

Medicare Parts C and D General Compliance Training



August 2025

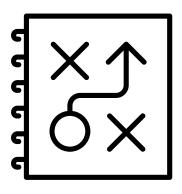
Compliance Program Training



Training

Completing training is indeed a critical component of an effective compliance program, but it is not sufficient on its own. An effective compliance program requires a comprehensive approach that includes several key elements beyond just training.

Our **FDRs** are responsible for establishing and executing an effective compliance program according to the **CMS** regulations and program guidelines.





Acronyms

Acronym	Term
CFR	Code of Federal Regulations
CMS	Centers for Medicare & Medicaid Services
FDR	First-Tier, Downstream, Related Entity
FWA	Fraud, Waste, Abuse
HHS	U.S. Department of Health & Human Services
MA	Medicare Advantage
MAO	Medicare Advantage Organization
MAPD	MA Prescription Drug
MLN	Medicare Learning Network®
OIG	Office of Inspector General
PDP	Prescription Drug Plan



CMS regulations and compliance program guidelines

Medicare Parts C and D Plan Sponsors, along with their first-tier, downstream, and related entities (FDRs), must comply with general compliance training requirements as outlined in the following regulations and sub-regulatory guidance:

- 42 Code of Federal Regulations (CFR) Section 422.503(b)(4)(vi)(C): This regulation specifies the compliance program
 requirements for Medicare Advantage (Part C) plans, including the need for training and education for employees and FDRs.
- <u>42 CFR Section 423.504(b)(4)(vi)(C):</u> Similar to the above, this regulation addresses the compliance program requirements for Medicare Prescription Drug Plans (Part D), emphasizing the importance of training.
- CMS Compliance Program Guidelines (<u>Chapter 9 of the Medicare Prescription Drug Benefit Manual</u> and <u>Chapter 21 of the Medicare Managed Care Manual</u>), Section 50.3.
- CMS Compliance Program Policy and Guidance webpage, downloads section.



Every year, billions of dollars are lost to fraud, waste, and abuse (FWA), impacting us all—including you.

Join us in the fight against FWA with our **training program** designed to help you **detect**, **correct**, **and prevent** these issues. Your participation is crucial; you are a **vital part of the solution**!

Remember, **compliance** is a shared responsibility! As someone who provides **health or administrative services** for **Medicare enrollees**, every action you take has the potential to influence the well-being of Medicare enrollees, the integrity of the **Medicare Program**, and the sustainability of the **Medicare Trust Fund**.

Together, we can make a difference!

Why do I need training?



Training requirements

Certain training requirements apply to those involved in Medicare Parts C and D. All employees of Medicare Advantage
Organizations (MAOs) and Prescription Drug
Plans (PDPs) (collectively referred to as "Sponsors" in this course) must complete training on compliance with CMS program rules.

As part of your commitment, you may need to complete **FWA training** within **90 days** of your initial hire. For more information on other **Medicare Parts C and D compliance trainings** and answers to common questions, please visit the **CMS website**.

Together, we can ensure compliance and protect the integrity of the Medicare program!





Plan types



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.



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.



Compliance program requirement

The Centers for Medicare & Medicaid Services (CMS) requires that all sponsors implement and maintain an effective compliance program for their Medicare Part C & Part D plans. As our First-Tier, Downstream, or Related Entity (FDR), we require this of you. An effective compliance program must:

- Articulate and demonstrate the organization's commitment to legal and ethical conduct.
- Provide clear guidance on how to handle compliance questions and concerns.
- Offer direction 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 tailored to the organization's **unique operations and circumstances**.
- Has adequate resources to support compliance efforts.
- Promotes the organization's Standards of Conduct.
- Establishes clear lines of communication for reporting noncompliance.

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**.





Seven core elements

•Articulate a commitment to adhere to all applicable Federal and State requirements while clearly defining compliance expectations in alignment with the organization's Standards of Conduct.

