

Mandatory Compliance Plan Requirements

CMS MA and Part D 2010 Fall Conference

Vernisha Robinson
Program Compliance and Oversight Group (PCOG)
Center for Medicare
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Today's presentation

- Overview of Mandatory Compliance Plan Requirements
- Updates to CMS Mandatory Compliance Plan Regulatory Requirements
- Focus of CMS Audits and Enforcement Actions
- Compliance Plan Effectiveness

Overview

- “Effective” compliance program is requirement to contract with CMS
- Seven (7) individual required elements implemented on an interdependent basis
- Program that prevents, detects, and responds to violations of law or policy (including fraud, waste, and abuse issues)
- “Proactive” vs. “reactive” approach to compliance

Overview

- Medicare-specific provisions (e.g., False Claims Act, Anti-Kickback Statute, etc.) must be incorporated into written policies/procedures and standards of conduct
- Program demonstrates the organization's commitment to a "culture" of compliance
- Requires engagement, support, and communication among governing body, senior executives ("C" level positions), and employees

Overview

- Defines expectations for employees for ethical and proper behaviors when conducting the Medicare line of business
- Identifies risks and responds to these risks in a proactive, comprehensive manner
- Includes specific measures to combat fraud, waste and abuse both internally and externally

Updates to Mandatory Compliance Plan Regulations

- Final Regulations - 75 Fed. Reg. 19678 (April 15, 2010)
 - 422 CFR 503(b)(4)(vi), 423 CFR 504(b)(4)(vi)
 - Regulation is effective June 7, 2010
 - Compliance program changes become effective 2011 plan year
- Most changes already contained in existing Medicare Drug Plan Manual Chapter 9 sub-regulatory guidance
- Updates specifically requires compliance program to be “effective”
- Updates provide more detailed regulatory requirements on each of the 7 compliance program elements

Updates to Mandatory Compliance Plan Regulations

Modified language in 422 CFR 503(b)(4)(vi) and 423 CFR 504(b)(4)(vi):

- “Adopt and implement”
- “an *effective* compliance program”
- “that includes measures to prevent, detect, and correct non-compliance with CMS program requirements”
- “as well as measures to prevent, detect, and correct fraud, waste, and abuse”
- “Must *at a minimum* include” the 7 core element requirements listed in the regulation

[*Emphasis added*]

Updates to Mandatory Compliance Plan Regulations

Element 1:

The organization must have written policies, procedures and standards of conduct that...

- The MA and Part D Sponsor's commitment to comply with all applicable federal and state standards
- Describe compliance expectations as embodied in standards of conduct
- Implement compliance operations
- Provide guidance to employees and others for dealing with potential compliance issues
- Identify how to communicate issues to compliance personnel
- Describe how issues are investigated and resolved
- Include policy of non-intimidation and non-retaliation for good faith participation in the compliance program

Updates to Mandatory Compliance Plan Regulations

Element 2:

Designation of a compliance officer (CO) and compliance committee (CC) “who report directly and are accountable to the organization’s chief executive or other senior management” (vs. “who are accountable to senior management”).

- CO must be an employee of the contracting entity, parent organization, or corporate affiliate
- CO may not be an employee of first tier, downstream, or related entity
- CO/CC must periodically report directly to the governing body of organization on activities/status of program, including issues identified, investigated, and resolved
- Governing body must: (1) be knowledgeable about content and operation of the compliance program; and (2) exercise reasonable oversight for implementation and effectiveness of program

Updates to Mandatory Compliance Plan Regulations

Element 3:

Each C/D plan sponsor must establish, implement and provide effective training and education between the CO and organization's employees including, "chief executive or other senior administrator" [new language], managers and "governing body members" [new language] and the organization's first tier, downstream and related entities.

- Must occur at a minimum annually and be made part of the orientation for:
 - a new employee
 - new first tier, downstream or related entities and
 - new appointment to chief executive, manager or governing body member
- First tier, downstream and related entities that have met FWA certifications through enrollment in FFS Medicare program or accreditation as a DMEPOS suppliers are deemed to have met the FWA training and education requirement

Updates to Mandatory Compliance Plan Regulations

Element 4:

Establishment and implementation of effective lines of communication, “ensuring confidentiality” [new language] between the Compliance officer, members of the Compliance committee, employees, managers and “governing body” [new language], and first tier, downstream and related entities:

- These lines of communication must be accessible to all
- Lines of communication allow for anonymous and confidential good faith reporting of potential compliance issues as they are identified.

