CareManagers Inc.

Medicare Advantage and Prescription Drug
Fraud, Waste and Abuse

Compliance Training
2009

Overview

- The Centers for Medicare & Medicaid Services regulation 42 CFR 422 and 423 requires all Part C Medicare Advantage (MA) and Part D Prescription Drug health plans, (also known as Plan Sponsors), to ensure that all of their first tier, downstream and related entities (together known as “delegated entities”) complete fraud, waste and abuse training no later than December 31, 2009 and annually thereafter.

- CareManagers is offering this presentation for fulfilling this training requirement to those individuals and organizations it contracts with to assist CareManagers in providing MA and Part D benefits or services under its contracts with Plan Sponsors.

- Plan Sponsors require all delegated entities to attest that they are in compliance with CMS regulatory requirements. Therefore, CareManagers must annually receive an *Attestation of Training Completion* from those individuals and organizations it contracts with to assist CareManagers in providing MA and Part D benefits or services under its contracts with Plan Sponsors.

Training Outline

- The Role of CMS
- What are Sponsors and Entities?
- Seven Elements of a Compliance Program
- Fraud, Waste, and Abuse Defined
- Pertinent Laws and Regulations
- Legal Actions
- Why Focus on Fraud, Waste and Abuse?
- Examples of Fraud, Waste, and Abuse
- Preventing Fraud, Waste and Abuse
- Reporting Fraud, Waste & Abuse
- Additional Resources
- Attestation of Training Completion

The Role of CMS

- The Centers for Medicare & Medicaid Services (CMS) is a government entity within the U.S. Department of Health and Human Services.

- CMS is responsible for oversight of the Medicare Program – including health plans such as Medicare Advantage (MA), Medicare Advantage Prescription Drug (MAPD), and Prescription Drug Plan (PDP).

- The main office for CMS is located in Baltimore, MD. CMS has 10 Regional Offices: Atlanta, Boston, Chicago, Dallas, Denver, Kansas City, New York, Philadelphia, San Francisco, and Seattle.

What are Sponsors and Entities?

Plan Sponsor: An entity that has a contract with CMS to offer one or more of the following Medicare Products:

- Medicare Advantage (MA) Plans
- Medicare Prescription Drug Plans
- 1876 Cost Plans

First Tier Entity: A party that enters into a written arrangement, acceptable to CMS, with a Plan Sponsor to provide administrative services or health care services for a Medicare eligible individual under the MA or Part D programs.

Examples include:

- Provider Organizations
- Pharmacy Benefits Manager (PBM)
- Hospitals

What are Sponsors and Entities?

