



Medicare Part D Compliance / Fraud, Waste & Abuse

2010 Annual Training for Network Pharmacies

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Welcome

Welcome to the Medicare Part D Compliance / Fraud, Waste and Abuse (FWA) Training Program for Network Pharmacies.

As part of the Medicare Part D Prescription Drug Benefit, CMS (Centers for Medicare & Medicaid Services) requires that all Sponsors and their “downstream entities”, which include pharmacy staff, engaged directly or indirectly in the administration or delivery of the Medicare Part D prescription drug benefit, receive training to detect, correct and prevent fraud, waste and abuse.

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Frequently Asked Questions

Q. Why am I required to take this training?

- A. The Centers for Medicare and Medicaid Services (CMS) require all Part D Sponsors to provide FWA training to all entities they are partnering with that provide benefits or services in the Part D programs, not just to the direct employees within their organization. Because network pharmacies are considered a “downstream entity” to Part D Plan Sponsor the training requirement applies. In order to meet the FWA training requirement for first tier, downstream, and related entities, PDP Sponsors may either provide the training directly or provide appropriate training materials to these delegated and contracted entities. The PDP sponsor is accountable for ensuring that materials have been provided to all entities.

Q. What are the ways I can complete this training?

- A. We are providing training materials that can be utilized in training your pharmacy staff. Download the materials and provide them to your staff for review. Make sure to keep detail records on the date the training was provided and the staff who attended.

You may also have received training materials from other qualified Medicare Part D Plan Sponsors, or participated in a training program sponsored by industry organizations such as National Association of Chain Drug Stores (NACDS) or National HealthCare Anti-Fraud Association (NHCAA). If that is the case, then all you need to do is follow the instructions below on how to certify that FWA training has been completed.

Q. What if my pharmacy is DMEPOS Certified?

- A. If your pharmacy/organization has been officially accredited as a supplier of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) by a CMS-deemed accreditation organization (AO) and deemed to have met the training and education requirements for FWA per 423.504 (vi)(C)(3), all you need to do is follow the instructions below on how to complete the Attestation.

Q. Can I provide my own training materials?

- A. No. Per CMS guidance, first tier, downstream, and related entities, including pharmacies, should not develop their own training.

Q. When does this training have to be completed?

- A. Training related to Medicare Part D Compliance, Fraud, Waste and Abuse must be completed by **December 31, 2010**. This is an annual requirement and must be completed before the end of each year.

Q. How do I document that I completed the training?

- A. Pharmacies must complete the online Attestation found at -

www.Caremark.com/PharmInfo (scroll to the Attestation link under the Pharmacy & Pharmacist Heading)

or

https://cvs.qualtrics.com/SE/?SID=SV_afmgQ8rhvnsJJhW

The Attestation allows you to confirm that all employees who have been identified as being involved directly or indirectly with the administration or delivery of the Medicare Part D Prescription Drug Benefit, including pharmacists and pharmacy technicians, have completed the 2010 Annual Medicare Part D Compliance / Fraud, Waste & Abuse Training as mandated by CMS. In addition, the pharmacy should maintain attendance logs detailing the date and time the training was provided and list those employees who were in attendance.

Q. How do I complete the Attestation?

- A. After training has been completed, the Pharmacist in Charge should log on to:

www.Caremark.com/PharmInfo (scroll to the Attestation link under the Pharmacy & Pharmacist Heading)

or

https://cvs.qualtrics.com/SE/?SID=SV_afmgQ8rhvnsJJhW

and complete the online form on behalf of the pharmacy staff, and submit. Be sure to print off a copy for your records. Individual attestations are not necessary.

Q. Who do I contact with questions about the training/Attestation?

- A. Questions regarding the training materials and attestation process can be directed to Malcolm Sutherland , Malcolm.sutherland@caremark.com.

Objective

The objective of this course is to help you understand the:

- Medicare Part D Compliance Program
- Medicare Part D Prescription Drug Benefit
- Key laws and regulations governing the benefit
- Areas that are at risk for FWA and your responsibility to report potential FWA

It will also highlight areas of potential compliance risk within the pharmacy environment, and how you can proactively minimize the risks associated with fraud, waste, and abuse.

At the conclusion of the training, you will be required to attest that you have completed the annual Medicare Part D Compliance / FWA Training Program for network pharmacies.

Section One Medicare and the Medicare Part D Compliance Program

Medicare

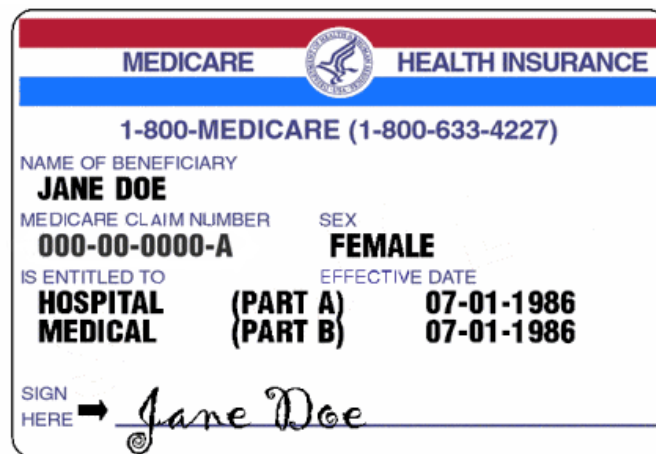
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Medicare is the nation's largest health insurance program, which covers nearly 40 million Americans. It is a government health insurance program for people age 65 or older, some disabled people under age 65, and people of all ages with end-stage renal disease.

