1. Combating Medicare Parts C and D Fraud, Waste and Abuse
2. Navigation Instructions
3. Terms and Conditions

The training program is intended to provide guidance only in identifying factors for consideration in the basic rules and regulations governing coverage, eligibility, marketing, and enrollment for Medicare, Medicare supplement insurance, Medicare health plans, and Part D prescription drug plans and is not intended as legal advice. While all reasonable efforts have been made to ensure the accuracy of the information contained in this document, AHIP shall not be liable for reliance by any individual upon the contents of the training program.

4. Introduction

The Medicare Learning Network® developed this content.

The Medicare Learning Network® (MLN) offers educational materials for health care professionals on CMS programs, policies, and initiatives.

5. Introduction- Course Objectives

After completing this course, you should be able to:

- Recognize FWA in the Medicare Program
- Identify major FWA laws and regulations
- Recognize potential consequences and violation penalties
- Identify methods to prevent FWA
- Identify how to report FWA
- Recognize how to correct FWA

6. Introduction – Course Overview
Lesson 1: What's Fraud, Waste & Abuse? Describes FWA and the laws that prohibit it.

Lesson 2: Your Role in the Fight Against Fraud, Waste & Abuse explains your role in the fight against FWA, including your responsibilities to prevent, report, and correct it.

7. 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 annual general compliance training requirements in the regulations and sub-regulatory guidance at:

- 42 Code of Federal Regulations (CFR) Section 422.503 (b)(4)(vi)(C) (https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422#se42.3.422_1503)
- 42 CFR Section 423.504 (b)(4)(vi)(C) (https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423#se42.3.423_1504)
- Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (https://www.federalregister.gov/documents/2018/04/16/2018-07179/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare#p-2081)
- Medicare Prescription Drug Benefit Manual, Chapter 9 [https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf], section 50.3.2 and Medicare Managed Care Manual, Chapter 21, https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c21.pdf

Sponsors and their FDRs may provide added specialized or refresher training on issues posing FWA risks based on the employee's job function or business setting.

8. Why do I need training
Every year, **billions** of dollars are improperly spent because of FWA. It affects everyone-**including you**. This training will help you prevent, detect, and correct FWA. You're part of the solution.

Combating FWA is everyone's responsibility. As a person 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.

9. Training Requirements: Plan Employees, Governing Body Members, and First-Tier, Downstream, or Related Entity Employees
Certain training requirements apply to people involved in Medicare Parts C and D administration. All Medicare Advantage Organization and Medicare drug plan (Part D) (collectively referred to in this course as sponsors) employees must get training to prevent, detect, and correct FWA.

FWA training must happen within 90 days of initial hire and at least annually thereafter.

Compliance Training, Education & Outreach (CTEO) for Medicare Part C & D Programs has more information (https://www.cms.gov/training-education/learn/get-training/compliance-training-education-outreach).

Learn more about Medicare Part C

Part C, or Medicare Advantage (MA), is a health insurance option available to Medicare enrollees. Private, Medicare-approved insurance companies run MA programs and arrange for, or directly provide, health care services to the patients who enroll in an MA plan.

MA plans must cover all services Medicare covers (except hospice care). They provide Medicare Parts A and Part B benefits and may also include prescription drug coverage and other supplemental benefits.

Learn more about Medicare Part D

Part D, the Prescription Drug Benefit, provides prescription drug coverage to patients enrolled in Medicare Part A or Part B who enroll in a Part D or an MA Prescription Drug (MA-PD) plan. Medicare-approved insurance and other companies provide prescription drug coverage to people living in a plan's service area.

10. Lesson 1 -Introduction and Learning Objectives
This lesson describes fraud, waste, and abuse (FWA) and the laws that prohibit it. It should take about 10 minutes to complete.

After completing the lesson, you should be able to:
- Recognize FWA in the Medicare Program
- Identify major FWA laws and regulations
- Recognize potential consequences of, and penalties for, FWA violations

11. Fraud
Fraud is knowingly submitting, or causing to be submitted, false claims or making misrepresentations of facts to get a federal health care payment when no entitlement would otherwise exist. Knowingly soliciting, getting, offering, or making payments (for example, kickbacks, bribes, or rebates) to encourage or reward referrals for items or services paid for by federal health care programs is fraud. Making prohibited referrals for certain designated health services is another example of fraud. Fraud requires intent to get payment and knowledge the actions are wrong.

