

PEACE OF MIND

EXPERTISE

CHOICE

THE MEDPRO GROUP DIFFERENCE

— GUIDELINE —

Developing an Effective Compliance Plan: A Guide for Healthcare Practices



This document does not constitute legal or medical advice and should not be construed as rules or establishing a standard of care. Because the facts applicable to your situation may vary, or the laws applicable in your jurisdiction may differ, please contact your attorney or other professional advisors if you have any questions related to your legal or medical obligations or rights, state or federal laws, contract interpretation, or other legal questions.

MedPro Group is the marketing name used to refer to the insurance operations of The Medical Protective Company, Princeton Insurance Company, PLICO, Inc. and MedPro RRG Risk Retention Group. All insurance products are underwritten and administered by these and other Berkshire Hathaway affiliates, including National Fire & Marine Insurance Company. Product availability is based upon business and/or regulatory approval and/or may differ among companies.

Contents

Introduction	1
Objectives	1
Background	1
The Importance of a Compliance Plan	2
The Fraud and Abuse Laws.....	3
The Anti-Kickback Statute.....	3
The Physician Self-Referral Law (Stark Law)	4
The False Claims Act	4
Exclusion Statute	5
Civil Monetary Penalties Law	6
The Seven Fundamental Elements of an Effective Compliance Program	6
Element One: Implementing Written Policies, Procedures, and Standards of Conduct	7
Element Two: Designating a Compliance Officer and Compliance Committee to Provide Program Oversight	8
Element Three: Using Due Diligence in the Delegation of Authority	9
Element Four: Educating Employees and Developing Effective Lines of Communication	9
Element Five: Conducting Internal Monitoring and Auditing	11
Element Six: Enforcing Standards Through Well-Publicized Disciplinary Guidelines.....	12
Element Seven: Responding Promptly to Detected Offenses and Undertaking Corrective Action.....	12
Conclusion.....	12
Resources.....	13
Endnotes	13

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, it's important to note that 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.

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 individual and small group healthcare practices for a number of 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 the Children's Health Insurance Program (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 is not a sufficient excuse for 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 medical board.

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.

“

Not understanding the law or failing to provide compliance training for staff usually is not a sufficient excuse for violations.”

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
- The Physician Self-Referral Law (Stark Law)
- The False Claims Act
- The Exclusion Authorities
- The Civil Monetary Penalties Law

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 their legal counsel.

The Anti-Kickback Statute

The Anti-Kickback Statute³ 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.⁴

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 Law⁵ 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.⁶ 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.

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.

Example of a Stark Law Violation

An orthopaedic 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.

The False Claims Act

The civil False Claims Act⁷ 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 up to \$23,331 per claim filed.⁸ Further, an analogous criminal False Claims Act⁹ 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 up to 30 percent 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 physician 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 Statute

Under the Exclusion Statute,¹⁰ 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.¹¹

Civil Monetary Penalties Law

The Civil Monetary Penalties Law¹² 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 Fundamental Elements of an Effective Compliance Program

HHS-OIG has declared that the elements described in Chapter 8 of the *United States Sentencing Commission Guidelines Manual* are the seven fundamental elements of an effective compliance program.¹⁴ 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 fundamental elements are:

1. Implementing written policies, procedures, and standards of conduct
2. Designating a compliance officer (CO) and compliance committee (CC) to provide program oversight

3. Using due diligence in the delegation of authority
4. Educating employees and developing effective lines of communication
5. Conducting internal monitoring and auditing
6. Enforcing standards through well-publicized disciplinary guidelines
7. Responding promptly to detected offenses and undertaking corrective action¹⁵

Each of the elements will be 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: Implementing Written Policies, Procedures, and Standards of Conduct

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

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 CC should be involved in developing the policies, 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 within 90 days of hire and at least annually, and employees should be asked to acknowledge their review and

“

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

understanding of the policies. Additionally, each practice should have guidelines for periodic review and updating of the compliance policies.

Element Two: Designating a Compliance Officer and Compliance Committee to Provide Program 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 report directly to the CEO or senior management and should have primary responsibility for the compliance program structure and administration.

The CO should be very familiar with the practice's operational and compliance activities. This point is crucial because a CO without any delegated authority will likely not be very effective. The CO's daily duties may include:

- Understanding and administering the compliance program
- 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 clinical and administrative duties aside from compliance duties. The practice also may choose to outsource the CO role to a vendor.

The CC is a multidisciplinary committee that reports directly to the CEO or other high-ranking person or people in the organization. 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: Using Due Diligence in the Delegation of Authority

The third element of an effective compliance plan requires that each healthcare practice's management team takes responsibility for, and engages in, proper due diligence in the hiring and periodic assessment of management employees.

