

Complete Healthcare Compliance Manual 2024

Program Self-Assessment

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A healthcare compliance program assessment involves the analysis of an organization's internal data to refine and improve the organization's compliance function. It is the process of gathering, reviewing, and discussing information from multiple sources in order to develop an understanding of the compliance program's strengths and weaknesses, such as the following:

- Development and implementation of the compliance program
- The level of working compliance knowledge
- The existence of a culture of compliance throughout the organization

Assessment methodologies for healthcare organizations should include several fundamental components:

- **Target definition:** What is being assessed and what is the scope of the assessment?
- **Identification of necessary data:** What information is needed for the assessment?
- **Information collection:** What is the process by which information will be requested and compiled for review?
- **Data analysis:** How will the information be reviewed, analyzed, and scored?
- **Development of conclusions and recommendations:** What are the results of the assessment and what action steps are available to improve the compliance program?
- **Responsibilities:** Who will be responsible for each prioritized step and within what time frames?
- **Prioritized process changes:** Of the identified recommendations, what is top priority for compliance program improvement?
- **Reevaluation:** How did the changes affect the compliance program, and what adjustments are needed in the future?

To successfully perform an assessment, it is essential to form a comprehensive understanding of what a compliance program is and what it means to that organization. This understanding will drive the assessment process for not only the evaluators, but also for the recipients of the assessment results.

Compliance Program Purpose and Effectiveness

The primary purpose of a compliance program is to promote organizational conformity to applicable federal and state laws, private and commercial payor requirements, and patient expectations. Healthcare compliance is the continuous process of understanding and adhering to the legal, ethical, and professional standards applicable to healthcare organizations. It requires the development of organizational processes established by policies and

procedures to define appropriate conduct, educate the workforce, and monitor/audit adherence to compliance directives. An effective compliance program can help protect healthcare organizations against fraud, waste, and abuse, as well as other potential liability areas.

A compliance program should articulate and demonstrate the organization's commitment to both the law and ethical standards. As such, compliance programs are designed to establish an organizational culture that promotes prevention, detection, and resolution of conduct that is inconsistent with the law or the organization's policies and standards of conduct.

The U.S. Federal Sentencing Guidelines for Organizations (FSGO) is a federal law that pertains to the assessment of damages in cases of fraud against the government; it includes the essential requirements of an effective compliance program.^[2] Effective healthcare compliance programs are premised on these seven elements, as outlined in chapter 8 of the FSGO. This is the industry standard for effective compliance programs. The seven elements are also the basis of the compliance program guidance documents published by the OIG for a variety of healthcare industry segments.

To help guide application of appropriate measures for ethical and legal operation, an effective compliance program will have implemented each of the following elements in a robust manner:

- High-level oversight
- Established standards and procedures
- Open lines of communication
- Education and training
- Auditing, monitoring, and reporting systems
- Response and corrective action
- Consistent discipline for noncompliance

Healthcare fraud has greatly increased the pace and intensity of oversight and investigation of healthcare organizations.^[3] Establishing an effective compliance program is a necessity to protect healthcare organizations against missteps within a highly regulated and rigorously scrutinized environment. An effective compliance program is a crucial component to preventing fraudulent claims and erroneous billing, preparing for potential audits, and avoiding ethical conflicts in business operations and patient care services.

Compliance program effectiveness continues to be a focal point of government oversight agencies. Simply having the necessary elements of a compliance program (such as a hotline, code of conduct, training, and policies and procedures) does not guarantee effectiveness. Several factors indicate the effectiveness of any compliance program, including but not limited to the following:

- Demonstration of an ethical culture in which organizational decision-making aligns ethical values to strategic goals.
- All members of the workforce (executives, employees, board members, medical staff, volunteers, vendors, etc.) are held to the same standards of professional conduct.
- The willingness of the workforce to speak up and ask questions, as well as the organization's responsiveness to those inquiries.

The hallmark of an effective compliance program is the organization's capacity to evolve and improve over time in response to incidents and lessons learned. In healthcare, effective compliance programs also achieve strategic goals, thereby allowing for the delivery of high-quality patient care.

