Combating Medicare Parts C and D Fraud, Waste, and Abuse Web-Based Training Course

2021

TABLE OF CONTENTS

| ACRONYMS | 3 |
|--|----|
| TITLE | 4 |
| INTRODUCTION | 5 |
| LESSON 1: WHAT IS FWA? | |
| LESSON 2: YOUR ROLE IN THE FIGHT AGAINST FWA | 32 |
| POST-ASSESSMENT | |
| APPENDIX A: RESOURCES | 66 |
| APPENDIX B: JOB AIDS | 68 |

ACRONYMS

The following acronyms are used throughout the course.

| ACRONYM | DEFINITION |
|---------|---|
| 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 |

TITLE

TITLE PAGE



INTRODUCTION

INTRODUCTION PAGE 1

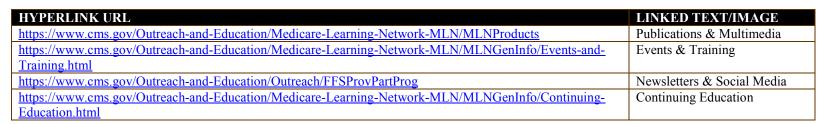
The Combating Medicare Parts C and D Fraud, Waste, and Abuse course is brought to you by the Medicare Learning Network®





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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 fraud, waste, and abuse (FWA) training requirements in the regulations and subregulatory 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 (<u>Chapter 9 of the Medicare Prescription Drug Benefit Manual</u> and <u>Chapter 21 of the Medicare Managed Care Manual</u>)

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.

| HYPERLINK URL | LINKED TEXT/IMAGE |
|---|--|
| https://www.ecfr.gov/cgi-bin/text- | 42 Code of Federal Regulations (CFR) Section 422.503 |
| idx?SID=c66a16ad53319afd0580db00f12c5572&mc=true&node=pt42.3.422&rgn=di | |
| <u>v5#se42.3.422_1503</u> | |
| https://www.ecfr.gov/cgi- | 42 CFR Section 423.504 |
| bin/retrieveECFR?gp=&SID=c66a16ad53319afd0580db00f12c5572&mc=true&r=PA | |
| RT&n=pt42.3.423#se42.3.423_1504 | |
| https://www.govinfo.gov/content/pkg/FR-2018-04-16/pdf/2018-07179.pdf | CMS-4182-F, Medicare Program; Contract Year 2019 Policy and |
| | Technical Changes to the Medicare Advantage and the Medicare |
| | Prescription Drug Benefit Programs |
| https://www.cms.gov/Medicare/Prescription-Drug- | Chapter 9 of the Medicare Prescription Drug Benefit Manual |
| Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf | |
| https://www.cms.gov/Regulations-and- | Chapter 21 of the Medicare Managed Care Manual |
| Guidance/Guidance/Manuals/Downloads/mc86c21.pdf | |

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 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.

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 living in a plan's service area.

| HYPERLINK URL | LINKED TEXT/IMAGE |
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| https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network- | Medicare Parts C and D compliance trainings and answers to common |
| MLN/MLNProducts/Downloads/Fraud-Waste Abuse-Training 12 13 11.pdf | questions |

Navigating and Completing This Course

Anyone providing health or administrative services to Medicare enrollees must satisfy general compliance and FWA training requirements. You may use this WBT course to satisfy the FWA requirements.

Visit the <u>Resources</u> page for disclaimers, a glossary, and frequently asked questions (FAQs). You may find this information useful as you proceed through this course.

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

Select the "MAIN MENU" button to return to the Main Menu. Then, select "Lesson 1: What Is FWA?"

LESSON 1: WHAT IS FWA?

LESSON 1 PAGE 1

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. 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

Fraud

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.

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

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.

Waste and Abuse

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, <u>Chapter 21 of the Medicare Managed Care Manual</u> and <u>Chapter 9 of the Prescription Drug Benefit Manual</u> on the Centers for Medicare & Medicaid Services (CMS) website.

| HYPERLINK URL | LINKED TEXT/IMAGE |
|---|---|
| https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf | Chapter 21 of the Medicare Managed Care Manual |
| https://www.cms.gov/Medicare/Prescription-Drug- | Chapter 9 of the Prescription Drug Benefit Manual |
| Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf | |

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.

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 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.

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.

