

The Center for Medicare and Medicaid Services (CMS) requires Sponsors to implement and maintain an effective compliance program for its Medicare Part C and Part D plans. A "Sponsor" is an organization that has a contract with the federal government to offer Medicare Advantage plans and/or prescription drug plans.

An effective 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 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, noncompliance
- Is fully implemented and is tailored to an organization's unique operations and circumstances
- Has adequate resources
- Promotes the organization's Standards of Conduct
- Established clear lines of communication for reporting non-compliance

An effective compliance program is essential to prevent, detect, and correct Medicare noncompliance as well as fraud, waste and abuse (FWA). It must, at a minimum, include the seven core compliance requirements.

Seven Core Compliance Program Requirements

CMS Requires an effective compliance program to include seven core requirements:

1. Written Policies and Procedures, and Standards of Conduct

These articulate the Sponsor's commitment to comply with all 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 compliance committee accountable and responsible for the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.
- 3. Effective Training and Education This covers the elements of the compliance plan as well as preventing, detecting and reporting fraud, waste and abuse (FWA). Tailor this training and education to the different employees and their responsibilities and job functions.
- 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 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 designated 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 all Sponsors will apply their training requirements and "effective lines of communication" to their FDRs. Having "effective lines of communication" means employees of the Sponsor and the Sponsors FDRs have several avenues to report compliance concerns.

Ethics: Do the Right Thing

As a part of the Medicare Program, you must conduct your 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 suspicious violations

How Do You Know What Is Expected of You?

The <u>Code of Conduct</u>, found on Cone Connects, Tools and Resources, Audit and Compliance Services, states the organization's compliance expectation and operational principles, culture and business operations.

Reporting Code of Conduct violations and suspected non-compliance is **everyone's** responsibility.

An organization's Code of Conduct and Policies and Procedures should identify the obligation and tell you how to report.

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 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 interests
- Claims processing
- Credentialing and provider networks
- Documentation and Timeliness Requirements
- Ethics
- FDER oversight and monitoring
- Health Insurance Portability and Accountability Act (HIPAA)
- Marketing and enrollment
- Pharmacy, formulary, and benefit administration
- 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
- Civil monetary penalties

Additionally, disciplinary standards for noncompliant behavior are required. Those who engage in non-compliant behavior may be subject to any of the following

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

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
- High premiums
- Lower benefits to individuals and employees
- Lower Star ratings
- Lower profits

How to Report Potential Non-Compliance

Employees of a Sponsor

- Call the Medicare Compliance Officer
- Make a report through your organization's website
- Call the Compliance Hotline

First-Tier, Downstream or Related Entity (FDR) Employees

- Talk to a Manager or Supervisor
- Call the Compliance and Privacy Helpline at 1-855-809-3042 or report online at www.conehealth.ethicspoint.com

Do Not Hesitate to Report Non-Compliance

When you report suspected non-compliance in good faith, the Employer cannot retaliate against you.

Each employer must offer reporting methods that are:

- Anonymous
- Confidential
- Non-retaliatory

What Happens If Non-Compliance is Detected?

Non-compliance must be investigated immediately and corrected promptly.

Internal monitoring should ensure.

- No recurrence of the same non-compliance
- Ongoing CMS requirements compliance
- Efficient and effective internal controls

• Protected enrolls

Compliance Is Everyone's Responsibility!

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

Detect & Report: Report detected potential non-compliance!

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

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

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.

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

In other words, fraud is intentionally submitting false information to the Government or a Government contractor to get money or a benefit. The Health Care Fraud Statute makes it a criminal offense to knowingly and willfully execute a scheme to defraud a health care benefit program. Health care fraud is punishable by imprisonment up to 10 years. It is also subject to criminal fines up to \$250,000.

Waste and Abuse

Waste includes practices that, directly or indirectly, result in unnecessary costs to the Medicare

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Program, such as overusing services. Waste is generally not considered to be caused by criminally negligent actions but rather by the misuse of resources.