The Criminal Health Care Fraud Statute (18 United States Code (USC) 1347) 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 up to 10 years. It is also subject to criminal fines up to $250,000. The statute prohibits knowingly and willfully executing, or attempting to execute, a scheme or lie connected to delivering or paying for health care benefits, items, or services to either:

- Defraud any health care benefit program
- Get (by means of false or fraudulent pretenses, representations, or promises) money or property owned by, or controlled by, any health care benefit program.

Example: Several doctors and medical clinics conspired in a coordinated scheme to defraud the Medicare program by submitting medically unnecessary power wheelchair claims.

Penalties for violating federal health care fraud laws include fines, imprisonment, or both.

12. Waste and Abuse

Waste describes practices that, directly or indirectly, result in unnecessary Medicare Program costs, like overusing services. Waste is generally not considered to be criminally negligent but rather a misuse of resources.

Abuse describes practices that, directly or indirectly, result in unnecessary Medicare Program costs. Abuse includes any practice that doesn't provide patients with medically necessary services or meet professionally recognized standards of care.

For the definitions of fraud, waste, and abuse, refer to Section 20, Chapter 21 of the Medicare Managed Care Manual (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf) and Chapter 9 of the Prescription Drug Benefit Manual on the Centers for Medicare & Medicaid Services (CMS) (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf) website.

13. Examples of FWA

Medicare **fraud** examples include:

- Knowingly billing for services of higher complexity than services actually provided or documented in patient medical records.
- Knowingly billing for services or supplies not provided, including falsifying records to show an item was delivered
- Knowingly ordering medically unnecessary patient items or services
- Paying for federal health care program patient referrals
- Billing Medicare for appointments that patients don't keep

Medicare **waste** examples include:

- Conducting excessive office visits or writing excessive prescriptions
- Prescribing more medications than necessary for treating a specific condition
- Ordering excessive lab tests

Medicare **abuse** examples include:

- Billing for unnecessary medical services
- Charging excessively for services or supplies
- Misusing codes on a claim, like upcoding (assigning an inaccurate medical procedure or treatment billing code to increase payment) or unbundling codes

14. Fraud, Waste, and Abuse Differences

There are differences among fraud, waste, and abuse. One of the primary differences is intent and knowledge. Fraud requires intent to get payment and knowledge the actions are wrong. Waste and abuse may involve getting an improper payment or creating unnecessary Medicare Program costs but don't require the same intent and knowledge.

15. Understanding Fraud, Waste, and Abuse

To detect FWA, you need to know the **laws**. The following pages provide high-level information about these laws:

- Federal Civil False Claims Act (FCA)
- Criminal Health Care Fraud Statute
- Anti-Kickback Statute (AKS)
- Physician Self-Referral Law (Stark Law)
- Civil Monetary Penalties Law (CMPL)
- Exclusion Statute
- Health Insurance Portability and Accountability Act (HIPAA)

For details about specific laws, review the applicable statute and regulations.

16**.** Federal False Claims Act

The civil FCA (31 USC 3729-3733) makes a person liable to pay damages to the Government if they knowingly:

- Conspire to violate the FCA
- Carry out other acts to get government property by misrepresentation
- Conceal or improperly avoid or decrease an obligation to pay the government
- Make or use a false record or statement supporting a false claim
- Present a false claim for payment or approval

Additionally, under the criminal FCA (18 USC 287), people or entities may face criminal penalties, including fines, imprisonment, or both, for submitting false, fictious, or fraudulent claims.

Examples:

A Florida Part C plan:

- hired an outside company to review medical records to find additional diagnosis codes it could submit to increase CMS risk capitation payments.
- 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 California medical clinic:

- used marketers to recruit people for medically unnecessary office visits.
- promised free, medically unnecessary equipment or free food to entice people.
- charged Medicare more than $1.7 million for the scheme.
- was sentenced to 37 months in prison.

Damages and Penalties
Penalties for violating the civil FCA may include recovery of up to 3 times the amount of the government's damages due to the false claims, plus $11,000 per false claim filed.

17**.** Federal False Claims Act (continued)
Whistleblowers: A person who exposes information or activity that is deemed illegal, dishonest, or violates professional or clinical standards.