Written Policies, Procedures, and Standards of Conduct



- Designate a compliance officer and compliance committee responsible for the program.
- •Senior management / Governing body must be engaged and exercise reasonable oversight.

Compliance Officer, Compliance Committee, & High-Level Oversight



•Covers elements of compliance plan as well as preventing, detecting, and reporting FWA. Tailored to roles and responsibilities, as needed.

Effective Training & Education



 Accessible to all, ensure confidentiality and provide different methods for anonymous good faith reporting at all levels, including for FDR(s).

Effective Lines of Communication



- Enforce Standards through well-published disciplinary guidelines.
- Perform OIG and GSA SAM Sanction Screening.

Well-Publicized Disciplinary Standards



- •Risk Assessment.
- Routine monitoring and auditing of operations, including FDRs, to evaluate risks.

Routine Monitoring & Auditing and Identifying Compliance Risks



•Measures to address noncompliance, identify root cause, and implement appropriate corrective actions to prevent recurrence.

Prompt Response for Compliance Issues





As part of the Medicare Program, you must conduct yourself ethically and legally—it's about doing the right thing!

- Act fairly
- Uphold high ethical standards in all actions
- Comply with all applicable laws, regulations, and CMS requirements
- Report suspected violations



Now that you have reviewed the general ethical guidelines on the previous page, how can you determine what is expected of you in specific situations?

- Standards of Conduct (or Code of Conduct) outline the organization's compliance expectations, operational principles, and core values. These standards may vary between organizations, so it is essential to tailor the content and delivery methods to align with your organization's unique culture and business operations.
 - It is everyone's responsibility to report violations of the Standards of Conduct and any suspected non-compliance.
 - The organization's Standards of Conduct, along with its Policies and Procedures, should clearly define this obligation and provide guidance on how to report any suspected non-compliance.



Do you know what is expected of you?

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:



For more information, refer to the <u>Compliance Program Guidelines in the</u> <u>Medicare Prescription Drug Benefit Manual and Medicare Managed Care Manual.</u>



Know the Consequences of Non-Compliance

Failure to adhere to Medicare Program requirements and CMS guidance can result in significant consequences, including but not limited to:

- Contract termination
- Criminal penalties
- Exclusion from participating in Federal health care programs
- Civil monetary penalties

Your organization must have disciplinary standards for non-compliant behavior. Individuals who engage in non-compliant actions may face any of the following:

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





Without effective programs to prevent, detect, and correct noncompliance, we all face significant risks, including:

Harm to Beneficiaries

- Delayed services
- Denial of benefits
- Difficulty accessing preferred providers
- Other barriers to care

Financial Consequences

- Increased insurance copayments
- Higher premiums
- Reduced benefits for individuals and employers
- Lower Star ratings
- Decreased profits

It is crucial that we prioritize compliance to safeguard the well-being of our beneficiaries. By implementing robust compliance programs, we can mitigate these risks and promote a more effective and equitable healthcare system.

Non-Compliance affects everybody



Don't hesitate to report potential non-compliance

There are several ways to report suspected or detected non-compliance or potential Fraud, Waste, and Abuse (FWA). CVS Health prohibits retaliation for raising concerns in good faith or cooperating in an investigation

First Tier, Downstream, Or Related Entity (FDR):

- Talk to your manager or supervisor
- Call your Ethics/Compliance Health Line
- Report to CVS Health through one of the methods provided below:

Need to report ethics and compliance concerns to CVS Health? No problem.

You can connect with us 24 hours a day, 7 days a week, 365 days a year.

Visit



CVS Health® Ethics Line <u>1-877-CVS-2040 (TTY: 711)</u> (<u>1-877-287-2040</u>)



CVS Health Online Ethics Line CVSHealth.com/EthicsLine



Chief Compliance Officer CVS Health One CVS Drive Woonsocket, RI 02895



What happens after non-compliance is detected?

Non-compliance must be investigated immediately and corrected promptly.

