Medicare General Compliance and Fraud, Waste & Abuse

Prepared by Amplifon Hearing Health Care

amplifon

About this Course

After completing this course, you will be able to:

- Recognize how a compliance program operates,
- Report compliance program violations,
- Define Fraud, Waste, and Abuse (FWA) in the Medicare program,
- Follow the major laws and regulations pertaining to FWA,
- Understand potential consequences and penalties associated with FWA violations.

The Need for Training

Compliance

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 must:

- Articulate and demonstrate an organization’s commitment to legal and ethical conduct.
- Provide guidance on how to handle compliance questions and concerns.
- Provide guidance on how to identify compliance violations and clear lines of communication for reporting non-compliance.
- Prevent, detect, and correct non-compliance.
- Fully implement and tailor to organization's unique operations and circumstances.
- Have adequate resources.
- Promote the organization's Standards of Conduct.

7 Requirements of all Compliance Programs

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 & Oversight

The Sponsor must designate a Compliance Officer and a Compliance Committee 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 preventing, detecting, and reporting FWA. Training should be tailored to be applicable to different employees and their responsibilities/job functions.

7 Requirements of all Compliance Programs

4

Effective Lines of Communication

Make effective lines of communication accessible to all, ensure confidentiality, and provide methods for anonymous and good-faith compliance issues reporting at Sponsor and first-tier, downstream, or related entity (FDR) levels.

5

Well-Publicized Disciplinary Standards

The 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 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.

Amplifon's Code of Ethics

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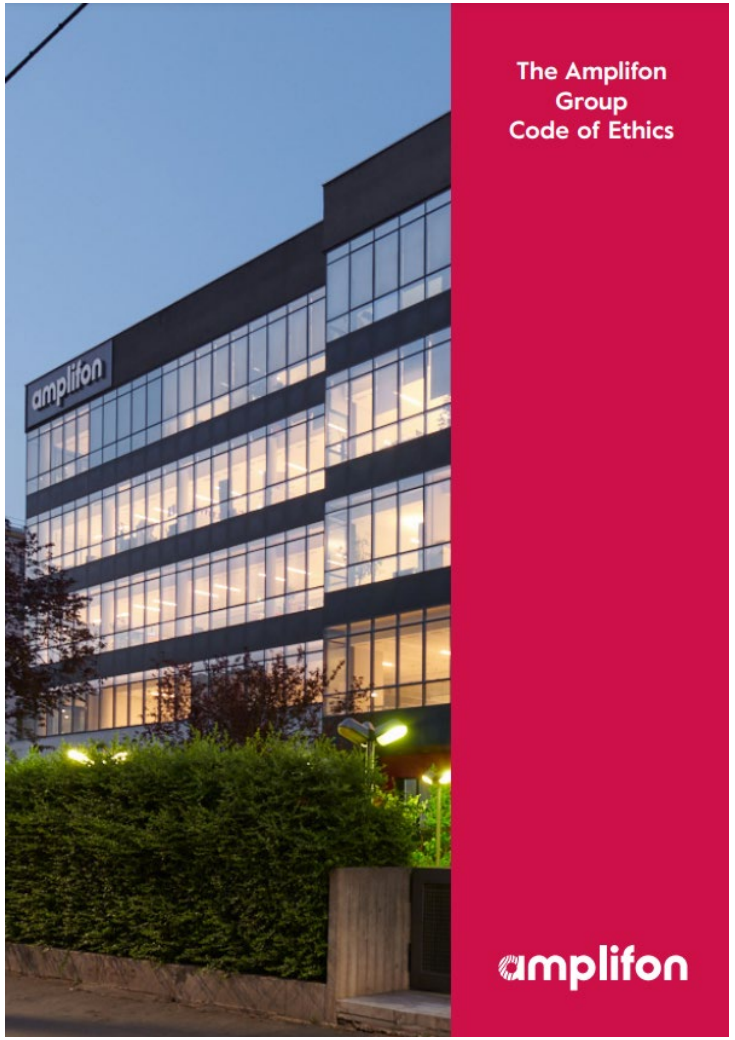
As part of the Medicare Program, you must conduct yourself in an ethical and legal manner. It's about doing the right thing!