Protected: A person who reports false claims or brings legal actions to recover money paid for false claims is protected from retaliation.

Rewarded: A person who brings a successful whistleblower lawsuit gets at least 15 percent, but not more than 30 percent, of the money government collects.

18. Criminal Health Care Fraud Statute
The Criminal Health Care Fraud Statute (18 USC 1347-1348)(https://uscode.house.gov/view.xhtml?req=(title:18%20section:1347%20edition:prelim)%20OR%20(granuleid:USC-prelim-title18-section1347)&f=treesort&edition=prelim&num=0&jumpTo=true) makes it a criminal offense to knowingly and willfully execute a scheme to defraud a health care benefit program.

The statute prohibits knowingly and willfully executing, or attempting to execute, a scheme or lie connected to delivering or paying for health care benefits, items, or services to either:

- Defraud any health care benefit program
- Get (by means of false or fraudulent pretenses, representations, or promises) money or property owned or controlled by any health care benefit program

Conviction under the statute doesn't require proof the violator knew the law or had specific intent to violate it.

Examples:
A Pennsylvania pharmacist:

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

The owner of multiple New York DME companies:

- Falsely represented themselves as an authorized vendor of a nonprofit health maintenance organization that administers a Medicare Advantage plan
- Didn't provide DME to patients as claimed
- Submitted almost $1 million in false claims to the nonprofit; was paid $300,000
- Pleaded guilty to one count of conspiracy to commit health care fraud

Damages and Penalties

Health care fraud is subject to criminal fines up to $250,000. It's also punishable by Imprisonment for up to 10 years or up to 20 years if the violation results in serious bodily injury. If the violation result**s** in death, a person could be imprisoned for any term of years, up to and including life.

19. Anti-Kickback Statute

The Anti-Kickback Statute (AKS) (42 USC 1320a-7b(b)) makes it a crime to knowingly and willfully offer, pay, solicit, or get any remuneration directly or indirectly to encourage or reward patient referrals or business generation involving any item or service payable by a federal health care program. When a provider offers, pays, solicits, or gets unlawful remuneration, they violate the AKS.

The safe harbor regulations (16 CFR 312.11) (https://www.ecfr.gov/current/title-16/chapter-I/subchapter-C/part-312/section-312.11) describe various payment and business practices that, although they potentially implicate the AKS, aren't treated as AKS offenses if they meet certain regulatory requirements. People and entities remain responsible for complying with all other laws, regulations, and guidance that apply to their businesses.

Example:

A physician operating a Rhode Island pain management practice:

- 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
- Was required to pay more than $750,000 restitution

Damages and Penalties

Violations are punishable by 1 or both:

- A fine up to $100,000
- Imprisonment up to 10 years

Section 1128B(b) of the Social Security Act has more information (https://www.ssa.gov/OP_Home/ssact/title11/1128B.htm).

20. Physician Self-Referral Law (Stark Law)

The Physician Self-Referral Law (42 USC Section 1395nn), often called the Stark Law, prohibits a physician from referring a patient to get designated health services from a provider with whom a physician or a physician's immediate family member has a financial relationship, unless an exception applies.

Designated health services:

- Clinical lab services
- DME and supplies
- Home health services
- Inpatient and outpatient hospital services
- Outpatient prescription drugs
- Parental and enteral nutrients, equipment, and supplies
- Physical therapy, occupational therapy, and outpatient speech-language pathology services
- Prosthetics, orthotics, and prosthetics devices and supplies
- Radiation therapy services and supplies
- Radiology and other imaging services

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.

Damages and Penalties

We don't pay Medicare claims tainted by an arrangement that doesn't comply with the Physician Self-Referral Law. The federal government may impose a penalty of not more than $15,000 for each service provided and may also fine people not more than $100,000 for each unlawful arrangement or scheme entered.

Physician Self-Referral webpage and section 1877 of the Social Security Act have more information.

