

	PCHP.CP.107 Prompt Response to Compliance and FWA Issues V3 PCHP.CP.107	
	Name:	PCHP.CP.107 Prompt Response to Compliance and FWA Issues
	ID Number:	PCHP.CP.107
	Approval Date:	01/18/2018
	Approved By:	Compliance Committee

Body

Policy Name: Prompt Response to Compliance and FWA Issues

Scope: Entire Piedmont workforce

Purpose: To ensure prompt response and implementation of applicable Corrective Action Plans relating to detected violations and/or non-compliance with Federal and State laws and standards, CMS regulations, and Piedmont's Code of Conduct and Compliance Plan, including issues of fraud, waste and abuse.

Definitions & Acronyms:

CMS: Centers for Medicare & Medicaid Services

CFR: Code of Federal Regulations

PBM: Pharmacy Benefit Manager

FDR: First Tier, Downstream or Related Entity

FWA: Fraud, Waste and Abuse

CAP: Corrective Action Plan

NBI MEDIC: National Benefit Integrity Medicare Drug Integrity Contractors

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

Issue Ticket: An Issue Ticket is used to track a particular problem, its status, and other relevant data to ensure the problem is worked through to resolution. The ticket is designed to help identify the root cause of the problem and address the 7 elements of an effective compliance plan to mitigate non-compliance.

CAP: A CAP is a more detailed version of the issue ticket requiring the addition of a comprehensive step by step action plan with projected and actual completion dates for each action item. The format includes space to record additional data, i.e. training records. CAPs are used for issues of a more serious or complicated nature, and may be used for issues identified in risk assessments.

Access to Care: The ability for a beneficiary to obtain medically necessary services or prescription drugs when needed. If a member is unable to obtain a benefit that is part of their Piedmont plan, it is considered an "access to care" issue.

Policy:

1. Piedmont will promptly respond to compliance issues as they are raised, investigate potential compliance problems as identified in the course of self-evaluations and audits, correct such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.
2. If Piedmont discovers evidence of misconduct related to payment or delivery of items or services under the contract, it will conduct a timely, reasonable inquiry into that conduct.
 - A. Piedmont must initiate a reasonable inquiry as quickly as possible, but no later than 2 weeks after the date the potential noncompliance or FWA incident was identified.

- B. For issues of a more urgent nature or involving access to care, Piedmont must initiate an immediate response. The compliance department should be notified both verbally and by email upon identification.
 - C. **For Medicare Advantage**, if the issue appears to involve potential fraud, waste or abuse and Piedmont does not have either the time or the resources to investigate in a timely manner, Piedmont should refer the matter to the NBI MEDIC within 30 days of the date the potential fraud, waste, or abuse is identified so that the potentially fraudulent or abusive activity does not continue.
3. Piedmont must conduct appropriate corrective actions (i.e., repayment of overpayments, disciplinary actions against responsible individuals, etc.) in response to potential compliance or FWA violations.
- A. Corrective actions must be designed to correct the underlying problem that results in program violations and to prevent future noncompliance.
 - B. A root cause analysis determines what caused or allowed the FWA, problem or deficiency to occur.
 - C. A corrective action must be tailored to address the particular FWA, problem or deficiency identified, and must include timeframes for specific achievements.
 - D. Piedmont must ensure that FDRs have corrected any deficiencies for FWA or program noncompliance.
 - 1). Piedmont must detail corrective actions in writing and include ramifications if the FDR fails to implement the corrective action satisfactorily.
 - 2). Piedmont must conduct follow-up audits and continue monitoring to ensure corrective action was effective.
 - E. Thorough documentation must be maintained of all deficiencies identified and corrective actions taken.
4. Piedmont should have procedures to voluntarily self-report potential fraud or misconduct related to a government program to CMS or its designee (NBI MEDIC, **Marketplace Integrity Team**) within the parameters set by Piedmont's Compliance Committee.
- A. Self-Reporting of FWA and Medicare program non-compliance is voluntary. CMS nonetheless strongly encourages self-reporting as an important practice in maintaining an effective compliance program.
 - B. Should Piedmont discover an incident of significant **government** program non-compliance, Piedmont should report the incident to CMS as soon as possible after its discovery. This will enable CMS to provide guidance to Piedmont on mitigation of the harm caused by the incident of non-compliance.
5. When a Fraud Alert is received by Piedmont, through CMS, a CMS designee, or delegated entity, Piedmont should review its contractual agreements with any of the identified parties in the alert. Piedmont is also obligated to review past paid claims from entities identified in a fraud alert, and review claims involving the identified providers.
6. Piedmont should maintain files for a period of 10 years on both in-network and out-of-network providers who have been the subject of complaints, investigations, violations, and prosecutions.

