

Title: Compliance Violations Investigations, Prompt Responses and Reporting	Policy Number: CMP08V.04
Issued For: <input checked="" type="checkbox"/> BayCare Select Health Plans, Inc.	Original Issue Date: 09/01/2018 Select one below and input date, if applicable: <input checked="" type="checkbox"/> Date Last Reviewed / Revised 07/08/2020 OR <input type="checkbox"/> Date Last Reviewed / No Revisions _____ OR <input type="checkbox"/> New Policy / N/A
Issuing Department: Compliance	Effective Date: 07/15/2020
Approved and Owned by: Joanna Tofani, Chief Compliance Officer <small>DocuSigned by:</small>  <hr/> Signature	Date Approved and By Whom: 07/15/2020 Compliance Committee

I. PURPOSE

To set forth BayCare Select Health Plans, Inc.’s (BayCare Select) policy and procedures for investigating and resolving reported allegations of non-compliance and FWA. Additionally, this policy describes the mechanisms for reporting actual or suspected compliance violations to regulatory agencies in the event disclosure to such agencies is indicated or required.

II. SCOPE

This policy applies to all BayCare Select Workforce members and the BayCare Select Board of Directors (Board), FDRs and where applicable, providers and members.

III. DEFINITIONS

CMS: The Centers for Medicare & Medicaid Services. This is the agency within the Department of Health and Human Services (HHS) that is responsible for directing the national Medicare program.

Compliance Violation: For the purpose of this policy a Compliance Violation is an activity that results or may result in the violation of any type of law or regulation, the Corporate Compliance Program, the Code of Conduct, or certain Policies and Procedures, whether deliberate or unintentional, by either an internal or external individual/entity. Compliance Violations may include, but are not limited to:

- Operational errors or failures (systems or processes) that result in actual or potential non-compliance and/or impact to beneficiaries, clients, customers, or vendors (i.e.

- untimeliness, inaccurate data, late payment, website errors/ functionality issues, etc.)
- Violation of regulatory requirements or guidelines
 - Fraud, waste, or abuse (FWA)
 - Unethical behavior
 - Improper accounting practices
 - Breach of confidentiality/privacy
 - Theft or improper use of BayCare Select assets
 - Misuse or improper access to or disclosure of protected health information
 - Discrimination, harassment, or retaliation
 - Falsifying documents
 - Kickbacks, inducements, or other illegal remuneration
 - Improper employment practices
 - Conflict of interest
 - Improper marketing or advertising activities
 - Attempts to conceal a violation or evidence of a potential violation
 - Failure to report a known or suspected violation or evidence of a potential or actual violation

First Tier, Downstream, or Related Entity (FDR): Has the meaning of the respective terms as defined in the Medicare Managed Care Manual, Chapter 21 – Compliance Program Guidelines and Prescription Drug Benefit Manual, Chapter 9 – Compliance Program Guidelines.

Fraud, Waste, and Abuse or FWA: Have the meanings of the respective terms as defined in the Medicare Managed Care Manual, Chapter 21 – Compliance Program Guidelines and Prescription Drug Benefit Manual, Chapter 9 – Compliance Program Guidelines.

MEDIC: The Medicare Drug Integrity Contractor (MEDIC) is an organization contracted by CMS for fraud and abuse monitoring. The MEDIC's primary role is to identify potential fraud and abuse in Medicare Part C and Part D.

Protected Health Information (PHI): Has the meaning of PHI as defined by the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, the Standards for Privacy of Individually Identifiable Health information at 45 CFR part 160 and part 164, subparts A and E, and the Security Standards for the Protection of Electronic PHI at 45 CFR part 160 and part 164, subpart C. Electronic Protected Health Information (ePHI) is Protected Health Information (PHI) transmitted by or maintained in electronic format.

Retaliation: Retaliation is defined as any adverse action that may include but is not limited to the following conduct: discharge, demotion, suspension, harassment, denial of promotion, transfer, or any other action that discriminates against the employee.

Workforce: For purposes of this policy, the full- and part-time employees, temporary employees, consultants, and volunteers of BayCare Select, and other persons whose conduct in the performance of work for BayCare Select is under the direct control of BayCare Select, whether or not they are paid by BayCare Select.

IV. OWNERSHIP

The Chief Compliance Officer (CCO) is responsible for administration and oversight, of this policy.