21. Civil Monetary Penalties (CMP) Law

The CMPL (42 USC 1320a-7a) authorizes the Office of Inspector General (OIG) to seek Civil Monetary Penalties (CMPs) and sometimes exclusions for a variety of health care fraud violations. Some violations that may justify CMPs include:

- Arranging for an excluded individual's or entity's services or items
- Failing to grant OIG timely records access
- Filing a claim you know, or should know, is for an item or service that wasn't provided as claimed or is false or fraudulent
- Filing a claim you know, or should know, is for an item or service for which we won't pay for
- Violating the AKS
- Violating Medicare assignment provisions

- Violating the Medicare physician agreement
- Providing false or misleading information expected to influence a discharge decision
- Failing to provide an adequate medical screening exam for patients who come to a hospital emergency department with an emergency medical condition or in labor
- Making false statements or misrepresentations on applications or contracts to participate in federal health care programs

Section 1128A(a) of the Social Security Act has more information.

Example:
A California pharmacy and its owner agreed to pay more than $1.3 million to settle allegations they submitted unsubstantiated Part D claims for brand name prescription drugs the pharmacy couldn't have dispensed based on inventory records.

Damages and Penalties
Penalties and assessments vary based on the type of violation. The penalties can be approximately $10,000 - $100,000 per violation. CMPs may also include an assessment of up to 3 times the amount claimed for each item or service, or up to 3 times the amount of remuneration offered, paid, solicited, or received.

22. Exclusion Statute
The Exclusion Statute (42 USC 1320a-7) requires the OIG exclude people and entities convicted of these offenses from participating in all federal health care programs:

- Medicare or Medicaid fraud, including offenses related to delivering Medicare or Medicaid items or services
- Patient abuse or neglect
- Felony convictions for other health care fraud, theft, or other financial misconduct
- Felony convictions for unlawful manufacture, distribution, prescribing, or dispensing of controlled substances

The OIG also maintains the List of Excluded Individuals and Entities (LEIE)(https://exclusions.oig.hhs.gov/).

The U.S. General Services Administration (GSA) administers the Excluded Parties List System (EPLS)(https://sam.gov/search/?index=ex&page=1&pageSize=25&sort=-relevance&sfm%5Bstatus%5D%5Bis_active%5D=true&sfm%5BsimpleSearch%5D%5BkeywordRadio%5D=ALL) which enables various federal agencies, including the OIG, to take debarment actions (excluding a company or person from doing business with the federal government).

Since the lists aren't the same, when looking for excluded people or entities, check both the LEIE and the EPLS. 42 Code of Federal Regulations (CFR) Section 1001.1901 has more information. https://www.ecfr.gov/current/title-42/chapter-V/subchapter-B/part-1001#p-1001.1901(a).

Example:
A pharmaceutical company pleaded guilty to two felony counts of criminal fraud for not filling required reports with FDA about oversized morphine sulfate tablets. The pharmaceutical firm executive was excluded based on the company's guilty plea. When the un-convicted executive was excluded, evidence showed he was involved in misconduct, which led to the company's conviction.

23. Health Insurance Portability and Accountability Act (HIPAA)
HIPAA created greater access to health care insurance, strengthened health care data privacy protection, and promoted health care industry standardization and efficiency.

HIPAA safeguards deter unauthorized access to protected health care information. As someone with access to protected health care information, you must comply with HIPAA.

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

Damages and Penalties
Violations may result in Civil Monetary Penalties (CMPs). In some cases, criminal penalties may apply.

24. Lesson 1 Summary
There are differences among FWA. One of the primary differences is **intent and knowledge**.

Fraud is knowingly submitting, or causing to be submitted, false claims or misrepresenting facts to get a federal health care payment for which no entitlement would otherwise exist.

Waste and abuse may involve getting an improper payment but not with the same intent and knowledge.

Laws and regulations exist that prohibit FWA. Penalties for violating these laws may include:

- Civil prosecution
- CMPs
- Criminal conviction, fines, or both
- Exclusion from all federal health care program participation
- Imprisonment
- Loss of professional license

Lesson 2

25. Introduction and Learning Objectives
This lesson explains your role in the fight against fraud, waste, and abuse (FWA), including your responsibilities to prevent, report, and correct it. It should take about 10 minutes to complete. Upon completing the lesson, you should be able to identify how to prevent, report, and correct FWA.

