

Compliance 101

*How to build and maintain
an effective compliance
and ethics program*

BY

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Introduction

What's in A Name?

You may have noticed that some organizations have compliance programs, others have integrity or ethics 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 or ethics 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 pick 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. In the United States, regulations such as employment and labor laws, wage and hour rules, OSHA, Nuclear Regulatory Commission requirements are all compliance-related activities. Moreover, each and every industry is subject to the regulations and guidance of regulatory bodies such as the United States Sentencing Commission (USSC), Food and Drug Administration (FDA), Environmental Protection Agency (EPA), Securities and Exchange Commission (SEC), Occupational Safety and Health Administration (OSHA), Federal Com-

munication Commission (FCC), and Federal Trade Commission (FTC). Finally, all organizations must maintain compliance with contract law and the agreements that they make with suppliers, competitors, customers, and other stakeholders. Through the implementation of a formal compliance program you will be able to demonstrate to these regulatory bodies and stakeholders that your organization is committed to act in accordance with the rules set out in the industry and the arrangements to which it has agreed. Should any of your organization's employees not be acting appropriately, this will more readily be discovered and resolved through the compliance program as well.

The focus of this book is on compliance for organizations that do business in the United States. However, most principles of a sound compliance and ethics program are applicable to organizations worldwide.

What Is a Compliance Program?

There are many definitions of a compliance program. On a very basic level it is about education, definition, prevention, detection, collaboration, and enforcement. It is a system of individuals, processes, and policies and procedures developed to ensure compliance with all applicable federal and state laws, industry regulations, and private contracts governing the actions of the organization. A compliance program is not merely a piece of paper or a binder on a shelf; it is not a quick fix to the latest hot problem; it is not a collection of hollow words. A compliance program—an *effective* compliance program—must be a living, ongoing process that is part of the fabric of the organization. A compliance program must be a commitment to an ethical way of conducting business and a system for helping individuals to do the right thing.

Who Needs a Compliance Program

- Private Businesses
- Publicly Traded Companies
- Foundations and other Non-Profit Organizations
- Government Agencies
- Schools
- Others

So, why do we need yet another formal program—this time on compliance? Perhaps a little historical perspective is in order. In the 1970s and early 1980s the U.S. 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 www.dii.org.)

The U.S. government 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 government 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
- Create a centralized source of information on industry regulations
- Develop a methodology that encourages employees to report potential problems
- 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 higher. A U.S. 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 government believes “the long-term benefits of implementing the program outweigh the costs.”¹ An effective compliance program is a sound investment.

Why Compliance Programs are Essential

- To reduce risk of probation and court-imposed programs
- To reduce imposition of government-designed programs
- To reduce risk of exclusion from governmental programs
- To reduce the threat of whistleblower or *qui tam* law suits
- To reduce the imposition of fines and sentences.

Top 10 List of Reasons to Implement a Compliance Program

1. Adopting a compliance program concretely demonstrates to the community at large that an organization has a strong commitment to honesty and responsible corporate citizenship.

One of the company’s greatest assets is its reputation and, once damaged, one of the most difficult to repair. An effective compliance program can both preserve and enhance an entity’s reputation by preventing fraud and abuse and/or by discovering inappropriate actions early and resolving them in a timely and proper manner.

2. Compliance programs reinforce employees’ innate sense of right and wrong.

People have an inherent sense of fair play and want a means to respond to conduct they perceive at a gut-level as wrong. A call to the hotline or a review of the compliance manual not only addresses this need but may identify issues that raise both ethical and legal concerns. By providing employees with ways to express concerns to management and to see a positive response, providers strengthen the relationship of trust with their employees.

3. An effective compliance program helps an organization fulfill its legal duty to government and other private business associates and partners.

By submitting a claim for reimbursement for an item or service, the organization affirmatively represents that the claim is truthful and the services were provided consistent with program requirements. By entering into a

contract, the organization affirmatively represents that the arrangement created, services provided, and compensation arranged are within legal parameters. As an integral part of the compliance program, internal monitoring of the claims development process helps ensure the accuracy of the organization's submissions.

