Contents

About the Authors........................................................................................................................................... vii

Introduction..................................................................................................................................................... ix

The Challenges of Compliance ................................................................................................................ ix

How to Use this Book ................................................................................................................................... x

Chapter 1: History and Evolution of Compliance ......................................................................................... 1

The History of Compliance ........................................................................................................................ 1

Why Is Compliance Important? .................................................................................................................. 5

Policies and Procedures............................................................................................................................... 6

Compliance Beyond Medicare Fraud ......................................................................................................... 7

Who Polices Corporate Compliance? .......................................................................................................... 8

High-Risk Practices ....................................................................................................................................... 9

Steps Toward Compliance .......................................................................................................................... 10

Chapter 2: OIG Guidance for Compliance Programs .................................................................................. 13

Compliance Program Guidance for Hospitals .......................................................................................... 13

Compliance Program Guidance for Other Healthcare Sectors ................................................................. 13

The OIG’s Risk Areas ..................................................................................................................................... 15

Voluntary Disclosure ..................................................................................................................................... 17

What Policies and Procedures Should Include .......................................................................................... 18

Outpatient Services ....................................................................................................................................... 19

Submission of Claims for Laboratory Services ........................................................................................ 20

Physicians at Teaching Hospitals ............................................................................................................... 21

Cost Reports .................................................................................................................................................. 21

Medical Necessity—Reasonable and Necessary Services .......................................................................... 22

Anti-Kickback and Self-Referral Concerns ................................................................................................. 22

Bad Debts ....................................................................................................................................................... 23

Credit Balances ............................................................................................................................................ 23

Retention of Records .................................................................................................................................... 23

Understanding the OIG’s Priorities ............................................................................................................. 24

Compliance as an Element of a Performance Plan ................................................................................... 24

Establishing a Compliance Officer and Committee ................................................................................. 25

Developing Lines of Communication ....................................................................................................... 27

Disciplinary Guidelines .............................................................................................................................. 27
Chapter 3: Key Regulations for Compliance .......................................................... 29
  U.S. Sentencing Guidelines Overview ............................................................. 29
  Recovery Audit Contractor Permanent Program ........................................... 31
  False Claims Act Defined ............................................................................... 31
  Medicaid Fraud Enforcement ......................................................................... 32
  Overview of Sarbanes-Oxley ......................................................................... 33
  HIPAA Privacy Rule ....................................................................................... 35
  Health Care Fraud Statute ............................................................................ 36
  Anti-Kickback Statute .................................................................................... 36
  Stark Law ........................................................................................................ 38
  Fair Market Value .......................................................................................... 39
  The Emergency Medical Treatment and Active Labor Act of 1986 ............ 42
  The Medicare Program ................................................................................ 42
  ACOs and Fraud and Abuse Laws ................................................................. 45

Chapter 4: Privacy and Security ........................................................................ 47
  What Is Considered PHI? ............................................................................... 47
  To What Entities or Persons Does HIPAA Apply? ......................................... 48
  How Do the HIPAA Regulations Apply to Contractors and Subcontractors? 48
  Mechanism to Ensure Business Associate Compliance ............................. 49
  The Privacy Rule ........................................................................................... 49
  The Security Rule .......................................................................................... 54
  Breach Notification ....................................................................................... 56
  Penalties and enforcement ............................................................................ 57
  Conclusion ...................................................................................................... 58
  Endnotes .......................................................................................................... 58

Chapter 5: Fair Market Value and Commercial Reasonableness ...................... 59
  Fair Market Value Defined ............................................................................ 59
  Commercial Reasonableness Defined .......................................................... 60
  Why Are Fair Market Value and Commercial Reasonableness Important? 61
  Monitoring of Compensation Arrangements .............................................. 62
  Approaches to Documenting Fair Market Value ......................................... 63
  Conclusion ...................................................................................................... 67

Chapter 6: Internal Strategies for Best Practices ............................................. 69
  Quality-of-Care Issues ................................................................................... 69
  Compliance Leaders and Quality of Care .................................................... 70
  How Compliance Officers Can Help Mend the Quality Crisis .................... 72
  Corporate Compliance for Board Members ................................................. 76
  Hotline Calls ................................................................................................ 76
  Whistleblowers ............................................................................................. 80
Chapter 7: The Risk Assessment ................................................................. 83
  The Importance of Risk Assessments....................................................... 84
  The Role of Risk Management................................................................. 84
  Government Focus on Risk Management................................................. 87
  Risk Management and Compliance Working Together............................ 88
  Identifying Risks .................................................................................... 88
  Beyond the Basics of Identifying High-Risk Activities ............................... 90
  Interviews and Questionnaire................................................................ 92
  Six Approaches to Managing Risk .......................................................... 93

