

Combating Medicare Parts C and D Fraud, Waste, and Abuse Web- based Training Course January 2018*

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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



Combating Medicare Parts C and D Fraud, Waste, and Abuse
Medicare Learning Network ®

TITLE

TITLE PAGE



INTRODUCTION PAGE 1

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



INTRODUCTION PAGE 2

The Medicare Learning Network® (MLN) offers free educational materials for health care professionals on the Centers for Medicare & Medicaid Services (CMS) programs, policies, and initiatives. Get quick access to the information you need.

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- [Events & Training](#)
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https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts	Publications & Multimedia
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNGenInfo/Events-and-Training.html	Events & Training
https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg	Newsletters & Social Media
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNGenInfo/Continuing-Education.html	Continuing Education



INTRODUCTION PAGE 3

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 sub-regulatory guidance at:

- [42 Code of Federal Regulations \(CFR\) Section 422.503\(b\)\(4\)\(vi\)\(C\)](https://www.ecfr.gov/cgi-bin/text-idx?SID=c66a16ad53319afd0580db00f12c5572&mc=true&node=pt42.3.422&rgn=div5#se42.3.422_1503)
- [42 CFR Section 423.504\(b\)\(4\)\(vi\)\(C\)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=c66a16ad53319afd0580db00f12c5572&mc=true&r=PART&n=pt42.3.423#se42.3.423_1504)
- [CMS-4159-F, Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs](https://www.gpo.gov/fdsys/pkg/FR-2014-05-23/pdf/2014-11734.pdf)
- Section 50.3.2 of the Compliance Program Guidelines ([Chapter 9 of the Medicare Prescription Drug Benefit Manual](#) and [Chapter 21 of the Medicare Managed Care Manual](#))

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

HYPERLINK URL	LINKED TEXT/IMAGE
https://www.ecfr.gov/cgi-bin/text-idx?SID=c66a16ad53319afd0580db00f12c5572&mc=true&node=pt42.3.422&rgn=div5#se42.3.422_1503	42 Code of Federal Regulations (CFR) Section 422.503
https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=c66a16ad53319afd0580db00f12c5572&mc=true&r=PART&n=pt42.3.423#se42.3.423_1504	42 CFR Section 423.504
https://www.gpo.gov/fdsys/pkg/FR-2014-05-23/pdf/2014-11734.pdf	CMS-4159-F, Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs
https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf	Chapter 9 of the Medicare Prescription Drug Benefit Manual
https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf	Chapter 21 of the Medicare Managed Care Manual



INTRODUCTION PAGE 4

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



INTRODUCTION PAGE 5

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.

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Fraud-Waste_Abuse-Training_12_13_11.pdf

Medicare Parts C and D compliance trainings and answers to common questions



INTRODUCTION PAGE 6

FWA Training Requirements Exception

There is one exception to the FWA training and education requirement. FDRs meet the FWA training and education requirements if they met the FWA certification requirement through either:

- Accreditation as a supplier of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)
- Enrollment in Medicare Part A (hospital) or B (medical) Program

If you are unsure if this exception applies to you, contact your management team for more information.



INTRODUCTION PAGE 7

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.

This course consists of two lessons and a Post-Assessment. Successfully completing the course requires completing all lessons and scoring 100 percent or higher on the Post-Assessment.

You do not have to complete the course in one session; however, you must complete at least one lesson before exiting the course. You can complete the entire course in about one hour.

Visit the CMS [Resources](#) page for disclaimers, a glossary, and frequently asked questions (FAQs). You may find this information useful as you proceed through this course



INTRODUCTION PAGE 8

Course Objectives

When you complete this course, you should correctly

- Recognize Fraud, Waste, and Abuse (FWA) in the Medicare Program
- Identify the major laws and regulations pertaining to FWA
- Recognize potential consequences and penalties associated with violations
- Identify methods of preventing FWA
- Identify how to report FWA
- Recognize how to correct FWA.



LESSON 1: WHAT IS FWA?

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



LESSON 1 PAGE 2

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.



LESSON 1 PAGE 3

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, [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

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-Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf	Chapter 9 of the Prescription Drug Benefit Manual



LESSON 1 PAGE 4

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



LESSON 1 PAGE 5

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 does not require the same intent and knowledge.



