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# Compliance Plans

An Ounce of Prevention is Worth a Pound of Cure

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# Introduction

# INTRODUCTION

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- The legal environment for pharmacies has become more complicated.
- Now, more than in the past, pharmacies are under the spotlight of government regulatory agencies.
- One reason for the increased scrutiny by regulatory agencies is the fact that demand for prescription drugs is increasing exponentially.
  - This demand is fueled by the 78 million “Baby Boomers” who are retiring at the rate of 10,000 per day.
  - Many of these Boomers will need maintenance drugs to treat chronic diseases.

# INTRODUCTION

- Another reason for the increased scrutiny is the fact that pharmacies are providing a number of services that go beyond what is offered by the traditional “walk-in” retail pharmacy:
  - Compounding
  - Specialty drugs
  - Infusion
  - Long-term care
  - Durable medical equipment
- And then, we come to an unpleasant reason for increased scrutiny: questionable business practices and fraud
  - Pharmacies are aggressively marketing compounded medications with high reimbursement
  - Pharmacies are engaging in questionable—sometimes fraudulent—marketing practices and arrangements with referral sources (e.g., physicians)

# INTRODUCTION

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- If a pharmacy is doing something it should not be doing, then “someone knows about it”
- Every existing employee, previous employee—indeed, any person—is a potential “whistleblower”
- The bottom line is that the pharmacy “lives in a glass house.” From a legal compliance standpoint, its operations must be pristine.

# INTRODUCTION

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- This webinar addresses how a pharmacy can implement a successful compliance plan.
  - It will discuss the reasons to do so
  - It will discuss why a compliance plan is necessary
  - It will discuss what steps can be taken to create a culture of compliance



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# The Patient Protection and Affordable Care Act

# PATIENT PROTECTION & AFFORDABLE CARE ACT

- The Senate Health Reform Bill, H.R. 3590, entitled the “Patient Protection and Affordable Care Act” (PPACA), was passed by the U.S. Senate on December 24, 2009.
- The House of Representatives passed the Senate Bill on March 22, 2010, and the President signed it into law on March 23, 2010.
- Pharmacies receiving federal funds are required to have a compliance plan that comply with the Federal Sentencing Guidelines.
- Chapter 9 of the Medicare Prescription Drug Benefit Manual contains interpretations, rules, and guidelines for Part D Plan Sponsors.
- Chapter 21 of the Medicare Managed Care Manual requires plan sponsors to maintain a corporate compliance plan.





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# Steps to Reduce the Risk of Being Subjected to an Enforcement Action

# EFFECTIVE CORPORATE COMPLIANCE PROGRAM

- A functioning corporate compliance plan will identify areas of concern prior to a regulator identifying the issues.

# WHY IMPLEMENT A COMPLIANCE PROGRAM

- First, an effective compliance plan will save a pharmacy money and stress.
- If providing durable medical equipment, the quality standards for suppliers of durable medical equipment, prosthetics, or products and supplies issued on August 14, 2006, require a compliance plan.
- It will reduce concerns with regulators such as the DEA, FDA, and state licensure boards.

# 10 REASONS TO IMPLEMENT A COMPLIANCE PROGRAM

1. Adopting a compliance program concretely demonstrates to the community at large that a provider has a strong commitment to honesty and responsible corporate citizenship.
2. Compliance programs reinforce employees' innate sense of right and wrong.
3. An effective compliance program helps a provider fulfill its legal duty to government and private payors.
4. Compliance programs are cost effective.
5. A compliance program provides a more accurate view of employee and contractor behavior relating to fraud and abuse.

# 10 REASONS TO IMPLEMENT A COMPLIANCE PROGRAM

6. The quality of care provided to patients is enhanced by an effective compliance program.
7. A compliance program provides procedures to promptly correct misconduct.
8. An effective compliance program may mitigate any sanction imposed by the government.
9. Voluntarily implementing a compliance program is preferable to waiting for the OIG to impose a corporate integrity agreement.
10. Effective corporate compliance programs may protect corporate directors from personal liability.

# COMPLIANCE OBSTACLES

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- Following are 10 obstacles that suppliers may face in implanting effective compliance programs ...