Chapter 8: Training Strategies ................................................................. 95
  Scope of Training ................................................................................... 95
  Who Should Be Trained? ......................................................................... 97
  Frequency and Timing of Training ........................................................ 97
  Training Development ........................................................................... 100
  General Compliance Training ............................................................... 101
  Training Evaluation .............................................................................. 102

Chapter 9: Monitoring and Auditing ......................................................... 105
  Understanding the Purposes of Monitoring and Auditing ......................... 105
  Determining the Overall Audit Plan ....................................................... 107
  Types of Audits ...................................................................................... 108
  Internal or External? ............................................................................. 109
  Universes and Sample Selection ........................................................... 110
  Legal Considerations ............................................................................ 111
  Data Collection and Analysis for Different Audit Types ............................ 112
  Audit Report Outline ............................................................................. 116
  Audit Life Cycle Tips ............................................................................ 117
  Monitoring Tools ................................................................................... 117

Chapter 10: Effective Internal Investigations .............................................. 119
  Before the Investigation Begins ............................................................ 119
  Triggers for an Internal Investigation .................................................... 120
  Employee Complaints ........................................................................... 121
  Internal Audits and Surveys ................................................................... 122
  Civil Suits and Qui Tam Relator Actions ................................................ 122
  Subpoenas and Search Warrants .......................................................... 123
  Preserving Attorney-Client Privilege and Work-Product Protection ............ 123
  Conducting Employee Interviews ......................................................... 125
  Avoiding Civil Liability ........................................................................ 126
  Disclosure of Overpayments .................................................................. 126
  Advantages and Disadvantages of Voluntary Disclosure .......................... 129

Important Compliance Terminology ....................................................... 133
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Introduction

Our primary goal in creating this edition of The Compliance Officer's Handbook is to provide novice and experienced compliance officers with a trusted guide to the intricacies of health care compliance. In this book you’ll find the detailed explanations, practice tools, and advice that will help you educate your organization about the importance of compliance, and assist you in effectively managing real compliance issues. Healthcare compliance touches every facet of the operation of a healthcare organization. Therefore, the more prepared you are in understanding these issues, the better you can serve your organization.

Above all, this book is meant to assist you and your organization in meeting compliance challenges and implementing an effective compliance program, while providing you with a practical approach to your role as a compliance officer.

The Challenges of Compliance

Compliance is challenging for individuals and organizations alike largely because the topic is extremely expansive. Imagine, in healthcare organizations issues concerning insurance, health information, accreditation, practitioner licensing, fraud and abuse, and reimbursement are only the tip of the iceberg. Often, healthcare organizations are dealing with real estate issues, complex technologies, and at the same time working towards being an active participant in the communities they serve.

The Federal regulations touching each of these issues are increasingly complex and exhaustive for organizations. The role of the compliance officer is to assist in implementing a program in which healthcare organizations can still reach their goals and broaden their services to the community, all while following the necessary rules and regulations to make that organization successful.

On a more individual level, working in compliance is considerably challenging because of the expansive operations that exist within organizations. As mentioned above, healthcare organizations have multiple participants and issues of concern on more local levels. For example, the goals of practitioners such as physicians, nurse practitioners, and physician assistants may not align with the goals of Federal regulations. Executives are often concerned with strategy for the organization as a whole while the legal staff may be concerned with individual legal issues that arise. However, each of these participants are required to remain compliant given these different goals or at the very least, procedures to reach those goals.

The compliance officer or the compliance staff is the person or group that assists in this alignment. The primary goal should be to create a compliant organization; however with competing goals and methods
of reaching those goals it can be tough to manage this process on your own. Therefore, the organization itself is required to take responsibility for maintaining effective compliance programs.

The managers need to ensure their individual departments are being compliant. Practitioners need to ensure they can properly function while maintaining compliance. And executives need to be able to develop strategy with compliance in mind. The compliance staff is the group that acts as the traffic light. The staff can properly educate the various drivers of the rules. The staff can reprimand those that do not follow the rules. However, ultimately those individuals need to take action on their own to remain compliant. This is the primary challenge for compliance officers and compliance staff.

