

HOW TO PREPARE FOR, SURVIVE, AND LEARN FROM A CMS COMPLIANCE PROGRAM AUDIT

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Steps for Compliance Audit Preparedness and Response

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1. Understand current compliance program requirements
2. Learn about 2010 compliance program audits
3. Engage senior leadership
4. Audit Preparation
5. Post-audit program alignment

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Defining Compliance Program Effectiveness

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Seven Compliance Program Elements

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- Regulatory requirements for MA and Part D plans
 - Updated April 15, 2010, 75 Fed. Reg. 19678; 422 CFR 503(b)(4)(vi) and 423 CFR 504(b)(4)(vi)
 - January 1, 2011 implementation deadline for updated requirements
 - More detail on CMS expectations
- Drawing from Ch. 9 of Medicare Prescription Drug Plan Benefit Manual
- Yesterday's "should" is becoming today's "must"
- Include first tier, downstream, and related entities (FDRs) under every element

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Be Prepared to Prove It

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- “Adopt and implement an effective compliance program”
- Show documentation
- Examples
 - Committee meeting agendas and minutes
 - Training sign-in logs
 - Hotline number at employees’ fingertips



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Highlights of Elements 1 and 2

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1. Written policies, procedures, standards of conduct

- Document all aspects of compliance with legal and regulatory requirements (**includes operational policies**)
- Update for changes in regulations and guidance
- Distribute code of conduct and relevant policies to FDRs
- Need a top-down culture of compliance

2. Compliance officer and committee report directly to senior management and board

- Compliance officer and committee **must report directly** to the board and CEO or other senior management
- Compliance officer should not hold other roles that could lead to self-policing
- Board and senior management must **be informed and engaged** in program

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Demonstrating Elements 1 and 2

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1. Written policies, procedures, standards of conduct

- How up-to-date are your compliance and operational policies? What is the process for keeping them current?
- Is your code of conduct clear and easy to find? Have you distributed it to FDRs or confirmed they have a similar code in place?
- How involved is senior management in code development and approval?

2. Compliance officer and committee report directly to senior management and board

- Is the Medicare compliance officer knowledgeable about, and focused on, MA and Part D compliance and operations?
- Does compliance officer report routinely on program and issues?
- Do job descriptions and committee charters stress MA and Part D compliance?

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Highlights of Elements 3 and 4

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3. Effective training and education

- **Orientation and annual** general compliance training for employees, senior management, **board members, and FDRs**
- Includes fraud, waste and abuse laws
- Specialized training by job function

4. Effective lines of communication

- Between compliance officer, compliance committee, employees, managers, board, and contractors
- Hotline communicated and accessible to all (**including providers and FDRs**) and available anonymously

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Demonstrating Elements 3 and 4

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3. Effective training and education

- Can you show through attendance sheets and other documentation that orientation and annual training is taking place?
- Did you provide training for FDRs? If not, do you have attestations that they conducted the required compliance training (including fraud, waste and abuse) internally?

4. Effective lines of communication

- Do you have anonymous reporting mechanisms in place?
- Do employees, providers, and FDRs know about them?
- How do you ensure non-retaliation for good faith reports?

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Highlights of Elements 5 and 6

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5. Well-publicized disciplinary standards and procedures encouraging compliance program participation

- Must communicate **and enforce** expectation of compliance, reporting and assisting with resolution of issues, non-retaliation and non-intimidation

6. Effective system for routine monitoring and identification of compliance issues

- Proper controls and oversight of internal operations **and contractors**
- Measure compliance program effectiveness with **routine data collection** and audits

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Demonstrating Elements 5 and 6

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5. Well-publicized disciplinary standards and procedures encouraging compliance program participation

- How do you publicize the disciplinary policy?
- Have you taken action against employees or FDRs in response to compliance violations (e.g. warnings, termination, performance penalties, contract termination)?
- How do you inform employees and FDRs that they have a duty to report potential compliance violations of fraud, waste and abuse?
- Are employees confident they could report without fear of retaliation?

6. Effective system for routine monitoring and identification of compliance issues

- Does the compliance officer receive routine reporting on compliance-related metrics?
- Do you focus compliance resources based on risk assessments?
- How do you classify and respond to identified risks?
- What are you doing to monitor and audit internal operations and FDRs?

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Highlights of Element 7

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7. Effective system for prompt response, investigation, and correction

- Prompt response to issues raised
- Investigations focused on root cause
- Correct problems at root cause level to reduce potential for recurrence
- Be **prepared to show correction to CMS with data**
- Take appropriate corrective action (disciplinary action, repayment of overpayments)

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Demonstrating Element 7

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7. Effective system for prompt response, investigation, and correction

- How did you handle recent reports and identified issues?
- Did the investigation identify the root cause?
- Did you verify the problem was resolved by collecting data after closing out the issue?