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

To know what is expected of you in a specific situation, the Code of Ethics states the organization's compliance expectations and their operational principles and values. The Code sets expectations around business conduct, human resources, and relationships with external partners (suppliers or third parties).

Amplifon representatives are expected to read and understand the Code of Ethics, linked to the right.



Non-Compliance

What is Non-Compliace?

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 identified the following Medicare Parts C and D high risk areas:

- Agent/broker misrepresentation
- Appeals/grievance review
- Beneficiary notices
- Conflicts of interest
- Claims processing
- Credentialing and provider networks
- Documentation & timeliness requirements
- Ethics
- FDR oversight and monitoring
- Health insurance Portability & Accountability Act (HIPAA)
- Marketing & enrollment
- Pharmacy, formulary, and benefit administration
- Quality of care

Failure to follow Medicare Program requirements and CMS guidance can lead to serious consequences, including contract termination, criminal penalties, and exclusion from participating in all Federal health care programs. Amplifon may also require mandatory training or re-training, disciplinary action, or termination to those who engage in non-compliant behavior.

Reporting Non-Compliance

As you can tell, we take compliance seriously at Amplifon. If you realize that an action you have taken may be a violation or concern, you should report directly to the Compliance department. Use the Compliance Hotline number **1-800-234-9314**. They will provide instructions and next steps.

Whistleblowing (reporting others)

The Whistleblowing policy was created to govern suspected or known breaches or violations that Amplifon employees (or third parties) become aware of, that they did not cause themselves. A Whistleblowing report should be filed when you know or suspect:

- Breaches of the Amplifon Code of Ethics,
- Breaches of the laws applicable to Amplifon including (but not limited to) anti-corruption laws,
- Breaches of laws, regulations, or measures enforced by American/Canadian Authorities,
- Breaches of internal policies and procedures, specifically policies concern conflict of interest and anti-corruption.

How to Report

All Amplifon employees and affiliates should feel free to report any questions or concerns regarding security or compliance to any member of: **Management**, **HR**, **Legal**, or **Compliance**.

- **Phone**: Anonymous unless you choose to share your name.
  - Inside the office: Ext. 4103
  - Outside the office: 1-800-234-9314 or 763-268-4103.
- **Email**: compliancedept@amplifon.com. Will be kept confidential, but the Compliance Department will see who the email is from.

Link to Group Whistleblowing Policy

True or False?

If you realize that an action **you** have taken may be a violation or concern, you should follow the Whistleblowing steps to report yourself.

See next page for answer.

False!

The Whistleblowing policy is used to **report others** that may be breaching or violating laws, regulations, policies, procedures, or the Code of Ethics. If you realize that an action **you** have taken may be a violation or concern, report it directly to the Compliance department.

The Need for FWA Training

Every year billions of dollars are improperly spent because of Fraud, Waste, and Abuse (FWA). It affects everyone - including you!

This training will help you detect, correct, and prevent FWA. You are a part of the solution!

Training Requirements

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.

Certain training requirements apply to people in Medicare Parts C* and D. These people must receive training for preventing, detecting, and correcting FWA:

- All employees of Medicare Advantage Organizations (MAOs)
- Anyone who is a downstream entity of a MAO
- Employees of Prescription Drug Plans (PDPs), aka "Sponsors".

Training must be completed within 90 days of initial hire, and at least annually thereafter.

Medicare Part C

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

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

Fraud, Waste, and Abuse Defined

Definitions

Fraud: Intentionally submitting false information to the Government or a Government contractor to get money or a benefit

Waste: Over-utilization of services, resulting in unnecessary cost to the Medicare Program

Abuse: Actions that may directly or indirectly result in unnecessary cost to the Medicare Program

What's the Difference?