This element implies that practice leaders should conduct thorough background checks on all new management employees and periodic background checks on existing management employees. The practice should undertake reasonable efforts to ensure that employees have not engaged in illegal activities or other conduct inconsistent with the practice's compliance and ethics program.

Further, the practice's management team should ensure due diligence when hiring or contracting with vendors and other agents.

Element Four: Educating Employees and Developing Effective Lines of Communication

The fourth core 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.

Compliance training should be mandatory for all employees. The initial training should be a comprehensive review of the compliance plan and code of conduct. Thereafter, an annual review training should occur that highlights any compliance program changes or new developments as well as re-emphasizes the practice's code of conduct.

“

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

To aid 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.

The fourth element also includes developing effective lines of communication, which involves making communication about compliance issues an integral part of the practice and having an “open-door” policy throughout the organization.

Recommendations for developing an open communication culture include the following:

- 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.
- Create an anonymous reporting process to prevent real or perceived retaliation (e.g., an anonymous hotline, an email drop box, or a well-promoted open-door policy).

Employees should have several ways to report compliance and ethical concerns. The CO and/or CC should evaluate the reporting process for effectiveness. 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 practice (e.g., any manager, the CO, or CC). The CO should be available and accessible for routine questions about compliance or ethics.

Element Five: Conducting Internal Monitoring and Auditing

The fifth element of an effective compliance program is creating a system for monitoring and auditing the effectiveness of the program. This system will help providers comply with CMS requirements and identify compliance risks.

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.

Auditing is a comprehensive review and requires more effort than monitoring. Auditing ensures compliance with statutory and CMS requirements and includes routine evaluations of the compliance program to determine the program's overall effectiveness.

Internal staff or an external contractor should conduct an audit at least annually. The audit should result in a written report of findings and recommendations that the CO and/or CC should follow up on as part of their responsibilities.

Conducting a formal baseline risk assessment is a crucial component of developing monitoring and auditing work plans. The risk assessment should include areas of concern identified by CMS and other authoritative

“

Conducting a formal baseline risk assessment is a crucial component of developing monitoring and auditing work plans.”

organizations as well as classification of risk levels. Areas identified as high-risk, such as coding/billing and working with excluded providers, should be audited more frequently.

The monitoring work plan should cover frequency of monitoring, person(s) responsible, and issues of concern for the organization. The auditing work plan should cover methods the practice will use to conduct internal investigations, a time limit for closing investigations, corrective action guidelines, and criteria for external independent contractor review and/or referral to CMS or OIG.

Element Six: Enforcing Standards Through Well-Publicized Disciplinary Guidelines

The sixth element of an effective compliance program is to ensure consistent and timely discipline when an investigation confirms a violation. Disciplinary guidelines must be clearly written and describe expectations and consequences for noncompliance.

Guidelines should include sanctions for failure to comply with the code of conduct, failure to detect noncompliance when routine observation or due diligence would have provided notice, and failure to report actual or suspected noncompliance.

“

Disciplinary guidelines must be clearly written and describe expectations and consequences for noncompliance.”

The practice should review disciplinary guidelines at least annually with all employees, and the information should be readily available for review so that employees are well aware of their obligations.

Element Seven: Responding Promptly to Detected Offenses and Undertaking Corrective Action

The final element of an effective compliance program is the use of corrective actions when vulnerabilities, noncompliance, or potential violations are identified. 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 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 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>

⁵ 42 U.S.C. § 1395nn

⁶ U.S. Department of Health and Human Services, Office of Inspector General, *A roadmap for new physicians*.

⁷ 31 U.S.C. §§ 3729-3733

⁸ 85 Fed. Reg. 37004

⁹ 18 U.S.C. § 287

¹⁰ 42 U.S.C. § 1320a-7

¹¹ U.S. Department of Health and Human Services, Office of Inspector General, *A roadmap for new physicians*.

¹² 42 U.S.C. § 1320a-7a

¹³ 42 U.S.C. § 1320a-7a(a)(5)

¹⁴ United States Sentencing Commission. (2018, November). Sentencing of organizations. In *United States Sentencing Commission guidelines manual*. Retrieved from <https://www.ussc.gov/guidelines/2018-guidelines-manual-annotated>

¹⁵ U.S. Department of Health and Human Services, Office of Inspector General, Health Care Fraud Prevention and Enforcement Action Team. (n.d.). *Health care compliance program tips*. Retrieved from <https://oig.hhs.gov/compliance/provider-compliance-training/files/compliance101tips508.pdf>

medpro.com

PATIENT SAFETY & RISK SOLUTIONS