



**Medicare Part D Training  
Community Providers  
2009**

# Introduction

- ◆ The objective of this presentation is to provide information to prescribing providers specific to their role in the administration and/or delivery of Medicare Part D benefits. This presentation covers:
  - Medicare Part D
  - Part D Program Standards
  - Medicare Part D Fraud, Waste & Abuse Guidance
  - Government initiatives
  - Medicare Part D Fraud, Waste & Abuse Risks
  - Fraud, Waste & Abuse Prevention
  - Coverage Determination, Exceptions and Appeals Process
  - Reporting suspicious Activity

# Medicare Part D

- ◆ Medicare Prescription Drug, Improvement, and Modernization Act of 2003-or the Medicare Modernization Act (MMA)-signed into law on December 8, 2003
- ◆ Largest legislation issue affecting Medicare benefits since its inception in 1965
- ◆ Effective January 1, 2006, Medicare provides voluntary prescription drug coverage called Medicare Part D
- ◆ Effective January 1, 2009, fraud, waste and abuse requirement becomes effective in final regulation

# Part D Program Standards

- ◆ Regulatory requirements under 42 CFR § 423.504
- ◆ 72 Federal Regulation 29368
  - ◆ **The final rule entitled, “Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes”, published December 5, 2007, updated the compliance plan requirements for Medicare Advantage (MA) organizations and Part D sponsors. Specifically, the compliance regulation states that a compliance plan, which must include measures to detect, correct, and prevent fraud, must consist of training, education and effective lines of communication. This change clarifies that MA organizations and Part D Sponsors need to apply these training and communication requirements to all entities they are partnering with in the MA and Part D programs.**

# Federal Register (FR) and the Code of Federal Regulation (CFR) [www.gpoaccess.gov/fr/index.html](http://www.gpoaccess.gov/fr/index.html)

- ◆ Published by the office of the Federal Register, National Archives and Records Administration (NARA), the *Federal Register* is the official daily publication for rules, proposed rules, and notices of federal agencies and organizations, as well as executive orders and other presidential documents. It is updated daily by 6 a.m. and is published Monday through Friday, except federal holidays.
- ◆ The *code of Federal Regulations* (CFR) is the codification of the general and permanent rules published in the *Federal Register* by the executive departments and agencies of the Federal Government. It is divided into 50 titles that represent broad areas subject to federal regulation. Each volume of the CFR is updated once each calendar year and is issued on a quarterly basis.

# Part D Medicare FWA Guidance

- ◆ Medicare Fraud, Waste & Abuse (FWA) guidance
  - Better known as Prescription Drug Benefit Manual, Chapter 9
  - Provides guidelines for Part D plan sponsors on how to implement the regulatory requirements under 42 CFR § 423.50(b)(4)(vi)(H) to have in place a comprehensive fraud and abuse plan to detect, correct and prevent fraud, waste and abuse as an element of the compliance plan.
- ◆ Applies to Health Plans and their “downstream entities”
  - “downstream entity” – down to the level of ultimate provider of both health and administrative services
- ◆ 70 pages of FWA compliance “requirements & recommendations”
- ◆ Available at:
  - [www.cms.hhs.gov/prescriptiondrugcovcontra/downloads/PDBManual\\_Chapter9\\_FWA.pdf](http://www.cms.hhs.gov/prescriptiondrugcovcontra/downloads/PDBManual_Chapter9_FWA.pdf)

# Government Initiatives

## ◆ Government Response

- More fraud & abuse laws & rules
- More audits and auditors
  - Centers for Medicare & Medicaid (CMS)
  - Medicare Drug Integrity Contractor “MEDICS”
- More Attorneys
  - 140 + Assistant US Attorneys trained on health care fraud
- More funding for HHS Office of Inspector General (OIG)
- More fraud & abuse programs
- More investigations and prosecutions

