

CMS Compliance Plan Audit How Ready Are You? Get Ready, Get Set, Go For a Perfect Score!



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Overview

- Quotes to Live and Die By
- Review CMS Audit Guide Compliance Plan Elements
- Review impact of CMS Proposed
- Rulemaking for MA and PDP Sponsors
- Share Successful Strategies for Securing Documents

Quotes to Live and Die By

- Forewarned, forearmed, to be prepared is half the victory
- If you are prepared, you will be confident and will do the job
- Always be prepared to start
- Timing Is Everything!
- If you don't have time to do it right the first time, how will you have time to do it the second time?

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CP01 Compliance with Federal and State Standards

The Sponsoring Organization must have and implement a compliance plan that consists of written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State standards, including the CMS Part D User's Manual, by the time a Part D contract with CMS is signed.

42 CFR 423.504(b)(4)(vi)(A)

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CMS Proposed Rulemaking For the Medicare Advantage and Medicare Prescription Drug Programs 10/22/2009

Clarifies existing policy and added language that written policies, procedures and standards of conduct must:

- Articulate the Part D plan sponsor's commitment to comply with all applicable Federal and State standards
- Describe compliance expectations as embodied in the standards of conduct
- Implement the operation of the compliance program
- Provided guidance to employees and others on dealing with potential compliance issues
- Identify how to communicate compliance issues to appropriate compliance personnel
- Describe how potential compliance issues are investigated and resolved
- Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials

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CP02 Designation of Compliance Officer and Committee

The Sponsoring Organization must have and implement a compliance plan that designates a compliance officer and compliance committee accountable to senior management. The Part D Compliance Officer and compliance committee functions may not be delegated or subcontracted.

42 CFR 423.504(b)(4)(vi)(B)

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CMS Proposed Rulemaking For the Medicare Advantage and Medicare Prescription Drug Programs 10/22/2009

- Clarifies that the compliance officer, vested with the day-to-day operations of the compliance program, must be an employee of the plan sponsor
- Adds that the compliance officer and committee must periodically report to the governing body on the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program
- Adds that the governing body must be knowledgeable about the compliance program and exercise reasonable oversight over the implementation and effectiveness of the program
- Clarifies existing CMS policy for senior management to be sufficiently engaged, informed, and to exercise appropriate governance over the organization's compliance program

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CP03 Effective Compliance Training

The Sponsoring Organization must have and implement a compliance plan that includes effective training and education between the compliance officer and Sponsor employees, managers, directors, first-tier, downstream, and related entities.

42 CFR 423.504(b)(4)(vi)(C)
Prescription Drug Benefit Manual Ch 9 Part D Program to Control FWA

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CMS Proposed Rulemaking For the Medicare Advantage and Medicare Prescription Drug Programs 10/22/2009

- Adds several key groups and individuals who are required to have compliance training and education.
- Clarifies that training must occur at least annually and must be made a part of orientation for a new employee, new first tier, downstream and related entities, and new appointment of a CEO, manager or governing body member
- Clarifies existing policy by adding language specifying that providers who have met this requirement through enrollment in the Medicare Fee-for-Service program are deemed to have met the fraud, waste and abuse requirement for Medicare Advantage sponsors. CMS did not propose similar “deeming” language for Medicare Prescription Drug first tier, downstream and related entities.

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CP04 Effective Lines of Communication

The Sponsoring Organization must have and implement a compliance plan that includes effective lines of communication between the compliance officer and Sponsor employees, contractors, first tier, downstream, and related entities, directors, members of the compliance committee, and company leadership.

42 CFR 423.504(b)(4)(vi)(D)

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CMS Proposed Rulemaking For the Medicare Advantage and Medicare Prescription Drug Programs 10/22/2009

- Clarified the requirement that these lines of communication are confidential and accessible to all
- Allow for compliance issues to be reported anonymously and in good faith as issues are identified

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CP05 Disciplinary Guidelines and Enforcement

The Sponsoring Organization must have and implement a compliance plan that includes the enforcement of standards through well-publicized disciplinary guidelines that are approved by the organization's governing body or a committee of the governing body.

42 CFR 423.504(b)(4)(vi)(E)

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CMS Proposed Rulemaking For the Medicare Advantage and Medicare Prescription Drug Programs 10/22/2009

Adds language that the disciplinary guidelines must be implemented to include:

- Policies that articulate expectations for reporting issues and their resolution
- Identify noncompliance or unethical behavior
- Provide for timely, consistent and effective enforcement of the standards when noncompliance or unethical behavior is detected

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CP06 Internal Monitoring and Auditing Procedures

The Sponsoring Organization must have and implement a compliance plan that includes procedures for effective internal monitoring and auditing.

42 CFR 423.504(b)(4)(vi)(F)

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CMS Proposed Rulemaking For the Medicare Advantage and Medicare Prescription Drug Programs 10/22/2009

Clarifies existing language that an effective system includes:

- Internal monitoring and audits
- External audits, as appropriate
- Audits should include the sponsoring organization's first tier entities

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CP07 Response to Detected Offenses and Corrective Action Plan

The Sponsoring Organization must have and implement a compliance plan that includes procedures to ensure a prompt response to detected offenses relating to the organization's contract as a Sponsoring Organization, and must conduct a timely, reasonable inquiry upon discovery of evidence of misconduct related to payment or delivery of prescription drug items or services under the contract. The Sponsoring Organization must also develop and conduct appropriate corrective actions in response to identified violations.