The central challenges for compliance programs are the operationalization of ethical standards and the elevation of values-based behaviors consistent with the Department of Justice's (DOJ) guidance, which emphasizes results over content alone.^[4]

Effectiveness Measurements

Often the effectiveness of an organizational compliance program is more qualifiable than quantifiable (i.e., a culture of trust, workforce integrity, promotion of compliant behaviors, response to issues of noncompliance, etc.). However, quantifiable metrics are available for comparison and outcomes determination, which when combined with a qualifiable evaluation can provide a meaningful gauge of the program's effectiveness.

Measurable aspects of a compliance program can include, but are not limited to, the following:

- Regular reporting of compliance-related activities and investigations to the organization's governing body, including documentation of questions asked and actions taken.
- Policies and procedures that are regularly reviewed and updated to provide context to an organization's ethical values and proper communication to the workforce and relevant external parties.
- Completion of regular and relevant workforce compliance training to integrate a culture of compliance into daily operations.
- Regular completion of a risk assessment and development of a compliance work plan to address identified risks.
- Confidential reporting processes so that the workforce has the ability to report concerns or questions of potential misconduct.
- Compliance program benchmarks, including staffing, salaries, budgets, program responsibilities, and activity metrics.

Program Administration

Although everyone in the organization is responsible for compliance, the Department of Health and Human Services Office of Inspector General's (OIG) compliance program guidance recommends designating a compliance officer and other appropriate oversight bodies.^[5] These may include a compliance committee and board of directors' subcommittee to operate and monitor the compliance program. Additionally, the second FSGO element of an effective compliance program—compliance program administration—expressly addresses the role of the board and high-level personnel in compliance programs.

As a whole, an organization's board is ultimately responsible for overseeing and managing efforts to manage risk and ensure compliance with applicable laws and regulations. Knowledge regarding content and operations of the compliance program, coupled with oversight of the execution of the program, form the foundation of the duties of the board to safeguard effectiveness.

Senior management plays a significant role in guiding successful implementation of an effective compliance program as well. Senior management must allocate sufficient human and financial resources to these efforts.

More importantly, senior management can also foster a robust ethical culture by setting a strong tone from the top and providing an example of ethical behavior and values to the workforce on a daily basis.

The compliance officer serves as the focal point for all organizational compliance activities. Designating a compliance officer with the appropriate authority is critical to the effectiveness of the program. Designating that executive position in the organization with direct access to the company's governing body, the CEO and all other senior management and legal counsel, is absolutely necessary.

Healthcare organizations cannot achieve an effective compliance program if the effort is not strategic and championed by leadership. The compliance program must be developed and implemented with an overarching and comprehensive strategy so that the workforce fully understands what needs to be done and can reliably carry out compliance measures in daily operations. To align compliance with strategy, an engaged leadership invested in achieving the objectives of the compliance program must participate fully in the requisite responsibilities and provide an example to the workforce. The organizational strategic plan must include necessary resources dedicated solely to compliance, such as human resources, technology, and training. Strategic planning must encompass compliance efforts in order to identify and mitigate risk, meet regulatory demands required for operational success, and achieve sustainable strategic results.

Important Assessment Factors

A periodic critical review of a compliance program is essential to assess whether or not it meets organizational objectives, accurately reflects the organization's operations, and addresses compliance risks. The compliance program must not only be in place, but it must also be evaluated regularly. Key factors to consider in the assessment include review of existing policies, practices, procedures, and internal controls related to the prevention of fraud, waste, and abuse. Further, individuals in the organization who have specific compliance responsibilities will provide important input regarding the effectiveness of the compliance program.

In its compliance program guidance for various healthcare organizations, the OIG includes the requirement of regular (typically at least annual) review of a compliance program.^[6] Accordingly, industry best practice includes performing annual internal assessments, with an additional external review every three years to provide an objective evaluation.

Internal controls, the review of which are the basis of an assessment, are processes in place designed to safeguard operational success and provide reasonable assurance regarding the achievement of operational objectives. Some of these objectives may include the effectiveness and efficiency of operations, compliance with applicable laws and regulations, and accurate and reliable financial reports. An effective internal controls environment that incorporates clear processes and guidelines ensures an organization's resources are used for their intended purposes, thereby minimizing the risk of misuse.

