Fraud, Waste and Abuse (FWA) Compliance Training

Heritage Provider Network
&
Arizona Priority Care

Fraud, Waste, and Abuse Defined

Fraud:

- An intentional act of deception, misrepresentation, or concealment in order to gain something of value.
- Occurs when an individual knows or should know that something is false and makes a knowing deception that could result in some unauthorized benefit to him/herself or another person.

Waste:

- Over-utilization of services (not caused by criminally negligent actions) and the misuse of resources.

Fraud, Waste, and Abuse Defined

Abuse:

- Excessive or improper use of services or actions that is inconsistent with acceptable business or medical practice.
- Refers to incidents that, although not fraudulent, may directly or indirectly cause financial loss.
- Involves payment for items or services where there was no intent to deceive or misrepresent, but the outcome results in unnecessary costs.

Examples of FWA

- Unnecessary procedures may cause injury or death.
- Diluted or substituted drugs may render treatment ineffective or expose the patient to harmful side effects or drug interactions.
- Writing prescriptions for drugs that are not medically necessary, often in mass quantities, and often for individuals who are not patients of a provider.
- Selecting or denying beneficiaries based on their illness profile or other discriminating factors.
- Limiting access to needed services—for example, by not referring a patient to an appropriate provider.

Examples of FWA

- Theft of a prescriber's Drug Enforcement Agency (DEA) number, prescription pad, or e-prescribing log-in information.
- Falsifying information in order to justify coverage.
- Falsely billed procedures create an erroneous record of the patient's medical history.
- Billing for services not rendered or supplies not provided, including billing for appointments the patient failed to keep.
- Double billing, such as billing both Medicare and the beneficiary, or billing Medicare and another insurer.
- Soliciting, offering, or receiving a kickback, bribe, or rebate (for example, paying for a referral of patients in exchange for the ordering of diagnostic tests, and other services or medical equipment).

Relevant Laws

The False Claims Act (FCA):

- Prohibits knowingly presenting a false claim for payment or approval; or making or using a false record or statement in support of a false claim;
- Prohibits knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay the Government; and,
- Prohibits conspiring to violate the False Claims Act.

The Anti-Kickback Statute:

- Makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program.
- Remuneration includes anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

Relevant Laws

The Beneficiary Inducement Statute:

- Prohibits certain inducements to Medicare beneficiaries, e.g., waiving the coinsurance and deductible amounts after determining in good faith that the individual is in financial need.

Self-Referral Prohibition Statute (Stark Law):

- Prohibits physicians from referring Medicare patients to an entity with which the physician or physician's immediate family member has a financial relationship—unless an exception applies.

Red Flag Rule (Identity Theft Protection):

- Requires "creditors" to implement programs to identify, detect, and respond to patterns, practices, or specific activities that could indicate identity theft.

Possible Civil and Criminal Penalties

False Claims Act

- For each false claim: $5,000 - $10,000
- If the government proves it suffered a loss, the provider is liable for three times the loss.

Anti-kickback Statute

- Up to five years in prison and fines of up to $25,000
- If a patient suffers bodily injury as a result of a scheme, the prison sentence may be 20+ years.

Administrative Sanctions

- Denial or revocation of Medicare provider number application.
- Suspension of provider payments.
- Addition to the OIG List of Excluded Individuals/Entities (LEIE).
- License suspension or revocation.

Your Responsibilities

As an employee or as a FDR of the company, you play a vital part in the prevention, detection, and in reporting any potential non-compliance and/or fraud, waste, and abuse.

- You are responsible in complying with all federal and state laws and regulations, company policies and procedures, and the company compliance program.
- You are responsible for reporting any violations to the laws, regulations, policies and procedures, and to the company's compliance program.
- You have a duty to follow the company's Code of Conduct, which articulates the commitment to act with integrity and outlines other ethical rules of behavior.

