

Complete Healthcare Compliance Manual

Introduction to Healthcare Compliance Program Fundamentals

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Effective compliance programs are instrumental to successfully run healthcare organizations that engage their workforce and implement ethical systems that contribute and provide patient care and services consistent with healthcare laws, rules, and regulations. The ever-changing regulatory landscape can be daunting. Running the daily operations of an effective program isn't easy. However, certain basic elements provide a guide to running an effective compliance program and, if monitored and implemented properly, make the job easier and help guide the organization out of harm's way.

What are the benefits of having an effective compliance program and the risks of not having one? This chapter explains those benefits and risks, and it details the by-now-familiar seven elements that apply to every compliance program. These elements are based on the seven steps outlined in the Federal Sentencing Guidelines issued by the United States Sentencing Commission (USSC). Every effective compliance program should begin with a formal commitment by the governing body/board to these elements. The seven elements drive an organization's operation and require tailoring to its unique circumstances to ensure that processes are efficient and effective. This chapter also provides a background on government programs and what expectations regulatory enforcement groups have set forth for effective programs, such as the United States Sentencing Commission (USSC), U.S. Department of Health & Human Services (HHS) Office of Inspector General (OIG), Department of Justice (DOJ), and the Centers for Medicare & Medicaid Services (CMS), among others.

The compliance profession has evolved and matured over the last 30 years, and much has been learned. This manual provides an overview of the major concepts as a useful refresher for veterans as well as a helpful go-to guide for newcomers. The following sources of information can be consulted on background, regulatory requirements, and reasons for voluntary and mandatory compliance programs. Keep these sources and concepts in mind when updating and maintaining a compliance program.

Benefits of a Compliance Program

On a very basic level, a compliance program is about prevention, detection, correction, collaboration, and enforcement. It is a system of policies, procedures, and processes developed and implemented to assure compliance with and conformity to all applicable federal and state laws and regulations governing a healthcare organization. An effective compliance program is not a quick fix to the latest hot problem nor a project that would ever be completed—it must be an ongoing process and part of the fabric of an organization, a commitment to an ethical way of conducting business, and a values-based system for doing the right thing. The compliance program relies on the participation of everyone at a healthcare organization.

There are many benefits to having a compliance program at an organization. The HHS OIG specifically addresses these benefits in all its program guidance documents. First and foremost, an effective compliance program safeguards an organization's legal responsibility to abide by applicable laws and regulations. Other important potential benefits identified by the OIG include the ability to:

- Demonstrate to employees and the community the organization's commitment to good corporate conduct.
- Identify and prevent criminal and unethical conduct.
- Improve the quality of patient care.
- Create a centralized source of information on healthcare regulations.
- Develop a mechanism for reporting.
- Develop procedures that allow the prompt and thorough investigation of alleged misconduct.
- Initiate immediate and appropriate corrective action.
- Reduce the organization's exposure to civil damages and penalties, criminal sanctions, and administrative remedies such as program exclusion.

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