COMBATING MEDICARE PARTS C AND D FRAUD, WASTE, AND ABUSE TRAINING

INNOVATIVE MANAGEMENT SYSTEMS, INC.

ACRONYMS

- The following acronyms are used throughout the course:

ACRONYM	DEFINITION
CFR	Code of Federal Regulations
CMS	Centers for Medicare & Medicaid Services
EPLS	Excluded Parties List System
FCA	False Claims Act
FDRs	First-tier, Downstream, and Related Entities
FWA	Fraud, Waste, and Abuse
HIPAA	Health Insurance Portability and Accountability Act
LEIE	List of Excluded Individuals and Entities
MA	Medicare Advantage
MAC	Medicare Administrative Contractor
MLN	Medicare Learning Network®
NPI	National Provider Identifier
OIG	Office of Inspector General
PBM	Pharmacy Benefits Manager
WBT	Web-Based Training

INTRODUCTION

- The Medicare Learning Network® (MLN) offers free educational materials for health care professionals on the Centers for Medicare & Medicaid Services (CMS) programs, policies, and initiatives. Get quick access to the information you need.
  - Publications & Multimedia
  - Events & Training
  - Newsletters & Social Media
  - Continuing Education

HYPERLINK URL	LINKED TEXT/IMAGE
https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/mln-publications	Publications & Multimedia
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNGenInfo/Events-and-Training.html	Events & Training
https://www.cms.gov/outreach-and-education/outreach/ffsprovpartprog/provider-partnership-email-archive	Newsletters & Social Media
https://www.cms.gov/Medicare/Medicare-Contracting/FFSProvCustSvcGen/CERT-Outreach-and-Education-Task-Force	Continuing Education

- This training assists Medicare Parts C and D plan Sponsors' employees, governing body members, and their first-tier, downstream, and related entities (FDRs) to satisfy their annual fraud, waste, and abuse (FWA) training requirements in the regulations and sub-regulatory guidance at:
  - 42 Code of Federal Regulations (CFR) Section 422.503(b)(4)(vi)(C)
  - 42 CFR Section 423.504(b)(4)(vi)(C)
  - CMS-4182-F Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs
  - Section 50.3.2 of the Compliance Program Guidelines (Chapter 9 of the Medicare Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual)
- Sponsors and their FDRs are responsible for providing additional specialized or refresher training on issues posing FWA risks based on the employee's job function or business setting.

HYPERLINK URL	LINKED TEXT/IMAGE
https://www.ecfr.gov/cgi-bin/text-idx?SID=c66a16ad5319afd0580db00f12c5572&mc=true&node=pt42.3.422&rgn=div5#se42.3.422_1503	42 Code of Federal Regulations (CFR) Section 422.503
https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=5cff780d3df38cc4183f2802223859ba&mc=true&r=PART&n=pt42.3.423	42 CFR Section 423.504
https://www.govinfo.gov/content/pkg/FR-2018-04-16/pdf/2018-07179.pdf	CMS-4182-F Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs
https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf	Chapter 9 of the Medicare Prescription Drug Benefit Manual
https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf	Chapter 21 of the Medicare Managed Care Manual

WHY DO I NEED TRAINING?

- Every year **billions** of dollars are improperly spent because of FWA. It affects everyone—**including you**.
- This training will help you detect, correct, and prevent FWA. **You** are part of the solution.
- Combating FWA is **everyone's** responsibility!
- As an individual who provides health or administrative services for Medicare enrollees, every action you take potentially affects Medicare enrollees, the Medicare Program, or the Medicare Trust Fund.

TRAINING REQUIREMENTS: PLAN EMPLOYEES, GOVERNING BODY MEMBERS, AND FIRST-TIER, DOWNSTREAM, OR RELATED ENTITY (FDR) EMPLOYEES

- Certain training requirements apply to people involved in Medicare Parts C and D.
  - All employees of IMS 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. Please contact the IMS Compliance Department for more information.
- **Learn more about Medicare Part C**
  - Medicare Part C, or Medicare Advantage (MA), is a health insurance option available to Medicare beneficiaries.
  - Private, Medicare-approved insurance companies run MA programs. These companies arrange for, or directly provide, health care services to the beneficiaries who enroll in an MA plan.
  - MA plans must cover all services Medicare covers (with the exception of hospice care). They provide Part A and Part B benefits and may also include prescription drug coverage and other supplemental benefits.
- **Learn more about Medicare Part D**
  - Medicare Part D, the Prescription Drug Benefit, provides prescription drug coverage to Medicare beneficiaries enrolled in Part A and/or Part B who enroll in a Medicare Prescription Drug Plan (PDP) or an MA Prescription Drug (MA-PD) plan.
  - Medicare-approved insurance and other companies provide prescription drug coverage to individuals living in a plan's service area.