Examples of internal controls reviewed during an assessment include the following:

- Existence and regular review of key compliance policies and procedures
- Regular reporting of compliance program activity to the governing body
- Assurance of appropriate staffing and resources necessary to meet the demands of the compliance program
- Verification that background/sanction checks are conducted in accordance with applicable rules and laws (e.g., employment, promotions, and credentialing)

- Evaluation of audit results conducted by external entities
- Monitoring for documentation of consistently applied disciplinary action

A meaningful assessment can provide invaluable insights with important recommendations for improving the compliance program's overall structure and effectiveness. Although feedback on the compliance program is important, there is a risk that organizational leadership may view a report and completion of recommendations as simply a "check the box" exercise. To get the most out of the assessment, a tactical approach is necessary for successful utilization of the results. First, each of the assessment recommendations should be aligned with the associated compliance program element. Leadership should determine whether it is a regulatory or organizational policy requirement or industry best practice. The report and associated findings should be presented, along with recommendations and a suggested prioritized schedule of milestones and deadlines, to affected leaders of the organization to secure commitments to mitigate identified gaps. This should include compliance department staff, department leads, the compliance committee, and the governing body committee or board. Finally, it is important to monitor improvement on a consistent basis and share lessons learned regularly.

The effectiveness of an organization's compliance program can have significant influence on the outcome of an external investigation. The United States Sentencing Commission and DOJ have specifically cited the presence of an effective compliance program as a key consideration for investigation and prosecution of criminal liability in organizations.

The FSGO states that compliance standards and procedures reasonably capable of reducing the prospect of criminal activity include the seven elements of an effective compliance program. Further, "if an organization can demonstrate that it had put in place an effective compliance program" the potential fine can be mitigated by 95% in some cases.^[7]

Similarly, DOJ states that its *Evaluation of Corporate Compliance Programs* can do the following:

Assist prosecutors in making informed decisions as to whether, and to what extent, the corporation's compliance program was effective at the time of the offense, and is effective at the time of a charging decision or resolution, for purposes of determining the appropriate (1) form of any resolution or prosecution; (2) monetary penalty, if any; and (3) compliance obligations contained in any corporate criminal resolution (e.g., monitorship or reporting obligations).^[8]

These two documents are the driving doctrines on the importance of an organization's compliance program and what impact an effective program will have during investigation and prosecution. In turn, other regulatory, policy, and financial oversight agencies follow the lead these key guidelines establish when evaluating organizations for financial matters, regulatory adherence, and policy variances.

Performing a Self-Assessment

The scope and scale of assessments can be daunting and a challenge to design; therefore, it is important to identify specific program attributes critical to the effectiveness of the compliance program. Healthcare organizations can evaluate the existence and effectiveness of internal controls necessary to meet strategic goals and objectives utilizing the seven-elements framework. Modifications to the assessment approach and methodology may be necessary to address identified gaps.

Planning an Assessment

Planning the assessment is a vital first step in the process, and it includes the involvement of people across the organization. The decision to perform an assessment should be made by organizational leadership and the governing body in coordination with the compliance department and the compliance committee. An assessment requested and authorized by the governing body carries the most weight both internally and externally. Strong organizational leadership will set the tone of the assessment, as well as affect the reception of its findings and recommendations.

The primary purpose of the assessment is to evaluate the existence and effectiveness of key fundamental program elements and engagement of the workforce in carrying out necessary organizational compliance activities. This includes identification of those organizational entities as well as the affected departments and leaders.

If resources and expertise allow, the assessment can be performed internally by the compliance department; however, an external review is a sound alternative for resource-limited organizations or those requiring a specialized assessment. Additionally, utilization of an external expert adds objectivity and provides insight into how the compliance function may be viewed by a government agency or business partner. As a best practice, an external assessment is recommended every three years to provide an objective evaluation.

