



Health System One | Health Network One | Therapy Network | Eye Management

2021 CMS General Compliance

Acronyms

The following acronyms are used throughout the course.

ACRONYM	TITLE TEXT
CFR	Code of Federal Regulations
CMS	Centers for Medicare & Medicaid Services
EPLS	Excluded Parties List System
FCA	False Claims Act
FDRs	First-tier, Downstream, and Related Entities
FWA	Fraud, Waste, and Abuse
HIPAA	Health Insurance Portability and Accountability Act
LEIE	List of Excluded Individuals and Entities
MA	Medicare Advantage
MAC	Medicare Administrative Contractor
MLN	Medicare Learning Network®
NPI	National Provider Identifier
OIG	Office of Inspector General
PBM	Pharmacy Benefits Manager
WBT	Web-Based Training



Introduction

This training assists Medicare Parts C and D plan Sponsors' employees, governing body members, and their first-tier, downstream, and related entities (FDRs) to satisfy their fraud, waste, and abuse (FWA) training requirements in the regulations and sub-regulatory guidance at:

- 42 Code of Federal Regulations (CFR) Section 422.503(b)(4)(vi)(C)
- 42 CFR Section 423.504(b)(4)(vi)(C)
- CMS-4182-F, Medicare Program Contract Year 2019 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs
- Section 50.3.2 of the Compliance Program Guidelines (Chapter 9 of the "Medicare Prescription Drug Benefit Manual" and Chapter 21 of the "Medicare Managed Care Manual")

Sponsors and their FDRs are responsible for providing additional specialized or refresher training on issues posing FWA risks based on the employee's job function or business setting.



Introduction

Why Do I Need Training?

- Every year billions of dollars are improperly spent because of FWA. It affects everyone – including you.
- This training helps you detect, correct, and prevent FWA. You are part of the solution.
- Combating FWA is everyone’s responsibility! As an individual who provides health or administrative services for Medicare enrollees, every action you take potentially affects Medicare enrollees, the Medicare Program, or the Medicare Trust Fund.

Training Requirements: Plan Employees, Governing Body Members, and First-Tier, Downstream, or Related Entity (FDR) Employees

- Certain training requirements apply to people involved in Medicare Parts C and D. All employees of Medicare Advantage Organizations (MAOs) and Prescription Drug Plans (PDPs) (collectively referred to in this course as “Sponsors”) must receive training for preventing, detecting, and correcting FWA.
- FWA training must occur within 90 days of initial hire and at least annually thereafter.
- More information on other Medicare Parts C and D compliance trainings and answers to common questions is available on the CMS website.

Learn more about Medicare Part C

Medicare Part C, or Medicare Advantage (MA), is a health insurance option available to Medicare beneficiaries. Private Medicare-approved insurance companies run MA programs. These companies arrange for, or directly provide, health care services to the beneficiaries who enroll in an MA plan. MA plans must cover all services Medicare covers with the exception of hospice care. They provide Part A and Part B benefits and may also include prescription drug coverage and other supplemental benefits.

Learn more about Medicare Part D

Medicare Part D, the Prescription Drug Benefit, provides prescription drug coverage to Medicare beneficiaries enrolled in Part A and/or Part B who enroll in a Medicare Prescription Drug Plan (PDP) or an MA Prescription Drug (MA-PD) plan. Medicare-approved insurance and other companies provide prescription drug coverage to individuals who live in a plan’s service area.



Introduction - Course Objectives

When you complete this course, you should correctly:

- Recognize FWA in the Medicare Program
- Identify the major laws and regulations pertaining to FWA
- Recognize potential consequences and penalties associated with violations
- Identify methods of preventing FWA
- Identify how to report FWA
- Recognize how to correct FWA



Lesson 1 - What is FWA?

This lesson describes Fraud, Waste, and Abuse (FWA) and the laws that prohibit it. It should take about 10 minutes to complete. Upon completing the lesson, you should be able to correctly:

- Recognize FWA in the Medicare Program
- Identify the major laws and regulations pertaining to FWA
- Recognize potential consequences and penalties associated with violations



Lesson 1 - What is FWA?

- **Fraud** is knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program. The Health Care Fraud Statute makes it a criminal offense to knowingly and willfully execute a scheme to defraud a health care benefit program. Health care fraud is punishable by imprisonment for up to 10 years. It is also subject to criminal fines of up to \$250,000
- **Waste** includes practices that, directly or indirectly, result in unnecessary costs to the Medicare Program, such as overusing services. Waste is generally not considered to be caused by criminally negligent actions but rather by the misuse of resources.
- **Abuse** includes actions that may, directly or indirectly, result in unnecessary costs to the Medicare Program. Abuse involves paying for items or services when there is not legal entitlement to that payment and the provider has not knowingly or intentionally misrepresented facts to obtain payment.

