Attachment A

Compliance Program Guidelines

Chapter 21 Medicare Managed Care Manual & Chapter 9 Medicare Prescription Drug Plan Benefit Manual
High Level Summary of Final Compliance Program Guidelines

Chapter Section	Update
Throughout Document	1. General typos/edits, syntax, verb tense changes, etc. 2. Revised to remove redundancy and repetitiveness 3. Added new sections or moved sections for clarity 4. Clarified "must" v. "should" v. "best practices"
TOC	1. Changed to reflect new and deleted sections as necessary 2. Indicate Element Number before each regulatory requirement (e.g., "Element II: Compliance Officer…")
10	1. Defined must, should, and "best practices" 2. Clarified the applicability of the Chapter to PACE plans
20	1. Revised "Abuse" 2. Defined "Appeal (Part C Plan)" 3. Defined "Appeal (Part D Plan)" 4. Revised "Audit" 5. Revised "Data Analysis" 6. Defined "Deemed Provider or Supplier" 7. Defined "DHHS" and removed "HHS" 8. Deleted "Edit" 9. Defined "Employees" 10. Defined "Enrollee" 11. Defined "External Audit" 12. Deleted "Fallback Prescription Drug Plan" 13. Defined "FDR" 14. Revised "Formulary" 15. Revised "Fraud" 16. Defined "FWA" 17. Defined "Governing Body" 18. Defined "GSA"

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Chapter Section	Update
	19. Defined “Internal Audit” 20. Deleted “MAO” 21. Deleted “MA Prescription Drug Plan (MA PD) 22. Deleted “MEDIC” and revised to “NBI MEDIC” 23. Deleted “Medicaid” 24. Deleted “Medical Review” 25. Defined “Monitoring Activities” 26. Revised “OIG” 27. Deleted “Part D Eligible Individual” 28. Deleted “Part D Plan” 29. Deleted “Part D Plan Sponsor” 30. Deleted “Pharmacy & Therapeutic (P&T) Committee” 31. Defined “PDP” 32. Deleted “Program for All Inclusive Care for the Elderly (PACE)” 33. Deleted “Secretary” 34. Revised “Sponsor” 35. Revised “TrOOP” 36. Revised “Waste”
40	1. Eliminated concept of “core functions” 2. Identified functions that have been delegated to FDRs 3. Identified factors to consider when determining FDR status 4. Left to Sponsor to decide on method to determine which entities are FDRs 5. Removed any contract requirements for FDRs; Added reference to Medicare Managed Care Manual Chapter 11 for more information on FDRs and contract requirements 6. Revised discussion of liability for FDR performance to be consistent with Medicare Managed Care Manual Chapter 11 7. Added chart illustrating FDR relationships in Medicare Part C operations 8. Revised chart illustrating FDR relationships in Medicare Part D operations 9. Deleted “FDR Contract Revocation” subsection 10. Deleted “Data Submission by FDR” subsection 11. Deleted “Preemption of State Laws” subsection

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Chapter Section	Update
50	Changed title from "Components of an Effective Compliance Program" to "Elements of an Effective Compliance Program"
50.1	Clarified that the regulatory criterion can be stated in policies & procedures or Standards of Conduct, but do not need to appear in both
50.1.1	1. Renamed section to "Standards of Conduct" 2. Defined "Standards of Conduct" 3. Described general content and purpose of Standards of Conduct 4. Clarified that Standards of Conduct may be in a separate document or as a supplement to a corporate Code of Conduct 5. Removed prescriptive content requirements for Standards of Conduct 6. Moved list of applicable laws, regulations, and other program requirements to Appendix B 7. Removed the requirement that governing body develop, review, or approve compliance policies and procedures; Section 50.2.3 indicates that the governing body may choose to participate in development, review, and approval of policies and procedures as part of its oversight duties 8. Clarified that the full board should review and approve the Standards of Conduct
50.1.2	1. Renamed section to "Policies and Procedures" 2. Defined "Compliance policies and procedures" 3. Described general content and purpose of policies and procedures 4. Removed prescriptive content requirements for Standards of Conduct included in former section 50.1.1 (including the requirement for policies and procedures around conflicts of interest) 5. Relocated clarification about Standards of Conduct being a separate document or a supplement to the Code of Conduct to Section 50.1.1 6. Relocated discussion about easy to read format and translation of documents to new Section 50.1.3
50.1.3	1. This section is the previous section 50.1.9, renumbered as 50.1.3, Titled "Distribution of Compliance Policies and Procedures and Standards of Conduct" 2. Relocated definition of "Compliance policies and procedures" to Section 50.1.2 3. Removed prescriptive content requirements for policies and procedures 4. Removed discussion of policies and procedures governing avoidance of conflict of interest 5. Provided examples of methods by which Sponsors can distribute policies and procedures and Standards of Conduct to FDRs or ensure that FDRs have comparable policies and Standards