## ◆ Agencies Involved

- Federal: OIG, DOJ, CMS

# Government Audits

- ◆ Medicare Part D Audits by the “MEDICS” & “CMS”
- ◆ Part D Medicare FWA Guidance (chapter 9) “Recommends” Extensive Audits
- ◆ Deficit Reduction Act Expands Medicare/Medicaid Data Match Program
  - Data mining looks for “patterns”
  - Funding grows from \$12M in 2006 to \$60M in 2010

## Defining Fraud, Waste & Abuse

- ◆ **Fraud:** Intentional deception or misrepresentation to get an unauthorized benefit
  - AKA: deliberately not telling the truth for profit
- ◆ **Abuse:** Acting with negligence or reckless disregard for the truth in a manner that could result in an unauthorized benefit
  - AKA: Playing fast-and-loose with the truth
- ◆ **Waste:** Over-utilization of services, or other practices that result in unnecessary costs
  - AKA: inappropriate spending of money

# Federal False Claims Law

- ◆ Among Other Things, Prohibits Knowingly:
  - Presenting to the government a false claim for payment
  - Causing someone else (plan) to submit to the government a false claim for payment
  - Making or using a false record or statement to get a claim paid by the government
  - Conspiring to get a false claim paid by the government
  - Making or using a false record to avoid or decrease an obligation to pay or reimburse the government

## Federal False Claims Law (cont.)

### ◆ Penalties

- Fines up to \$11,000 for each false claim
- Plus treble damages (3x) suffered by the government
- Trial costs
- Exclusion from Medicare & Medicaid
- Can lead to criminal prosecution

## Federal False Claims Law (cont.)

- ◆ Whistleblower Lawsuits (“Qui Tam”):
  - Employee or private citizen sues on behalf of the government
  - Plaintiff receives as much as 30% of the total award
    - remainder goes to the government
- ◆ Whistleblower Protections
  - Employers may not retaliate against employees who report or help investigate false claims
  - No negative employment consequences such as being fired, demoted, suspended or harassed
  - Remedies against retaliation include job reinstatement with double back pay and other “special” damages

## NM Medicaid False Claims Act (dual eligible)

- ◆ The NM Medicaid False Claims Act (NMMFCA) was signed into law in 2004.
- ◆ The purpose is to deter persons from causing or assisting to cause the state to pay Medicaid claims that are false and to provide remedies for obtaining treble damages and civil recoveries for the state.
- ◆ The NMMFCA increases the states ability to bring a lawsuit for Medicaid fraud and recoup funds.
- ◆ NM's Attorney General prosecutes Medicaid fraud.

## NM Medicaid False Claims Act (cont) (dual eligible)

- ◆ The NMMFCA contains a whistleblower provision that provides incentives for people who come forward with knowledge and evidence of false claims submitted to Medicaid.
- ◆ Whistleblowers may receive up to 25% of the amount recovered.
- ◆ Employee whistleblowers are entitled to all relief necessary to make the employee whole, including reinstatement, double the amount of back pay, and compensation for any special damages sustained.

# Anti-Kickback Laws

## ◆ Federal Law

- Prohibits “knowingly and willfully” committing fraud
- It is prohibited to offer, pay, solicit or receive any “remuneration”
- It is prohibited to provide inducements or rewards due to patient “referrals”

## ◆ Penalties

- Criminal: “jail time”, \$25,000 fine, mandatory exclusion
- Civil: penalties & fines, permissive exclusion

# Anti-Kickback Safe Harbors

- ◆ Many complicated exceptions (“Safe Harbors”)
  - Personal services contracts
    - Payment based on fair market value of services, not value of referral
  - Sale of practice
  - Proper discounts and rebates
- ◆ Examples
  - Drug “switching” programs-if structured incorrectly
  - Drug rebate programs-if structured incorrectly
  - Pharmacy paid to “steer” patients to specific Part D plan

# Self-Referral Laws

## ◆ Federal “Stark” Law”

- Physician refers patients to a pharmacy to have Rx filled and the physician (or immediate family member) has a financial relationship with that pharmacy, the pharmacy cannot bill Medicare or Medicaid unless a statutory exception applies
  - Example: physician’s spouse owns the pharmacy

