e-Compliance Training

General Compliance and Fraud, Waste & Abuse - November 2019

THIS TRAINING SESSION IS RECOMMENDED FOR:

All staff members in practices receiving payments from federally funded programs, such as Medicare and Medicaid.

Training Objectives

This training module consists of two parts:

1. Medicare Parts C & D General Compliance Training; and
2. Medicare Parts C & D Fraud, Waste, and Abuse (FWA) Training.

All persons who provide health or administrative services to Medicare enrollees must satisfy general compliance and FWA training requirements. This module may be used to satisfy both requirements.

Medicare Parts C & D General Compliance Training and Fraud, Waste, and Abuse Training

Developed by the Centers for Medicare & Medicaid Services

IMPORTANT NOTICE

This training module consists of two parts: (1) Medicare Parts C & D General Compliance Training and (2) Medicare Parts C & D Fraud, Waste, and Abuse (FWA) Training. All persons who provide health or administrative services to Medicare enrollees must satisfy general compliance and FWA training requirements. This module may be used to satisfy both requirements.

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. Compliance and combating FWA is everyone's responsibility. As an individual who provides health or administrative services for Medicare enrollees, your every action potentially affects Medicare enrollees, the Medicare Program, or the Medicare Trust Fund.

Training Requirements: Plan Employees, Governing Body Members, and First-Tier, Downstream, or Related Entity (FDR) Employees

Certain training requirements apply to people involved in performing or delivering the Medicare Parts C and D benefits. All employees of Medicare Advantage Organizations (MAOs) and Prescription Drug Plans (PDPs) (collectively referred to in this WBT course as "Sponsors") and the entities with which they contract to provide administrative or health care services for enrollees on behalf of the sponsor (referred to as "FDRs") must receive training about compliance with CMS program rules and FWA.

Part I: Medicare Parts C & D General Compliance Training

Introduction and Learning Objectives

This lesson outlines effective compliance programs. Upon completing the lesson, you should be able to correctly:

. Recognize how a compliance program operates; and

- Recognize how compliance program violations should be reported.

Compliance Program Requirement

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

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

What Is an Effective Compliance Program?

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

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

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

For more information, refer to:

- 42 Code of Federal Regulations (CFR) Section 422.503(b)(4)(vi) on the Internet: https://www.gpo.gov/fdsys/pkg/CFR-2014-title42-vol3/pdf/CFR-2014-title42-vol3-sec422-503.pdf
- 42 CFR Section 423.504(b)(4)(vi) on the Internet: https://www.gpo.gov/fdsys/pkg/CFR-2014-title42-vol3/pdf/CFR-2014-title42-vol3-sec423-504.pdf
- "Medicare Managed Care Manual," Chapter 21 on the CMS website: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf
- "Medicare Prescription Drug Benefit Manual," Chapter 9: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf

Seven Core Compliance Program Requirements

CMS requires that an effective compliance program must include seven core requirements:

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

2. *Compliance Officer, Compliance Committee, and High-Level Oversight*
   The Sponsor must designate a compliance officer and a compliance committee that will be accountable and

responsible for the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.

The Sponsor's senior management and governing body must be engaged and exercise reasonable oversight of the Sponsor's compliance program.

3. *Effective Training and Education*
   This covers the elements of the compliance plan as well as prevention, detection, and reporting of FWA. This training and education should be tailored to the different responsibilities and job functions of employees.

4. *Effective Lines of Communication*
   Effective lines of communication must be accessible to all, ensure confidentiality, and provide methods for anonymous and good- faith reporting of compliance issues at Sponsor and FDR levels.

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

6. *Effective System for Routine Monitoring, Auditing, and Identifying Compliance Risks*
   Conduct routine monitoring and auditing of Sponsor's and FDR's operations to evaluate compliance with CMS requirements as well as the overall effectiveness of the compliance program.

   NOTE: Sponsors must ensure that FDRs performing delegated administrative or health care service functions concerning the Sponsor's Medicare Parts C and D program comply with Medicare Program requirements.

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

Compliance Training-Sponsors and their FDRs

CMS expects that all Sponsors will apply their training requirements and "effective lines of communication" to their FDRs. Having "effective lines of communication" means that employees of the Sponsor and the Sponsor's FDRs have several avenues to report compliance concerns.

Ethics–Do the Right Thing!

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

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

How Do You Know What Is Expected of You?