4. Compliance programs are cost-effective.

Although an effective compliance program requires a commitment of significant resources, those expenditures are insignificant in comparison to the disruption and expense of defending against a fraud investigation. Moreover, the increased communication and monitoring of operations and financials, which results from compliance activities, can create efficiencies and more streamlined processes.

5. A compliance program provides a more accurate view of employee and contractor behavior relating to fraud and abuse.

An effective compliance program provides ongoing training of employees and contractors, monitors their understanding and compliance with program rules, and provides the mechanisms to discipline those individuals who violate the company's code of conduct. It is through these vehicles that a provider can have reasonable assurances that it is acting in conformance with applicable rules.

6. The quality of care provided to clients is enhanced by an effective compliance program.

As part of a comprehensive compliance program, a code of conduct sets forth the company's vision of itself as a company providing an item or service of value. This vision statement and its implementation through training of employees, continued self-assessment, and prompt response to identified deficiencies enhances the provider's ability to deliver products or services of the highest quality.

7. A compliance program provides procedures to promptly correct misconduct.

A comprehensive compliance program provides established procedures for promptly and efficiently responding to problems that may arise. Through

early detection and reporting, a company can minimize the loss to the government from false claims, the penalties and sanctions imposed by the SEC and other regulatory bodies, and/or the fines and repercussions of violating contracts. Thereby, companies can reduce their exposure to civil damages and penalties, and criminal and administrative sanctions.

8. An effective compliance program may mitigate any sanction imposed by the government.

Even those companies that implement compliance programs may engage in conduct that violates applicable statutes and regulations. The Organizational Sentencing Guidelines of the U.S. Sentencing Commission provide for a reduction in criminal fines in cases where the organization has an effective program to prevent and detect violations of the law. Government agents place substantial weight on the existence of an effective compliance program that predates the government's investigation. Furthermore, government investigators tend to give more leniency to individuals and entities who prove to be forthcoming with requested information, communicative and cooperative with the investigation, and proactive with regard to implementing corrective actions—each of which occur more readily with an established compliance program.

9. Voluntarily implementing a compliance program is preferable to waiting for the government to impose a corporate integrity agreement.

Where a company seeks to resolve its liability for the submission of false claims or other violations of government requirements, the government must decide whether the company or individual should be excluded from participating in federal programs. Generally, the government will agree to waive its exclusion authority only if the company or individual has in place measures that will ensure the abuses will not recur. If the organization does not have an effective compliance program in place, the government will require a program that is enforceable under the terms of a mandatory corporate integrity agreement. An integrity agreement has detailed policy, training, audit, and reporting requirements that are typically in force for three to five years and involve substantial oversight of the organization by the government.

10. Effective corporate compliance programs may protect corporate directors from personal liability.

The fiduciary duties of corporate directors require that they keep themselves adequately informed concerning the operations and finances of the company. An effective compliance program designed to assure compliance with applicable legal requirements has been recognized as meeting this duty of care.

Avoidance of penalties and fines should be a major incentive for organizations to implement a compliance program. Should the government find an organization is guilty of fraud and abuse, the penalties can be severe. The financial implications due to loss of business can be profound.

Without a compliance program in place, there is also increased threat of *qui tam* lawsuits. It is the False Claims Act (FCA) that empowers the U.S. government to investigate and bring civil action in fraud cases. The FCA, implemented during the Civil War to control war-time price gouging, also allows private citizens to bring civil actions against an organization in the name of the United States. The act provides significant financial incentives for private citizens to come forward. Such actions are called *qui tam* suits. *Qui tam* is a whistleblower. The term is abbreviated from the Latin phrase "*Qui tam pro domino rege quam pro se ipso in hac parte sequitur*" or "he who brings the action for the king as well as for himself." In fraud and abuse actions, the whistleblower can be eligible to receive anywhere from 15 percent to 25 percent of the settlement. Unfortunately, such actions are not rare. In 2003 there were 326 *qui tam* suits filed, about 20 percent of which the government joined. Also in 2003 civil fraud recoveries totaled \$2.1 billion, which is a 75 percent increase over the prior year's recoveries (\$1.1 billion) and brings total recoveries to over \$12 billion since Congress substantially strengthened the civil False Claims Act in 1986. The HCA, Inc. recovery alone was \$641 million. A whistleblower portion of a 15 percent fee would have amounted to approximately \$96 million. And the government has no requirements or expectations about a whistleblower informing or approaching the organization first, creating a "*qui tam* paradox." The government promotes an environment of trust where problems are brought forward and resolved; yet whistleblowers are rewarded whether they have tried to solve the problem internally or not. It is not out of the realm of possibility for an organization to hear about an issue for the first time directly from the government.

