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The Compliance Officer's Handbook

Fourth Edition

Robert Wade, Esq, and Alex Krouse, JD, MHA

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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 healthcare compliance. In this book, you'll find 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 expansive. Imagine, in healthcare organizations, that 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 and complex technologies and at the same time working toward being active participants in the communities they serve.

The federal regulations touching each of these issues are exhaustive and increasingly complex 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 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 whereas the legal staff may be concerned with individual legal issues that arise. However, each of these participants is 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 assisting with 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. Therefore, the organization itself is required to take responsibility for maintaining effective compliance programs.

Managers need to ensure that their individual departments are being compliant. Practitioners need to ensure that 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 who 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 has increasingly become an organizational component over the past 20 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. 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 for organizations themselves.

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 on 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 have become a necessary component of any compliance officer's daily activities. This section covers, in depth, many of the privacy and security issues that hospitals face.

Chapter 5: Revenue Cycle Compliance

All compliance programs should include processes targeted to the revenue cycle, including coding, billing, and reimbursement. This chapter discusses how the revenue cycle operates, risk areas, and strategies to mitigate risk.

Chapter 6: Fair Market Value and Commercial Reasonableness

Fair market value considerations relate to many if not all of the relationships that hospitals have with physicians. A compliance officer should be well versed on the matter. This chapter provides a detailed understanding of fair market value.

Chapter 7: Internal Strategies for Best Practices

Developing best practices for compliance requires 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. This chapter also details best practices on how to structure the compliance department and how the compliance function relates to other hospital departments, executive leadership, and the board.

Chapter 8: The Risk Assessment

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

Chapter 9: 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 a culture of compliance within your organization.

Chapter 10: 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 11: 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. 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. Above all, the information in this book is both practical and timely, and it will assist you in the daily compliance challenges that your organization faces.

In addition to the practical information found in the chapters, the book also includes many forms and documents that 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. You will find downloadable versions of these tools at the HCPro website address listed on the copyright page at the beginning of this book.

About the Authors

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Robert A. Wade, Esq., is a partner in the law firm of Barnes & Thornburg LLP. He concentrates his practice on representing healthcare clients, including large health systems, hospitals, ambulatory surgical centers, physician groups, physicians, and other medical providers. Wade's expertise includes representing clients with respect to the Stark Act, Anti-Kickback Statute, False Claims Act, and Emergency Medical Treatment and Active Labor Act of 1986.

Wade is nationally recognized in all aspects of healthcare compliance, including developing, monitoring, and documentation of an effective compliance program. He has experience in representing healthcare clients with respect to issues being investigated by the Department of Justice and the Office of Inspector General and experience negotiating and implementing corporate integrity agreements. His expertise includes assisting clients in documenting and defending financial arrangements between healthcare providers, including referring physicians, as being fair market value and commercially reasonable. He has operationally practical experience, having served as a general counsel and organizational integrity officer for a multihospital system for six and a half years.

Wade is also the creator of Captain Integrity (*www.captainintegrity.com*), a unique compliance program branding and education resource that has received national recognition and has been used by many hospitals, health systems, and other providers.

Alex Krouse, JD, MHA

Alex Krouse, JD, MHA, is an attorney with extensive experience in healthcare operations specific to provider alignment initiatives. He provides advice to health systems on new healthcare initiatives, effective utilization of healthcare professionals, and strategic provider alignment. This includes addressing significant business and legal issues, ranging from the Stark Law to Medicare reimbursement regulations. In addition to his experience in healthcare operations and strategy, Krouse is a national thought leader in provider compensation strategy, including fair market value. He serves on multiple national committees focused on provider compensation and writes and speaks extensively on fraud and abuse issues and emerging regulatory issues. Prior to practicing law, Krouse gained experience in hospital operations both in a large health system and in a community hospital.

Chapter 1

History and Evolution of Compliance

Welcome to healthcare 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.

Due to the complex regulatory and third-party payer requirements, compliance issues will arise in every healthcare entity. Many regulations and requirements necessitate different responses. By way of example, physician supervision or medical record documentation requirements may differ from the requirements of third-party payers. The goal of an effective compliance program is to understand risk areas, test risk areas, and take corrective actions when necessary.

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) has issued model compliance guidance in addition to an annual document called a *Work Plan* that outlines the focus areas related to fraud and abuse by medical providers. The model guidance and *Work Plan* cover all healthcare sectors. To make sense of this guidance, you must first understand why the OIG has recommended compliance programs for the healthcare industry.

