



Policy: HH.2020
Title: **Conducting Compliance Investigations**
Department: Office of Compliance
Section: Regulatory Affairs & Compliance

CEO Approval: /s/ Michael Hunn 11/20/2024

Effective Date: 12/01/2012

Revised Date: 11/07/2024

Applicable to: ☒ Medi-Cal
☒ OneCare
☒ PACE
☐ Administrative

I. PURPOSE

This policy outlines the process for conducting and overseeing compliance investigations, or inquiries into allegations, of violations of the CalOptima Health Code of Conduct, any statute, regulation, or guideline applicable to federal and/or state health care programs, or of CalOptima Health's policies and procedures.

II. POLICY

A. CalOptima Health's Employees, Governing Body, and First Tier, Downstream and Related Entities (FDRs), have affirmative obligations under CalOptima Health's Compliance Program to report all violations and suspected violations of law, regulations, and/or policies and procedures (hereafter, "policies"), the CalOptima Health Code of Conduct, and/or other compliance issues. CalOptima Health maintains various disclosure and reporting mechanisms (i.e., Compliance and Ethics Hotline) which allow such individuals to fulfill these obligations.

1. CalOptima Health's Employees, Governing Body, and FDRs shall commence such preliminary investigations within the time frame identified in Section III.B.1.

B. CalOptima Health has a non-Retaliation policy regarding the reporting and investigating of incidents of non-compliance with applicable laws, regulations, the CalOptima Health Code of Conduct, and/or policies, or other compliance issues, as outlined in CalOptima Health Policy HH.3012: Non-Retaliation for Reporting Violations.

C. The Chief Compliance Officer or Designee is responsible for investigating potential non-compliance with applicable laws, regulations, the CalOptima Health Code of Conduct, and/or policies, or other compliance issues involving CalOptima Health, including its officers and Employees, and refer matters to the Compliance Committee, as appropriate. Potential non-compliance with applicable laws, regulations, and/or policies, or other compliance issues, may be discovered through, for example, reports to CalOptima Health's Compliance and Ethics Hotline, complaints, routine Monitoring, or regulatory audits.

D. The Chief Compliance Officer or Designee shall promptly conduct a preliminary review of potential incidents of non-compliance with applicable laws, regulations, the CalOptima Health Code of Conduct, and/or policies, or other compliance issues, to determine whether there is sufficient credible information and basis to warrant to a full compliance investigation of the matter. In

conducting such preliminary review, the Chief Compliance Officer or Designee may refer the matter to another appropriate CalOptima Health department, including referrals to the Chief Human Resources Officer, who is responsible for investigations related to Employee harassment and discrimination and related matters.

- E. The Privacy Officer or Designee in collaboration with the Security Officer or Designee, shall be responsible for investigations of potential violations of Protected Health Information (PHI) under the Health Insurance Portability and Accountability Act (HIPAA) of 1996, as amended, including implementing regulations, the Health Information Technology for Economic and Clinical Health (HITECH) Act, and applicable state privacy, security, and confidentiality laws.
- F. Whenever there is credible evidence that suggests violation of criminal, civil, or administrative laws, the Chief Compliance Officer, or Designee may consult with CalOptima Health's legal counsel for further guidance regarding reports to law enforcement agencies or state or federal regulators, or other appropriate actions.
- G. Whenever there is credible evidence that suggests Fraud, Waste, or Abuse, the Chief Compliance Officer, or Designee, shall evaluate, investigate, and report the matter as appropriate, in accordance with CalOptima Health Policies HH.1105: Fraud, Waste, and Abuse Detection and HH.1107: Fraud, Waste, and Abuse Investigation and Reporting.
- H. In conducting internal investigations, CalOptima Health shall respect the rights of all persons involved in the investigation, including those persons accused of non-compliance, in accordance with CalOptima Health Policy HH.3012: Non-Retaliation for Reporting Violations. CalOptima Health strictly prohibits Retaliation against Employees for reporting compliance concerns, and/or participating in internal investigations.

