Implementing a Core Set of Compliance Policies and Procedures

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Introduction

A focus group of Health Care Compliance Association (HCCA) and Association of Healthcare Internal Auditors (AHIA) members has been meeting throughout the past ten months to explore opportunities to better define and explain auditing and monitoring, clarify the roles of compliance and internal audit functions as they address issues within their healthcare organizations, and develop guidance and reference materials on key aspects of health care auditing and monitoring processes. The *Seven Component Framework developed* by the HCCA/AHIA focus group for compliance auditing and monitoring is comprised of the following activities:

1. Perform a risk assessment and determine the level of risk
2. Understand laws and regulations
3. Obtain and/or establish policies for specific issues and areas
4. Educate on the policies and procedures and communicate awareness
5. Monitor compliance with laws, regulations, and policies
6. Audit the highest risk areas
7. Re-educate staff on regulations and issues identified in the audit

This article provides guidance on implementing a core set of compliance policies and procedures. This is the sixth in a series of articles prepared by the HCCA/AHIA auditing and monitoring focus group.

Implementing a Core Set of Compliance Policies and Procedures

The requirement to establish written policies and procedures is listed as the first element of the seven elements of an effective compliance program identified by the Department of Health and Human Services Office of Inspector General (OIG). This fact demonstrates the importance of healthcare organizations having written compliance policies and procedures to serve as a guide for establishing and maintaining an effective compliance program.

The policies and procedures developed by an organization should address its principal risks, clarify the purpose of the compliance program, establish internal standards for compliance with laws and regulations, aid in the communication of organizational values and expectations regarding employee behavior, and facilitate employees' understanding of the consequences of non-compliance, for both the organization and the individual.[1]

This article focuses on the following steps necessary to implement a core set of compliance policies and procedures:

1. Determining those policies and procedures most relevant to your organization.
2. Identifying the various types of compliance policies and procedures.

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[1] HCCA Evaluating and Improving a Compliance Program, April 4, 2004 (Page 11)

3. Establishing the role of the Compliance Officer related to the Implementation of compliance policies and procedures.
4. Implementing a process for ongoing communication and updating of compliance policies and procedures.

Determining Those Policies and Procedures Most Relevant to Your Organization

In preparing to develop your organization's compliance policies and procedures, it is important to establish some "ground rules" to aid in consistent and effective communication of those policies and procedures.

- First, establish a standard format in which all policies and procedures will be written. Having a standard will provide consistency in how the policies and procedures look and allow employees to readily recognize them as relevant to compliance.
- Second, it is important to establish a controlled revision process for all policies and procedures, including maintaining a history of changes made over time. A crucial part of this revision process is to ensure the policies and procedures are reviewed and approved by all relevant parties before being communicated to the entire organization.
- Third, ensure the policies and procedures are readily available to employees, management, and the Board for quick reference/clarification. Having these policies and procedures in a location and format that is easy for employees to find and read increases the likelihood that they will have an adequate understanding of them.

An organization should develop policies and procedures which are designed to address its principal business risks. This is facilitated by the organization periodically assessing its risks to identify and prioritize its greatest risk areas. Tips on how to conduct a compliance risk assessment can be found in the article titled "Performing a Compliance Risk Assessment" published in the November 2004 issue of Compliance Today. The risk assessment should take into consideration issues identified in the OIG Work Plan, recent enforcement actions by the OIG and other government agencies, as well as any significant internal control weaknesses which have been previously identified within the organization.[2]

In developing its core set of compliance policies and procedures, an organization should include policies and procedures that describe the purpose, function, and authority of its compliance program. Start by reviewing the objectives, rights, and authorities that have been outlined in your organization's compliance charter and the job description of your Corporate Compliance Officer. Additionally, review the established Code of Conduct and those processes in place to promptly identify and remedy instances of non-compliance to ensure that the organization's policies and procedures address the seven elements of an effective compliance program as defined by the OIG.

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[2] HCCA Evaluating and Improving a Compliance Program, April 4, 2004 (Page 11)

Identifying the Various Types of Compliance Policies and Procedures[3]

Establishing an effective compliance program does not require the development of hundreds or even dozens of policies and procedures. Most compliance programs include policies and procedures that fall into the following categories:

- Policies relating to the operation of the compliance program (CP) – These policies are typically focused on "operationalizing" the compliance program. Policies may include information regarding the compliance program itself, the reporting mechanisms that have been established, expectations regarding employee conduct related to various compliance issues, and corrective/disciplinary actions for violations of the code of conduct.
- Policies addressing the organization's significant compliance-related risks (CR) – Healthcare organizations face compliance risks related to numerous and complex regulations. The policies to address these risks may vary based on the type or specialty of an organization.