The History of Compliance

Compliance is not a new notion. Its history 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 triple the value of each false claim made against a government agency. At first glance, it may not seem clear how 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 or fraudulent activities conducted by healthcare providers who receive governmental funding (such as to support research).

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 tools 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.

FIGURE 1.1

What Is Fraud?	What Is Abuse?
• 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	• 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 or standards • Unfair and unreasonable pricing • Restrictions of patient choice • Restrictions of competition • Failure to provide quality services • Failure to provide services/supplies billed • Financially enticing beneficiaries to receive service from specific providers/suppliers

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, reasonable, necessary, and consistent with billing documentation and grant/funding requirements.

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 use the broad and far-reaching powers of the FCA in the healthcare industry. Further, under the Patient Protection and 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. New initiatives are implemented every year. The government has consistently recovered more money from settlements and judgments than what it spends on various auditing/review initiatives.

Chapter 2

OIG Guidance for Compliance Programs

The Office of Inspector General (OIG) believes that an effective compliance program is a sound investment for providers. With the increased complexity of integrated delivery systems, it is useful to understand that guidance from the OIG has been directed to various segments of the healthcare industry. In this chapter, we will cover the OIG's *Compliance Program Guidance for Hospitals,* provide an overview of the OIG's suggestions, and explain how to implement them.

Compliance Program Guidance for Hospitals

The OIG issues an annual *Work Plan* that describes the various projects on which the Office of Audit Services, Office of Evaluation and Inspections, Office of Investigations, and Office of Counsel to the Inspector General will focus their attention in the upcoming year. The *Work Plan* includes projects planned in each of the department's major entities: Centers for Medicare & Medicaid Services (CMS), the public health agencies, and the Administrations for Children, Families, and Aging. Visit *http://oig.hhs.gov/reports-and-publications/workplan/index.asp* for information on the most recent *Work Plan.* In more recent years, the OIG has issued an annual plan that is updated on a monthly basis. The agency also releases a list of Active *Work Plan* Items. Organizations can use these resources to focus their compliance efforts.

The OIG first published compliance guidance in 1998 and a supplemental guidance in 2005. The initial guidance and all subsequent compliance publications are intended to help reduce fraud and abuse. Today, the OIG continues that aim and includes guidelines for hospitals as for well as a wide variety of healthcare organizations that serve beneficiaries of Medicare, Medicaid, and other federal healthcare programs. The goal of these documents is to establish behaviors that promote a higher level of ethics and compliance in the healthcare industry.

The OIG works with CMS, the Department of Justice (DOJ), and various other sectors of the healthcare community to develop these guidelines. Although they are voluntary, they are considered industry best practices, so it is strongly recommended that hospitals implement the applicable recommendations.

Chapter 3

Key Regulations for Compliance

This chapter will discuss the regulations, guidelines, and statutes to which healthcare facilities must adhere. Healthcare is one of the most highly regulated industries in the world. Adherence to these laws is critical; therefore, a compliance officer must understand the complexity within these statutes and regulations.

Legal Counsel and Education

All compliance officers should ensure that they have immediate access to an attorney who specializes in healthcare regulatory compliance. This individual can work within the organization or may be in private practice. Such access to legal counsel is critical to the compliance officer being able to provide independent and objective insight into an organization's compliance with certain laws and regulations. In addition, a compliance officer should receive regular education on key regulations. Doing so will ensure that the individual is in a position to best educate the organization on changes to regulations and statutes.

U.S. Sentencing Guideline Overview

Congress created the sentencing guidelines in 1987 to meet several goals: to create uniform sentencing for different regions of the country, to stiffen penalties for drug-related and violent offenses, and to guarantee tougher sentences for white-collar criminals. The guidelines created a matrix of sentencing ranges depending on each defendant's criminal history and crime. To deviate from these ranges, judges had to find very unusual circumstances.

In 1991, Congress introduced guidelines for sentencing organizations, as opposed to sentencing individuals. These rules established mandatory fines rather than sentences (given that an organization cannot be sentenced to prison) and set a scale based on the organization's size, the nature of the crime, how the organization discovered the crime, and how the organization handled the problem. These new regulations planted the first seeds of compliance and compliance programs in the sentencing guidelines.

Then, in April 2004, the U.S. Sentencing Commission announced proposed revisions to the federal organizational sentencing guidelines to toughen the criteria for effective compliance and ethics programs. These changes made the standards for such programs more rigorous and put greater responsibility on boards of directors and executives to oversee and manage compliance programs. The guidelines also incorporated the concept of testing a compliance program for effectiveness.