The federal government department that administers the Medicare program is the **Department of Health and Human Services'** (HHS) **Centers for Medicare & Medicaid Services** (CMS).

There are currently four parts to Medicare:

- **Part A** – Hospital Insurance (in-patient care)
- **Part B** – Medical Insurance
 - pays for outpatient hospital services as well as other services
 - Helps pay for Durable Medical Equipment (DME), supplies, and select prescription drugs - such as immunosuppressive agents
- **Part C** - Medicare Advantage
 - Delivery of Part A and Part B health benefits through managed care organizations
- **Part D** – Prescription Drug Insurance
 - Helps pay for prescription drugs, certain vaccines and certain medical supplies (e.g. needles and syringes for insulin)



Sample Card

Medicare Part D

Medicare Part D is a prescription drug program for Medicare eligible individuals. It helps beneficiaries pay for prescription drugs. CVS Caremark, through its subsidiaries, participates in this program in several ways:

- CVS Caremark Part D Services, LLC, and RxAmerica, LLC are prescription benefit managers (PBMs) that provide services in support of their clients' Medicare Part D plans.
- SilverScript Insurance Company (SSIC) and Accendo Insurance Company are Medicare Prescription Drug Plans (PDPs) that contract with Medicare to provide prescription drug plans in all 50 states, the District of Columbia and Puerto Rico.

This Medicare Part D Compliance /FWA training program is designed to:

- Detect, correct, and prevent fraud, waste and abuse
- Promote a culture of ethical behavior
- Comply with all laws and regulations

Fraud

Acting in a dishonest manner with the intent to obtain a benefit or service that you know you are not entitled to.

Waste

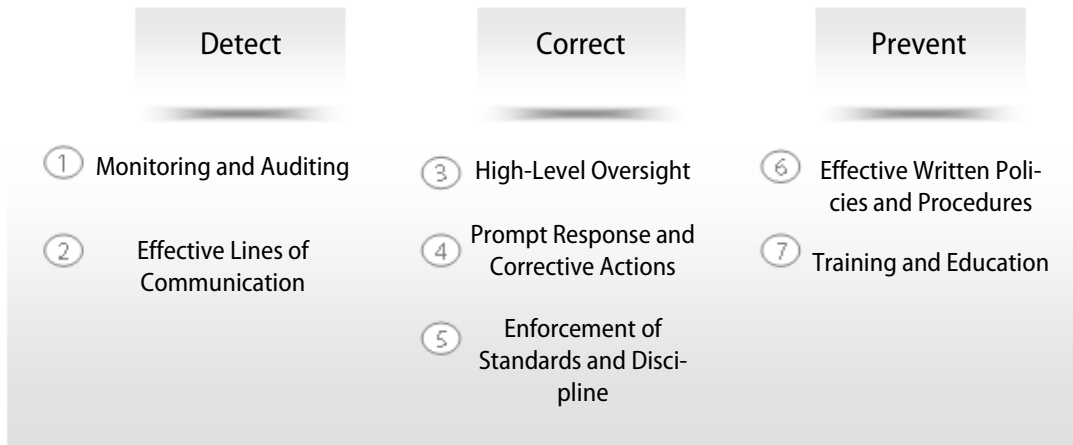
Behavior or conduct that results in the use of more resources than needed.

Abuse

Inappropriately taking advantage of the Medicare Part D program for personal benefit.

The Medicare Part D Compliance/FWA Program - 7 Key Elements

CMS requires that **seven key elements** are included in any Compliance / FWA program. Each of these helps to detect, correct and prevent issues that arise in the course of our business that could compromise the integrity of our organization and our ability to perform Part D services in compliance with the requirements of the program. These seven elements are as follows:



Many Medicare payment errors are simply mistakes. The vast majority of Medicare Part D Providers are committed to providing high quality care and/or services.

However, there are individuals intent on abusing or defrauding Medicare, thereby cheating the program out of millions of dollars annually.

Because fraud, waste and abuse could occur in each part of our daily operations, we must be watchful in our daily duties to help detect, correct, and prevent possible fraud, waste and abuse.

Section Two - Laws and Regulations

The success of the Medicare Part D prescription drug benefit depends on your compliance with federal and state rules related to the Medicare Part D program.

This section outlines some of the key federal compliance requirements that you need to follow as you perform your everyday duties.

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The laws and regulations section will:

- Discuss the key laws and regulations that manage the Medicare Part D benefit.
- Discuss the risk of Intermediate Sanctions, which can occur if these laws are violated.

Laws and Regulations

Here are several laws and regulations that apply to pharmacies who administer the Medicare Part D prescription drug benefit.

False Claims Act

This law makes it illegal for anyone to knowingly file, or make someone else file, a **false claim for payment** with the federal government. This includes submitting wrong or fraudulent claims for prescription drugs dispensed to beneficiaries in a government program such as Medicare Part D.

