

HCCA Compliance 101, Fifth Edition

Chapter 1. Compliance Programs: History and Benefits

Many rules and regulations, along with their enforcement, have shaped compliance programs over the years. Regulations and compliance challenges often emerge as a response to different events going on in the nation, such as the COVID-19 pandemic that began in 2020.

The many compliance challenges throughout 2020 and 2021 included: primary healthcare providers driven to use different or enhanced delivery models, such as telehealth, with their respective challenges; organizations dealing with talent management issues, such as working remotely, recruitment, and retention; supply shortages, replacement issues, price gouging, and fraud related to supplies; increased information security events; fraud schemes related to vaccines, COVID-19 testing, and remedies purported to be “cures” for the virus; privacy events; issues around security and confidentiality with remote workers; and physical and property safety issues (i.e., vacant real estate, demonstrations, and crowd control).

Over time, we have seen responses from regulators that are specific to national events. In 2001, for example, revelations of a massive accounting fraud scandal at energy giant Enron Corporation led to bankruptcy and left shareholders with worthless stock.^[1] As scandals like Enron were exposed, regulators emphasized the importance of governing authority, accountability, and transparency. The federal government enacted sweeping changes with the Sarbanes-Oxley Act of 2002 and then the focused amendment in chapter eight of the 2004 U.S. Federal Sentencing Guidelines (FSG). As these types of responses are seen, compliance programs must adapt accordingly.

Historically, some of the first regulations date back to the 1800s. The False Claims Act (FCA) was enacted in 1863 and amended several times, the latest amendment being in 2010. The act was originally passed by Congress because suppliers of goods were defrauding the Union Army during the American Civil War. The FCA imposes liability on persons and companies that defraud government programs. Its qui tam provision permits citizens unaffiliated with the government to file actions on its behalf (called “whistleblowing”), and those whistleblowers can receive up to 30% of any recovered damages. In the past several years other regulators have joined the focus on enforcement of key rules and regulations.

Events in the 1970s to early 1980s led to one of the most important pieces of government guidance for compliance programs. At that time, the U.S. Department of Defense (DOD) was paying exorbitantly high prices for supplies. News stories (and late-night talk show jokes) reported on the outrageous prices—\$435 hammers and \$640 toilet seats. June Gibbs Brown was the Inspector General for the DOD at that time. Under her influence, defense industry suppliers developed voluntary self-regulatory guidelines—the Defense Industry Initiative—designed to help eliminate waste and bring prices into line.^[2] Contract compliance currently remains a strong focus and expectation for all businesses providing services to the federal government.

The U.S. Federal Sentencing Guidelines Manual (FSG) was developed in 1991 by the United States Sentencing Commission. Chapter eight of the FSG focuses on compliance programs for organizations.^[3] It was the first time in history that government guidance was developed to cross all industries and provided the essential elements for compliance program development. The FSG has since become the basic infrastructure for the seven elements of compliance programs. These elements were also the foundation for the U.S. Department of Health & Human

Services Office of Inspector General compliance program guidance. These elements are discussed further in the chapters of this book.

Healthcare Compliance Timeline

- 1986: False Claims Act is amended.
- 1991: U.S. Federal Sentencing Guidelines Manual is amended.
- 1996: Health Insurance Portability and Accountability Act (HIPAA) passes.
- 1997: Health Care Fraud and Abuse Control Program is established.
- 1998–2008: HHS OIG issues compliance program guidance for different healthcare industry segments.^[4]
- 2015: HHS OIG issues “Practical Guidance for Health Care Governing Boards on Compliance Oversight.”^[5]
- 2017: OIG and HCCA issue “Measuring Compliance Program Effectiveness—A Resource Guide.”^[6]
- 2017, 2019, and 2020: DOJ issues and updates “Evaluation of Corporate Compliance Programs” guidance.^[7]

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