NAVIGATING AND COMPLETING THIS COURSE

- Anyone providing health or administrative services to Medicare enrollees must satisfy general compliance and FWA training requirements.
- This course consists of one lesson and a Post-Assessment quiz containing 10 questions.
- Successfully completing the course requires completing the lesson and scoring 70 percent or higher on the Post-Assessment.
- Visit the Resources slide for more information which you may find useful as you proceed through this course.

WHAT IS FWA?

LEARNING OBJECTIVES

- This 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 to prevent FWA
  - Identify how to report FWA
  - Recognize how to correct FWA

FRAUD

- **Fraud** is knowingly submitting, or causing to be submitted, false claims or making misrepresentations of fact to get a federal health care payment when no entitlement would otherwise exist. Knowingly soliciting, getting, offering, or paying remuneration (for example, kickbacks, bribes, or rebates) to induce or reward referrals for items or services reimbursed by federal health care programs. Making prohibited referrals for certain designated health services is another example.
  - Fraud requires intent to get payment and knowledge the actions are wrong.
- The Health Care Fraud Statute makes it a criminal offense to *knowingly and willfully* execute a scheme to defraud a health care benefit program.
  - Health care fraud is punishable by **imprisonment up to 10 years**.
  - It is also subject to **criminal fines up to $250,000**.

FRAUD (CONTINUED)

- The Criminal Health Care Fraud Statute (18 United States Code (USC) 1347) makes it a criminal offense to *knowingly and willfully* execute a scheme to defraud a health care benefit program.
  - Health care fraud is punishable by **imprisonment up to 10 years**.
  - It is also subject to **criminal fines up to $250,000**.
- The statute prohibits knowingly and willfully executing, or attempting to execute, a scheme or lie connected to delivering or paying for health care benefits, items, or services to either:
  - Defraud any health care benefit program
  - Get (by means of false or fraudulent pretenses, representations, or promises) money or property owned by, or get controlled by, any health care benefit program
- Example: Several doctors and medical clinics conspire in a coordinated scheme to defraud the Medicare Program by submitting medically unnecessary power wheelchair claims.
- **Penalties**: Penalties for violating the Criminal Health Care Fraud Statute may include fines, imprisonment, or both.

RED FLAGS – FRAUD

THESE SITUATIONS ARE WARNINGS OR DISCREPANCIES THAT ATTRACT ATTENTION TO POTENTIAL FRAUD AND ABUSE.

ALTHOUGH NOT EVIDENCE OF FRAUD AND ABUSE, A PATTERN OF RED FLAGS CAN INCREASE SUSPICION AND JUSTIFY FURTHER INVESTIGATION.

RED FLAGS CAN BE GENERAL OR SPECIFIC TO A LINE OF BUSINESS AND SHOULD BE REPORTED **IMMEDIATELY**.

- Unusual provider billing practices or suspicious provider activity
  - Altering dates of service
  - Unbundling or upcoding services
  - Offering to waive patient's copayment or coinsurance
- Discrepancy between diagnosis and treatment
- Resubmitting claims and unsupported coding changes (i.e. altering service codes, altering/falsifying diagnosis) to gain payment or change financially responsible party
- Intentional misrepresentation to get higher payment by altering claim forms, medical records, or receipts
- Deliberate provision of unwarranted or non-medically necessary services for financial gain
- Patients questioning services provided
  - Services not rendered
  - Does not know provider
- Modification of the provider of service to a different provider
- Verbal denials – obtaining a denial decision from a physician reviewer by phone and documenting in the case file
  - May lead to fraud as it is processed without physician validation of signature or electronic identifier

WASTE AND ABUSE

- **Waste** describes practices that, directly or indirectly, result in unnecessary costs to the Medicare Program, such as overusing services.
  - Waste is generally not considered to be caused by criminally negligent actions but rather by the misuse of resources.
- **Abuse** describes practices that, directly or indirectly, result in unnecessary costs to the Medicare Program.
  - Abuse includes any practice that doesn't provide patients with medically necessary services or meet professionally recognized standards of care.

For the definitions of fraud, waste, and abuse, refer to Section 20, Chapter 21 of the Medicare Managed Care Manual and Chapter 9 of the Prescription Drug Benefit Manual on the CMS website.

RED FLAGS – ABUSE

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RED FLAGS CAN BE GENERAL OR SPECIFIC TO A LINE OF BUSINESS AND SHOULD BE REPORTED **IMMEDIATELY**.

