MEDICARE PARTS C & D PART 1: FRAUD, WASTE AND ABUSE TRAINING

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**Medicare Parts C & D Part 1: Fraud, Waste and Abuse Training**

**Activity Description**
With an anticipated increase in prescriptions resulting from the Affordable Care Act and Medicaid expansion, US pharmacy departments (including hospital, retail, long term, etc.) will have an influx of orders and fraudulent activity will be on the rise. Many pharmacists may not recognize healthcare fraud or are unaware of the legal consequences. Our goal is to define healthcare fraud, waste and abuse and identify next steps discovered.

**Target Audience**
The target audience for this activity is pharmacists and pharmacy technicians in hospital, community, and retail pharmacy settings.

**Learning Objectives**
After completing this activity, the pharmacist will be able to:
- Describe the regulatory requirement for training and education
- Identify the scope of fraud, waste, and abuse
- Recognize obligation of everyone to detect, prevent, and correct fraud, waste, and abuse
- Identify how to report fraud, waste, and abuse
- Recognize laws pertaining to fraud, waste, and abuse

After completing this activity, the pharmacy technicians will be able to:
- Describe the regulatory requirement for training and education
- Identify the scope of fraud, waste, and abuse
- Recognize obligation of everyone to detect, prevent, and correct fraud, waste, and abuse
- Identify how to report fraud, waste, and abuse
- Recognize laws pertaining to fraud, waste, and abuse

**Accreditation**

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ABOUT THE AUTHOR
Pharmacist/Attorney Erica Lindsay, PharmD, MBA, Esq. graduated from Florida A&M University College of Pharmacy with a PharmD degree, a MBA from Purdue University, and a Juris Doctor degree from North Carolina Central University. Lindsay is an active member of various organizations including American Bar Association (ABA), Chicago Bar Association (CBA) and Health Care Compliance Association (HCCA). She has worked in pharmacy compliance for over 15 years and has developed, evaluated, and implemented corporate compliance plans for hospitals and clinics. Currently, Lindsay is an ethics and compliance professional consulting clients through complex pharmacy regulations and guidelines, including 340B, Medicare and Medicaid billing, and HIPAA compliance.

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Medicare Parts C & D Part 1: Fraud, Waste and Abuse Training
Developed by: The Centers for Medicare & Medicaid Services

Faculty
Erin Lindsay, PharmD, MBA, Esq.

Objectives
1. Describe the regulatory requirement for training and education
2. Identify the scope of fraud, waste, and abuse
3. Recognize obligation of everyone to detect, prevent, and correct fraud, waste, and abuse
4. Identify how to report fraud, waste, and abuse
5. Recognize laws pertaining to fraud, waste, and abuse

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Define Medicare & Medicaid

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Requirements

The Social Security Act and CMS regulations and guidance govern the Medicare program, including parts C and D.

- Part C and Part D sponsors must have an effective compliance program which includes measures to prevent, detect and correct Medicare non-compliance as well as measures to prevent, detect and correct fraud, waste, and abuse.
- Sponsors must have an effective training for employees, managers and directors, as well as their first tier, downstream, and related entities.

Where Do I Fit In?

Part C: Medicare Advantage Organization and Part D: Prescription Drug Plan, and Medicare Advantage-Prescription Drug Plan

(A Larger Image of Chart Will Be Available In Handout)

What are My Responsibilities?

You are a vital part of the effort to prevent, detect, and report Medicare non-compliance as well as possible fraud, waste, and abuse.

- **FIRST** your organization is required to comply with all applicable statutory, regulatory, and other Part C or Part D requirements, including adopting and implementing an effective compliance program.
- **SECOND** you have a duty to the Medicare Program to report any violations of laws that you may be aware of.
- **THIRD** you have a duty to follow your organization’s Code of Conduct that articulates your organization’s commitment to standards of conduct and ethical rules of behavior.

Compliance Program Requirements

At a minimum, a compliance program must include the 7 core requirements:

1. Written Policies, Procedures and Standards of Conduct;
2. Compliance Officer, Compliance Committee and High Level Oversight;
3. Effective Training and Education;
4. Effective Lines of Communication;
5. Well Publicized Disciplinary Standards;
6. Effective System for Routine Monitoring and Identification of Compliance Risks; and
7. Procedures and System for Prompt Response to Compliance Issues
8. **Periodic Assessments**

How Do I Prevent Fraud, Waste and Abuse?