How to Use this Book

Compliance as an organizational component has been an increasing result over the past twenty years largely due to the extensive and complicated Federal regulations in the healthcare industry. These complex regulations create exposure for large healthcare delivery systems and small provider practices alike. Knowing this, this book is broken down into the essential topics to make you a more effective member of your organization and to allow your compliance program to be organized and implemented in an effective manner. The book is organized as follows:

Chapter 1: History and Evolution of Compliance

In this chapter, you will more fully understand the history of compliance and how compliance has become a necessary tool for both the government and internally within organizations.

Chapter 2: OIG Guidance for Compliance Programs

The Office of Inspector General provides valuable information related to the proper operation and development of compliance programs. This chapter addresses those materials.

Chapter 3: Key Regulations for Compliance

Compliance officers deal with key laws and regulations in nearly all of their daily activities. This chapter focuses on the key areas in which compliance officers should focus, along with a brief explanation of those laws and regulations.

Chapter 4: Privacy and Security

With the proliferation of electronic health records and the constant exchange of patient data, privacy and security has become a necessary component of any compliance officer’s daily activities. This section covers, in-depth, many of the privacy and security issues hospitals face.

Chapter 5: Fair Market Value

Fair market value considerations relate to many, if not all of the relationships hospitals have with physicians. A compliance officer should be well-versed on the matter. This chapter provides a detailed understand of fair market value.
Chapter 6: Internal Strategies for Best Practices

Developing best practices for compliance require specific internal strategies. This chapter focuses on how developing best practices and developing internal strategies go hand in hand. The practical strategies provided in this chapter will help compliance officers develop strategies for their own organizations.

Chapter 7: The Risk Assessment

Understanding risk is an important element of a compliance officer’s job. However, performing a risk assessment truly provides you and your organization with an advanced understanding of risk. This chapter provides a detailed plan for developing your own risk assessment.

Chapter 8: Training Strategies

Compliance programs are most effective when the staff and organization as a whole take an ownership interest in compliance. This chapter focuses on important training methods to build this culture of compliance within your organization.

Chapter 9: Monitoring and Auditing

A compliance officer must routinely monitor and audit various areas within the hospital or healthcare organization to ensure compliance. This chapter provides the practical tips for implementing monitoring and auditing programs.

Chapter 10: Effective Internal Investigations

Internal investigations are important because they not only assist the organization in strengthening the compliance program but they also help ensure that the organization is willing and able to maintain compliance. Although internal investigations may highlight weaknesses in your compliance program, it is absolutely necessary to understand the process of an investigation. This chapter will give you the tools and knowledge to manage an effective internal investigation.

The chapters in this book will provide you, your staff, and your organization with a strong understanding of the history of compliance and the current issues facing hospitals on a daily basis. The information will help compliance officers and compliance staff develop internal strategies, risk assessments, monitoring plans, and the knowledge to effectively manage an internal investigation.

In addition to the practical information found in the chapters, the book also includes many forms and documents which may be used on a daily basis in compliance offices. Many of the forms were drafted specifically so compliance officers could use them within their own organizations. Some of the forms include the Income Guarantee Monthly Report form, the Community Need Checklist, the Employment Justification Analysis Form, and the Non-Monetary Benefit Tracking Form. Above all, the information in this book is both practical and timely, and it will assist you in the daily compliance challenges your organization faces. You will find downloadable versions of these tools at the HCPro website address listed on the copyright page at the beginning of this book.
Chapter 1

History and Evolution of Compliance

It is no easy task to comply with all the legal requirements that govern the practice of medicine, including statutes, rules, regulations, and policies set by the government, insurance programs, and payers. But to participate in any governmental health insurance program, a provider must do exactly that—maintain corporate compliance. To aid you in reaching that goal, this book will provide practical and operationally sensitive guidance to assist in identifying and preventing potential problems; it will also provide recommendations on what to do if problems are found.

Your organization has implemented a corporate compliance program because it is committed to identifying and preventing potential problems. “Corporate compliance” refers to your organization’s pledge to operate within the statutes, rules, regulations, and policies set by the government, insurance programs, and payers.

The Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) issues an annual document called a Work Plan that outlines the focus areas related to fraud and abuse by medical providers. To make sense of this document, you must first understand why the OIG is recommending compliance programs for the healthcare industry.