26. Where Do I Fit In?
As someone who provides health or administrative services to a Part C or Part D enrollee, you're likely an employee of a:

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

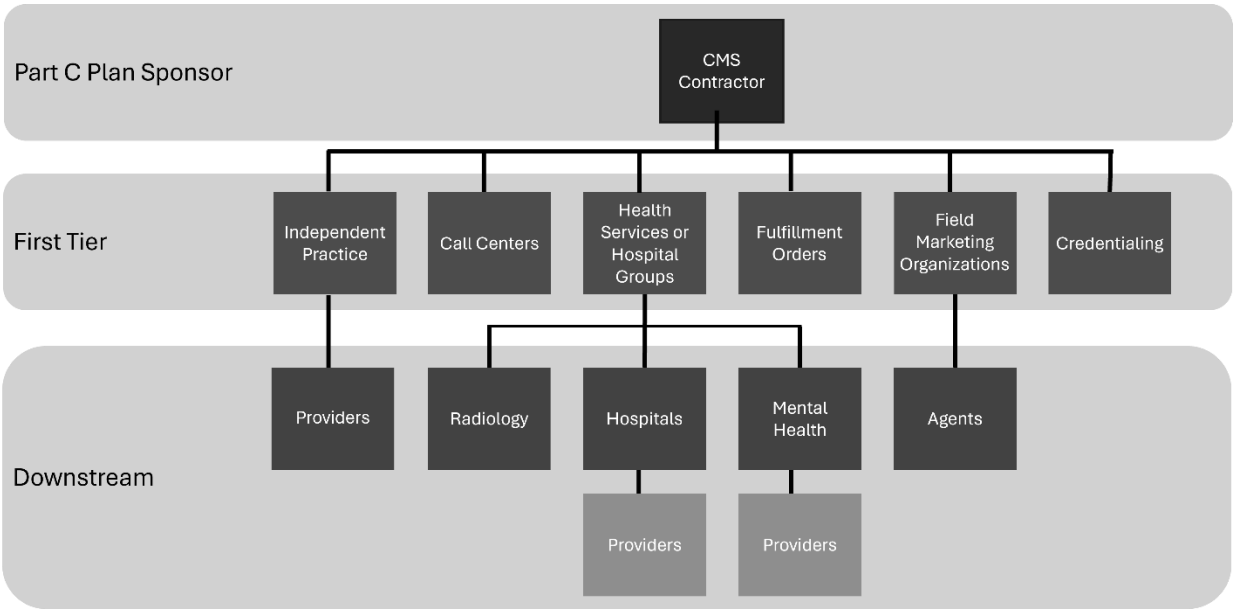
27. Where Do I Fit In? (continued)
Part C Plan Sponsor is a CMS Contractor. Part C Plan Sponsors may enter into contracts with first-tier downstream, or related entities (FDRs). This stakeholder relationship flow chart shows examples of functions relating to the Sponsor's Part C contracts. Part C Plan Sponsor first-tier and related entities 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 an agent may be the downstream entity. Downstream entities may contract with other downstream entities. Hospitals and mental health facilities may contract with providers.

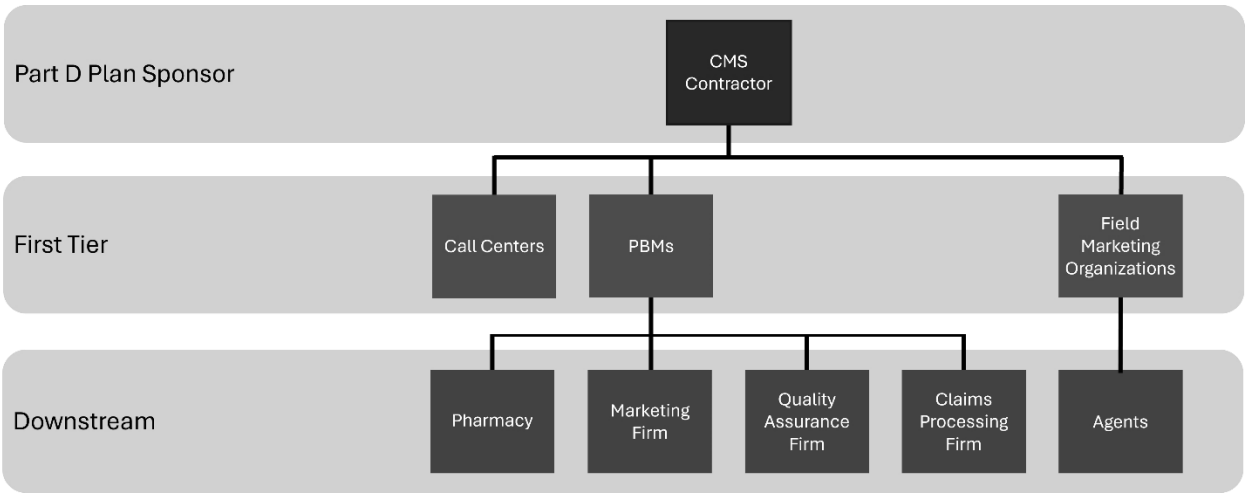
A Part D Plan Sponsor is a CMS Contractor that may enter into contracts with FDRs. This stakeholder relationship flow chart shows examples of functions relating to the Sponsor's Part D contracts. Sponsor first-tier and related entities may contract with downstream entities to fulfill their contractual obligations to the Sponsor.