V. POLICY

- A. It is BayCare Select's policy to comply with applicable federal, state and local laws and all rules and regulations established by regulatory agencies, including CMS, and to promptly investigate any allegation of a Compliance Violation.
- B. Actual and suspected Compliance Violations may be reported via a variety of mechanisms, including but not limited to via BayCare Select's anonymous hotline, via email or in person. See CMP20 Non-Retaliation / Duty to Report.
- C. Regardless of the mechanism used to report an actual or suspected Compliance Violation, the report of the issue must be immediately directed to the CCO for documentation, processing, and reporting. This includes alleged violations of HIPAA Privacy and Security requirements. The CCO will be responsible for the investigation, coordinating with the BayCare System points of contact on HIPAA Privacy and Security incidents / investigations, as needed.
- D. All reports of actual or suspected Compliance Violations are taken seriously and investigated timely.
- E. BayCare Select Workforce members and FDRs are required to cooperate fully in investigations and to assist in the resolution of Compliance Violations.
- F. The CCO documents and oversees corrective actions for confirmed non-compliance and/or FWA.
- G. BayCare Select strives to maintain the confidentiality of any individual or FDR who reports a compliance concern or violation, to the fullest extent permissible by law and practically possible. However, disclosure of an individual's identity, if known, may be necessary in order to fully investigate the concern.

VI. PROCEDURES

A. Investigation of Alleged Compliance Violation:

- 1. When an inquiry or allegation of a Compliance Violation is received, the CCO or his or her designee (investigator), will open a case in an incident tracking tool which will be maintained by the BayCare Select Compliance Department.
- 2. The investigator maintains all documentation related to the case in the BayCare Select's Compliance Department incident tracking tool for access and availability throughout the course of the investigation.
- 3. The investigator initiates a case investigation as soon as possible, but no later than two weeks, after an actual or suspected Compliance Violation is identified.

4. The investigator takes direction from the CCO on the investigation. At any point in the investigation, the CCO may seek assistance from Legal Counsel, Team Resources, the Compliance Committee and/or BayCare Select leadership and management as necessary and appropriate.
 - a. Legal Counsel is involved in the investigation and decision-making on any actual or suspected Compliance Violation deemed to be potentially unlawful.
 - b. The CCO:
 - i. Has the authority to conduct compliance investigations independently;
 - ii. May, at his or her discretion and with approval by the President, retain external assistance (such as outside counsel, auditors, or other experts) to conduct compliance investigations, if necessary. If the President is allegedly involved in an actual or suspected Compliance Violation and the CCO wishes to retain external assistance, the CCO may seek approval to do so from the Board;
 - iii. Will notify the Chair of the Board if an actual or suspected Compliance Violation involves an executive officer or Board member;
 - iv. Will notify the Chair of the Board if an actual or suspected Compliance Violation involves the CCO to recuse him/herself from involvement in the investigation.
5. If necessary and appropriate, investigations will be conducted confidentially with notice to appropriate members of leadership and / or the Board Chair.
6. The investigator investigates to determine the validity of the Compliance Violation. Depending upon the nature of the actual or suspected Compliance Violation, will use necessary tools to conduct the investigation (i.e., interviews, document review). The investigator reviews the specific issues cited in the allegation and, in doing so, may contact other departments to establish the facts of the inquiry/allegation. Investigations are conducted in a fair and impartial manner, and may include any of the following activities:
 - a. Telephone or in-person interviews with:
 - i. The person or entity making the report, if known;
 - ii. The subject of the report;
 - iii. Persons in an authoritative position over, subordinate to, or a co- worker of the subject of the report;
 - iv. Any other person or entity identified in the allegation, either directly or indirectly.
 - b. Review of relevant documents, communications, such as personnel files, customer service or claims files, analysis reports, or medical records.
7. If in the course of a compliance investigation, it is determined that the presence of employees under investigation may jeopardize the investigative process, the CCO may, in coordination with Team Resources and Legal Counsel, request that those employees be removed from their specific work activity or be suspended from their employment

until the investigation is completed. The nature and length of such suspension will be determined on a case by case basis as necessary to the circumstances of each investigation. The final decisions regarding employee reassignment or suspension will be made by Team Resources.