- Billing for medical services that are:
  - Unnecessary;
  - Inappropriate;
  - Unwarranted; or
  - Questionable/unproven treatments and/or care
- Rendering treatment or care which does not meet professionally recognized standards of care
- Rendering services or supplies which are not medically necessary
  - Medical necessity of a service is the over-arching criterion for payment, in addition to the CPT requirements for reporting the appropriate Evaluation and Management level of service.
- Charging excessively for services or supplies
- Rendering, referring, or recommending treatment/care, tests, services, or supplies which would not have been rendered or utilized in the absence of insurance
- Misusing claim codes, such as upcoding or unbundling codes
- Health plan denies requested specialty care or hospitalizations in order to reduce medical loss ration and maximize profit
- Provider or health plan deliberately and systematically deters member from receiving medically necessary services in order to maximize service funds or capitation revenue

EXAMPLES OF FRAUD, WASTE, AND ABUSE (FWA)

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

- Knowingly billing for services of higher complexity than services actually provided or documented in patient medical records.
- Knowingly billing for services or supplies not provided, including falsifying records to show item delivery.
- Knowingly ordering medically unnecessary patient items or services.
- Paying for federal health care program patient referrals.
- Billing Medicare for appointments patients don't keep.

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

- Conducting excessive office visits or writing excessive prescriptions.
- Prescribing more medications than necessary for treating a specific condition.
- Ordering excessive laboratory tests.

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

- Billing unnecessary medical services.
- Charging excessively for services or supplies.
- Misusing codes on a claim, like upcoding (assigning an inaccurate medical procedure or treatment billing code to increase payment) or unbundling codes.

INAPPROPRIATELY ALTERING/MODIFYING DATA/DOCUMENTS

- Employees are prohibited from inappropriately altering, modifying, or deleting data or documents to comply with regulatory requirements, including turnaround timeframes.
- IMS' systems maintain audit trails in order to capture and track all modifications, revisions, or deletions to data and documents, and these audit trails are monitored to ensure such actions are appropriate.
  - The audit trails track when such modifications or deletions were made, which modifications/deletions occurred, and by whom.
  - The ability to modify, revise, or delete data or documents is also limited based on the employee's roles and responsibilities. IMS' Department Supervisors are responsible for determining which employees are authorized to review, modify, and/or delete information, along with determining which circumstances modification or deletion is appropriate.

DIFFERENCES AMONG FRAUD, WASTE, AND ABUSE

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

UNDERSTANDING FWA

- To detect FWA, you need to know the **law**.
- The following slides provide high-level information about the following laws:
  - Federal Civil False Claims Act (FCA)
  - Criminal Health Care Fraud Statute
  - Anti-Kickback Statute (AKS)
  - Physician Self-Referral Law (Stark Statute)
  - Civil Monetary Penalties Law (CMPL)
  - Exclusion Statute
  - Health Insurance Portability and Accountability Act (HIPAA)

FEDERAL CIVIL FALSE CLAIMS ACT (FCA)

- The civil FCA (31 USC 3729-3733) makes a person liable to pay damages to the Government if they knowingly:
  - Conspire to violate the FCA
  - Carry out other acts to get government property by misrepresentation
  - Conceal or improperly avoid or decrease an obligation to pay the Government
  - Make or use a false record or statement supporting a false claim
  - Present a false claim for payment or approval

- Additionally, under the criminal FCA (18 USC 287), individuals or entities may face criminal penalties, including fines, imprisonment, or both for submitting false, fictitious, or fraudulent claims.
- For more information, refer to 31 United States Code (USC) Sections 3729–3733.

Damages and Penalties

Penalties for violating the civil FCA may include recovery of up to 3 times the amount of the government's damages due to the false claims, plus $11,000 per false claim filed.

CIVIL FALSE CLAIMS ACT: EXAMPLES

A Medicare Part C plan in Florida:

- Hired an outside company to review medical records to find additional diagnosis codes it could submit to increase risk capitation payments from CMS
- Was informed by the outside company that certain diagnosis codes previously submitted to Medicare were undocumented or unsupported
- Failed to report the unsupported diagnosis codes to Medicare
- Agreed to pay $22.6 million to settle FCA allegations

The owner-operator of a medical clinic in California:

- Used marketers to recruit individuals for medically unnecessary office visits
- Promised free, medically unnecessary equipment or free food to entice individuals
- Charged Medicare more than $1.7 million for the scheme
- Was sentenced to 37 months in prison

CIVIL FALSE CLAIMS ACT: EXAMPLES (CONT'D)

- A physician knowingly submits claims for medical services not provided or for a higher level of medical services than actually provided.
- Changing dates, medical records, and/or condition or diagnosis treated (e.g., service is not supported by the patient's medical record.
- Service is miscoded.
- Service is already covered under another claim.