• Make sure you are up to date with laws, regulations, policies.
• Ensure you coordinate with other payers.
• Ensure data/billing is both accurate and timely.
• Verify information provided to you.
• Be on the lookout for suspicious activity.

Policies and Procedures

Every sponsor, first tier, downstream, and related entity must have policies and procedures in place to address fraud, waste, and abuse. These procedures should assist you in detecting, correcting, and preventing fraud, waste, and abuse.

Understanding Fraud, Waste and Abuse

In order to detect fraud, waste, and abuse you need to know the Law.
Fraud

Intentionally deceiving, providing false statements, or misrepresentation in order to obtain an unauthorized benefit for yourself or another person.

Purposely billing Medicare for products or services that were never provided or received.

Fraudulent activity is knowingly, willfully, and intentionally committed or committed with reckless disregard.

Waste and Abuse

Waste: overutilization of services, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare Program.

Waste is generally not considered to be caused by criminally negligent actions but rather the misuse of resources.

Abuse: includes actions that may, directly or indirectly, result in unnecessary costs to the Medicare Program.

Abuse involves payment for items or services when there is not legal entitlement to that payment and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment.

Differences Between Fraud, Waste, and Abuse

One of the primary differences is Intent and Knowledge

Fraud requires the person to have an intent to obtain payment and the knowledge that their actions are wrong.

Waste and abuse may involve obtaining an improper payment, but does not require the same intent and knowledge.

Indicators of Potential Fraud, Waste, and Abuse

The following slides present issues that may be potential fraud, waste, or abuse. Each slide provides areas to keep an eye on, depending on your role as a sponsor, pharmacy, or other entity involved in the Part C and/or Part D programs.
Key Indicators: Potential Beneficiary Issues

- Does the prescription look altered or possibly forged?
- Have you filled numerous identical prescriptions for this beneficiary, possibly from different doctors?
- Is the person receiving the service/picking up the prescription the actual beneficiary (identity theft)?
- Is the prescription appropriate based on beneficiary’s other prescriptions?
- Does the beneficiary’s medical history support the services being requested?

Key Indicators: Potential Provider Issues

- Does the provider write for diverse drugs or primarily only for controlled substances?
- Are the provider’s prescriptions appropriate for the member’s health condition (medically necessary)?
- Is the provider writing for a higher quantity than medically necessary for the condition?
- Is the provider performing unnecessary services for the member?

Key Indicators: Potential Provider Issues

- Is the provider’s diagnosis for the member supported in the medical record?
- Does the provider bill the sponsor for services not provided?

Key Indicators: Potential Pharmacy Issues

- Are the dispensed drugs expired, fake, diluted, or illegal?
- Do you see prescriptions being altered (changing quantities or Dispense As Written)?
- Are proper provisions made if the entire prescription cannot be filled (no additional dispensing fees for split prescriptions)?
- Are generics provided when the prescription requires that brand be dispensed?
Key Indicators: Potential Pharmacy Issues

- Are PBM’s being billed for prescriptions that are not filled or picked up?
- Are drugs being diverted (drugs meant for nursing homes, hospice, etc. being sent elsewhere)?

Key Indicators: Potential Wholesaler Issues

- Is the wholesaler distributing fake, diluted, expired, or illegally imported drugs?
- Is the wholesaler diverting drugs meant for nursing homes, hospices, and AIDS clinics and then marking up the prices and sending to other smaller wholesalers or to pharmacies?

Key Indicators: Potential Manufacturer Issues

- Does the manufacturer promote off label drug usage?
- Does the manufacturer provide samples, knowing that the samples will be billed to a federal health care program?

Key Indicators: Potential Sponsor Issues

- Does the sponsor offer cash inducements for beneficiaries to join the plan?
- Does the sponsor lead the beneficiary to believe that the cost of benefits are one price, only for the beneficiary to find out that the actual costs are higher?
- Does the sponsor use unlicensed agents?
- Does the sponsor encourage/support inappropriate risk adjustment submissions?
How Do I Report Fraud, Waste, or Abuse?

Reporting Fraud, Waste and Abuse

Everyone is required to report suspected instances of fraud, waste, and abuse.

Your sponsor’s Code of Conduct and Ethics should clearly state this obligation.

Sponsors may not retaliate against you for making a good faith effort in reporting.