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

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| https://www.govinfo.gov/content/pkg/USCODE-2017-title31/pdf/USCODE- | 31 United States Code (USC) Sections 3729–3733 |
| 2017-title31-subtitleIII-chap37-subchapIII.pdf | |

Civil FCA (continued)

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.

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'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

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| https://www.govinfo.gov/content/pkg/USCODE-2017-title18/pdf/USCODE-2017-title18-partI-chap63-sec1346.pdf | 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.

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| https://www.govinfo.gov/content/pkg/USCODE-2017-title18/pdf/USCODE-2017-title18-partI-chap63-sec1347.pdf | 18 USC Section 1347 |

Anti-Kickback 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 <u>Social Security Act (the Act)</u>, <u>Section 1128B(b)</u>.

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.

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| https://www.govinfo.gov/content/pkg/USCODE-2017-title42/pdf/USCODE-2017-title42-chap7- | 42 USC Section 1320a-7b(b) |
| subchapXI-partA-sec1320a-7b.pdf | |
| https://www.ssa.gov/OP_Home/ssact/title11/1128B.htm | Social Security Act (the Act), Section 1128B(b) |

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 $\underline{42~USC~Section}$ $\underline{1395nn}$.

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 <u>Physician Self-Referral</u> 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.

| HYPERLINK URL | LINKED TEXT/IMAGE |
|---|---------------------------------|
| https://www.govinfo.gov/content/pkg/USCODE-2017-title42/pdf/USCODE-2017-title42-chap7-subchapXVIII-partE- | 42 USC Section 1395nn |
| sec1395nn.pdf | |
| 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 |

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 <u>42 USC 1320a-7a</u> and <u>the Act, Section 1128A(a)</u>.

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.

| HYPERLINK URL | LINKED TEXT/IMAGE |
|--|---------------------------|
| https://www.govinfo.gov/content/pkg/USCODE-2017-title42/pdf/USCODE-2017-title42-chap7-subchapXI-partA- | 42 USC 1320a-7a |
| sec1320a-7a.pdf | |
| https://www.ssa.gov/OP_Home/ssact/title11/1128A.htm | the Act, Section 1128A(a) |
| | |

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 <u>EPLS</u> 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.

| HYPERLINK URL | LINKED TEXT/IMAGE |
|--|--------------------------------------|
| https://exclusions.oig.hhs.gov | LEIE |
| https://www.sam.gov | EPLS |
| https://www.govinfo.gov/content/pkg/USCODE-2017-title42/pdf/USCODE-2017-title42-chap7- | 42 USC Section 1320a-7 |
| subchapXI-partA-sec1320a-7.pdf | |
| https://www.govinfo.gov/content/pkg/CFR-2017-title42-vol5/pdf/CFR-2017-title42-vol5-sec1001- | 42 Code of Federal Regulations (CFR) |
| <u>1901.pdf</u> | Section 1001.1901 |

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 <u>HIPAA webpage</u>.

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.

| HYPERLINK URL | LINKED TEXT/IMAGE | |
|---------------------------|-------------------|--|
| https://www.hhs.gov/hipaa | HIPAA webpage | |

Lesson 1 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 1 Review

Now that you completed Lesson 1, let's do a quick knowledge check. Your Post-Assessment score is unaffected by the following questions.

Knowledge Check

Select the correct answer.

Which of the following requires intent to obtain payment and the knowledge the actions are wrong?

- o A. Fraud
- o B. Abuse
- o C. Waste



Knowledge Check

Select the correct answer.

Which of the following is NOT potentially a penalty for violation of a law or regulation prohibiting fraud, waste, and abuse (FWA)?

- o A. Civil Monetary Penalties
- o B. Deportation
- o C. Exclusion from participation in all Federal health care programs



You completed Lesson 1: What Is FWA?

Now that you have learned about FWA and the laws and regulations prohibiting it, let's look closer at your role in the fight against FWA.

Select the "MAIN MENU" button to return to the course Main Menu. Then, select "Lesson 2: Your Role in the Fight Against FWA" to begin Lesson 2.

LESSON 2: YOUR ROLE IN THE FIGHT AGAINST FWA

LESSON 2 PAGE 1

Lesson 2: 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 correctly:

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

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.