When submitting claims data to Part D plans for payment, you should ensure that the data is true and accurate to best of your knowledge. This Act also allows individuals to file actions against federal contractors claiming fraud against the government. In addition, it makes it illegal for a person to make or use (or get someone else to make or use) fake records to get a false claim paid by any part of the federal government. Should you become aware of any information that may indicate the inaccuracy of these claims or records, you have a continuing obligation to report it.

Anti-Kickback Statute

This statute prohibits anyone from offering **inducements** to purchase or use health products or services if these products or services are reimbursable in whole or in part by the federal government. For purpose of this law, an "inducement" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. Importantly, a violation of this statute by a health care provider can result in exclusion from participation in the Medicare and other federal healthcare programs. In addition, this statute carries both civil and criminal penalties for violation.

Beneficiary Inducement Statute

This statute makes it illegal to offer **remuneration** that a person knows is likely to influence a beneficiary to select a particular provider or pharmacy.

For purposes of this statute, "remuneration" is defined to include, without limitation, waivers of co-payments and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value.

Because a prescription drug plan ("PDP") is not considered a provider or supplier, inducements offered to beneficiaries to join a PDP are not covered by this law. However, **incentives offered to Medicare beneficiaries to use a particular pharmacy are covered by this statute.**

Medicare Modernization Act

These rules **govern every aspect of Medicare Part D Plan's activities**, including marketing to potential enrollees, grievance and appeals process but most importantly, forming pharmacy networks, developing formularies and reporting drug costs.

Intermediate Sanctions

It is important that we understand these regulations since violations can result in civil and federal penalties.

CMS can impose intermediate sanctions on our PDPs for:

- Engaging in discriminatory practices
- Providing false information to CMS
- Imposing excessive premiums on members
- Inappropriately disenrolling or refusing to re-enroll an individual
- Failing to provide a plan member with medically necessary items or services that are required under law or contract
- Employing or contracting with any health care provider that is excluded from participation in the Medicare program.

Exercise One:

Instructions

Based on what you have reviewed so far, read the following scenario, then choose the answer that best fits the example.

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The Attorney General of Pennsylvania filed criminal charges against two pharmacists for billing insurance claims for nearly \$1 million worth of prescription drugs that were not prescribed by any doctors and were not dispensed to any customers. The pharmacists were also accused of creating drug prescriptions (Levitra, Marinol, Restoril and Pexeva) and submitting the claims to CMS for more than \$155,000 in reimbursements. They also submitted more than \$180,000 in claims by using the names of employees who worked for businesses near the pharmacy.

The law or statute that is violated in this example would be the:

- A. False Claims Act
- B. Beneficiary Inducement Statute
- C. Anti-Kickback Statute

Exercise Two:

Instructions

Based on what you have reviewed so far, read the following scenario, then choose the answer that best fits the example.

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A large pharmaceutical company encouraged a nursing home pharmacy to increase the number of elderly patients taking medication for a diagnosis that required prescriptions relating to psychosis. To do so, these pharmacists persuaded physicians to prescribe drugs manufactured by this pharmaceutical company for their patients. As a result, these actions increased market share for the pharmaceutical company's antipsychotic drug against competing pharmaceutical companies.

In return for the nursing home pharmacy efforts, the drug maker paid the pharmacy tens of millions of dollars. The monies were based on the market share of some of the pharmaceutical company's drugs, as well as sponsorship of the nursing home pharmacy meetings, and grants. They also made payments for nursing home pharmacy data, like the prescribing habits of doctors, previously provided to the drug maker for free.

The law or statute that is violated in this example would be the:

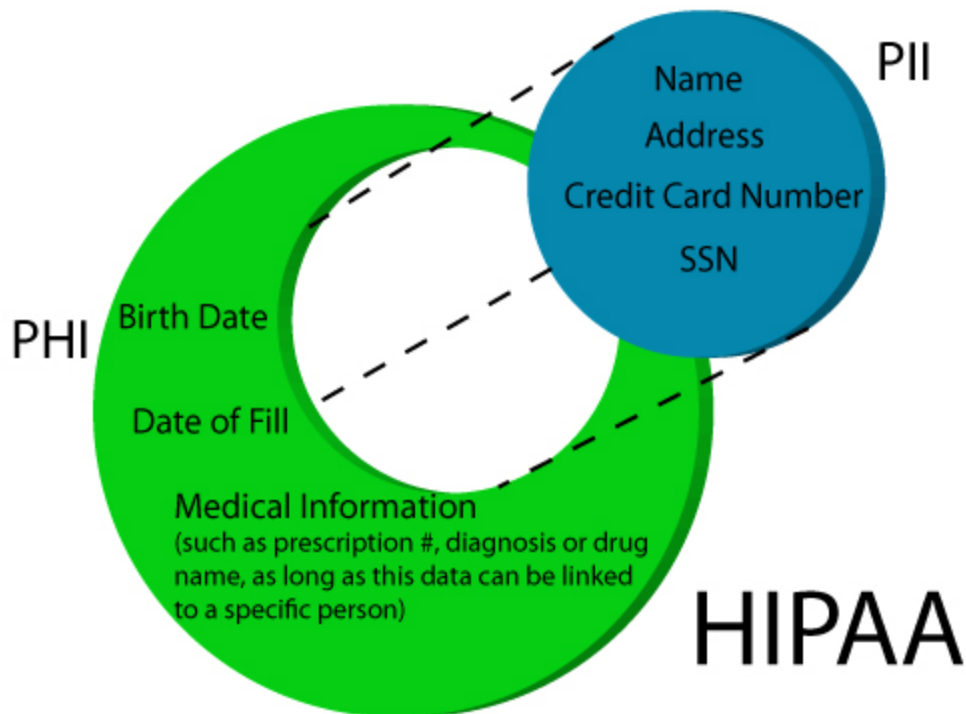
- A. False Claims Act
- B. Beneficiary Inducement Statute
- C. Anti-Kickback Statute

