



Elements IV & V

Lines of Communication / Disciplinary Standards



Focused Training Compliance Program Guidelines

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Today's Agenda

- Part I – Overview of Element IV Requirements
- Part II – Overview of Element V Requirements
- Part III – Case Study: SponsorX
- Part IV – Frequently Asked Questions

“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

Part I – Overview of Element IV

Effective Lines of Communication

Sponsor must:

- Establish / implement effective lines of communication
- Accessible to all including First-Tier, Downstream, and Related Entities (FDRs)
- With method for anonymity and confidentiality

42 C.F.R. § 422.503(b)(4)(vi)(D)

42 C.F.R. § 423.504(b)(4)(vi)(D)

Effective Lines of Communication (cont.)

- Compliance Officer: Employees (including FDRs)
- Compliance Officer: Line management
- Compliance Officer: FDR Management
- Compliance Department: Special Investigations Unit (SIU),
Human Resources (HR), etc.
- Compliance Officer: Enrollees

Requirement to Report

Sponsors must make it **mandatory** that employees, members of the governing body, FDRs report compliance concerns and actual or suspected FWA to the Sponsor.

- Include in Standards or Conduct and/or
- Policies and Procedures (Ps & Ps)
- Reinforce through training, compliance presentations, disciplinary actions

Compliance Officer (CO) to Employees (incl. FDRs)

CO to Employees

- Changes in laws, regulations, Ps & Ps
- Do you have an effective system to **timely** distribute CMS' HPMS memos, Fraud Alerts, changes to regulatory requirements and policy updates etc., to all who need to receive them?
- Do you communicate or follow up with employees to confirm appropriate interpretation of CMS requirements and expectations?

Employees (incl. FDRs') to CO

Employees to CO

Questions, concerns, problems

- Do employees know who the CO is?
- Do employees know how to reach the CO?
 - What is the contact information?
 - Where is the office located?
- Does the CO conduct exit interviews?

Anonymous / Accessible

- Multiple reporting methods preferred
- At least one method for anonymous reporting.
- Accessible 24 hours/7 days; publicized to all
- FDR employees can report to the FDR: FDR management required to send inquiry to Sponsor.

Confidential

- Would your employees feel comfortable reporting suspected FWA or noncompliance?
- Feedback during exit interviews?
- Have you surveyed them?
- Let employees know that confidentiality will be maintained to the greatest extent possible.

Non-retaliation

- Notification of protection from retaliation must be publicized
- Policy of non-retaliation must be enforced
- Tone from the top speaks the loudest about company values
- Are your employees fearful to report noncompliance or FWA?
 - Organizational culture?
 - Provide examples of common types of retaliatory behavior
- Recent situations in the workplace that have the potential to be classified as retaliation?
 - Pre and post assessments of how the non-retaliation policy “lives” within the organization

Be Responsive to Reporter

- Employees will not report if they think it is a pointless act.
- Act timely on the employee's report
- Let the employee know that you are doing so
- Inform of outcome, if possible; if not, inform that investigation is being conducted and action will be taken

Line Management to CO

Line Management to CO

- Implement a streamlined **process** for managers and supervisors to communicate to the compliance officer.
- The process should allow for a consistent and timely follow-up of employee reports of noncompliance and/or suspected or actual FWA
- Best Practices: scheduled check-ins, standardized managers meeting to provide noncompliance/FWA reports to CO, shared databases or tracking mechanism, etc.

FDR Management to CO

CO to FDR Management FDR Management to CO

- Implement a streamlined **process** for all Medicare Parts C and D contractors/vendors (FDRs) to communicate to the Sponsor's compliance officer of all non-compliance and/or suspected or actual FWA reported by the FDR employees.
- Compliance issues or concerns that affect the function being performed by the FDR on the Sponsor's behalf must be reported and resolved timely (*e.g., beneficiaries unable to access medical care or prescription drugs, inappropriate sales and enrollment activities, false claims, etc.*)

Tracking/Response

- Sponsor must **track** all reports of program noncompliance and FWA.
- Sponsor must have a system in place to **respond** to reports of program non-compliance and FWA.
- Sponsor must be **proactive** to obtain information from employees, line managers and FDRs regarding compliance and FWA concerns/reports

Compliance Dept. / SIU

Compliance Department to SIU

SIU to Compliance Department

A formal policy and procedure will inform staff of both departments (*compliance and special investigation unit*) as to when communication is necessary and what must be communicated.

Compliance Dept. / HR

Compliance Dept. to Human Resources

Human Resources to Compliance Dept.

- Formal policy and procedure regarding communications when communications when HR has compliance program-related responsibilities

Communications with Enrollees

Compliance Dept. To Enrollees

Enrollees to Compliance Dept.