The History of Compliance

Compliance is not a new notion. Its history actually reaches back to the 1860s, during the Civil War era, when the False Claims Act (FCA) was passed to prevent profiteers from selling bogus goods to the Union Army. Amended several times since, this act mandates fines and penalties of double and triple the value of each false claim made against a government agency. At first glance, it may not seem like a law created to protect the government in wartime has anything to do with healthcare practices. However, the FCA has in fact become a powerful weapon against fraudulent claims issued by healthcare providers.

In 1996, the Health Insurance Portability and Accountability Act (HIPAA) authorized the creation of the Medicare Integrity Program. This program directed federal agencies (including HHS, the Department of Justice [DOJ], and the Department of Labor) to develop an array of weapons to combat fraudulent claims and abusive practices of healthcare providers. For the purposes of governmental interpretation, “fraud” is a
deliberate act intended to obtain improper payment, and “abuse” is a repeated act that may not be deliberate but that nevertheless results in improper payment.

The OIG goes to great lengths to assert that it intends to take action against providers who commit deliberate acts of fraud. It states that providers aren’t subject to penalties for innocent errors, but for offenses committed with actual knowledge, reckless disregard, or deliberate ignorance of the falsity of the claims. However, the OIG also notes that providers and their staff members must commit sufficient resources and use auditing and monitoring programs to ensure that the claims they file are accurate.

To begin the federal crackdown on healthcare fraud, Congress allocated $100 million to the Medicare Integrity Program and authorized the program to create the Medicare Integrity Account. This account receives proceeds from fraud and abuse investigations and may use them to fund additional investigation activity. In addition to these funds, additional annual allocations are scheduled for issuance by Congress.

Amendments to HIPAA further strengthened the program in 1997, and additional regulations were added under the Balanced Budget Act of 1998 and the Balanced Budget Relief Act of 1999. These acts were not the first to regulate healthcare, but they were the first to employ the broad and far-reaching powers of the FCA in the healthcare industry. Further, under the Affordable Care Act (ACA), the government has increased resources to combat healthcare fraud, waste, and abuse. The ACA provided increased sentencing for fraud and abuse in excess of $1,000,000, increased use of predictive modeling technology to identify inappropriate claims, and allocated an additional $350,000,000 to the Medicare Integrity Program over 10 years to increase fraud and abuse investigations.

What brought these actions about? A combination of factors persuaded Congress, federal agencies, and the American public that the economics of U.S. healthcare delivery could be improved. The first of these factors was the cost of improved and necessary technology. As we discovered more and more technical means to improve care, public demand for the newest and best technological innovations increased—and so, despite the increased cost of these new diagnosis methods, healthcare providers began to use them.

The associated costs of new equipment were inevitably passed on to patients, health insurers, and federal reimbursement programs as healthcare providers approved the technology for Medicare and Medicaid reimbursement. As physicians’ diagnoses improved, so did patient outcomes, but the cost of care also increased.

The American public objected to this increase, which was evident in the steady rise of their out-of-pocket expenses. Health insurers and managed care companies passed as much cost along to patients and program beneficiaries as possible through increased premiums, copayments, and deductibles. Many Americans found these higher costs unmanageable, and private citizens and employers began to drop or limit health insurance coverage. Managed care insurers tried to cut costs by limiting treatment options, but this tactic was increasingly challenged by physicians who were unwilling to potentially compromise their quality of care.

As advances in medicine increased life spans, Medicare and state Medicaid actuaries became increasingly aware of the longevity and number of recipients accessing these programs. The enrollment age of 65
has not changed since the inception of the Medicare program even though the average length of life has steadily increased. The architects of the Medicare and Medicaid programs likely did not anticipate the sheer number of senior citizens now enrolling.

In addition, there was increasing evidence of deliberate acts of fraud on the part of some healthcare providers. Under the complex prospective payment system, Maximum Allowable and Acceptable Charge schedules, and the Resource-Based Relative Value Scale system used by Medicare, as well as various entitlement programs used by state Medicaid programs, some providers deliberately selected billing practices that maximized the reimbursement obtained through these programs. In some cases, financial experts theorize that in order to maximize payment, hospitals, specialty care programs, and physicians may have intentionally classified basic services as more complex, or billed for services that were not rendered at all or were not medically necessary.