FALSE CLAIMS ACT: CASE STUDY

- Vista Clinical Diagnostics, LLC; Access Dermpath, Inc.; and Advanced Clinical Laboratories, Inc. violated the False Claims Act by submitting claims to Medicare and Medicaid that contained manipulated diagnosis codes:
  - Billed Medicare and Medicaid for clinical laboratory services using diagnosis codes that are generated by a macro and inserted into beneficiaries' reimbursement submissions.
  - The diagnosis codes were generated by the Defendants and not provided by the beneficiaries' physicians.
  - Occurred during the period from January 1, 2017, through December 31, 2021
  - This case was filed by a former employee of Vista Clinical Diagnostics, under the qui tam, or whistleblower, provisions of the False Claims Act
- The three companies have agreed to pay the United States, the State of Florida, the State of North Carolina, and the Commonwealth of Virginia $2.5 million to resolve allegations that they violated the False Claims Act.

CIVIL FCA, CONTINUED

- **Whistleblowers**
  - A whistleblower is a person who exposes information or activity that is deemed illegal, dishonest, or violates professional or clinical standards.
- **Protected:**
  - Persons who report false claims or bring legal actions to recover money paid on false claims are protected from retaliation.
- **Rewarded:**
  - Persons who bring a successful whistleblower lawsuit receive at least 15 percent, but not more than 30 percent, of the money the government collects.

CRIMINAL HEALTH CARE FRAUD STATUTE

- The Criminal Health Care Fraud Statute (18 USC 1346-1349) states:
  - "Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice to defraud any health care benefit program or 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… shall be **fined under this title or imprisoned not more than 10 years, or both**."
- Conviction under the statute does not require proof the violator knew the law or had specific intent to violate it.

EXAMPLES	
A Pennsylvania pharmacist: • Submitted Medicare Part D Claims for non-existent prescriptions and drugs not dispensed. • Pleaded guilty to health care fraud. • Got a 15-month prison sentence and was ordered to pay more than $166,000 in restitution to the plan	The owner of multiple New York Durable Medical Equipment (DME) companies: • Falsely represented themselves as one of a nonprofit health maintenance organization's (that administered a Medicare Advantage plan) authorized vendors. • Didn't provide DME to any patients as claimed. • Submitted almost $1 million in false claims to the nonprofit; $300,000 was paid • Pleaded guilty to one count of conspiracy to commit health care fraud

RED FLAGS – HEALTH CARE FRAUD

RED FLAGS SHOULD BE REPORTED **IMMEDIATELY**.

- Obstructing an investigation or audit by withholding or delaying information or documentation.
- A medical group altering documents to pass an audit by changing dates on a case file to give the appearance of compliance with timeframes.
- A nurse writing a verbal denial for a decision that was not made by the doctor.

CRIMINAL HEALTH CARE FRAUD

- Persons who knowingly make a false claim may be subject to:
  - Criminal fines up to $250,000
  - Imprisonment for up to 20 years
- If the violations resulted in death, the individual may be imprisoned for any term of years or for life.
- For more information, refer to 18 USC Section 1347.

MEDICARE ADVANTAGE FRAUD CASE STUDY

- The Cigna Group Made its Enrollees Appear Sicker to Get More Federal Money
  - Cigna used in-home assessments (HRA)s to report severe conditions without adequate support in underlying medical records.
  - It also had medical coders perform chart reviews to look for additional diagnoses, but lacked adequate support.
  - The government alleged that MAOs operated by Cigna purposefully submitted untruthful diagnoses to increase its payments.
- **The Impact: Financial Consequences and Greater Oversight**
  - Cigna paid the government $172 million dollars to settle the case.
  - HHS-OIG negotiated a 5-year Corporate Integrity Agreement (CIA), increasing Cigna's internal oversight through rigorous internal monitoring & independent review.

HHS-OIG has made oversight and enforcement of managed care a top priority

ANTI-KICKBACK STATUTE

- The Anti-Kickback Statute (AKS) (42 USC 1320a-7b(b)) makes it a crime to knowingly and willfully offer, pay, solicit, or get any remuneration directly or indirectly to induce or reward patient referrals or business generation involving any item or service payable by a federal health care program. When a provider offers, pays, solicits, or gets unlawful remuneration, they violate the AKS.
- The safe harbor regulations (42 CFR 1001.952) describe various payment and business practices that, although they potentially implicate the AKS, aren't treated as AKS offenses if they meet certain regulatory requirements. Individuals and entities remain responsible for complying with all other laws, regulations, and guidance that apply to their businesses.
- **Damages and Penalties**
  - Violations are punishable by:
    - A fine up to **$25,000**
    - Imprisonment **up to 5 years**, or both

ANTI-KICKBACK STATUTE: EXAMPLE

- A physician operating a pain management practice in Rhode Island:
    - Conspired to solicit and get kickbacks for prescribing a highly addictive version of the opioid Fentanyl
    - Reported patients had breakthrough cancer pain to secure insurance payments
    - Got $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 was required to pay more than $750,000 in restitution.