Examples of first-tier entities include call centers, pharmacy benefit managers (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 an agent could be a downstream entity.

I'm an employee of a Part C Plan Sponsor or their first-tier or downstream entity



I'm an employee of a Part D Plan Sponsor or their first-tier or downstream entity



28. What Are My Responsibilities?

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

- **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 you may know about.
- **THIRD,** you have a duty to follow your organization's Code of Conduct that describes you and your organization's commitment to standards of conduct and ethical rules of behavior.

29. How Do I Prevent Fraud, Waste, and Abuse?

- 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 guidance
- Verify all information you get

30. Stay Informed About Policies and Procedures
Know your entity's policies and procedures.

Every Sponsor and FDR must have FWA policies and procedures that should help you detect, prevent, report, and correct FWA.

Standards of Conduct should describe the Sponsor's expectations that:

- All employees conduct themselves ethically
- Appropriate mechanisms are in place for anyone to report noncompliance 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 organization's top to its bottom.

31. Report Fraud, Waste, and Abuse
Everyone must report suspected FWA. Your Sponsor's Code of Conduct should clearly state this obligation. Sponsors may not retaliate against you for making a good faith reporting effort.

Report any potential FWA concerns to you or your Sponsor's compliance department. They'll 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 should have a mechanism for reporting potential FWA by employees and FDRs. Sponsors 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.

32. Reporting Fraud, Waste, and Abuse Outside Your Organization
If warranted, Sponsors and FDRs must report potentially fraudulent conduct to government authorities, like the Office of Inspector General (OIG), the U.S. Department of Justice (DOJ), or CMS.

People 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 Fraud, Waste, and Abuse

When reporting suspected FWA, include:

- Contact information for the source, suspects, and witnesses
- Alleged FWA details
- Alleged Medicare rules violated
- Suspect's history of compliance, education, training, and communication with your organization or other entities

Where to Report FWA

Medicare Providers:
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
- Online: (https://oig.hhs.gov/fraud/report-fraud/)
- Mail: U.S. Department of Health & Human Services Office of Inspector General
  ATT: OIG Hotline Operations
  PO Box 23489
  Washington, DC 20026

Parts C and D:
Investigations Medicare Drug Integrity Contractor (I MEDIC) at 1-877-7SafeRx (1-877-772-3379)

All other Federal health care programs:
CMS Hotline at 1-800-MEDICARE (1-800-633-4227) or TTY 1-877-486-2048

Medicare Patients:
4HR's for Fighting Medicare Fraud

33. Corrective Action
Once FWA 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 how to develop a corrective action plan. The actual plan varies, depending on the circumstances. In general:

- Design the corrective action to fix the underlying problem that results in FWA violations and prevents future noncompliance.
- Tailor the corrective action to address the FWA problem or identified deficiency; include timeframes for specific actions.
- Document corrective actions addressing noncompliance 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 Actions

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, like marketing, enrollment, or payment suspension
- Employment or provider contract termination

34. Potential Fraud, Waster, and Abuse Indicators
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 delivering Parts C and D enrollee benefits.

Each page also includes a real-world example of FWA. Consider the example provided and how you might mitigate these situations.

35. Real-World Example: Potential Patient Issues
Patient: I'm calling to ask why I was billed for 5 urine pregnancy tests last month.

Lab: That seems a little high, but these types of tests are routine for women of a certain age.