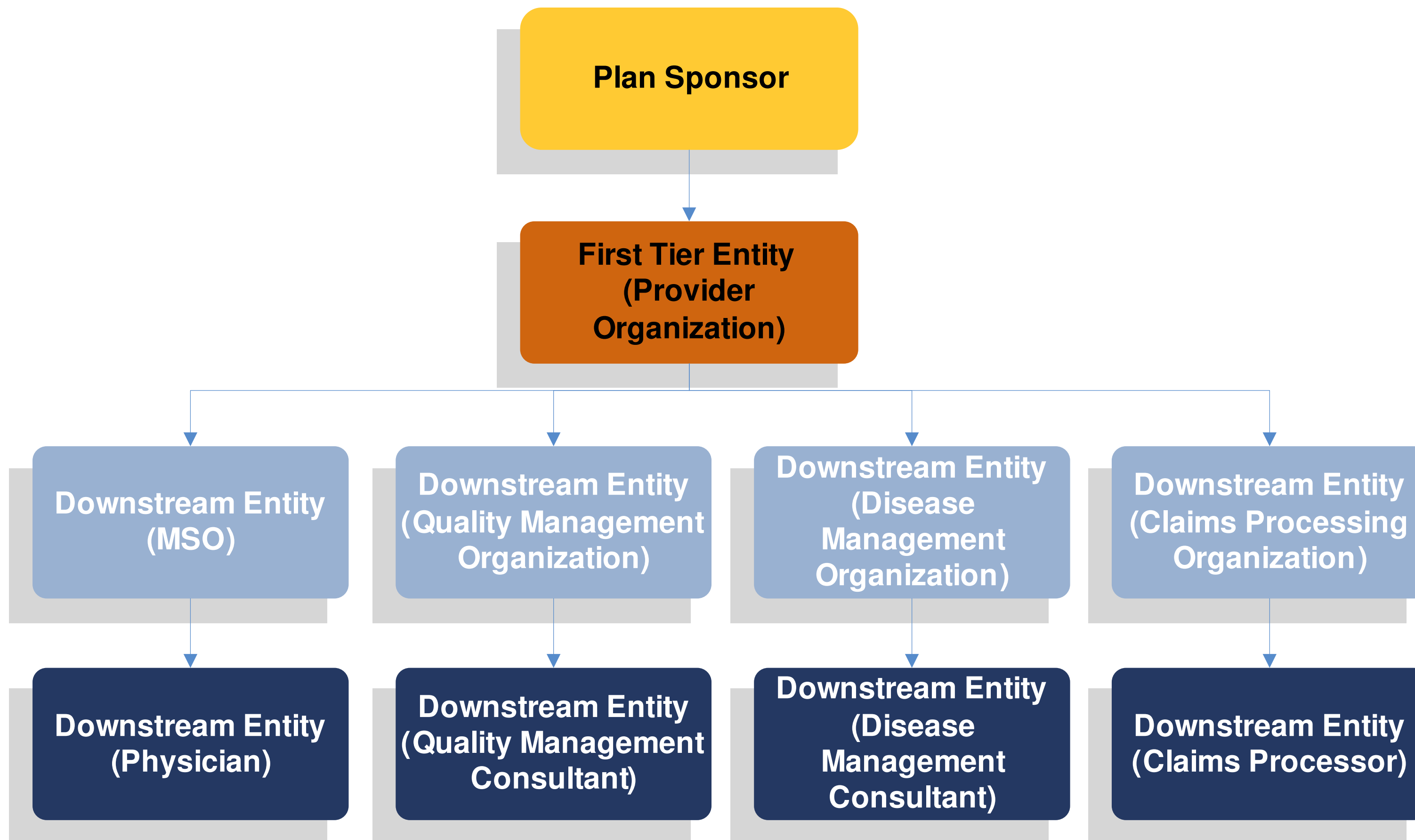
Downstream Entity: A party that enters into a written arrangement, acceptable to CMS, with persons or entities involved in the MA or Part D benefit, below the level of the arrangement between a Plan Sponsor and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services. *CareManagers is a downstream entity.*

Other examples include:

- Management Services Organizations (MSO)
- Disease Management Organizations
- Claims Processing Organizations

Related Entity: An entity that is related to the Plan Sponsor by common ownership or control and performs some of the Plan Sponsor's management functions under contract or delegation; furnishes services to Medicare enrollees under an oral or written agreement; or leases real property or sells materials to the Plan Sponsor at a cost of more than $2,500 during a contract period.

First Tier and Downstream Examples



Seven Elements of a Compliance Program

Federal law requires Medicare Advantage and Part D Plan Sponsors to implement and maintain a Compliance Program that incorporates measures to detect, prevent, and correct fraud, waste and abuse.

The Office of the Inspector General (OIG) has identified seven core elements of a Compliance Program:

1. **Written Standards of Conduct:** Development and implementation of policies and
   – procedures and other operating guidelines that address specific areas of potential
   – fraud, waste and abuse.

2. **High Level Oversight:** Designation of an individual and a committee charged with responsibility and authority of operating and monitoring the Compliance Program.

3. **Compliance Training**: Development and implementation of regular and effective
   – training, such as this one.

4. **Internal Monitoring and Auditing**: Use of risk evaluation and audits to monitor compliance and assist in the reduction of identified problem areas.

Seven Elements of a Compliance Program

5. **Disciplinary Mechanisms**: Development and implementation of policies to consistently enforce standards.

6. **Effective Lines of Communication**: Establishment of lines of communication between the compliance officer and the organization's employees, managers and directors and members of the compliance committee, as well as first tier, downstream and related entities.
   - Includes a system to receive, record and respond to compliance questions, or reports of potential or actual non-compliance, while maintaining confidentiality.
   - First tier, downstream and related entities must report compliance concerns and suspected or actual misconduct involving the MA or Part D programs to the Plan Sponsor.

7. **Procedure for Responding to Detected Offenses**: Development and implementation of policies to respond to and initiate corrective actions to prevent similar offenses including a timely and responsible inquiry.

Fraud, Waste & Abuse Defined

Fraud is an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. Examples of fraud include: billing for services not furnished or at a higher rate than is actually justified; soliciting, offering or receiving a kickback, bribe or rebate; deliberately misrepresenting services which results in unnecessary cost, improper payments or overpayment; and violating the physician self-referral ("Stark") prohibition.

