



Element I

Written Policies, Procedures and Standards of Conduct



Focused Training Compliance Program Guidelines

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Today's Agenda

Part I – Overview of Element I Requirements

Part II – Case Study: The RutRo Case;
Lessons Learned

Part III – Questions and Answers Session

Part I – Overview of Element I

Element I

Written Policies, Procedures and Standards of Conduct

Must have policies, procedures and standards of conduct that:

- Articulate commitment to comply with Federal and State standards
- Describe compliance expectations
- Implement operation of compliance program
- Provide guidance on dealing with compliance issues
- Identify how to communicate compliance issues
- Describe how compliance issues are investigated and resolved
- Include policy of non-intimidation and non-retaliation

“Must” ... “Should” ... “Best Practices”

- Must:*** Requirements created by statute or regulation; no discretion
- Should:*** Expectations identified in Guidelines; discretion as to how you accomplish effectiveness
- Best Practices:*** Procedures that work well for some Sponsors; may not work for all

Standards of Conduct

- AKA “Code of Conduct”, etc.
- State overarching principles and values
- Describe expectations of ethical behavior
- Require reporting of noncompliance and potential FWA
- Indicate how reported issues addressed

Standards of Conduct (cont.)

- Stated in separate Medicare document or within corporate Code of Conduct
- Update Standards to incorporate changes in law
- Standards communicate that compliance is everyone's responsibility

Standards of Conduct (cont.)

- Compliance and ethics valued at highest levels of authority in the organization
- Approved by full governing body
- Best Practice: Governing Body resolution stating sponsor's commitment to compliant, lawful and ethical conduct

Policies and Procedures

- Detailed and specific
- Operation of compliance program:
 - Compliance reporting structure
 - Training requirements
 - Reporting mechanisms
 - How investigations conducted
 - How issues are resolved
 - Monitoring and Auditing

Policies and Procedures (cont.)

- Touch upon operational areas
- Update with changes to laws and requirements
- Easy to read and comprehend
- Translation as necessary

Distribution Policies and Procedures

- To all employees within 90 days of hire, when updated and annually
- Sponsor discretion in distribution method
- Examples:
 - Hard Copy
 - Electronic
 - Intranet

Distribution (cont.)

- To all FDR employees within 90 days hire
- Sponsor provides own Standards to FDRs or ensures FDRs have comparable Standards
- Examples:
 - Fax Blast
 - FDR Portal
 - Contract Materials

Distribution (cont.)

- Demonstrate Standards distributed to FDRs
- Periodic monitoring based on risk assessment
- Audit sample of FDRs
- Review FDR Standards and compliance policies

Determining Effectiveness

- Policies must be implemented
- Achieve desired results
- Updated appropriately
- Enforced
- Messaged from top-down
- Culture reflects Standards

Part II – Case Study and Lessons Learned

Case Study

RutRo Health Plan, Inc.

RutRo Health Plan, Inc.

- MA, MA-PD
- Commercial enrollment: 1 million
- Medicare enrollment: 125,000
- Wholly owned subsidiary of a public company
- Corporate headquarters in Texas
- Medicare operations in Maryland

RutRo: Poll – Where to articulate requirements

- 1. Within what document must sponsors articulate the requirements outlined in the compliance program regulations regarding policies, procedures and Standards of Conduct?**
 - A. Standards of Conduct
 - B. Policies and Procedures
 - C. Standards of Conduct and/or Policies and Procedures
 - D. None of the above

Answer: C

Standards of Conduct and/or Policies and Procedures

- The requirements outlined in the compliance program regulations regarding content of policies and procedures and Standards of Conduct, may be stated in either compliance policies and procedures and/or the Standards of Conduct.

RutRo: Poll – Distribution of Standards/Policies

2. **When must Standards of Conduct and policies and procedures be distributed to employees?**
 - A. Within 90 days of hire
 - B. Annually
 - C. When the Standards/policies are updated
 - D. All of the above

Answer: D

All of the above

- Sponsors must distribute Standards of Conduct and compliance policies and procedures to employees within 90 days of hire, annually thereafter, and whenever the Standards/policies are updated.

RutRo: Poll – What entity promotes Standards?

- 3. What entity is responsible for promoting the Standards of Conduct?**
- A. Compliance Department
 - B. Senior Leadership and Governing Body
 - C. Both A and B
 - D. None of the above

Answer: C

Both A and B

- The Compliance Department, Senior Leadership and the Governing Body are all responsible for promoting the Standards of Conduct. Compliance is the responsibility of everyone within the organization.

Lessons Learned: Ineffective Compliance Practices

- Policies not updated regularly
- Governing body does not review/approve
- No compliance message from leadership
- Volunteers, temps, etc. do not receive Standards
- Employees unfamiliar with Standards

Lessons Learned: Best Practices

- Input from operational department leaders
- Operational department policies detail compliance risks
- Governing body resolution
- Widely publicized and in various formats

Part III – Questions and Answers Session

Questions and Answers Session

- In preparation for today's focused training, we requested that sponsors submit questions to the Medicare Parts C and D Compliance Program Guidelines mailbox.

Questions and Answers

Q: The “Standards of Conduct” content requirements are typically very similar to and redundant of “Compliance Policies”. Will CMS allow plans to use the Compliance Program Policies for the dual purpose as the de facto “Standards of Conduct”, so long as the content is there?

A: Sponsors may combine their Standards of Conduct and Compliance Policies and Procedures into one document, as long as the document contains all of the content as required by the Compliance Program regulations and guidance. The portion of any such document that reflects the “Standards,” should be approved by the full governing body.

Questions and Answers

- Q. CMS requires plans to “distribute” the Compliance Policies and Standards of Conduct. Does “distribute” mean we can send it out via email with instructions to read it, or must we have individual employee confirmation of receipt?**
- A.** Sponsors have discretion regarding how they distribute policies and Standards, but they must ensure their choice of distribution is effective, and sponsors must be able to demonstrate to CMS that each of their employees have received the Standards of Conduct and policies and procedures.

Questions and Answers

- Q.** Could you provide some guidance on policy and procedure updates where rule changes occur. Since there are logistics to making these changes, is a 60 day compliance timeframe a reasonable expectation that would meet the CMS standards in cases where no specific implementation date is provided in the memo or guidance?
- A.** Sponsors must ensure that policy and procedure updates occur within a reasonable time and are effectively implemented. Reasonable timeframes must be determined on a case-by-case basis.

Questions/Answers

The Division of Compliance Enforcement (DCE) has a streamlined process for responding timely to policy questions or inquiries:

[Parts C and D CP Guidelines@cms.hhs.gov](mailto:Parts_C_and_D_CP_Guidelines@cms.hhs.gov)

The Part C and Part D Compliance and Audits webpage provides information regarding Compliance Program Policy and Guidance, Compliance and Enforcement Actions taken by CMS, and Program Audits relating to Medicare Plans.

<http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/index.html>