

# Mandatory Compliance Plan Requirements

CMS MA and Part D 2010 Fall Conference

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(September 8, 2010)

# 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:

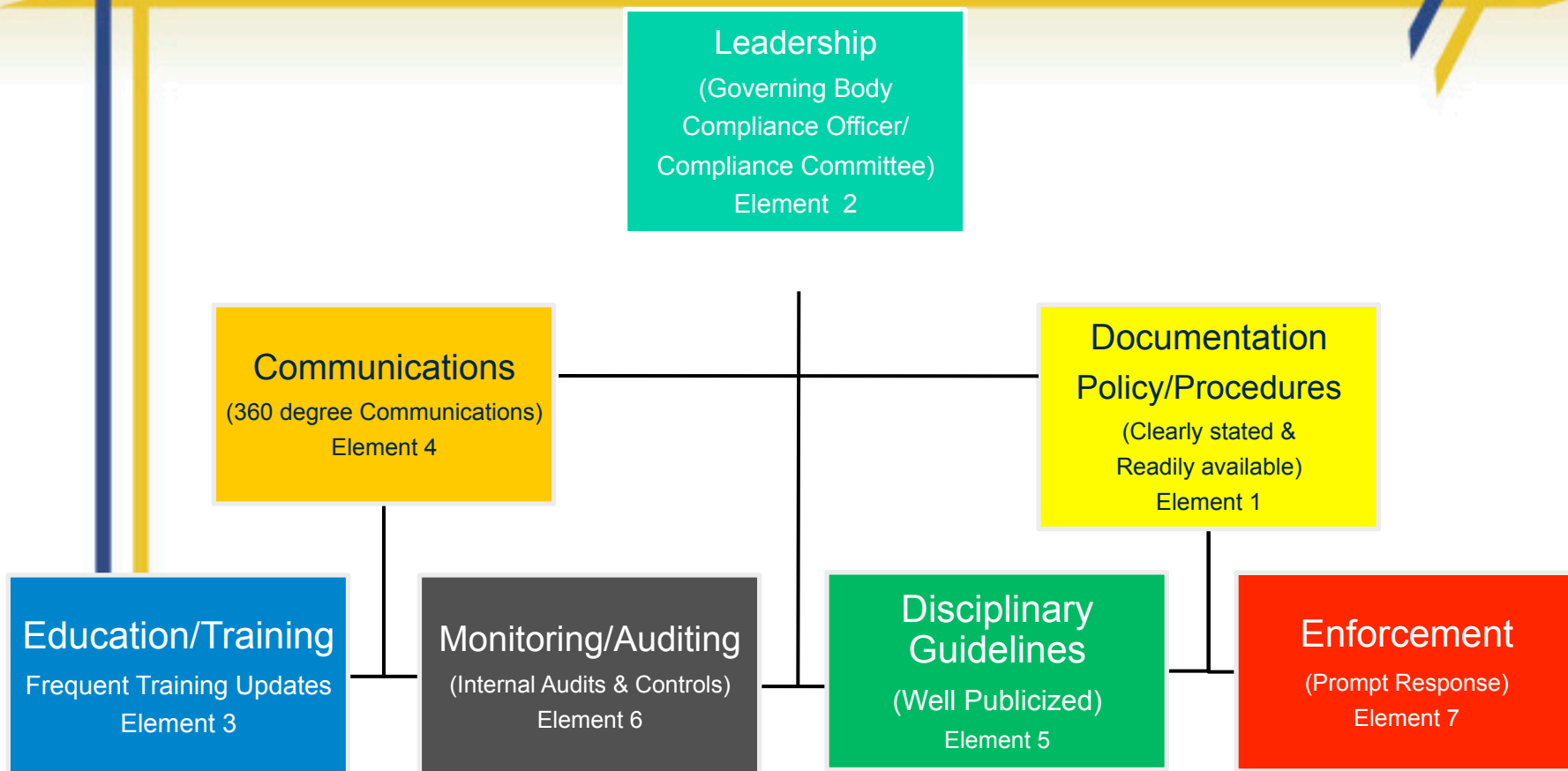
Element 2: Compliance Officer/Committee not reporting or communicating directly to the governing body.

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

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