❗ In other words, fraud is intentionally submitting false information to the Government or a Government contractor to get money or a benefit.

For the definitions of fraud, waste, and abuse, refer to Section 20, Chapter 21 of the “Medicare Managed Care Manual” and Chapter 9 of the “Prescription Drug Benefit Manual” on the Centers for Medicare & Medicaid Services (CMS) website.



Lesson 1 - Examples of FWA

Examples of actions that may constitute Medicare fraud include:

- Knowingly billing for services not furnished or supplies not provided, including billing Medicare for appointments that the patient failed to keep
- Billing for non-existent prescriptions
- Knowingly altering claim forms, medical records, or receipts to receive a higher payment

Examples of actions that may constitute Medicare waste include:

- Conducting excessive office visits or writing excessive prescriptions
- Prescribing more medications than necessary for the treatment of a specific condition
- Ordering excessive laboratory tests

Examples of actions that may constitute Medicare abuse include:

- Unknowingly billing for unnecessary medical services
- Unknowingly billing for brand name drugs when generics are dispensed
- Unknowingly excessively charging for services or supplies
- Unknowingly misusing codes on a claim, such as upcoding or unbundling codes



Lesson 1 - Differences Among Fraud, Waste, and Abuse

There are differences among fraud, waste, and abuse. One of the primary differences is intent and knowledge. Fraud requires intent to obtain payment and the knowledge that the actions are wrong. Waste and abuse may involve obtaining an improper payment or creating an unnecessary cost to the Medicare Program, but does not require the same intent and knowledge.

Understanding FWA

- To detect FWA, you need to know the law.
- The following pages provide high-level information about the following laws:
 - Civil False Claims Act, Health Care Fraud Statute, and Criminal Fraud
 - Anti-Kickback Statute
 - Stark Law (Physician Self-Referral Law)
 - Exclusion from all Federal health care programs
 - Health Insurance Portability and Accountability Act (HIPAA)
- For details about the specific laws, such as safe harbor provisions, consult the applicable statute and regulations



Lesson 1 - Civil False Claims Act (FCA)


The civil provisions of the FCA make a person liable to pay damages to the Government if he or she knowingly:

- Conspires to violate the FCA
- Carries out other acts to obtain property from the Government by misrepresentation
- Conceals or improperly avoids or decreases an obligation to pay the Government
- Makes or uses a false record or statement supporting a false claim
- Presents a false claim for payment or approval

For more information, refer to 31 United States Code (USC) Sections 3729-3733 .

Damages and Penalties

Any person who knowingly submits false claims to the Government is liable for three times the Government's damages caused by the violator plus a penalty.

 **Whistleblowers:** A whistleblower is a person who exposes information or activity that is deemed illegal, dishonest, or violates professional or clinical standards.

Protected: Persons who report false claims or bring legal actions to recover money paid on false claims are protected from retaliation.

Rewarded: Persons who bring a successful whistleblower lawsuit receive at least 15 percent, but not more than 30 percent of the money collected.

EXAMPLES

A Medicare Part C plan in Florida:

- Hired an outside company to review medical records to find additional diagnosis codes it could submit to increase risk capitation payments from CMS
- Was informed by the outside company that certain diagnosis codes previously submitted to Medicare were undocumented or unsupported
- Failed to report the unsupported diagnosis codes to Medicare
- Agreed to pay \$22.6 million to settle FCA allegations

The owner-operator of a medical clinic in California:

- Used marketers to recruit individuals for medically unnecessary office visits
- Promised free, medically unnecessary equipment or free food to entice individuals
- Charged Medicare more than \$1.7 million for the scheme
- Was sentenced to 37 months in prison



Lesson 1 - Health Care Fraud Statute

Health Care Fraud Statute

- The Health Care Fraud Statute states, “Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice to defraud any health care benefit program ... shall be fined under this title or imprisoned not more than 10 years, or both.”
- Conviction under the statute does not require proof that the violator had knowledge of the law or specific intent to violate the law. For more information, refer to 18 USC Sections 1346-1347.

Criminal Health Care Fraud

- Persons who knowingly make a false claim may be subject to:
 - Criminal fines up to \$250,000
 - Imprisonment for up to 20 years
- If the violations resulted in death, the individual may be imprisoned for any term of years or for life.
- For more information, refer to 18 USC Section 1347.

EXAMPLES

A Pennsylvania pharmacist:

- Submitted claims to a Medicare Part D plan for non-existent prescriptions and drugs not dispensed
- Pleaded guilty to health care fraud
- Received a 15-month prison sentence and was ordered to pay more than \$166,000 in restitution to the plan

The owners of multiple Durable Medical Equipment (DME) companies in New York:

- Falsely represented themselves as one of a nonprofit health maintenance organization’s (that administered a Medicare Advantage plan) authorized vendors
- Provided no DME to any beneficiaries as claimed
- Submitted almost \$1 million in false claims to the nonprofit; \$300,000 was paid
- Pleaded guilty to one count of conspiracy to commit health care fraud



Lesson 1 - Anti-Kickback Statute

Health Care Fraud Statute

- The Anti-Kickback Statute prohibits knowingly and willfully soliciting, receiving, offering, or paying remuneration (including any kickback, bribe, or rebate) for referrals for services that are paid, in whole or in part, under a Federal health care program (including the Medicare Program).
- For more information, refer to 42 USC Section 1320a-7b(b).

