- Annual Compliance Training Requirement for Medicare Advantage and Medicare Next Generation Accountable Care Organization(ACO) providers
  - Chapter 11 of the Medicare Managed Care Manual
  - Section XVII(A)(d) of the CMS Next Generation ACO Agreement

- Please review the handout provided and contact me with any questions

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Introduction and Learning Objectives

This lesson outlines effective compliance programs. It should take about 15 minutes to complete. Upon completing the lesson, you should be able to correctly:

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

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.

- 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.

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.

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.

Seven Core Compliance Program Requirements (continued)

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–Sponsors (Health Plans) and their 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   CLOSE WINDOW

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.

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

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
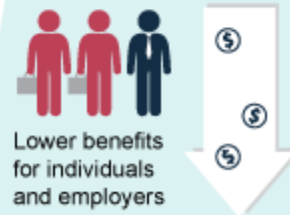- Other hurdles to care

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

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 (888) 933-9044; 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 corrected promptly.

However, internal monitoring should continue to ensure:

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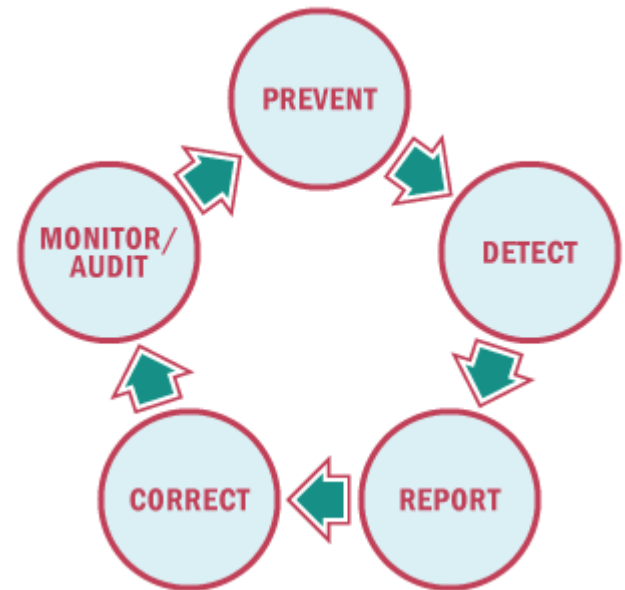- Enrollees are protected.

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!

Lesson Review

Now that you have completed the Compliance Program Training lesson, let's do a quick knowledge check. The following questions do not contribute to your overall course score in the Post-Assessment.

Knowledge Check

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) (CORRECT)**
- D. Wait to confirm someone is processing the appeals before taking further action
- E. Contact your supervisor

Knowledge Check

A sales agent, employed by the Sponsor's First Tier or Downstream entity, submitted an application for processing and requested two things: 1) to backdate 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 (CORRECT)**

- E. Contact law enforcement and the Centers for Medicare & Medicaid Services (CMS) to report the sales agent's behavior

Knowledge Check

You work for a Sponsor. Last month, while reviewing a monthly report from the Centers for Medicare & Medicaid Services (CMS), you identified multiple individuals who are not enrolled in the plan but for whom the Sponsor is being paid. 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 (CORRECT)**

- 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

Knowledge Check

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 (CORRECT)**

You've completed the lesson!

Now that you have learned about compliance programs, let's take a post assessment to see how much you've learned!

Post-Assessment

This assessment asks you 10 questions about Medicare Parts C and D compliance programs.

Question 1 of 10

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

Select the correct answer.

- A. True
- **B. False**

Question 2 of 10

Ways to report a compliance issue include:

Select the correct answer.

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

Question 3 of 10

What is the policy of non-retaliation?

Select the correct answer.

- 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

Question 4 of 10

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.

Select the correct answer.

- **A. True**
- B. False

Question 5 of 10

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.

Select the correct answer.

- A. True
- **B. False**

Question 6 of 10

Medicare Parts C and D plan Sponsors are not required to have a compliance program.

Select the correct answer.

- A. True
- **B. False**

Question 7 of 10

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

Select the correct answer.

- A. True
- **B. False**

Question 8 of 10

Standards of Conduct are the same for every Medicare Parts C and D Sponsor.

Select the correct answer.

- A. True
- B. False

Question 9 of 10

Correcting non-compliance _____.

Select the correct answer to fill in the blank.

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

Question 10 of 10

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

Select the correct answer.

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