LESSON 1 PAGE 6

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



LESSON 1 PAGE 7

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

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.

<https://www.gpo.gov/fdsys/pkg/USCODE-2016-title31/pdf/USCODE-2016-title31-subtitleIII-chap37-subchapIII.pdf>

31 USC Sections 3729-3733

For more information, refer to [31 United States Code \(USC\) Sections 3729-2733](#)

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



LESSON 1 PAGE 8

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.



LESSON 1 PAGE 9

Health Care Fraud Statute

The Health Care Fraud Statute states that “Whoever knowingly and willfully executes, or attempts to execute, a scheme to ... defraud any health care benefit program ... shall be fined ... 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

HYPERLINK URL	LINKED TEXT/IMAGE
https://www.gpo.gov/fdsys/pkg/USCODE-2016-title18/pdf/USCODE-2016-title18-part1-chap63-sec1346.pdf	18 USC Sections 1346–1347



LESSON 1 PAGE 10

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; or

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](#).

HYPERLINK URL	LINKED TEXT/IMAGE
https://www.gpo.gov/fdsys/pkg/USCODE-2016-title18/pdf/USCODE-2016-title18-partI-chap63-sec1347.pdf	18 USC Section 1347



LESSON 1 PAGE 11

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 U.S.C. Section 1320A-7b\(b\)](#) on the Internet.

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.

HYPERLINK URL	LINKED TEXT/IMAGE
https://www.gpo.gov/fdsys/pkg/USCODE-2016-title42/pdf/USCODE-2016-title42-chap7-subchapXI-partA-sec1320a-7b.pdf	42 USC Section 1320a-7b(b)
https://www.ssa.gov/OP_Home/ssact/title11/1128B.htm	Social Security Act (the Act), Section 1128B(b)



LESSON 1 PAGE 12

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](#).

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](#).

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.gpo.gov/fdsys/pkg/USCODE-2016-title42/pdf/USCODE-2016-title42-chap7-subchapXVIII-partE-sec1395nn.pdf	42 USC Section 1395nn
https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral	Physician Self-Referral webpage
https://www.ssa.gov/OP_Home/ssact/title18/1877.htm	the Act, Section 1877



LESSON 1 PAGE 13

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.

HYPERLINK URL	LINKED TEXT/IMAGE
https://www.gpo.gov/fdsys/pkg/USCODE-2016-title42/pdf/USCODE-2016-title42-chap7-subchapXI-partA-sec1320a-7a.pdf	42 USC 1320a-7a
https://www.ssa.gov/OP_Home/ssact/title11/1128A.htm	the Act, Section 1128A(a)



LESSON 1 PAGE 14

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 US 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 U.S.C. 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.gpo.gov/fdsys/pkg/USCODE-2016-title42/pdf/USCODE-2016-title42-chap7-subchapXI-partA-sec1320a-7.pdf	42 USC Section 1320a-7
https://www.gpo.gov/fdsys/pkg/CFR-2016-title42-vol5/pdf/CFR-2016-title42-vol5-sec1001-1901.pdf	42 Code of Federal Regulations (CFR) Section 1001.1901



LESSON 1 PAGE 15

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](https://www.hhs.gov/hipaa).

Damages and Penalties

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

EXAMPLE

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



LESSON 1 PAGE 16

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 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 programs participation
- Imprisonment
- Loss of professional license



LESSON 1 PAGE 17

Lesson 1 Review

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



LESSON 1 PAGE 18

Knowledge Check

Select the correct answer.

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

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

Correct Answer: A



LESSON 1 PAGE 19

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)?

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

Correct Answer: B



LESSON 1 PAGE 20

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.



Lesson 2: Your Role in the Fight Against Fraud, Waste, and Abuse

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 Fraud, Waste, and Abuse;
- Identify how to report Fraud, Waste, and Abuse; and
- Recognize how to correct Fraud, Waste, and Abuse



LESSON 2 PAGE 2

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 (Medical 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 office; clinical laboratory; customer service provider; claims processing and adjudication company; a company that handles enrollment; disenrollment; and membership functions; and contracted sales agent)
- Downstream entity (Examples: pharmacies; doctor 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®)



LESSON 2 PAGE 3

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.



LESSON 2 PAGE 4

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.



LESSON 2 PAGE 5

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



LESSON 2 PAGE 6

Stay Informed About Policies and Procedures

Know your entity's policies and procedures.