Damages and Penalties

Violations are punishable by:

- A fine up to \$25,000
- Imprisonment up to 5 years

For more information, refer to the Social Security Act (the Act), Section 1128B(b) .

EXAMPLE

From 2012 through 2015, a physician operating a pain management practice in Rhode Island:

- Conspired to solicit and receive kickbacks for prescribing a highly addictive version of the opioid Fentanyl
- Reported patients had breakthrough cancer pain to secure insurance payments
- Received \$188,000 in speaker fee kickbacks from the drug manufacturer
- Admitted the kickback scheme cost Medicare and other payers more than \$750,000
- The physician must pay more than \$750,000 restitution and is awaiting sentencing



Lesson 1 - Stark Law (Physician Self-Referral Law)

- The Stark Law prohibits a physician from making referrals for certain designated health services to an entity when the physician (or a member of his or her family) has:
 - An ownership/investment interest
 - A compensation arrangement
- Exceptions may apply.
- For more information, refer to 42 USC Section 1395nn.

Damages and Penalties

Medicare claims tainted by an arrangement that does not comply with the Stark Law are not payable. A penalty of around \$24,250 may be imposed for each service provided. There may also be around a \$161,000 fine for entering into an unlawful arrangement or scheme.

For more information, visit the Physician Self-Referral webpage and refer to the Act, Section 1877.

EXAMPLE

A California hospital was ordered to pay more than \$3.2 million to settle Stark Law violations for maintaining 97 financial relationships with physicians and physician groups outside the fair market value standards or that were improperly documented as exceptions.



Lesson 1 - Civil Monetary Penalties (CMP) Law

The Office of Inspector General (OIG) may impose civil penalties for several reasons, including:

- Arranging for services or items from an excluded individual or entity
- Providing services or items while excluded
- Failing to grant OIG timely access to records
- Knowing of an overpayment and failing to report and return an overpayment
- Making false claims
- Paying to influence referrals

For more information, refer to 42, USC 1320a-7a and the Act, Section 1128A(a) .

Damages and Penalties

The penalties can be around \$15,000 to \$70,000 depending on the specific violation. Violators are also subject to three times the amount:

- Claimed for each service or item
- Of remuneration offered, paid, solicited, or received

EXAMPLE

A California pharmacy and its owner agreed to pay over \$1.3 million to settle allegations they submitted claims to Medicare Part D for brand name prescription drugs that the pharmacy could not have dispensed based on inventory records.



Lesson 1 - Exclusion

- No Federal health care program payment may be made for any item or service furnished, ordered, or prescribed by an individual or entity excluded by the OIG. The OIG has authority to exclude individuals and entities from federally funded health care programs and maintains the List of Excluded Individuals and Entities (LEIE).
- The U.S. General Services Administration (GSA) administers the Excluded Parties List System (EPLS), which contains debarment actions taken by various Federal agencies, including the OIG. You may access the EPLS on the System for Award Management (SAM) website.
- When looking for excluded individuals or entities, check both the LEIE and the EPLS since the lists are not the same. For more information, refer to 42 USC Section 1320a-7 and 42 Code of Federal Regulations Section 1001.1901.

EXAMPLE

A pharmaceutical company pleaded guilty to two felony counts of criminal fraud related to failure to file required reports with the U.S. Food and Drug Administration concerning oversized morphine sulfate tablets. The pharmaceutical firm executive was excluded based on the company's guilty plea. At the time the unconvicted executive was excluded there was evidence he was involved in misconduct leading to the company's conviction.



Lesson 1 - Health Insurance Portability and Accountability Act (HIPAA)

- HIPAA created greater access to health care insurance, strengthened the protection of privacy of health care data, and promoted standardization and efficiency in the health care industry.
- HIPAA safeguards deter unauthorized access to protected health care information. As an individual with access to protected health care information, you must comply with HIPAA.
- For more information, visit HIPAA webpage.

Damages and Penalties

Violations may result in Civil Monetary Penalties. In some cases, criminal penalties may apply.

EXAMPLE

A former hospital employee pleaded guilty to criminal HIPAA charges after obtaining protected health information with the intent to use it for personal gain. He was sentenced to 12 months and 1 day in prison.