Reporting Fraud, Waste and Abuse

Do not be concerned about whether it is fraud, waste, or abuse.
Just report any concerns to your compliance department or your sponsor’s compliance department.
Your sponsor’s compliance department area will investigate and make the proper determination.

Reporting Fraud, Waste and Abuse

Every Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA-PDs) sponsor is required to have a mechanism in place in which potential Fraud, Waste or Abuse may be reported by employees, first tier, downstream, and related entities.

Each sponsor must be able to accept anonymous reports and cannot retaliate against you for reporting. Review your sponsor’s materials for the ways to report fraud, waste, and abuse.

When in doubt, call the MA-PD or PDP fraud, waste, and abuse Hotline or the Compliance Department.
Reporting

The OIG National Fraud Hotline
800-HHS-TIPS (800-447-8477)

Website Link: http://oig.hhs.gov/fraud/
Report Fraud Link

Fax 1-800-223-8164 (max 10 pages)

Email HHSTips@oig.hhs.gov

Professional Oaths

Oath of a Pharmacist
A pharmacist shall:
• Promote the welfare of humanity and shall not
practice or allow to be practiced any profession for
which he is not qualified.
• Act with honesty and integrity in all professional
transactions.
• Avoid conflict of interest.
• Maintain professional competence through
continued education.

Florence Nightingale Pledge
Nurse Ethic Oath
• A nurse shall
• Uphold the standards of nursing as set forth by the
American Nurses Association.
• Promote the welfare of humanity.
• Maintain professional competence through
continued education.

Correction

Once fraud, waste, or abuse has been detected it
must be promptly corrected. Correcting the problem
saves the government money and ensures you are in
compliance with CMS’ requirements.
How Do I Correct Issues?

Once issues have been identified, a plan to correct the issue needs to be developed. Consult your compliance officer or your sponsor’s compliance officer to find out the process for the corrective action plan development.

The actual plan is going to vary, depending on the specific circumstances.

Laws You Need to Know About

Three Areas of Federal/State Law

Criminal

- Incarceration or Probation
- Each element of statute allegedly violated by the accused must be proven by the government – Beyond a Reasonable Doubt

Civil

- Money Damages awarded based on Preponderance of the Evidence

Administrative

- Interest in protecting consumer Public Health and Welfare
- Issuing authority of professional license – i.e. Board of Pharmacy
- Professional Regulation by an Administrative Law Judge

Civil Fraud Civil False Claims Act

Prohibits:

- Presenting a false claim for payment or approval;
- Making or using a false record or statement in support of a false claim;
- Conspiring to violate the False Claims Act;
- Falsely certifying the type/amount of property to be used by the Government;
- Certifying receipt of property without knowing if it’s true;
- Buying property from an unauthorized Government officer; and
- Knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay the Government.
Civil False Claims Act Damages and Penalties

The damages may be tripled. Civil Money Penalty between $5,000 and $10,000 for each claim.

Criminal Fraud

Knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program; or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program.

Criminal Fraud Penalties

If convicted, the individual shall be fined, imprisoned, or both. If the violations resulted in death, the individual may be imprisoned for any term of years or for life, or both.

Anti-Kickback Statute

Prohibits:

Knowingly and willfully soliciting, receiving, offering or paying remuneration (including any kickback, bribe, or rebate) for referrals for services that are paid in whole or in part under a federal health care program (which includes the Medicare program).
Anti-Kickback Statute Penalties

Fine of up to $25,000, imprisonment up to five (5) years, or both fine and imprisonment.

Stark Statute
(Physician Self-Referral Law)

Prohibits a physician from making a referral for certain designated health services to an entity in which the physician (or a member of his or her family) has an ownership/investment interest or with which he or she has a compensation arrangement (exceptions apply).

Stark Statute Damages and Penalties

Medicare claims tainted by an arrangement that does not comply with Stark are not payable. Up to a $15,000 fine for each service provided. Up to a $100,000 fine for entering into an arrangement or scheme.

Exclusion

No Federal health care program payment may be made for any item or service furnished, ordered, or prescribed by an individual or entity excluded by the Office of Inspector General.
HIPAA

Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191)

Created greater access to health care insurance, protection of privacy of health care data, and promoted standardization and efficiency in the health care industry.

Safeguards to prevent unauthorized access to protected health care information.

As a individual who has access to protected health care information, you are responsible for adhering to HIPAA.