Many healthcare practices created programs (such as imaging services within physician practices) and even entire facilities (such as long-term acute care hospitals and freestanding imaging centers) to obtain reimbursement from specialized services. These programs and actions placed additional strain on the Medicare Trust Fund, a fund already stretched by increasing numbers of beneficiaries and covered procedures.

In an effort to reduce fraud and abuse, Congress in 1996 passed HIPAA, a far-reaching statute that has affected every aspect of healthcare delivery. In addition to helping employees transfer their health insurance coverage from job to job, HIPAA provided for fraud and abuse investigation of healthcare organizations, established a new payment mechanism for hospital outpatient services, and allowed for other extensive changes in business practices and regulation for care providers.

With funding ensured by HIPAA through establishment of the Medicare Integrity Program, federal agencies began to gear up to conduct extensive fraud and abuse investigations. Hospitals and affiliated large academic physician practices were a natural first target, due to their size and the thousands of complex services and procedures they billed for each year. Investigators targeted obvious examples of fraudulent activity and rapidly opened cases against major hospital corporations, drug and device manufacturers, and physician practices. Settlements have resulted in the government collecting hundreds for every dollar spent on investigations.

In fiscal year 2012, the DOJ and HHS announced that they recovered $4.2 billion and stated that for every dollar spent, the government recovered $7.90. During fiscal years 2009–2012, the government recovered $14.9 billion. The HHS stated in a press release that the government’s successful recoveries were made possible by the Health Care Fraud Prevention and Enforcement Action Team, which was created in 2009. According to the HHS release, “the Justice Department opened 1,131 new criminal health care fraud investigations involving 2,148 potential defendants, and a total of 826 defendants were convicted of health care fraud–related crimes during the year. The Department also opened 885 new civil investigations.”

State Medicaid Fraud Control Units (MFCU) recovered $1.7 billion during fiscal year 2011. In that time, 10,685 Medicaid fraud investigations were conducted resulting in 824 convictions. A total of $208.6 million
was spent for the MFCUs during that fiscal year, of which federal funds represented $156.7 million, according to OIG statistics. In addition to other significant accomplishments of the MFCUs in prosecuting patient abuse in detecting and deterring fraud,” stated the OIG, “[the $1.7 billion in recoveries translate] to a return on investment (ROI) of $8.39 per $1 expended by the Federal and State governments for operation of the MFCUs.” Thus, focus on Medicaid fraud and abuse issues needs to occur.

On the heels of widely publicized reports of fraud in the 1960s and 1970s, the defense industry mandated corporate compliance and integrity programs for contracting companies. Following this example, the OIG became convinced that voluntary compliance programs were the most effective means of addressing fraud among healthcare providers. The OIG has issued compliance program guidance documents for numerous types of care providers: home health agencies, durable medical equipment suppliers, nursing facilities, hospitals, laboratories, third-party billing companies, pharmaceutical manufacturers, ambulance suppliers, and physician practices. In part, these documents aim to lead providers toward development of what federal investigators will consider effective fraud prevention programs.

### What is fraud?
- Crimes of guile and deceit
- Intentional and material false statements or representations made to obtain some benefit to which one is not entitled
- Intentionally retaining monies received from the government that the provider later learns it is not entitled to retain
- Reckless disregard for compliance with statutes, rules, and regulations
- Violations that occur when actions are committed for oneself or on behalf of another party
- Acts performed knowingly, willfully, and intentionally
- Violations that warrant criminal, civil, or administrative action
- Civil fraud, which has a lower standard of proof and lesser penalties than criminal fraud

### What is abuse?
- Practices resulting, directly or indirectly, in unnecessary increased costs
- Overuse of medical services, products, or both
- Medically unnecessary services or products
- Failure to conform to professionally recognized codes
- Unfair and unreasonable pricing
- Restrictions of patient choice
- Restrictions of competition
- Failure to provide quality services
The typical guidance found in these documents is structured and offers a very broad overview of what a compliance program may incorporate. Some have rightfully noted that the guidance is voluntary, not mandatory. However, because the OIG is the agency that usually investigates potential healthcare fraud and abuse (and because it may recommend further investigation by agencies such as the DOJ), adopting its guidance can help providers avoid trouble and act as an important negotiating point if an organization is investigated or self-reports an issue.

Why Is Compliance Important?

A compliance program may help to lower your organization’s potential liability for errors—such as inaccurate coding or incorrect billing—after they have been made.