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Insights from November 10, 2010 CMS Proposed Rule Preamble

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- “Our reviews have found that many MA and Part D compliance officers lack basic knowledge about the requirements of the MA and Part D programs.”
- “[M]any compliance officers do not seem to understand that we expect sponsors to actively ensure compliance with Medicare program requirements; that those requirements are distinct from any commercial health or drug plan benefits they may administer; and that they should not rely solely on subcontractors or CMS to identify and resolve . . . compliance matters for them.”
(Emphasis added)

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November 10, 2010 CMS Proposed Rule – Compliance Officer Training

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- Proposed changes to 42 CFR Section 423.504 to address perceived deficiencies
- Compliance officers would be required to complete annual Medicare Advantage (MA) and Part D training beginning in 2013
- “Program knowledge and operational awareness” are essential for MA and Part D compliance officers
- Guidance would set specific training requirements – expect one or two days of program specific training offered by an entity with expertise in MA and Part D compliance or by CMS

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Designating a Medicare Compliance Officer – Balancing Specialized Expertise and Rank

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To satisfy CMS expectations, Medicare compliance officer needs strong knowledge of MA and Part D program requirements and operations

- Expect to be evaluated on depth of compliance officer’s knowledge
- Expertise requires some degree of specialized focus

As a practical matter, Medicare compliance officer also needs high level of authority within organization

- Sufficient clout to obtain needed attention and resources
- Meaningful formal and informal lines of communication with senior leadership, including CEO and board members
- Officer level employees tend to have broad spans of control as opposed to specialized focus

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2010 Compliance Program Effectiveness Audits

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2010 CMS Compliance Plan Audits

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- Intensive on-site performance and compliance audits of MA and Part D plans in 2010 to evaluate true effectiveness of compliance program
 - Some only received compliance program audit
 - Others received operational performance audits along with compliance program effectiveness audit
- Risk-based selection of plans for audit
- Evaluation of fraud, waste and abuse programs, especially in high-fraud geographic areas
- Source: Tranchida, Brenda, "Panel Discussion: 2010 On-Site Performance Audits, CMS 2010 Medicare Advantage and Prescription Drug Plan Fall Conference," September 8, 2010

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2010 CMS Compliance Plan Audits

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- **Very aggressive time table**
- Less than one week to produce extensive documents and responses to questionnaire
- Auditors (could be between 10 and 30 individuals) on site one week after receiving documents
- On-site interview and document requests

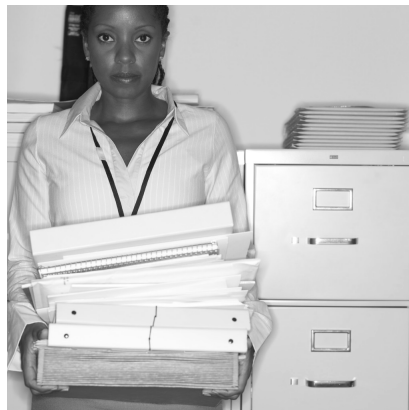


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2010 Compliance Plan Audits

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- **Extensive document production** - examples
- All reports made to compliance officer
- List of all employees
- Compliance program budget
- All reports by compliance officer to senior management and board
- Risk assessment methodology and results



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2010 Compliance Plan Audits

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- **Detailed questionnaire**
 - examples
- Are all employees sufficiently informed about MA and Part D requirements?
- Are core processes documented in a way that facilitates change?
- Are all policies and procedures up to date?



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2010 Compliance Plan Audits

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- **Interviews**
 - Board Member(s)
 - Senior Executives
 - Compliance Personnel
 - Other Employees at all levels
- **Facility Tours**



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Engage Senior Leadership

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Engage Senior Leadership

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- Education is an essential component of the Compliance Officer's job
- **Without top-down support from well-informed senior management, a compliance program cannot be effective**



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Key Messages - Impact on Board of Directors

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- In a compliance audit, the CEO and at least one board member will be interviewed to assess how well they understand and are overseeing the compliance program
- The seven compliance program elements are required by regulation for MA and Part D, and they have become more stringent
 - e.g. Starting in 2011, every board member must receive Medicare compliance training upon joining board and then every year

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Board of Directors Has Ultimate Responsibility for Compliance Program

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- “The **governing body** . . . must be knowledgeable about the content and operation of the compliance program and must exercise reasonable oversight with respect to the implementation and effectiveness of the **compliance programs.**”⁴² C.F.R. §§ 422.503(b)(4)(vi)(B) and 423.504(b)(4)(vi)(B) (emphasis added)
- Management needs to equip the board of directors with the information it needs to fulfill its oversight duties
 - Regulatory requirements for compliance program
 - Compliance program operation and significant issues

Key Messages – Star Ratings

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- In addition to quality measures, CMS audit results factor into the plan star ratings posted on medicare.gov
- Therefore, audit results can indirectly affect financial results
- Beginning in 2012, MA plans with higher star ratings will bid against higher benchmarks than their lower-rated competitors
- Star rating level will also determine what percentage of the rebate (for MA plans with bids below benchmark) can be used to supplement benefits