Whether performed internally or externally, a proper assessment requires an investment in time, effort, and staff. In most organizations, the assessment's management will likely fall to the senior compliance executive. Significant coordination and management are required for document acquisition and review, interview scheduling and performance, and analyses and reporting.

Additionally, the organization must determine whether the assessment will be performed under attorney-client privilege. The attorney-client relationship affords a distinct right to have assessment information protected from required disclosure to any third party, including business associates, competitors, government agencies, and even criminal justice authorities. Another benefit to performing an assessment under the direction of counsel is that knowledge of any performance or documentation gaps uncovered can be examined and addressed with a lower probability that the results will be discoverable in legal proceedings.

Some of the essential components reviewed during an assessment include the following:

Background Materials

- Industry benchmark information: budgets, staffing, and salaries
- Regulatory requirements
- Government updates
- Professional associations' (HCCA, AHIA, AHLA, AAPC, etc.) guidance about recent industry updates
- Others

Compliance Program Materials

- Administrative and operational information (i.e., organizational and structural relationships and committee meeting agendas and minutes)

- Compliance program documents (i.e., compliance program plan and charter, code of conduct, compliance risk assessment and work plans, compliance activity dashboard, compliance committee charter and membership, compliance officer job description, and essential compliance policies)
- Internal and external audits (i.e., government payors, third-party payors, information technology, and Medicare overpayments and repayments)
- Training and education information (i.e., compliance training materials, communication materials, and interview forms)
- Listing of any management or board compliance concerns or questions

Interviews

- Introduction and questions
- Contact person for scheduling
- Interviewees

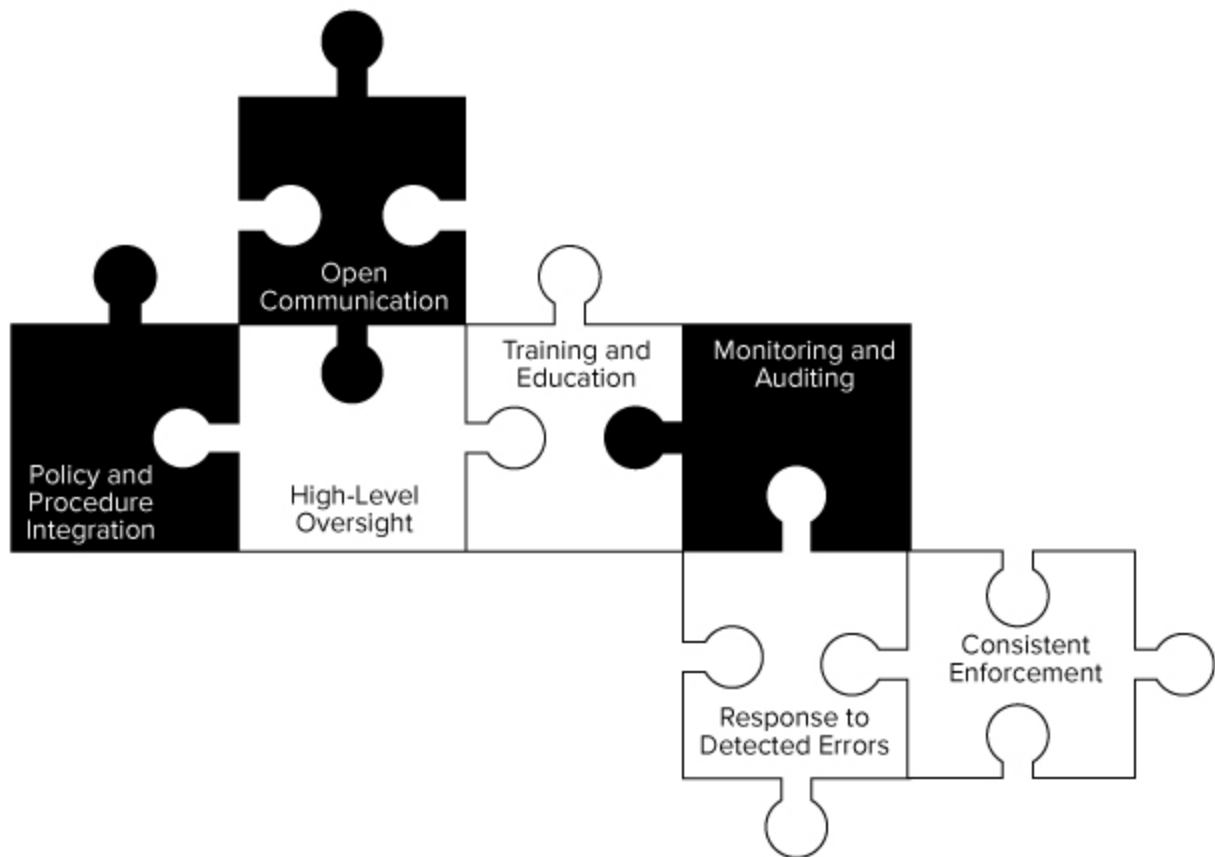
The assessment is designed to evaluate an organization's existing compliance program and provide meaningful feedback on the effectiveness of the various elements and identified gaps. There is no prescribed method for performing an assessment; however, consideration must be given to the organizational structure and departments to be included in the review scope. Due to the ever-evolving regulatory environment and the associated requirements, it is important to evaluate a significant amount of information in complex organizational structures.