III. PROCEDURE

A. Preliminary Investigation

1. The Chief Compliance Officer or Designee shall:
 - a. Evaluate all incidents of potential non-compliance with applicable laws, regulations, and/or policies, the CalOptima Health Code of Conduct, or other compliance issues regardless of source;
 - b. Determine whether there is sufficient information and basis to proceed with a full investigation of the incident/matter, or whether additional information is necessary;
 - c. Determine the appropriate approach to be taken as a result of the information provided, such as, but not limited to a Corrective Action Plan (CAP), an educational letter (Reminder of Contractual Obligations), a Warning letter, or other actions as deemed appropriate;
 - d. Determine whether the incident/matter is an inquiry, or is otherwise appropriate for referral to another CalOptima Health department, or whether it is a non-issue that warrants closure of the compliance matter;
 - e. Determine whether the incident, if verified to be true, would necessitate a referral or report to one (1) or more of CalOptima Health's regulatory agencies or such agency's designated contractor.

- f. If applicable, report the incident to Centers for Medicare & Medicaid Services (CMS) and/or the Department of Health Care Services (DHCS) in accordance with CalOptima Health Policy MA.9124: CMS Self-Disclosure.
2. If the Chief Compliance Officer or Designee determines that a full investigation of the incident is appropriate, he or she shall review whether CalOptima Health needs to take any preventive or corrective actions prior to the completion of the full investigation, including, without limitation, preliminary reports to regulatory agencies, placement of Employees on administrative leave, etc. The Chief Compliance Officer or Designee may recommend the temporary or permanent cessation of internal activities that may be the cause of, or contribute to, the alleged non-compliance, as appropriate. The Chief Compliance Officer or Designee may consult with CalOptima Health's legal counsel on such actions, as needed.
3. The Chief Compliance Officer or Designee shall determine if an investigation is warranted. The Chief Compliance Officer or Designee shall establish the scope of the investigation based on the following factors, to include, but not be limited to:
 - a. The availability of individuals who may be involved;
 - b. The time frame of the alleged violations;
 - c. Whether the alleged violations appear to be an isolated incident, or pattern of improper conduct;
 - d. Whether the alleged violations indicate a systemic, or procedural, deficiency in a department's operation; and
 - e. The time requirements for conducting the investigation, including, any regulatory obligations for commencement and completion of the investigation.
4. Prior to initiating the investigation, the Chief Compliance Officer or Designee shall fully explore and understand all the allegations and related issues raised in a complaint.
5. Based on the scope of the investigation, the Chief Compliance Officer or Designee shall develop an investigative plan. The Chief Compliance Officer may delegate investigative activities but retains ultimate supervision and responsibility for compliance investigations.
6. The Chief Compliance Officer shall assume responsibility for carrying out the investigation or shall assign a qualified person to carry out the investigation, who is organizationally removed from any of the parties directly involved in the investigation.

B. Investigation

1. The Chief Compliance Officer or Designee shall initiate the investigation promptly and generally no later than fourteen (14) calendar days after the potential non-compliance is reported (and earlier if the regulatory requirement dictates such and/or if the matter requires more immediate resolution).
2. All communications, evidence, and reports shall be saved, logged, and sequentially numbered upon receipt by the Chief Compliance Officer or Designee and maintained in the investigation case file.