- **EXAMPLE**: A provider receives cash or below-fair-market-value rent for medical office space in exchange for referrals.

FRAUD AND KICKBACK OFFENSES: CASE STUDY

- A Licensed Professional Counselor (LPC) with a psychotherapy services practice in Pennsylvania:
  - Notified through Medicaid audit that he had received over $225,000 in payments from Medicaid for services that he had not documented.
  - Medicaid told the LPC that they would begin to collect the overpayment by deducting the overpayment in installments from future payments Medicaid would make to him.
  - Upon learning the collection of overpayments, the LPC began submitting fraudulent claims to Medicaid for psychotherapy services that he never provided.
  - The LPC also engaged in a scheme to pay kickbacks to his Medicaid patients in order to induce them to receive psychotherapy services from him.
  - The kickbacks to patients were in the form of cash payments, money orders, and Wal-Mart and VISA gift cards.
  - The LPC pleaded guilty to one count of health care fraud and one count of violating the federal anti-kickback statute.
- The judge ordered the LPC to pay restitution of $695,048 to Medicaid. The LPC was sentenced to three years of probation, with the first year of which he must serve in home confinement under electronic monitoring, for health care fraud and kickback offenses.

PHYSICIAN SELF-REFERRAL LAW (STARK LAW)

- The Physician Self-Referral Law (42 USC 1395nn), often called the Stark Law, prohibits a physician from referring a patient to get designated health services from a provider with whom a physician or physician's immediate family member has a financial relationship, unless an exception applies.
- Designated health services:
  - Clinical lab services
  - Physical therapy, occupational therapy, and outpatient speech-language pathology services
  - Radiology and other imaging services
  - DME and supplies
  - Parenteral and enteral nutrients, equipment, and supplies
  - Prosthetics, orthotics, and supplies
  - Home health services
  - Outpatient prescription drugs
  - Inpatient and outpatient hospital services

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.

PHYSICIAN SELF-REFERRAL LAW (STARK LAW)

- **Damages and Penalties**
  - Medicare claims tainted by an arrangement that does not comply with the Stark Statute are **not payable**.
  - A penalty of approximately **$15,000** can be imposed for each service provided.
  - There may also be a fine over **$100,000** for entering into an unlawful arrangement or scheme.

- For more information, visit the Physician Self-Referral webpage and refer to the Act, Section 1877.

CIVIL MONETARY PENALTIES LAW (CMPL)

- The Civil Monetary Penalties Law (CMPL) (42 USC 1320a-7a) authorizes the Office of Inspector General (OIG) to seek Civil Monetary Penalties (CMPs) and sometimes exclusions for a variety of health care fraud violations. Violations that may justify CMPs include:
  - Arranging for an excluded individual's or entity's services or items
  - Failing to grant OIG timely records access
  - Filing a claim you know or should know is for an item or service that wasn't provided as claimed or is false or fraudulent
  - Filing a claim you know or should know is for an item or service for which we won't make payment
  - Violating the AKS
  - Violating Medicare assignment provisions
  - Violating the Medicare physician agreement
  - Providing false or misleading information expected to influence a discharge decision
  - Failing to provide an adequate medical screening exam for patients who present to a hospital emergency department with an emergency medical condition or in labor
  - Making false statements or misrepresentations on applications or contracts to participate in federal health care programs

CIVIL MONETARY PENALTIES LAW (CMPL)

- **Example:** A California pharmacy and its owner agreed to pay over $1.3 million to settle allegations they submitted unsubstantiated Medicare Part D claims for brand name prescription drugs the pharmacy couldn’t have dispensed based on inventory records.

- **Damages and Penalties**
  - Penalties and assessments vary based on the type of violation.
  - Penalties can be approximately $10,000 to $50,000 per violation.
  - CMPs may also include an assessment of up to 3 times the amount claimed for each item or service, or up to 3 times the amount of remuneration offered, paid, solicited, or received.

EXCLUSION STATUTE

- The Exclusion Statute (42 USC 1320a-7) requires the OIG exclude individuals and entities convicted of these offenses from participating in all federal health care programs:
  - Medicare or Medicaid fraud, as well as other offenses related to delivering Medicare or Medicaid items or services
  - Patient abuse or neglect
  - Felony convictions for other health care-related fraud, theft, or other financial misconduct
  - Felony convictions for unlawful manufacture, distribution, prescribing, or dispensing controlled substances
- The OIG also maintains the List of Excluded Individuals and Entities (LEIE) website.
- The U.S. General Services Administration (GSA) administers the Excluded Parties List System (EPLS), which enables various federal agencies, including the OIG, to take debarment actions.
- When looking for excluded individuals or entities, check both the LEIE and the EPLS since the lists are not the same. For more information, refer to 42 USC Section 1320a-7 and 42 Code of Federal Regulations (CFR) Section 1001.1901.