Best Practices for Preventing FWA

- Ensure you are familiar and up to date with laws, regulations, company policies and procedures, and the company's compliance program.
- Monitor claims/billing for accuracy—ensure coding reflects services provided.
- Monitor medical records—ensure documentation supports services rendered.
- Perform regular internal audits.
- Establish effective lines of communication with colleagues and staff members, verifying information provided to you.
- Report any suspicious activity or any potential FWA to your supervisor, Compliance Officer, or Human Resources.
- Be on the lookout for suspicious activity and take action if you identify a problem.

Discussing Potential Fraud

Do

- Avoid any reference to potentially fraudulent claims activity
- Emphasize that a random review of the file is in process
- Prepare detailed documentation of all telephone calls

Don’t

- Write on claims, bills, or other documentation
- Make any assumptions
- Mention that a claim is under investigation for fraud
- Make accusatory remarks to any callers.

Reporting Potential FWA

Everyone has the right and responsibility to report possible fraud, waste, or abuse.

Report issues or concerns to:

- Your organization's compliance office or compliance hotline and/or,
- 1-800-MEDICARE.

Remember:

You may report anonymously and retaliation is prohibited when you report a concern in good faith.

Whistleblower Protections

Whistleblower: An employee, former employee, or member of an organization who reports misconduct to people or entities that have the power to take corrective action.

A provision in the False Claims Act allows individuals to:

- Report fraud anonymously
- Sue an organization on behalf of the government and collect a portion of any settlement that results

Employers cannot threaten or retaliate against whistleblowers.

Remediation of Detected FWA

Once fraud, waste, and abuse has been detected it must be promptly corrected to prevent further continuance, to prevent unnecessary costs, and to ensure compliance with federal and state laws and regulations.

Remediation of Detected FWA:

- An investigation and review of suspected non-compliance or FWA will be conducted.
- If through the investigation the violation is proved to have occurred, a corrective action will be immediately initiated, which may include:
  - Making any applicable restitutions;
  - Implementing system changes to ensure that similar violations do not occur in future; and,
  - Reporting any violations to the appropriate persons/institutions.

Consequences of Committing FWA

The following are potential penalties for anyone who commits fraud, waste, or abuse and may vary depending on the violation:

- Termination of employment or contract
- Civil Money Penalties
- Criminal Conviction/Fines
- Civil Prosecution
- Imprisonment
- Loss of Provider License, if applicable
- Exclusion from Federal Health Care programs

Exclusion Lists

- We do not employ or contract with individuals listed on the exclusion lists maintained by the Office of Inspector General (OIG/LEIE) or System for Award Management (SAM).

- This is part of the new hire and credentialing process and is conducted prior to hire/contracting and monitored on a monthly basis.

Balance Billing

- Balance billing occurs when a provider or hospital charges the patient for Medicare covered services.

- Federal and State laws prohibit billing members for covered services that are not the responsibility of the member, which could include co-pays, co-insurance, deductibles or administrative fees.

- Providers who engage in balance billing may be subject to sanctions by the Health Plans, CMS, DHS and other industry regulators.

Providers cannot balance bill a Medicare eligible beneficiary for any covered benefit.

Balance Billing Examples

- When a provider bills a patient to compensate for the difference they are allowed to charge. For example, if the provider charges $100 for a service, but the insurance only allows a charge of $70, the provider may not bill the patient for the remaining $30.

- Provider offices charging administrative fees for appointments, completing forms, or referrals.

- Non-contracted or fee-for-service providers charging members who are enrolled in managed care for any part of a covered service.

Approved Billing Practices

- Providers may bill patients who have a monthly share of cost obligation but only until that obligation is met for the month.

- Providers may bill for all services that are **NOT** covered by the patient's managed care plan.

- Providers may bill for co-payments or co-insurance fees required by the patient's health insurance.

Best Practices for Preventing Balance Billing

- Verify the patient's eligibility and coverage of benefits at every visit – don't rely solely on the information presented by the patient (i.e. health insurance card, benefit summary, etc.)