3. All information gathered by the Chief Compliance Officer or Designee during the investigation shall be held in confidence, in accordance with applicable state and federal law, except as specifically authorized by CalOptima Health policies and procedures, and applicable law.
4. The Chief Compliance Officer or Designee shall:
 - a. Conduct interviews, in person and in private, with one (1) interviewee at a time;
 - b. Follow professional interview principles and techniques; and
 - c. Ensure circumstance and content of the interview are supported by a witness for sensitive interviews.
5. The Chief Compliance Officer or Designee shall have a full understanding of the relevant laws, regulations, and government guidance pertinent to the investigation before conducting the investigation and may consult with CalOptima Health's legal counsel for guidance on the subject matter at issue.
6. Investigations shall be completed within a reasonable time period, and as expeditiously as possible, based on the circumstances, including but not limited to, consideration of relevant statutory and/or regulatory requirements (e.g., overpayment disclosure and refunding requirements); the potential that the matter involves Fraud or Abuse; and/or the potential for ongoing financial or other harm to CalOptima Health, any federal or state health care program, and/or any individual while the investigation is conducted.
7. The Chief Compliance Officer or Designee shall review whether there are sufficient internal resources, or whether resources are needed to conduct the investigation. If resources are necessary, the Chief Compliance Officer, or Designee, may consult with CalOptima Health's legal counsel to determine the best course of action.

C. Involvement of Legal Representation

1. Any member of a CalOptima Health Governing Body, Employee, or FDR who is the subject of an investigation is free to retain independent counsel. If a member of a CalOptima Health Governing Body, Employee, or FDR is already represented by counsel, the Chief Compliance Officer or Designee shall discuss ramifications with CalOptima Health's legal counsel before proceeding.
2. If a member of a CalOptima Health Governing Body, Employee, or FDR is being interviewed, and requests the presence of an attorney, the interview shall be stopped, and the Chief Compliance Officer or Designee shall notify CalOptima Health's legal counsel.
3. If the interview is with a member of a CalOptima Health Governing Body, Employee, or FDR who is suspected of serious misconduct, CalOptima Health's legal counsel shall advise the member of a CalOptima Health Governing Body, Employee, or FDR of the seriousness of the matter and CalOptima Health's policy to disclose the result of its investigation to other government agencies, including appropriate state and/or federal law enforcement agencies.

D. Documenting and reporting findings of the investigation

1. For every interview, the Chief Compliance Officer or Designee shall prepare a written interview report covering all the key points derived from that contact.

2. The Chief Compliance Officer or Designee shall:
 - a. Write the investigation report;
 - b. File with the original written communication; and
 - c. Include a summary of the individual's complaint, a chronology of events, the investigator's findings/conclusions, and, as appropriate, recommended actions with specific responsibilities assigned to managers to ensure implementation.
3. The Chief Compliance Officer or Designee shall review root cause analyses, corrective action plans, remediation plans, and future monitoring/auditing plans, as appropriate, to address verified incidents of non-compliance or deficiencies to ensure they do not recur in the future. The Chief Compliance Officer or Designee may consult with the CalOptima Health Compliance Committee, legal counsel, Human Resources Department, or other parties, as necessary and appropriate, to develop these plans.
4. The Chief Compliance Officer or Designee shall report the findings to the Compliance Committee, as appropriate, along with recommendations for final corrective action, in order to confirm completion of the investigative tasks. The Compliance Committee can determine if additional steps are necessary to complete the investigation.
5. The Chief Compliance Officer or Designee shall distribute and report complete investigations to the Compliance Committee. No copies shall be provided to other parties, unless requested to do so and approved by the Chief Compliance Officer, or Designee.
6. If potential legal issues exist, the report shall be provided to CalOptima Health's legal counsel for appropriate action.
7. If the investigation and report have been requested or directed by CalOptima Health's legal counsel, the report should be marked "Attorney-Client Privilege" or "Attorney Work Product," as requested by CalOptima Health's legal counsel, and furnished only to CalOptima Health's legal counsel. Under those circumstances, it shall be the responsibility of CalOptima Health's legal counsel to report and advise management about the facts, circumstances, and alternative courses of action.
8. Upon review of the report by the Compliance Committee, the Chief Compliance Officer or Designee shall act upon the findings and recommendations for corrective action measures and determine whether adverse actions should be taken against any parties, and if so, determine the Sanction itself. The Chief Compliance Officer, or Designee, as appropriate, may consult with CalOptima Health's legal counsel in making the necessary decisions.
9. Before taking action on the results of an investigation, the Chief Compliance Officer or Designee shall ensure that the complainant (if known) has received general feedback on the results of the investigation, but not the details of the investigation, or any specific action or decisions relating to any individual.
10. The Chief Compliance Officer or Designee shall report the results of an investigation to the CalOptima Health Board of Directors and the Chief Executive Officer, as appropriate.