Abuse includes actions that may, directly or indirectly, result in unnecessary costs to the Medicare Program. Abuse involves paying for items or services when there is no legal entitlement to that payment, and the provider has not knowingly or intentionally misrepresented facts to obtain payment.

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

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

Examples of FWA

Examples of actions that may constitute Medicare fraud include:

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

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

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

Examples of actions that may constitute Medicare abuse include:

- Unknowingly billing for unnecessary medical services
- Unknowingly billing for brand name drugs when generics are dispensed
- Unknowingly excessively charging for services or supplies
- Unknowingly misusing codes on a claim, such as upcoding or unbundling codes

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 Fraud, Waste and Abuse

To detect FWA, you need to know the law.

The following pages provide high-level information about the following laws:

- Civil False Claims Act, Health Care Fraud Statute, and Criminal Fraud
- Anti-Kickback Statute
- Stark Statute (Physician Self-Referral Law)
- Exclusion from all Federal health care programs
- Health Insurance Portability and Accountability Act (HIPAA)

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

Civil False Claims Act

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

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- 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

For more information, refer to <u>31 United States Code</u> (USC) Sections 3729-3733

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

Health Care Fraud Statute

The Health Care Fraud Statute 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. For more information, refer to <u>18 USC Sections 1346-1347</u>

Stark Statute (Physician Self-Referral Law)

The Stark Statute prohibits a physician from making referrals for certain designated health services to an entity when the physician (or a member of his or her family) has:

An ownership/investment interest or

A compensation arrangement

Exceptions may apply. For more information, refer to 42 USC Section 1395nn

Damages and Penalties

Medicare claims tainted by an arrangement that does not comply with the Stark Statute are not payable. A penalty of around **\$24,250** can be imposed for each service provided. There may also be around a **\$161,000** fine for entering into an unlawful arrangement or scheme.

For more information, visit the Physician Self-Referral webpage and refer to the Act, Section 1877. <u>Physician Self-Referral</u> and <u>The Act,</u> <u>Section 1877</u>

Civil Monetary Penalties (CMP) Law

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

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

For more information, refer to 42 USC 1320a-7a and the Act, 1128A(a).

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.

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 <u>42 USC</u> <u>Section 1320a-7</u> and <u>42 Code of Federal Regulations (CFR) Section 1001.1901</u>

Health Insurance Portability and Accountability Act (HIPAA)

HIPAA created greater access to health care insurance, strengthened the protection of privacy of health care data, and promoted standardization and efficiency in the health care industry.

HIPAA safeguards deter unauthorized access to protected health care information. As an individual with access to protected health care information, you must comply with HIPAA.

For more information, visit the HIPAA webpage. https://www.hhs.gov/hipaa/index.html

Damages and Penalties

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

Medicare Advantage Training documents can be found on Cone Connects Audit and Compliance Services: <u>Medicare Advantage Training</u> **or** <u>https://www.conehealth.com/about-us/complianceand-integrity/</u>

References

Center for Medicare and Medicaid Services. <u>Medicare Parts C and D General Compliance</u> <u>Training Web Based Training Course.</u> <u>https://www.cms.gov/Outreach-and-</u> <u>Education/Medicare-Learning-Network-</u> <u>MLN/MLNProducts/Downloads/MedCandDGenCo</u> mpdownload.pdf 2019.

Center for Medicare and Medicaid Services. <u>Combating Medicare Parts C and D Fraud, Waste</u> <u>and Abuse Web-Based Training Course</u>. <u>https://www.cms.gov/Outreach-and-</u> <u>Education/Medicare-Learning-Network-</u> <u>MLN/MLNProducts/Downloads/CombMedCandDF</u> <u>WAdownload.pdf</u> 2019.

These training materials adhere to the CMS Medicare Learning Network training materials on "Medicare Parts C and D General Compliance. Training and Combating Parts C and D Fraud, Waste and Abuse Training"