THE MEDPRO GROUP DIFFERENCE

Guideline

Developing an Effective Compliance Plan: A Guide for Healthcare Practices

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Contents

Introduction

A compliance plan is a formal statement of a healthcare practice's intention to conduct itself ethically in regard to business operations, government regulations, and patient services and care. The purpose of a formal compliance plan is twofold: (1) it provides a blueprint for the practice's compliance program and accomplishing the aforementioned goals, and (2) it encourages employees to report unethical conduct.

Federal law requires healthcare practices to develop and implement formal compliance programs.[1] This guideline provides an overview of the role of compliance in healthcare and discusses how practices can take steps to ensure they are meeting compliance obligations. However, compliance is very complex, and new developments in audit focuses occur annually. Healthcare practices should consult legal counsel to provide detailed guidance on compliance program development and implementation.

Note: This guideline focuses on the federal fraud and abuse laws, but healthcare organizations also must comply with other laws and regulations depending on the type of facility and services provided. Examples of other laws and regulations include the Health Insurance Portability and Accountability Act, the Emergency Medical Treatment and Labor Act (EMTALA), the Safe Medical Devices Act, the Americans with Disabilities Act, and more. Covering all of these aspects is beyond the scope of this guideline, but healthcare organizations should be aware of which laws and standards apply to them.

Objectives

The objectives of this guideline are to:

- Explain why compliance plans are important for healthcare practices
- Review federal fraud and abuse laws
- Describe the seven essential elements of an effective compliance plan

Background

Since 1976, the Department of Health and Human Services' Office of Inspector General (HHS-OIG) has been working to prevent fraud, waste, and abuse in federally funded healthcare programs, such as Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).

HHS-OIG's primary function is to protect the integrity of HHS programs as well as the health and welfare of program beneficiaries.

HHS-OIG has published voluntary compliance program guidance for healthcare practices for years. In the 1990s, HHS-OIG began providing voluntary compliance tools and resources to help healthcare providers avoid submitting erroneous claims and engaging in unlawful conduct involving federal healthcare programs. However, because HHS-OIG's guidance was voluntary, not all healthcare providers and organizations felt compelled to develop compliance programs.

With the implementation of the Patient Protection and Affordable Care Act (ACA) in 2010, compliance programs became mandatory. Section 6401 of the ACA stipulates that healthcare providers must establish compliance programs as a condition of enrollment in Medicare, Medicaid, or CHIP.[2]

The Importance of a Compliance Plan

Having a compliance plan is important for many reasons beyond the most obvious — it's required by law. An effective compliance plan is crucial for preventing fraudulent claims and erroneous billing, preparing for potential audits, and avoiding ethical conflicts in business operations and patient care services.

Additionally, if noncompliance with the law results in an HHS-OIG complaint and investigation, the consequences can be significant. Not understanding the law or failing to provide compliance training for staff usually does not excuse violations.

The possible penalties that the government can impose for submitting fraudulent or erroneous claims or violating state or federal fraud and abuse laws include completion of a corporate integrity agreement; exclusion from Medicare, Medicaid, and CHIP programs; civil and criminal penalties; and/or a referral to the provider's state professional board.

"Not understanding the law or failing to provide compliance training for staff usually does not excuse violations."

By implementing and adhering to the requisite compliance plan, healthcare providers and practices will generally meet their legal obligations and send a clear message to staff and the public that the practice is committed to conducting itself in an ethical manner, promoting good employee conduct, and providing quality patient care.

The Fraud and Abuse Laws

All healthcare administrators and practicing healthcare providers should have at least a basic understanding of state and federal fraud and abuse laws. The federal fraud and abuse laws that apply to healthcare providers are:

- The Anti-Kickback Statute[3]
- The Physician Self-Referral Law (Stark Law)[4]
- The False Claims Act[5]
- The Exclusion Authorities[6]
- The Civil Monetary Penalties Law[7]

The government agencies responsible for enforcing these laws are the U.S. Department of Justice, HHS-OIG, and the Centers for Medicare & Medicaid Services (CMS).

