

Compliance Plan Requirements and Evaluating Effectiveness

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Overview

- The New Regulation: New Compliance Program Requirements
- Compliance Effectiveness:
 - What does “effectiveness” look like?

Compliance Program Requirements

- Seven (7) individual requirements that are most effective on an interdependent basis
- Prevents, detects and responds to violations of law or policy
- Medicare-specific provisions that must be complied with (e.g., False Claims Act, Anti-Kickback Statute, etc.) incorporated into written policies/procedures and standards of conduct

Compliance Program Requirements

- Demonstrates the organization's commitment to a "culture" of compliance
- Requires engagement and communication among governing body, senior executives, and employees
- Defines expectations for employees for ethical and proper behaviors when conducting the Medicare line of business

Compliance Program Requirements

- Promotes a “proactive” vs. “ reactive” approach
- Identifies risks which may have been undetected internally
- Prevents, detects and responds to violations of law or policy

Why are Compliance Programs Important?

- Requirement to contract with CMS
- Roadmap to prevention, early detection and responding to non-compliance issues before they develop into larger issues

Why are Compliance Programs Important?

- Beneficiary impact
- Financial Impact
- Operational Impact
- Regulatory Impact
- Reputational Impact

Audit Focus: 2010 and 2011

- Compliance programs will be a focus of PDP and MAO audits
- 2010 audits will address compliance program requirements, in effect prior to April 15 update to regulation
- 2011 audits will address updated requirements, which were included in the April 15 regulatory change

2010 Enforcement Actions

Substantial deficiencies with compliance programs led to enforcement actions:

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

Enforcement Actions on CMS Website:

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

Compliance Plan Audits

- Compliance Plan Audits
 - On-site
 - Not just a “paper exercise” (“print, post and pray”)
 - Focused on evaluating effectiveness—find and fix problems:
 - Prevent, detect, and respond timely and effectively to compliance issues
 - Validation, including requirements to implement programs to control and combat fraud, waste and abuse (FWA)
- Guidance - Chapter 9 (Prescription Drug Manual) will be updated; uniform set of guidance for PDPs/MAOs

The Updated 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 with new Plan year: January 1, 2011
- Most changes already contained in existing Medicare Drug Plan Manual, Chapter 9, sub-regulatory guidance
- New regulation specifically requires compliance program to be “effective” – this has been in Chapter 9 since 2006
- New regulation provides more detailed regulatory requirements on each of the seven compliance program elements; speaks specifically to “effectiveness”

New Regulation: Introduction

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]

New Regulation: Element 1

Element 1:

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

- Demonstrate 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

New Regulation: Element 2

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

New Regulation: Element 3

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 DMEPOS suppliers are deemed to have met the FWA training and education requirement

New Regulation: Element 4

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

New Regulation: Element 5

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 is detected

New Regulation: Element 6

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 unit
- 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

