

# Mandatory Compliance Programs

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# Today's presentation

- Overview of Mandatory Compliance Plan Requirements for Medicare Advantage and Drug Plan Sponsors
- Updates That Strengthen CMS Mandatory Compliance Plan Regulatory Requirements
- Focus of CMS Audits and Enforcement Actions
- CMS Efforts to Evaluate Mandatory Compliance Plan Effectiveness Requirements



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## Overview

- “Effective” compliance program is requirement to contract with CMS as an Medicare Advantage or Drug Plan Sponsor
- 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)
- Requires “proactive” vs. “reactive” approach to compliance



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## 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 execution and outcomes demonstrate the organization’s commitment to a “culture” of compliance
- Requires engagement, support and communication among governing body, senior executives (“C” level positions), and employees



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## 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



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## MA/Drug Plan Compliance Programs

- From inception of these 2 programs - mandatory health care compliance plans
- 7 Elements based on federal sentencing guidelines
- Compliance programs must be “effective”
- Requires “C” level (CEO, CFO, CCO) leadership active knowledge, engagement and exercise of reasonable oversight for implementation and effectiveness



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## MA/Drug Plan Compliance Programs

- Complicated health care compliance scenarios
- Host of applicable health care laws, regulations and contractual requirements (and fraud, waste and abuse (FWA) requirements).
- Often exist within established commercial business infrastructure and compliance models
- Often delegating major functions to other entities (pharmacy benefit managers - PBMs); must exercise proper oversight over these other businesses to ensure compliance



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## Expansion of Mandatory Compliance Programs

- Intense focus of health care oversight entities (e.g., GAO, OIG, Congressional committees)
- Affordable Care Act Sections 6401/6102: expanded mandatory compliance programs to rest of Medicare program (FFS providers/suppliers) and to the Medicaid (providers/suppliers, nursing facilities/skilled nursing facilities) and CHIP programs.
- States also requiring compliance programs – e.g., New York Medicaid program



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## 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
- Updates specifically requires compliance program to be “effective”
- Updates provide more detailed regulatory requirements on each of the 7 compliance program elements



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## 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*]



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## 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



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## 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 (emphasis added)



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## 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



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## 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.



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## 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



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## 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



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## 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.



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## 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>



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## Focus of CMS Audits and Enforcement Actions

- 2010 – first time CMS conducted on-site comprehensive effectiveness audits of MA/Drug plan compliance programs
- If chosen for program audit also receive a compliance plan effectiveness audit
- Selection based on risk assessment
- Note: most entities had required basic structures in place - lacking in effective oversight processes, including internal controls over processes, and outcome measurements



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## 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 systemic process 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)



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## Evaluating Effectiveness – CMS Audits

Element 1: Standards of conduct are not being made available to delegated 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.



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## Evaluating Effectiveness – CMS Audits

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

Element 3: Training/education not extending down to delegated entities. Training and education programs not measured to determine effectiveness.

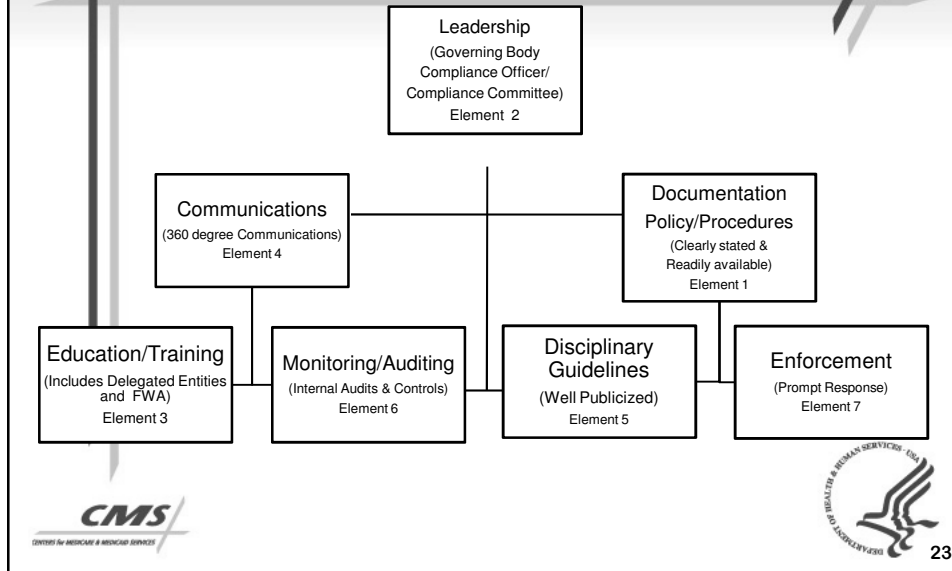
Element 6: Risk assessments not being conducted; monitoring and auditing of delegated entities not being conducted or do not result in follow-up programmatic actions.

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



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# 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



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## 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 and awareness
- Decrease /Increase in Medicare beneficiary and PBM fraud, waste, and abuse
- Evaluate the effectiveness of your compliance plan



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## Evaluating Effectiveness

**Structure** (7 required elements) x

**Process** (how structure is implemented) x

**Outcomes** (are structure and process reducing number and severity of non-compliance) =  
**EFFECTIVENESS**



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## Evaluating Effectiveness

- Key business operations managers accountable for compliance, not CCO.
- Governing body and “C” level execs engaged.
- Use of metrics (“scorecard”) of some sort to assure measurement occurs and focus on improvement
- Example – use of a point system
  - Points added for implementing structures (7 required elements), oversight processes and achieving positive outcomes.
  - Points deducted for lack of structure, processes, regulatory notices, fines, sanctions.



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## Key Points

- Effective compliance programs are cornerstone to achieving health care compliance
- Mandatory compliance programs for MA/Drug plans since inception of programs; expanding to rest of health care sectors by Affordable Care Act
- Structure, process and outcomes “scorecard” metrics approach for determining effectiveness
- Likelihood that MA/Drug plan oversight/audit experiences will inform new FFS, Medicaid and CHIP compliance plan requirements



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## Questions?

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