Chapter 4

Privacy and Security

In 1996, Congress enacted the Health Insurance Portability and Accountability Act (HIPAA), forever changing the way people and organizations interact with protected health information (PHI). The primary purpose of enacting HIPAA was to protect the security of health information and to standardize the methods by which this information is exchanged. In 2009, Congress enacted the Health Information for Economic and Clinical Health (HITECH) Act to address breach notification issues. HIPAA, as amended by HITECH, includes the Privacy Rule and the Security Rule. In 2013, the final HIPAA Omnibus Rule was issued, which implemented changes to HIPAA that were mandated by HITECH (generally referred to as the "HIPAA regulations").

The HIPAA regulations include the Privacy Rule, the Security Rule, and the Breach Notification Rule. These particular rules are discussed in detail throughout the chapter; however, compliance officers should be aware that privacy and security issues require close analysis of the laws and the particular situation presented by each issue. These rules require organizations to have a thorough understanding of the ways in which they use, store, or disclose PHI. As a preliminary issue, then compliance officers need to understand the concept of PHI.

What Is Considered PHI?

Under the HIPAA regulations, individually identifiable health information that is transmitted, accessed, or held by certain groups, in any form, is protected. In particular, PHI refers to any individually identifiable health information that can be transmitted or maintained in any form or medium. In short, if health information (including an individual's name or address) is held by a group, entity, or person covered under HIPAA, then that information is likely considered PHI so long as it could be used to identify that individual. Keep in mind that some health information can be deidentified so that it can no longer be used to identify an individual. Deidentification must meet the standard of an expert determination or the safe harbor according to which 18 identifiers have been removed and there is no residual identifiable information. If the information is deidentified, then it is no longer considered PHI, but even deidentification must follow rigorous requirements. However, not all organizations must comply with the HIPAA regulations.

Chapter 5

Revenue Cycle Compliance

All compliance programs should include processes targeted to the revenue cycle, with a specific focus on coding and billing compliance. The revenue cycle is key to the organization's financial health but also represents serious risks. To create an effective revenue cycle compliance program, it is imperative that the organization understand the unique compliance risks associated with coding, billing, and reimbursement. In recent years, government agencies such as the Office of Inspector General (OIG) and the Centers for Medicare & Medicaid Services (CMS) have put substantial focus on payment issues including upcoding, lack of documentation, and billing for services not performed.

As a compliance officer, you must be a key partner in and resource for the revenue cycle. It will be your duty to provide guidance, ensuring that revenue cycle processes comply with all applicable regulations and best practices. The revenue cycle is complex, with many interconnected functions. To effectively manage revenue cycle compliance risks, you will need to go beyond a general understanding of your organization's revenue cycle structure and key revenue cycle principles.

Compliance Risks in the Revenue Cycle and Coding Processes

Healthcare organizations are obligated by several regulations, such as the False Claims Act (FCA), to ensure that their payment mechanisms and billing systems are accurate. Failing to comply with these regulations can result in serious consequences, ranging from substantial monetary penalties to accusations of criminal wrongdoing. In addition, poor billing and payment systems present a basic financial risk to an organization. Inaccurate bills can result in underpayments as easily as overpayments and will impact data used to forecast the organization's financial performance. Understanding these risks will help compliance officers better communicate the need for a high-functioning revenue cycle compliance program.

There are specific state and federal laws that can result in penalties for inappropriate coding and billing. Other chapters in this book discuss some of the major federal regulations, including the FCA, the Health Care Fraud Statute, and the Anti-Kickback Statute, in more detail. In addition to the state and federal laws that mandate appropriate coding and billing practices, organizations have numerous contracts with third-party payers. These contracts typically include coding and billing requirements and charge the provider organization with managing a compliance program.

If it is found that an organization has been billing inappropriately, the penalties can range from repayment to criminal liability, if there was intent to defraud the government. Although most billing issues are technical in nature, all represent a compliance risk that must be mitigated. Therefore, the compliance officer must have a robust understanding of these risks, as well as the technical nature of billing and coding processes.

Chapter 6

Fair Market Value and Commercial Reasonableness

Compliance officers are typically tasked with evaluating compensation arrangements and providing oversight to ensure that all financial arrangements with referral sources are both fair market value and commercially reasonable. This can be a challenging task, as there are frequently competing factors in the evaluation of a financial arrangement. Such factors may include the demand by the referral source, general market conditions (i.e., supply and demand of the service), the business objectives of your client, and benchmark data or other general market indications of relative value for the financial arrangement. Compliance officers will need to weigh each of these factors and assist their organizations in developing sufficient supporting documentation to prove that financial arrangements are both fair market value and commercially reasonable.

