Elite Health Plan	Dept: Corporate
	Effective Date: January 1, 2025
POLICIES AND PROCEDURES	Policy No: PC401
	Revised
Subject: Compliance – Prompt Response to Detected Offenses	Page **1** of **6**

Reviewed and Accepted By:

(Committee or Department Head) _____ Board Of Directors_____

Authorized Signature: ____ _____ **Date:** ___1/27/2025_____

Purpose: To ensure a process is in place to respond to detected offenses, to initiate corrective action to prevent similar offenses, and to report to government authorities when appropriate.

Scope/Limitations: This policy and procedure applies to all individuals employed, contracted, volunteer or otherwise representing Elite Heath Plan; and those of any FDRs who participate in the administration of Elite Health Plans E's programs.

Policy: Elite Health Plan follows the Centers for Medicare & Medicaid Services (CMS) requirements contained in the Medicare Compliance Program Guidance as well as Parts 422 and 423 of Title 42 of the Code of Federal Regulations (CFR). It is the policy of Elite Health Plan to comply with all applicable regulations and guidance related to MA and Part D lines of business and to implement appropriate corrective actions in response to potential or identified non-compliance with applicable requirements. Non-compliance with regulations or guidance applicable to Medicare programs may be identified through: · Internal Audit department auditing; · Compliance department risk reviews, auditing, or other monitoring; Special Investigations Unit (SIU) activities, delegation oversight, hotline reporting, etc.

All identified issues or potential issues, regardless of how they are reported, are reviewed by the Compliance Officer taking into consideration the following:

- Does the issue have a negative impact on beneficiaries? ·
- How many beneficiaries are affected? ·
- Is there significant harm or potential harm to members?
- Could the issue result in a high volume of calls or complaints to CMS or the Plan? ·
- Does the issue impact access to care for beneficiaries? ·
- Is the deficiency a result of a systemic issue that may impact the Company's ability to comply with applicable requirements?
- Does the issue require CMS intervention to resolve? ·
- Could there be political or media interest in the issue that could generate calls to CMS?
- Does the issue involve or was it caused by a delegate or vendor over whom the Plan has oversight responsibility?
- Did the issue involve or impact a key compliance area of focus, such as enrollment/disenrollment, sales/marketing allegations, appeals and grievances, delegated vendors and access to prescription drugs?

If the Compliance Officer or designee determines the issue is reportable to CMS, the Compliance department reports the issue to the appropriate CMS designee within 48 hours of identification of the potential non-compliance. The Compliance department tracks Issue Write-Ups within its Virtual Compliance Officer, or Virtual Incident Manager Software. A Corrective Action Request may be issued if corrective action deliverables are not completed timely and the delay is not justified.

Any reported issue that affects member access to care or well-being (including financial wellbeing) is escalated to Executive Management and Delegation Oversight, and the Compliance Committee, should the corrective action plan due date fall past due beyond 30 days. Corrective Action Plans (CAP) may be required when deficiencies with CMS rules are identified through auditing or monitoring activities. Failure to cooperate with the CAP process may result in disciplinary action, up to and including termination of employment, or termination of delegated responsibility. CAP tasks typically include, but may not be limited to: · Review and revision, as applicable, of policies, procedures, desktop work instructions, workflows, member materials, and others, to ensure compliance with CMS regulation and guidelines; · Training of applicable staff on policies, procedures, desktop work instructions, workflows, member materials, and others; Periodic self-auditing/monitoring by the applicable functional areas process to ensure compliance is achieved and maintained; and Reporting of self-audit/monitoring results to Compliance and Compliance Committees with oversight authority.

The Compliance department reviews CAPs developed and associated tasks to determine if it is reasonable to expect compliance to be achieved and maintained once the corrective action plan is effectuated and brought to the Corporate Compliance Committee with a recommendation to approve and move towards validation, if acceptable. If concerns are identified, the Compliance department and/or the functional area owner work to revise the corrective action plan as appropriate. The Plan requires all FDRs to submit a CAP when deficiencies are identified through compliance audits, ongoing monitoring or self-reporting. Elite Health Plan will take administrative action, which may include termination of the contract, if an FDR does not comply with a CAP or does not meet its regulatory obligations as outlined in its contract with Elite Health Plan and/or the Plan Manual. Identified deficiencies that involve potential fraud, waste, abuse or illegal activity are referred to the MEDIC, the Office of the Inspector General (OIG), and/or law enforcement as appropriate. CMS issues alerts to Part D sponsors concerning fraud schemes identified by law enforcement officials. The Plan complies with requests by law enforcement, CMS and CMS' designees regarding monitoring of providers within the Plan’s network that CMS has identified as potentially abusive or fraudulent

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Policy/Procedure:

1. Corrective Action Requests When non-compliance is identified by the Compliance department or a regulatory agency, the Compliance department:

a. Initiates a CAR by completing portion Corrective Action Request template;

b. Submits the CAR template to the Corporate Compliance Committee and functional area owner of process. Vice President(s) of the applicable functional area for completion.

