pharmpix
RX BENEFIT MANAGEMENT

PharmPix Pharmacy Network Provider: Fraud, Waste and Abuse (FWA) and General Compliance Training

CHANGING THE WAY PBM WORKS, NOW AND FOREVER

OBJECTIVES

- Understand what is Fraud, Waste and Abuse.
- Learn about FWA Program Requirements.
- Identify possible FWA cases.
- Learn about laws pertaining to fraud, waste, and abuse.
- How to report suspected FWA.

APPLICABILITY

"Every year *millions* of dollars are improperly spent because of fraud, waste, and abuse. It affects everyone.

Including YOU.

This training will help you detect, correct, and prevent fraud, waste, and abuse.

YOU are part of the solution."

*** Cited from the CMS Fraud, Waste and Abuse training deck.**

APPLICABILITY

Fraud, Waste, and Abuse regulations apply to:

1. Part C or D Sponsor Employees
2. First Tier Entity
   a. Example: PBM, claims processing companies, etc.
3. Downstream Entities
   a. Example: Pharmacy
4. Related Entity:
   a. Example: Entity that has a common ownership or control of Part C/D Sponsor.

* Cited from the CMS Fraud, Waste and Abuse training deck.

RESPONSIBILITIES

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

* Cited from the CMS Fraud, Waste and Abuse training deck.

WHAT IS FRAUD, WASTE AND ABUSE?

- Fraud
  - It is the intentional misleading or deceitful conduct that deprives another of his/her resources or rights.
    - Fraud always involves intent and some violation of trust

WHAT IS FRAUD, WASTE AND ABUSE?

- Waste
  - Occurs when someone makes careless or extravagant expenditures, incurs in unnecessary expenses, or grossly mismanages resources.
    - It may or may not provide the person with personal gain

WHAT IS FRAUD, WASTE AND ABUSE?

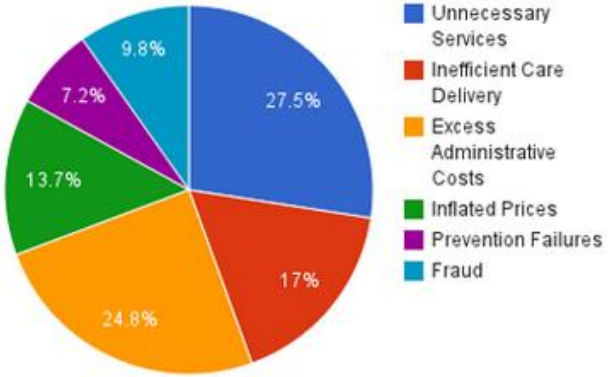
- Abuse
  - Includes, but is not limited to the misuse or destruction of resources, using the power of an official position inappropriately, or any other seriously improper practice that cannot be prosecuted as fraud.
    - Is very close to fraud, but is often not prosecutable as such.

TYPES OF HEALTH CARE FRAUD

- Billing for services not rendered
- Billing for more expensive services or procedures than were actually provided
- Performing medically unnecessary services
- Falsifying a patient's diagnosis to justify tests
- Accepting kickbacks for patient referrals

HOW BIG IS THE PROBLEM?

- In 2008, the United States spent more than $2.3 trillion on health care
  - NHCAA estimates conservatively that at least 3%--or more than **$70 billion**--was lost to fraud.
  - IOM estimates the US loses around **$750 billion** annually to medical fraud, inefficiencies, and other reasons.



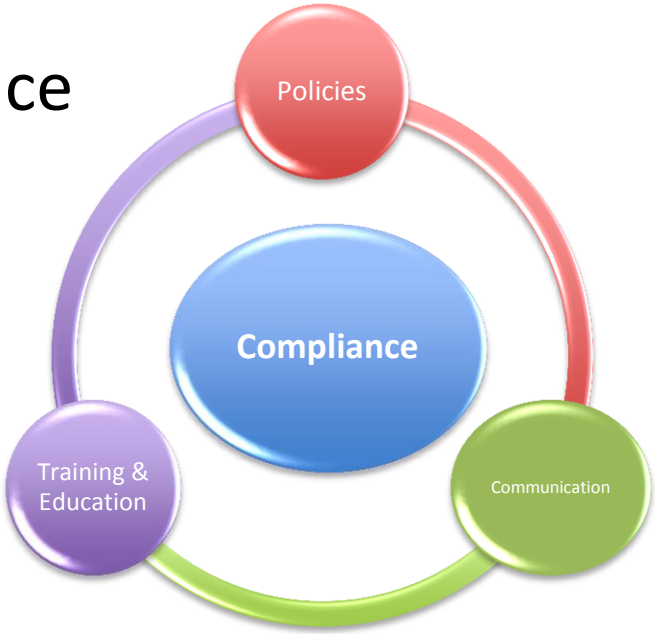
INTRODUCTION TO FRAUD, WASTE AND ABUSE (FWA) REQUIREMENTS

- CMS requires Part D Plan sponsors to establish a program to control fraud waste and abuse in the administration of the Part D benefit.