This section will provide a brief overview of these important laws affecting all healthcare providers, organizations, and vendors. However, the information provided herein is for general reference only. For more detailed information about these laws or for specific questions, healthcare practices should work with legal counsel.

The Anti-Kickback Statute

The Anti-Kickback Statute prohibits the knowing and willful offering, paying, soliciting, or receiving of anything of value ("kickbacks") to induce or reward patient referrals or the generation of business involving any item or service payable by federal healthcare programs.[8] This statute has safe harbor provisions that protect certain business arrangements; however, very specific requirements must first be met for those provisions to apply.

Violations of the Anti-Kickback Statute can result in administrative sanctions, fines, jail terms, and exclusion from participation in federal healthcare programs.

Example of an Anti-Kickback Statute Violation

A healthcare provider accepts money or gifts from a pharmaceutical or durable medical equipment company in exchange for the provider referring patients to that vendor.

The HHS-OIG warns that healthcare providers are an attractive target for kickback schemes because they are a potential source of referrals for other healthcare providers, pharmaceutical organizations, and medical supply companies.

The Physician Self-Referral Law (Stark Law)

The Stark Law prohibits healthcare providers from referring Medicare or Medicaid patients for certain designated health services to an entity with which the healthcare provider or an immediate family member has a financial relationship, unless an exception applies under the law.[9] A financial relationship may include any form of ownership interest, an investment interest, or some other form of compensation arrangement.

The Stark Law also prohibits the entity providing the designated health services from submitting claims to Medicare or Medicaid for services that involved a prohibited referral.

Example of a Stark Law Violation

An orthopedic physician refers all of his patients to his privately owned physical therapy center without giving the patients other options or notice that he owns the physical therapy center.

Examples of designated health services include clinical laboratory services, any form of outpatient therapy services (e.g., physical, occupational, and speech therapy), radiology and certain other imaging services, and durable medical equipment and supplies.

The False Claims Act

The civil False Claims Act prohibits the submission of claims for payment to Medicare or Medicaid that the healthcare provider knows or *should have* known to be false or fraudulent.

Penalties for filing false claims may be up to three times the actual loss plus an additional penalty that is linked to inflation.[10] Further, an analogous criminal False Claims Act[11] can result in criminal penalties and imprisonment for submitting false claims.

The False Claims Act includes a whistleblower provision (qui tam action) that allows individuals to file a lawsuit on behalf of the United States if they have knowledge that an organization is defrauding the government.

Whistleblowers can potentially receive a portion of the money the government recovers. The possibility of significant compensation and the desire to do the right thing has led many former or current employees of healthcare organizations to file whistleblower actions.

Example of a False Claims Act Violation

A healthcare provider submits claims for payment to a federally funded healthcare program for procedures that were not actually performed or for treatments/services that were medically unnecessary.

Exclusion Authorities

HHS-OIG must exclude individuals or entities from participation in all federal healthcare programs when certain offenses are committed. Examples of criminal offenses that will result in exclusion include:

- Medicare or Medicaid fraud
- Patient abuse or neglect
- Felony convictions for other healthcare-related fraud, theft, or other financial misconduct
- Felony convictions for unlawful manufacture, distribution, prescription, or dispensing of controlled substances

HHS-OIG also has discretionary exclusion authority for certain offenses such as:

- Misdemeanor convictions for unlawful distribution, prescription, or dispensing of controlled substances
- Suspension, revocation, or surrender of a license for reasons bearing on professional competence, professional performance, or financial integrity
- Provision of unnecessary or substandard services
- Submission of false or fraudulent claims
- Engaging in unlawful kickback arrangements
- Defaulting on health education loans or scholarships

Employers or contractors who bill directly or indirectly for items or services furnished by an excluded provider may also be subject to civil penalties.[12]

Civil Monetary Penalties Law

The Civil Monetary Penalties Law allows HHS-OIG to seek civil monetary penalties and/or exclusion for many offenses. Adjustments allow for increases in civil monetary penalty ranges due to annual inflation. Penalties can range from several hundred to multimillion dollars based on the violation(s) cited.