New Regulation: Element 7

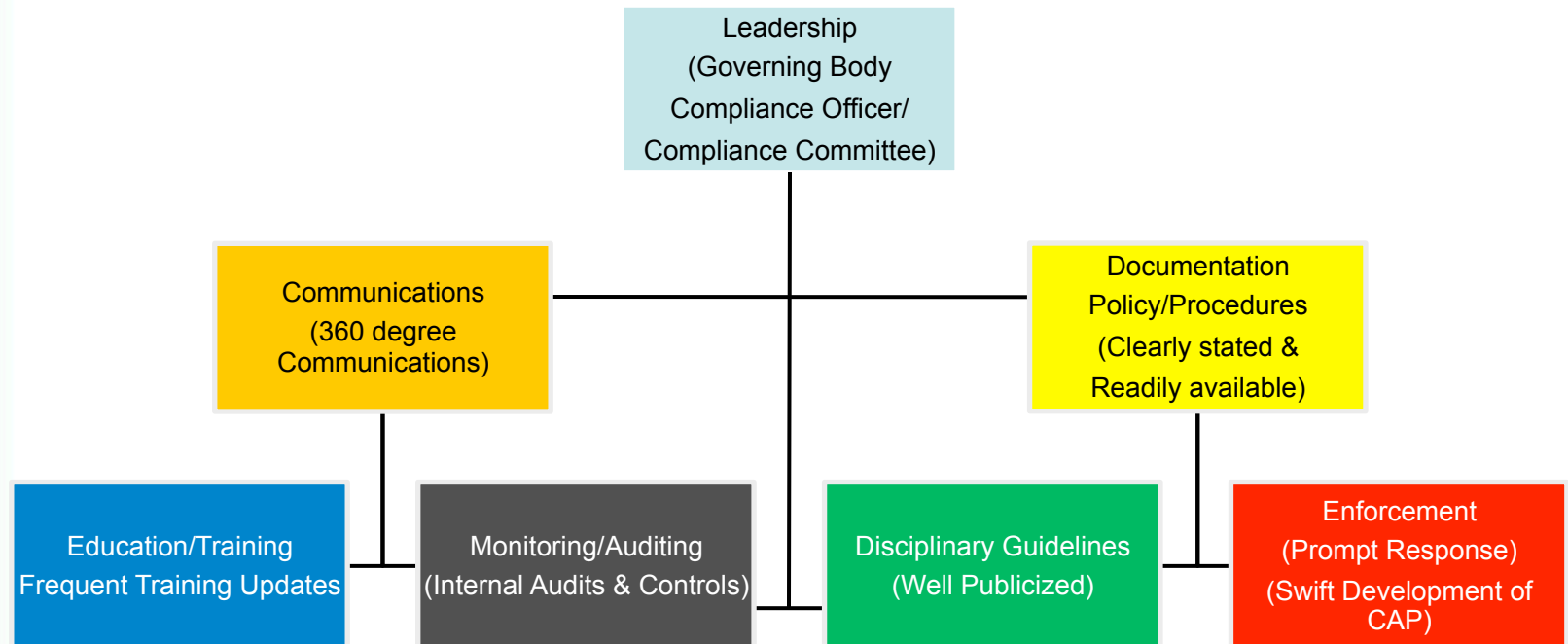
Element 7:

“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 the 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
 - Should have procedures in place to voluntarily self-report potential fraud and misconduct related to the program to CMS, or its designee

Demonstrating an Effective Compliance Program

7 Elements of a Successful Compliance Program



Areas for Measurement

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

Areas for Measurement

Process: How your system works

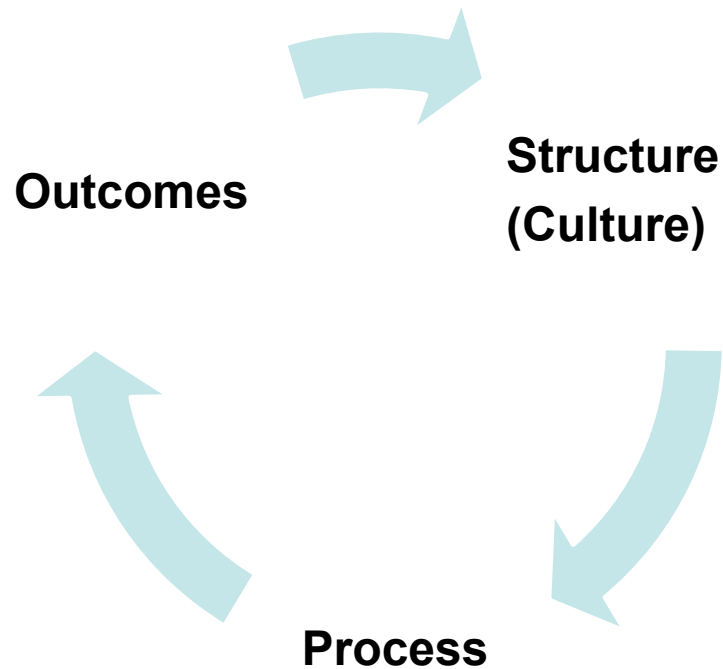
- Ongoing risk assessments & monitoring activities
- Incorporating new regulatory and policy changes
- Response and prevention
- Enforcement and discipline
- Systemic corrections
- Accountability of operational areas to compliance department

Areas for Measurement

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

What Does “Effectiveness” Look Like?



Key Points

- This is a CMS-wide **TOP PRIORITY**
- CMS will be communicating to the OIG, GAO, and other legislative bodies about the results of compliance program effectiveness audits
- Ongoing monitoring and auditing

Questions

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