


Element II

Compliance Officer, Compliance Committee, High Level Oversight



Focused Training Compliance Program Guidelines

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Today's Agenda

- Part I – Overview of Element II Requirements
- Part II – Case Study: The RutRo Case;
Lessons Learned
- Part III – Questions and Answers Session

Part I – Overview of Element II

Element II

Foundation of an Effective Compliance Program

- ✧ **Compliance Officer , Compliance Committee** – accountable to CEO; obligation to report
- ✧ **Governing Body** – oversight requirements
- ✧ **Reporting Structures** – free, unfiltered flow of information to the board, CEO
- ✧ **High Level Oversight** – engagement by CEO and senior management in compliance program oversight

“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

Element II

Compliance Officer

Compliance Officer

- Reports directly to and is accountable to CEO or other senior management
- Is vested with day-to-day operations of the compliance program
- Is an employee of the Sponsor, its parent company or a corporate affiliate
- Is not an employee of the Sponsor's first tier, downstream or related entities ("FDRs")
- Reports periodically directly to the Sponsor's governing body on activities and status of compliance program, including issues investigated, identified and resolved by compliance program

42 CFR §§ 422.503(b)(4)(vi)(B); 423.504(b)(4)(vi)(B)

Dedicated Compliance Officer Full-Time?

- ✧ Compliance officer should be full-time.
- ✧ Compliance officer dedicated to Medicare line of business not required but strongly recommended.

Compliance Officer Employment

- ✧ Must be an employee of sponsor, sponsor's parent company, sponsor's corporate affiliate
- ✧ May not be employed by sponsor's FDRs
- ✧ If compliance officer employed by sponsor's parent or corporate affiliate, sponsor must be able to demonstrate that he/she has:
 - Detailed involvement in and detailed familiarity with sponsor's operational and compliance activities

Compliance Officer Reporting to CEO

- ✧ The Compliance Officer **must** report directly and be accountable to the CEO “or other senior management”.
- ✧ *CEO “or other senior management”* = CEO or equivalent, such as President
- ✧ *“Report directly”* = direct reporting of information
- ✧ *“Report directly”* ≠ supervisory relationship

Compliance Officer Reporting to CEO (cont.)

- ✧ Direct reporting from compliance officer to CEO
 - In person reports preferred
 - Day-to-day compliance reports may be routed from Compliance Officer to CEO through divisional presidents
 - May not be routed through operational management
- ✧ Sponsor must ensure that Compliance Officer's reports actually reach the CEO
- ✧ Compliance Officer must have express authority to provide unfiltered, in person reports to CEO

Compliance Officer Reporting to Governing Body

- ✧ The Compliance Officer must periodically report “*directly to*” governing body.
- ✧ “*Directly to*” = in person OR through the compliance infrastructure.
- ✧ Compliance Officer must have express authority to provide unfiltered, in-person reports to governing body

Reporting – Best Practices

- ✧ Sponsors with a Corporate Compliance Officer and Medicare Compliance Officer allow the Medicare Compliance Officer to regularly attend board meetings and make in-person reports
- ✧ Compliance Officer meets at least once a year in Executive Session (without CEO or others present) with Board

Compliance Officer Independence

- ✧ Compliance Officer cannot be effective if he/she is not independent and free of conflict of interest or fear of reprisal:
 - Compliance Officer does not have duties in operational areas that could lead to self-policing
 - Compliance Officer does not also serve as counsel to the Sponsor

Compliance Accountability

- ✧ Compliance Officer is accountable for the compliance program to the CEO and to the governing body.
- ✧ Compliance Officer takes responsibility for the compliance program design and infrastructure.
- ✧ Everyone, including key business operations managers, not the Compliance Officer, are accountable for compliance results.

Compliance Officer Duties

- ✧ Compliance Officer has broad responsibility for the Medicare compliance program.
 - Develop and/or review policies and procedures that implement the compliance program
 - Attend Medicare operations staff meetings
 - Monitor compliance performance by operational areas
 - Enforce disciplinary standards, ensuring consistency
 - Implement system for assessment of risk
 - Develop auditing work plan
 - Review auditing and monitoring reports
 - Develop and/or review procedures for FDR oversight
 - Coordinate with Human Resources and Special Investigation Unit
 - Monitor effectiveness of corrective actions