Below is a representative list of the types of policies and procedures that most healthcare organizations should consider including as part of its core set of compliance policies and procedures:

Category	Policy & Procedure Description	Category	Policy & Procedure Description
CP	Code of Conduct	CR	HIPAA Privacy Program
CP	Compliance Education/Training	CR	HIPAA Security Program
CP	Conflict of Interest	CR	Inpatient Transfers Between Related Facilities
CP	Corporate Compliance Program	CR	Licensure and Certification
CP	Compliance / Ethics Hotline	CR	Medical Necessity and Advance Beneficiary Notice (ABN)
CP	Government Investigations	CR	Patient Rights
CP	Internal Investigations	CR	Physician Financial Arrangements
CR	Accepting/Offering Gifts	CR	Physician Recruiting
CR	Charity Care	CR	Records Management
CR	Coding of Evaluation and Monitoring Charges	CR	Research Study/Grant Compliance
CR	Coding of Medical Records	CR	Resident Medical Education
CR	Corrective Action – Patient Billing and Human Resources	CR	Responding to Subpoenas / Search Warrants
CR	Discounting of Services	CR	Sanction Screening of Excluded Parties

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[3] HCCA Evaluating and Improving a Compliance Program, April 4, 2004 (Page 10)

Category	Policy & Procedure Description	Category	Policy & Procedure Description
CR	Employee Use of Electronic Communications	CR	Self-Reporting of Violations of Laws/Regulations
CR	EMTALA	CR	Vendor Relations

Establishing the Role of the Compliance Officer Related to the Implementation of Compliance Policies and Procedures

The Compliance Officer serves as the focal point for compliance activities and is responsible for oversight of the development, implementation, and daily operation of the compliance program and any related policies and procedures. The Compliance Officer is also responsible for identifying those compliance policies and procedures which are required for the organization.

The Compliance Officer works in conjunction with organizational management and its Board to ensure the compliance policies and procedures currently in place or under development:

- are in agreement with existing processes,
- satisfy all legal and regulatory requirements,
- reflect the focus of the organization's compliance program,
- can be reasonably implemented and followed, and
- are periodically reviewed to identify those in need of updating. [4]

Additionally, the Compliance Officer should monitor corrective actions and disciplinary measures taken to ensure that they are effectively and consistently applied. It is essential that appropriate action is taken and documented when there are instances of non-compliance with policies and procedures.

Implementing a Process for Ongoing Communication and Updating of Compliance Policies and Procedures

The specific policies and procedures necessary to establish and maintain an effective compliance program vary widely from one organization to the next. Yet, all programs should include the same basic principles of commitment of organizational management at the highest levels, an established collection of processes designed to provide adequate internal controls, and regularly conducting a self-assessment of the organization's existing program. A byproduct of doing so is that these organizations are often better able to prevent, detect, and correct problems. Organizations which have a culture that promotes and embraces compliance are more likely to have effective compliance programs. [5]

A vital step in successfully implementing a core set of compliance policies and procedures is to effectively communicate them to all employees and other relevant parties. Effective communication and awareness activities include publishing and distributing the policies and procedures as well as providing adequate education and training to facilitate an effective understanding.

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[4] HCCA Evaluating and Improving a Compliance Program, April 4, 2004 (Page 12)

[5] OIG Supplemental Program Compliance Guidance for Hospitals, January 2005 (Page 67)

An important aspect of implementing a core set of compliance policies and procedures in an organization is to establish a protocol for periodically reviewing and updating them to ensure they are accurate and relevant in light of any changes in laws, regulations, or internal processes. This may be accomplished by conducting a self-review of the established compliance policies and procedures within an organization at least every three years and comparing them to the OIG's seven elements of an effective compliance program. Some organizations may gain additional benefits by having an external party assess the entire compliance program, including a review of any established policies and procedures.

About the HCCA/AHIA Auditing and Monitoring Focus Group

The HCCA/AHIA auditing and monitoring focus group will be developing the final article regarding the seven components to expand on the roles of compliance and internal audit functions, provide detailed "how to steps", and discuss the essential coordination links between compliance, internal audit, legal, and management that are necessary for each component. This final article will address compliance education/awareness tools and techniques.

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