Waste is the extravagant, careless or needless expenditure of healthcare benefits or services that results from deficient practices or decisions. Examples of waste include over-use of services and misuse of resources.

Abuse is a practice that is inconsistent with sound fiscal, business, or medical practices and results in unnecessary costs to the healthcare system. Examples of abuse include: charging in excess for services or supplies; providing medically unnecessary services; providing services that do not meet professionally recognized standards; and billing Medicare based on a higher fee schedule than is used for patients not on Medicare.

Pertinent Laws and Regulations

FALSE CLAIMS ACT

The False Claims Act, in part, prohibits any person from:

- Knowingly presenting, or causing to be presented, to an officer or employee of the United States Government a false or fraudulent claim for payment or approval.
- Knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.
- Conspiring to defraud the Government by getting a false or fraudulent claim allowed or paid.
- A violator may be liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person.

Pertinent Laws and Regulations

FALSE CLAIMS ACT (cont.)

- The False Claims Act has Whistleblower protections. A Whistleblower is an employee, former employee or member of an organization who reports misconduct to people or entities that have the power to take corrective action.

- A provision in the False Claims Act allows individuals to:
  - Report fraud anonymously.
  - Sue an organization on behalf of the government and collect a portion of any settlement that results.

- Employers cannot threaten or retaliate against whistleblower

Pertinent Laws and Regulations

ANTI-KICK BACK STATUTE

- The Anti-Kickback Statute makes it a criminal offense to knowingly and willfully solicit, receive, offer or pay remuneration (including any kickback, bribe or rebate) in return for:
  - Referrals for the furnishing or arranging of any items or service reimbursable by a Federal health care program.
  - Purchasing, leasing, ordering or arranging for the purchasing or leasing of an item or service reimbursable by a Federal health care program.

- Remuneration is defined as the transfer of anything of value, directly or indirectly, overtly or covertly in cash or in kind. When this happens, both parties are held in criminal liability of the impermissible “kickback” transaction.

- Penalties include up to $25,000 or imprisonment of up to five years or both.

Pertinent Laws and Regulations

PHYSICIAN SELF-REFERRAL PROHIBITION STATUTE

The Physician Self-Referral Prohibition Statute, commonly referred to as the “Stark Law,” prohibits:

- A physician from referring Medicare patients for certain designated health services to an entity with which the physician or a member of the physician’s immediate family has a financial relationship--unless an exception applies.
- An entity from presenting or causing to be presented a bill or claim to anyone for a designated health service furnished as a result of a prohibited referral.

Pertinent Laws and Regulations

FEDERAL HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA)

- HIPAA contains provisions and rules related to protecting the privacy and security of protected health information (PHI).
- HIPAA Privacy: The Privacy Rule outlines specific protections for the use and disclosure of PHI. It also grants rights specific to members.
- HIPAA Security: The Security Rule outlines specific protections and safeguards for electronic PHI.
- **If you become aware of a potential breach of protected information, you must comply with the security breach and disclosure provisions under HIPAA and, if applicable, with any business associate agreement.**

Legal Actions

A provider, supplier or health care organization that has been convicted of fraud may receive a significant fine, prison sentence or be temporarily or permanently excluded from the Medicare program or other Federal health care programs, and in some states, loose their license.

Failure to comply with fraud and abuse laws may result in:

- Investigations referred to the Office of Inspector General (OIG).
- Civil monetary penalties that can result in up to $10,000 per violation and exclusion from the Medicare program.
- Denial or revocation of a Medicare Provider Number.
- Suspension of payment.

Why Focus on Fraud, Waste & Abuse?

- The United States spends more than $2 trillion on health care every year. The National Health Care Anti-Fraud Association estimates conservatively that at least 3 percent- or more than $60 billion each--is lost to fraud.[1]

- Fraud, waste and abuse programs save Medicare dollars and that benefits taxpayers, government, health plans and beneficiaries.

- Detecting, correcting and preventing fraud, waste and abuse requires collaboration between:
  - You
  - Providers of services, such as physicians, nurse and pharmacies
  - State and federal agencies
  - Beneficiaries

Source:

Statement by Daniel R. Levinson, Inspector General, Office of the Inspector General, U.S. Department of Health and Human Services; before the Senate

Special Committee on Aging, United States Senate, on combating Fraud, Waste and Abuse in Medicare and Medicaid (May 06, 2009).