## ◆ Complicated exceptions

- Bona fide personal services arrangement

## ◆ Penalties

- \$15,000 fine per claim and possible exclusion
- Potential anti-kickback liability (if intentional violation)

## Beneficiary Inducement Civil Monetary Penalty Law

- ◆ Prohibits any payment, discount, or other “remuneration”
- ◆ Applies to beneficiaries enrolled in government health care programs
- ◆ Incentive to beneficiaries to patronize a particular provider
- ◆ Rationale: discourage over-utilization of health care supplies and services
- ◆ Applies to all government programs
- ◆ Penalties
  - Fines up to \$10,000 per violation plus treble damages
  - Potential exclusion from participation in government programs

## Beneficiary Inducement Example

- ◆ Waiving of co-payments
  - “May” if does not advertise waiver;
  - “May” if does not routinely waive; AND
  - “May” if waiver is based on a good faith assessment of the patient’s financial needs

# Program Exclusion Lists

## ◆ Federal Exclusion Law

- OIG can exclude individuals and organizations from participating in Medicare, Medicaid and other government programs
- Reasons for exclusion include:
  - Violating fraud and abuse laws
  - Licensing board actions (e.g., suspended license)
  - Default on federal student loans
  - Controlled substances violations, other crimes, etc.

## Program Exclusion Lists (cont.)

- ◆OIG posts list of excluded individuals
  - <http://exclusions.oig.hhs.gov>
  - List is updated monthly
- ◆GSA maintains its own list
  - <http://epls.arnet.gov>

## Employing Excluded Individuals

- ◆ Prohibition on employing excluded individuals
  - OIG: Pharmacies can't bill for “services performed by, prescribed by, processed by or are involved in any way in filling prescriptions” who are excluded from federal and state programs to Medicare beneficiaries.
  - Prohibition “also extends to payment for administrative and management services not directly related to patient care, but that are a necessary component of providing items and services to federal and state program beneficiaries”.

## Penalties for Employing Excluded Individuals

- ◆ Payment will not be made for items or services furnished by an excluded employee or contractor
- ◆ Civil penalties of \$10,000 “for each item or service”
- ◆ Treble damages

## Monitoring for OIG/GSA Exclusion or Debarment

- ◆ It is required to monitor all employees within each practice on an annual basis
- ◆ Retain a log demonstrating this activity which is accessible during an audit
- ◆ Create a policy and procedure identifying:
  - ◆ Timeline for completion
  - ◆ Format
  - ◆ handling of employees identified as excluded

## Part D FWA Risks Prescribing Provider

- ◆ Illegal remuneration schemes
  - Prescriber is offered, or paid or solicits, or receives unlawful remuneration to induce or reward the prescriber to write prescriptions for drugs or products
- ◆ Prescription drug switching
  - Drug switching involves offers of cash payments or other benefits to a prescriber to induce the prescriber to prescribe certain medications rather than others
- ◆ Script mills
  - Provider writes a prescriptions for drugs that are not medically necessary, often in mass quantities, and often for patients that are not theirs. These scripts are usually written, but not always, for controlled drugs for sale on the black market, and might include improper payments to the provider.

## Part D FWA Risks Prescriber (cont.)

- ◆ Provision of false information
  - Prescriber falsifies information (not consistent with medical record) submitted through a prior authorization or other formulary oversight mechanism in order to justify coverage. Prescriber misrepresents the dates, descriptions of prescriptions or other services furnished, or the identity of the individual who furnished the services. Prescriber prescribes more medication per month than the patient requires, but verbally instructs the patient to take less than prescribed to save money.
- ◆ Theft of prescriber's DEA number or prescription pad
  - Prescription pads and/or DEA numbers can be stolen from prescribers. This information could illegally be used to write prescriptions for controlled substances or other medications often sold on the black market. In the context of e-prescribing, includes the theft of the provider's authentication (log in) information.