- Understand patient rights pertaining to billing protections.

- Take appropriate action if balance billing occurs. Tell the member not to pay the bill and reverse any charges as necessary.

CMS Fraud, Waste, and Abuse (FWA) Training

Heritage Provider Network
&
Arizona Priority Care

Introduction

Anyone who conducts business with Heritage Provider Network and Arizona Priority Care, including employees, FDRs, vendors, and other entities, are required to participate in the CMS Fraud, Waste, and Abuse training, as mandated by CFR §§ 422.503(b)(4)(vi)(C)(3) and 423.504(b)(4)(vi)(C)(4)).

The Medicare Parts C and D General Compliance Training course is brought to you by the Medicare Learning Network®, a registered trademark of the U.S. Department of Health & Human Services (HHS)

Introduction

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 WBT for your reference.

This WBT course was prepared as a service to the public and is not intended to grant rights or impose obligations. This WBT 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.

Note: The referenced Web-Based Training (WBT) is available on the CMS website.

Introduction

This training module will assist Medicare Parts C and D plan Sponsors employees, governing body members, and their first-tier, downstream, and related entities (FDRs) in satisfying the 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);
- 42 CFR Section 423.504(b)(4)(vi)(C);
- CMS-4159-F, Medicare Program Contract Year 2018 Policy and Technical Changes in the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; and
- 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").

Introduction

Sponsors and their FDRs may use this module to satisfy FWA training requirements. 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.

Acronym	Title Text
CFR	Code of Federal Regulations
FDR	First-tier, Downstream, and Related Entity
FWA	Fraud, Waste, and Abuse
WBT	Web-Based Training

Introduction

Welcome to the Medicare Learning Network® (MLN) - Your free Medicare education and information resource! The MLN is home for education, information, and resources for the health care professional community. The MLN provides access to the CMS Program information you need, when you need it, so you can focus more on providing care to your patients. Serving as the umbrella for a variety of CMS education and communication activities, the MLN offers:

1. MLN Educational Products, including MLN Matters® Articles;
2. Web-Based Training (WBT) Courses (many offer Continuing Education credits);
3. MLN Connects® National Provider Calls;
4. MLN Connects® Provider Association Partnerships;
5. MLN Connects® Provider eNews; and
6. Provider electronic mailing lists.

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Note: The referenced Medicare Learning Network (MLN) is available on the CMS website and offers various courses including Fraud, Waste, and Abuse.

Introduction

ACRONYM	TITLE TEXT
CMS	Centers for Medicare & Medicaid Services
MLN	Medicare Learning Network®
HYPERLINK URL	**LINKED TEXT/IMAGE**
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts	MLN Educational Products
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles	MLN Matters® Articles
https://learner.mlnlms.com	WBT Courses
https://www.cms.gov/Outreach-and-Education/Outreach/NPC	MLN Connects® National Provider Calls
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLN-Partnership	MLN Connects® Provider Association Partnerships
https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg	MLN Connects® Provider eNews
HYPERLINK URL/JAVASCRIPT	**LINKED TEXT IMAGE**
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Publications-Items/CMS1243324.html	Provider Electronic Mailing Lists

Introduction

Why Do I Need Training?

- 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.

- 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

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.

Introduction

Learn more about Medicare Part C

Medicare Part C, or Medicare Advantage (MA), is a health plan choice available to Medicare beneficiaries. MA is a program run by Medicare-approved private insurance companies. These companies arrange for, or directly provide, health care services to the beneficiaries who elect to enroll in an MA plan.

MA plans must cover all services that Medicare covers with the exception of hospice care. MA plans provide Part A and Part B benefits and may also include prescription drug coverage and other supplemental benefits.

