

	PCHP.CP.106 Routine Monitoring, Auditing and Identification of Compliance Risks V3 PCHP.CP.106	
	Name:	PCHP.CP.106 Routine Monitoring, Auditing and Identification of Compliance Risks
	ID Number:	PCHP.CP.106
	Approval Date:	01/18/2018
	Approved By:	Compliance Committee

Body

Policy Name: Routine Monitoring, Auditing and Identification of Compliance Risks

Scope: Entire Piedmont Workforce

Purpose: Establishes protocols for internal monitoring and auditing methods to evaluate Piedmont and its first tier entities' compliance with Federal and State laws and standards, CMS regulations and continuing guidance, Centra's Code of Conduct and Piedmont's Compliance Plan.

Definitions & Acronyms:

- CMS: Centers for Medicare & Medicaid
 CFR: Code of Federal Regulations
 FDR: First Tier, Downstream and Related Entity
 PBM: Pharmacy Benefit Manager
 FWA: Fraud, Waste and Abuse

Audit: A formal review of compliance with a particular set of standards (e.g., policies and procedures, laws and regulations) used as base measures.

Monitoring: Regular reviews performed as part of normal operations to confirm ongoing compliance and to ensure that corrective actions are undertaken and effective.

Piedmont: "Piedmont" collectively refers to Piedmont Community Health Plan (PCHP), Piedmont Community HealthCare (PCHC) and any future entities that are owned, affiliated with and/or operated by Piedmont.

Policy:

1. Piedmont must establish and implement an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate Piedmont's, including FDRs', compliance with regulatory requirements and the overall effectiveness of the compliance program.
2. Piedmont will engage in internal monitoring and auditing that is designed to evaluate compliance with government regulations, sub-regulatory guidance, contractual agreements, and all applicable Federal and State laws, as well as internal policies and procedures to protect against non-compliance and potential FWA.
3. Piedmont must develop a monitoring and auditing work plan that addresses the risks associated with the **state and federal health care programs**. The Compliance Officer and Compliance Committee are key participants in this process.
4. Piedmont must have a system of ongoing monitoring and auditing that is reflective of its size, organization, risks and resources to assess performance in, at a minimum, areas identified as being at risk. The Compliance Officer will oversee the monitoring and auditing work plan with the assistance of the Compliance Specialist(s), Internal Auditor, and/or applicable committee. Compliance Officer or his/her

designee must receive regular reports from those who are conducting the audits regarding the results of auditing and monitoring and the status and effectiveness of corrective actions taken. Updates on monitoring and auditing results will be provided to the Compliance Committee, the CEO and the Board of Directors.

5. Piedmont must establish and implement policies and procedures to conduct a formal assessment of Piedmont's major compliance and FWA risk areas, such as through a risk assessment. Piedmont's assessment must take into account all business operational areas. Piedmont may consider the following when determining risks in the operational areas:

- A. Size of the department;
- B. Complexity of work;
- C. Amount of training that has taken place;
- D. Past compliance issues;
- E. Regulatory requirements; and
- F. Budget

6. Risks identified by the risk assessment will be ranked to determine which risk areas will have the greatest impact on Piedmont, and Piedmont must prioritize the monitoring and auditing strategy accordingly.

- A. Because risks change and evolve with changes in laws, regulations and operational matters, there will be an ongoing review of potential risks of non-compliance and FWA and a periodic re-evaluation of the assessment.
- B. Risk areas identified through CMS audits and oversight, as well as internal monitoring and auditing, are considered priority risks.

7. Results of the risk assessment will be used to develop a monitoring and auditing work plan. The Compliance Committee may be asked for opinions on the Monitoring and Auditing Work Plan.

- A. The Compliance Officer, or his/her designee, may coordinate with each department to develop the monitoring and auditing work plan based upon the results of the risk assessment. The work plan may include:

- 1). The audits to be performed;
- 2). Audit schedules, including start and end dates;
- 3). Announced or unannounced audits;
- 4). Audit methodology;
- 5). Necessary resources;
- 6). Types of audit – desk or onsite;
- 7). Person(s) responsible;
- 8). Final Audit report due date to compliance officer; and
- 9). Follow up activities from findings.

- B. Piedmont must include in their work plans a process for responding to all monitoring and auditing results and a process for conducting follow-up reviews of areas found to be non-compliant to determine if the implemented corrective actions have fully addressed the underlying problems.