## Part D FWA Risks Medicare Beneficiary

- ◆ Misrepresentation of status
- ◆ Identity theft
- ◆ TrOOP manipulation
- ◆ Prescription forging or altering
- ◆ Prescription diversion and inappropriate use
- ◆ Resale of drugs on black market
- ◆ Prescription stockpiling
- ◆ Doctor shopping
- ◆ Improper coordination of benefits
- ◆ Marketing schemes

# Avoiding “Waste”

- ◆ Drug utilization review (DUR)
  - Federal law requires states to establish DUR programs
  - Prospective DUR
    - Review Rx before filled to prevent drug therapy problems and abuse
  - Retrospective DUR
    - Review claims data after prescriptions have been filled to identify FWA
  - Educational outreach
    - Enhance provider knowledge
- ◆ Tiered co-pays
  - Tier 1 Preferred Generic
  - Tier 2 Preferred Brand
  - Tier 3 Non-preferred Generic and Brand
  - Tier 4 Specialty drug

# FWA Prevention

- ◆ CMS is requiring training
  - General compliance
  - Specialized compliance
- ◆ Create policies and procedures
  - Based on Medicare FWA guidance (chapter 9)
  - Monitor OIG/GSA exclusion lists
  - Obtain certification statements when applicable
    - Health Plans are required to obtain from prescribing providers
- ◆ Prepare for Audits

## FWA Prevention (cont.)

- ◆ Follow your compliance program guidance
  - Seven element identified by OIG:
    1. Implement written policies and procedures
    2. Compliance officer and committee
    3. Conduct effective training & education
    4. Develop effective lines of communication
    5. Conduct internal monitoring & auditing
    6. Enforce standards through well-publicized disciplinary guidelines
    7. Corrective Action

# CMS Part D Appeals Process

- ◆ Short decision making timeframes
  - CMS requests responses without delay
  - Insurance Plans must communicate Initial Coverage Determinations:
    - No later than 24 hrs for an expedited request
    - No later than 72 hrs for an standard request

## CMS Part D Appeals Process (cont.)

- ◆ Request made by prescribing provider
  - A coverage determination (initial decision) can be requested by:
    - Beneficiary
    - By an appointed representative
    - Prescribing provider
  - Prescribing provider may also request an expedited redetermination (first level of appeal) on behalf of the beneficiary
  - Prescribing providers may not request a standard redetermination (first level of appeal) or a reconsideration (second level of appeal) unless appointed as representative

## CMS Part D Appeals Process (cont.)

- ◆ Prescribing provider supporting statements
  - Prescribing providers have an important role in the exceptions process
  - When a beneficiary requests a formulary or tiering exception, the prescribing provider must provide the insurance plan with an oral or written statement to support the exception request
    - The timeframe for making a decision on an exception request does not begin until the prescribing provider's supporting statement is received by the plan

## Suspicious Activity may be Reported through the following:

- ◆ The LHP Part D Fraud, Waste and Abuse hotline @ 505-727-5384
- ◆ To the following LHP Compliance/FWA Staff by phone, via e-mail or in person:
  - Ann Greenberg, LHP Ethics and Compliance Officer 727-5392  
[Ann.greenberg@lovelace.com](mailto:Ann.greenberg@lovelace.com)
  - Lupe Chavez, Medicare Part D FWA 727-5524  
[lupe.chavez@lovelace.com](mailto:lupe.chavez@lovelace.com)
  - Joe Castro, FWA Compliance 727-5298  
[joseph.castro@lovelace.com](mailto:joseph.castro@lovelace.com)
  - By completing the suspicious activity reporting form (available through the LHP Compliance Department)
- ◆ The Medicare Integrity Drug Contractor (MEDIC) @ (877)772-3379

# Thank You!

- ◆ You have completed the Medicare Part D Community Provider training
- ◆ Please take a few moments to complete and submit the attestation form to the LHP compliance department (available on the LHP internet)
  - ◆ **Fax :**  
# 505-727-5510
  - ◆ **Mail:**  
LHP Compliance Department  
4101 Indian School Rd NE  
Albuquerque, New Mexico 87110