# 10 OBSTACLES IN IMPLEMENTING A COMPLIANCE PROGRAM

1. Creating buy-in and enthusiasm
2. Changing past behavior
3. Lack of or poor communication
4. Too many roles for compliance officer
5. Not enough financial support
6. Integrating compliance with other systems
7. Overcoming fear of retaliation/retribution
8. Finding qualified people
9. Lack of procedures
10. Education and training



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# How a Corporate Compliance Program Should be Structured



# HOW A CORPORATE COMPLIANCE PROGRAM SHOULD BE STRUCTURED

- There are 7 required elements of an effective compliance program
  1. Written Policies and Procedures

This element will include a code of conduct covering such areas as:

    - a) Relationships with physicians and others in a position to influence business
    - b) Conflicts of interest
    - c) Receipt of improper payments or gifts
    - d) Employment practices
    - e) Billing practices, and
    - f) Organizational and financial records and many others.
  2. Designation of a Compliance Officer and Compliance Committee
  3. Auditing and Monitoring

# HOW A CORPORATE COMPLIANCE PROGRAM SHOULD BE STRUCTURED

4. Developing Effective Lines of Communication
5. Enforcement of Disciplinary Standards
6. Auditing and Monitoring
7. Response to Offenses and Corrective Action

# HOW A CORPORATE COMPLIANCE PROGRAM SHOULD BE STRUCTURED

- It is important to note that in order to be deemed “effective,” the compliance program must be something more than a set of documents that simply restate these 7 elements.
- These 7 basic elements must be specifically implemented by the organization and be designed to address past, existing and future activities of the organization.

# IDENTIFYING RISK AREAS

- It is not enough for suppliers to implement policies and procedures generally geared at educating staff and identifying potential regulatory and statutory violations.
- The organization is required to implement policies and procedures targeted at specific risk areas of concern to the individual company.
- Pharmacies should consider the following areas
  - Waiver of copayments
  - Avoiding improper compounding
  - Off-label use of a drug
  - “Own use” contract
  - Value-added services vs. prohibited inducements
  - Compliance with laws regulating drug samples
  - Relationships with sales agents

# IDENTIFYING RISK AREAS

- The OIG has provided multiple compliance guidance documents, including for DME and pharmaceutical manufacturers. In its guidance to DME suppliers, it sets out areas of concern. These areas also should be considered by pharmacies when drafting their corporate compliance program:
  - Billing for items or services not provided;
  - Billing for services that the supplier believes may be denied;
  - Billing patients for denied charges without a signed written notice;
  - Duplicate billing;
  - Billing for items or services not ordered;
  - Using a billing agent whose compensation arrangement violates the reassignment rule;
  - Upcoding;
  - Unbundling items or supplies;
  - Billing for new equipment and providing used equipment;
  - Continuing to bill for rental items after they are no longer medically necessary;
  - Resubmission of denied claims with different information in an attempt to be improperly reimbursed;

# IDENTIFYING RISK AREAS

- Refusing to submit a claim to Medicare for which payment is made on a reasonable charge or fee schedule basis;
- Inadequate management and oversight of contracted services, which results in improper billing;
- Charge limitations;
- Providing and/or billing for substantially excessive amounts of DME items or suppliers;
- Providing and/or billing for an item or service that does not meet the quality and standard of the DME item claimed;
- Capped rentals;
- Failure to monitor medical necessity on an ongoing basis;
- Delivering or billing for certain items or supplies prior to receiving a physician's order and/or appropriate CMN;
- Falsifying information on the claim form, CMN, and/or accompanying documentation;
- Completing portions of CMNs reserved for completion only by the treating physician or other authorized person;

# IDENTIFYING RISK AREAS

- Altering medical records;
- Manipulating the patient's diagnosis in an attempt to receive improper payment;
- Failing to maintain medical necessity documentation;
- Inappropriate use of place of service codes;
- Cover letters that encourage physicians to order medically unnecessary items or services;
- Improper use of the KX modifier;
- Routine waiver of deductibles and coinsurance;
- Providing incentives to actual or potential referral sources (e.g., physicians, hospitals, patients, skilled nursing facilities, home health agencies or others) that may violate the anti-kickback statute or other similar federal or state statute or regulation;
- Compensation programs that offer incentives for items or services ordered and revenue generated;
- Joint ventures between parties, one of which can refer Medicare or Medicaid business to the other;
- Billing for items or services furnished pursuant to a prohibited referral under the Stark physician self-referral law;