B. Outcomes of Investigation:

1. Upon conclusion of the investigation, the investigator will meet with the CCO and outline the findings of the investigation, recommended disciplinary action, and if necessary, referral to regulatory agencies or law enforcement, and any other appropriate corrective actions. The CCO will make a final determination as to whether the allegation was:
 - a. founded (firm evidence to support),
 - b. unfounded (evidence does not support), or
 - c. inconclusive or unsubstantiated (not precisely determined or supported).
2. **Founded Allegations:** Immediate steps will be taken to correct any founded compliance violation. The CCO (or designee), with advice from Legal Counsel or others as appropriate, will determine any necessary corrective actions to timely address the allegation and notify affected parties, including the individual alleging the compliance violation.
 - a. **CAPs and Disciplinary Action:**
 - i. Individuals involved in a founded Compliance Violation will be subject to disciplinary action, in accordance with CMP21 Disciplinary Standards, and the CCO may also request a corrective action plan (CAP), in accordance with CMP23 Corrective Action Plan. FDRs involved in a founded Compliance Violation may be subject to contractual penalties, up to and including termination of their contract, and/or the CCO may request a CAP, in accordance with CMP23 Corrective Action Plan. The individual/FDR will be informed of the allegation and outcome of the investigation and will be provided an opportunity to submit a written appeal to the CCO if desired prior to any corrective or disciplinary action being implemented.
 - 1) The CCO will validate that the CAP / disciplinary actions implemented adequately correct the root cause(s) of the founded Compliance Violation.
 - 2) If overpayments are underpayments are involved, the CCO will ensure the CAP timely corrects the overpayment or underpayment.
 - 3) If Prescription Drug Events (PDE) are involved and must be reversed, the CCO will work with BayCare Select's Pharmacy Benefit Manager to ensure the PDEs are timely reversed.
 - ii. As soon as a Compliance Violation is identified, business owners and FDRs are expected to take immediate actions as necessary to resolve or minimize the impact of a Compliance Violation and prevent recurrence, without waiting for a formal CAP to be requested.

- b. **Self-Disclosures to CMS:** If it is determined that criminal activity, a violation of the law affecting a federal health care benefit, or a violation of any other activity that is governed by a regulatory agency has occurred, the CCO is responsible for escalating the issue for determination as to whether any required disclosure to outside authorities is necessary.
- i. While CMS encourages self-reporting of significant issues of noncompliance and FWA, self-reporting issues is voluntary and at the discretion of the BayCare Select CCO.
 - ii. When the CCO evaluates whether to self-report an issue to CMS, he/she will consider multiple factors, which may include (but is not limited to):
 - 1) The level, extent or duration, and/or likelihood of actual or potential beneficiary harm, either physical or financial;
 - 2) The level, extent, and/or likelihood of actual or potential financial impact to health plan operations;
 - 3) Evidence of significant failure to comply with Medicare regulations;
 - 4) Evidence that fraud, waste or abuse is confirmed;
 - 5) Potential or actual damage to BayCare Select's reputation, such that continuing operations could be impacted;
 - 6) Whether the incident involved actual or potential breach of protected health information;
 - 7) Whether the incident resulted in overpayment from the government; or failure to refund overpayments to the government in accordance with regulations.
 - iii. If the CCO determines that an issue is significant and recommends it be disclosed to CMS, the CCO will first discuss the matter with the President of BayCare Select.
 - 1) If the President of BayCare Select disagrees with the CCO and does not think the issue is significant and should not be self-reported to CMS, the CCO will escalate the matter to the Chair of the Board.
 - 2) If the Chair of the Board and President disagree with the CCO and do not think the issue significant and should be self-reported to CMS, then the issue will not be reported to CMS.
 - 3) If the President and/or the Chair of the Board agree, the CCO will BayCare Select submit both an oral (if possible) and written self-disclosure report to BayCare Select's CMS Account Manager. The CCO will cooperate fully with and timely reply to any requests by the CMS Account Manager for follow-up information or actions regarding the issue.
 - iv. The CCO communicates all issues disclosed to CMS to the Compliance Committee.

- c. **Self-Disclosures to the Office of Civil Rights:** In the event of an actual or potential breach of PHI, the CCO will coordinate with the BayCare System Privacy Officer and follow the BayCare System policies and procedures to determine whether to disclose to the Office of Civil Rights. The CCO communicates all issues disclosed to the Office of Civil Rights to the Compliance Committee.
- d. **Referral of FWA Cases to the I-MEDIC:** If a case is confirmed to involve fraud, the CCO may, at his or her discretion, refer the case to the I-MEDIC and / or state authorities, in coordination with BayCare Select's SIU which is a FDR delegated function. When the CCO evaluates whether to refer the case to the I-MEDIC, he/she will consider multiple factors, which may include (but is not limited to):

- 1. Detected or reported criminal, civil, or administrative law violations;
- 2. Cases that extend beyond the Parts C and D plans, involving multiple health plans, multiple states, or widespread schemes;
- 3. Cases involving known patterns of fraud;
- 4. Cases demonstrating a pattern of fraud or abuse threatening the life or well-being of beneficiaries; and
- 5. Cases involving a scheme with large financial risk to the Medicare Program or beneficiaries.