Fraud is the ***intent*** to obtain payment with the knowledge that the actions taken 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 for up to 10 years and is also subject to criminal fines of up to $250,000.

Waste and Abuse is the act of obtaining improper payment ***without*** knowing actions were wrong or having intent to do wrong. **Waste** is generally not caused by criminally negligent actions, but rather by the misuse of resources. **Abuse** involves paying for items or services when there is no legal entitlement to that payment, and the provider has not knowingly or intentionally misrepresented facts to obtain payment.

FWA Laws

FWA Laws

In order to detect FWA, you need to know the law. These next sections will provide high-level information about the following laws:

- Civil False Claims Act (FCA)
- Health Care Fraud Statute
- Criminal Health Care Fraud
- Anti-Kickback Statute
- Stark Statute (Physician Self-Referral Law)
- Civil Monetary Penalties (CMP) Law
- Exclusion From All Federal Health Care Programs

Civil False Claims Act (FCA)

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

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

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.

FCA Example #1

A Medicare Plan 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.

They were informed that certain diagnosis codes previously submitted to Medicare were undocumented or unsupported. They failed to report the unsupported diagnosis codes to Medicare.

They agreed to pay $22.6 million to settle the FCA allegations.

FCA Example #2

The owner-operator of a medical clinic in California used marketers to recruit individuals for medically unnecessary office visits. They promised free, medically unnecessary testing or free food to entice individuals.

They charged Medicare more than $1.7 million for the scheme. The owner-operator was sentenced to 37 months in prison.

Health Care Fraud Statute

Health Care Fraud Statute

The Health Care Fraud Statue states; "Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice to defraud any health care benefit program ... shall be fined under this title or imprisoned not more than 10 years, or both."

Conviction under the statute does not require proof the violator had knowledge of the law or specific intent to violate the law.

Health Care Fraud Statute Examples

Example #1

A Pennsylvania pharmacist submitted claims to a Medicare Part D plan for non-existent prescriptions and drugs not dispensed.

The pharmacist pleaded guilty to health care fraud. They received a 15-month prison sentence and was ordered to pay more than $166,000 in restitution to the plan.

Example #2

The owner of multiple Durable Medical Equipment (DME) companies in New York falsely represented themselves as one of a non-profit health maintenance organization's (that administered a Medicare Advantage plan) authorized vendors.

They provided no DME to any beneficiaries as they claimed. They submitted almost $1 million in false claims to the nonprofit; $300,000 was paid.

They pleaded guilty to one count of conspiracy to commit health care fraud.

Criminal Health Care Fraud

Persons who knowingly make a false claim may be subject to criminal fines up to $250,000 and/or 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.

Anti-Kickback Statute

Anti-Kickback Statute

The Anti-Kickback Statute prohibits knowingly and willfully soliciting, receiving, offering, or paying remuneration (including any kickback, bribe, or rebate) for referrals for services that are paid, in whole or in part, under a Federal health care program (including the Medicare Program).

Violations are punishable by a fine up to $25,000 and/or imprisonment up to 5 years.

Anti-Kickback 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. The physician reported that patients had breakthrough cancer pain to secure insurance payments, and received $188,000 in speaker fee kickbacks from the drug manufacturer.

The physician 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.

Stark Statute (Physician Self-Referral)

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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 agreement.

Medicare claims tainted by an arrangement that does not comply with the Stark Statute are not payable. A penalty of around $24,250 can be imposed for each service provided. There may also be around $161,00 fine for entering into unlawful arrangements or schemes.

Stark Statute 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.

Civil Monetary Penalties (CMP) Law

Civil Monetary Penalties (CMP) Law

The Office of Inspector General (OIG) may impose civil penalties for several reasons, including:

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

The penalties can be around $15,000 to $70,000 depending on the specific violation. Violators are also subject to three times the amount claimed for each service or item, or, three times the amount of remuneration offers, paid, solicited, or received.