- The Part D Plan sponsor should have an internal investigative unit that should monitor public and private investigation and litigation activity concerning pharmacy FWA and networks with others concerning these investigations.

INTRODUCTION TO FRAUD, WASTE AND ABUSE (FWA) REQUIREMENTS

- Specific requirements include:
  - Written Policies and Procedures and Standards of Conduct
  - Compliance Officer and Compliance Committee
  - Training and Education
  - Effective lines of communication



pharmpix RX BENEFIT MANAGEMENT

INTRODUCTION TO FRAUD, WASTE AND ABUSE (FWA) REQUIREMENTS

- Specific requirements include (cont.):
  - Enforcement of Standards through well publicized disciplinary guidelines
  - Monitoring and Auditing
  - Corrective Action Procedures
  - Comprehensive Fraud and Abuse Plans-Procedures to voluntarily self-report potential fraud or misconduct

SETTINGS OF FRAUD

- Part D Sponsors
- PBM
- Community Pharmacy
- Prescriber
- Wholesaler
- Beneficiaries

PART D SPONSORS

- Marketing
- Enrollment/disenrollment
- Reimbursement
- Failure to provide medically necessary care
- Manipulation of TrOOP
- Rebates, pricing, discounts

PBM

- Drug switching
- Inappropriate formulary decisions
- Drug shorting
- Pressuring prescribers to change
- Pricing

COMMUNITY PHARMACIES

- Drug Shorting
- Inappropriate billing
- Prescription forging
- Dispensing expired or returned drugs
- Diverting medications

PRESCRIBERS

- Illegal remuneration
- Script mills
- Drug switching for consideration
- Providing false information

BENEFICIARIES

- Card Sharing
- Identity Theft
- TrOOP Manipulation
- Rx Forging or Altering
- Rx Diversion or Inappropriate use
- Resale of drugs on black market
- Doctor shopping
- Improper COB

Expectation is to work pharmacy investigations and make referrals.

Part D excerpts:

- "…Sponsors must have procedures…to identify and address fraud, waste and abuse
- …and a comprehensive fraud and abuse plan to detect…fraud waste and abuse
- …and a process to refer potential violations…to Federal and State enforcement agencies
- …for those sponsors who have an (Special Investigation Unit) SIU, CMS views the work of the SIU as critical if…[fraud is to be identified]."

ALLEGATION EXAMPLES WITHIN PART D INVESTIGATIONS:

- Pharmacy up-coding to a more expensive prescription.
- Billing for non-existent prescriptions.
- Illegal use of physician DEA numbers, prescription forging by members.
- Pharmacy prescription splitting, billing for partial fills, billing for non-covered prescriptions, generic switching to maximize reimbursement.
- Prescription diversion; doctor and pharmacy shopping.

ACTIVITIES AT THE PROVIDER LEVEL RESULTING IN FWA ON PART D PROGRAMS

- **Up-coding and billing for non-existent prescriptions**

  - A customer suspected that the pharmacist was billing for prescriptions he never ordered or received; and billing for more product than was dispensed

ACTIVITIES AT THE PROVIDER LEVEL RESULTING IN FWA ON PART D PROGRAMS

- **Inappropriate generic substitution**

  - A pharmacist pleaded guilty to 15 counts of filing false claims. The pharmacist billed for prescriptions never provided and also for dispensing generic drugs and billing for more expensive brand name medications.

ACTIVITIES AT THE PROVIDER LEVEL RESULTING IN FWA ON PART D PROGRAMS

- **Billing for partial fills and for prescriptions not picked up**

  Two national pharmacy chains paid the over $400,000 for billing for smaller amounts than were actually dispensed. When an individual pharmacy did not have sufficient stock to totally fill a prescription, the pharmacy would partially fill the prescription and bill for the full amount. The customer was instructed to return for the balance. If the customer failed to pick up the balance of the prescription, the claim was not corrected to reflect the partial fill.

ACTIVITIES AT THE PROVIDER LEVEL RESULTING IN FWA ON PART D PROGRAMS

Other Examples:

- Billing for non-covered prescriptions as covered items
- Generic switching to maximize reimbursement
- Billing for extra refills-dispensing adulterated prescription drugs
- Prescription diversion-illegal remuneration scheme
- Script-mills-prescription diversion-resale of drugs on black market
- Doctor shopping-illegal remuneration schemes
- Doctor-Pharmacy-Member diversion conspiracy
- Prescription diversion and inappropriate use

DATA ANALYSIS TO DETECT FWA CASES

Use data analysis to recognize unusual trends, changes in utilization, and prescription patterns.

