Complete Healthcare Compliance Manual
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]

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