Examples of Fraud, Waste & Abuse: Billing

- Billing for services not furnished and/or supplies not provided; this includes billing Medicare for appointments that the patient failed to keep.
- Billing that appears to be a deliberate application for duplicate payment for the same services or supplies, billing both Medicare and the beneficiary for the same service or billing both Medicare and another insurer in an attempt to get paid twice.
- Altering claims forms, electronic claim records, medical documentation, etc., to obtain a higher payment amount.
- Unbundling (billing for each component of the service instead of billing or using all inclusive code).
- Billing based on “gang visits” such as a physician visiting a nursing home and billing for 20 nursing home visits without furnishing any specific service to individual patients.
- Misrepresentations of dates and descriptions of services furnished or the identity of the beneficiary or the individual who furnished the services.
- Billing Medicare based on a higher fee schedule than is used for patients not on Medicare.

Examples of Fraud, Waste & Abuse: Beneficiary

Identity Theft

- Using a member's I.D. card that does not belong to that person to obtain prescriptions, services, equipment, supplies, doctor visits and/or hospital stays.

Doctor Shopping

- Visiting a number of doctors to obtain multiple prescriptions for painkillers or other drugs. Might point to an underlying scheme (stockpiling or black market resale).

Resale of Drugs or Black Market

- Falsely reporting loss or theft of drugs or feigns illness to obtain drugs for resale on the black market.

Improper Coordination of Benefits

- Beneficiary fails to disclose multiple coverage policies, or leverages various coverage policies to "game" the system.

Examples of Fraud, Waste & Abuse: Prescriber

Illegal Payment Schemes

- Prescriber is offered, paid, solicits or receives unlawful payment to induce or reward the prescriber to write prescriptions for drugs or products.

Script Mills

- Prescribers write 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 prescriber.

Theft of Prescriber's Drug Enforcement Agency (DEA) Number or Prescription Pad

- Prescription pads and/or DEA numbers stolen from prescribers. This information could illegally be used to write prescriptions for controlled substances or other medications sold on the black market.

Examples of Fraud, Waste & Abuse: Retail Pharmacy

Inappropriate Billing Practices

- Examples of Fraud, Waste & Abuse:
Retail Pharmacy
- Billing for non-existent prescriptions
- Billing for brand when generics are dispensed
- Billing for non-covered prescriptions as covered items

Prescription Drug Shorting

- Providing less than the prescribed quantity but billing for the fully-prescribed amount.

Dispensing Expired or Adulterated Drugs

- Dispensing drugs that are expired, or have not been stored or handled in accordance with manufacturer and FDA requirements.

Bait and Switch Pricing

- Bait and switch pricing occurs when a beneficiary is led to believe that a drug will cost one price, but at the point of sale the beneficiary is charged a higher amount.

Forging or Altering

- Where existing prescriptions are altered, by an individual without the prescriber's permission to increase quantity or number of refills.

Examples of Fraud, Waste & Abuse: Pharmaceutical Manufacturer

Illegal Off-label Promotion

- Promotion of off-label drug usage through marketing, financial incentives or other promotion campaigns.

Illegal Usage of Free Samples

- Providing free samples to prescribers knowing and expecting prescriber to bill Medicare for the sample.

Kickbacks, Inducements, Other Illegal Payments

- Inappropriate marketing or promotion of products reimbursable by federal health care programs.
- Inappropriate discounts or educational grants.

Examples of Fraud, Waste & Abuse: Wholesaler

Counterfeit, Impure Drugs through Black Market

- Black market includes fake, diluted, expired, illegally imported drugs.

Diverters

- Individuals who illegally gain control of discounted medicines and mark up the prices and move them to small wholesalers.

Inappropriate Documentation of Pricing Information

- Submitting false or inaccurate pricing or rebate information.

Examples of Fraud, Waste & Abuse: Pharmacy Benefits Manager (PBM)

Prescription Drug Switching

- PBM receives a payment to switch a beneficiary from one drug to another or influence prescriber to switch patient to a different drug

Prescription Drug Splitting or Shorting

- PBM mail order pharmacy intentionally provides less than the prescribed quantity, does not inform the patient or make arrangements to provide the balance and bills for the fully-prescribed amount
- Splits prescription to receive additional dispensing fees

Inappropriate Formulary Decisions

- PBMs or their P&T committees make formulary decisions where cost takes precedence over clinical efficacy and appropriateness of formulary drugs

Failure to Offer Negotiated Prices

- Occurs when a PBM does not offer a beneficiary the negotiated price of a Part D drug

Examples of Fraud, Waste & Abuse: Plan Sponsor

Failure to Provide Medically Necessary Services

- Fails to provide medically necessary items or services that the organization is required to provide (under law or under the contract) to a Part D plan enrollee, and that failure adversely affects (or is substantially likely to affect) the enrollee.