HIPAA and Personal Information

The Health Insurance Portability and Accountability Act (HIPAA) provides a set of rules that must be followed by health care organizations to ensure that they meet certain minimum standards with regard to protecting the privacy and security of information of patients and beneficiaries.

Protected Health Information (PHI) is personal health information that can be tied to a single person and that is obtained by or on behalf of a health plan or health care provider.

Personally Identifiable Information (PII) is personal information that can be tied directly to a single person. PII is a subset of PHI.



HIPAA Privacy and Security Rules

The **Privacy Rule** specifies the purposes for which PHI may be used and disclosed, and requires that PHI in any form (paper, electronic, or oral) be kept secure. It also provides individuals with certain rights regarding their PHI, including to:

- Inspect, amend, receive an accounting of certain disclosures of their PHI
- Request confidential communications of their PHI,
- Receive proper notice regarding how their PHI may be used and disclosed

The **Security Rule** specifies certain administrative, technical, and physical requirements for keeping ePHI secure, and to protect it from unauthorized access, modification or destruction.

When accessing PHI of Part D beneficiaries, pharmacy staff must be aware of potential HIPAA violations, including:

- Employees sharing PHI with more individuals than required to complete their job duties.
- Failure to use approved encryption software when sharing PHI electronically with appropriate external sources.

Employees with access to PHI may violate HIPAA regulations if they do not undertake the appropriate beneficiary verification procedures before sharing PHI with the beneficiary.

Steps you can take to mitigate PHI risk:

- Ensure that beneficiary authentication procedures are undertaken any time that PHI is being shared with a beneficiary.
- Ensure employees complete mandatory HIPAA training.
- Use appropriate encryption methods and software to encrypt all PHI being transmitted externally, if appropriate.

Bottom Line

Safeguard all PHI that you use or access, and only access PHI to the extent necessary in order for you to perform your duties.

Section Three

Medicare Part D Vulnerabilities

This section describes potential schemes, risks, and vulnerabilities to the Medicare Part D benefit. This should be helpful for pharmacies in identifying potential risk areas present in the Medicare Part D benefit.

The schemes identified with each group are not necessarily unique to that particular group.

Pharmacy Fraud, Waste and Abuse

Without appropriate oversight and due diligence among the pharmacy staff, there are many risks for potential FWA. Below are just some examples you should watch out for and take steps to guard against.

Inappropriate Billing Practices

The following are some types of billing practices that are not allowed and can result in varying levels of sanction, up to and including criminal charges:

Inappropriate billing practices (Pharmacy Level)	
Incorrectly billing for a secondary payer.	Billing for non-existent prescriptions.
Billing multiple payers for the same prescriptions, except as required for coordination of benefit transactions.	Billing for brand when generics are dispensed.
Billing for medications purchased from non-licensed wholesalers.	Inappropriate use of dispense as written (“DAW”) codes.
Prescription splitting to receive additional dispensing fees.	Billing for an item not dispensed.

Additional Schemes, Risks, and Vulnerabilities

There are additional FWA risks at the pharmacy level that include the following:

Prescription drug shorting occurs when pharmacy staff provide less than the prescribed quantity and intentionally does not inform the beneficiary, or makes arrangements to provide the balance but bills for the prescribed amount.

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. One example of this type of scheme is when the pharmacy switches the prescribed medication to a form that increases the pharmacy's reimbursement.

Prescription forging or altering occurs when existing prescriptions are altered to increase the quantity or the number of refills, without the prescriber's authorization. Usually the medications are diverted after being billed to the Medicare Part D program.

Dispensing expired or adulterated prescription drugs occurs when pharmacies dispense drugs after the expiration date on the package. This also includes drugs that are intended as samples not for sale, or have not been stored or handled in accordance with manufacturer and FDA requirements.

Prescription refill errors occur when pharmacy staff deliberately provide a number of refills different from the number prescribed by the provider.

Failure to offer negotiated prices occurs when a pharmacy charges a beneficiary the wrong amount.

Prescriber Fraud, Waste and Abuse

Detecting potential FWA by the prescriber may be more difficult in the pharmacy. The following are types of prescriber FWA that you should be alert for and should report if you believe they have occurred:

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Illegal Remuneration Schemes occur when a prescriber is **offered, paid, solicits, or receives compensation** as an inducement, or reward for writing prescriptions for drugs or products.

Prescription Drug Switching involves **offers of cash payments or other benefits** to a prescriber to induce him/her to prescribe certain medications rather than others.