Examples of chargeable offenses include violating the fraud and abuse laws, EMTALA violations, and making false statements or misrepresentations on applications or contracts to participate in the federal healthcare programs.

Additionally, any healthcare provider who offers any type of compensation to Medicare and Medicaid beneficiaries as an incentive to see a certain provider is in violation of the Beneficiary Inducement provision of the Civil Monetary Penalties Law.[13]

The Seven Essential Elements of an Effective Compliance Program

HHS-OIG has identified seven elements of an effective compliance program. These elements are meant to guide healthcare providers and organizations in the process of developing well-defined plans and strategies for their own compliance programs. The seven elements are:

1. Written policies and procedures
2. Compliance leadership and oversight
3. Training and education
4. Effective lines of communication with the compliance officer (CO) and disclosure program
5. Enforcing standards: consequences and incentives
6. Risk assessment, auditing, and monitoring
7. Responding to detected offenses and developing corrective action initiatives[14]

Each of the elements is discussed in greater detail in subsequent pages, along with implementation recommendations. HHS-OIG also encourages providers to seek help and support as needed from outside experts in billing and coding, legal counsel knowledgeable in fraud and abuse laws, and the comprehensive resources available at HHS-OIG's website.

Element One: Written Policies and Procedures

An effective compliance program is dependent on written policies and procedures, which memorialize the healthcare practice's expectations with regard to compliance. Further, these documents explain the practice's commitment to legal standards, ethical conduct, and quality care.

"A code of conduct identifies model behavior for employees and explains how to report suspected instances of compliance violations or unethical activity."

Each healthcare practice's compliance policies should include a code of conduct that defines the organizational mission, values, expectations, and guiding principles for workplace behavior. A code of conduct identifies model behavior for employees and explains how to report suspected instances of compliance violations or unethical activity.

The designated CO and compliance committee (CC) should help develop the policies and procedures, which should specifically delineate their respective duties. Once developed, compliance policies and procedures should be reviewed with, and distributed to, all employees of the practice. The review should occur as part of new hire orientation and at least annually, and employees should be asked to acknowledge their review and understanding of the policies. Additionally, each practice should have guidelines for reviewing and updating the compliance policies at least annually.

Element Two: Compliance Leadership and Oversight

As part of the second element, each healthcare practice should designate two key roles — CO and CC — and assign duties to the respective roles. The CO should be very familiar with the practice's operational and compliance activities.

The CO should report directly to the CEO or board and should have primary responsibility for the compliance program structure and administration. This point is crucial because a CO without any delegated authority will likely lack effectiveness. The CO's daily duties may include:

- Understanding and administering the compliance program
- Advising the CEO, board, and other senior leaders on compliance risks
- Being informed about the outcomes of audits and monitoring

- Reporting on compliance enforcement activities
- Assessing/reviewing the compliance program

For smaller healthcare practices, the CO might have other responsibilities aside from compliance duties. However, HHS-OIG advises that the CO should "maintain a degree of separation from the entity's delivery of health care items and services and related operations."[15] Some practices may choose to outsource the CO role to a vendor.

The CO should chair the CC, which is a multidisciplinary committee of leaders from various departments (e.g., billing and coding, clinical and medical, finance, information technology, health information management, human resources, legal, operations, risk management, marketing/sales, etc.). The CO and CC are jointly responsible for certain duties related to administering the compliance program. These responsibilities include:

- Developing, reviewing, and updating compliance policies and procedures
- Developing and auditing the work plan and risk assessment plan
- Attending meetings for operations staff
- Monitoring and auditing compliance performance
- Enforcing compliance program requirements at all levels of the organization
- Recommending policy, procedure, and process improvements
- Enforcing disciplinary standards

Element Three: Training and Education

The third element of an effective compliance program is training and education to ensure adequate understanding of the expectations set forth in the compliance plan and code of conduct. The CO and CC should develop a comprehensive training plan tailored to the needs of the organization.