Compliance applies to all areas of the organization. That said, due to the high degree of regulatory scrutiny, certain departments and operational functions are central to the assessment itself. These include revenue cycle, physician compensation arrangements, information technology, human resources, real estate and joint ventures, accreditation, and supply chain. It is important to review materials and interview key individuals who are responsible for these areas to evaluate the strength of internal controls. Other departments and operational functions should be included in the assessment based on the organizational strategic plan and any known or potential risks.

Sample Assessment Approach

Diagram 1 illustrates how the seven elements of an effective compliance program fit together in various ways to form a cohesive whole. An assessment should take all of them into account, not only as unique components, but also as to how they integrate to comprise a larger function of the organization. The following are ways each element should be studied and what questions should be answered as part of an assessment.

Diagram 1. Parts of a Program



High-Level Oversight

- Has the organization’s leadership provided the resources—human, financial, time, etc.— necessary for compliance program effectiveness?
- Is the reporting structure, both formal and informal, appropriate to allow the free flow of information? Are reporting measures in place for administration, function, and oversight within the hierarchy of the organization itself?
- Can areas of the organization’s structure be strengthened to create a more effective compliance program?

Policy and Procedure Integration

- How are policies and procedures developed? Are they maintained and updated as needed?
- How are policies and procedures shared with employees, appropriate subcontractors, volunteers, and/or vendors?
- Does the organization have policies and procedures specific to the code of conduct, conflicts of interest, and confidentiality?
- Has the organization created a process for the flow of regulatory updates and governmental communications appropriate to an employee’s function?
- Given the potential for compliance risk, does the organization perform exit interviews of departing employees with an opportunity for discussion of any known risks?

- Is there a method in place for sharing any discovered risks with the appropriate compliance officer or functional leader?

Open Communication

- Does the organization have a confidential method to allow employees to share concerns about potential risk and ask questions without fear of reprisal? If so, what are the policies and procedures around reaction by the organization's leadership?
- How does the organization respond to potentially adverse findings by external auditors?

Training and Education

- What are the organization's policies and procedures for consistent employee onboarding, both facing the new employee and in screening prior to hire?
- Does the organization provide regular training and educational materials? How are they delivered, how often, and to which employees? Is leadership also trained regularly?
- Does the organization review its training materials for updates to regulations and policies, both internal and external? How often, and how is the material evaluated?

Auditing and Monitoring

- What processes does the organization follow for auditing and monitoring (as required by governmental payors and/or internal review of billed claims)?
- Has the organization enabled its employees through awareness of vital concepts, such as HIPAA Privacy and Security Rules, quality of care, and accuracy of submitted claims?
- Given federal laws regarding exclusion screening, how does the organization follow these laws and document its regular adherence?
- Does the organization share the results of its auditing and monitoring activities to the hierarchy above, and if so, how does it do so in a constructive way that allows for improvement and mitigation of future risk?