Lesson 1 - Lesson Summary

- There are differences among fraud, waste, and abuse (FWA). One of the primary differences is intent and knowledge. Fraud requires the person have intent to obtain payment and the knowledge his or her actions are wrong. Waste and abuse may involve obtaining an improper payment but not the same intent and knowledge.
- Laws and regulations exist that prohibit FWA. Penalties for violating these laws may include:
 - Civil Monetary Penalties
 - Civil prosecution
 - Criminal conviction, fines, or both
 - Exclusion from all Federal health care program participation
 - Imprisonment
 - Loss of professional license

Lesson Review

Now that you have completed Lesson 1, let's do a quick knowledge check.



Lesson 1 - Knowledge Check

Select the correct answer.

1. Which of the following requires intent to obtain payment and the knowledge that the actions are wrong?
 - A. Fraud
 - B. Waste
 - C. Abuse

2. Which of the following is NOT potentially a penalty for violation of a law or regulation prohibiting Fraud, Waste, and Abuse (FWA)?
 - A. Civil Monetary Penalties
 - B. Deportation
 - C. Exclusion from participation in all Federal health care programs

Correct Answers: 1. A 2. B



Lesson 2 - Your Role in the Fight Against FWA

Introduction and Learning Objectives

This lesson explains the role you can play in fighting against Fraud, Waste, and Abuse (FWA), including your responsibilities for preventing, reporting, and correcting FWA. It should take about 10 minutes to complete. Upon completing the lesson, you should be able to correctly:

- Identify methods of preventing FWA
- Identify how to report FWA
- Recognize how to correct FWA



Lesson 2 - Your Role in the Fight Against FWA

Where Do I Fit In?

As a person providing health or administrative services to a Medicare Part C or Part D enrollee, you are likely an employee of a:

- Sponsor (Examples: Medicare Advantage Organization [MAO] or a Prescription Drug Plan [PDP])
- First-tier entity (Examples: Pharmacy Benefit Management [PBM]; hospital or health care facility; provider group; doctor's office, clinical laboratory; customer service provider; claims processing and adjudication company; a company that handles enrollment, disenrollment, and membership functions; and contracted sales agents)
- Downstream entity (Examples: pharmacies, doctor's office, firms providing agent/broker services, marketing firms, and call centers)
- Related entity (Examples: Entity with common ownership or control of a Sponsor, health promotion provider, or SilverSneakers®)

I am an employee of a Part C Plan Sponsor or an employee of a Part C Plan Sponsor's first-tier or downstream entity.

- The Part C Plan Sponsor is a CMS Contractor. Part C Plan Sponsors may enter into contracts with FDRs. This stakeholder relationship flow chart shows examples of functions relating to the Sponsor's Medicare Part C contracts. First-tier and related entities of the Medicare Part C Plan Sponsor may contract with downstream entities to fulfill their contractual obligations to the Sponsor.
- Examples of first-tier entities may be independent practices, call centers, health services/hospital groups, fulfillment vendors, field marketing organizations, and credentialing organizations. If the first-tier entity is an independent practice, then a provider could be a downstream entity. If the first-tier entity is a health service/hospital group, then radiology, hospital, or mental health facilities may be the downstream entity. If the first-tier entity is a field marketing organization, then agents may be the downstream entity. Downstream entities may contract with other downstream entities. Hospitals and mental health facilities may contract with providers.

I am an employee of a Part D Plan Sponsor or an employee of a Part D Plan Sponsor's first-tier or downstream entity.

- The Part D Plan Sponsor is a CMS Contractor. Part D Plan Sponsors may enter into contracts with FDRs. This stakeholder relationship flowchart shows examples of functions that relate to the Sponsor's Medicare Part D contracts. First-tier and related entities of the Part D Plan Sponsor may contract with downstream entities to fulfill their contractual obligations to the Sponsor.
- Examples of first-tier entities include call centers, PBMs, and field marketing organizations. If the first-tier entity is a PBM, then the pharmacy, marketing firm, quality assurance firm, and claims processing firm could be downstream entities. If the first-tier entity is a field marketing organization, then agents could be a downstream entity.



Lesson 2 - Your Role in the Fight Against FWA

What Are Your Responsibilities?

You play a vital part in preventing, detecting, and reporting potential FWA, as well as Medicare non-compliance.

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

How Do You Prevent FWA?

- Look for suspicious activity
- Conduct yourself in an ethical manner
- Ensure accurate and timely data and billing
- Ensure coordination with other payers
- Know FWA policies and procedures, standards of conduct, laws, regulations, and CMS's guidance
- Verify all received information

Stay Informed About Policies and Procedures

- Know your entity's policies and procedures.
- Every Sponsor and First-Tier, Downstream, or Related Entity (FDR) must have policies and procedures that address FWA. These procedures should help you detect, prevent, report, and correct FWA.
- Standards of Conduct should describe the Sponsor's expectations that:
 - All employees conduct themselves in an ethical manner
 - Appropriate mechanisms are in place for anyone to report non-compliance and potential FWA
 - Reported issues will be addressed and corrected
- Standards of Conduct communicate to employees and FDRs that compliance is everyone's responsibility, from the top of the organization to the bottom.