EXAMPLE

A pharmaceutical company pleaded guilty to two felony counts of criminal fraud related to failure to file required reports with the U.S. Food and Drug Administration concerning oversized morphine sulfate tablets. The pharmaceutical firm executive was excluded based on the company's guilty plea. At the time the unconvicted executive was excluded, there was evidence he was involved in misconduct leading to the company's conviction.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

- HIPAA created greater access to health care insurance, strengthened health care data privacy protection, and promoted standardization and efficiency in the health care industry.
- HIPAA safeguards deter unauthorized access to protected health care information. As someone with access to protected health care information, you must comply with HIPAA.
- For more information, visit the HIPAA webpage.

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.

- **Damages and Penalties**
  - Violations may result in Civil Monetary Penalties.
  - In some cases, criminal penalties may apply.

SUMMARY

- There are differences among fraud, waste, and abuse (FWA). One of the primary differences is **intent** and **knowledge**.
  - Fraud is knowingly submitting, or causing to be submitted, false claims or making misrepresentations of fact to get a federal health care payment for which no entitlement would otherwise exist.
  - Waste and abuse may involve getting an improper payment but not the same intent and knowledge.
- Laws and regulations exist that prohibit FWA. Penalties for violating these laws may include:
  - Civil Monetary Penalties
  - Civil prosecution
  - Criminal conviction, fines, or both
  - Exclusion from all Federal health care program participation
  - Imprisonment
  - Loss of professional license

YOUR ROLE IN THE FIGHT AGAINST FWA

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 correctly:
  - Identify methods of preventing FWA
  - Identify how to report FWA
  - Recognize how to correct FWA

WHERE DO I FIT IN?

- As someone who provides health or administrative services to a Medicare Part C or Part D enrollee, you are likely an employee of a:
  - Sponsor (Medicare Advantage Organization [MAO] or a Prescription Drug Plan [PDP])
  - First-tier entity
    - Examples: Pharmacy Benefit Management [PBM]; hospital or health care facility; provider group; doctor's office; clinical laboratory; customer service provider; claims processing and adjudication company; a company that handles enrollment, disenrollment, and membership functions; and contracted sales agents
  - Downstream entity
    - Examples: pharmacies, doctor's office, firms providing agent/broker services, marketing firms, and call centers
  - Related entity
    - Examples: Entity with common ownership or control of a Sponsor, health promotion provider, or SilverSneakers®

WHERE DO I FIT IN?

I am an employee of a Part C and/or D Plan Sponsor or an employee of a Part C and/or D Plan Sponsor's first-tier or downstream entity (FDR).

- A Part C and/or D Plan Sponsor is a CMS Contractor. Part C Plan Sponsors may enter into contracts with FDRs.
- First-tier and related entities of the Medicare Part C and/or D 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, PBMs, 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.
    - If the first-tier entity is a PBM, then the pharmacy, marketing firm, quality assurance firm, and claims processing firm could be downstream entities.
- Downstream entities may contract with other downstream entities.
  - Hospitals and mental health facilities may contract with providers.

WHAT ARE YOUR RESPONSIBILITIES?

- You play an important role in preventing, detecting, and reporting potential FWA, as well as Medicare noncompliance.
  - **FIRST**, you must comply with all applicable statutory, regulatory, and other Medicare Part C or Part D requirements, including adopting and using an effective compliance program.
  - **SECOND**, you have a duty to the Medicare Program to report any compliance concerns and suspected or actual violations you may know.
  - **THIRD**, you have a duty to follow IMS' Code of Conduct that describes IMS and your commitment to standards of conduct and ethical rules of behavior.

HOW DO YOU PREVENT FWA?

Look for suspicious activity

Conduct yourself ethically

Ensure accurate and timely data and billing

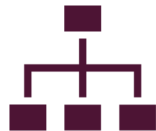
Ensure coordination with other payers

Know FWA policies and procedures, standards of conduct, laws, regulations, and CMS' guidance

Verify all information you get

STAY INFORMED ABOUT POLICIES AND PROCEDURES

Know IMS' policies and procedures.



Every Sponsor and First-Tier, Downstream, and Related Entity (FDR) must have FWA policies and procedures.

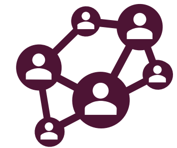
These procedures should help you detect, prevent, report, and correct FWA.

The IMS Code of Conduct describes IMS' expectations that:

- All employees conduct themselves ethnically

- Appropriate mechanisms are in place for anyone to report noncompliance and potential FWA

- Reported issues will be addressed and corrected



The IMS Code of Conduct communicates to employees and FDRs that compliance is everyone's responsibility, from the top of the organization to the bottom.

