Medicare Parts C and D General Compliance and Fraud, Waste, and Abuse (FWA) Training

Prepared by:
Anh Nguyen- Compliance Dept.

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Acronyms

The following acronyms are used throughout this presentation:

Acronym	Title Text
AKS	Anti-Kickback Statute
CFR	Code of Federal Regulations
CMP	Civil Monetary Penalty
CMS	Centers for Medicare & Medicaid Services
DOJ	U.S. Department of Justice
EPLS	Excluded Parties List System
FCA	False Claims Act
FDR	First-tier, Downstream, and Related Entity
FWA	Fraud, Waste, and Abuse
HHS	U.S. Department of Health & Human Services

Acronym	Title Text
HIPAA	Health Insurance Portability and Accountability Act
LEIE	List of Excluded Individuals and Entities
MA	Medicare Advantage
MAC	Medicare Administrative Contractor
MAO	Medicare Advantage Organization
MA-PD	MA Prescription Drug
NPI	National Provider Identifier
OIG	Office of Inspector General
PBM	Pharmacy Benefits Manager
PDP	Prescription Drug Plan

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)
- 42 CFR Section 423.504(b)(4)(vi)(C)
- Section 50.3 of the Compliance Program Guidelines (Chapter 9 of the Medicare Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual)
- The "Downloads" section of the CMS Compliance Program Policy and Guidance webpage

Completing this training in and of itself does not ensure a Sponsor has an "effective Compliance Program." Sponsors and their FDRs are responsible for establishing and executing an effective compliance program according to the CMS regulations and program guidelines.

Why is Training Important?

Every year, **billions** of dollars are improperly spent because of fraud, waste, and abuse (FWA). It affects everyone—**including you**. This training helps you detect, correct, and prevent FWA. **You** are part of the solution.

Compliance 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.

Who Should Be Trained?	Anyone who provides health or administrative services to Medicare enrollees should complete general compliance and FWA training, including employees of Medicare Advantage Organizations (MAOs) and Prescription Drug Plans (PDPs) (collectively referred to as "Sponsors"), governing body members, and first-tier, downstream, and related entity (FDR) employees.

Medicare Parts C and D

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.

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 living in a plan's service area.

GENERAL COMPLIANCE

This section of the training should assist you in:

- Recognizing how a compliance program operates
- Recognizing how compliance program violations should be reported

Compliance Program Requirement

The Centers for Medicare & Medicaid Services (CMS) requires Sponsors to implement and maintain an effective compliance program for its Medicare Parts C and D plans. An effective compliance program must:

- Articulate and demonstrate an organization's commitment to legal and ethical conduct
- Provide guidance on how to handle compliance questions and concerns
- Provide guidance on how to identify and report compliance violations

Effective Compliance Program

An effective compliance program fosters a culture of compliance within an organization and, at a minimum:

- Prevents, detects, and corrects non-compliance
- Is fully implemented and is tailored to an organization's unique operations and circumstances
- Has adequate resources
- Promotes the organization's Standards of Conduct
- Establishes clear lines of communication for reporting non-compliance

An effective compliance program is essential to prevent, detect, and correct Medicare non-compliance as well as fraud, waste, and abuse (FWA). It must, at a minimum, include the seven core compliance program requirements.

Seven Core Compliance Program Elements

CMS requires an effective compliance program to include seven core requirements:

1. **Written Policies, Procedures, and Standards of Conduct**
   These articulate the Sponsor's commitment to comply with all applicable Federal and State standards and describe compliance expectations according to the Standards of Conduct.

2. **Compliance Officer, Compliance Committee, and High-Level Oversight**
   The Sponsor must designate a compliance officer and a compliance committee accountable and responsible for the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program. The Sponsor's senior management and governing body must be engaged and exercise reasonable oversight of the Sponsor's compliance program.

3. **Effective Training and Education**
   This covers the elements of the compliance plan as well as preventing, detecting, and reporting FWA. Tailor this training and education to the different employees and their responsibilities and job functions.