Federal Health Care Regulations

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Consequences of Committing Fraud, Waste, or Abuse

The following are potential penalties. The actual consequence depends on the violation.

- Civil Money Penalties
- Criminal Conviction/Fines
- Civil Prosecution
- Imprisonment
- Loss of Provider License – Administrative Law
- Exclusion from Federal Health Care programs
Scenario #1

In a retail pharmacy, the staff encourages patients to enroll in auto-refill for medications on their profile. Once due, auto-refills are processed and filed in the cashiers' area for 7 days. After 7 days, the cashiers place the prescriptions back on the shelf for resale after removing patient's information but the claims are not reversed in the system.

What do you do?

Scenario #2

Your job is to submit risk diagnosis to CMS for purposes of payment. As part of this job you are to verify, through a certain process, that the data is accurate. Your immediate supervisor tells you to ignore the sponsor's process and to adjust/add risk diagnosis codes for certain individuals.

What do you do?

Scenario #1 Answer

Answer: B or C

Report the incident to the compliance department (via compliance hotline or other mechanism) or if you are comfortable discussing the situation with your immediate supervisor, reach out to them directly.

The compliance department is responsible for investigating and taking appropriate action.

Your sponsor/supervisor may NOT intimidate or take retaliatory action against you for good faith reporting concerning a potential compliance, fraud, waste, or abuse issue.
Scenario #2

A. Do what is asked of your immediate supervisor
B. Report the incident to the compliance department (via compliance hotline or other mechanism)
C. Discuss concerns with immediate supervisor
D. Contact law enforcement

Scenario #2 Answer

Answer: B
Report the incident to the compliance department (via compliance hotline or other mechanism)

The compliance department is responsible for investigating and taking appropriate action. Your sponsor/supervisor may NOT intimidate or take retaliatory action against you for good faith reporting concerning a potential compliance, fraud, waste, or abuse issue.

Scenario #3

You are in charge of payment of claims submitted from providers. You notice a certain diagnostic provider (“Doe Diagnostics”) has requested a substantial payment for a large number of members. Many of these claims are for a certain procedure. You review the same type of procedure for other diagnostic providers and realize that Doe Diagnostics’ claims far exceed any other provider that you reviewed.

What do you do?

Scenario #3

A. Call Doe Diagnostics and request additional information for the claims
B. Consult with your immediate supervisor for next steps
C. Contact the compliance department
D. Reject the claims
E. Pay the claims
Scenario #3 Answer

Answers B or C
Consult with your immediate supervisor for next steps
or
Contact the compliance department

Either of these answers would be acceptable. You do not want to contact the provider. This may jeopardize an investigation. Nor do you want to pay or reject the claims until further discussions with your supervisor or the compliance department have occurred, including whether additional documentation is necessary.

Questions and Answers

This concludes the Medicare Parts C & D Fraud,
Waste and Abuse training.

Please look for Part II of the webinar,
Medicare Parts C & D Compliance training.
1. Fraud Waste and Abuse is regulated by CMS? True or False  
   a. True  
   b. False  

2. CMS requires an effective compliance program for sponsors of Part C and Part D?  
   a. True  
   b. False  

3. Which is a 7 core requirement of a compliance program  
   a. Drug Monitoring  
   b. 340B audits  
   c. Compliance Officer, Compliance Committee and High Level Oversight  
   d. HIPAA reporting  

4. Which is not role recognized as a participant in Part C/Part D programs  
   a. Beneficiary  
   b. Provider  
   c. Manufacturer  
   d. Chief Compliance Officer  

5. Does pharmacist have an obligation to report fraud?  
   a. True  
   b. False  

6. True or False: To commit fraud, intent must be established.  
   a. True  
   b. False  

7. Overuse or Misuse of services and resources is an example of:  
   a. Fraud  
   b. Waste  
   c. Abuse  
   d. Overcharge  

8. True or False: A practitioner can be convicted of Criminal charges and not convicted of civil charges for the same case.  
   a. True  
   b. False
9. Which State Agency can revoke a pharmacist’s professional license?
   a. Department of Bureau of Motor Vehicles
   b. State Board of Pharmacy
   c. State’s Medical Board
   d. Department of Health and Human Services

10. True or False: Whistleblowers DO NOT have protection from retaliation once they report fraudulent activity against their employer.
    a. True
    b. False

   Please submit your final responses on freeCE.com. Thank you.