Lesson 2 - Your Role in the Fight Against FWA

Report FWA

- Everyone must report suspected instances of FWA. Your Sponsor's Code of Conduct should clearly state this obligation. Sponsors may not retaliate against you for making a good faith effort in reporting.
- Report any potential FWA concerns you have to your compliance department or your Sponsor's compliance department. Your Sponsor's compliance department will investigate and make the proper determination. Often, Sponsors have a Special Investigations Unit (SIU) dedicated to investigating FWA. They may also maintain an FWA Hotline.

- ⓘ • Every Sponsor must have a mechanism for reporting potential FWA by employees and FDRs. Each Sponsor must accept anonymous reports and cannot retaliate against you for reporting.
- Review your organization's materials for the ways to report FWA.
- When in doubt, call your Compliance Department or FWA Hotline.



Lesson 2 - Your Role in the Fight Against FWA

Reporting FWA Outside Your Organization

- If warranted, Sponsors and FDRs must report potentially fraudulent conduct to Government authorities, such as the Office of Inspector General, the Department of Justice (DOJ), or CMS.
- Individuals or entities who wish to voluntarily disclose self-discovered potential fraud to OIG may do so under the Self-Disclosure Protocol (SDP). Self-disclosure gives providers the opportunity to avoid the costs and disruptions associated with a Government- directed investigation and civil or administrative litigation.

Details to Include When Reporting FWA

- When reporting suspected FWA, include:
 - Contact information for the information source, suspects, and witnesses
 - Alleged FWA details
 - Alleged Medicare rules violated
 - The suspect's history of compliance, education, training, and communication with your organization or other entities

Where To Report FWA

HHS Office of Inspector General:

Phone: 1-800-HHS-TIPS (1-800-447-8477) or
TTY 1-800-377-4950

Fax: 1-800-223-8164

Email: HHSTips@oig.hhs.gov

Online: [Forms.OIG.hhs.gov/
hotlineoperations/index.aspx](https://Forms.OIG.hhs.gov/hotlineoperations/index.aspx)

For Medicare Parts C and D:

Investigations Medicare Drug Integrity
Contractor (I MEDIC) at 1-877-7SafeRx (1-877-
772-3379)

For all other Federal health care programs:

CMS Hotline at 1-800-MEDICARE (1-800-633-
4227) or TTY 1-877-486-2048

Medicare beneficiary website: [Medicare.gov/
forms-help-and-resources/report-fraud-and-
abuse/fraud-and-abuse.html](https://www.Medicare.gov/forms-help-and-resources/report-fraud-and-abuse/fraud-and-abuse.html)



Lesson 2 - Your Role in the Fight Against FWA

Correction

- Once fraud, waste, or abuse is detected, promptly correct it. Correcting the problem saves the Government money and ensures your compliance with CMS requirements.
- Develop a plan to correct the issue. Ask your organization's compliance officer about the development process for the corrective action plan. The actual plan is going to vary, depending on the specific circumstances. In general:
 - Design the corrective action to correct the underlying problem that results in FWA program violations and to prevent future non-compliance.
 - Tailor the corrective action to address the particular FWA, problem, or deficiency identified. Include timeframes for specific actions.
 - Document corrective actions addressing non-compliance or FWA committed by a Sponsor's employee or FDR's employee, and include consequences for failure to satisfactorily complete the corrective action.
 - Monitor corrective actions continuously to ensure effectiveness.

Corrective Action Examples

Corrective actions may include:

- Adopting new prepayment edits or document review requirements
- Conducting mandated training
- Providing educational materials
- Revising policies or procedures
- Sending warning letters
- Taking disciplinary action, such as suspension of marketing, enrollment, or payment
- Terminating an employee or provider



Lesson 2 - Your Role in the Fight Against FWA

Indicators of Potential FWA

- Now that you know about your role in preventing, reporting, and correcting FWA, let's review some key indicators to help you recognize the signs of someone committing FWA.
- The following pages present potential FWA issues. Each page provides questions to ask yourself about different areas, depending on your role as an employee of a Sponsor, pharmacy, or other entity involved in the delivering Medicare Parts C and D benefits to enrollees.

Key Indicators: Potential Beneficiary Issues

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

Key Indicators: Potential Provider Issues

- Are the provider's prescriptions appropriate for the member's health condition (medically necessary)?
- Does the provider bill the Sponsor for services not provided?
- Does the provider write prescriptions for diverse drugs or primarily for controlled substances?
- Is the provider performing medically unnecessary services for the member?
- Is the provider prescribing a higher quantity than medically necessary for the condition?
- Does the provider's prescription have their active and valid National Provider Identifier on it?
- Is the provider's diagnosis for the member supported in the medical record?