Inappropriate Enrollment/Disenrollment

- Improperly reporting enrollment and disenrollment data to CMS to inflate prospective payments. For example, Sponsor fails to effect timely disenrollment of beneficiary from CMS systems upon beneficiary's request.

Marketing Schemes

- Offering beneficiaries a cash payment as an encouragement to enroll in a Medicare Plan.
- Unsolicited door-to-door marketing.
- Use of unlicensed agents.
- Enrollment of individual in a Medicare Plan without such individual's knowledge or consent.
- Stating that a marketing agent/broker works for or is contracted with the Social Security Administration or CMS.

Preventing Fraud, Waste & Abuse

Prevention and detection of fraud, waste and abuse requires the involvement and collaboration between:

- Centers for Medicare & Medicaid Services
- Medicare beneficiaries
- Medicare contractors
- Physicians, suppliers, and other providers
- Quality Improvement Organizations
- State and Federal law enforcement agencies such as :
  - Office of Inspector General of the Department of Health and Human Services
  - Federal Bureau of Investigation
  - Department of Justice

Preventing Fraud, Waste & Abuse

How can **you** and **your organization** prevent potential fraud, waste and abuse?

- Understand your organization's policies and procedures, including standards of conduct and reporting potential fraud, waste and abuse.
- Identify your organization's compliance officer and compliance hotline.
- Conduct effective training and education.
- Enforce standards of conduct.
- Develop effective lines of communication between compliance officer, employees and downstream entities.
- Conduct internal monitoring and auditing, including detection through medical review and data analysis.
- Maintain confidentiality of protected health information (PHI).
- Implement a comprehensive fraud, waste and abuse program

Reporting Fraud, Waste & Abuse

Everyone has the right and responsibility to report possible fraud, waste and abuse. You may report anonymously and retaliation is prohibited when you report a concern in good faith. To report suspected fraud, waste and abuse, please contact any of the following:

- CareManagers' anonymous confidential 24/7 Ethics Hotline at hotline@caremanagers.com .
- CareManagers' Compliance Officer, Nikki Schreiber, at 732-819-7600 or nikki@caremanagers.com .
- The Compliance Officer or compliance hotline of the applicable Plan Sponsor(s) with whom you participate; compliance hotline numbers are available on each Plan Sponsor's web sites.

Additional Resources

- Centers for Medicare and Medicaid Services (CMS)
  www.cms.hhs.gov
- CMS Fraud & Abuse General Information:
  www.cms.hhs.gov/MDFraudAbuseGenInfo
- Medicare Learning Network (MLN) Fraud & Abuse Job Aid
  http://www.cms.hhs.gov/MLNProducts/downloads/081606_Medicare_Fraud_and _Abuse_brochure.pdf
- Office of Inspector General Department of Health and Human Services:
  http://oig.hhs.gov/
- Code of Federal Register (see 42 CFR 422.503 and 42 CFR 422.504
  http://www.cms.hhs.gov/quarterlyproviderupdates/downloads/cms4124fc.pdf
- CMS' Prescription Drug Benefit Manual – Chapter 9:
  http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter 9_FWA.pdf
- Physician Self-Referral Law:
  www.cms.hhs.gov/PhysiciansSelfReferral

Attestation of Training Completion

What should you do next?

- Please report to your compliance officer that you have completed this training. **Remember, training must be completed by December 31, 2009.**
- An attestation form and sample training log have been provided to your authorized representative. Your organization must be able to submit records of training logs documenting employee participation in the training upon request.
- An authorized representative of your organization must attest to the completion of this training. Failure to do so could result in the loss of your organization's contract to provide Medicare Part C & D services.
- The attestation statement is critical for CareManagers Inc. and the Plan Sponsors it has contracted with to ensure that all first tier, downstream and delegated entities have completed fraud, waste and abuse training.
- An authorized representative of your organization must submit the completed attestation form to CareManagers Inc. by January 15, 2010.