

Medicare Parts C and D General Compliance Training

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Introduction

This course was current at the time it was published. Medicare policy changes frequently so links to the source documents have been provided within the course for your reference.

This course was prepared as a service to the public and is not intended to grant rights or impose obligations. This course may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.

Completing this training satisfies the Medicare Parts C and D plan Sponsors annual general compliance training requirements in the regulations and sub-regulatory guidance at:

- 42 Code of Federal Regulations (CFR) Section 422.503(b)(4)(vi);
- 42.CFR Section 423.504(b)(4)(vi);
- Section 50.3 of the Compliance Program Guidelines (Chapter 9 of the “Medicare Prescription Drug Benefit Manual” and Chapter 21 of the “Medicare Managed Care Manual”); and
- June 17, 2015, Health Plan Management System (HPMS) memo: Update – Reducing the Burden of the Compliance Program Training Requirements. (Keep up-to-date with the most recent memos on the [CMS Compliance Program Policy and Guidance](#) website.)

While Sponsors are required to complete this training or use this module’s downloaded content to satisfy compliance training requirements, completing this training in and of itself does not ensure that a Sponsor has an “effective compliance program.” Sponsors are responsible for establishing and executing an effective compliance program according to the Centers for Medicare & Medicaid Services (CMS) regulations and program guidelines.

HYPERLINK URL/JAVASCRIPT	LINKED TEXT/IMAGE
https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ComplianceProgramPolicyandGuidance.html	CMS Compliance Program Policy and Guidance

Why Do I Need Training?

Every year **billions** of dollars are improperly spent because of Fraud, Waste, and Abuse (FWA). It affects everyone – **including you**. This training helps you detect, correct, and prevent FWA. **You** are part of the solution. Compliance is everyone's responsibility. As an individual who provides health or administrative services for Medicare enrollees, your every action potentially affects Medicare enrollees, the Medicare Program, or the Medicare Trust Fund.

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

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

General Compliance training must occur within 90 days of initial hire and at least annually thereafter.

Where Do I Fit in the Medicare Program?

Medicare Advantage Organization, Prescription Drug Plan, and Medicare Advantage Prescription Drug Plan

First Tier: Independent Practice Associations, Call Centers, Health Services/Hospital Groups, Fulfillment Vendors, Field marketing Organizations, Credentialing, PBM

Downstream: Providers, Radiology, Hospitals, Mental Health, Agents, Pharmacy, Quality Assurance Firm, Claims Processing Firm

Course Content:

This course consists of General Compliance program training and a post review assessment. Anyone who provides health or administrative services to Medicare enrollees must satisfy General Compliance and FWA training requirements. Reviewing this course will satisfy the CMS General Compliance training requirements.

Course Objectives:

When you complete this course, you should be able to correctly:

- Recognize how a compliance program operates; and
- Recognize how compliance program violations should be reported.

Compliance Program Requirement:

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

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

What Is an Effective Compliance Program?

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

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

For more information, refer to:

- [42 Code of Federal Regulations \(CFR\) Section 422.503\(b\)\(4\)\(vi\)](#) on the Internet;
- [42 CFR Section 423.504\(b\)\(4\)\(vi\)](#) on the Internet;
- ["Medicare Managed Care Manual," Chapter 21](#) on the CMS website; and
- ["Medicare Prescription Drug Benefit Manual," Chapter 9](#) on the CMS website.

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.

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

Seven Core Compliance Program Requirements

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

- 1. Written Policies, Procedures, and Standards of Conduct:** These articulate the Sponsor's commitment to comply with all applicable Federal and State standards and describe compliance expectations according to the Standards of Conduct.
- 2. Compliance Officer, Compliance Committee, and High-Level Oversight:** The Sponsor must designate a compliance officer and a compliance committee that will be accountable and responsible for the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program. The Sponsor's senior management and governing body must be engaged and exercise reasonable oversight of the Sponsor's compliance program.
- 3. Effective Training and Education:** This covers the elements of the compliance plan as well as prevention, detection, and reporting of FWA. This training and education should be tailored to the different responsibilities and job functions of employees.
- 4. Effective Lines of Communication:** Effective lines of communication must be accessible to all, ensure confidentiality, and provide methods for anonymous and good-faith reporting of compliance issues at Sponsor and 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 that FDRs performing delegated administrative or health care service functions concerning the Sponsor's Medicare Parts C and D program comply with Medicare Program requirements.
- 7. Procedures and System for Prompt Response to Compliance Issues** The Sponsor must use effective measures to respond promptly to non-compliance and undertake appropriate corrective action.

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

Ethics–Do the Right Thing!

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

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

How Do You Know What Is Expected of You?