Lesson 2 - Your Role in the Fight Against FWA

Key Indicators: Potential Pharmacy Issues

- Are drugs being diverted (drugs meant for nursing homes, hospice, and other entities being sent elsewhere)?
- Are the dispensed drugs expired, fake, diluted, or illegal?
- Are generic drugs provided when the prescription requires dispensing brand drugs?
- Are PBMs billed for unfilled or never picked up prescriptions?
- Are proper provisions made if the entire prescription is not filled (no additional dispensing fees for split prescriptions)?
- Do you see prescriptions being altered (changing quantities or Dispense As Written)?

Key Indicators: Potential Wholesaler Issues

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

Key Indicators: Potential Manufacturer Issues

- Does the manufacturer promote off-label drug usage?
- Does the manufacturer knowingly provide samples to entities that bill Federal health care programs for them?

Key Indicators: Potential Sponsor Issues

- Does the Sponsor encourage or support inappropriate risk adjustment submissions?
- Does the Sponsor lead the beneficiary to believe that the cost of benefits is one price, when the actual cost is higher?
- Does the Sponsor offer beneficiaries cash inducements to join the plan?
- Does the Sponsor use unlicensed agents?



Lesson 2 - Your Role in the Fight Against FWA

Lesson 2 Summary

- As a person providing health or administrative services to a Medicare Parts C or D enrollee, you play a vital role in preventing fraud, waste, and abuse (FWA). Conduct yourself ethically, stay informed of your organization's policies and procedures, and keep an eye out for key indicators of potential FWA.
- Report potential FWA. Every Sponsor must have a mechanism for reporting potential FWA. Each Sponsor must accept anonymous reports and cannot retaliate against you for reporting.
- Promptly correct identified FWA with an effective corrective action plan

Lesson 2 Review

Now that you have completed Lesson 2, let's do a quick knowledge check.



Lesson 2 - Your Role in the Fight Against FWA

Select the correct answer.

- 1. A person drops 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?**
 - a. Fill the prescription for 160
 - b. Fill the prescription for 60
 - c. Call the prescriber to verify the quantity
 - d. Call the Sponsor’s compliance department
 - e. Call law enforcement

- 2. Your job is to submit a risk diagnosis to the Centers for Medicare & Medicaid Services (CMS) for the purpose of payment. As part of this job, you use a process to verify the data is accurate. Your immediate supervisor tells you to ignore the Sponsor’s process and to adjust or add risk diagnosis codes for certain individuals. What should you do?**
 - a. Do what your immediate supervisor asked you to do and adjust or add risk diagnosis codes
 - b. Report the incident to the compliance department (via compliance hotline or other mechanism)
 - c. Discuss your concerns with your immediate supervisor
 - d. Call law enforcement



Lesson 2 - Your Role in the Fight Against FWA

Select the correct answer.

3. You are in charge of paying claims submitted by providers. You notice a certain diagnostic provider (“Doe Diagnostics”) 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 Doe Diagnostics’ claims far exceed any other provider that you reviewed. What should you do?
- a. Fill the prescription for 160
 - b. Fill the prescription for 60
 - c. Call the prescriber to verify the quantity
 - d. Call the Sponsor’s compliance department
 - e. Call law enforcement
4. You are performing a regular inventory of the controlled substances in the pharmacy. You discover a minor inventory discrepancy. What should you do?
- a. Call local law enforcement
 - b. Perform another review
 - c. Contact your compliance department (via compliance hotline or other mechanism)
 - d. Discuss your concerns with your supervisor
 - e. Follow your pharmacy’s procedures

Correct Answers: 1. C 2. B 3. B 4. E



FWA Training: Post-Assessment

Select the correct answer.

1. **Once a corrective action plan is started, the corrective actions must be monitored annually to ensure they are effective.**
 - a. True
 - b. False

2. **Ways to report potential fraud, waste, and abuse (FWA) include:**
 - a. Do what your immediate supervisor asked you to do and adjust or add risk diagnosis codes
 - b. Report the incident to the compliance department (via compliance hotline or other mechanism)
 - c. Discuss your concerns with your immediate supervisor
 - d. Call law enforcement

3. **Any person who knowingly submits false claims to the Government is liable for five times the Government's damages caused by the violator plus a penalty.**
 - a. True
 - b. False

4. **These are examples of issues that can be reported to a Compliance Department: suspected fraud, waste, and abuse (FWA); potential health privacy violation, and unethical behavior/employee misconduct.**
 - a. True
 - b. False



FWA Training: Post-Assessment

Select the correct answer. (continued)

5. **Bribes or kickbacks of any kind for services that are paid under a Federal health care program (which includes Medicare) constitute fraud by the person making as well as the person receiving them.**
 - a. True
 - b. False