Beyond following the general ethical guidelines on the previous page, how do you know what is expected of you in a specific situation? Standards of Conduct (or Code of Conduct) state compliance expectations and the principles and values by which an organization operates. Contents will vary as Standards of Conduct should be tailored to each

individual organization's culture and business operations. If you are not aware of your organization's standards of conduct, ask your management where they can be located.

Everyone has a responsibility to report violations of Standards of Conduct and suspected non-compliance. An organization's Standards of Conduct and Policies and Procedures should identify this obligation and tell you how to report suspected non-compliance.

What Is Non-Compliance?

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

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

Know the Consequences of Non-Compliance

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

- Contract termination;
- Criminal penalties;
- Exclusion from participation in all Federal health care programs; or
- Civil monetary penalties.

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

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

For more information, refer to the Compliance Program Guidelines in the "Medicare Prescription Drug Benefit Manual" and "Medicare Managed Care Manual" on the CMS website:

https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html

Non-Compliance Affects Everybody

Without programs to prevent, detect, and correct non-compliance, we all risk:

Harm to beneficiaries, such as:

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

Less money for everyone, due to:

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

How to Report Potential Non-Compliance - First-Tier, Downstream, or Related Entity (FDR) Employees

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

Don't Hesitate to Report Non-Compliance - There can be no retaliation against you for reporting suspected non-compliance in good faith.

Each Sponsor must offer reporting methods that are:

- Anonymous;
- Confidential; and
- Non-retaliatory.

What Happens After Non-Compliance Is Detected?

After non-compliance is detected, it must be investigated immediately and promptly corrected. However, internal monitoring should continue to ensure: there is no recurrence of the same non-compliance; ongoing compliance with CMS requirements; efficient and effective internal controls; and enrollees are protected.

What Are Internal Monitoring and Audits?

- Internal monitoring activities are regular reviews that confirm ongoing compliance and ensure that corrective actions are undertaken and effective.
- Internal auditing is a formal review of compliance with a particular set of standards (for example, policies and procedures, laws, and regulations) used as base measures.

Lesson Summary

Organizations must create and maintain compliance programs that, at a minimum, meet the seven core requirements. An effective compliance program fosters a culture of compliance. To help ensure compliance, behave ethically and follow your organization's Standards of Conduct. Watch for common instances of non-compliance, and report suspected non-compliance.

Know the consequences of non-compliance, and help correct any non-compliance with a corrective action plan that includes ongoing monitoring and auditing.

Compliance Is Everyone's Responsibility!

Prevent: Operate within your organization's ethical expectations to prevent non-compliance!

Detect & Report: If you detect potential non- compliance, report it!

Correct: Correct non-compliance to protect beneficiaries and save money!

Lesson Review - Knowledge Check

Now that you have completed the Compliance Program Training lesson, let's do a quick knowledge check. The following questions do not contribute to your overall course score in the Post-Assessment.

1. You discover an unattended email address or fax machine in your office that receives beneficiary appeals requests. You suspect that no one is processing the appeals. What should you do?

   Select the correct answer.

   A. Contact law enforcement
   B. Nothing
   C. Contact your compliance department (via compliance hotline or other mechanism)
   D. Wait to confirm someone is processing the appeals before taking further action
   E. Contact your supervisor

   CORRECT ANSWER: C

2. A sales agent, employed by the Sponsor's First-Tier or Downstream entity, submitted an application for processing and requested two things: 1) to back-date the enrollment date by one month, and 2) to waive all monthly premiums for the beneficiary. What should you do?

   Select the correct answer.

   A. Refuse to change the date or waive the premiums, but decide not to mention the request to a supervisor or the compliance department
   B. Make the requested changes because the sales agent determines the beneficiary's start date and monthly premiums
   C. Tell the sales agent you will take care of it,but then process the application properly (without the requested revisions)–you will not file a report because you don't want the sales agent to retaliate against you
   D. Process the application properly (without the requested revisions)–inform your supervisor and the compliance officer about the sales agent's request
   E. Contact law enforcement and the Centers for Medicare & Medicaid Services (CMS) to report the sales agent's behavior

   CORRECT ANSWER: D

3. You work for a Sponsor. Last month, while reviewing a monthly report from CMS, you identified multiple enrollees for which the Sponsor is being paid, who are not enrolled in the plan. You spoke to your supervisor who said not to worry about it. This month, you have identified the same enrollees on the report again. What should you do?

   Select the correct answer.

   A. Decide not to worry about it as your supervisor instructed – you notified him last month and now it's his responsibility

Interactive Training Reminder

Compliance Training is an interactive training program in which you can address questions with other staff members or supervisors to obtain clarification for situations in your work setting.