Seven Core Compliance Program Elements (cont'd)

4. **Effective Lines of Communication**
   Make effective lines of communication accessible to all, ensure confidentiality, and provide methods for anonymous and good-faith compliance issues reporting at Sponsor and FDR levels. **NOTE:** CMS expects all Sponsors will apply their "effective lines of communication" requirements to their FDRs. Having "effective lines of communication" means employees of the Sponsor and the Sponsor's FDRs have several avenues to report compliance concerns.

5. **Well-Publicized Disciplinary Standards**
   Sponsor must enforce standards through well-publicized disciplinary guidelines.

6. **Effective System for Routine Monitoring, Auditing, and Identifying Compliance Risks**
   Conduct routine monitoring and auditing of Sponsor's and FDR's operations to evaluate compliance with CMS requirements as well as the overall effectiveness of the compliance program. **NOTE:** Sponsors must ensure FDRs performing delegated administrative or health care service functions concerning the Sponsor's Medicare Parts C and D program comply with Medicare Program requirements.

7. **Procedures and System for Prompt Response to Compliance Issues**
   The Sponsor must use effective measures to respond promptly to non-compliance and undertake appropriate corrective action.

Ethics: Do the Right Thing!

As part of the Medicare Program, you must conduct yourself in an ethical and legal manner. It's about doing the right thing!

- Act fairly and honestly
- Adhere to high ethical standards in all you do
- Comply with all applicable laws, regulations, and CMS requirements
- Report suspected violations

How Do You Know What Is Expected of You?

- Now that you've read the general ethical guidelines on the previous page, how do you know what is expected of you in a specific situation?
- Standards of Conduct (or Code of Conduct) state the organization's compliance expectations and their operational principles and values. Organizational Standards of Conduct vary. The organization should tailor the Standards of Conduct content to their individual organization's culture and business operations. Ask management where to locate your organization's Standards of Conduct.
- Reporting Standards of Conduct violations and suspected non-compliance is **everyone's** responsibility.
- An organization's Standards of Conduct and Policies and Procedures should identify this obligation and tell you how to report suspected non-compliance.

What Is Non-Compliance?

Non-compliance is conduct that does not conform to the law, Federal health care program requirements, or an organization's ethical and business policies. CMS identified the following Medicare Parts C and D high risk areas:

- Agent/broker misrepresentation
- Appeals and grievance review (for example, coverage and organization determinations)
- Beneficiary notices
- Conflicts of interest
- Claims processing
- Credentialing and provider networks
- Documentation and Timeliness requirements
- Ethics
- FDR oversight and monitoring
- Health Insurance Portability and Accountability Act (HIPAA)
- Marketing and enrollment
- Pharmacy, formulary, and benefit administration
- Quality of care

For more information, refer to the Compliance Program Guidelines in the Medicare Prescription Drug Benefit Manual and Medicare Managed Care Manual.

Know the Consequences of Non-Compliance

Failure to follow Medicare Program requirements and CMS guidance can lead to serious consequences, including:

- Contract termination
- Criminal penalties
- Exclusion from participating in all Federal health care programs
- Civil monetary penalties

Additionally, your organization must have disciplinary standards for non-compliant behavior. Those who engage in non-compliant behavior may be subject to any of the following:

- Mandatory training or re-training
- Disciplinary action
- Termination

Non-Compliance Affects Everybody

Without programs to prevent, detect, and correct non-compliance, we all risk:
Harm to beneficiaries, such as:

- Delayed services
- Denial of benefits
- Difficulty in using providers of choice
- Other hurdles to care

Less money for everyone, due to:

- High insurance copayments
- Higher premiums
- Lower benefits for individuals and employers
- Lower Star ratings
- Lower profits

How to Report Potential Non-Compliance

Employees of a Sponsor

- Call your Compliance Officer
- Make a report through your organization's website
- Call the Compliance Hotline

First-Tier, Downstream, or Related Entity (FDR) Employees

- Talk to a Manager or Supervisor
- Call your Ethics/Compliance Help Line
- Report to the Sponsor

Beneficiaries

- Call the Sponsor's Compliance Hotline or Customer Service
- Make a report through the Sponsor's website
- Call 1-800-Medicare

Don't Hesitate to Report Non-Compliance

When you report suspected non-compliance in good faith, the Sponsor can't retaliate against you.