# IDENTIFYING RISK AREAS

- Improper telemarketing practices;
- Improper patient solicitation activities and high-pressure marketing of non-covered or unnecessary services;
- Co-location of DME items and supplies with the referral source;
- Non-compliance with the federal, state and private payor supplier standards;
- Providing false information on the Medicare DME supplier enrollment form;
- Misrepresenting a person's status as an agent or representative of Medicare;
- Knowing misuse of a supplier number, which results in improper billing;
- Failing to meet individual payor requirements;
- Performing tests on a beneficiary to establish medical necessity;
- Failing to refund overpayments to a health care program;
- Failing to refund overpayments to patients;
- Improper billing resulting from a lack of communication between different departments within the supplier; and supplier, the physician, and the patient;
- Employing persons excluded from participation in federal health care programs.



# COMPLIANCE PROGRAM FOLLOW UP

- Once the corporate compliance program is implemented, a pharmacy must continue to take steps on an on-going basis to ensure that the plan remains effective.
- A pharmacy should continually monitor its compliance program to ensure that it does not need updating to reflect new laws or regulations and to ensure that it contains up-to-date policies and procedures for compliance and HIPAA privacy and security guidelines.
- It should also perform routine self-audits to track the effectiveness of its compliance plan in preventing regulatory and legislative violations.

# COMPLIANCE PROGRAM UPDATING

- In order for a corporate compliance program to be effective it must be updated on a regular basis.
- In reviewing a corporate compliance program to determine if it requires updating, a pharmacy should take note of the following:
  - What was the date of implementation of the corporate compliance program?
  - Has the pharmacy's scope of practice changed since implementation of the compliance plan?
  - Is the company following its obligations under the corporate compliance program to continually train its employees?
  - Is the corporate compliance officer in tune with regulatory changes in the health care industry?

# HIPAA COMPLIANCE PLAN

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- Companies should be diligent in monitoring their HIPAA compliance and ensuring that their employees continue to follow the procedures set forth in the supplier's HIPAA compliance plan.

# FACILITY POLICIES & PROCEDURES

- Many pharmacies do not have comprehensive policy and procedure manuals.
- It is important that pharmacies continually monitor matters related to employment practices, company harassment policies, confidentiality and other day-to-day operational issues.
- Pharmacies need to designate an individual who will be responsible for monitoring legislative and regulatory changes that are relevant to the operation of their businesses.

# SELF-AUDITS

- Self-auditing and monitoring has many advantages and very few disadvantages for the pharmacy.
  - Routine
    - An effective internal audit process will become part of what the company does. It will become as much part of the daily, weekly, or monthly tasks as filing or working denials.
  - Periodic
    - An effective audit procedure takes place periodically. The exact period is not crucial, but audits should occur at defined time intervals.
    - At the very least, audits should be performed annually.
    - Also note that audit frequency is influenced by the scope of the audit.
    - More frequent audits have the advantage of allowing a company to more quickly find and correct problems.

# SELF-AUDITS

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- Eventually Cover All Areas of Exposure
- Individuals Held Accountable
  - Individuals should be held accountable both for the performance of the audits and for implementing any changes that result from the audits.
- Documentation of the Audit
  - Proper documentation of an audit must be maintained.
  - The scope of a pharmacy's audit should depend on the pharmacy's identified risk areas and resources.



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# Conclusion

# CONCLUSION

- It is clear that a compliance plan should be tailored to an organization's size and complexity.
- A pharmacy should use the resources it has available to implement a compliance program that is both appropriate for its needs and designed to address its specific risk areas.
- The organization should not hesitate to reach outside its walls for assistance.
- Organizations such as the Health Care Compliance Association are available to assist entities of all sizes in obtaining more information about compliance issues and updated information about changes to statutory and regulatory provisions.
- There are numerous resources for suppliers to assist in implementation of a corporate compliance program including consultants, national and state associations, and health care attorneys.



# CONCLUSION

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- The bottom line is that corporate compliance programs are here to stay.
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- They have been made a priority by the OIG and CMS, and suppliers need to work diligently to implement an effective corporate compliance program for their organization.



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# Questions?



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# Thank You

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