The CCO communicates all FWA cases referred to the I-MEDIC to the Compliance Committee.

- e. **Reports to Law Enforcement:** If it is determined that a BayCare Select Workforce member or FDR acted in violation of the law, the CCO will notify Legal Counsel. Legal Counsel will determine whether to voluntarily report the matter to outside authorities.
- 3. **Unfounded Allegations:** If an investigation results in a determination that the allegation is not supported by the evidence, no corrective action is warranted, and the case is closed. The CCO (or designee), with advice from Legal Counsel or others as appropriate, will notify affected parties of the disposition of the case, including the individual alleging the compliance violation.
 - 4. **Inconclusive or Unsubstantiated Allegations:** If the allegation is found to be made in good faith but unsubstantiated, no corrective action is warranted and the case is closed. The CCO (or designee), with advice from Legal Counsel or others as appropriate, will notify affected parties of the disposition of the case, including the individual alleging the compliance violation.
- C. **Reporting:** The CCO regularly reports statistics involving actual or suspected Compliance Violations, including (at a minimum) the number of incidents reported, source, method, incident status, volume trends, and outcomes to the Compliance Committee.

D. Documentation:

1. The BayCare Select Compliance Department will take appropriate steps to secure or prevent the destruction of documents or other evidence relevant to the investigation.
2. Records of the investigation will contain documentation of the alleged violation, a description of the investigative process, copies of interview notes and key documents, a log of the witnesses interviewed and the documents reviewed, the results of the investigation, e.g., any disciplinary action taken, and the corrective action implemented.
3. Compliance incidents reported via the methods described herein are documented within the Compliance Department's incident tracking system.
4. A record of all alleged compliance violations reported, even if the determination is that there is not enough information to investigate the allegation, is maintained by the Compliance Department in its incident tracking system. At a minimum, the Compliance Department's incidents tracking system contains:
 - a. Report Date
 - b. Reporter's Name (if revealed)
 - c. Allegation Type and Priority
 - d. Referral Source
 - e. Case Status (open/closed)
 - f. Investigator and Summary of Allegation
 - g. Determination and Resolution
5. Investigation files are retained by the BayCare Select Compliance Department in accordance with CMP13 Health Plan Document and Data Retention.
6. The Legal Department will serve to advise the investigation as to issues of chain of custody and privilege.

VII. REGULATORY REFERENCES / CITATIONS

Medicare Managed Care Manual, Chapter 21 – Compliance Program Guidelines and Prescription Drug Benefit Manual, Chapter 9 – Compliance Program Guidelines, Section 50.7
42 C.F.R. 422.503(b)(4)(vi)(G)
42 C.F.R. 423.504(b)(4)(vi)(G)

VIII. RELATED POLICIES & PROCEDURES

BayCare Select Code of Conduct
CMP13 Health Plan Document and Data Retention
CMP20 Non-Retaliation / Duty to Report
CMP21 Disciplinary Policy
CMP23 Corrective Action Plans
CMP29 BayCare Select System Breach Notification Policies and Procedures

IX. ATTACHMENTS

None

VERSION & REVIEW HISTORY:

Version #	Action (Original Issue, Reviewed, Revised)	Date Action Taken	Brief Summary of Revision, if applicable	Individual Taking Action	Effective Date	Date Approved and By Whom
01	Original Issue	09/01/2018	N/A	Unknown	09/01/2018	Unknown
02	Reviewed	07/25/2019	Annual review; no substantive changes.	Paul Christy, CCO	08/01/2019	NA - Larry Costello, President
03	Revised	06/26/2020	Annual review; significant rewrite and substantive changes throughout. Incorporated content of CMP18 into CMP08 – archived CMP 18.	Joanna Tofani, CCO	06/26/2020	06/26/2020 Compliance Committee
04	Revised	07/08/2020	Specified that SIU is a delegated function in Procedures section 2.d.	Joanna Tofani, CCO	07/15/2020	07/15/2020