
Managing Legal Compliance in the Health Care Industry

GEORGE B. MOSELEY III, MBA, JD
Lecturer in Health Law and Management
Department of Health Policy and Management
Harvard School of Public Health
Boston, Massachusetts



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5 Wall Street
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978-443-5000
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www.jblearning.com

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Dedication

Dedicated to the education and empowerment of the students and faculty at the Oglala Lakota College in South Dakota and the Islamic University of Gaza in Palestine.



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Preface

Every organization in the country, in every industry, must obey a long list of laws. Normally, it is not enough to simply be aware of the laws and assume that every employee will follow them. Some employees will make innocent mistakes in their work procedures, resulting in a technical violation of the law. Others may not fully understand the recommended way of performing the procedures and inadvertently carry them out in an illegal manner. A few people may approach their jobs with a casual, inattentive, even reckless attitude. It is not surprising then, when violations of the law occur. In the worst-case situation, an employee deliberately commits an illegal act, for monetary gain or under pressure to meet a performance goal. Regardless of the culpability of the employee or the organization, if the responsible government agency learns of the violation, there will be consequences.

The consequences may be trivial or extremely serious. The employee may receive a verbal warning and retraining in how to perform a particular task; the organization may be required to reimburse the government agency for an overpayment that was made. At the other extreme, the employee may be dismissed, while his or her employer negotiates a multimillion dollar settlement and is excluded from participating in federal programs for a period of years. It is far preferable to prevent the mistakes and subsequent violations in the first place.

The accepted method of doing this is to establish and maintain a compliance program. Over the last two decades in the United States, a template for such programs has evolved. It is now used by thousands of organizations in nearly every sector of the economy.

The healthcare industry has a special need for compliance programs and people who can manage them. It has been the subject of a never-ending stream of new laws and regulations unlike that faced by any other industry. The government agencies responsible for the laws are constantly ramping up their enforcement efforts. This is not surprising for an economic sector that accounts for nearly one-fifth of the U.S. gross national product.

These are just a few of the headlines for healthcare fraud cases during 3 months in early 2013.

- New Jersey Doctor Sentenced to Five Months in Prison for Taking Cash Kickbacks for Medicare and Medicaid Patient Referrals
- Former Registered Nurse Sentenced in Miami to 111 Months in Prison in Connection with \$63 Million Mental Healthcare Fraud Scheme
- Florida Physician to Pay \$26.1 Million to Resolve False Claims Allegations
- Maryland's St. Joseph's Medical Center Agrees to pay \$4.9 Million for Medically Unnecessary Hospital Admissions
- Healthcare Practitioner Sentenced to Six Months in Prison, Six Months Home Detention, for Accepting Cash Kickbacks for Patient Referrals
- Major New Jersey Hospital Pays \$12.5 Million to Resolve Kickback Allegations
- EMH Regional Medical Center and North Ohio Heart Center to Pay \$4.4 Million to Resolve False Claims Act Allegations
- Florida-Based American Sleep Medicine to Pay \$15.3 Million for Improperly Billing Medicare and Other Federal Healthcare Programs
- Amgen Inc. Pleads Guilty to Federal Charge in Brooklyn and Pays \$762 Million to Resolve Criminal Liability and Civil Fraud Allegations
- Sanofi U.S. Agrees to Pay \$109 Million to Resolve False Claims Act Allegations of Free Product Kickbacks to Physicians
- Doctor and Owner of Medical Supply Company Plead Guilty in Million-Dollar Power Wheelchair Scam

The agency of the Department of Health and Human Services, responsible for enforcing laws against fraud abuse, maintains a list of its 10 Most Wanted Fugitives: <https://oig.hhs.gov/fraud/fugitives/index.asp>. In the fiscal year 2012, the US Department of Justice recovered over \$3 billion in cases of healthcare fraud.