Response to Detected Errors

- When mistakes are identified, how does the organization respond to them, both in the immediate corrective sense, as well as in future steps to avoid repetition of the error?
- What actions are taken in response to reviews performed by external parties?
- How does information flow upward to the board of directors or highest level of organizational hierarchy?

Consistent Enforcement

- Is the organization's exclusion screening process applied consistently, and is it thorough both in action and in documentation?

- Does the human resources department have policies and procedures in place to document disciplinary action(s) taken as appropriate for noncompliance behavior by employees? How is this information maintained, and how is it communicated to the leadership?

Gathering Assessment Information

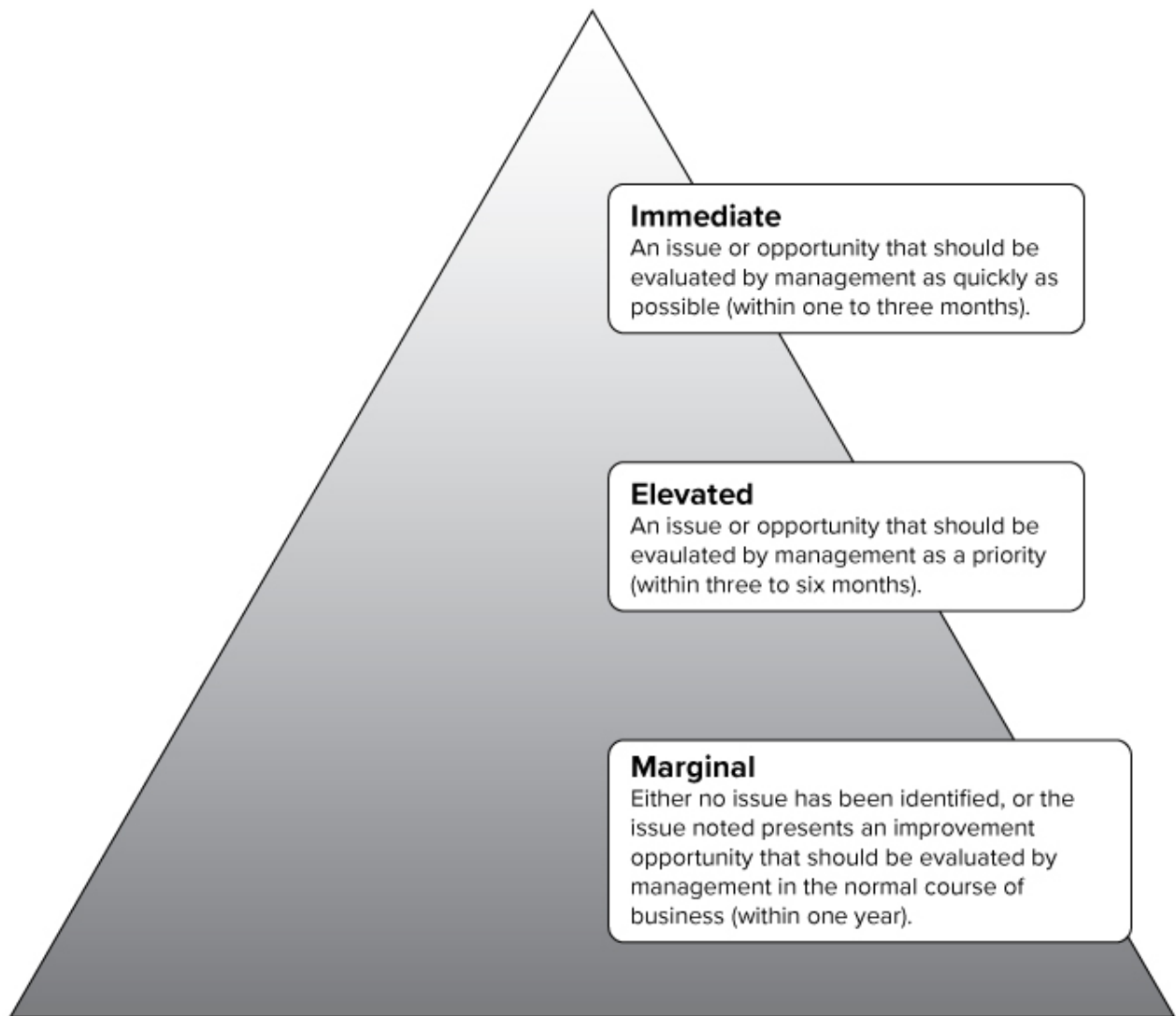
As with any critical evaluation process, there will be challenges to obtaining the necessary information for the assessment. To address these challenges, it is important that the assessor is knowledgeable of compliance program fundamentals and organizational strategic goals. Additionally, as individuals involved in the assessment will have varying levels of familiarity with compliance, the assessment process itself may provide an opportunity to offer education related to key elements of compliance that affect various departments and operational functions. Similarly, the recommendations provided must take into consideration the operational aspects of each area. Implementation of compliance program improvements must be attainable for the affected departments to achieve the desired result of a robust and effective compliance program.