Script Mills

This occurs when providers write prescriptions for drugs that are **not medically necessary**, often in large quantities, and often for patients that are not theirs. This may show up as a pattern of one prescriber writing a high number of prescriptions for a particular medication for a series of beneficiaries. These scripts are often for controlled drugs sold on the black market, and the situation may also involve improper payments to the provider.

Provision of False Information

The prescriber may falsify information (not consistent with the medical record) and then submit this information through a prior authorization or other formulary oversight mechanism in order to obtain coverage. This information is false when it shows incorrect dates, descriptions of prescriptions or other services furnished, or falsifies the identity of the individual who furnished the services. This may be indicated when a prescription is contrary to a beneficiary's medication history or previous claims history.

Theft of Prescriber's DEA and/or NPI 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, this includes the theft of the provider's authentication (log in) information. The pharmacy staff should look for questionably written scripts, such as:

- Mis-spelled drug names
- Quantities and dosing outside of normal patterns
- An extraordinary number of people with unusually similar prescriptions arriving at the pharmacy within a short period of time, such that it would heighten your suspicion
- Submission of a prescription from a legitimate physician, but the information on the pad appears to have been altered

Medicare Part D Plan Member (Beneficiary)

FWA

It is important to mention that not all of the following examples are initiated by beneficiaries. There are some schemes conducted by beneficiaries in which other beneficiaries are unknowing victims of the scheme. The pharmacy staff should be on the lookout for the following:

Prescription Diversion and Inappropriate Use

Beneficiaries may get prescription drugs from a provider, possibly for a condition they do not have, and then give or sell this medication to someone else. This scheme may also include the inappropriate consumption or distribution of a beneficiary's medications by a caregiver or someone else.

Identity Theft

This is an example of fraud when an individual **uses another person's** Medicare card number to obtain prescriptions.

Misrepresentation of Status

A Medicare beneficiary **misrepresents personal information**, such as identity, eligibility, or a specific medical condition in order to illegally receive the drug benefit. Individuals who are no longer covered under a drug benefit plan may still attempt to use their identity card to obtain prescriptions.

Prescription Forging or Altering

This occurs when **prescriptions are altered**, by someone other than the prescriber or pharmacist without prescriber approval, in order to raise the quantity or number of refills.

Provider Shopping

This involves beneficiaries who seek out other physicians to receive prescriptions for the same types of drugs from multiple prescribers at the same time. There are a few situations to watch out for:

- A beneficiary having a history of prescriptions written by multiple providers within a short period of time. This may signal a potentially abusive situation, or a beneficiary attempting to get drugs outside of a proper drug review.
- Another example is a beneficiary that may consistently call to request early refills. The beneficiary may also claim to have lost or misplaced the original prescription fill in order to request an early refill override.
- A beneficiary calls on numerous occasions, trying to obtain details on what types of doctors can prescribe specific types of drugs (i.e. pain killers).

Provider shopping might be indicative of other underlying schemes, such as stockpiling or resale on the black market. These types of examples may need to be investigated further to prevent harm to the beneficiary or financial harm to the pharmacy, PBM or plan.

Pharmacy Shopping:

These are situations in which beneficiaries are receiving **multiple prescriptions from multiple pharmacies for the same drug**, often times simultaneously, in order to cover up the quantities and types of prescriptions received. Pharmacy shopping can occur in several ways. Here are a few things to watch for:

- Beneficiary showing a history of getting his/her prescriptions from several different pharmacies within a short period of time.
- Prescriptions that are filled at a pharmacy that is a far distance from their home address.
- Prescriptions that are being filled for the same drugs (e.g. controlled substances / narcotics) at different pharmacies. This is potential fraud or abuse and may also signal a provider issue.

Resale of drugs on black market:

A beneficiary may falsely report the loss or theft of drugs or fake illness to obtain drugs for resale on the black market.

Prescription stockpiling:

Some beneficiaries attempt to “game” their drug coverage by obtaining and storing large quantities of drugs in order to:

- avoid out-of-pocket costs,
- protect against periods of non-coverage (i.e., by purchasing a large amount of prescription drugs and then disenrolling), or
- resell on the black market.

Improper Coordination of Benefits:

This is another example of “gaming” the system where the beneficiary fails to disclose multiple coverage policies, or leverages various coverage policies.

E1 Process

One way to reduce the potential for non-compliance or fraud, waste and abuse, is for pharmacy staff to ensure claims are billed in the proper manner to the correct plan.

A service that assists pharmacy staff in processing claims effectively, is the Eligibility Facilitator Service or E1 process. This service is available for pharmacy staff to utilize when attempting to process prescriptions for eligible Medicare Part D beneficiaries who do not have access to their eligibility information when attempting to fill a prescription.

You would utilize this service:

- When patients do not have their Part D plan card or eligibility information
- To determine proper billing order

Utilization of this service reduces potential fraud, waste and abuse by:

- Helping to ensure claims are billed under the proper beneficiary's plan
- Assisting the pharmacy in providing the appropriate level of service to beneficiaries and receiving proper payment for these services
- Ensuring claims are billed at the time of service and avoids having to submit and process paper claims or adjustments after the prescription has been dispensed

You can obtain more information on this topic by contacting Relay Health, the TrOOP Facilitator, at :

<http://medifacd.relayhealth.com> , or calling the Relay Health Help Desk toll-free at 1-800-388-2316.