- **Methods of communication to and from enrollees**
 - To educate about the identification of FWA
 - To instruct about the reporting of FWA
 - To enable them to easily report suspected FWA
 - To enable them to report anonymously, if desired.
- **Best practices**
 - Provide common examples of FWA and hotline number or website in Evidence of coverage (EOC), Summary of Benefits (SB), explanation of benefits form (EOB), newsletters, etc.

Part II – Overview of Element V

Well-Publicized Disciplinary Standards

Sponsor must:

- Establish and implement disciplinary policies and procedures that reflect clear, specific disciplinary standards

42 C.F.R. § 422.503(b)(4)(vi)(E)

42 C.F.R. § 423.504(b)(4)(vi)(E)

Disciplinary Policies

Disciplinary policies must describe expectations for:

- Reporting noncompliance, unethical or illegal behavior
- Participating in required training
- Assisting in resolution of compliance issues

42 C.F.R. § 422.503(b)(4)(vi)(E)

42 C.F.R. § 423.504(b)(4)(vi)(E)

Disciplinary Policies (cont.)

Disciplinary policies must:

- Identify noncompliant, unethical or illegal behavior, through examples of inappropriate conduct employees might encounter in their jobs
- Provide for timely, consistent and effective enforcement of standards
- Disciplinary action must be appropriate to seriousness of violation

42 C.F.R. § 422.503(b)(4)(vi)(E)

42 C.F.R. § 423.504(b)(4)(vi)(E)

Publication

- Employees and FDRs must know what to expect should they violate the Sponsor's standards of conduct or ethical requirements
- Disciplinary standards must be widely and prominently publicized

Timely and Consistent Enforcement

- **Under all the circumstances**, within a reasonable time from when the behavior was identified
- Disciplinary measures must be consistently enforced across the organization

Effective Enforcement

- Enforcement must be effective
- Disciplinary action must be appropriate to the seriousness of the violation

Best Practices

- Celebrate compliance initiatives and leadership of persons or teams
- Company recognition
- Nominal prizes, departmental parties
- Opportunities for positive points on annual performance review

Best Practices

- Become transparent within the organization
- Publish de-identified disciplinary actions taken to demonstrate that the Sponsor acts on violations of the Standards of Conduct.

Proof of Enforcement

Must maintain records of disciplinary actions for **10 years**, including, at a minimum:

- Date violation reported
- Description of violation
- Date of investigation
- Summary of findings
- Disciplinary action taken
- Date disciplinary action taken

Highlights – Element IV

- Effective lines of communication must run in multiple directions
- Require employees and FDRs to report – be proactive with FDRs
- Create a formal process for managers to communicate compliance issues
- Coordinate tracking and response to compliance and FWA reports coming from multiple sources

Highlights – Element V

- Widely and prominently publicize disciplinary standards
- Be consistent in taking disciplinary action and in disciplinary measures imposed across all levels
- Impose disciplinary action that is appropriate to the violation
- Maintain records in sufficient detail to be useful

Part III – Case Study

Case Study

SponsorX Health Plan

Sponsor X

- MA, MA-PD only
- Medicare enrollment: 200,000
- 500 employees, multiple functions contracted out and performed by FDRs
- SponsorX has just hired a new Compliance Officer, Ralph
- SponsorX has 8 administrative FDRs and a provider network with whom it contracts directly
- In addition to managing and administering the Part D benefit, the PBM provides the pharmacy network

Poll #1: Multiple Hotlines, No Ps & Ps

What Ralph discovered during a review of SponsorX' Compliance Program:

SponsorX has 3 hotlines

Line 1: Operated by the Medicare compliance department for Medicare program noncompliance reports,

Line 2: Operated by the SIU for FWA reports

Line 3: Enrollee hotline answered by Customer Service.

SponsorX has no written policies or procedures for hotline calls, Each Department handles calls in it's own way

SponsorX has very diligent people working in each department who are very reliable and committed to promoting ethics.

Poll #1: Multiple Hotlines, No Ps & Ps

Ralph is not concerned about this.
In fact, he is happy!

Q: Is this a problem?

- A. No, because it's better to have more than one hotline.
- B. No, because the employees who handle the calls are very diligent, reliable and dedicated individuals.
- C. Yes, because each hotline has a different purpose.
- D. Yes, because there are no policies and procedures for hotline operations, coordination or tracking.

Answer: D

Problem: No Coordination, Ps & Ps

- **Ineffective Lines of Communication**
- SponsorX has no coordinated system and no real tracking mechanism. All tracking is “informal” via word-of mouth.
- Depending on mechanism of reporting, calls are logged, recorded, responded to and documented differently and inconsistently.