Assessment Report and Response

Following the review of materials and interviews with key stakeholders, the compliance officer (or another employee ultimately responsible for the assessment) should identify compliance program strengths and areas for improvement. Additionally, the results should be collectively confirmed by compliance department staff to establish the assessment findings and recommendations. In accordance with industry best practices, recommendations should address aspects identified for improvement, and critical observations should be provided to the organization's compliance committee and governing body. The assessment should generally include findings associated with leadership's role in compliance, compliance program resources, operationalization of key concepts, reporting to the governing body, and organizational initiatives.

Given the potential risk involved in the various elements reviewed during an assessment, the organization should establish a method for prioritizing the issues discovered. This prioritization should inform decision-making by leadership and the compliance officer, both in terms of resource assignment and timeliness. Diagram 2 shows an example method for prioritization.

Diagram 2. Assessment Issue Prioritization



Once the assessment is complete and the report has been produced, it is important to develop a work plan that contains actionable items. The assessment report should create a roadmap for prioritized improvement opportunities following the report priority rankings. The improvement opportunities should be cooperatively developed with department leads and should be monitored on a consistent basis. Lessons learned throughout the process should be noted and shared with leadership as part of continued program development.

Compliance program assessment is a vital and valuable tool for healthcare organizations. It provides the quantifiable goals necessary to assist continual compliance program improvement. Similarly, an effective compliance program is key to ensuring an organization is positioned to address issues. Misconduct and compliance concerns affect the achievement of strategic goals and objectives for the organization as a whole; a solid compliance program is a healthcare organization's best and strongest opportunity to prevent them before they manifest—assessment helps ensure compliance programs not only exist but are also effective in achieving those organizational goals.

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practice administration, internal audit, quality outcomes, and healthcare advocacy. A former corporate compliance officer and clinical department director, she has a demonstrated record of success in program development and expansion, as well as the ability to form mutually beneficial relationships. Susan is a hands-on manager and decisive team leader with highly developed negotiation skills and experience cultivating strategic healthcare business partnerships, recruiting physicians and other healthcare professionals, directing teams, developing performance improvement measures, and creating effective training programs.

2 USSG § 8 (U.S. Sentencing Comm’n 2018).

3 Shelby Livingston, “Feds Amassed \$2.6 billion from 2019 Healthcare Fraud Cases,” *Modern Healthcare*, January 9, 2020, <https://www.modernhealthcare.com/legal/feds-amassed-26-billion-2019-healthcare-fraud-cases>.

4 U.S. Department of Justice Criminal Division, *Evaluation of Corporate Compliance Programs* (updated June 2020), <https://www.justice.gov/criminal-fraud/page/file/937501/download>.

5 Publication of the OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8,987 (Feb. 23, 1998) .

6 “Compliance Guidance,” U.S. Department of Health & Human Services Office of Inspector General, accessed February 17, 2021, <https://oig.hhs.gov/compliance/compliance-guidance/index.asp>.

7 USSG § 8 (U.S. Sentencing Comm’n 2018).

8 U.S. Dep’t of Justice Criminal Div., *Evaluation of Corporate Compliance Programs*.

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