42 CFR 423.504(b)(4)(vi)(G)
Prescription Drug Manual Ch 9 Part D Program to Control FWA

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CMS Proposed Rulemaking For the Medicare Advantage and Medicare Prescription Drug Programs 10/22/2009

Clarifies existing policy to more specifically describe:

- Implementation of a system and procedures for promptly responding to compliance issues as they are raised
- Investigating potential compliance problems identified in course of self-audits
- Correcting such problems promptly and thoroughly to reduce the potential for reoccurrence and ensuring ongoing compliance with CMS requirements

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CP08 Comprehensive Fraud and Abuse Plan

The Sponsoring Organization must have and implement a compliance plan that includes a comprehensive plan to detect, correct, and prevent fraud, waste, and abuse.

42 CFR 423.504(b)(4)(vi)(H)
Prescription Drug Manual Ch 9 Part D Program to Control FWA

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CP09 Executive Manager and Policy-Making Body

The Sponsoring Organization must have an executive manager and policy-making body that exercises oversight and control over policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees. The policy-making body must control the appointment and removal of the executive manager.

42 CFR 423.504(b)(4)(i and iii)

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Document Retrieval

- Identify departments who maintain and/or support key functions
 - Integrity Office
 - Corporate Affairs
 - Corporate Training and/or vendor
 - Compliance Department
- Submit request for supporting documentation

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Organizing Documents

- Determine approach
- Determine naming convention
- Create repository for storing documents
- Create master documentation log

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General Documents

- Medicare C & D Compliance Program
- PBM Compliance Program
- Organizational Charts

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Audit

- ❑ MCD Compliance Audit Policy
- ❑ MCD Compliance Annual Audit Plan
- ❑ Internal Audit Annual Audit Plan
- ❑ Sample Audit Report

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Compliance Officer and Committees

- ❑ Corporate Compliance Officer
 - Resume
 - Position Description
- ❑ Medicare C & D Compliance Officer
 - Resume
 - Position Description
- ❑ Corporate Compliance Committee Charter
- ❑ MCD Compliance Committee Charter
- ❑ FWA Steering Committee Charter

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Communication

- ❑ Code of Business Conduct (CBC)
- ❑ CBC Distribution Policy/Procedure
- ❑ Hotline Answering Policy/Procedure
- ❑ Hotline Database Policy/Procedure
- ❑ Integrity Office Communication Materials
- ❑ Websites and Copies Relevant Articles
- ❑ Hotline Complaint Log for Audit Period
- ❑ Vendor CBC
- ❑ Vendor CBC Distribution Policy/Procedure
- ❑ MCD Compliance Issue Tracking Policy/Procedure
- ❑ MCD Compliance Issue Log for Audit Period

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Discipline

- ❑ Corporate Policy
- ❑ Corporate Website
- ❑ Employee Acknowledgement
- ❑ Disciplinary Process, Suspension, Termination Policy/Procedure
- ❑ Producer Oversight & Disciplinary Action Policy/Procedure

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Investigation

- ❑ Corporate Integrity Process
- ❑ Hotline Investigative Process
- ❑ MCD Investigative Process
- ❑ CTM Complaint Process
- ❑ Potential Misconduct Process
- ❑ MSR Complaint Process
- ❑ Quality of Care Complaint Process
- ❑ Sample Reports Part D Fraud Investigation

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Monitoring

- ❑ Initial Conflict of Interest (COI) Policy/Procedure
- ❑ Annual COI Policy/Procedure
- ❑ COI Part D First Tier Entities Policy/Procedure
- ❑ Employee & Applicant Sanction List Verification Policy/Procedure
- ❑ Provider & Vendor Sanction List Verification Policy/Procedure
- ❑ Sanction Screening Part D First Tier Entities Policy/Procedure
- ❑ Delegated Entities Oversight Policy/Procedure
- ❑ Delegated Entity Oversight Sample Reports

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Monitoring

- ❑ Quarterly Risk Assessment Emails
- ❑ MCD Compliance Regulatory Notification Policy/Procedure
- ❑ Regulatory Notification Log for Audit Period
- ❑ MCD Compliance Corrective Action Plan Log for Audit Period
- ❑ List of Part D First Tier Entities

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Policies MCD Compliance

- ❑ Compliance Program
- ❑ Internal Certification for Attestations
- ❑ Disclosure
- ❑ Document Retention
- ❑ Privacy/Confidentiality
- ❑ RPC Disposition Reports
- ❑ RPC Probe Studies
- ❑ Approval of Marketing Materials
- ❑ Determine if Policies Needed from Business Units

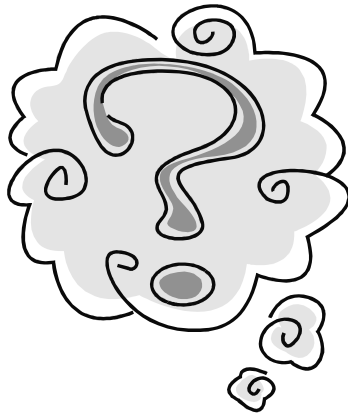
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Training

- ❑ Board of Directors Training
- ❑ Integrity Training Policy/Procedure
- ❑ MCD Compliance Training Policy/Procedure
- ❑ MCD Training Modules
- ❑ Privacy Training Policy/Procedure
- ❑ PBM Compliance Training Policy/Procedure
- ❑ Training Logs, as requested

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Question and Answer Session



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