Coordination with State Pharmacy Assistance Programs

State Pharmacy Assistance Programs (SPAPs) are state-run programs usually available to beneficiaries with limited income or resources. They usually provide assistance to beneficiaries, either by covering a portion of their Part D premiums or providing supplemental coverage that fills in the gaps in Part D's coverage, such as paying for drugs obtained in the coverage gap phase of the Part D benefit.

Effective coordination between SPAPs and Part D Plans can go a long way to:

- Prevent double billing
- Ensure that the Part D Plans remain the primary payer, and
- Ensure that benefits are coordinated so that SPAP payments are properly included in TrOOP.

Protecting the Public: Illegally Sold/Counterfeit Drugs

In order to protect the public from the use of counterfeit drugs and devices, the National Association of Boards of Pharmacy (NABP), in collaboration with pharmacy representatives, the Food and Drug Administration (FDA), the Drug Enforcement Agency (DEA), state regulatory authorities, and the wholesale distributor industry formulated the Model Rules for the Licensure of Wholesale Distributors. These model rules are intended to protect the integrity of the drug supply by putting into effect uniform standards for the purpose of protecting the public health against counterfeit drugs. U.S. law defines counterfeit drugs as those sold under a product name without proper authorization.

The drugs that are most at risk for counterfeiting are usually single source injectable drugs, and drugs that are commonly prescribed, have substantial wholesale cost with high mark up, or are in limited supply.

Model Rules for the Licensure of Wholesale Distributors



Susceptible Drugs*

The top 5 most often abused prescription drugs include:

- Alprazolam (Xanax)
- Hydrocodone (Vicodin, Lorcet, Lortab)
- Unspecified benzodiazepines (Diazepam)
- Oxycodone (OxyContin, Percocet, Percodan, Tylox)
- Methadone

*A list of the most frequently abused or illegally sold/counterfeited pharmaceutical substances are updated and published periodically by The National Association of Drug Diversion Investigators, Inc., (naddi.org), for your reference

Drugs Excluded From Part D Coverage

A drug is considered to be a Part D drug only if prescribed for a “medically accepted indication.” Coverage for other than a medically accepted indication is not permitted under the statute because such drugs would not be considered Part D drugs.



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Medicare Part D drugs, specifically exclude certain drugs or classes of drugs. Therefore, it is important for Part D plans not to pay for these excluded drugs unless they are covered as part of an enhanced benefit .

Examples of Drug Classes NOT covered by Part D:

- Non-prescription (OTC)
- Benzodiazepines and Barbiturates
- Agents used for symptomatic relief of colds and coughs
- Anorexia, weight loss or gain
- Agents used for cosmetic purposes or hair growth
- DESI 5 and DESI 6 agents (drugs which are safe, but deemed less than effective by the FDA's Drug Efficacy Study Implementation)

During the billing process, pharmacy staff should receive a system-generated notification if the drug is an excluded Part D drug.

Medicare Part B vs. Part D Drug Coverage

Before the Medicare Modernization Act (MMA), Medicare beneficiaries received coverage for a limited number of drugs provided under Parts A and B.

Now, with the Medicare Part D prescription drug benefit, it is possible for inappropriate duplicate coverage between A, B, and D drugs. Crossover between Parts B and D is more likely because they contain specific drugs that may be covered under both programs, depending on the circumstances under which they are prescribed. Keep in mind that the Part D benefit does not change coverage or rules for drugs currently covered under Part B. If a drug is covered under Part B in a particular situation it is, by definition, not covered under Part D in that situation.

Some drugs will always be covered by Part B because of the service being provided. However, pharmacy staff should continue to be diligent in determining whether to bill Part B or Part D.

Potential Schemes

Here are some situations that could occur due to the crossover between Parts B and D.

Home Infusion

Home infusion pharmacies are often paid delivery and dispensing fees for certain self-injectable medications even if the beneficiary self-administers. Since they are part of both Part B and Part D networks, they may inappropriately submit the claim for coverage under the wrong benefit.

Duplicate Billing

Claims could be submitted by a provider under both the medical benefit for Part B and the pharmacy benefit for Part D. Control mechanisms such as the prior authorization process identify by diagnosis and other qualifying factors if a drug is covered under Part B or Part D. This process helps to prevent the claim from being paid under the wrong benefit.

Crossover Drugs

Some of the medications that are crossover drugs are usually purchased and administered in the physician's office. These medications represent a potential revenue stream to the physician's office.

In some cases, the beneficiary may be able to purchase the drug under the Part D benefit at a community pharmacy and bring it to the physician's office for administration. In these circumstances, the physician may inappropriately bill for both the drug and the injection of the drug under Part B.

Differential Copays

Beneficiaries may have different cost sharing obligations if a crossover drug is paid under Part B versus Part D, or vice versa. They could improperly submit a claim to the inappropriate payer in an effort to lower their cost sharing obligations.

Exercise Three

The following scenario represents a situation where fraud, waste and abuse can take place. Read through the scenario then answer the question that follows.

