Health System One | Health Network One | Therapy Network | Eye Management

2021 CMS General Compliance

Introduction

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 general compliance 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)
- 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)
- The "Downloads" section of the CMS Compliance Program Policy and Guidance webpage

Completing this training in and of itself does not ensure a Sponsor has an "effective Compliance Program." Sponsors and their FDRs are responsible for establishing and executing an effective compliance program according to the CMS regulations and program guidelines.

Lesson Compliance Training

Course Objectives

After completing this course, you should correctly:

- Recognize how a compliance program operates
- Recognize how compliance program violations should be reported

Introduction and Learning Objectives

This lesson outlines effective compliance programs. It should take about 15 minutes to complete. After completing this lesson, you should correctly:

- Recognize how a compliance program operates
- 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 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

Lesson Compliance Training

- 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
    ◦ Establishes clear lines of communication for reporting non-compliance

- 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.

Lesson Compliance Training — Seven Core Compliance Program Requirements.

CMS requires an effective compliance program to 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 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 of 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 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.

Lesson Compliance Training

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 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
- Report suspected violations

How Do You Know What Is Expected of You?

Now that you have read the general ethical guidelines, how do you know what is expected of you in a specific situation?

- Standards of Conduct (or Code of Conduct) state the organization's compliance expectations and their operational principles and values. Organizational Standards of Conduct vary. The organization should tailor the Standards of Conduct content to their individual organization's culture and business operations. Ask management where to locate your organization's Standards of Conduct.
- Reporting Standards of Conduct violations and suspected non-compliance is everyone's responsibility.
- An organization's Standards of Conduct and Policies and Procedures should identify this obligation and tell you how to report suspected non-compliance.

Lesson Compliance Training

What is Non-Compliance?

Non-compliance is conduct that does not conform to the law, Federal health 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 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
- Quality of care

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

(!) **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, 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
- Termination

Lesson Compliance Program Training

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

How to Report Potential Non-Compliance

1. Employees of a Sponsor

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

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

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

3. Beneficiaries

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

(!) **Don't Hesitate to Report Non-Compliance**

When you report suspected non-compliance in good faith, the Sponsor can't retaliate against you. Each Sponsor must offer reporting methods that are:

- Anonymous
- Confidential
- Non-retaliatory

Lesson Compliance Program Training

What Happens After 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 compliance with CMS requirements
- Efficient and effective internal controls
- Protected enrollees

What Are Internal Monitoring and Audits?

Internal monitoring activities include regular reviews confirming ongoing compliance and taking effective corrective actions.

Internal auditing is a formal review of compliance with a particular set of standards (for example, policies, procedures, laws, and regulations) used as base measures.

Lesson Compliance Program Training

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.

Lesson Review

Now that you have completed the lesson, let's do a quick knowledge check

⊙ **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!

Compliance Training: Post Assessment

Knowledge Check - Select the Correct Answer

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

   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

2. **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 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

Compliance Training: Post Assessment

Knowledge Check - Select the Correct Answer (continued)

3. **You work for a Sponsor. Last month, while reviewing a Centers for Medicare & Medicaid Services (CMS) monthly report, you identified multiple enrollees not enrolled in the plan, but for whom the Sponsor is paid. You spoke to your supervisor who said don't worry about it. This month, you identify the same enrollees on the report again. What should you do?**

   a. Decide not to worry about it as your supervisor instructed – you notified him/her last month and now it's his/her responsibility

   b. Although you know 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 to avoid identification

   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

4. **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

Correct Answers: **1.** C **2.** D **3.** B **4.** E

Compliance Training: Post Assessment

Select the correct answer.

1. **Compliance is the responsibility of the Compliance Officer, Compliance Committee, and Upper Management only.**
   - **A.** True
   - **B.** False

2. **Ways to report a compliance issue include:**
   - **A.** Telephone hotlines
   - **B.** Report on the Sponsor's website
   - **C.** In-person reporting to the compliance department/supervisor
   - **D.** All of the above

3. **What is the 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
   - **C.** Protects employees who, in good faith, report suspected non-compliance
   - **D.** Prevents fights between employees

4. **These are examples of issues that can be reported to a Compliance Department: suspected fraud, waste, and abuse (FWA); potential health privacy violation, and unethical behavior/employee misconduct.**
   - **A.** True
   - **B.** False

5. **Once a corrective action plan begins addressing non-compliance or fraud, waste, and abuse (FWA) committed by a Sponsor's employee or first-tier, downstream, or related entity's (FDR's) employee, ongoing monitoring of the corrective actions is not necessary.**
   - **A.** True
   - **B.** False

Compliance Training: Post Assessment

Select the correct answer.

6. **Medicare Parts C and D plan Sponsors are not required to have a compliance program.**
    - **A.** True
    - **B.** False

7. **At a minimum, an effective compliance program includes four core requirements**
    - **A.** True
    - **B.** False

8. **Standards of Conduct are the same for every Medicare Parts C and D Sponsor**
    - **A.** True
    - **B.** False

9. **Correcting non-compliance _____.**
    - **A.** Protects enrollees, avoids recurrence of the same non-compliance, and promotes efficiency
    - **B.** Ensures bonuses for all employees
    - **C.** Both A and B

10. **What are some of the consequences for non-compliance, fraudulent, or unethical behavior?**
    - **A.** Disciplinary action
    - **B.** Termination of employment
    - **C.** Exclusion from participating in all Federal health care programs
    - **D.** All of the above

Appendix A: Resources

Disclaimers

This course was current at the time it was published or uploaded onto the web. Medicare policy changes frequently so links to the source documents have been provided 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.

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Glossary

For glossary terms, visit the Centers for Medicare and Medicaid Services Glossary.

Appendix B: Job Aids

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.

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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.

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   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.

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Appendix B: Job Aids

Job Aid B: Resources

- Compliance Education Materials: Compliance 101
- Health Care Fraud Prevention and Enforcement Action Team
- Provider Compliance Training
- Office of Inspector General's (OIG's) Provider Self-Disclosure
- Protocol
- Part C and Part D Compliance and Audits - Overview
- Physician Self-Referral
- Avoiding Medicare Fraud & Abuse: A Roadmap for Physicians
- Safe Harbor Regulations

HYPERLINK URL	LINKED TEXT/IMAGE
https://oig.hhs.gov/compliance/101	Compliance Education Materials: Compliance 101
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/protocol.asp	Office of Inspector General's (OIG's) Provider Self-Disclosure Protocol
https://www.cms.gov/medicare/compliance-and-audits/part-c-and-part-d-compliance- and-audits	Part C and Part D Compliance and Audits - Overview
https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral	Physician Self-Referral
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Publications-Items/CMS1254524.html	Avoiding Medicare Fraud & Abuse: A Roadmap for Physicians
https://oig.hhs.gov/compliance/safe-harbor-regulations	Safe Harbor Regulations

Appendix B: Job Aids

HYPERLINK URL	LINKED TEXT/IMAGE
https://www.ecfr.gov/cgi-bin/text-idx?SID=c66a16ad53319afd0580db00f12c5572&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.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
https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ComplianceProgramPolicyandGuidance.html	CMS Compliance Program Policy and Guidance webpage
https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Fraud-Waste_Abuse-Training_12_13_11.pdf	Medicare Parts C and D Compliance Trainings and Answers to Common Questions
https://www.cms.gov/Medicare/Prescription-Drug- Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf	Medicare Prescription Drug Benefit Manual
https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf	Medicare Managed Care Manual
https://www.cms.gov/apps/glossary	Centers for Medicare and Medicaid Services Glossary