Fair Market Value Defined

According to the Stark Law, fair market value is defined as follows (CMS, 2004):

> *Fair market value means the value in arm's-length transactions, consistent with the general market value. 'General market value' means the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement.*
>
> *Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.*
>
> *With respect to rentals and leases described in § 411.357(a), (b), and (l) (as to equipment leases only), 'fair market value' means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee. For purposes of this definition, a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.*

Chapter 7

Internal Strategies for Best Practices

As a compliance officer, you should be seeking to establish best practices regarding compliance risk areas. Once a risk area is identified, either because an issue was discovered or the risk area has become a focus of the government, you should establish internal safeguards and protocols to minimize risks.

These internal strategies should involve all stakeholders that have responsibility for or oversight regarding the risk area.

This chapter is intended to identify and discuss risk areas on which healthcare compliance officers should focus that are not otherwise covered by a separate chapter in this book. This chapter is not intended to identify best practices for all risk areas, as each organization is unique and each industry sector has its own risk areas that are not generally applicable to all healthcare industry sectors.

This chapter also discusses best practices for structuring the compliance function. Structure and operational accountability will depend greatly on the size and financial health of the organization and the organization's culture. Although this chapter will outline some guidelines related to structural best practices, these guidelines should be viewed as suggestions.

Quality-of-Care Issues

One risk area is quality of care. This issue is a top priority for the U.S. Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS), the HHS Office of Inspector General (OIG), and the U.S. Department of Justice (DOJ). It also has always been an issue for state surveyors, state attorneys general, and Medicaid Fraud Control Units as they examine skilled nursing facilities, hospitals, and other medical providers. In fact, quality of care is a regular topic on the OIG's *Work Plan*.

Because quality of care continues to be a priority for both the state and federal government, consider the following questions and concerns when examining your compliance program:

- Evaluate the procedure in place to monitor quality of care. Is an oversight board in place? Is quality of care part of your compliance plan? How are quality-of-care problems handled?
- Educate staff members, both professional and nonprofessional, on quality of care and the ethical responsibility each has in this area. Is quality of care in your mission statement? Are the goals and charitable duties of the facility in concert with quality of care?
- Immediately address problems or concerns regarding quality of care and errors. Is there a clear line of communication among the staff, the compliance officer, and the board to address

Chapter 8

The Risk Assessment

Risk is defined as the possibility that an event will occur that will adversely affect the achievement of objectives. Numerous internal and external risks can negatively affect the business intentions of management and the board. The healthcare industry is complex, and risk is everywhere. From patient safety risks to fraud and abuse risks, it is important to understand the significant risks your organization faces and to implement appropriate safeguards to mitigate them. There is no such thing as a risk-free endeavor in the healthcare industry.

So why is it important to identify risk exposures? Doing so:

- Is part of a good internal control process
- Permits your organization to assess and incur risk in a strategic fashion
- Permits establishment of safeguards to control/mitigate risks
- Ensures effective and efficient use of resources
- Focuses your audit/compliance plan on the areas of greatest risk
- Demonstrates understanding of your organization's strategic plan and helps ensure the plan's success
- Helps eliminate/reduce the risk of untoward outcomes
- Provides management and the board with an independent evaluation of risks and controls and helps contribute to risk management, control, and governance
- Demonstrates understanding of the legal and regulatory environment in which your organization functions
- Provides management with training on risk and control awareness
- Helps your organization comply with the requirements of the Sarbanes-Oxley Act (SOX) (if applicable)
- Is good business practice
- Decreases potential for negative public disclosure

Chapter 9

Training Strategies

Education and training are critical components of an effective compliance plan. Training and education set the tone for the compliance program and the ethics of the organization. In addition, effective education helps in meeting the training criteria of the Federal Sentencing Guidelines, which state that the organization should take reasonable steps to periodically and practically communicate its standards, procedures, and other aspects of the compliance and ethics program. The information should be appropriate to individuals' respective roles and responsibilities.

Training also serves as a preventive control, which can be an important component for meeting external financial audit expectations, including the entity-level controls that are required as part of Sarbanes-Oxley for public companies.

This chapter will discuss and review current training programs and methods and explain how to develop and evaluate new training programs and methods.