Each Sponsor must offer reporting methods that are:

- Anonymous
- Confidential
- Non-retaliatory

What Happens After Non-Compliance Is Detected?

Non-compliance must be investigated immediately and corrected promptly.

Internal monitoring should ensure:

- No recurrence of the same non-compliance
- Ongoing CMS requirements compliance
- Efficient and effective internal controls
- Protected enrollees

What Are Internal Monitoring and Audits?

Internal monitoring activities include regular reviews confirming ongoing compliance and taking effective corrective actions.

Internal auditing is a formal review of compliance with a particular set of standards (for example, policies, procedures, laws, and regulations) used as base measures.

Summary

- Organizations must create and maintain compliance programs that, at a minimum, meet the seven core requirements. An effective compliance program fosters a culture of compliance.
- To help ensure compliance, behave ethically and follow your organization's Standards of Conduct. Watch for common instances of non-compliance, and report suspected non-compliance.
- Know the consequences of non-compliance, and help correct any non-compliance with a corrective action plan that includes ongoing monitoring and auditing.

Compliance Is Everyone's Responsibility!

Prevent: Operate within your organization's ethical expectations to prevent non-compliance!
Detect & Report: Report detected potential non-compliance!
Correct: Correct non-compliance to protect beneficiaries and save money!

WHAT IS FRAUD, WASTE, AND ABUSE (FWA)?

This section of the training should assist you in:

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

Defining 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 up to 10 years. It is also subject to criminal fines up to $250,000.

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

Defining FWA (cont'd)

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 no legal entitlement to that payment, and the provider has not knowingly or intentionally misrepresented facts to obtain payment.

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.

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 the patient failed to keep
- Billing for nonexistent 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 treating 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

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 the actions are wrong. Waste and abuse may involve obtaining an improper payment or creating an unnecessary cost to the Medicare Program but do not require the same intent and knowledge.

Detecting 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 Statute (Physician Self-Referral Law)
- Exclusion from all Federal health care programs
- Health Insurance Portability and Accountability Act (HIPAA)

For details about specific laws, such as safe harbor provisions, consult the applicable statute and regulations.

Penalties for violating these laws may include:

- Civil Monetary Penalties (CMPs)
- Civil prosecution
- Criminal conviction, fines, or both
- Exclusion from all Federal health care program participation
- Imprisonment
- Loss of professional license

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.

FCA Examples

FCA Example 1: 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

FCA Example 2: 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

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 the violator had knowledge of the law or specific intent to violate the law. For more information, refer to 18 USC Sections 1346–1347.

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

- Falsely represented themselves as one of a nonprofit health maintenance organization (HMO)’s (that administered an MA 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

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.

Anti-Kickback Statute (AKS)

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.

Stark Statute (Physician Self-Referral Law)

The Stark Statute 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 or
- A compensation arrangement

Exceptions may apply. For more information, refer to 42 USC Section 1395nn.

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

Medicare claims tainted by an arrangement that does not comply with the Stark Statute are not payable. A penalty of around **$24,250** can 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.

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 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 or
- 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 unsubstantiated claims to Medicare Part D for brand name prescription drugs the pharmacy could not have dispensed based on inventory records.

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 (CFR) 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.

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 the 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.

YOUR ROLE IN THE FIGHT AGAINST FWA

This section of the training should assist you in:

- Identifying methods of preventing FWA
- Identifying how to report FWA
- Recognizing how to correct 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** (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®)

Where Do I Fit In? (continued)

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 flow chart 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.

What Are Your 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 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' guidance
- Verify all received information

Stay Informed About Policies and Procedures

- Know your entity's policies and procedures.
- Every Sponsor and First-Tier, Downstream, and 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 noncompliance and potential FWA
  - Reported issues will be addressed and corrected
- Standards of Conduct communicate to employees and FDRs compliance is everyone's responsibility, from the top of the organization to the bottom.