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Key Messages – Expansion Applications

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- Regulatory compliance can impact future business opportunities, specifically ability to expand service area or offer additional MA and Part D products
- Compliance program audit results factor into annual CMS performance reviews, CMS HPMS Memo, "2010 Application Cycle Past Performance Review Methodology," Dec. 12, 2010
- CMS considers past performance in deciding whether to approve applications for service area applications or new products for current plan sponsors, 42 CFR 422.502(b) and 423.503(b)

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Key Messages - Enforcement

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- CMS actively used its enforcement authority in 2010
 - 1 immediate termination
 - 5 suspensions of enrollment and marketing
 - 10 civil monetary penalties, ranging from \$2,000 to \$586,800
- Enforcement actions are very public – CMS sanction letters detailing deficiencies are posted online

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Audit Preparation

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Prepare Your People

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- Set expectation that compliance and audit staff will be in fire-drill mode for several weeks, possibly with short notice
- Assign legal counsel
- Inform other key personnel of their roles
- Prepare briefing books for senior management
- Be sure all employees have fresh knowledge of the basics (e.g. how to report, code of conduct, compliance officer, security policies)
- Determine unified audit strategy

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Assemble and Review Relevant Documentation

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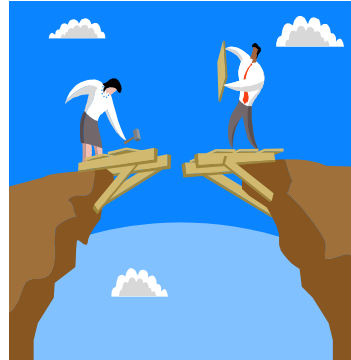
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|--|---|
| <input type="checkbox"/> Compliance, audit, and fraud plans and policies | <input type="checkbox"/> All training policies, content, calendars, and logs |
| <input type="checkbox"/> Compliance officer position description | <input type="checkbox"/> Records of compliance related disciplinary actions |
| <input type="checkbox"/> All compliance related reporting relationships and reports (to/from compliance officer) | <input type="checkbox"/> Risk assessments |
| <input type="checkbox"/> Detailed employee listings | <input type="checkbox"/> FDR monitoring policies and records |
| <input type="checkbox"/> Compliance committee charter, members, minutes, reports | <input type="checkbox"/> Records of identified issues, investigations, and corrective actions |

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Address Gaps Identified

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- Assess the big picture: What “story” will your assembled documentation tell?
- Identify and prioritize issues
 - ▣ Severity
 - ▣ Time needed to resolve
- Begin to address gaps, knowing audit may occur before completion



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Post-Audit Program Enhancements

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Fix It Quickly

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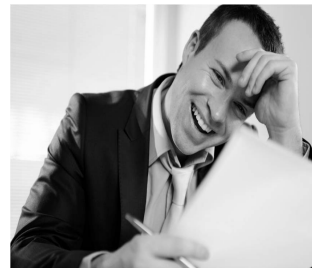
- Don't expect a drawn-out corrective action plan (CAP) approval process (e.g. plan submits a CAP with future deadlines for issue resolution)
- Current regulations authorize CMS to give plan notice of deficiencies and a reasonable opportunity of at least 30 days to “develop and implement a corrective action plan to correct the deficiencies” 42 CFR 422.510(c)(1) and 423.509(c)(1) (emphasis added)
- Anticipate a report of findings with a fixed deadline to –
 - Correct the problems identified
 - Document results showing underlying deficiencies have been corrected
 - Attest that deficiencies have been corrected and compliance program has been modified to address findings

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Align Priorities with Audit Results

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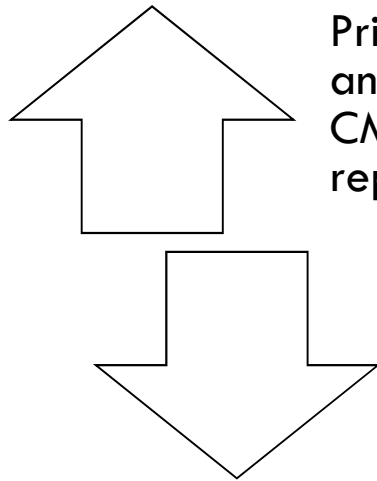
- Find the good news
- After you read the audit report and digest what **is** there, evaluate what **is not** there
- What compliance program components were examined and did not have findings?



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Align Priorities with Audit Results

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Prioritize findings and areas of focus in CMS audit notice and report documents

Don't spend resources on initiatives that are not aligned with audit results

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You are Positioning Your Company to Succeed in a Federalized Regulatory Environment

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Commercial Health Plans Post Health Care Reform

Medicare Advantage and Part D

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