Scope of Training

The scope of the training for the compliance program will depend on many factors. Each compliance officer may have a different group or depth of regulations for which he or she is responsible. The compliance officer should develop a comprehensive list of the regulatory risk areas that will be used as a guide when developing the compliance training plan. Initially, many compliance programs may focus on only billing and coding or only Anti-Kickback and Stark laws. As the compliance program matures, other in-depth areas can be targeted for education.

Another topic related to scope of training is the depth of that training, which differs based on the level of risk exposure. In some cases, the only training needed may be awareness that a regulation exists and basic guidance about whom to call if an employee has questions. Alternatively, an employee in another position may need to understand the details of the regulation to compliantly conduct his or her responsibilities.

For example, there are laws surrounding what gifts may be given to a public official. Most employees in their normal course of business will not have a reason to offer such gifts, so the basic guidance may be to provide general education regarding the prohibitions related to gifts to public officials, with direction to contact the head of government affairs (if there is an individual in this role) or the legal or compliance department if the situation occurs.

Chapter 10

Monitoring and Auditing

A significant component of effective compliance programs as defined by the Federal Sentencing Guidelines is "monitoring and auditing to detect criminal conduct." In addition to detecting criminal conduct, most compliance programs also monitor and audit to detect errors that may not be intentional.

Given the complexity of regulation at the federal and state levels regarding billing and coding, unintentional billing errors can occur even in the most vigilant organization. A comprehensive audit program can help to detect these issues.

Understanding the Purposes of Monitoring and Auditing

In its *Compliance Program Guidance for Hospitals,* the Office of Inspector General (OIG) outlines its expectations for an effective healthcare compliance program, including monitoring and auditing of coding and billing for services rendered to government beneficiaries. The OIG recommends that providers perform audits of coded data at least annually and suggests that monitoring of coded data be performed on a regular basis.

Audits serve two very important purposes. First, they help to identify errors or patterns of error. Second, they serve as ongoing oversight of your organization's coding and billing functions.

There are distinct differences between auditing and monitoring. Auditing looks at the sample item (the unit being measured, such as billing claims or contract payment) in detail. Audits seek to determine whether the claims submitted are correct based on the services provided. Monitoring, on the other hand, seeks to determine whether necessary processes are being performed correctly. Monitoring usually occurs after errors or omissions are identified in audits. It ensures that safeguards or changes in processes that were implemented as a result of audit findings are effective and being followed.

A classic example of the difference between auditing and monitoring can be seen in credit balances. Credit balances can exist in any industry where bills are sent out and payment is expected. In healthcare, a credit balance is most often defined as a negative balance in a patient's accounts receivable that may be the result of an employee posting error (e.g., payment posted to the wrong account), an overpayment by a payer, or other reason. For example, the hospital submits a bill (e.g., UB-04) for a three-day acute care hospital stay. Based upon the contract with the payer, the hospital has an expected payment. When the actual payment is received from the payer, it is higher than what was expected, resulting in a credit balance. A typical hospital policy requires that any credit balances be reviewed every 30 days until resolved, which is defined as doing the research to determine whether the balance was caused by an improper posting of a contractual adjustment, a posting error to the wrong account, or an overpayment by the payer (who is thus owed a refund).

by the OIG generally allow a 5% overpayment error rate. If the error exceeds 5%, CIAs generally require additional testing and extrapolation, which could result in statistically valid reviews.

Although a claims error rate can be reported, such as reporting that issues were identified in 50% of claims reviewed, a net financial impact may be preferred. For example, one might report a net $1,000 overpayment from a universe of $100,000 reimbursement resulting in a 1% net overpayment error rate ($1,000/$100,000 = 0.01). This net overpayment of $1,000 could have identified a $5,000 overpayment and a $4,000 underpayment ($5,000 – $4,000 = $1,000). Sometimes it is a better practice to report results using the error rate based upon reimbursement as opposed to the percentage of claims reviewed where errors were identified.

When making any type of repayment to a payer, the focus should be on the error rate by reimbursement received, calculated both as a net dollar amount and as a net percentage based upon the reimbursement received. When making such repayments, the underpayments as well as any overpayments are typically reported.

Contract policy

Figure 10.1 shows an example of an audit for a medical director contract. In this case, the auditing standard is the policy, and there are notations about effective dates. Particularly for arrangements that have been in place for a period of time, the policy that is in effect when the arrangement is commenced may govern certain elements—for example, the approvals that are required for contract execution, or the documentation that is required as part of the file in the legal department.