Learn more about Medicare Part D

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

Acronym	Title Text
MA	Medicare Advantage

Introduction

FWA Training Requirements Exception

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

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

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

Introduction

Course Content

This WBT course consists of two lessons:

1. What Is FWA?

2. Your Role in the Fight Against FWA

Anyone who provides 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.

Introduction

Course Objectives

When you complete this course, 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;
- Identify methods of preventing FWA;
- Identify how to report FWA; and
- Recognize how to correct FWA.

Lesson 1: What is FWA?

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

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

Acronym	Title Text
FWA	Fraud, Waste, and Abuse

Lesson 1: What is FWA?

Fraud is knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program, or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program.

The Health Care Fraud Statute makes it a criminal offense to knowingly and willfully execute a scheme to defraud a health care benefit program. Health care fraud is punishable by imprisonment for up to 10 years. It is also subject to criminal fines of up to $250,000

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

Lesson 1: What is FWA?

Waste includes overusing services, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare Program. 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 payment for items or services when there is not legal entitlement to that payment and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment.

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

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

Lesson 1: What is FWA?

Examples of actions that may constitute Medicare **fraud** include:

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

Examples of actions that may constitute Medicare **waste** include:

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

Lesson 1: What is FWA?

Examples of actions that may constitute Medicare **abuse** include:

- Billing for unnecessary medical services;
- Billing for brand name drugs when generics are dispensed;
- Charging excessively for services or supplies; and
- Misusing codes on a claim, such as upcoding or unbundling codes.

Difference Among Fraud, Waste, and Abuse

There are differences among fraud, waste, and abuse. One of the primary differences is intent and knowledge.

- Fraud requires intent to obtain payment and the knowledge that the actions are wrong.

- Waste and abuse may involve obtaining an improper payment or creating an unnecessary cost to the Medicare Program, but does not require the same intent and knowledge.

Lesson 1: Understanding FWA

To detect FWA, you need to know the law.

The following screens 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 healthcare programs; and
- Health Insurance Portability and Accountability Act (HIPAA).

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

Lesson 1: Civil False Claims Act (FCA)

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

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

For more information, refer to **31 United States Code (U.S.C.) Sections 3729-3733** on the Internet.

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.

Lesson 1: Civil False Claims Act (FCA)

EXAMPLE

A Medicare Part C plan in Florida:

- Hired an outside company to review medical records to find additional diagnosis codes that could be submitted to increase risk capitation payments from Centers for Medicare & Medicaid Services (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; and
- Agreed to pay $22.6 million to settle FCA allegations.

ACRONYM	TITLE TEXT
FCA	False Claims Act

HYPERLINK URL	LINKED TEXT/IMAGE
http://www.gpo.gov/fdsys/pkg/USCODE-2013-title31/pdf/USCODE-2013-title31-subtitleIII-chap37-subchapIII.pdf	31 United States Code (U.S.C.) Sections 3729-3733

Lesson 1: Civil False Claims Act (FCA)

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: 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 that the violator had knowledge of the law or specific intent to violate the law. For more information, refer to 18 U.S.C. Section 1346 on the Internet.

EXAMPLE

A Pennsylvania pharmacist:

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

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

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

HYPERLINK URL	LINKED TEXT/IMAGE
http://www.gpo.gov/fdsys/pkg/USCODE-2013-title18/pdf/USCODE-2013-title18-partI-chap63-sec1346.pdf	18 U.S.C. Section 1346

Lesson 1: Criminal Fraud

Criminal 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 U.S.C. Section 1347 on the Internet.

Hyperlink URL	Linked Text/Image
http://www.gpo.gov/fdsys/pkg/USCODE-2011-title18/pdf/USCODE-2011-title18-partI-chap63-sec1347.pdf	18 U.S.C. Section 1347

Lesson 1: Anti-Kickback Statute

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.