Write down any questions that you have about the training topic and address them with your Training Coordinator or supervisor.

B. Although you have seen notices about the Sponsor's non-retaliation policy, you are still nervous about reporting – to be safe, you submit a report through your compliance department's anonymous tip line so you cannot be identified
C. Wait until the next month to see if the same enrollees appear on the report again, figuring it may take a few months for CMS to reconcile its records – if they are, then you will say something to your supervisor again
D. Contact law enforcement and CMS to report the discrepancy
E. Ask your supervisor about the discrepancy again

CORRECT ANSWER: B

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

Select the correct answer.

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

Part II: Combating Medicare Parts C & D Fraud, Waste, And Abuse - Lesson I

Introduction and Learning Objectives

The following lesson describes Fraud, Waste, and Abuse (FWA) and the laws that prohibit it. 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;
- Identify methods of preventing FWA;
- Identify how to report FWA; and
- Recognize how to correct FWA.

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

Waste and Abuse

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":

- https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf; and

Chapter 9 of the "Prescription Drug Benefit Manual":

- https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html

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 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.

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; and
- Unknowingly misusing codes on a claim, such as up-coding or unbundling codes.

Differences Among Fraud, Waste, and Abuse

There are differences among fraud, waste, and abuse. One of the primary differences is intent and knowledge. Fraud requires intent to obtain payment and the knowledge that the actions are wrong. Waste and abuse may involve obtaining an improper payment or creating an unnecessary cost to the Medicare Program, but do not require the same intent and knowledge.

Understanding FWA

To detect FWA, you need to know the law. The following sections provide information about the laws that prohibit FWA:

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.

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. The Civil Monetary Penalty (CMP) may range from $5,500 to $11,000 for each false claim.

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 the 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.

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.

For more information on the Civil False Claims Act, refer to 31 United States Code (U.S.C.) Sections 3729-3733: https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD032207Att2.pdf

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.

Examples:

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 health care fraud.

For more information, refer to 18 U.S.C. Section 1346: https://www.govinfo.gov/app/details/USCODE-2015-title18/USCODE-2015-title18-partI-chap63-sec1346

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; or
- Both.

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: https://www.govinfo.gov/app/details/USCODE-2011-title18/USCODE-2011-title18-partI-chap63-sec1347

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).

Damages and Penalties

Violations are punishable by:

- A fine of up to $25,000;
- Imprisonment for up to 5 years; or
- Both.

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.

For more information, refer to the Social Security Act, Section 1128B(b):
https://www.ssa.gov/OP_Home/ssact/title11/1128B.htm

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).

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.

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.

For more information on Physican Self-Referral Law, refer to:

- http://www.gpo.gov/fdsys/pkg/USCODE-2013-title42/pdf/USCODE-2013-title42-chap7-subchapXVIII-partE-sec1395nn.pdf
- https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html
- https://www.ssa.gov/OP_Home/ssact/title18/1877.htm

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.

Note Regarding Screening for Exclusion:

In 2012, the U.S. General Services Administration merged the Excluded Parties List System (EPLS) into the System for Award Management (SAM). The EPLS no longer exists. In addition, the Office of Inspector General states the following in its "Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs":

"We recommend that providers use the LEIE as the primary source of information about OIG exclusions because the LEIE is maintained by OIG; is updated monthly; and provides more details about persons excluded by OIG than GSA's SAM, such as the statutory basis for the exclusion action, the person's occupation at the time of exclusion, the person's date of birth, and address information."

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.

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.

For more information, refer to the Act, Section 1128A(a): https://www.ssa.gov/OP_Home/ssact/title11/1128A.htm

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.

The United States 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 https://www.sam.gov. If looking for excluded individuals or entities, make sure to check both the LEIE and the EPLS since the lists are not the same.

[See Note in column at left.]

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.

For more information, refer to 42 U.S.C. Section 1320a-7 and 42 Code of Federal Regulations Section 1001.1901 at: https://www.govinfo.gov/app/details/CFR-2007-title42-vol4/CFR-2007-title42-vol4-sec1001-1901

Health Insurance Portability and Accountability Act (HIPAA)

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.

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.

For more information, visit http://www.hhs.gov/ocr/privacy.

FWA - 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.

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

FWA- Lesson 1 Review - Knowledge Check

Now that you have completed Lesson 1, let's do a quick knowledge check.

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

   Select the correct answer.

   A. Fraud
   B. Abuse
   C. Waste

   CORRECT ANSWER: A

2. Which of the following is NOT potentially a penalty for violation of a law or regulation prohibiting Fraud, Waste, and Abuse (FWA)?