c. Creates a CAP in the software to track the corrective actions;

d. Works with the Functional Area Owner and Vice Present, as requested, to assist with identification of the Root Cause, Corrective Action Plan, and Corrective Action Plan Tasks;

e. Reviews the completed Corrective Action Request upon receipt to ensure the Root Cause, Corrective Action Plan, and Corrective Action Plan Tasks were documented appropriately and it is reasonable to expect that compliance will be achieved and maintained once the plan and associated tasks are effectuated;

f. Works with the Functional Area owner or VP(s) to revise the corrective action plan and/or associated tasks if concerns are identified;

g. Documents the Root Cause, Corrective Action Plan, and Corrective Action Plan Tasks in the software;

h. Creates Tasks in the software CAP to track each of the corrective action deliverables to closure;

i. Requests and tracks updates to the corrective action deliverables;

j. Escalates to the Corporate Compliance Committee; or Delegation Oversight Committee, or Executive Team if a corrective action deliverable is non-timely and the delay is not justified;

k. Ensures non-compliance issues that affect member access to care or well-being (including financial well-being) are escalated to Executive Management when the corrective action plan due date falls past due beyond 30 days;

l. Records closure of the corrective action plan in the software once confirmation is received that the CAP has been validated and compliance was achieved and, where warranted, monitoring is conducted to ensure compliance is maintained; and

m. Advises the reporting Functional Area Owner, VP, or FDR the issue is closed and that the Compliance department may perform validation monitoring anytime in the future to confirm compliance is maintained.

2. Issue Write Ups Upon receipt of an Issue Write-Up not related to possible fraud or other misconduct, the Compliance department:

a. Ensures the reporting functional area completed write up in software system for tracking and that it is completed appropriately and includes, at a minimum:

i. The affected CMS contract(s); ii. An executive summary of the issue; iii. The regulatory and/or internal requirement(s) that apply to the issue;
iv. A description of the incident;
v. A description of similar incidents that occurred previously; vi. The number and demographics of impacted members;
vii. A root cause analysis; and viii. The corrective action plan describing steps to correct and prevent recurrence of the issue.

b. Determines if it is reasonable to expect that compliance will be achieved and maintained once the plan and associated tasks are effectuated;
c. Works with the owner(s) to revise the corrective action plan and/or associated tasks if concerns are identified;
d. Software updated to track the issue;
e. Determines if the issue is reportable to CMS;

i. If yes, the issue is reported to the applicable CMS designee within 48 hours of identifying the issue. The report to CMS includes all facts in sections 1a through 1h above that are known at the time the report is made.

f. Advises the reporting functional area whether the issue was reported to CMS;
g. Tracks and records updates to corrective action deliverables in the software;

h. Escalates to Compliance Committee; Delegation Oversight Committee for FDRs, and Executive Team if a corrective action deliverable is non-timely and the delay is not justified; i. Ensures reported issues that affect member access to care or well-being (including financial well-being) are escalated to Executive Management by the Compliance Officer when the corrective action plan due date falls past due beyond 30 days;
j. Records closure of the issue in software once confirmation is received the applicable owner(s) and compliance can be shown or does their own validation audit for compliance to demonstrate was achieved and, where warranted, monitoring is conducted to ensure compliance is maintained; and
k. Advises the reporting owner(s) the issue is closed and that the Compliance department may perform validation monitoring anytime in the future to confirm compliance is maintained. Issues Related to Possible Fraud or Illegal Activity Upon identification of a MA or Part D compliance issue related to possible fraud or illegal activity, the Medicare Compliance department or reporting Business Unit promptly routes the issue to the SIU for investigation and possible referral to the MEDIC, OIG, and/or other law agency. Reports all compliance activity through the governance committee structure and ultimately the Board of Directors.

Definitions

Associate: Associate For purposes of this policy and procedure, the term “associate” includes regular employees, temporary employees, volunteers, and board members, members, operational units, entities, or departments with specific business functionality. Centers for Medicare & Medicaid Services (CMS) The Federal agency within the U.S. Department of Health and Human Services (HHS) that administers the Medicare and Medicaid programs.

Compliance Officer An associate employed full time by the Plan responsible, either directly or through delegation, for overseeing the company’s compliance program.

Compliance Program: A written document that defines the specific manner in which the compliance program is implemented across the organization.

Corrective Action Request (CAR) Request for corrective action to address an adverse finding.

Corrective Action Plan (CAP) A description of the actions to be taken to correct deficiencies identified during an audit, ongoing monitoring, or self-reporting; and to ensure future compliance with the applicable requirements. A CAP usually contains accountabilities and sets timelines. Delegation

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Oversight Committee is responsible for overseeing the ongoing compliance of delegated medical, dental, vision, chiropractic, alternative care and mental health service providers.

Downstream Entity Any party that enters into a written arrangement, acceptable to CMS, below the level of the arrangement between Elite Health Plan and a first tier entity. These written arrangements continue down to the level of ultimate provider of health, pharmacy and/or administrative services to members. First Tier Entity Any party that enters into a written arrangement acceptable to CMS with Elite Health Plan to provide administrative services or health care or pharmacy services for a Medicare eligible individual under a MA or Part D Plan. The term will also include delegates, such as providers, third party administrators, or other entities who have been delegated responsibility for activities defined in this policy.

Medicare Advantage (MA) An organization that is a public or private entity organized and licensed by a state as a risk-bearing entity that is certified by CMS as meeting the requirements to offer an MA plan. Medicare Advantage Organization (MAO) An organization that is a public or private entity organized and licensed by a State as a risk-bearing entity that is certified by CMS as meeting the requirements to offer an MA plan.

References: Title 42 Code of Federal Regulations (CFR) · 42 C.F.R. §422.503(b)(4)(vi)(G) · 42 C.F.R. §423.504(b)(4)(vi)(G) CMS Medicare Managed Care Manual • Chapter 11 - Medicare Advantage Application Procedures and Contract Requirements – Section 20.1 • Chapter 21 – Medicare Compliance Program Guidelines – Section 50.7 Prescription Drug Benefit Manual • Chapter 9 – Medicare Compliance Program Guidelines