Lesson 1: 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 of up to $25,000
- Imprisonment for up to 5 years

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

HYPERLINK URL	LINKED TEXT/IMAGE
http://www.gpo.gov/fdsys/pkg/USCODE-2013-title42/pdf/USCODE-2013-title42-chap7-subchapXI-partA-sec1320a-7b.pdf	42 U.S.C. Section 1320A-7b(b)
https://www.ssa.gov/OP_Home/ssact/title11/1128B.htm	Social Security Act (the Act), Section 1128B(b)

Lesson 1: Anti-Kickback Statute

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; and
- Admitted the kickback scheme cost Medicare and other payers more than $750,000.

The physician must pay more than $750,000 restitution and is awaiting sentencing.

Lesson 1: Stark 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 apply).

For more information, refer to 42 U.S.C. Section 1395nn on the Internet.

Damages and Penalties

Medicare claims tainted by an arrangement that does not comply with the Stark Statute are not payable. A penalty of up to $24,250 may be imposed for each service provided. There may also be up to 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.

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

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
http://www.gpo.gov/fdsys/pkg/USCODE-2013-title42/pdf/USCODE-2013-title42-chap7-subchapXVIII-partE-sec1395nn.pdf	42 U.S.C. Section 1395nn
https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral	https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral
https://www.ssa.gov/OP_Home/ssact/title18/1877.htm	the Act, Section 1877

Lesson 1: Civil Monetary Penalties Law

The Office of Inspector General (OIG) may impose Civil penalties for a number of reasons, including:

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

For more information, refer to the Act, Section 1128A(a) on the Internet.

Damages and Penalties

The penalties range from $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.

Lesson 1: Civil Monetary Penalties Law

EXAMPLE

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

ACRONYM	TITLE TEXT
OIG	Office of Inspector General
HYPERLINK URL	LINKED TEXT/IMAGE
http://www.ssa.gov/OP_Home/ssact/title11/1128A.htm	the Act, Section 1128A(a)

Lesson 1: Exclusion

No Federal health care program payment may be made for any item or service furnished, ordered, or prescribed by an individual or entity excluded by the OIG. The OIG has authority to exclude individuals and entities from federally funded health care programs and maintains the List of Excluded Individuals and Entities (LEIE). You can access the LEIE at https://exclusions.oig.hhs.gov on the Internet.

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 at the Systems for Award Management (SAM) website.

When looking for excluded individuals or entities, make sure to 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 Section 1001.1901 on the Internet.

Lesson 1: Exclusion

EXAMPLE

A pharmaceutical company pleaded guilty to two felony counts of criminal fraud related to failure to file required reports with the Food and Drug Administration concerning oversized morphine sulfate tablets. The executive of the pharmaceutical firm was excluded based on the company's guilty plea. At the time the executive was excluded, he had not been convicted himself, but there was evidence he was involved in misconduct leading to the company's conviction.

ACRONYM	TITLE TEXT
EPLS	Excluded Parties List System
LEIE	List of Excluded Individuals and Entities
HYPERLINK URL	**LINKED TEXT/IMAGE**
https://exclusions.oig.hhs.gov/	https://exclusions.oig.hhs.gov
https://www.sam.gov/	https://www.sam.gov/
http://www.gpo.gov/fdsys/pkg/USCODE-2013-title42/pdf/USCODE-2013-title42-chap7-subchapXI-partA-sec1320a-7.pdf	42 U.S.C. Section 1320a-7
http://www.gpo.gov/fdsys/pkg/CFR-2014-title42-vol5/pdf/CFR-2014-title42-vol5-sec1001-1901.pdf	42 Code of Federal Regulations Section 1001.1901

Health Insurance Portability and Accountability Act

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

HIPAA safeguards help prevent 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 http://www.hhs.gov/ocr/privacy on the Internet.

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.

ACRONYM	TITLE TEXT
HIPAA	Health Insurance Portability and Accountability Act

Lesson 1: Summary

There are differences among FWA. One of the primary differences is intent and knowledge. Fraud requires that the person have intent to obtain payment and the knowledge that their actions are wrong. Waste and abuse may involve obtaining an improper payment but do not require 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;
- Exclusion from participation in all Federal health care programs;
- Imprisonment; or
- Loss of provider license.