Compliance training should be mandatory for all board members, leaders, providers, staff members, and contractors. The initial training should be a comprehensive review of the compliance plan and code of conduct. Thereafter, an annual review training should occur that reemphasizes the practice's compliance policies and code of conduct and addresses any

ongoing areas of concern. Training on, and communication about, any compliance program changes or new developments should occur prior to introducing or modifying processes.

The training plan also should include targeted trainings based on specific compliance risks and individual's roles and responsibilities (e.g., billing and coding, documentation, records release, advertising, referrals, and so on).

> "Training programs should be interactive and include actual compliance scenarios that employees and managers might encounter."

To aide in information retention, training programs should be interactive and include actual compliance scenarios that employees and managers might encounter. Additionally, the CO should communicate compliance messages via other informal training methods, such as posters, newsletters, emails, and intranet communications.

Element Four: Effective Lines of Communication With the Compliance Officer and Disclosure Program

The fourth element includes developing effective lines of communication, which involves making communication about compliance issues an integral part of the practice, having an "open-door" policy throughout the organization, and fostering a nonpunitive culture in which personnel feel empowered to disclose compliance concerns.

Recommendations for developing effective lines of communication include the following:

- Actively inform employees about various ways they can contact the CO and/or CC, and post this information in physical and virtual common spaces (e.g., breakrooms and the organization's intranet).
- Ensure communication channels foster dialogue rather than one-way communication.
- Educate employees about the importance of reporting issues in a timely manner.
- Develop a formal process for managers to communicate compliance issues and results to staff members.
- Create multiple reporting channels, including an anonymous option, for employees to report concerns regarding compliance issues.

- Develop written policies that enforce confidentiality and support a nonpunitive approach to disclosure of potential compliance violations.

The CO and/or CC should evaluate the effectiveness of the process for reporting compliance issues. Questions to consider include the following:

- Are employees familiar with what compliance/ethical issues they should report?
- Are employees aware of the reporting process and to whom they should report concerns?
- Are employees aware of the specified timeframe for reporting compliance/ethical issues?

Furthermore, employees should feel comfortable reporting issues to multiple individuals within the organization (e.g., managers, the CO, or CC). The CO should be available and accessible for routine questions about compliance or ethics.

Element Five: Enforcing Standards: Consequences and Incentives

The fifth element of a successful compliance program is developing consequences for noncompliance and incentives for compliance. Consequences might depend on the scenario and could be nonpunitive (e.g., remedial education) or punitive (e.g., verbal or written warning, suspension, or termination).

Employees should understand how the organization identifies, investigates, and responds to reports of noncompliance. Additionally, written disciplinary guidelines should clearly delineate consequences for noncompliance, including sanctions for:

- Failure to comply with the code of conduct or compliance policies (either inadvertently or intentionally)
- Failure to detect noncompliance when routine observation or due diligence would have provided notice
- Failure to report actual or suspected noncompliance

Disciplinary guidelines should be accessible and reviewed at least annually with all employees so they are aware of their obligations.

When an investigation confirms a violation, the organization should ensure consistent and timely discipline. HHS-OIG notes that "All levels of employees should be subject to the same consequences for the commission of similar offenses."[16]

In addition to developing consequences to discourage noncompliance, the CO and CC should consider developing incentives to encourage employee engagement with the compliance program. These incentives might be based on specific contributions to the program or actions taken to support and improve compliance activities. Incentives can take many forms, including compensation, recognition, and other rewards.

Element Six: Risk Assessment, Auditing, and Monitoring

The sixth element of an effective compliance program involves assessing compliance risks and creating work plans for auditing and monitoring these risks as well as the effectiveness of the compliance program.

The CC should conduct compliance risk assessments at least annually and may find it helpful to coordinate with other functions within the organization to maximize resources and eliminate redundancy. The assessment should pull data from various sources to evaluate risks that may arise from violating state or federal laws or other standards or legal requirements. Additionally, the risk assessment should include areas of concern that CMS and other authoritative organizations have identified.

The CC and CO should review the results from risk assessments to help inform the development of auditing and monitoring activities. This review should include classifying identified risks into different risk levels. The organization should more frequently audit areas identified as high-risk, such as coding/billing and working with excluded providers.