Internal monitoring should focus on the following key areas:

- 1. Prevention of Reoccurrence: Implement measures to ensure that the same non-compliance issues do not happen again.
- 2. Ongoing Compliance with CMS Requirements: Regularly review and update practices to ensure continued adherence to all Centers for Medicare & Medicaid Services (CMS) requirements.
- 3. Efficient and Effective Internal Controls: Establish and maintain robust internal controls that facilitate compliance and mitigate risks associated with non-compliance.
- **4. Protection of Enrollees:** Ensure that the rights and well-being of enrollees are safeguarded throughout the compliance process.





What are internal monitoring and auditing



Internal Monitoring

Ongoing process aimed at ensuring compliance with laws, regulations, and internal policies. It focuses on the day-to-day operations of the organization to identify and address compliance issues as they arise.



Internal Auditing

A periodic, formal, independent evaluation of operations, controls, and compliance with policies and regulations. It aims to provide assurance that risk management, control, and governance processes are functioning effectively.



Our FDRs must establish and maintain compliance programs that meet the seven core requirements to foster a culture of compliance.

- **Prevent:** Operate within ethical expectations to prevent non-compliance.
- Detect & Report: Identify and report potential noncompliance issues.
- Correct: Address non-compliance to protect beneficiaries

Adhere to your organization's Standards of Conduct. Monitor for and report instances of non-compliance.

Understand the consequences of non-compliance. Incorporate ongoing monitoring and auditing in corrective action plans to ensure compliance.

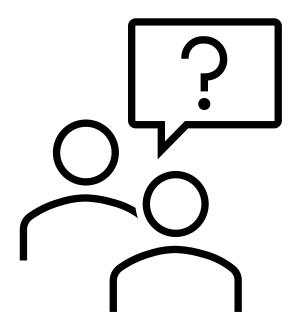
Compliance is everyone's responsibility!



Knowledge Check

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

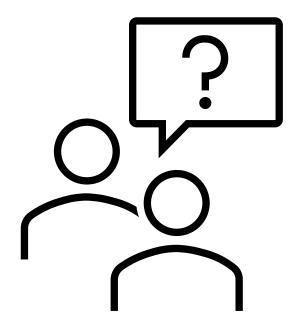
- Contact Law Enforcement
- B. Nothing
- C. Contact your Compliance department (via compliance hotline or other mechanism)
- D. Wait to confirm someone is processing the appeals before taking further action.
- E. Contact your supervisor.





A sales agent, employed by the Sponsor's first tier, downstream, or related entity (FDR), 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?

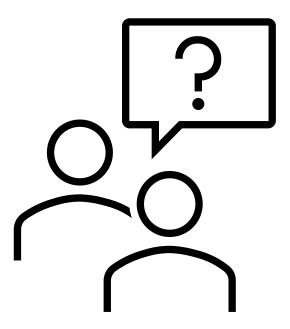
- A. Refuse to change the date or waive the premiums but decide not to mention the request to a supervisor or the compliance department.
- B. Make the requested changed because the sales agent determines the beneficiary start date and monthly premiums.
- C. Tell the sales agent you will take care of it but then process the application properly (without the requested revisions) you will not a 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 compliance officer about the sales agent's request.
- E. Contact law enforcement and CMS to report the sales agent's behavior





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

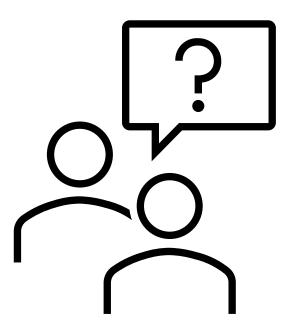
- A. True
- B. False





Ways to report a compliance issue include:

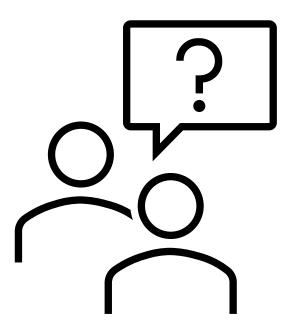
- A. Telephone Hotline
- B. Report on the Sponsor's website
- C. In-Person reporting to the compliance department/supervisor
- D. All of the above