Lesson 2: Your Role In The Fight Against FWA

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

- Identify methods of preventing FWA;
- Identify how to report FWA; and
- Recognize how to correct FWA.

ACRONYM	TITLE TEXT
FWA	Fraud, Waste, and Abuse

Lesson 2: Where Do I Fit In?

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

- Sponsor (Medicare Advantage Organization (MAO);
- 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); or
- Related entity (Examples: Entity with common ownership or control of a Sponsor, health promotion provider, or SilverSneakers®).

Lesson 2: Where Do I Fit In?

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 shows examples of functions that relate 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.

Lesson 2: Where Do I Fit In?

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 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: What Are Your Responsibilities?

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

- FIRST, you must comply with all applicable statutory, regulatory, and other Medicare Part C or Part D requirements, including adopting and using an effective compliance program.

- SECOND, you have a duty to the Medicare Program to report any compliance concerns, and suspected or actual violations that you may be aware of.

- 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: How Do You Prevent FWA?

How Do You Prevent FWA?

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

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; and
- Reported issues will be addressed and corrected.

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

ACRONYM	TITLE TEXT
FDRs	First-Tier, Downstream, or Related Entities

Lesson 2: Report FWA

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

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

Every Sponsor must have a mechanism for reporting potential FWA by employees and FDRs. Each Sponsor must accept anonymous reports and cannot retaliate against you for reporting. Review your organization's materials for the ways to report FWA.

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

Lesson 2: Report FWA

Reporting FWA Outside Your Organization

If warranted, Sponsors and FDRs must report potentially fraudulent conduct to Government authorities, such as the Office of Inspector General, the Department of Justice, 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, you should include:

- Contact information for the source of the information, suspects, and witnesses;
- Details of the alleged FWA;
- Identification of the specific Medicare rules allegedly violated; and
- The suspect's history of compliance, education, training, and communication with your organization or other entities.

Lesson 2: Report FWA

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: **https://forms.oig.hhs.gov/hotlineoperations**

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): **https://www.stopmedicarefraud.gov**

ACRONYM	TITLE TEXT
CMS	Centers for Medicare & Medicaid Services

Lesson 2: Correction

Once fraud, waste, or abuse has been detected, it must be promptly corrected. Correcting the problem saves the Government money and ensures you are in compliance with CMS requirements.

Develop a plan to correct the issue. Consult your organization's compliance officer to find out the process for the corrective action plan development. 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; and
- Once started, continuously monitor corrective actions to ensure they are effective.

Lesson 2: Correction

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; or
- Terminating an employee or provider.

ACRONYM	TITLE TEXT
CMS	Centers for Medicare & Medicaid Services

Lesson 2: 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 screens present issues that may be potential FWA. Each page provides questions to ask yourself about different areas, depending on your role as an employee of a Sponsor, pharmacy, or other entity involved in the delivery of Medicare Parts C and D benefits to enrollees.

Lesson 2: Key Indicators

Key Indicators: Potential Beneficiary Issues

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

Lesson 2: Key Indicators

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?
- Is the provider's diagnosis for the member supported in the medical record?

Lesson 2: Key Indicators

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 that brand drugs be dispensed?
- Are PBMs being billed for prescriptions that are not filled or picked up?
- Are proper provisions made if the entire prescription cannot be filled (no additional dispensing fees for split prescriptions)?
- Do you see prescriptions being altered (changing quantities or Dispense As Written)?

ACRONYM	TITLE TEXT
PBM	Pharmacy Benefit Managers

Lesson 2: Key Indicators

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 and then marking up the prices and sending to other smaller wholesalers or pharmacies?

Key Indicators: Potential Manufacturer Issues

- Does the manufacturer promote off-label drug usage?
- Does the manufacturer provide samples, knowing that the samples will be billed to a Federal health care program?