By voluntarily implementing a compliance program, an organization may do the following:

- Demonstrate its commitment to honest and responsible corporate conduct
- Increase the likelihood of preventing, identifying, and correcting unlawful and unethical behavior at an early stage
- Encourage employees to report potential problems to allow for appropriate internal inquiry and corrective action
- Minimize any financial loss to the government and taxpayers, as well as any corresponding financial loss to the facility, through early detection and reporting
- Protect its reputation

Risks of noncompliance

Healthcare organizations that are not in compliance with certain government rules and regulations may face harsh penalties that could result in monetary settlements, mandated compliance programs (through corporate integrity or certification of compliance agreements with the government), exclusion from government-sponsored programs (such as Medicare and Medicaid), and possible criminal prosecution and incarceration for intentional and egregious acts.

Organizations suspected of fraud or abuse must deal with government audits, reviews, and interviews of employees. These investigations usually result in hefty legal expenses for the provider, the potential for a costly civil monetary settlement, negative public perception, and a general disruption of operations. As noted earlier, if organizations are found by the OIG to have consistently failed to comply with a regulation or law, they will most likely have to negotiate and operate under a corporate integrity agreement, which is a government-designed and mandated compliance program, to continue participating in government-sponsored healthcare programs. These agreements can be onerous and costly.
As a compliance officer, your goal should be to develop a compliance program that identifies problems so they can be fixed proactively, thus ensuring your organization never has the need for a corporate integrity agreement.

**Solvency of the Medicare Trust Fund**

To understand the need for compliance activities in the healthcare industry, one only needs to look at the financial viability of the Medicare Trust Fund. The financial outlook for Medicare continues to raise concerns, with total expenditures anticipated to increase faster than workers’ earnings or the overall economy.

In the *2013 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, the trustees projected that the Medicare Trust Fund will remain solvent until 2026, up from their 2012 projection that placed the insolvency date at 2024. Despite this small improvement, there is still concern that the Medicare Trust Fund will become insolvent unless drastic changes are made.

There are four significant methods available to protect the Medicare Trust Fund:

1. Economic growth that results in increased income and Medicare revenue
2. Aggressive efforts to fight waste, fraud, and abuse
3. Changes in payments
4. Changes in coverage (both eligibility and services/procedures)

**Policies and Procedures**

Policies and procedures are critical components of any compliance program. The OIG’s 1998 *Compliance Program Guidance for Hospitals* states that one of the seven elements of a comprehensive compliance program should be “the development and distribution of written standards of conduct as well as written policies and procedures that promote the hospital’s commitment to compliance and that addresses specific areas of potential fraud, such as claim development and submission processes, code gaming and financial relationships with physicians and other healthcare professionals.”

The *Guidance* further states that “every compliance program should require the distribution of written compliance policies that identify specific areas of risk to the hospital. These policies should be developed under the direction and supervision of the chief compliance officer and compliance committee, and, at a minimum, should be provided to all individuals who are affected by the particular policy at issue, including the hospital’s agents and independent contractors.”
Compliance Beyond Medicare Fraud

Without a doubt, compliance officers in the healthcare sector initially spent an overwhelming—but necessary—amount of time on Medicare fraud issues. Most hospitals formed compliance departments as a result of the antifraud initiatives taken by the OIG and the DOJ.

Although these issues are important, compliance involves more than Medicare fraud. The compliance department’s role is to assist the institution in complying with all laws, including employment laws, environmental laws, antitrust laws, and tax-exempt status protection for tax-exempt organizations.

In many other industries, antitrust laws are a standard compliance concern. However, in healthcare, antitrust issues continue to take center stage. This fact is well documented in the March 2013 report of the Federal Trade Commission (FTC)’s *Overview of FTC Antitrust Actions in Health Care Services and Products*. In the 199-page *Overview*, the FTC describes the actions and activities of its Health Care Division, which touched all sectors of the healthcare industry, including pharmaceutical and device manufacturers, hospitals, and physician groups. The federal government, state attorneys general, and private parties each have a role in antitrust law enforcement. Compliance officers must deal specifically with two federal agencies that enforce the antitrust laws: the DOJ and the FTC.