Poll #2: How to Report

- SponsorX's management does not allow the posting of anything on the office walls
- FDRs receive a quarterly email newsletter from SponsorX with general compliance information

Poll #2: How to Report

Once again, Ralph is not concerned.

Question: Is there a problem?

- A. Yes. SponsorX's corporate art would be enhanced by hotline posters.
- B. Yes, this is insufficient communication of how to report.
- C. No. Between the annual training and the reference in the newsletter that there is a hotline, employees and FDRs reasonably should be aware of how to report.
- D. No, SponsorX thinks reporting is overrated.

Answer: B

Problem: Not Prominently Publicized

- **Ineffective Lines of Communication**
- The methods for reporting noncompliance or FWA must be widely and prominently publicized .
- Annual training alone is not enough.
- Even annual training with a small, non-prominent reference to a hotline and the identity of the compliance officer with his email address in the newsletter is not enough.
- Make it easy for employees and FDRs to report.
 - User-friendly, anonymous system
 - Easy to determine the number to call

Poll #3 – Disciplinary Records

Ralph looks at Marketing Department

Spreadsheet data includes:

- **CTM complaint number and date**
- **Name of agent**
- **One word description of complaint**
- **One word description of findings**
- **Action taken**

Poll #3 – Disciplinary Records

Ralph is relieved that SponsorX has been keeping track of disciplinary actions. Still, since CMS is coming next week for an audit, he is wondering if there possibly could be a problem.

Question: Is this a problem?

- A. Yes, since the spreadsheet is lacking detail.
- B. Yes, since the Sponsor must use a commercial program to keep track of disciplinary actions.
- C. No, since SponsorX has recognized the need to keep a record of disciplinary actions taken.
- D. No, since the disciplinary action taken is recorded.

Answer: A

Problem :Not Enough Detail

- **There are requirements for the amount of detail that must be recorded.**
- Date violation reported: Was investigation started timely?
- Meaningful description of alleged violation: severity? Was disciplinary action appropriate to the violation and consistent with similar violations?
- Date of investigation: Was investigation started timely?
- Summary of findings: Does the action appear to have been investigated properly?
- Disciplinary action taken: Does the punishment match the crime?
- Date disciplinary action: Was the action taken timely?

Problem – Not Enough Detail (cont.)

- **Date of violation** : Timeliness of investigation and disciplinary action
- **Meaningful description of violation** : Appropriateness and consistency of disciplinary action
- **Date of investigation** : Timeliness
- **Summary of findings** : Sufficiency of investigation
- **Date of disciplinary action** : Timeliness

Poll #4 – Effective Discipline?

Certain agents are repeatedly re-educated for “misrepresentation”; others lose commission, or are terminated, for the same thing.

Question: Is this a problem?

- A. No, since SponsorX is taking disciplinary action for all proven violations.
- B. No, since SponsorX has shown that it will terminate if necessary
- C. Yes, since re-education is not an appropriate disciplinary measure.
- D. None of the above.

Answer: D

Problem : Not consistent; inappropriate

- 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

Part IV – Frequently Asked Questions

Frequently Asked Questions

Q: Does CMS have a template for the “reported issues” or hotline log?

A: CMS does not have a template for tracking reported issues. The sponsor will have to demonstrate to CMS that it acted promptly on the report and reached a resolution within a reasonable time under the circumstances. In addition, the sponsor will want to capture enough information about the nature of the report to be able to determine if there is a trending problem. The 2013 audit protocols require the sponsor to list all reports including an identification number, source of the report, how the issue was reported, the date of the report, a description of the issue, the date of resolution and how the issue was resolved. (See also Slides 39 and 40 regarding tracking disciplinary actions)

Frequently Asked Questions

Q: We have a small compliance department in our relatively small organization. Therefore, we communicate informally in ad hoc meetings about reports of noncompliance. Must we have a formal tracking system or is it enough to keep track informally through our meeting notes?

A. There must be a formal tracking system. The sponsor does not have to purchase a system but can use a spreadsheet or other sponsor-created system for keeping track of reported issues of noncompliance and suspected or detected FWA.

Frequently Asked Questions

Q: In our organization, it is the Human Resources Department rather than the Compliance Department that handles selecting and imposing disciplinary measures. Is this a violation of CMS requirements?

A: It is not a violation. The sponsor may choose how it wishes to comply with Element V. The Compliance Officer does not necessarily have to select and impose the disciplinary measures. However, the Compliance Officer is responsible for ensuring that disciplinary measures are timely, consistent, appropriate to the violation and effective. Therefore, the Compliance Officer must have a system for communicating with Human Resources to satisfy him/herself that these requirements are being met. In addition, as previously discussed, disciplinary measures must be tracked.

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>