The government also can impose a corporate integrity agreement (CIA) against the organization. In order to avoid lengthy and expensive litigation, an organization that negotiates a CIA with the government admits no fault or liability but does submit itself to a government plan for correction action. Government-imposed CIAs have been onerous in the past—and there is every reason to think they will become more onerous in the future. CIAs have usually had a three- to five-year duration, and some are being extended to eight or 10 years. Furthermore, follow-up for CIAs is becoming more severe with more unannounced audits. Moreover, reporting requirements can be extensive. In some cases a government-appointed monitor is put in charge of the organization's compliance program. On the other hand, and an expensive alternative, the government may require the organization to retain the services of an independent review organization (IRO), usually a consulting or accounting firm, to monitor the compliance program.

An organization found guilty of fraud is also subject to fines. In 1984 the U.S. Congress enacted the Sentencing Reform Act of 1984, which was designed to correct inequities in federal sentences. This legislation includes the *Federal Sentencing Guidelines*, which includes guidance for assessing fines and detailed methods for calculation of a “culpability score.” There are four aggravating factors to a culpability score:

- If an upper-level employee has “participated in, condoned or was willfully ignorant of the offense”
- If the violation is a repeat offense
- If the government was hindered during its investigation
- If awareness of and tolerance of the violation were pervasive

There are also four mitigating factors:

- If the organization had a compliance program in effect, even though there was a violation
- If the organization reported the violation promptly
- If the organization cooperated with the government investigators
- If the organization accepted responsibility for the violation

These factors can have a profound effect on the amount of a fine. They also provide insight into the government approach to compliance programs.

Although a “one size fits all” compliance program does not exist, the government outlines seven basic compliance elements that can be tailored to fit the needs and financial realities of any given organization. The government believes that every effective compliance program begins with a formal commitment to these seven basic elements, based on and expanding upon the seven steps of the federal sentencing guidelines. The seven basic compliance program elements are:

1. Written standards of conduct and policies and procedures
2. Designation of a chief compliance officer and other appropriate bodies
3. Effective education and training
4. Audits and evaluation techniques to monitor compliance
5. Establishment of reporting processes and procedures for complaints
6. Appropriate disciplinary mechanisms
7. Investigation and remediation of systemic problems

The guidelines should be distributed, read, and studied carefully by all employees of an organization, as they make up the backbone of a good compliance program.

Summary of Compliance Program Benefits

- Preventing false or inaccurate claims from being submitted to the government and/or private companies
- Preventing false or inaccurate financial statements from being generated and published
- Fulfilling the fundamental mission of the organization through ethical business conduct and business efficiency
- Improving the quality of services provided

- Demonstrating to employees and the community the organization's strong commitment to honest and responsible conduct
- Providing a more accurate view of employee and contractor behavior related to fraud and abuse
- Improving the operational efficiency of the billing and reporting process
- Improving overall communication between and within departments
- Identifying and preventing inappropriate and unethical conduct
- Improving financial performance
- Creating a centralized source for distributing information on laws, statutes, regulations, and other directives related to fraud and abuse and other related issues
- Encouraging employees to report potential fraud
- Allowing for thorough investigations of suspected inappropriate actions
- Providing an "early warning" system for identifying problems
- Minimizing an organization's exposure to various civil and criminal damages and penalties
- Minimizing an organization's exposure to *qui tam* or whistleblower suits or other actions of frustrated or disgruntled employees.