

## HCCA Compliance 101, 4th Edition

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### 1 What's in a Name?

You may have noticed that some organizations have **compliance** programs, and others have ethics/integrity programs. They are often considered synonymous, but a subtle distinction can be made between the two terms. It is generally thought that the title “compliance program” implies a primary concern with following rules and regulations, whereas the title “integrity program” puts the emphasis on values and doing the right thing. There may be differences in approach and subtleties of content, but there are basic elements common to both compliance and integrity/ethics programs. Those common elements, whatever the title of the program, are the focus of this book, although for convenience sake the term “compliance program” will be used throughout. Each organization must choose a title—or perhaps create an entirely new title—depending on its needs and culture.

You may not be aware of it, but there are probably many compliance activities already occurring in your organization. Things like employment and labor laws, the **Equal Employment Opportunity Commission (EEOC)** and **Employee Retirement Income Security Act (ERISA)** regulations, **Department of Labor** wage and hour rules, **Occupational Safety and Health Administration (OSHA)**, Nuclear Regulatory Commission requirements, **Joint Commission** survey preparation, American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF)—these are all compliance-related activities. Increasingly, too, other areas have come under close compliance scrutiny, such as academic research. Departments coordinating such research activities in your organization should have a compliance-related process dedicated to risks associated with research. This could be a stand-alone compliance program or could be a part of the corporate compliance program.

### What is a Compliance Program?

There are many definitions of a compliance program. On a very basic level, it is about prevention, detection, collaboration, and enforcement. It is a system of policies, procedures and processes developed to assure compliance with and conformity to all applicable federal and state laws governing the organization. A compliance program should never be just a piece of paper or a binder on a shelf; it is not a quick fix to the latest hot problem; it should not be hollow words. A compliance program—an effective compliance program—must be an ongoing process, a part of the fabric of the organization, a commitment to an ethical way of conducting business, and a values based system for doing the right thing.

### Who Needs a Compliance Program?

- Physician Organizations
- Managed Care Organizations
- Ambulance or Transportation Suppliers
- Third Party Billing Companies
- Pharmaceutical Manufacturers
- Hospitals/Academic Medical Centers
- Laboratories
- Research Organizations

- DME Distributors
- Home Health Agencies/Hospices/Skilled Nursing Facilities
- Behavioral Health Organizations
- Accountable Care Organizations (ACOs)
- Ambulance Providers
- Others

So, why do we need yet another program on compliance? Perhaps a little historical perspective is in order. In the 1970s and early 1980s, the Department of Defense was paying exorbitantly high prices for supplies. You may remember the news stories (and the late-night talk show jokes) about \$200 hammers and \$500 toilet seats. June Gibbs Brown was the **Inspector General (IG)** for the Defense Department at that time. Under her influence, the defense industry suppliers developed voluntary self-regulatory guidelines, called the Defense Industry Initiative, designed to help eliminate waste and bring prices into line. (See the website at [www.dii.org](http://www.dii.org).) In the early 1990s, the **Department of Health and Human Services (HHS)** IG started a similar process for our industry.

The HHS Office of the Inspector General (**OIG**) in conjunction with the Justice Department is responsible for enforcing the rules and regulations under the Medicare and Medicaid laws outlined as part of the Social Security Act and administered by the **Centers for Medicare and Medicaid Services (CMS)**. Starting in 2003, the maximum amount available to OIG for its Health Care Fraud and Abuse Control (HCFAC) Account for Medicare and Medicaid related fraud, waste, and abuse activities was capped at \$160 million. Later laws allowed that cap to grow each year based on the change in the consumer price index. In FY 2015, the HHS Secretary and the Attorney General certified \$279.7 million in mandatory funding to the Account. In addition, Congress gives funds directly to HHS for fraud enforcement efforts. In 2015, Congress appropriated \$672 million. The government estimates that the extent of health care fraud has amounted to more than tens of billion of dollars annually. In the Justice Department, health care fraud is a key priority. With health care fraud such a major priority for the government, the stakes are high.

The OIG specifically addresses the benefits of a compliance program in all its program guidances. First and foremost, of course, an effective compliance program safeguards the 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 health care regulations
- Develop a mechanism for reporting
- Develop procedures that allow the prompt, 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.

While the cost and the time involved may seem daunting, the cost of not having a compliance program could be much more substantial. An OIG official has allegedly been quoted as saying that you can pay on the front end, or you can pay on the back end. Compliance is not cheap! "While it may require significant additional resources or reallocation of existing resources to implement an effective compliance program," the OIG believes "the long-

term benefits of implementing the program outweigh the costs.”<sup>[1]</sup> An effective compliance program is a sound investment.

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