FIGURE 10.1

Compliance Audit Department Contracting for Medical Director Services	
SECTION A - GENERAL INFORMATION:	
Sample number:	
Medical director name:	
Hospital number:	
Hospital name:	
Original, renewal, or amended contract?	
Last commencement date (original or amended date):	Commenced after policy first effective? __ Yes __ No
Policy number in effect at the date of agreement:	
Term:	
Contractual payment:	
Estimate of time/hours for duties to be performed:	

FIGURE 10.1 (CONT.)

SECTION B - CONTRACT STRUCTURE AND APPROVAL	Yes/No	Comments
1. Was supporting documentation submitted with the contract term sheet, including:	__ Check if section is not applicable because the contract commenced prior to the effective date of the policy or is an Auto Renewal Contract Term Sheet	
a. Documentation of duties to be performed		
b. Documentation of the hours to be worked		
c. Documentation of and signature upon the FMV calculations		
d. Medical Director Agreement, Record Certification, and Business Approvals		
e. A list of other physician directors at the hospital and their hours and compensation		
f. Copy of the contract to be reviewed (if not drafted by legal) or current contract if an amendment		
2. Was the Contract Term Sheet appropriately approved by the:	__ Check if section is not applicable because the contract commenced prior to the effective date of the policy or is an Auto Renewal Contract Term Sheet	
a. SVP?		
b. CEO of the hospital?		
c. Compliance department?		
3. Is there a fully executed contract, including:		
a. A list of duties to be performed by the director?		
b. The physician's and SVP's signature?		
c. A term of not less than one year?		
d. A rate consistent with the rate approved per the contract term sheet?		

FIGURE 10.1 (CONT.)

SECTION C- PAYMENTS						Yes/No	Comments
1. Are the medical director payments in accordance with the terms of the contract? (see Payment Calculation items a–e below)							
Payment Calculation - Medical Director							
Month (period ending)	a. Compensation paid	b. Hours reported	c. Contract rate	d. Compensation due	e. Difference	f. Was time sheet included?	g. Was time sheet signed by CEO and physician?
Month 1				$0.00	$0.00		
Month 2				$0.00	$0.00		
Month 3				$0.00	$0.00		
Month 4				$0.00	$0.00		
Month 5				$0.00	$0.00		
Month 6				$0.00	$0.00		
Month 7				$0.00	$0.00		
Month 8				$0.00	$0.00		
Month 9				$0.00	$0.00		
Month 10				$0.00	$0.00		
Month 11				$0.00	$0.00		
Month 12				$0.00	$0.00		
Total hours worked during the period: 0.00							
Average hours worked per month: 0.00							

SECTION D - SERVICE LOGS/ DOCUMENTATION OF PERFORMANCE	Yes/No	Comments
1. Is documentation available in the form of time sheets and/or other records demonstrating that all required duties have been performed in accordance with the terms of the contract?		See Payment Calculation, Section C, item f.
2. Is time sheet or other time reporting records signed by the CEO and physician?		See Payment Calculation, Section C, item g.
3. Was the "Medical Director for IRF Form" completed monthly by the physician?		Applicable only if the medical director is an IRF full-time medical director.

FIGURE 10.1 (CONT.)

SECTION E - OPERATIONAL TESTING	Yes/No	Comments
1. Is there a fully executed Business Associate Agreement signed by the CEO and physician?		
2. Is there evidence of completion of CIA requirements for the director? (This is a requirement for all medical directors and any program directors who work more than 160 hours per year. Should be completed within 30 days of the director's start date.)		
FINAL REPORTING QUESTIONS	Yes/No	Comments
1. Each arrangement was structured and approved in compliance with organization policies in effect at the start or renewal of the arrangement, including documentation of FMV.		See Section B
2. All payments for the most recent twelve (12)-month period have been made or received in accordance with the terms of the arrangement.		See Section C
3. Any required service logs or other documentation of performance of required duties has been completed in compliance with the terms of the arrangement and applicable policies.		See Section D

Many of the questions in this audit are based upon the organization's specific policy requirements. As an example, consider the fair market value of the compensation in the contract. Some organizations may require an outside valuation to be performed for each contract; other organizations may require valuations only for contracts above a certain overall threshold or above certain hourly rates that depend upon the type of service or specialty of the contracted provider (e.g., compensation over the 75th percentile of an applicable benchmarking entity, like Sullivan Cotter or the Medical Group Management Association).

Another difference may be the personnel that are required for approval. In some organizations, the compliance officer may approve each contract with a referral source. In others, he or she may not be involved at all in the approval process. As the scope of the audit is considered, the organization may decide not to test the approval portion at all, instead only looking at the payments and whether they match the terms of the executed contract.