   Select the correct answer.

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

   CORRECT ANSWER: B

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.

Part II: Combating Medicare Parts C & D Fraud, Waste, And Abuse - 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. 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.

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;
- 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®).

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.

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.

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.

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;
- Know FWA policies and procedures, standards of conduct, laws, regulations, and CMS' guidance; and
- Verify all information provided to you.

Stay Informed About Policies and Procedures

Familiarize yourself with 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.

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.

Do not be concerned about whether it is fraud, waste, or abuse. Just report any concerns to your compliance department or your Sponsor's compliance department. Your Sponsor's compliance department area will investigate and make the proper determination. Often, Sponsors have a Special Investigations Unit (SIU) dedicated to investigating FWA. They may also maintain an FWA Hotline.

Every Sponsor must have a mechanism for reporting potential FWA by employees and FDRs. Each Sponsor must accept anonymous reports and cannot retaliate against you for reporting. Review your organization's materials for the ways to report FWA. When in doubt, call your Compliance Department or FWA Hotline.

Reporting FWA Outside Your Organization

If warranted, Sponsors and FDRs must report potentially fraudulent conduct to Government authorities, such as the Office of Inspector General, 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;
- Alledged Medicare rules violated; and
- 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: 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

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.

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.

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 lists present issues that may be potential FWA. Each list 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.

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?

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?
- Does the provider's prescription have their active and valid National Provider Identifier on it?

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)?

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?

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?

FWA - 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.

FWA - Lesson 2 Review - Knowledge Check

Now that you have completed Lesson 2, let's do a quick knowledge check.

1. A person comes to your pharmacy to drop 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?

   Select the correct answer.
   - 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

2. 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 verify, through a certain process, that the data is accurate. Your immediate supervisor tells you to ignore the Sponsor's process and to adjust/add risk diagnosis codes for certain individuals. What should you do?

   Select the correct answer.
   - A. Do what your immediate supervisor asked you to do and adjust/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

3. You are in charge of payment of 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?

   Select the correct answer.
   - 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, or other mechanism)
   - C. Reject the claims
   - D. Pay the claims

   CORRECT ANSWER: B

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

   Select the correct answer.
   - 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

This training module is intended to be a general summary. It is not intended to take the place of either the written law or regulations. CMS encourages review of specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.

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

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

Compliance Education Materials: Compliance 101
https://oig.hhs.gov/compliance/101

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

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

LAWS

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 3729–3733
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 Law 42 U.S.C. Section 1395nn
http://www.gpo.gov/fdsys/pkg/USCODE-2013-title42/pdf/USCODE-2013-title42-chap7-subchapXVIII-partE-sec1395nn.pdf

e-Compliance Training Test

General Compliance and Fraud, Waste & Abuse - November 2019

NAME: _____ DATE: _____

SIGNATURE: _____ STAFF POSITION: _____

Return your test to your supervisor or Compliance Coordinator upon completion. Individual tests will be maintained to document participation and understanding of the information. Review the training information to find the correct answers to any questions that may have been missed.

1 The following are all potential penalties for violating fraud, waste, and abuse (FWA) laws: civil monetary penalties, imprisonment, exclusion from Federal healthcare programs.

Select One **T** **F**

2 At a minimum, an effective compliance program includes four core elements.

Select One **T** **F**

3 Any person who knowingly submits false claims to the Government is liable for five times the Government's damages caused by the violator plus a penalty.

Select One **T** **F**

4 Once a corrective action plan is started, the corrective actions must be monitored continuously to ensure they are effective.

Select One **T** **F**

5 Bribes or kickbacks of any kind for services that are paid under a Federal healthcare program constitute fraud by the person making as well as the person receiving them.

Select One **T** **F**

6 Abuse involves payment for items or services when there is no legal entitlement to that payment and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment.

Select One **T** **F**

7 A provider who violates the Civil False Claims Act may have to pay a Civil Monetary Penalty (CMP) of $20,000 for each false claim.

Select One **T** **F**

8 Compliance is the responsibility of the Compliance Officer, Compliance Committee, and Upper Management only.

Select One **T** **F**

9 Waste includes any misuse of resources such as the overuse of services, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare Program.

Select One **T** **F**

10 Some of the laws governing Medicare Parts C and D fraud, waste, and abuse (FWA) include the False Claims Act, the Anti-Kickback Statute, and the Health Care Fraud Statute.

Select One **T** **F**

Click Here to Take Your Quiz