Beyond following the general ethical guidelines on the previous page, how do you know what is expected of you in a specific situation? Standards of Conduct (or Code of Conduct) state compliance expectations and the principles and values by which an organization operates. Contents will vary as Standards of Conduct should be tailored to each individual organization's culture and business operations. If you are not aware of your organization's standards of conduct, ask your management where they can be located.

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

What Is Non-Compliance?

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

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

Know the Consequences of Non-Compliance

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

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

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

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

NON-COMPLIANCE AFFECTS EVERYBODY!

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

- Harm to beneficiaries, such as:
- Delayed services
- Denial of benefits
- Difficulty in using providers of choice
- Other hurdles to care

Less money for everyone, due to:

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

Don't Hesitate to Report Non-Compliance

There can be no retaliation against you for reporting suspected non-compliance in good faith. Each sponsor must offer reporting methods that are:

- Anonymous
- Confidential; and
- Non-retaliatory

How to Report Potential Non-Compliance - Employees of a Sponsor

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

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

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

Beneficiaries

- Call the Sponsor's Compliance Hotline or Customer Service;
- Make a report through the Sponsor's website; or
- Call 1-800-Medicare

What Happens After Non-Compliance Is Detected?

After non-compliance is detected, it must be investigated immediately and promptly corrected. However, internal monitoring should continue to ensure:

- There is no recurrence of the same non-compliance;
- Ongoing compliance with CMS requirements;
- Efficient and effective internal controls; and
- Enrollees are protected.

What Are Internal Monitoring and Audits?

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

Lesson Summary:

Organizations must create and maintain compliance programs that, at a minimum, meet the seven core requirements. An effective compliance program fosters a culture of compliance.

To help ensure compliance, behave ethically and follow your organization's Standards of Conduct. Watch for common instances of non-compliance, and report suspected non-compliance.

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

Compliance is Everyone's Responsibility!

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

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

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

Monitor: *Regular reviews to confirm ongoing compliance and ensure corrective action is undertaken.*

Audit: *Formal review of compliance with a particular set of standards.*

Lesson Review:

Now that you have completed the Compliance Program Training review, let's do a quick knowledge check.

Knowledge Check #1:

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

Select the correct answer.

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

Answer: C

Knowledge Check #2:

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

Select the correct answer.

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

Answer: D

Knowledge Check #3:

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

Select the correct answer.

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

Answer: B

Knowledge Check #4:

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

Select the correct answer.

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

Answer: E

Additional Resources

For more information on laws governing the Medicare program and Medicare noncompliance or for additional healthcare compliance resources please see:

- Title XVIII of the Social Security Act
- Medicare Regulations governing Parts C and D (42 C.F.R. §§ 422 and 423)
- Civil False Claims Act (31 U.S.C. §§ 3729-3733)
- Criminal False Claims Statute (18 U.S.C. §§ 287,1001)
- Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))
- Stark Statute (Physician Self-Referral Law) (42 U.S.C. § 1395nn)
- Exclusion entities instruction (42 U.S.C. § 1395w-27(g)(1)(G))
- The Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Public Law 104-191) (45 CFR Part 160 and Part 164, Subparts A and E)
- OIG Compliance Program Guidance for the Healthcare Industry:
<http://oig.hhs.gov/compliance/compliance-guidance/index.asp>

Resources Resource	Website
Compliance Education Materials: Compliance 101	https://oig.hhs.gov/compliance/101
Health Care Fraud Prevention and Enforcement Action Team Provider Compliance Training	https://oig.hhs.gov/compliance/provider-compliance-training
OIG's Provider Self-Disclosure Protocol	https://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf
Part C and Part D Compliance and Audits - Overview	https://www.cms.gov/medicare/compliance-and-audits/part-c-and-part-d-compliance-and-audits
Physician Self-Referral	https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral
A Roadmap for New Physicians: Avoiding Medicare Fraud and Abuse	https://oig.hhs.gov/compliance/physician-education
Safe Harbor Regulations	https://oig.hhs.gov/compliance/safe-harbor-regulations

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The MLN is home for education, information, and resources for the health care professional community. The MLN provides access to the CMS Program information you need, when you need it, so you can focus more on providing care to your patients.

Serving as the umbrella for a variety of CMS education and communication activities, the MLN offers:

1. [MLN Educational Products](#), including [MLN Matters® Articles](#);
2. [WBT Courses](#) (many offer Continuing Education credits);
3. [MLN Connects® National Provider Calls](#);
4. [MLN Connects® Provider Association Partnerships](#);
5. [MLN Connects® Provider eNews](#); and
6. [Provider Electronic Mailing Lists](#).

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https://learner.mlnlms.com	WBT Courses
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