These two agencies cooperate by releasing joint policy statements, such as the *Horizontal Merger Guidelines*, the *Guidelines on Collaborations Among Competitors*, and the *Statements on Antitrust Enforcement in Health Care*. These guidelines are not law, but antitrust enforcement agencies use them extensively when evaluating the antitrust implications of a healthcare transaction. The Sherman Antitrust Act and the Clayton Antitrust Act are the core antitrust statutes.

**Sherman Antitrust Act**

The Sherman Antitrust Act consists of two provisions: Section 1 (conspiracies in restraint of trade) and Section 2 (monopolies).

**Section 1: Conspiracies in restraint of trade**

This section prohibits “contracts, combinations, and conspiracies” in restraint of trade. However, the courts interpret this section as applying only to agreements that “substantially” restrain trade. For this to be the case, two or more parties capable of conspiring must have reached an agreement that substantially restrains trade.

To evaluate a Section 1 claim, find out whether there are two separate economic entities and whether the entities are acting on their own behalf or are acting as “one economic entity.” For example, the following parties are typically acting as one economic entity:

- Parent and subsidiary corporations
- A hospital and its collective medical staff
- Corporations and their employees
The next question is whether the agreement represents a substantial restraint of trade. The courts have determined that certain actions such as price fixing, market allocation agreements, and various types of boycotts are so clearly anticompetitive that they automatically violate antitrust laws. Under this scenario (called the “per se” analysis), defendants cannot offer any justification for the conduct.

For other agreements that do not fall into the “per se” category, the “rule of reason” applies. Under this rule, the court, after hearing the entities’ procompetitive justifications, considers whether the activity as a whole substantially affects competition.

These cases often center on complex market definition issues and seek answers as to whether the defendants have “market power” to injure the competitive process. The court must analyze the product and geographic components of the market. The product market represents the item or service at issue. It includes the service and its reasonable substitutes. In the geographic market analysis, the court questions how far consumers are willing to go for substitute services.

Often, antitrust cases under the “rule of reason” are won or lost depending on the product and geographic market definition issues. Under the “rule of reason,” defendants may offer justification for their conduct. Because healthcare is perceived as being a local issue, the geographic market may not be very large.

Section 2: Monopolies

This section of the Sherman Antitrust Act prohibits organizations from illegally forming or maintaining monopolies. Monopolies are not illegal if organizations form them as the result of historic patterns, due to superior products, or by accident. Nevertheless, for this rule to apply, only one organization has to be involved. Under this section, organizations are also prohibited from attempting or conspiring to monopolize. In general, it is more difficult for the government to prove monopolization than it is to prove that an organization violated Section 1.

Clayton Antitrust Act

Antitrust enforcers heavily use Section 7 of the Clayton Antitrust Act. This section governs mergers. Many of the fundamental antitrust principles apply, such as defining the relevant product and geographic markets.

Section 7 examines whether a merger is likely to “substantially lessen competition or tend to create a monopoly.” It focuses on predictions and is not bound by the current status of the competitive market.

Who Polices Corporate Compliance?

Government agencies and government-hired contractors, which are well funded and have substantial claims databases, are on the lookout for outliers and instances of provider noncompliance. Through the years, they have become more aggressive in identifying and investigating potential errors and negotiating settlements.
The following is a list of the major players in healthcare compliance enforcement:

- **The OIG.** The OIG is the primary investigative and enforcement arm of HHS. OIG agents and lawyers investigate and prosecute violators for suspected healthcare fraud and abuse and, when warranted, negotiate corporate integrity agreements. In addition, the agency provides compliance education and guidance to the industry.

- **Centers for Medicare & Medicaid Services (CMS).** CMS is recognized primarily for its rulemaking authority. However, because CMS is also responsible for Medicare, it has contracted private organizations to review Medicare claims. These contractors, called carriers and fiscal intermediaries, look for outliers and abnormalities that might result in refunds of overpayments.

- **The DOJ and U.S. Attorneys’ Offices.** The DOJ civilly and criminally prosecutes organizations for healthcare fraud and abuse, often under the Anti-Kickback Statute, the Physician Self-Referral Law (Stark), and the FCA. These investigations often result in civil settlements and criminal indictments, which frequently involve incarceration.

- **The FBI.** The FBI assists the DOJ and the OIG by investigating suspected healthcare fraud. Healthcare fraud continues to be an enforcement priority, and it is well funded under HIPAA.