- C. Piedmont's work plan must include a schedule that lists all of the monitoring and auditing activities of the audit year. Sponsors must audit their operational areas and the delegated entities. A standard Auditing and Monitoring Report tool is used to ensure appropriate items are included in each audit, such as:

- 1). Audit Objectives (Regulation or policy requirements);
- 2). Scope and Methodology;
- 3). Findings
 - a. Condition;
 - b. Criteria;
 - c. Cause;
 - d. Effect; and
- 4). Recommendations

8. In developing the types of audits to include in the work plan, Piedmont must:

- A. Determine which risk areas will most likely affect the sponsor, and prioritize the monitoring and audit strategy accordingly; identify which areas are likely to have the most impact on Piedmont.
 - B. Utilize appropriate methods in:
 - 1). Selecting sponsor facilities, pharmacies, providers, claims, and other areas for audit;
 - 2). Determining appropriate sample size;
 - 3). Assess compliance with internal processes and procedures;
 - 4). Extrapolating audit findings using statistically valid methods that comply with generally accepted auditing standards to the full universe;
 - 5). Applying targeted or stratified sampling methods driven by data mining and complaint monitoring.
 - 6). Examining the performance of the compliance program, including a review of training, reporting mechanisms, investigation files, OIG/GSA exclusion list screenings, evidence of employee receipt of Code of Conduct and other attestations used for compliance; and
 - 7). Conduct follow up review by auditing, monitoring or otherwise of areas previously found non-compliant to determine if the implemented corrective actions have fully addressed the underlying problem.
9. The Compliance Officer and Compliance Committee must ensure the implementation of an audit function appropriate to Piedmont's size, scope and structure.
- A. The audit function may be performed by a separate audit department or may be performed by the compliance department.
 - B. Staff dedicated to the audit function will be responsible for monitoring and auditing the sponsor's operational areas to ensure compliance with applicable regulations.
 - C. Adequate resources must be devoted to the audit function considering factors such as size and scope of Piedmont's government programs, its compliance history, current compliance risks, and the amount of resources necessary to meet the goals of its annual work plan.
 - D. Participants in the audit function must be knowledgeable about CMS operational requirements for the areas under review.
 - E. Piedmont must ensure that auditors are independent and do not engage in self-policing.
 - F. Piedmont must ensure that the audit staff have access to the relevant personnel, information, records, and areas of operation under review, including the operational areas at the plan and FDR level.
10. Piedmont will conduct an audit of the compliance program effectiveness (CPE), and the results must be shared with the governing body. The CPE audit should occur at least annually. Staff who are not part of the compliance department should be trained and utilized to perform the audit, or, Piedmont may choose to outsource the CPE audit to external auditors.
11. Piedmont must develop a strategy to monitor and audit its first tier entities to ensure that they are in compliance with all applicable laws and regulations, and to ensure that the first tier entities are monitoring the compliance of the entities with which they contract (i.e. downstream). Refer to PCHP.DE.102 Oversight of First Tier, Downstream and Related Entities for additional guidance.
12. Tracking, Documenting and Reporting Audit Results
- A. At the conclusion of an audit, a comprehensive report will be prepared and distributed to the Compliance Officer and department or first tier entity, within a reasonable timeframe.
 - B. The Compliance Committee will be provided audit results at the quarterly Compliance Committee Meetings.
 - C. The Board of Directors will be provided results of the annual audit on Compliance Program Effectiveness, and any other audit that the Compliance Officer or Committee deems necessary.
 - D. Audit and monitoring activities will be tracked and documented to show the extent to which operational areas and FDRs are meeting compliance goals.

PROCEDURES

1. Piedmont's Compliance Department will develop an annual monitoring and auditing work plan incorporating various resources, including but not limited to:

- A. All Operational areas and FDRs
 - B. Annual Risk Assessment
 - C. CMS Audit Protocols and Common Findings
 - D. Exchange Regulations
 - E. NCQA Standards
2. Operational Areas and FDRs
 - A. Each operational department and FDR is responsible for basic monitoring and auditing activities within their own area to protect against non-compliance with policies and procedures, government regulations, and contractual agreements.
 - B. Departments/FDRs will respond to areas found to be non-compliant, and ensure corrective actions have fully addressed the underlying problem. Non-compliant issues must be reported to the Compliance Department.
 - C. Each department/FDR will provide the Compliance Department with regular reports showing the results of auditing and monitoring and the status and effectiveness of corrective actions taken.
 3. Annual Risk Assessment - Piedmont's Compliance Department conducts an annual risk assessment to determine the types and levels of risks in each of the operational departments. The annual risk assessment includes:
 - A. A review of the Risk Assessment process reminding operational departments of what to keep in mind and how the scoring system works.
 - B. Issues identified in the previous Risk Assessment are discussed and rescored for measurable results.
 - C. The business owners and compliance leads are asked to identify any new risks in their operational areas that may have been identified through internal monitoring and auditing, CMS Audit Protocols and Common Findings, or changes in laws and regulations.
 - D. The new risks are scored for impact, likelihood and controls.
 - E. All risks are then prioritized.
 - F. Based on prioritizations from the risk assessment, the Compliance Department will determine the operational departments in which to audit.
 4. CMS Audit Protocols and Common Findings
 - A. The Compliance Department will review the Audit Protocols when they are released to obtain any information regarding changes to the CMS Audit policy.
 - B. The Compliance Department will promptly review and distribute any new Common Findings memos released by CMS.
 - C. All departments should regularly review the Common Findings memos from CMS, identify any potential areas associated with their job functions, and make adjustments in the policies and procedures as necessary.
 - D. The Compliance Department will consider incorporating applicable protocols and common findings into the annual auditing and monitoring work plan.
 5. Work Plan Development
 - A. Piedmont's Compliance Department will take into consideration all findings from the reviews associated with Procedures 1-4, above.
 - B. The work plan will include categories, frequency and types of the audits for the **audit** year.
 - C. Audits in the work plan may require follow-up review, and extra time will be allocated in the plan to incorporate these reviews.
 - D. The work plan will encompass audits and monitoring over operational areas, FDRs and the Compliance Program.
 6. Audit of Piedmont's Operations, FDRs and Compliance Program
 - A. Piedmont's compliance department is responsible for conducting audits of the operational areas.
 - B. **Piedmont's compliance department and respective business owner are responsible for conducting audits of Piedmont's FDRs.**
 - 1). **Compliance Department facilitates and oversees FDR compliance program requirement audits.**
 - 2). **Business Owner facilitates and oversees FDR delegated function audits.**
 - C. In an effort to achieve the most effective audit results, operational departments and FDRs will allow the Compliance Department unfettered access to relevant personnel, information, records and areas of operation under review.
 - D. Piedmont will outsource the audit process for Compliance Program Effectiveness (CPE).
 7. The Auditing process may include but is not limited to:

- A. Review the Policy and Procedure for the area.
- B. Review CMS guidance to make sure the Policy and Procedure is up to date.
- C. Run any available report(s).
- D. Pull a valid sample.
- E. Audit the samples pulled.
- F. Write summary of audit.
 - 1). Objective
 - 2). Scope and Methodology
 - 3). Findings
- G. Provide Summary of Audit to Department VP and Manager, Compliance Officer, Compliance Committee and Board of Directors if applicable.
- H. Issuance of a Corrective Action Plan if applicable.
- I. Follow up review of areas previously found non-compliant to determine if corrective actions have fully addressed the underlying problem.
- J. Maintain all back up documentation in audit folder.

Equipment: None

Forms and Letters: None

Reference(s): [42 CFR Sections 422.503\(b\)\(4\)\(vi\)\(F\), 423.504\(b\)\(4\)\(vi\)\(F\)](#); Medicare Managed Care Manual, Chapter 21 and Prescription Drug Benefit Manual, Chapter 9 (Rev. 1-11-13) – Compliance Program Guidelines, Section 50.6

Interdisciplinary Review: None

Policy History:

Date	Revision No.	Reason for Change	Sections Affected
01/06/2011	Draft		All
01/19/2011	NEW	<ul style="list-style-type: none"> ▪ Policy template modified changing header and adding Definitions and History sections ▪ Approved by Compliance Committee 	All
07/11/2012	1.0	<ul style="list-style-type: none"> ▪ Responsible Area/Dept changed from Compliance to Organization Wide and Delegated Entities ▪ Method for determining audits to conduct was changed from CMS Universal Audit Guide to areas of necessity based on current problems, CMS surveillance guidance, and OIG work plan (Procedure 1). ▪ Audit schedule is a work in progress rather than a fully developed annual plan (Procedures 2). 	Header and Procedures
01/11/2013	2.0	<ul style="list-style-type: none"> ▪ Reformatted Policy Header. ▪ Updated policies and procedures in conjunction with issuance of new Chapters 9 and 21 of the PDBM and MMCM. 	Header, Policies and Procedures
03/04/2014	3.0	<ul style="list-style-type: none"> ▪ Annual Review and Updated Audit/Monitoring Tool 	All
02/19/2015	4.0	<ul style="list-style-type: none"> ▪ Changed any reference to compliance specialist to compliance manager. ▪ Removed Audit/Monitoring Tool template as it is subject to change for various audits. 	Policy, Procedures, and Attachment
12/17/2015	5.0	<ul style="list-style-type: none"> ▪ Converted Policy to Centra format, new 	All

		numbering system, and new housing location on Centra's Intranet.	
12/29/2016	6.0	<ul style="list-style-type: none"> ▪ Updated language on risk assessment ▪ Added VP and Board of Directors to audit distribution process ▪ Minor clarifications made to language ▪ Removed reference to attachment and removed attachment 	All
1/18/2018	7.0	<ul style="list-style-type: none"> ▪ Updated Policies 3 & 9 to incorporate all books of business ▪ Updated Policy 11 to reference new FDR Oversight Policy. ▪ Updated Procedure 1 to include additional resources ▪ Updated Procedure 6 to specify which departments conduct audits of FDRs. 	Policies 3, 9, 11 Procedures 1, 6

Document Link Manager
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Attachment Manager
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