CMP Example

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

Exclusion

Exclusion

No Federal health care program payment may be made for any item or service furnished, ordered, or prescribed by an individual or entity excluded by the OIG. The OIG has authority to exclude individuals and entities from federally funded health care programs and maintains the List of Excluded Individuals and Entities (LEIE).

The U.S. General Services Administration (GSA) administers the Excluded Parties List System (EPLS), which contains debarment actions taken by various Federal agencies, including the OIG. You may access the EPLS on the System for Award Management (SAM) website.

Exclusion 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.

Your Responsibilities

Your Responsibilities

You play a vital role in preventing, detecting, and reporting FWA, as well as Medicare noncompliance.

1. First, you must comply with all applicable statutory, regulatory, and other Medicare requirements, including adopting and using an effective compliance program.
2. Second, you have a duty to the Medicare Program to report any compliance concerns and suspected or actual violations of which you may be aware.
3. 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?

- Report suspicious activity
- Conduct yourself in an ethical manner
- Ensure accurate and timely data and billing
- Know and follow your entity's policies and procedures
- Know FWA laws, policies, procedures, standards of conduct, laws, regulations, and CMS guidelines
- Verify all received information

Stay Informed

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

Standards of Conduct

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

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

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

Correction

Correction

Once fraud, waste, or abuse is detected, promptly correct it. Correcting the problem saves the Government money and ensures your compliance with CMS requirements. Develop a plan to correct the issue. Ask your organization's Compliance Officer about the development process for the corrective action plan. The actual plan is going to vary, depending on the specific circumstances, but in general:

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

Corrective Action Examples

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

Indicators of Potential FWA

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

If you spot something like the issues outlined in this section, please alert the Compliance team and/or your supervisor.

Potential Provider Issues

(meaning anyone providing services)

Key Indicators

- Are the provider's prescriptions appropriate (medically necessary) for the member's hearing health condition?
- Does the provider bill for services not provided?
- Is the provider properly documenting all services billed?
- Is the provider performing medically unnecessary services for the member?
- Is the provider prescribing a higher quantity than medically necessary for the condition?
- Does the provider's prescription/order have their active and valid National Provider Identifier on it?
- Is the provider's diagnosis for the member supported in the medical record?

Potential Wholesaler Issues

Key Indicators

- 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?

Potential Manufacturer Issues

Key Indicators

- Does the manufacturer follow the applicable Federal and state laws for hearing aids?
- Does the manufacturer appropriately follow safety, quality, and labeling requirements?

Potential Sponsor/Plan Issues

Key Indicators

- Does the Sponsor/Plan lead the beneficiary to believe the cost of benefits is one price, when the actual cost is higher?
- Does the Sponsor/Plan offer beneficiaries cash inducements to join the plan?
- Does the Sponsor/Plan use unlicensed agents?

Additional Resources

Additional Resources

For additional information and training on Medicare Compliance and/or Fraud, Waste & Abuse, we encourage you to bookmark and explore the following links:

Medicare Learning Network (MLN), including the MLN Matters Articles. MLN is home for education, information, and resources for the health care professional community.

CMS National Training Program. The Centers for Medicare & Medicaid (CMS) National Training Program provides materials and training opportunities to help you better understand and educate others about Medicare, Medicaid, and the Federally-facilitated Health Insurance Marketplace.

Congratulations!

As a person providing health or administrative services to a Medicare Part C or D enrollee, you play a vital role in preventing fraud, waste, and abuse (FWA). Conduct yourself ethically, stay informed of your organization's policies and procedures, and keep an eye out for key indicators of potential FWA.

You have successfully completed this Medicare General Compliance and Fraud, Waste, and Abuse course! Make sure to enter in the date and everyone who completed the training in the CMS General Compliance and Fraud, Waste, and Abuse Training Log