Every Sponsor and First-Tier, Downstream, or Related Entity (FDR) must have policies and procedures that address FWA. These procedures should help you detect, prevent, report, and correct FWA.

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

- All employees conduct themselves in an ethical manner
- Appropriate mechanisms are in place for anyone to report non-compliance and potential FWA
- Reported issues will be addressed and corrected

Standards of Conduct communicate to employees and FDRs compliance is everyone's responsibility, from the top of the organization to the bottom.



LESSON 2 PAGE 7

Report FWA

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

Report any potential FWA concerns you have to your compliance department or your Sponsor's compliance department. Your Sponsor's compliance department will investigate and make the proper determination. Often, sponsors have a Special Investigations Unit (SIU) dedicated to investigating FWA. They may also maintain an FWA Hotline.

Every Sponsor must have a mechanism for reporting potential FWA by employees and FDRs. Each Sponsor must accept anonymous reports and cannot retaliate against you for reporting.

Review your organization's materials for the ways to report FWA.

When in doubt, call your Compliance Department or FWA Hotline.



LESSON 2 PAGE 8

Reporting FWA Outside Your Organization

If warranted, Sponsors and FDRs must report potentially fraudulent conduct to Government authorities, such as the Office of Inspector General, the Department of Justice, or CMS.

Individuals or entities who wish to voluntarily disclose self-discovered potential fraud to OIG may do so under the Self-Disclosure Protocol (SDP). Self-disclosure gives providers the opportunity to avoid the costs and disruptions associated with a Government-directed investigation and civil or administrative litigation.

Details to Include When Reporting FWA

When reporting suspected FWA, include:

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

WHERE TO REPORT FWA

HHS Office of Inspector General:

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

Fax: 1-800-223-8164

Email: HHSTips@oig.hhs.gov

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

For Medicare Parts C and D:

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](https://www.medicare.gov/forms-help-and-resources/report-fraud-and-abuse/fraud-and-abuse.html)

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



LESSON 2 PAGE 9

Correction

Once fraud, waste, or abuse is detected, promptly correct it. Correcting the problem saves the Government money and ensures your compliance with CMS requirements.

Develop a plan to correct the issue. Ask your organization's compliance officer about the development process for the corrective action plan. The actual plan is going to vary, depending on the specific circumstances. In general:

- Design the corrective action to correct the underlying problem that results in FWA program violations and to prevent future non-compliance.
- Tailor the corrective action to address the particular FWA, problem, or deficiency identified. Include timeframes for specific actions.
- Document corrective actions addressing non-compliance or FWA committed by a Sponsor's employee or FDR's employee, and include consequences for failure to satisfactorily complete the corrective action.
- Monitor corrective actions continuously to ensure effectiveness.

Corrective Action Examples

Corrective actions may include:

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



LESSON 2 PAGE 10

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



LESSON 2 PAGE 11

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?



LESSON 2 PAGE 12

Key Indicators: Potential Provider Issues

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



LESSON 2 PAGE 13

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)?



LESSON 2 PAGE 14

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?



LESSON 2 PAGE 15

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?



LESSON 2 PAGE 16

Key Indicators: Potential Sponsor Issues

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



LESSON 2 PAGE 17

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 PAGE 18

Lesson 2 Review

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



LESSON 2 PAGE 19

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?

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

Correct Answer: C



LESSON 2 PAGE 20

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?

- A. Do what your immediate supervisor asked you to do and adjust or add risk diagnosis codes
- B. Report the incident to the compliance department (via compliance hotline or other mechanism)
- C. Discuss your concerns with your immediate supervisor
- D. Call law enforcement

Correct Answer: B



LESSON 2 PAGE 21

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 that Doe Diagnostics’ claims far exceed any other provider that you reviewed. What should you do?

- 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)
- C. Reject the claims
- D. Pay the claims

Correct Answer: B



LESSON 2 PAGE 22

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?

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

Correct Answer: E



LESSON 2 PAGE 23

You Completed Lesson 2: Your Role in the Fight Against FWA

You have completed the CMS Medicare Learning Network® portion of Part 2 of Saint Louis University's Annual Compliance Update Training. There is additional content at the end of the Appendices specific to Saint Louis University. Please listen carefully as you will be tested over this additional material.