A Medicare Part D plan member dropped off a prescription for Vicodin, enough for thirty days supply. You appropriately checked all their paperwork and identity and everything checked out correctly. You dispense the correct amount of Vicodin and the plan member was satisfied and off on their way.

Ten days later the same plan member returns to your pharmacy. They inform you that their dispensed prescription of Vicodin was stolen. The plan member also informed you that they had already reported their stolen prescription to the proper authorities, obtained another script from the same prescriber, but in the meantime they were still out of the medication. This is the third time in the past year that this situation happened with this plan member resulting in additional scripts being written.

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This scenario could be an example of what type of potential FWA?

- A. Billing for non-existent prescriptions
- B. Prescription stockpiling
- C. Identity Theft
- D. Misrepresentation of Status
- E. Provider shopping

Exercise Four

The following scenario represents a situation where fraud, waste and abuse can take place. Read through the scenario then answer the question that follows.

Sammantha Smith walks into your pharmacy and inquires if her prescription for Percocet is ready. You ask to see Samantha Smith's Medicare Part D card. Upon review, you notice that the card bearer's name states "Sandra Smith" and not Samantha Smith. Samantha replies "It is a printing error and I am waiting for my corrected card in the mail." She also states, "My back hurts me a great deal from my car accident and I really need this prescription to ease my pain so I can return to work".

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What should be the most appropriate action for you to take?

- A. Provide the prescription to Samantha Smith
- B. Provide the prescription to Samantha Smith and then later in the day call the prescriber to verify the prescription
- C. Immediately contact the CVS Caremark Help Desk and confirm the beneficiary's claim and eligibility

Pharmacy Audit Department

CVS Caremark Pharmacy Audit department audits pharmacies for fraud, waste, or abuse. These audits are reviewed by the Medicare Part D Compliance / FWA Program when potential fraudulent activity is identified.

The Pharmacy Audit department focuses on 3 types of audits



Fraudulent activity reported to the Pharmacy Management Review Committee (PMRC).

Section Four

CVS Caremark Network Pharmacy Responsibilities

The “Medicare Part D Network Standards” and the “Medicare Part D Addendum” Sections of the CVS Caremark Provider Network Manual stipulate specific requirements that pharmacies and pharmacy staff must adhere to. Here is a short list reviewing some key responsibilities pertaining to the Medicare Part D aspect of the Manual.

Training

This training is a CMS requirement for pharmacy staff who are involved with the administration or delivery of the Medicare Part D prescription drug benefit. Pharmacy staff must complete this training on an annual basis.

Proof of your completion of this training must be made available to the Medicare Part D Compliance Department, upon request.

Audit Cooperation

It is the responsibility of pharmacy staff to cooperate with CVS Caremark, and any of its subsidiaries or affiliates as necessary, to support CVS Caremark in carrying out its downstream monitoring responsibilities, including but not limited to, allowing CVS Caremark to inspect, evaluate and audit your pharmacy’s books and records.

Record Retention

The pharmacy must maintain its books and records relating to its services, for a period of at least ten (10) years, or longer as otherwise required by law [C.F.R. § 423.505(d)].

CMS-10147

The “Medicare Prescription Drug Coverage and Your Rights” notice is distributed to providers for use in instructing Part D beneficiaries about their appeal rights, and provides instructions to Medicare Part D beneficiaries on how to contact their Part D Plan. You must have it conspicuously posted at your location or available for beneficiary distribution.

OIG/GSA Exclusion List Process

Pharmacies must verify that they have researched and will continue to monitor the OIG exclusion list database to ensure none of its employees, vendors or contractors are OIG excluded. This check must be conducted at least yearly.

CVS Caremark is required to implement a process to identify Medicare Part D Claims that were submitted for drugs that were prescribed by an excluded provider and to provide the pharmacy with notification to deny these claims.

This notification appears as “Provider is an OIG excluded provider” when the claim is submitted for processing. It is the pharmacy’s responsibility to deny these claims unless in your professional judgment as a pharmacist it is an emergency situation. You should then contact the CVS Caremark Help Desk and follow their instructions.

Claims Adjudication Requirements

The pharmacy requirements for submitting claims to a Part D plan or its PBM are as follows:

- Pharmacies are required to submit Medicare Part D Claims within ninety (90) days of the original fill date.
- Pharmacies should ensure that they are submitting valid physician prescriber IDs when submitting claims
- Medicare Part D Claims that are not processed through the on-line adjudication system are still eligible for processing for up to one (1) year from the original date of fill.
- To determine if a claim is eligible for processing, you can call the appropriate CVS Caremark Help Desk.
- The CVS Caremark Help Desk can also provide directions on how to submit a Medicare Part D Claim that could not be submitted on-line.

Section Five - Reporting



You are required to report any suspected non-compliance and/or fraud, waste or abuse with any of CMS's rules and regulations as soon as you become aware of it.

When calling the CVS Caremark Ethics Line, you have an assurance of anonymity and non-retaliation in the reporting process, and confidentiality to the extent reasonably possible.

You have an obligation to disclose any action or situation that is, or may appear to be, a conflict of interest that would make it difficult for you to perform your work objectively or effectively.