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 (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: <u>HHSTips@oig.hhs.gov</u>

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

Medicare beneficiary website: Medicare.gov/forms-help-and-resources/report-fraud-and-abuse/help-fight-medicare-fraud

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 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
- Sending warning letters
- Taking disciplinary action, such as suspension of marketing, enrollment, or payment
- Terminating an employee or provider

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 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 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?

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, 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 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 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.

Lesson 2 Review

Now that you completed Lesson 2, let's do a quick knowledge check. Your Post-Assessment score is unaffected by the following questions.

Knowledge Check

Select the correct answer.

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?

- o A. Fill the prescription for 160
- o B. Fill the prescription for 60
- o C. Call the prescriber to verify the quantity
- o D. Call the Sponsor's compliance department
- o E. Call law enforcement



Knowledge Check

Select the correct answer.

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?

- o 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)
- o C. Discuss your concerns with your immediate supervisor
- o D. Call law enforcement



Knowledge Check

Select the correct answer.

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 you reviewed. What should you do?

- o A. Call Doe Diagnostics and request additional information for the claims
- B. Consult with your immediate supervisor for next steps or contact the compliance department (via compliance hotline, Special Investigations Unit [SIU], or other mechanism)
- o C. Reject the claims
- o D. Pay the claims



Knowledge Check

Select the correct answer.

You are performing a regular inventory of the controlled substances in the pharmacy. You discover a minor inventory discrepancy. What should you do?

- o A. Call local law enforcement
- o B. Perform another review
- o C. Contact your compliance department (via compliance hotline or other mechanism)
- o D. Discuss your concerns with your supervisor
- o E. Follow your pharmacy's procedures



APPENDIX A: RESOURCES

RESOURCES PAGE 1 OF 1

Disclaimers

This Web-Based Training (WBT) 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 within the course 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 <u>Centers for Medicare & Medicaid Services Glossary</u>.

| HYPERLINK URL | LINKED TEXT/IMAGE |
|-----------------------------------|---|
| https://www.cms.gov/apps/glossary | Centers for Medicare & 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 <u>42 USC Section 1320a-7a</u>

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

| HYPERLINK URL | LINKED TEXT/IMAGE |
|---|----------------------------|
| https://www.govinfo.gov/content/pkg/USCODE-2017-title42/pdf/USCODE-2017-title42-chap7-subchapXI-partA- | 42 USC Section 1320a-7b(b) |
| sec1320a-7b.pdf | |
| https://www.govinfo.gov/content/pkg/USCODE-2017-title31/pdf/USCODE-2017-title31-subtitleIII-chap37- | 31 USC Sections 3729–3733 |
| <u>subchapIII.pdf</u> | |
| https://www.govinfo.gov/content/pkg/USCODE-2017-title42/pdf/USCODE-2017-title42-chap7-subchapXI-partA- | 42 USC Section 1320a-7a |
| <u>sec1320a-7a.pdf</u> | |
| https://www.govinfo.gov/content/pkg/USCODE-2017-title18/pdf/USCODE-2017-title18-partI-chap15-sec287.pdf | 18 USC Section 287 |
| https://www.govinfo.gov/content/pkg/USCODE-2017-title42/pdf/USCODE-2017-title42-chap7-subchapXI-partA- | 42 USC Section 1320a-7 |
| <u>sec1320a-7.pdf</u> | |
| https://www.govinfo.gov/content/pkg/USCODE-2017-title18/pdf/USCODE-2017-title18-partI-chap63-sec1347.pdf | 18 USC Section 1347 |
| https://www.govinfo.gov/content/pkg/USCODE-2017-title42/pdf/USCODE-2017-title42-chap7-subchapXVIII-partE- | 42 USC Section 1395nn |
| sec1395nn.pdf | |

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 & Abuse: A Roadmap for 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- | OIG's Provider Self-Disclosure Protocol |
| <u>Disclosure-Protocol.pdf</u> | |
| https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral | Physician Self-Referral |
| https://www.cms.gov/Outreach-and-Education/Medicare-Learning- | A Roadmap for New Physicians: Avoiding Medicare Fraud and Abuse |
| Network-MLN/MLNProducts/MLN-Publications-Items/CMS1254524.html | |
| https://oig.hhs.gov/compliance/safe-harbor-regulations | Safe Harbor Regulations |

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/help-fight-medicare-fraud