Patient: I'm sure that's true, but I'm a 75-year-old man so I'm not sure it was necessary.

Lab: Oh my, that's suspicious. Let's investigate who billed these codes and make sure we report this for further investigation. It's possible your MBI has been compromised or a provider made a billing mistake.

Many plan sponsors provide detailed websites and consumer materials to help guide their patients on how to look for signs of identity theft and provide directions on what to do if they believe their medical identity has been compromised, which is likely in the scenario above.

36. Key Indicators: Potential Patient Issues
- Does the prescription, medical record, or lab test look altered or possibly forged?
- Does the patient's medical history support the requested services?
- Have you filled numerous identical prescriptions for this patient, possibly from different doctors?
- Is the person getting the medical service the actual patient (identity theft)?
- Is the prescription appropriate based on the patient's other prescriptions?

37. Real-World Example: Potential Provider Issues

In January 2024, Noridian Healthcare Solutions released a letter to clinicians advising them on the importance of indicating the administration method of insulin on prescriptions. Part B covers insulin provided through a non-disposable infusion pump. Part D covers insulin provided through a syringe or a disposable pump. Noridian's letter emphasized the importance of documenting this distinction to avoid improper billing to the incorrect payer.

38. Key Indicators: Potential Provider Issues

- Are the provider's prescriptions appropriate for the patient'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?
- Does the provider perform medically unnecessary patient services?
- Does the provider prescribe a higher quantity than medically necessary for the condition?
- Does the provider's prescription include their active and valid NPI?
- Is the provider's patient diagnosis supported in the medical record?

39. Real-World Example: Potential Pharmacy Issues

Several DOJ investigations identified pharmacies double billing for drugs dispensed in a single-use vial. These pharmacists were found to pool the remaining drug from partially used vials to use on a new patient or billing for 1 single-use vial as two separate vials. Some of these pharmacies also admitted to selling counterfeit or misbranded drugs. Whistleblowers in these pharmacies helped identify this fraudulent activity.

40. Key Indicators: Potential Pharmacy Issues

- Are drugs meant for nursing homes, hospices, and other entities being diverted somewhere else?
- Are 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 "dispensed as written")?
- Are Eligibility facilitation services (E1s) and their information being used for purposes other than for determining patient eligibility?

41. Real-World Example: Potential Wholesaler Issues

In October 2023, industry trade group Pharmaceutical Cargo Security Coalition issued an alert warning its members that FDA is investigating trafficking schemes of counterfeit versions of weight loss drugs (Ozempic, Mounjaro, etc.) into U.S. pharmacies. FDA also found high rates of "no delivery schemes" where the purchaser made payment but never got the product from the wholesaler.

42. 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 HIV/AIDS clinics; marking up the prices, and sending to other smaller wholesalers or pharmacies?

43. Real-World Example: Potential Manufacturer Issues

Most of Medicare's highest-priced drugs have been granted at least 1 orphan drug designation, qualifying their manufacturers for Orphan Drug Act financial incentives. This led to concerns of manufacturers benefiting from the financial incentives of the Orphan Drug Program.

44. Key Indicators: Potential Manufacturers Issues

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

45. Real-World Example: Potential Sponsor Issues

Several plan sponsors were identified as using kickbacks to encourage patients to select their plan. In a recent case, agents were paid $200 for each patient they successfully referred to a subsidiary of a Medicare Advantage plan. This kickback disincentivized the agent from selecting the plan that was the best fit for the patient.

Report concerns related to sponsors violating the Anti-Kickback Statue to CMS.

46. Key Indicators: Potential Sponsor Issues

- Does the Sponsor encourage or support inappropriate diagnoses for risk adjustment?
- Does the Sponsor lead the beneficiary to believe the benefits cost a certain price when the actual cost is higher?
- Does the Sponsor offer patients cash incentives to join the plan?
- Does the Sponsor use unlicensed agents?

47. Lesson 2 Summary

As a person providing health or administrative services to Part C or D enrollee, you play an important part in preventing FWA. Conduct yourself ethically, stay informed of your organization's policies and procedures, and be aware of potential FWA indicators.

- Report potential FWA. Every sponsor must have a mechanism to report potential FWA. Sponsors must accept anonymous reports and can't retaliate against you for reporting.
- Promptly correct identified FWA with an effective corrective action plan.