Procedures:

1. Conducting a Timely and Reasonable Inquiry

A. Non-Compliance Issues (Issue Tickets)

- 1). Piedmont employees and all contracted FDRs who suspect an issue of noncompliance has occurred

should use any of the methods of reporting available to them in PCHP.CP.104 – Effective Lines of Communication.

- 2). For timely inquiry into business-related compliance issues, employees should rely on policy PCHP.TKT.101 to correctly identify, create, maintain, and close issues. The Ticket system is structured to have operational and departmental areas promptly respond to the issues that have been identified in their business function no later than 2 weeks after identification. **If the issue involves access to care, the response should be immediate and the compliance department should be notified both verbally and by email.**
- 3). Reasonable inquiry may include, but is not limited to:
 - i. Reviewing guidance to determine or confirm non-compliance
 - ii. Review past issues to determine if issue is new or a recurrence
 - iii. Interview employees or FDRs for factual basis of the issue

B. FWA Issues

- 1). Piedmont employees and all contracted FDRs who suspect an issue of FWA should use any of the methods of reporting available to them in PCHP.CP.104 – Effective Lines of Communication.
- 2). Upon receipt of any potential FWA concern from any source, the Compliance Officer and/or Compliance Department will conduct a preliminary investigation of the FWA matter as quickly as possible, but no later than 2 weeks after the date the potential FWA incident was identified.
- 3). Reasonable inquiry may include, but is not limited to:
 - i. Checking the Better Business Bureau
 - ii. Inquire with Delegated Entities if specific providers are cited
 - iii. Checking the OIG/SAM for exclusion(s)
 - iv. General internet searching for complaints or other articles on the subject/provider
 - v. Contact provider's office directly
 - vi. Inquire with complainant to get further information
 - vii. Check criminal database(s) for potential charges/convictions
 - viii. Contact the Bureau of Insurance with the state
 - ix. Review the NBI MEDIC Website
 - x. **Review of the PLATO Website**
- 4). **For Medicare Advantage**, if Piedmont does not have either the time or the resources to investigate the potential fraud or abuse in a timely manner, Piedmont will refer the matter to the NBI MEDIC within 30 days of the date the potential fraud or abuse was identified.

2. Corrective Action Plans (Internal and FDRs)

- A. For issues of a more serious or complicated nature or those identified through internal compliance audits, the Compliance Officer or Compliance Committee may require a written corrective action plan (CAP) to be designed to correct the underlying problem that resulted in program violations, and to prevent future noncompliance.
- B. When Piedmont discovers FWA or non-compliance with an FDR, Piedmont will issue a written notice (CAP) detailing the elements of the corrective actions required, including ramifications if the FDR fails to implement the corrective action satisfactorily. Piedmont will continue to monitor corrective actions after their implementation to ensure that they are effective.
- C. All CAPs must be prepared using the Corrective Action Plan Template which will be provided by the Compliance Department as an addendum to an Issue Ticket.
- D. The CAP should be completed in its entirety to provide a comprehensive step by step action plan with projected and actual completion dates for each action item. The CAP and Issue Ticket ensure all relevant items are addressed including but not limited to:

- 1). Policy and Procedures: Was a policy in place to address the issue? If so, does it require updating? If not, was one created?
 - 2). Compliance Officer/Committee and Governing Body: See Procedure 3 below – "Self-Reporting of Significant Non-Compliance and Potential Fraud, Waste and Abuse" below.
 - 3). Training and Education: Was training or retraining of staff or FDRs necessary?
 - 4). Communication: How was the issue identified? (Risk Assessment, Hotline, FDR, Audit Report)
 - 5). Disciplinary Actions: Were disciplinary actions taken?
 - 6). Auditing and Monitoring: What follow-up auditing or monitoring is needed?
 - 7). Prompt Response: Conduct appropriate and corrective actions in response to the potential violation referenced.
- E. All CAP owners shall work their CAP to resolution. Once completed, the owner should advise the Compliance Officer or designee that the CAP is ready for closure.
- F. The Compliance Department will maintain records of all CAPs in accordance with Piedmont's Record Retention policy.