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

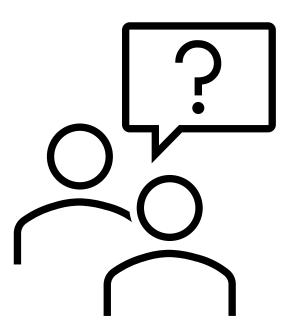
- A. Call local law enforcement
- B. Perform another review
- C. Contact your compliance department (via compliance hotline or other mechanism)
- D. Discuss your concerns with your supervisor
- E. Follow your pharmacy's procedures





What is a policy of non-retaliation?

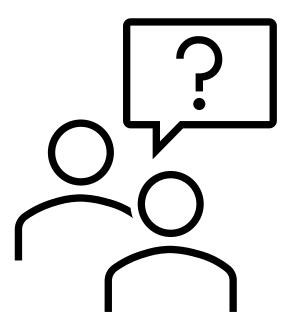
- A. Allows the Sponsor to discipline employees who violate the Code of Conduct
- B. Prohibits management and supervisor from harassing employees for misconduct
- Protects employees, who in good faith, report suspected non-compliance
- D. Prevents fights between employees





An FDR of a Medicare Parts C and D plan sponsor are not required to have a compliance program.

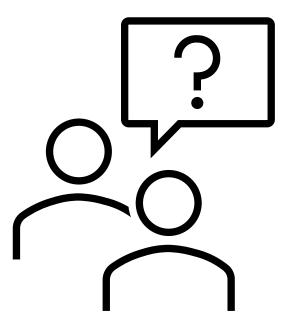
- A. True
- B. False





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

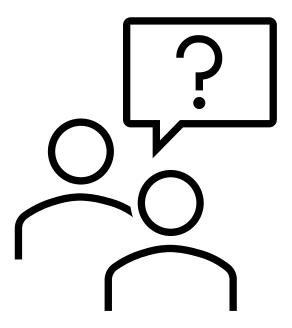
- A. True
- B. False





What are the consequences for non-compliance, fraudulent, or unethical behavior?

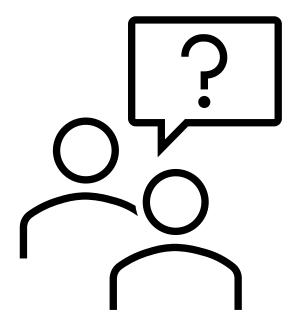
- A. Disciplinary action
- B. Termination of employment
- Exclusion from participating in all Federal health care programs
- D. All of the above





What is the primary purpose of monitoring and auditing within a compliance program?

- A. To create new policies and procedures
- B. To identify and address potential compliance issues before they escalate
- C. To conduct employee performance reviews
- D. To evaluate the financial performance of the organization





Knowledge Check Answers

- 1. C: Contact your Compliance department (via compliance hotline or other mechanism)
- 2. D: Process the application properly (without the requested revisions) inform your supervisor and compliance officer about the sales agent's request.
- 3. B: False
- 4. D: All of the above
- 5. E: Follow your pharmacy's procedures
- 6. C: Protects employees, who in good faith, report suspected non-compliance
- 7. B: False
- 8. B: False
- 9. D: All of the above
- 10. B: To identify and address potential compliance issues before they escalate



Resources



Job Aid: Seven Core Compliance Program Requirements

The Centers for Medicare & Medicaid Services (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 to 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 fraud, waste, and abuse (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 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 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.



Job Aid: Resources

- Office of Inspector General (OIG) Compliance Education Materials
- OIG Provider Self-Disclosure Protocol
- OIG Avoiding Medicare Fraud & Abuse: A Roadmap for Physicians
- OIG Health Care Fraud Prevention and Enforcement Action Team (HEAT) Provider Compliance Training
- OIG Safe Harbor Regulations
- CMS Part C and Part D Compliance and Audits Overview
- CMS Physician Self-Referral



Medicare Learning Network®

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.

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