- Members utilization report, by volume of prescriptions filled.
- Members controlled substances report.
- Members using multiple pharmacies, multiple prescribers to obtain multiple controlled prescriptions.
- Prescriber utilization report – top prescribers by volume of prescriptions filled.
- Prescriber controlled substances report.
- Comparison of geographic location of prescriber, member and pharmacy

OTHER APPLICABLE LAWS & STATUTES

- Deficit Reduction Act of 2005 - Title VI, Ch. 3 , § 6033;
  - It requires entities such as Health Plans that receive federal funds, to establish written policies providing detailed information about fraud, waste and abuse in Federal health care programs.
- False Claims Act - 31 United States Code § 3729-3733
  - 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

OTHER APPLICABLE LAWS & STATUTES

- Crimes and Criminal Procedure - 18 United States Code § 1347
  - 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 - 42 United States Code § 1320a-7b(b)
  - 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).

OTHER APPLICABLE LAWS & STATUTES

- Stark Statute - 42 United States Code § 1395nn
  - 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).
- Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191)
  - Safeguards to prevent unauthorized access to protected health care information.
- Exclusion - 42 U.S.C. § 1395(e)(1), and 42 C.F.R. § 1001.1901
  - 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.

OTHER APPLICABLE LAWS & STATUTES

- Criminal Health Care Fraud Statute
  - Prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud a health care program or to obtain money or property owned by or under the control of a health care program.
  - Proof of knowledge or intent to violate the law is not required.

CORRECTION AND DISCIPLINARY ACTIONS

- Civil Money Penalties
- Criminal Conviction/Fines
- Civil Prosecution
- Imprisonment
- Loss of Provider License
- Exclusion from Federal Health Care programs

REPORTING FWA

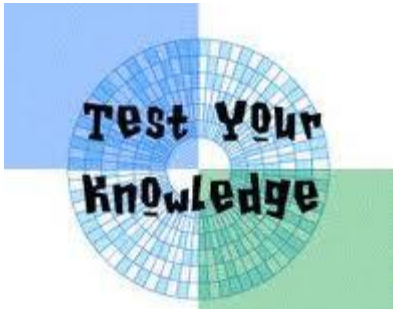
- Do not be concerned about whether it is fraud, waste, or abuse. Just report any concerns to your compliance department or your sponsor's compliance department.
- Telephone: (787)522-5252
- Email: ppx_compliance@pharmpix.com
- Web: www.pharmpix.com

CASE STUDY QUESTIONS

Scenario #1

A person comes to your pharmacy to drop off a prescription for a beneficiary who is a “regular” customer. The prescription is for a controlled substance with a quantity of 160. This beneficiary normally receives a quantity of 60, not 160. You review the prescription and have concerns about possible forgery.

What is your next step?



CASE STUDY QUESTIONS

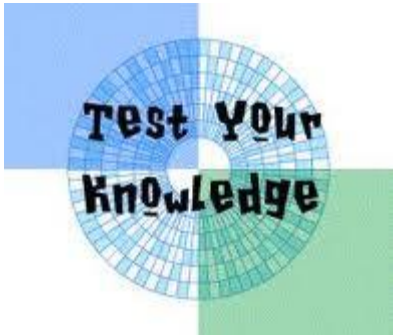
A. Fill the prescription for 160

B. Fill the prescription for 60

C. Call the prescriber to verify quantity

D. Call the sponsor's compliance department

E. Call law enforcement

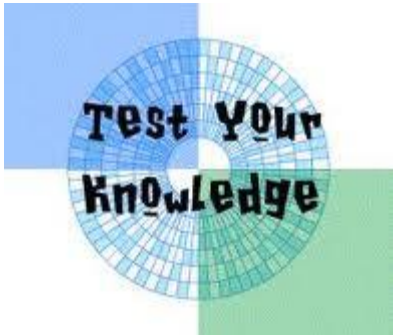


CASE STUDY QUESTIONS

Scenario #2

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?



CASE STUDY QUESTIONS

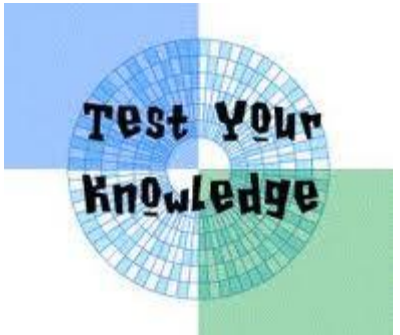
A. Call Doe Diagnostics and request additional information for the claims

B. Consult with your immediate supervisor for next steps

C. Contact the compliance department

D. Reject the claims

E. Pay the claims



REFERENCES

- **CMS' Prescription Drug Benefit Manual – Chapter 9**
- **CMS' Medicare Managed Care Manual – Chapter 21**
  - http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf
- **CMS' Prescription Drug Benefit Manual**
  - http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html
- **CMS' Medicare Managed Care Manual**
  - http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019326.html
- **Code of Federal Regulations (see 42 CFR 422.503 and 42 CFR 423.504)**
  - http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR
- **Office of the Inspector General – Fraud Information**
  - http://oig.hhs.gov/fraud/
- **Medicare Learning Network (MLN) Fraud & Abuse Job Aid**
  - http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Fraud_and_Abuse.pdf