Compliance Officer Qualifications

- ✧ Training or experience working with MA, MA-PD or PDP programs
- ✧ Commitment to ethics and integrity
- ✧ Commitment to continuous improvement
- ✧ Approachable
- ✧ Ability to work with board and executives
- ✧ Authority that is commensurate with responsibility
- ✧ *Best practice* – Compliance Officer is a member of senior management

Compliance Officer Authority

- ✧ Compliance Officer should have authority to, in his/her discretion:
 - Interview employees
 - Review contracts, data submissions
 - Seek advice from legal counsel
 - Report potential FWA outside the organization
 - Conduct audits of FDRs, Medicare operations
 - Recommend policy, procedure, process improvement
 - Enforce compliance program requirements at all levels of the organization

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Compliance Committee

Compliance Committee

- Reports directly to and is accountable to CEO or other senior management
- Reports periodically directly to the Sponsor's governing body on activities and status of compliance program, including issues investigated, identified and resolved by compliance program

42 CFR §§ 422.503(b)(4)(vi)(B); 423.504(b)(4)(vi)(B)

Compliance Committee Requirements

- ✧ Must address Medicare compliance issues
- ✧ Separate Medicare compliance committee not required
- ✧ Accountable to CEO and governing body
- ✧ Must provide regular reports to CEO and governing body on status and activities of the compliance program, including issues identified, investigated and resolved

Compliance Committee Reporting Structure

Example of Compliance Committee Reporting Structure:

Medicare Compliance Committee

reports to:

Corporate Compliance Committee

reports to:

Governing Body/CEO

Compliance Committee Membership

- ✧ Multi-disciplinary committee with varied backgrounds and expertise
 - e.g., auditors, medical personnel (pharmacists, pharmacy technicians, registered nurses), managers of various Medicare operational areas, Human Resources, Legal Department, etc.
- ✧ Senior management engagement
- ✧ Reflects size and scope of the Sponsor's Medicare plans

Element II

Governing Body

Governing Body

- ✧ Exercises reasonable oversight of the implementation and effectiveness of the compliance program
- ✧ Is knowledgeable about the content and operation of the compliance program

What is “Reasonable Oversight”?

- ✧ Approval of Standards of Conduct by the full Board
- ✧ Understanding the compliance program structure
- ✧ Being informed about the outcomes of audits and monitoring
- ✧ Being informed of governmental compliance enforcement activity
- ✧ Receiving regular, periodic updates from compliance officer and compliance committee
- ✧ Reviewing performance and effectiveness assessments of the compliance program

Other Oversight Activities

- ✧ May be performed by governing body, senior management or compliance committee
- ✧ Development, approval, annual review of compliance policies and procedures
- ✧ Review of dashboards, scorecards, self-assessment tools and other mechanisms that reveal compliance issues
- ✧ Evaluation of senior management's commitment to ethics and the compliance program

Element II

Senior Management

- ✧ Engagement of the CEO (or senior-most leader) and other senior leadership with the compliance program's operations is crucial to its success
- ✧ Tone at the top – that which is valued by the board, CEO and senior leadership will be noticed and valued by the employees

Determining Effectiveness

- ✧ Governing body should be looking at measurable evidence that the compliance program is timely detecting and correcting (i.e. non-recurrence of) Medicare program noncompliance and FWA
- ✧ Measurable Evidence
 - Use of quantitative measurement tools
 - Report, track, and compare compliance results over time in key operational areas
 - Scorecards, dashboards, key performance indicators

Indicators of an Effective Compliance Program

- ✧ Tracking and reviewing compliance results in key operational areas as well as other risk areas.
 - Open and closed corrective action plans
 - FDR compliance
 - CMS enforcement activity (Notices of Noncompliance, Warning Letters)

Indicators of an Effective Compliance Program (cont.)

- ✧ Finding problems early before large impact
- ✧ Decrease in beneficiary complaints, CTMs
- ✧ Effective resolution of problems – compliance issues not recurring
- ✧ Data analysis is detecting FWA

Indicators of an Effective Compliance Program (cont.)

- ✧ System to ensure effective implementation of new or updated Medicare requirements.

- ✧ Example: Tracking CMS issued HPMS memos
 - Receipt
 - Distribution to all appropriate individuals/business units
 - Implementation
 - Monitoring (e.g., quality control, timely implementation)

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

Poll: Which Governing Body?

Which Board of Directors – RutRo's or Parent Co.'s – must exercise reasonable oversight of RutRo's Medicare compliance program?

