether decisions are consistent. Your organization should consider the implications of incentives and whether the incentives encourage compliant behavior.

Look at the annual review of compensation. You should expect appropriate incentives to perform in accordance with the compliance and ethics program. Expect to see appropriate disciplinary measures in place for criminal conduct and for failing to take reasonable steps to prevent or detect criminal conduct.

Question 3 – Does the compliance program work in practice?

Under the guidance, address these categories:

- Continuous improvement, periodic testing and review
- Investigation of misconduct
- Analysis and remediation of any underlying misconduct

Continuous improvement, periodic testing and review

Continuous improvement, periodic testing and review consist of internal audit, control testing (monitoring), evolving updates (continuous improvement), and a culture of compliance. The auditing and control testing components provide the greatest possibilities for collaboration between compliance and internal audit. Designing an audit plan and testing controls are ideal areas for the two programs to collaborate.

Consider whether these activities are an integral part of the compliance program:

- Revisions to the program consider lessons learned
- Reasonable steps are in place to ensure the organization's compliance and ethics program is followed, including monitoring and auditing to detect criminal activity
- Periodically evaluating the effectiveness of the program

Investigation of misconduct

Investigation of misconduct requires properly scoped examinations by qualified personnel and appropriate responses to unethical conduct and violations of policies and procedures. Ensure that investigations have been properly scoped and that necessary corrective action incorporated techniques recommended in the guidance. An effective investigation structure will have an established means of documenting the organization's disciplinary action or remediation measures taken.

Analysis and remediation

Analysis and remediation of any problems include root cause analysis, prior weakness, payment systems, vendor management, red flags, corrective action, and accountability. The area provides another opportunity for compliance and internal audit to work together.

This section is valuable for your organization if you are seeking to lessen any potential penalty. A hallmark of a compliance program that is working effectively in practice is that the organization can conduct an effective and thoughtful root cause analysis of misconduct, and then address that cause through timely and appropriate remediation.

Prosecutors are instructed to look at the extent and pervasiveness of the misconduct, who was involved, and the remedial actions taken by the organization after the conduct was discovered. Your organization should be tying together the analysis and remediation with other areas and processes to determine the full scope of any compliance issue.

Connection to other compliance guidance

Understand how this guidance ties into two other compliance guidance documents.

- Office of Inspector General's [Seven Elements of an Effective Compliance Program](#)

Effective investigations of misconduct should document any disciplinary action or remediation measures taken.

- [Measuring Compliance Program Effectiveness: A Resource Guide](#) – HCCA-OIG Compliance Effectiveness Roundtable

Within these guidelines, multiple common elements exist. Several of the questions asked by the DOJ guidance are similar to those asked by other guidance. In addition to having similar questions, some requirements overlap.

The overlap in these guides focuses around the following areas:

- Risk management/risk assessment
- Policies and procedures
- Training and communication
- Investigations and discipline
- Program structure

In addition to the overlap, common takeaways from guidance are the following:

- Paper compliance is no longer sufficient.
- Metrics and data are especially important.
- Program effectiveness needs to be demonstrated.
- A violation does not equate to an ineffective program if you can demonstrate significant change (improvement) during the investigation process.

You will need to tie the various guidance together in a way that demonstrates your program's effectiveness.

Evaluate your program with data and metrics

Your program evaluation will be facilitated by a tool that accumulates, summarizes and displays the information that answers the three fundamental questions regarding program design, resources and empowerment, and effectiveness in practice.

In conjunction with this article, a free, Excel-based tool is available to AHIA members at AHIA.org in the Virtual Learning Audit Resource Center, under the [Professional Resources](#) tab. Search by using these key words: compliance effectiveness spreadsheet.

This tool lists the requirements of the DOJ Guidance and the "Measuring Compliance Program Effectiveness: A Resource Guide" with references to how those guidances overlap. In addition to evaluating and measuring your program, the tool displays the quantitative results of your review.

Exhibit 1 – DOJ corporate compliance program dashboard

Question	Requirement description	NA at this time	Not Satisfied	Partially Satisfied	Fully Satisfied	Total
1	Is the corporation's compliance program well designed?	24	0	0	0	24
2	Is the program being applied earnestly and in good faith? In other words, is the program adequately resourced and empowered to function effectively?	13	0	0	0	13
3	Does the corporation's compliance program work in practice?	13	0	0	0	13
	Totals	50	0	0	0	50
	Percentages	100%	0	0	0	100%

The tool begins with an overview and a summary of all your collected data points. The data points are based on responses to questions that allow you to evaluate whether your program is meeting a given requirement. Exhibit 1 is an example of a summary tab that accumulates the answers to the questions in the tool.

In addition to the high-level overview, further dashboards are tied to each fundamental question and the seven areas under the “Measuring Compliance Program Effectiveness: A Resource Guide.” Also, some individual tabs go into detail for each fundamental question or element as needed. Within the options for each of these tabs are the detailed actions for each area and a way to mark where your program is regarding the individual questions under the parts.

At the end of each area is a column for cross-references where a match is made to the guidance resources that allow you to explore additional detail to confirm whether an item has been captured.

Summary

Prosecutors are required to assess two important aspects of a compliance program.

- The adequacy and effectiveness of the organization's compliance program at the time of the offense.
- The adequacy and effectiveness of the program at the time of the charging decision. At the time of the charging

decision, prosecutors should look at what the program has done during the investigation to show improvement and lessons learned.

Prosecutors still have a focus on root cause analysis to understand what failed in the compliance program. Your program must demonstrate the capacity to improve and evolve during an investigation. Your program needs to gather data and metrics and demonstrate how the information and/or metrics informed your company's compliance program.

Remember that paper alone is no longer enough to demonstrate an effective compliance program. Rather, your compliance program must have verifiable data and metrics that show how your program is satisfying the three fundamental questions. Conduct an internal audit to measure the effectiveness of your organization's compliance program. **NP**



Joseph Zielinski, JD, CHC, CHRC, is a healthcare attorney at the Dinsmore law firm in Indianapolis, Ind. He concentrates his practice on long term care and specializes in compliance. Joe can be reached at (317) 860-5314 and Joseph.Zielinski@dinsmore.com.