Because of persistent dissatisfaction with the performance of the healthcare system, public and private payors, government enforcement authorities, accreditation agencies, industry and professional associations, and healthcare organizations themselves regularly launch new programs and initiatives. Accountable care organizations, balanced scorecards, evidence-based medicine, pay-for-performance, patient-centered medical homes, and bundled payments are some of the current examples.

Each imposes new laws, regulations, and program requirements that demand compliance.

The only effective way for healthcare organizations to keep up is to develop more and more sophisticated compliance programs. They must write policies and procedures to guide employee work behaviors, and back them up with education and training. They must apply disciplinary action against employees who do not follow their instructions. When misconduct occurs, the organizations must be prepared promptly to launch investigations and take corrective actions. They must appoint high-level people to manage this complex compliance infrastructure full time. As the laws change, compliance programs must be updated and expanded.

It always has been a wise business decision to adopt an effective compliance program. High-performing healthcare organizations have had them for at least 20 years. They have received strong encouragement to do so from the federal government, especially in the form of Compliance Program Guidances tailored to the unique features of different types of organizations. At the beginning, the Guidances made clear that they were voluntary. That has changed.

The healthcare reform law enacted in 2010, known officially as the Patient Protection and Affordable Care Act, has made compliance programs mandatory for healthcare organizations participating in Medicare, Medicaid, and the Children's Health Insurance Program. Because many organizations survive on the reimbursements from these programs, it is imperative that they operate compliance programs that meet the government's criteria.

Those that try to get by with inadequate compliance activities can expect to come under closer regulatory and enforcement scrutiny. There is a greater likelihood that they will be held liable for fraud, abuse, and waste. Organizations that embrace compliance will experience fewer investigations and prosecutions. If violations occur, the penalties will be less severe.

For most healthcare organizations, no time deadline has yet been set for implementation of compliance programs. The Department of Health and Human Services, with its Office of the Inspector General (OIG), has the responsibility for defining the "core elements" of the mandated compliance programs. It has not yet begun to issue the necessary regulations. The OIG rolled out the original Compliance Program Guidances over a period of years. The requirements for the new mandatory programs also are likely to come out one at a time for each type of healthcare organization, starting with the most troublesome. Some segments of the healthcare system have not yet voluntarily implemented even modest compliance programs.

Savvy organizations will not wait until firm, binding compliance guidelines have been published. When they do, they are not likely to differ substantially from the requirements in the existing Compliance Program Guidances. In those Guidances and other sources, there is an ample foundation for designing a compliance program that, with a few tweaks, will satisfy government regulators. Every healthcare organization should be developing its first compliance program or updating an existing program—now.

By themselves, healthcare organizations do not have the expertise to develop and maintain compliance programs. The initial designers and leaders of compliance programs were self-taught. Lawyers and consultants began to offer advice. Over time, a burgeoning industry has emerged to help organizations manage their compliance activities. There are compliance-oriented consulting firms, professional associations, journals and periodicals, webinars and conferences, and websites.

Several colleges and universities offer individual courses on compliance issues. At a few, it is possible to earn a graduate certificate in healthcare compliance. It is just a matter of time until associate degrees in compliance will be available. Extensive education in compliance matters is appropriate for people who one day, as chief compliance officers, will report directly to the CEO and the governing board of large organizations.

Helping healthcare organizations stay on the right side of the law has become a legitimate career path. This text is targeted at people pursuing such careers. It serves also as a comprehensive introduction to the compliance landscape for anyone who works, as a manager or employee, in healthcare organizations.

The structure of the text follows a learning progression. The starting point is to understand exactly what requirements must be complied with. Section I explains the primary laws that healthcare organizations must obey. Many of them are unique to the healthcare field. The organizations manage their compliance through complex, multifaceted compliance programs. Section II describes each of the components in the program recommended by the federal government. The specific terms of a compliance program will differ slightly for each type of healthcare organization. Section III covers all of the organization types that are the subject of a federal Compliance Program Guidance. Together, they encompass most of the U.S. healthcare system.

I wish the professionals and students who read this text, with the coaching of their instructors and mentors, great success in their careers as compliance officers and managers in the healthcare industry.