- A. RutRo's Board of Directors
- B. Parent Co.'s Board of Directors
- C. Either RutRo's Board or Parent Co.'s Board
- D. Both RutRo's Board and Parent Co.'s Board

Answer: C

Organization Has Option to Choose

- ✧ “The governing body of the organization that contracted with CMS or its parent company may oversee the Medicare compliance program.”

Chapters 9, 21 § 50.2.3

RutRo: Poll – Reporting to Board of Directors

The Compliance Officer has reported severe staffing shortage in Compliance Department to CEO. Should she also report it to the RutRo's Board of Directors?

- A. Yes.
- B. Yes, but only if the CEO refuses to add staff.
- C. No, its up to the CEO to notify the Board if he thinks its necessary.
- D. No, its not a critical issue.

Answer: A

Must Report to Board

- ✧ Yes. A severe staffing shortage in the compliance department is a critical issue of which the governing body should be notified by the Compliance Officer.

RutRo Poll -- Documentation

The Board of Directors' Audit Committee meets but minutes are not kept. Will copies of internal emails suffice for documentation of reasonable oversight of Medicare compliance program?

- A. Yes.
- B. Yes, but only if prepared by corporate secretary
- C. No. Board meetings must be documented in minutes, but minimal detail is required.
- D. No. Reasonable oversight must be documented in detailed minutes.

Answer: A

Any Detailed Documentation

- ✧ Yes. There must be contemporaneous documentation that reflects reasonable oversight of the Medicare compliance program. The documentation does not have to be in the form of minutes.
- ✧ Documentation should be detailed as to date, time, duration, attendees, summary of discussion, actions taken, requests for follow-up and summary of reports provided.

RutRo Poll: Which CEO?

Commercial Division CEO reports to RutRo CEO

Government Division CEO reports to RutRo CEO

RutRo CEO reports to RutRo Board

Which CEO ultimately accountable for
Compliance Program oversight?

- A. RutRo CEO
- B. President/CEO – Government Division
- C. President/CEO – Commercial Division
- D. Both RutRo CEO and CEO Govt.
Division

Answer: A

Sponsor's CEO

- ✧ The Sponsor's CEO must be engaged in compliance program oversight.
- ✧ Must receive periodic reports from compliance officer of:
 - Risk areas
 - Corrective action strategies
 - Results of compliance monitoring
- ✧ Must be informed of all governmental enforcement activity e.g. Notices of Noncompliance, Warning letters, Imposition of Sanctions

Lessons Learned: Ineffective Compliance Structures

Compliance Officer

- ✧ Is given the responsibility but not the status and authority within the company necessary to do his/her job effectively
- ✧ Does not inform the CEO and/or the Board about problems within the compliance program or operational problems within the Medicare line of business
- ✧ Is not taken seriously by staff or senior management – lack of credibility
- ✧ Acts as the police without efforts to achieve buy-in by and accountability of employees and managers

Lessons Learned:

Ineffective Compliance Structures

Governing Body

- ✧ Medicare compliance is agenda item only twice a year despite significant ongoing compliance issues
- ✧ Accepts only written reports from compliance officer; no in-person contact
- ✧ Is unaware that CMS has issued five Notices of Noncompliance and two warning letters in the last six months because:
 - Compliance Officer's reports so high level that they omit important detail
 - No requirement that Board be informed of all CMS enforcement activity
- ✧ Is not informed of audit results, or monitoring, tracking and trending of compliance results

Lessons Learned: Ineffective Compliance Structures

Compliance Committee

- ✧ Monthly schedule for meetings not followed.
- ✧ Condoned absenteeism by key personnel
- ✧ Minutes are not always taken; when there are minutes, they are vague and unclear, do not reflect who attended or how long the meeting lasted
- ✧ Issues identified in one meeting, not followed up on in subsequent meetings; issues remain unresolved month after month
- ✧ No follow-up on whether corrective actions are preventing re-occurrence of the identified compliance issue

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: Compliance Committee duty is to ensure that training and education are effective and appropriately completed. Is there a standard as to how CMS will evaluate the effectiveness of compliance and FWA training?

A: There is no one standard for determining the effectiveness of training and education. Sponsors must develop methods and/or factors by which they determine if their training and education is effective.

For example, if employees do not know that they are required to report Medicare program noncompliance and potential FWA or how to report, the Sponsor (and CMS) may question the effectiveness of the training.