Lesson 2: Key Indicators

Key Indicators: Potential Sponsor Issues

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

Lesson 2 Summary

As a person who provides health or administrative services to a Medicare Parts C or D enrollee, you play a vital role in preventing 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 be able to accept anonymous reports and cannot retaliate against you for reporting.

Promptly correct identified FWA with an effective corrective action plan.

Appendix A: Resources

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 document for your reference.
This WBT course was prepared as a service to the public and is not intended to grant rights or impose obligations. This WBT 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)

Glossary

For the Centers for Medicare & Medicaid Services (CMS) Glossary, visit https://www.cms.gov/apps/glossary on the CMS website.

ACRONYM	TITLE TEXT
CMS	Centers for Medicare & Medicaid Services
WBT	Web-Based Training
MLN	Medicare Learning Network®

Appendix B: Job Aids

Job Aid A: Applicable Laws for Reference

LAW	Available At
Anti-Kickback Statute 42 U.S.C. Section 1320A-7b(b)	http://www.gpo.gov/fdsys/pkg/USCODE-2013-title42/pdf/USCODE-2013-title42-chap7-subchapXI-partA-sec1320a-7b.pdf
Civil False Claims Act 31 U.S.C. Sections 37 9–3733	http://www.gpo.gov/fdsys/pkg/USCODE-2013-title31/pdf/USCODE-2013-title31-subtitleIII-chap37-subchapIII.pdf
Civil Monetary Penalties Law 42 U.S.C. Section 1320a-7a	http://www.gpo.gov/fdsys/pkg/USCODE-2013-title42/pdf/USCODE-2013-title42-chap7-subchapXI-partA-sec1320a-7a.pdf
Criminal False Claims Act 18 U.S.C. Section 287	http://www.gpo.gov/fdsys/pkg/USCODE-2013-title18/pdf/USCODE-2013-title18-partI-chap15-sec287.pdf
Exclusion 42 U.S.C. Section 1320a-7	http://www.gpo.gov/fdsys/pkg/USCODE-2013-title42/pdf/USCODE-2013-title42-chap7-subchapXI-partA-sec1320a-7.pdf
Health Care Fraud Statute 18 U.S.C. Section 1347	http://www.gpo.gov/fdsys/pkg/USCODE-2013-title18/pdf/USCODE-2013-title18-partI-chap63-sec1347.pdf
Physician Self-Referral La 42 U.S.C. Section 1395nn	http://www.gpo.gov/fdsys/pkg/USCODE-2013-title42/pdf/USCODE-2013-title42-chap7-subchapXVIII-partE-sec1395nn.pdf

Appendix B: Job Aids

Job Aid B: Resources

Resources	Website
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
A Roadmap for New Physicians: Avoiding Medicare Fraud and Abuse	https://oig.hhs.gov/compliance/physician-education
Safe Harbor Regulations	https://oig.hhs.gov/compliance/safe-harbor-regulations

Appendix B: Job Aids

Job Aid B: Resources

Resource	Website
Compliance Education Materials: Compliance 101	https://oig.hhs.gov/compliance/101
Health Care Fraud Prevention and Enforcement Action T am 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
Part C and Part D Compliance and Audits - Overview	https://www.cms.gov/medicare/compliance-and-audits/part-c-and-part-d-compliance-and-audits
Physician Self-Referral	https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral
A Roadmap for New Physicians: Avoiding Medicare Fraud and Abuse	https://oig.hhs.gov/compliance/physician-education
Safe Harbor Regulations	https://oig.hhs.gov/compliance/safe-harbor-regulations

Appendix B: Job Aids

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

HHS Office of Inspector General:

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

Fax: 1-800-223-8164

Email: HHSTips@oig.hhs.gov

Online: https://forms.oig.hhs.gov/hotlineoperations 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): https://www.stopmedicarefraud.gov