"Auditing is a comprehensive review that ensures compliance with statutory and CMS requirements and includes routine evaluations of the compliance program to determine the program's overall effectiveness."

Auditing is a comprehensive review that ensures compliance with statutory and CMS requirements and includes routine evaluations of the compliance program to determine the program's overall effectiveness. HHS-OIG explains that the CC should create "a schedule of audits to be conducted based on risks identified by the

annual risk assessment" and should ensure that the CO "has the capacity to perform or oversee additional audits based on risks identified throughout the year. . ."[17]

Healthcare practices may choose to have internal staff or external contractors conduct audits. Audits should result in written reports and recommendations that the CO and/or CC should follow up on as part of their responsibilities.

Monitoring is less time intensive than auditing, but happens more frequently. Monitoring may include reviewing procedures to gauge whether they are working as intended and following up on recommendations and corrective action plans to ensure they have been implemented. Monitoring should occur on a regular basis, such as weekly or monthly, and the organization should determine frequency of monitoring, people responsible, and issues of concern that require monitoring.

Element Seven: Responding to Detected Offenses and Developing Corrective Action Initiatives

The final element of an effective compliance program is responding to detected offenses and developing corrective actions. As a result of auditing, monitoring, and/or disclosure, the CO and CC will likely encounter results or reports that point to compliance vulnerabilities or violations. These situations will require investigation and possibly corrective actions.

Investigations may require interviews, review of data, email searches, and audits. HHS-OIG warns that the CO and the organization's legal counsel must take steps to safeguard documents and other evidence to prevent intentional or unintentional destruction. Additionally, a record of the investigation should be compiled, which includes:

- Documentation of the alleged violation
- Details about the investigative process
- Copies of interview notes and key documents
- A record of witnesses interviewed and the documents reviewed
- The results of the investigation
- Any disciplinary or corrective action taken[18]

The organization's compliance plan should include the process for conducting internal investigations, a time limit for closing investigations, corrective action guidelines, and criteria for external independent contractor review and/or notification to appropriate government authorities. Examples of corrective action include staff education, repayment of overpayments, and disciplinary action against responsible employees.

Conclusion

Healthcare compliance is a complex topic that involves numerous regulations and layers of oversight. However, at its core, compliance is intended to promote ethical conduct and business practices. By developing and adhering to an effective compliance plan and educating staff, healthcare practices can prevent fraudulent activity, promote ethical behavior and business practices, and support quality care.

Resources

For more information about fraud and abuse and developing an effective compliance program, see HHS-OIG's compliance resources and *General Compliance Program Guidance* as well as MedPro's *Risk Resources: Healthcare Compliance*.

Endnotes

[1] Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 et seq. (2010)

[2] Ibid.

[3] 42 U.S.C. § 1320a–7b(b)

[4] 42 U.S.C. § 1395nn

[5] 31 U.S.C. §§ 3729–3733

[6] 42 U.S.C. § 1320a-7

[7] 42 U.S.C. § 1320a–7a

[8] U.S. Department of Health and Human Services, Office of Inspector General. (n.d.). *A roadmap for new physicians: Avoiding Medicare and Medicaid fraud and abuse*. Retrieved from https://oig.hhs.gov/compliance/physician-education/index.asp

[9] U.S. Department of Health and Human Services, Office of Inspector General, *A roadmap for new physicians*.

[10] U.S. Department of Justice Civil Division. (2024, February 23 [last updated]). The False Claims Act. Retrieved from www.justice.gov/civil/false-claims-act

[11] 18 U.S.C. § 287

[12] U.S. Department of Health and Human Services, Office of Inspector General, *A roadmap for new physicians*.

[13] 42 U.S.C. § 1320a-7a(a)(5)

[14] U.S. Department of Health and Human Services, Office of Inspector General. (2023, November). *General compliance program guidance.* Retrieved from https://oig.hhs.gov/compliance/general-compliance-program-guidance/

[15] Ibid.

[16] Ibid.

[17] Ibid.

[18] Ibid.

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