- **State MFCUs.** The Medicaid fraud units use the techniques devised by the federal agencies to spot possible fraud and abuse in state Medicaid programs. They often partner with federal law enforcement to make fraud cases. State MFCUs are expanding their efforts to investigate fraud issues.

- **The Office for Civil Rights (OCR).** The OCR is the HHS arm that investigates violations of the patient health information Privacy and Security rules within HIPAA.

- **Private payers.** Private payers establish security units or divisions to investigate fraud within or against their health plans.

### High-Risk Practices

Government agencies, along with fiscal intermediaries, are on the lookout for billing activity that could indicate fraud or abuse. Following are the common practices that would lead to government scrutiny.

#### Upcoding

Upcoding involves using a higher-paying billing code rather than the code that actually reflects services furnished to a patient. It can range from a physician claiming a higher-level evaluation and management service than he or she rendered to elaborate schemes wherein entire sets of services are coded inappropriately. In the hospital setting, the focus is on code pairs (known as diagnosis-related groups) for similar medical conditions, with one pair resulting in a higher reimbursement depending on the condition of the patient and the level of services provided.
Billing for services not rendered
This involves submitting a claim representing that the provider performed a service when the provider did not actually perform all or part of the service.

Billing for medically unnecessary services
Such billing involves claims that intentionally seek reimbursement for services not warranted by the patient’s current and documented medical condition. Providers should only bill for services that meet Medicare’s “reasonable and necessary” standard.

Duplicate billing
Duplicate billing is submitting more than one claim for the same service or submitting bills to more than one primary payer at the same time.

Unbundling
Medicare requires organizations to bill certain tests and procedures together, providing a single reduced reimbursement for the bundle. Unbundling is the practice of submitting such bills in fragments to maximize reimbursement.

Kickbacks
Kickbacks involve offering anything of value, in cash or in kind, with the intent to induce referrals.

Improper place of service codes
Place of service codes are two-digit codes established by CMS that represent the setting in which a medical service was provided. For example, place of service code 11 represents that a service was performed in a physician’s office, whereas place of service code 22 represents that the service was performed in an outpatient hospital department. Improper use of these codes can result in overpayment.

Physician financial arrangements with designated health service entities
All financial arrangements between physicians (and their family members) and designated health service entities (e.g., hospitals) must meet all components of a Stark Law exception; if they do not, the physician cannot refer to the entity, and the entity cannot bill for services rendered from the tainted referral. All such arrangements must be both fair market value and commercially reasonable.

Steps Toward Compliance
Your involvement can help improve your organization’s culture of compliance. Here are some simple things you can do:

- Learn and be able to articulate the ways in which your job is critical to the organization’s compliance efforts. Consider how errors on your part could place the organization in jeopardy.
• Be willing to take extra steps concerning your compliance duties—ask hard questions and, when in doubt, double-check policies or seek outside assistance from knowledgeable healthcare attorneys or consultants.

• Act and inquire in accordance with the concepts expressed in your organization’s code of conduct.

• Feel free to raise issues with supervisors or managers informally or by using more formal reporting mechanisms (e.g., hotlines). It is better to ask questions and raise issues than to leave matters unresolved.

• View compliance as an opportunity rather than as a burden; consider it a critical component of your organization’s overall quality improvement process.

• Actively request and seek training and education when you need it.

• Regard auditing and monitoring findings as opportunities for improvement.

• Take the time to study new policies or procedures as they arise and incorporate them into your job. If you are confused, ask questions and be flexible.

Endnotes


3. Id.
Packed with legal insights from two experts on the latest CMS and OIG regulations, this third edition of *The Compliance Officer’s Handbook* delivers the tools, practical examples, and interpretations you need to build and maintain an effective compliance program in the post–Affordable Care Act era.

In this edition, you will find the latest and best practices for risk assessment, HIPAA compliance, training, monitoring, auditing for compliance, and a host of other organizational responsibilities. Included is a new, comprehensive chapter dedicated to HIPAA authorization and notification requirements, especially as related to privacy, security, and breach notification. Also new to this edition is essential, in-depth coverage of the requirements for establishing, monitoring, and documenting fair market value and commercial reasonableness between referral sources—knowledge you need to avoid violating the Stark Law and anti-kickback statute, or worse yet, the False Claims Act, which triples government damages.

Whether you are an experienced compliance officer or new to the position, this edition of *The Compliance Officer’s Handbook* is your essential guide to designing and maintaining an effective compliance program in your organization.