Chapter 11

Effective Internal Investigations

The day will come when a hotline call, a routine claims review, or a whistleblower's complaint brings a compliance concern or some bad news from the compliance front. An employee or competitor may suggest that someone within your organization has engaged in criminal or civil acts or omissions. If these events occur, you must ask the following questions: Is the whistleblower correct? What is the possibility that the issue identified is true? Has the auditor unearthed a previously unrecognized problem? The answers to these questions may cause you to decide whether to undertake an internal investigation.

It is important to note that this chapter concerns internal investigations. Internal investigations can run the gamut from a simple review of a discrete potential compliance issue (e.g., medical report given to wrong patient) up to and including an alleged criminal violation, such as a violation of the Anti-Kickback Statute (e.g., above fair market value compensation to a group of employed neurosurgeons). Regardless of the issue being reported, and regardless of the source, it is important that the compliance officer ensure that a thorough investigation/review is conducted to determine whether any reported allegation is substantiated. As you will learn in this chapter, the scope of the investigation will depend upon the issue being reported. Although this chapter primarily deals with major investigations, the same steps should be considered by the compliance officer related to any compliance issue. Although all reported issues should be investigated, even issues that are brought to the attention of the organization through an anonymous hotline report, investigations concerning greater potential liability, including large repayments, warrant heightened consideration and safeguards.

In many companies, the compliance officer is the first to become aware of a potential compliance problem that could lead to civil or criminal liability or even a simple repayment or reprocessing of claims. A best practice is to give the compliance officer the authority to conduct internal investigations. If this is not the case, however, it is likely that the board of directors or other governing committee will have the ultimate authority to make that decision.

One of the primary tasks for the compliance officer, therefore, is to provide the decision-maker with enough information to make a reasonable and rational decision about the scope and conduct of an internal investigation. Because of potential negative investigation results, it is important for compliance officers to be able to report directly to the board on important matters. The inability to do so can negatively impact the board's response to alleged noncompliant conduct.

Appendix

Important Compliance Terminology

The following are some important compliance terms with which you should become familiar.

TERM	DEFINITION
Accountable care organization (ACO)	A group of doctors, hospitals, and other healthcare providers that comes together voluntarily to give coordinated, high-quality care to its Medicare patients. Savings through an ACO can be shared with the ACO participants.
Administrative simplification	Title II, Subtitle F of HIPAA, which authorizes the U.S. Department of Health and Human Services (HHS) to adopt standards for transactions and code sets that are used to exchange health data; adopt standard identifiers for health plans, healthcare providers, employers, and individuals for use on standard transactions; and adopt standards to protect the security and privacy of personally identifiable health information.
Admitting diagnosis code	A code indicating a patient's diagnosis at admission.
Advance beneficiary notice	A notice that a doctor or supplier should give a Medicare beneficiary to sign when the doctor or supplier provides a service that he or she believes Medicare will not pay for or consider medically necessary. Even though Medicare may not cover the service, the treating physician may still believe that the patient needs it.
Affordable Care Act (ACA)	A federal law adopted in March 2010 as part of President Obama's healthcare reform agenda. Its full name is the Patient Protection and Affordable Care Act. The ACA is multifaceted, including enhanced enforcement provisions, expansion of Medicaid eligibility, and establishment of health insurance exchanges. It also prohibits health insurers from denying coverage based upon preexisting conditions.
AMA	A professional organization for physicians, also known as the American Medical Association. The AMA is the secretariat of the National Uniform Claim Committee, which has a formal consultative role under HIPAA. The AMA also maintains the current procedural terminology medical code set.
Ambulatory care	A term referring to all types of health services that do not require an overnight hospital stay.
American Hospital Association (AHA)	A healthcare industry association that represents the concerns of institutional providers. The AHA hosts the National Uniform Billing Committee, which has a formal consultative role under HIPAA.
Balance billing	When doctors or hospitals charge more than a payer-approved amount for the service received by a patient.
Benchmark	An identifiable indicator of superior performance by a medical care provider, which can be used as a reference to raise the mainstream of care for Medicare beneficiaries. The relative definition of "superior" will vary, but in many instances, a superior benchmark would be a provider that appears in the top 10% of all providers for more than one year for the specific indicator.
Beneficiary	A person who has health insurance through the Medicare or Medicaid program.