If you suspect issues of non-compliance or potential fraud, waste and abuse, you must report the issue to your supervisor or to any of the other resources available to you, including the resources on the following page.

Resources



CVS Caremark Help Desk - This Help Desk is an interactive voice response (IVR) system available 24 hours a day, 7 days a week. It is a resource available to support you as a pharmacy employee and your pharmacy by responding and providing requisite information regarding:

- beneficiary claims
- eligibility
- drug coverage
- program clarification

The CVS Caremark Provider Manual provides you with the specific number for you to call based on your Bank Identification Numbers (BINs). These numbers are also available on the CVS Caremark website www.caremark.com/pharmInfo under Pharmacy Help Desk.

CVS Caremark Ethics Line (877-CVS-2040) - You can contact the CVS Caremark's Ethics Line by phone or email (Ethics.BusinessConduct@cv.com). Remember, you have an assurance of anonymity and non-retaliation in the reporting process, and confidentiality to the extent reasonably possible.

Medicare Fraud Hotline

1-888-277-4149

Medicare.fraud@caremarkrx.com

Diane Nobles

CVS Caremark Chief Compliance Officer

Email: diane.nobles@caremark.com

Todd Meek

Medicare Part D Compliance Officer

Email: todd.meek@caremark.com

Patrick Jeswald

Director, Compliance / Fraud, Waste & Abuse

Email: patrick.jeswald@caremark.com

Privacy Office

Email: privacy.officer@caremark.com

Ellen Hodge

Privacy Director

Email: ellen.hodge@caremark.com

Wrap-up

In this course, Medicare Part D Compliance / Fraud, Waste and Abuse (FWA) Training Program, we have:

- Defined the Medicare Part D prescription drug benefit
- Described the laws and regulations governing the benefit
- Identified the risk areas vulnerable to fraud, waste and abuse
- Outlined your responsibility to report potential FWA within the Program
- Listed contact information

Answer Key and Explanations

Exercise One

The law or statute that is violated in this example would be

A. False Claims Act (Correct) – The pharmacists knowingly filed false claims to be reimbursed by the government. These claims were not prescribed by any doctor and were not dispensed to any customers.

B. Beneficiary Inducement Statute (Incorrect) – The pharmacists were not providing any type of incentives that would have influenced a beneficiary to select their pharmacy for their prescriptions. These prescriptions were written fraudulently therefore no beneficiaries were involved.

C. Anti-Kickback Statute (Incorrect) – The pharmacists were providing fraudulent prescriptions for their benefit to the government. There was no payment in return for their referral recommendations to anyone outside the government.

Exercise Two

The law or statute that is violated in this example would be the:

A. False Claims Act (Incorrect) – The prescriptions that were filled were provided to actual residents of the nursing home; there were no fraudulent claims. No one was submitting a false claim payment to the federal government .

B. Beneficiary Inducement Statute (Incorrect) – Neither the pharmaceutical company nor the nursing home pharmacy were providing any incentives that may influence plan members to force them to select a particular provider or pharmacy for their prescriptions.

C. Anti-Kickback Statute (Correct) – The pharmaceutical company was providing monies to the nursing home pharmacies as a kickback to pharmacists to encourage prescribers to write a prescription of certain antipsychotic drugs. These antipsychotic drugs were only manufactured by this particular pharmaceutical company. The actions of the nursing home pharmacy resulted in the pharmaceutical company increasing its market share of its antipsychotic prescription drugs over their competitors.

Answer Key and Explanations

Exercise Three

This scenario could be an example of what type of potential FWA?

A. **Incorrect** – Though billing for non-existent prescriptions is an example of potential FWA, this scenario does not indicate that a valid prescription did not exist.

B. **Correct** – There is a potential this plan member is attempting to “game” their coverage by obtaining and storing prescriptions and stockpiling them. There is a potential that the plan member is attempting to sell the narcotic on the black market or avoid out-of-pocket costs. There has been a history of issues regarding this member’s ability to keep their prescription safe.

C. **Incorrect** – Though Identity Theft is an example of potential FWA, there is no instance of the plan member having additional scripts written without their knowledge. The plan member has been providing the correct paperwork before their medication has been dispensed to them.

D. **Incorrect** – Though Misrepresentation of Status is an example of potential FWA, the plan member is not providing incorrect personal information (identity, eligibility or a specific medical condition); their paperwork is correct. This member is still covered under this drug benefit plan and their identity card is valid.

E. **Incorrect** – Though Provider Shopping is an example of potential FWA, this plan member is submitting scripts from the same provider and not numerous prescriptions from different providers.

Exercise Four

What should be the most appropriate action for you to take?

A. **Incorrect** – Though Sandra Smith provided a Medicare Part D card it is unclear if this person is the actual owner of the card. Sandra Smith could have stolen this card and is attempting to receive this prescription via Identity Theft.

B. **Incorrect** – Delaying a call for clarifications, especially after providing the prescription does not prevent Fraud, Waste and Abuse. If there is any reason to question the validity of the card and / or prescription you should error on caution and immediately call the CVS Caremark Help Desk.

C. **Correct** – You should immediately call the CVS Caremark Help Desk. The CVS Caremark Help Desk can resolve issues regarding eligibility amongst plan members. This might be a case of Identity Theft.