3. Self-Reporting of Significant Non-Compliance and Potential Fraud, Waste and Abuse

- A. Certain criteria will be analyzed to determine if an issue rises to the level of reporting to the Compliance Committee, CEO, Board of Directors, CMS and/or other government entities. All CAPs will be reported to senior leadership.
- B. **Voluntarily self-reporting:** The following criteria will be used to determine whether the issue should be reported to CMS:
- 1) Potential for direct beneficiary impact;
 - 2) Number of beneficiaries affected;
 - 3) Risk level of harm to beneficiary;
 - 4) Issue warrants reporting to MEDIC or other government authority;
 - 5) Potential for financial impact to the beneficiary, CMS or the plan;
 - 6) Significant system failures (case by case);
 - 7) Common findings issues; and
 - 8) Required by CMS contract.
- C. **NBI MEDIC:** The following criteria will be used to determine whether a Medicare case should be reported to NBI MEDIC:
- 1) Suspected, detected or reported criminal, civil, or administrative law violations;
 - 2) Allegations that extend beyond the health plans, involving multiple health plans, multiple states, or widespread schemes;
 - 3) Allegations involving known patterns of fraud;
 - 4) Pattern of fraud or abuse threatening the life or wellbeing of beneficiaries; and
 - 5) Scheme with large financial risk to a government program or beneficiaries.
- More specific information on making referrals to the NBI MEDIC can be found at the [HPMS](#) website.
- D. Piedmont will also consider reporting the conduct to government authorities such as the Office of Inspector General (through the OIG's Provider Self-Disclosure Protocol), or the Department of Justice, should the issue rise to the level of severity that warrants OIG/DOJ inclusion.
- E. Piedmont maintains a history of complaints, investigations, violations, and prosecutions in accordance with Piedmont's Record Retention Policy.

Equipment: None

Forms and Letters: None

Reference(s): [42 CFR Sections 422.503\(b\)\(4\)\(vi\)\(G\), 423.504\(b\)\(4\)\(vi\)\(G\)](#); Medicare Managed Care Manual,

Chapter 21 and Prescription Drug Benefit Manual, Chapter 9 (Rev. 1-11-13) – Compliance Program Guidelines, Section 50.7

Interdisciplinary Review: Compliance Committee

Policy History

Date	Revision No.	Reason for Change	Sections Affected
01/19/2011	Draft		All
07/22/2011	NEW	<ul style="list-style-type: none"> ▪ Policy template modified changing header ▪ Approved by Compliance Committee 	All
07/10/2012	1.0	<ul style="list-style-type: none"> ▪ Responsible Area/Dept updated to include Delegated Entities ▪ Policy template modified adding Definitions and History sections ▪ Policy updated with Product Manager/Management responsibilities ▪ Added Compliance mail tray downstairs for greater anonymous access; updated attached Violation Form. 	Header, Definitions, Procedures, History & Attachment A
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 PDBM and MMCM. 	Header, Policies and Procedures
03/07/2014	3.0	<ul style="list-style-type: none"> ▪ Updated procedure Section I #2 to remove upstairs and downstairs Compliance trays and add InTouch anonymous reporting contact. 	Procedures
02/16/2015	4.0	<ul style="list-style-type: none"> ▪ Added definitions and processes associated with the new Issue Ticket system. ▪ Removed CAPS Template attachment and provided new location for both the Issue Ticket and CAPS forms on Intranet and S drive. 	Definitions and Procedures
03/23/2015	4.1	<ul style="list-style-type: none"> ▪ Added step under Procedure 3.A.4). where by the Ticket Owner will return the completed ticket to the Submitter for review prior to sending to Compliance for closure. ▪ In Procedure 4.A., generalized schedule for Review Team Meetings to be as needed. 	Procedures
02/04/2016	5.0	<ul style="list-style-type: none"> ▪ Converted Policy to Centra format ▪ Reorganized some policy language, removed the full ticketing language ▪ Included changes to ticketing, CAP, and self-reporting ▪ Updated response time to include immediate response and compliance department notification required for access to care and other urgent issues ▪ Added Definition of Access to Care 	All
12/29/2016	6.0	<ul style="list-style-type: none"> ▪ Updated CAP language 	Procedure 2 and 3

1/18/2018	7.0	<ul style="list-style-type: none"> ▪ Added reporting of CAPs to senior leadership ▪ Specified Medicare Advantage for NBI MEDIC referrals, and updated NBI MEDIC Website to HPMS. ▪ Added references to Marketplace Integrity and PLATO 	Policy 2 & 4 Procedure 1(B)(3) & (4) Procedure 3(C)
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