Reporting 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.

Reporting FWA Outside Your Organization

If warranted, Sponsors and FDRs must report potentially fraudulent conduct to Government authorities, such as the OIG, the U.S. 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

For Medicare Parts C and D:

- National Benefit Integrity Medicare Drug Integrity Contractor (NBI 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

Correction

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 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 noncompliance.
- Tailor the corrective action to address the particular FWA, problem, or deficiency identified. 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 Action Examples:

Corrective actions may include:

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

Indicators of Potential FWA

The following are key indicators of potential FWA issues. Each indicator 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 Medicare Parts C and D benefits to enrollees.

Potential Beneficiary Issues	Potential Provider Issues	Potential Pharmacy Issues	Potential Wholesaler Issues	Potential Manufacturer Issues	Potential Sponsor 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 beneficiary (identity theft)? • Is the prescription appropriate based on the beneficiary's other prescriptions?	• 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 NPI on it? • Is the provider's diagnosis for the member supported in the medical record?	• 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)?	• 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, marking up the prices, and sending to other smaller wholesalers or pharmacies?	• Does the manufacturer promote off-label drug usage? • Does the manufacturer knowingly provide samples to entities that bill Federal health care programs for them?	• Does the Sponsor encourage or support inappropriate risk adjustment submissions? • Does the Sponsor lead the beneficiary to believe 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?

Summary

- As a person providing health or administrative services to a Medicare Part 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.

RESOURCES

Seven Core Compliance Program Requirements

The Centers for Medicare & Medicaid Services (CMS) requires that an effective compliance program must include seven core requirements:

1. **Written Policies, Procedures, and Standards of Conduct:** These articulate the Sponsor's commitment to comply with all applicable Federal and State standards and describe compliance expectations according to the Standards of Conduct.
2. **Compliance Officer, Compliance Committee, and High-Level Oversight:** The Sponsor must designate a compliance officer and a compliance committee to be accountable and responsible for the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program. The Sponsor's senior management and governing body must be engaged and exercise reasonable oversight of the Sponsor's compliance program.
3. **Effective Training and Education:** This covers the elements of the compliance plan as well as prevention, detection, and reporting of fraud, waste, and abuse (FWA). This training and education should be tailored to the different responsibilities and job functions of employees.
4. **Effective Lines of Communication:** Effective lines of communication must be accessible to all, ensure confidentiality, and provide methods for anonymous and good-faith reporting of compliance issues at Sponsor and first-tier, downstream, or related entity (FDR) levels.
5. **Well-Publicized Disciplinary Standards:** Sponsor must enforce standards through well-publicized disciplinary guidelines.
6. **Effective System for Routine Monitoring, Auditing, and Identifying Compliance Risks:** Conduct routine monitoring and auditing of Sponsor's and FDR's operations to evaluate compliance with CMS requirements as well as the overall effectiveness of the compliance program. **NOTE:** Sponsors must ensure FDRs performing delegated administrative or health care service functions concerning the Sponsor's Medicare Parts C and D program comply with Medicare Program requirements.
7. **Procedures and System for Prompt Response to Compliance Issues:** The Sponsor must use effective measures to respond promptly to non-compliance and undertake appropriate corrective action.

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
- Criminal Health Care Fraud Statute: 18 USC Section 1347
- Physician Self-Referral Law: 42 USC Section 1395nn

Compliance and FWA Resources

- Compliance Education Materials: Compliance 101
- Health Care Fraud Prevention and Enforcement Action Team Provider Compliance Training
- Office of Inspector General's (OIG's) Provider Self-Disclosure Protocol
- Part C and Part D Compliance and Audits - Overview
- Physician Self-Referral
- Avoiding Medicare Fraud & Abuse: A Roadmap for Physicians
- Safe Harbor Regulations

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

For Medicare Parts C and D:

National Benefit Integrity Medicare Drug Integrity Contractor (NBI 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