6. **Waste includes any misuse of resources, such as the overuse of services or other practices that, directly or indirectly, result in unnecessary costs to the Medicare Program.**
 - a. True
 - b. False

7. **Abuse involves payment for items or services when there is no legal entitlement to that payment and the provider has not knowingly or intentionally misrepresented facts to obtain payment.**
 - a. True
 - b. False

8. **Some of the laws governing Medicare Parts C and D fraud, waste, and abuse (FWA) include the Health Insurance Portability and Accountability Act (HIPAA), the False Claims Act, the Anti-Kickback Statute, and the Health Care Fraud Statute.**
 - a. True
 - b. False



FWA Training: Post-Assessment

Select the correct answer. (continued)

9. You can help prevent fraud, waste, and abuse (FWA) by doing all of the following:

- Look for suspicious activity
- Ensure accurate and timely data and billing
- Ensure you coordinate with other payers
- Verify all information provided to you
- Conduct yourself in an ethical manner
- Keep up to date with FWA policies and procedures, standards of conduct, laws, regulations, and the Centers for Medicare & Medicaid Services (CMS) guidance

- a. True
- b. False

10. What are some of the penalties for violating fraud, waste, and abuse (FWA) laws?

- a. Civil Monetary Penalties
- b. Imprisonment
- c. Exclusion from participation in all Federal health care programs
- d. All of the above



Appendix A: Resources

Disclaimers

This course was current at the time it was published or uploaded onto the web. Medicare policy changes frequently so links to the source documents have been provided for your reference.

This course was prepared as a service to the public and is not intended to grant rights or impose obligations. This course may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.

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Glossary

For glossary terms, visit the Centers for Medicare and Medicaid Services Glossary.



Appendix B: Job Aids

Job Aid A: Applicable Laws for Reference

- Anti-Kickback Statute 42 USC Section 1320A-7b(b)
- Civil False Claims Act 31 USC Sections 3729–3733
- Civil Monetary Penalties Law 42 USC Section 1320a-7a
- Criminal False Claims Act 18 USC Section 287
- Exclusion 42 USC Section 1320a-7
- Health Care Fraud Statute 18 USC Section 1347
- Physician Self-Referral Law 42 USC Section 1395nn

HYPERLINK URL	LINKED TEXT/IMAGE
https://www.gpo.gov/fdsys/pkg/USCODE-2016-title42/pdf/USCODE-2016-title42-chap7-subchapXI-partA-sec1320a-7b.pdf	42 USC Section 1320A-7b(b)
https://www.gpo.gov/fdsys/pkg/USCODE-2016-title31/pdf/USCODE-2016-title31-subtitleIII-chap37-subchapIII.pdf	31 USC Sections 3729–3733
https://www.gpo.gov/fdsys/pkg/USCODE-2016-title42/pdf/USCODE-2016-title42-chap7-subchapXI-partA-sec1320a-7a.pdf	42 USC Section 1320a-7a
https://www.gpo.gov/fdsys/pkg/USCODE-2016-title18/pdf/USCODE-2016-title18-partI-chap15-sec287.pdf	18 USC Section 287
https://www.gpo.gov/fdsys/pkg/USCODE-2016-title42/pdf/USCODE-2016-title42-chap7-subchapXI-partA-sec1320a-7.pdf	42 USC Section 1320a-7
https://www.gpo.gov/fdsys/pkg/USCODE-2016-title18/pdf/USCODE-2016-title18-partI-chap63-sec1347.pdf	18 USC Section 1347
https://www.gpo.gov/fdsys/pkg/USCODE-2016-title42/pdf/USCODE-2016-title42-chap7-subchapXVIII-partE-sec1395nn.pdf	42 USC Section 1395nn



Appendix B: Job Aids

Job Aid B: Resources

- Health Care Fraud Prevention and Enforcement Action Team Provider Compliance Training
- OIG's Provider Self-Disclosure Protocol
- Physician Self-Referral
- Avoiding Medicare Fraud and Abuse: A Roadmap for New Physicians
- Safe Harbor Regulations

HYPERLINK URL	LINKED TEXT/IMAGE
https://oig.hhs.gov/compliance/provider-compliance-training	Health Care Fraud Prevention and Enforcement Action Team Provider Compliance Training
https://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf	OIG's Provider Self-Disclosure Protocol
https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral	Physician Self-Referral
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Publications-Items/CMS1254524.html	Avoiding Medicare Fraud and Abuse: A Roadmap for New Physicians
https://oig.hhs.gov/compliance/safe-harbor-regulations	Safe Harbor Regulations



Appendix B: Job Aids

Job Aid C: Where to Report Fraud, Waste, and Abuse (FWA)