Questions and Answers

- Q. There is an apparent contradiction in Chapters 9 and 21 with regard to whether the Sponsor's parent's governing body or the Sponsor's own governing body must oversee the Medicare compliance program. Does a Sponsor have the flexibility to structure its governing body oversight at either the level of the contract holder or of the contract holder's parent company?**
- A. Yes.** The Sponsor (contract holder) may choose to have either its own governing body or that of its parent company conduct oversight of the Medicare compliance program. The contradictory statements are in Section 50.2, which states that the Sponsor's governing body is responsible for Medicare compliance program oversight, not its parent company's body. In contrast, Section 50.2.3 states the governing body of the organization that contracted with CMS or its parent company may oversee the Medicare compliance program. This inconsistency is an error.

Questions and Answers

- Q. Please confirm if the following is accurate:
PACE programs with prescription drug benefit programs must comply with the following Compliance Program Element 6 – Effective System for Routine Monitoring, Auditing, and Identification of Compliance Risks and Element 7 – Procedures and System for Prompt Response to Compliance Issues and need not comply with Elements 1 through 5?**
- A. This is correct. However, CMS strongly encourages PACE programs with prescription drug benefit programs to voluntarily implement the Compliance Program Guidelines for Element 1 through 5 in addition to the required Elements 6 and 7.**

Questions and Answers

- Q. “Sponsors must assess the scope of the existing Compliance Officer’s responsibilities....when determining whether a single Compliance Officer can effectively implement the Medicare compliance program. Does CMS expect plans to perform this assessment and document it in writing?”**
- A.** Each Sponsor must use its judgment in determining whether it should perform the assessment. CMS cannot dictate every set of circumstances that might trigger a reasonable Sponsor to question whether its compliance officer is overburdened. It depends on the size, scope, structure, and member enrollment, and how well the Sponsor is currently meeting the regulatory requirements of the Medicare program. There is no requirement that any such assessment be in writing – although highly recommended for documentation purposes.

Questions and Answers

- Q. What is meant by “the Compliance Officer’s reports to the Sponsor’s governing body must be made through the compliance infrastructure”?**
- A.** The Compliance Officer’s reports to the governing body must be made either directly, in person or, if not in person, then through the compliance committee. Often the Compliance Officer serves as the Chair of the compliance committee. In that case, the Compliance Officer would be reporting to the governing body both in his/her capacity as the Compliance Officer and as the Chair of the compliance committee. If someone other than the Compliance Officer is the Chair of the compliance committee, then the Compliance Officer can report to the compliance committee who, usually through the Chair, can then report the information to the governing body.

Questions and Answers

- Q. “The Compliance Officer should not serve in both compliance and operational areas (e.g., where the Compliance Officer is also the CFO, COO, or GC)”. Can the Compliance Officer report to those people, without actually serving in those roles himself?**
- A.** The Compliance Officer’s reports on the status and activities of the compliance program cannot be routed to the CEO and governing body through operational management. The regulations do not prohibit the Compliance Officer from reporting administratively to operational leaders such as the CFO, COO, or GC. However, CMS believes that in order to be effective, the Compliance Officer must be independent and be able to freely enforce compliance requirements up and down the organization’s chain of command.

Questions and Answers

- Q. “It is a best practice for the Compliance Officer to be a member of senior management.” Having the Compliance Officer be apart of senior management adds immediate impact to the role’s effectiveness and authority needed to implement tough changes.**
- A.** CMS agrees. The Compliance Officer has the responsibility to implement tough compliance decisions and changes. He/She requires status, credibility and authority to be regarded seriously by those both above and below him/her in the corporate hierarchy.

Questions and Answers

- Q. “Duties of the Compliance Officer may include, but are not limited to....” Is this list to be examples that are optional or minimally-required duties?**
- A.** The listed duties in section 50.2.1 of the Compliance Program Guidelines are among those typically carried out by Compliance Officers. However, the list is optional as the Sponsor may delegate any of those duties to someone else within the organization other than the Compliance Officer.

Questions and Answers

- Q. “Reviewing effectiveness of the system of internal controls designed to ensure compliance with Medicare regulations in daily operations.” Is it CMS’ expectation that plans implement a system of internal controls over operational areas?**
- A.** Yes. CMS requires that the Sponsor have a system of internal controls in all of its Medicare operational areas to ensure that those areas are operating in compliance with federal regulations and CMS requirements.

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>