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Chapter Section	Update
50.1.4	Deleted section to avoid repeating regulatory criteria
50.1.5	Deleted section to avoid repeating regulatory criteria
50.1.6	Deleted section to avoid repeating regulatory criteria
50.1.7	Deleted section to avoid repeating regulatory criteria
50.1.8	Governing body responsibilities with respect to compliance policies and procedures and Standards of Conduct are discussed in Section 50.2.3
50.1.9	1. Renumbered section as 50.1.3 (as noted above) 2. Provided examples of distribution methods 3. Relocated discussion of easy to read format and translating documents from Section 50.1.2 4. Clarified distribution to FDRs 5. Eliminated the requirement that FDRs use each Sponsor's Standards of Conduct and policies and procedures; Explained that FDRs may use comparable Standards of Conduct and policies and procedures provided that they meet CMS requirements
50.2	Minor language revisions to accurately reflect the regulation language in 42 C.F.R. §§ 422.503(b)(4)(vi)(B) and 422.504(b)(4)(vi)(B)
50.2.1	1. Clarified that there is no requirement for a Compliance Officer dedicated solely to the Medicare program 2. Clarified requirement regarding employment of Compliance Officer by Sponsor's parent organization or corporate affiliate 3. Defined "direct reporting relationship" 4. Clarified the reporting structure from Compliance Officer to CEO 5. Identified the board responsible for oversight and clarified Compliance Officer's reporting relationships 6. Added to the list of things for which the Compliance Officer should have authority
50.2.2	1. Clarified that there is no requirement for a compliance committee dedicated solely to the Medicare program 2. Clarified the compliance committee's reporting relationships 3. Clarified that Compliance Officer often chairs compliance committee

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Chapter Section	Update
50.2.3	1. Identified the board responsible for oversight 2. Incorporated the discussion of a full board resolution stating commitment to compliant, lawful and ethical conduct from Section 50.1.1 3. Incorporated concept that the governing body may choose to participate in development of Ps&Ps as part of its oversight duties 4. Removed discussion of required frequency for review of the compliance program status 5. Clarified what reasonable governing body oversight includes, and identified duties which may be delegated to senior management 6. Provided examples of activities in which the board or a board committee may choose to be involved 7. Incorporated discussion about approval of SOC by the full board and not a committee 8. Provided examples of indicators of the effectiveness of a compliance program
50.3	Minor language revisions to accurately reflect the regulation language in 42 C.F.R. §§ 422.503(b)(4)(vi)(C) and 422.504(b)(4)(vi)(C)
50.3.1	1. Clarified that Sponsor employees (including governing body members) must receive general compliance training within 90 days of hire 2. Added examples of how sponsors may satisfy general compliance training requirement 3. Removed general compliance "training" requirement for FDRs, and instead clarified that Sponsors must ensure that general compliance information is communicated to their FDRs 4. Provided examples of ways in which Sponsors may communicate general compliance information and expectations to FDRs
50.3.2	1. Removed this section. 2. Former section 50.3.3 "Fraud, Waste and Abuse Training becomes new section 50.3.2
50.3.3	1. Section renumbered as 50.3.2 2. Clarified that additional, specialized or refresher training may be provided based upon FWA risks associated with job function 3. Required Sponsors to provide FDRs with FWA training, provide FDRS with training materials or use CMS FWA training 4. Added reference to HMPS memo on FWA Training Module and instructions for access 5. Indicated when FWA training should occur 6. Removed pharmacy exception regarding training materials
50.3.4	Removed section