BEST PRACTICES FOR PREVENTING FRAUD AND ABUSE

- Establishing effective lines of communication to report fraud and abuse.
- Monitoring claims for accuracy, including ensuring coding reflects services provided.
- Monitoring medical records, including ensuring documentation supports services rendered.
- Instituting system safeguards.
- Performing regular internal department/operational audits and monitoring activities.
- Effective education of physicians, providers, suppliers, and members.

REPORTING FWA

- Everyone must report suspected FWA.
  - IMS' Code of Conduct clearly states this obligation and IMS may not retaliate against you for making a good faith effort in reporting.
- Report any potential FWA concerns you have to the IMS Compliance Department.
  - IMS also maintains a hotline that accepts anonymous reports.
  - IMS' Compliance Department will investigate and make the proper determination.
- IMS has mechanisms for reporting potential FWA by employees and FDRs.
  - IMS also accepts anonymous reports and cannot retaliate against you for reporting.
  - When in doubt, call IMS' Compliance Department or FWA hotline.
- When a serious non-compliance or Fraud, Waste, & Abuse issue occurs, the matter will be referred to the Health Plan within (7) days of discovery, as plans are required to report all delegate FWA issues to the I-MEDIC via the CMS FWA Portal.

WHERE TO REPORT FWA INSIDE THE ORGANIZATION

Any reports of possible non-compliance or fraud can be submitted to the Innovative Management Systems' Compliance Department in the following ways:

- **Email**: Compliance@imsmso.com
- **Phone Hotline**: 1-855-222-1025
  - This hotline is available 24 hours a day, 7 days a week
  - Reports can be made **anonymously**
- **Web Portal**: www.lighthouse-services.com/imsmso
  - You can file a report on the web portal **anonymously**
- **Fax**: 1-323-832-8141
- **In-Person**: Reports may be made in person to the IMS Compliance Officer, Renee Kimm

- IMS' non-retaliation policy states that there will be **NO RETALIATION** against you for reporting suspected non-compliance in good faith.

REPORTING FWA OUTSIDE THE ORGANIZATION

- If warranted, Sponsors and FDRs must report potentially fraudulent conduct to Government authorities, such as the Office of Inspector General (OIG), the U.S. Department of Justice (DOJ), or CMS.
  - Individuals or entities who wish to voluntarily disclose self-discovered potential fraud to OIG may do so under the Self-Disclosure Protocol (SDP).
  - Self-disclosure gives providers the opportunity to avoid the costs and disruptions associated with a Government-directed investigation and civil or administrative litigation.
- **Details to Include When Reporting FWA**
  - When reporting suspected FWA, include:
    - Contact information for the information source, suspects, and witnesses
    - Alleged FWA details
    - Alleged Medicare rules violated
    - The suspect's history of compliance, education, training, and communication with the organization or other entities

WHERE TO REPORT FWA OUTSIDE THE ORGANIZATION

- 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
  - **Online**: OIG.HHS.gov/report-fraud
  - **Mail**: U.S. Department of Health and Human Services Office of Inspector General
    - Attn: OIG Hotline Operations, P.O. Box 23489, Washington, DC 20026
- For Medicare Parts C and D:
  - Investigations Medicare Drug Integrity Contractor (I MEDIC) at 1-877-7SafeRx (1-877-772-3379)
- For all other Federal health care programs:
  - CMS Hotline at 1-800-MEDICARE (1-800-633-4227) or TTY 1-877-486-2048
- Medicare beneficiary website:
  - https://www.medicare.gov/

CORRECTIVE ACTION

- Once fraud, waste, or abuse is detected, promptly correct it.
  - Correcting the problem saves the Government money and ensures your compliance with CMS requirements.
- Develop a plan to correct the issue.
- Ask the IMS Compliance Department how to develop a corrective action plan. The actual plan varies depending on circumstances. In general:
  - Design the corrective action to fix the underlying problem that results in FWA violations and prevents future noncompliance.
  - Tailor the corrective action to address the particular FWA problem or identified deficiency. Include timeframes for specific actions.
  - Document corrective actions addressing noncompliance or FWA committed by an employee or FDR's employee and include consequences for failing to satisfactorily complete the corrective action.
  - Monitor corrective actions continuously to ensure effectiveness.

CORRECTIVE ACTION EXAMPLES

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

POTENTIAL FWA INDICATORS

- 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 slides present potential FWA issues.
- Each slide provides questions to ask yourself about different areas, depending on your role as an employee of a Sponsor, pharmacy, or other entity involved in delivering Medicare Parts C and D benefits to enrollees.