TERM	DEFINITION
Notice of proposed rulemaking	A document that describes and explains regulations that the federal government proposes to adopt at some future date and that invites interested parties to submit related comments. These comments can then be used in developing a final regulation.
Observation	Medicare defines observation services as an outpatient hospital stay in which an individual receives medical services to help the doctor decide whether the individual should be admitted to the hospital as an inpatient or discharged. Observation stays typically last no more than 24–48 hours.
Outlier	Additions to a full-episode payment in cases where costs of services delivered are estimated to exceed a fixed-loss threshold.
Part A (Medicare)	Hospital insurance that pays for inpatient hospital stays, care in a skilled nursing facility, hospice care, and some home healthcare.
Part B (Medicare)	Medical insurance that helps pay for doctors' services, outpatient hospital care, and other medical services that are not covered by Part A.
Part C (Medicare)	Medical insurance that is provided through a provider organization, such as an insurance entity. Medicare Part C is commonly referred to as "Medicare Advantage." Patients enrolling in Medicare Part C must have Medicare Parts A and B.
Part D (Medicare)	Prescription drug insurance that can be voluntarily purchased by a Medicare beneficiary.
Payer	In healthcare, an entity that assumes the risk of paying for medical treatments. This can be an uninsured patient, Medicare, Medicaid, Tricare, a self-insured employer, a health plan, or an HMO.
Postpayment review	The review of a claim after a determination and payment has been made to the provider or beneficiary.
Prospective payment system	A method of reimbursement in which Medicare payment is made based on a predetermined, fixed amount. The payment amount for a particular service is derived based on the classification system of that service (e.g., DRGs for inpatient hospital services).
Protected health information (HIPAA)	Individually identifiable health information transmitted or maintained in any form or medium, which is held by a covered entity or its business associate. This information identifies the individual or offers a reasonable basis for identification. It is created or received by a covered entity or an employer. Protected health information relates to a past, present, or future physical or mental condition, provision of healthcare, or payment for healthcare.
Quality	How well a health plan keeps its members healthy or treats them when they are sick. Good-quality healthcare means doing the right thing at the right time, in the right way, for the right person, and getting the best possible results.
Quality Improvement Organization (QIO)	A group of practicing doctors and other healthcare experts. QIOs are paid by the federal government to check and improve the care given to Medicare patients. They must review patients' complaints about the quality of care given by inpatient hospitals, hospital outpatient departments, hospital emergency rooms, skilled nursing facilities, home health agencies, private fee-for-service plans, and ambulatory surgical centers.
Referral	An "okay" from a patient's primary care doctor for the patient to see a specialist or get certain services. In many Medicare managed care plans, a patient must obtain a referral before receiving care from anyone except his or her primary care doctor. If a patient does not get a referral first, the plan may not pay for his or her care.

TERM	DEFINITION
Revenue code	Payment codes for services or items in FL 42 of the UB-92 found in Medicare/NUBC (National Uniform Billing Committee) manuals (42X, 43X, etc.).
Secondary payer	An insurance policy, plan, or program that pays second on a claim for medical care. This could be Medicare, Medicaid, or other health insurance, depending on the situation.
Skilled nursing facility	A Medicare-approved facility that provides short-term post-hospital extended care services at a lower level of care than provided in a hospital. A skilled nursing facility has staff and equipment to give skilled nursing care, skilled rehabilitation services, and other related health services.
Social Security Act	Public Law 74-271, enacted on August 14, 1935, with subsequent amendments. The Social Security Act consists of 20 titles, four of which have been repealed. The Health Insurance and Supplementary Health Insurance programs are authorized by Title XVIII of the Social Security Act.
Split/shared service	A patient encounter where the physician and a qualified nonphysician practitioner each personally perform a substantive portion of the service. The interaction with the patient must be face-to-face, and each must perform at least one of the following three components: history, examination, or medical decision-making. A split/shared evaluation and management encounter applies only in the following settings: hospital inpatient, hospital outpatient, hospital observation, emergency department, hospital discharge, office, and nonfacility clinic visits.
Supplier	Generally, any entity, person, or agency that gives a patient a medical item or service, like a wheelchair or walker.
Third-party administrator	An entity that is required to make or that is responsible for making payment on behalf of a group health plan.
Trading partner	External entity with whom business is conducted (i.e., customer). This relationship can be formalized via a trading partner agreement. (Note: A trading partner of an entity for some purposes may also be considered a business associate of that same entity for other purposes.)
Transaction	Under HIPAA, the exchange of information between two parties to carry out financial or administrative activities related to healthcare.
TRICARE	The Department of Defense's health insurance program for active duty and retired military personnel and their family members.
UB-92	An electronic format of the CMS-1450 paper claim form that has been in general use since 1993 for institutional services.

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