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.

The Medicare Learning Network® (MLN)

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GLOSSARY

For glossary terms, visit the [Centers for Medicare & Medicaid Services Glossary](https://www.cms.gov/apps/glossary).

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 [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](#)

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

Job Aid B: Resources

[Health Care Fraud Prevention and Enforcement Action Team Provider Compliance Training](https://oig.hhs.gov/compliance/provider-compliance-training)

[OIG's Provider Self-Disclosure Protocol](https://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf)

[Physician Self-Referral](https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral)

[Avoiding Medicare Fraud & Abuse: A Roadmap for Physicians](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Publications-Items/CMS1254524.html)

[Safe Harbor Regulations](https://oig.hhs.gov/compliance/safe-harbor-regulations)

HYPERLINK URL	LINKED TEXT/IMAGE
https://oig.hhs.gov/compliance/provider-compliance-training	Health Care Fraud Prevention and Enforcement Action Team Provider Compliance Training
https://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf	OIG's Provider Self-Disclosure Protocol
https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral	Physician Self-Referral
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Publications-Items/CMS1254524.html	Avoiding Medicare Fraud & Abuse: A Roadmap for Physicians
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](https://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](https://www.medicare.gov/forms-help-and-resources/report-fraud-and-abuse/fraud-and-abuse.html)

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

The Health
Insurance
Portability and
Accountability
Act (HIPAA)



HIPAA Privacy & Security

- ▶ Protect and enhance the rights of consumers
- ▶ Ensure strong privacy protections without interfering with access to quality of healthcare
- ▶ Improve the efficiency and effectiveness of healthcare delivery



Scope of Privacy Rule

Individually identifiable health information also known as protected health information (PHI)

- ▶ Paper
- ▶ Oral
- ▶ Electronic



What Does HIPAA Privacy Mean to Healthcare Staff?

- ▶ HIPAA impacts the majority of healthcare operations
- ▶ Its more than a medical records issue
- ▶ There are specific requirements in how health information is handled and maintained
- ▶ There is more patient involvement in use and disclosure
- ▶ There is more workforce accountability about use and disclosures
- ▶ It requires training & education of workforce



What is Covered?

Protected Health Information (PHI)

- ▶ Individually Identifiable Health Information
- ▶ Created, Received, or Transmitted



When It is NOT Covered

De-Identified Information

Information that is de-identified is no longer considered to be protected health information, and is thus exempt from the other provisions of the regulation

Means of De-Identifying:

- ▶ Removing
- ▶ Coding
- ▶ Encrypting
- ▶ Otherwise eliminating or concealing



Authorization for Disclosure



The release, transfer, provision of access to, or divulging in any other manner of PHI outside the covered entity holding the information.



Minimum Necessary

Privacy
Rights of
Patient



Covered Entity
need for the
information
(for use or disclosure)



Protected Health Information



- ▶ Electronic Health Information
- ▶ Only access information which is needed to perform work related duties
- ▶ Access to the system is monitored electronically



HIPAA Security

Requirements

- ▶ Ensure confidentiality, integrity, and availability of ePHI
- ▶ Identify and protect against threats
- ▶ Protect against impermissible uses and disclosures
- ▶ Ensure compliance of workforce



Reporting

Saint Louis University Compliance Hotline

- ▶ Available and answered 24/7
- ▶ Caller / reporter may remain anonymous
- ▶ Protection provided

SAINT LOUIS UNIVERSITY COMPLIANCE



**TOLL FREE HOTLINE
877-525-5669**



Physician Billing, Coding & Documentation

- ▶ You cannot submit a bill for someone else's work.
- ▶ Copy and paste, per payer's guidelines, cannot be used to support a billed service.
- ▶ Saint Louis University Compliance will fail providers on audit if the only documentation to support a billed service has been copy and pasted.



EMR Audit Tool

- Our EPIC Audit Tool can identify and highlight copy and pasted documentation.
- The audit tool identifies:
 - Where the material was copied from;
 - When the original material was written; and
 - The original author.



POST-ASSESSMENT

You have completed part 2 of Saint Louis University's Annual Compliance Update. Please exit the presentation and proceed to the quiz in Banner. After you complete the quiz, be sure to click on submit so your completion of the course can be recorded within Banner.