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Chapter Section	Update
50.3.5	Removed section
50.4	Minor language revisions to accurately reflect the regulation language in 42 C.F.R. §§ 422.503(b)(4)(vi)(D) and 422.504(b)(4)(vi)(D)
50.4.2	1. Renamed section to "Communication and Reporting Mechanisms" for consistency with regulations 2. Permitted FDRs that partner with multiple Sponsors to train their employees on FDR's reporting processes including emphasis that reports must be made to the appropriate Sponsor
50.5.1	1. Added disciplinary policy requirement that employees must participate in required training
50.5.3	Clarified that records should be maintained for all compliance violation disciplinary actions
50.6	1. Minor language revisions to accurately reflect the regulation language in 42 C.F.R. §§ 422.503(b)(4)(vi)(F) and 422.504(b)(4)(vi)(F) 2. Revised title to include "Auditing" in accordance with the regulation language
50.6.2	Renamed Section "Development of a System to Identify Compliance Risks "
50.6.5	1. Renamed Section "Audit of the Sponsor's Operations and Compliance Program" 2. Clarified the appropriate parties responsible for auditing the compliance program
50.6.6	1. Renamed to Monitoring and Auditing FDRs 2. Clarified that Sponsors must monitor first tier entities for all compliance program requirements, and may conduct risk assessment of first tiers to select reasonable number to audit 3. Clarified that Sponsors must ensure that first tier entities are monitoring compliance of entities with which they contract (the Sponsors' "downstream" entities) and that Sponsors monitor compliance of related entities
50.6.7	1. Renamed "Tracking and Documenting Compliance and Compliance Program Effectiveness" 2. Added best practice tools for sponsors to use to track and document their compliance program

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50.6.8	1. Renamed section "OIG/GSA Exclusion" 2. Included the Medicare Exclusion Database (MED) and the GSA Excluded Parties List System (EPLS) to the OIG List of Excluded Individuals and Entities (LEIE List) monthly screening requirement 3. Revised explanation of MED 4. Included explanation of GSA EPLS 5. Included volunteers and consultants to positions for which exclusion checking is required 6. Clarified that after initial checks are performed for new hires/new contractors, sponsors need only review the monthly updates and supplement files for the exclusions databases monthly thereafter (as opposed to re-screening against entire database monthly). .
50.6.10	1. Clarified that Sponsors are not required to perform law enforcement activities 2. Revised list of potential SIU responsibilities
50.6.11	Expanded list of documentation which may be reviewed by CMS during an on-site audit
50.7	Minor language revisions to accurately reflect the regulation language in 42 C.F.R. §§ 422.503(b)(4)(vi)(G) and 422.504(b)(4)(vi)(G)
50.7.1	1. Replaced "misconduct" with FWA 2. Expanded time within which Sponsor may refer investigations to the NBI MEDIC from two weeks to thirty days
50.7.2	1. Replaced "misconduct" with FWA
50.7.3	1. Renamed section "Procedures for Self-Reporting Potential FWA and Significant Non Compliance" 2. Revised – reporting to NBI MEDIC is fraud *or abuse* 3. Replaced "misconduct" with FWA 4. Replaced "potential" with "suspected, detected or reported"
50.7.6	1. New section – explains actions Sponsors may take in response to CMS-Issued Fraud Alerts 2. Former section "Identifying Providers with a History of Complaints" now 50.7.7
50.7.7	Formerly section 50.7.6
60	Removed this section
60.1	Removed this section
Appendices	Added Appendix B with Laws and Regulations to Consider in Standards of Conduct and/or Training