- HHS Office of Inspector General:
Phone: 1-800-HHS-TIPS (1-800-447-8477) or TTY 1-800-377-4950
Fax: 1-800-223-8164
Email: HHSTips@oig.hhs.gov
Online: Forms.OIG.hhs.gov/hotlineoperations/index.aspx
- For Medicare Parts C and D:
Investigations Medicare Drug Integrity Contractor (I MEDIC) at 1-877-7SafeRx (1-877-772-3379)
- For all other Federal health care programs:
CMS Hotline at 1-800-MEDICARE (1-800-633-4227) or TTY 1-877-486-2048
- HHS and U.S. Department of Justice (DOJ): [Medicare.gov/forms-help-and-resources/report-fraud-and-abuse/fraud-and-abuse.html](https://www.Medicare.gov/forms-help-and-resources/report-fraud-and-abuse/fraud-and-abuse.html)

HYPERLINK URL	LINKED TEXT/IMAGE
mailto:hhstips@oig.hhs.gov	HHSTips@oig.hhs.gov
https://forms.oig.hhs.gov/hotlineoperations/index.aspx	Forms.OIG.hhs.gov/hotlineoperations/index.aspx
https://www.medicare.gov/forms-help-and-resources/report-fraud-and-abuse/fraud-and-abuse.html	Medicare.gov/forms-help-and-resources/report-fraud-and-abuse/fraud-and-abuse.html



Links to Source Documents

HYPERLINK URL	LINKED TEXT/IMAGE
https://www.ecfr.gov/cgi-bin/text-idx?SID=c66a16ad53319afd0580db00f12c5572&mc=true&node=pt42.3.422&rgn=div5#se42.3.422_1503	42 Code of Federal Regulations (CFR) Section 422.503
https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=c66a16ad53319afd0580db00f12c5572&mc=true&r=PART&n=pt42.3.423#se42.3.423_1504	42 CFR Section 423.504
https://www.gpo.gov/fdsys/pkg/FR-2014-05-23/pdf/2014-11734.pdf	CMS-4159-F, Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs
https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf	Chapter 9 of the Medicare Prescription Drug Benefit Manual
https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf	Chapter 21 of the Medicare Managed Care Manual
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Fraud-Waste_Abuse-Training_12_13_11.pdf	Medicare Parts C and D compliance trainings and answers to common questions
http://www.gpo.gov/fdsys/pkg/USCODE-2013-title31/pdf/USCODE-2013-title31-subtitleIII-chap37-subchapIII.pdf	31 USC Sections 3729-3733



Links to Source Documents

HYPERLINK URL	LINKED TEXT/IMAGE
https://www.gpo.gov/fdsys/pkg/USCODE-2016-title18/pdf/USCODE-2016-title18-partI-chap63-sec1346.pdf	18 USC Sections 1346–1347
https://www.gpo.gov/fdsys/pkg/USCODE-2016-title18/pdf/USCODE-2016-title18-partI-chap63-sec1347.pdf	18 USC Section 1347
https://www.gpo.gov/fdsys/pkg/USCODE-2016-title42/pdf/USCODE-2016-title42-chap7-subchapXI-partA-sec1320a-7b.pdf	42 USC Section 1320a-7b(b)
https://www.ssa.gov/OP_Home/ssact/title11/1128B.htm	Social Security Act (the Act), Section 1128B(b)
https://www.gpo.gov/fdsys/pkg/USCODE-2016-title42/pdf/USCODE-2016-title42-chap7-subchapXVIII-partE-sec1395nn.pdf	42 USC Section 1395nn
https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral	Physician Self-Referral webpage
https://www.ssa.gov/OP_Home/ssact/title18/1877.htm	the Act, Section 1877
https://www.gpo.gov/fdsys/pkg/USCODE-2016-title42/pdf/USCODE-2016-title42-chap7-subchapXI-partA-sec1320a-7a.pdf	42 USC 1320a-7a
http://www.ssa.gov/OP_Home/ssact/title11/1128A.htm	the Act, Section 1128A(a)
https://exclusions.oig.hhs.gov	LEIE
https://www.sam.gov	EPLS



Links to Source Documents

HYPERLINK URL	LINKED TEXT/IMAGE
http://www.gpo.gov/fdsys/pkg/CFR-2014-title42-vol5/pdf/CFR-2014-title42-vol5-sec1001-1901.pdf	42 Code of Federal Regulations Section 1001.1901
http://www.hhs.gov/hipaa	HIPAA webpage
mailto:hhstips@oig.hhs.gov	HHSTips@oig.hhs.gov
https://forms.oig.hhs.gov/hotlineoperations/index.aspx	Forms.OIG.hhs.gov/hotlineoperations/index.aspx
https://www.medicare.gov/forms-help-and-resources/report-fraud-and-abuse/fraud-and-abuse.html	Medicare.gov/forms-help-and-resources/report-fraud-and-abuse/fraud-and-abuse.html
https://www.cms.gov/apps/glossary	Centers for Medicare and Medicaid Services Glossary