KEY INDICATORS: POTENTIAL PATIENT ISSUES

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

KEY INDICATORS: POTENTIAL PROVIDER ISSUES

- Are the provider's prescriptions appropriate for the patient'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?
- Does the provider perform medically unnecessary patient services?
- Does the provider prescribe a higher quantity than medically necessary for the condition?
- Does the provider's prescription include their active and valid National Provider Identifier?
- Is the provider's patient diagnosis supported in the medical record?

KEY INDICATORS: POTENTIAL PHARMACY ISSUES

- Are drugs being diverted (drugs meant for nursing homes, hospice, and other entities being sent somewhere else)?
- Are dispensed drugs expired, fake, diluted, or illegal?
- Are generic drugs provided when the prescription requires dispensing brand drugs?
- Are PBMs billed for unfilled or never picked up prescriptions?
- Are proper provisions made if the entire prescription is not filled (no additional dispensing fees for split prescriptions)?
- Do you see prescriptions being altered (changing quantities or Dispense As Written)?
- Are Eligible Facilitations Services (E1s) and their information being used for purposes other than determining patient eligibility?

KEY INDICATORS: POTENTIAL WHOLESALER ISSUES

- Is the wholesaler distributing fake, diluted, expired, or illegally imported drugs?
- Is the wholesaler diverting drugs meant for nursing homes, hospices, and Acquired Immune Deficiency Syndrome (AIDS) clinics, marking up the prices, and sending to other smaller wholesalers or pharmacies?

KEY INDICATORS: POTENTIAL MANUFACTURER ISSUES

- Does the manufacturer promote off-label drug use?
- Does the manufacturer knowingly provide samples to entities that bill Federal health care programs for them?

KEY INDICATORS: POTENTIAL SPONSOR ISSUES

- Does the Sponsor encourage or support submitting inappropriate risk adjustments?
- Does the Sponsor lead the patient to believe the benefits cost a certain price, when the actual cost is higher?
- Does the Sponsor offer patients cash incentives to join the plan?
- Does the Sponsor use unlicensed agents?

SUMMARY

- As someone providing health or administrative services to a Medicare Part C or D enrollee, you play an important part in preventing fraud, waste, and abuse (FWA).
- Conduct yourself ethically, stay informed of your organization's policies and procedures, and keep an eye out for key indicators of potential FWA.
- Report potential FWA.
  - IMS has mechanisms for reporting potential FWA.
  - IMS accepts anonymous reports and cannot retaliate against you for reporting.
- Promptly correct identified FWA with an effective corrective action plan.

RESOURCES

URL	SOURCE
https://www.cms.gov/glossary	CMS Glossary
https://www.govinfo.gov/content/pkg/USCODE-2017-title42/pdf/USCODE-2017-title42-chap7-subchapXI-partA-sec1320a-7b.pdf	Anti-Kickback Statute 42 USC Section 1320a-7b(b)
https://www.govinfo.gov/content/pkg/USCODE-2017-title31/pdf/USCODE-2017-title31-subtitleIII-chap37-subchapIII.pdf	Civil False Claims Act 31 USC Sections 3729–3733
https://www.govinfo.gov/content/pkg/USCODE-2017-title42/pdf/USCODE-2017-title42-chap7-subchapXI-partA-sec1320a-7a.pdf	Civil Monetary Penalties Law 42 USC Section 1320a-7a
https://www.govinfo.gov/content/pkg/USCODE-2017-title18/pdf/USCODE-2017-title18-partI-chap15-sec287.pdf	Criminal False Claims Act 18 USC Section 287
https://www.govinfo.gov/content/pkg/USCODE-2017-title42/pdf/USCODE-2017-title42-chap7-subchapXI-partA-sec1320a-7.pdf	Exclusion 42 USC Section 1320a-7
https://www.govinfo.gov/content/pkg/USCODE-2017-title18/pdf/USCODE-2017-title18-partI-chap63-sec1347.pdf	Criminal Health Care Fraud Statute 18 USC Section 1347
https://www.govinfo.gov/content/pkg/USCODE-2017-title42/pdf/USCODE-2017-title42-chap7-subchapXVIII-partE-sec1395nn.pdf	Physician Self-Referral Law 42 USC Section 1395nn

RESOURCES

URL	SOURCE
https://oig.hhs.gov/compliance/provider-compliance-training/	Health Care Fraud Prevention and Enforcement Action Team Provider Compliance Training
https://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf	OIG's Provider Self-Disclosure Protocol
https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral	Physician Self-Referral
https://oig.hhs.gov/compliance/physician-education/roadmap_web_version.pdf	Avoiding Medicare Fraud & Abuse: A Roadmap for Physicians
https://oig.hhs.gov/compliance/safe-harbor-regulations/	Safe Harbor Regulations

QUESTIONS OR CONCERNS?

If you have any questions or concerns, please contact IMS' Compliance Department:

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- **Phone Hotline**: 1-855-222-1025
- **Fax**: 1-323-832-8141