Updates to Mandatory Compliance Plan Regulations

Element 5:

The organization must have well-publicized disciplinary standards “through the implementation of procedures which encourage good faith participation in the compliance program by all affected individuals” [new language]:

- These standards must include policies that:
 - Articulate expectations for reporting and assisting in resolution of compliance issues
 - Identify non-compliance or unethical behavior
 - Provide for timely, consistent, and effective enforcement of standards when non-compliance or unethical behavior detected

Updates to Mandatory Compliance Plan Regulations

Element 6:

Establish and implement “effective system for routine monitoring and identification of compliance risks” [new language]

Additional requirements:

- System includes routine internal monitoring of compliance risk areas by business units
- System includes periodic internal audits to confirm results of monitoring
- External audits of entity as appropriate, including to evaluate first tier compliance with requirements
- Evaluation of overall effectiveness of the compliance program

Updates to Mandatory Compliance Plan Regulations

Element 7:

Establish and implement procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence and ensure ongoing compliance with CMS requirements” [new language].

- If the sponsor discovers evidence of misconduct related to payment or delivery of prescription drug items or services under the contract, it must conduct a timely reasonable inquiry into that conduct
- Must conduct appropriate corrective actions
- And the sponsor should have procedures to voluntarily self-report potential fraud and misconduct related to the program to CMS, or its designee.

Focus of CMS Audits and Enforcement Actions

2010 Enforcement Actions Based on Deficiencies in Compliance Plan Requirements:

- Immediate Contract Termination (1)
- Marketing & Enrollment Sanction (2)

Enforcement Actions on CMS Website:

<http://www.cms.hhs.gov/MCRAAdvPartDEnrolData/EA/list.asp>

Focus of CMS Audits and Enforcement Actions

- Sponsors chosen for program audits based on risk analysis
- Any sponsors chosen for program audits will also receive a compliance plan effectiveness audit

Focus of CMS Audits and Enforcement Actions

Compliance Plan Audits:

- On-site
- Not just a “paper exercise” (“print, post, and pray”)
- Validation activities (data, personnel, documentation)
- Evaluating Effectiveness – (e.g., can you show you have a system for proactively finding and fixing non-compliance and FWA issues?)
- Includes focus on requirements to implement programs to control and combat fraud, waste, and abuse (FWA)

Focus of CMS Audits and Enforcement Action

Preliminary observations of deficiencies:

Element 1: Standards of conduct are not being made available to delegated entities (“FDRs” - first tier, downstream and related entities)

Element 1: Written policies and procedures are out of date/not Medicare specific. Do not reflect Medicare current laws (e.g., ACA False Claims Act requirement to report overpayments) and regulatory requirements. Also do not reflect entity’s operational practices.

Element 2: Governing body/”C” level management are not knowledgeable about compliance/FWA issues and/or not exercising proper oversight of Medicare operations.

Focus of CMS Audits and Enforcement Action

Preliminary observations:

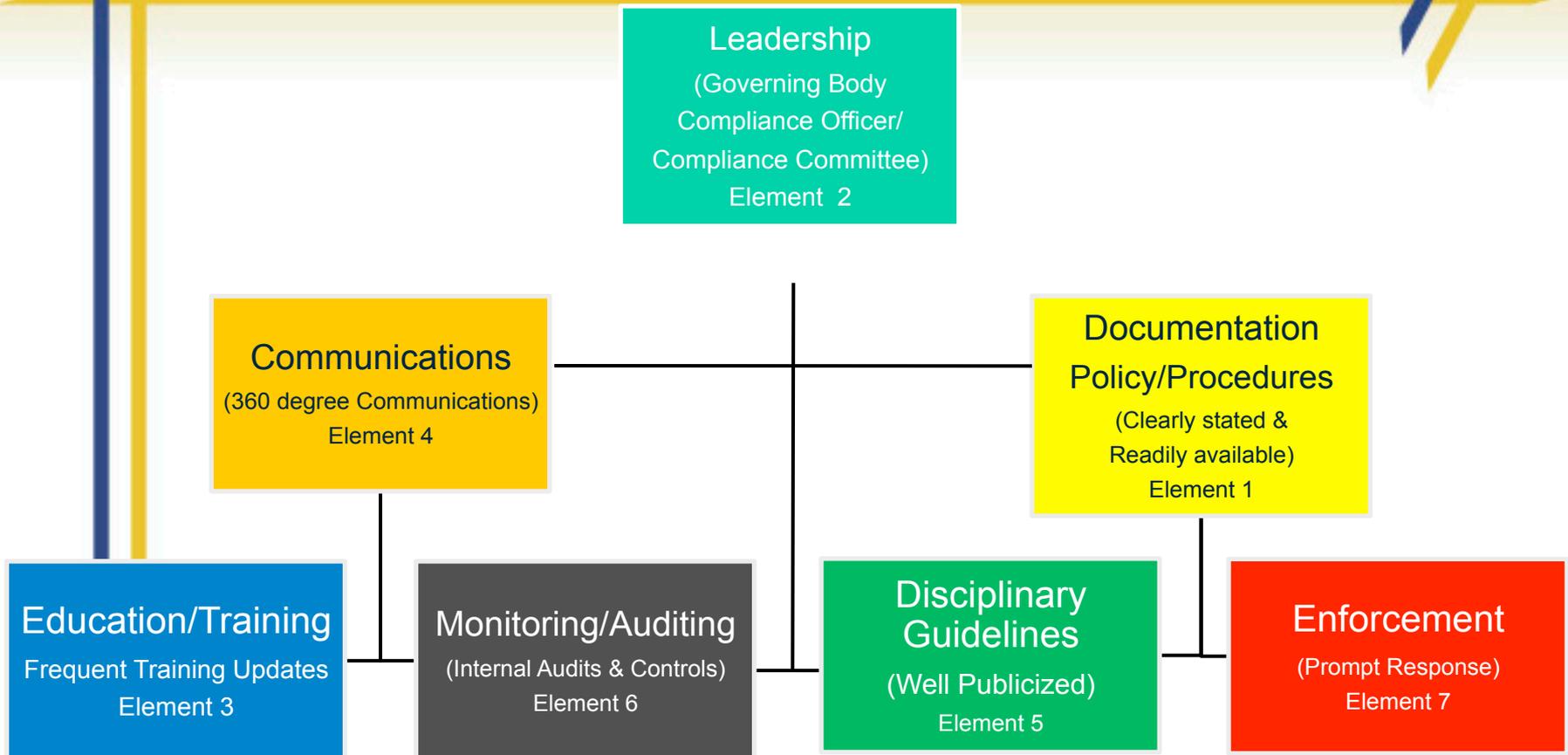
Element 2: Compliance Officer/Committee not reporting or communicating directly to the governing body.

Element 3: Training/education not extending down to FDRs. Training and education programs not measured for effectiveness.

Element 6: Risk assessments not being conducted; monitoring and auditing of first tier, downstream and related entities (FDR's) not being conducted or result in programmatic actions.

FWA requirements: Need for more proactive, targeted efforts to prevent, detect and respond to fraud, waste abuse issues.

Compliance Plan Effectiveness



Compliance Plan Effectiveness

Structure: the overall make up of the organization

- “*Culture*” of compliance endorsed by leadership
- Information exchange between the Compliance Officer, Senior Executives, Governing Body, and employees
- Policies & procedures
- Reporting mechanisms
- Education & training

Compliance Plan Effectiveness

Process: How your system works

- Ongoing risk assessments & monitoring activities
- Incorporating new regulatory and policy changes
- Response and prevention
- Enforcement and discipline
- Systemic corrections
- Accountability of operational areas to compliance department

Compliance Plan Effectiveness

Outcomes: Trends/Results

- Monitoring and audit results trigger a need for updated procedures and retraining employees
- Proper internal controls over delegated entities performing operational functions
- Employee engagement
- Decrease /Increase in Medicare beneficiary and PBM fraud, waste, and abuse
- Evaluate the effectiveness of your compliance plan

Key Points

- Compliance plan effectiveness a top CMS Priority
- Heightened focus of CMS audit and enforcement activities
- Focus of CMS oversight entities (e.g., GAO, OIG, Congressional Committees)
- Congressional Focus - Affordable Care Act requires mandatory compliance plans for all Medicare FFS, Medicaid and CHIP entities
- New regulatory requirements effective 2011

Questions

Contact information

Vernisha.robinson@cms.hhs.gov

(410) 786-6674