IV. ATTACHMENT(S)

Not Applicable

V. REFERENCE(S)

- A. CalOptima Health Compliance Plan
- B. CalOptima Health Contract with the Centers for Medicare & Medicaid Services (CMS) for Medicare Advantage
- C. CalOptima Health Contract with the Department of Health Care Services (DHCS) for Medi-Cal
- D. CalOptima Health PACE Program Agreement
- E. CalOptima Health Policy HH.1105: Fraud, Waste, and Abuse Detection
- F. CalOptima Health Policy HH.1107: Fraud, Waste, and Abuse Investigation and Reporting
- G. CalOptima Health Policy HH.3012: Non-Retaliation for Reporting Violations
- H. CalOptima Health Policy MA.9124: CMS Self-Disclosure
- I. Health Information Technology for Economic and Clinical Health (HITECH) Act
- J. Health Insurance Portability and Accountability Act (HIPAA) of 1996, including implementing regulations
- K. Medicare Managed Care Manual, Chapter 21
- L. Medicare Prescription Drug Benefit Manual, Chapter 9
- M. Title 42, Code of Federal Regulations (C.F.R.), §455.15
- N. Title 42, Code of Federal Regulations (C.F.R.), §455.2
- O. Welfare and Institutions Code, §14043.1(a)

VI. REGULATORY AGENCY APPROVAL(S)

None to Date

VII. BOARD ACTION(S)

Date	Meeting
12/01/2016	Regular Meeting of the CalOptima Board of Directors
12/07/2017	Regular Meeting of the CalOptima Board of Directors
12/06/2018	Regular Meeting of the CalOptima Board of Directors
12/05/2019	Regular Meeting of the CalOptima Board of Directors
12/03/2020	Regular Meeting of the CalOptima Board of Directors
12/20/2021	Special Meeting of the CalOptima Board of Directors
12/01/2022	Regular Meeting of the CalOptima Health Board of Directors
11/07/2024	Regular Meeting of the CalOptima Health Board of Directors

VIII. REVISION HISTORY

Action	Date	Policy	Policy Title	Program(s)
Effective	12/01/2012	HH.2020	Conducting Internal Investigations	Medi-Cal
Revised	04/01/2014	HH.2020	Conducting Internal Investigations	Medi-Cal
Revised	09/01/2015	HH.2020	Conducting Internal Investigations	Medi-Cal
Revised	12/01/2016	HH.2020	Conducting Compliance Investigations	Medi-Cal OneCare OneCare Connect PACE

Action	Date	Policy	Policy Title	Program(s)
Revised	12/07/2017	HH.2020	Conducting Compliance Investigations	Medi-Cal OneCare OneCare Connect PACE
Revised	12/06/2018	HH.2020	Conducting Compliance Investigations	Medi-Cal OneCare OneCare Connect PACE
Revised	12/05/2019	HH.2020	Conducting Compliance Investigations	Medi-Cal OneCare OneCare Connect PACE
Revised	12/03/2020	HH.2020	Conducting Compliance Investigations	Medi-Cal OneCare OneCare Connect PACE
Revised	12/20/2021	HH.2020	Conducting Compliance Investigations	Medi-Cal OneCare OneCare Connect PACE
Revised	12/31/2022	HH.2020	Conducting Compliance Investigations	Medi-Cal OneCare PACE
Revised	09/01/2023	HH.2020	Conducting Compliance Investigations	Medi-Cal OneCare PACE
Revised	11/07/2024	HH.2020	Conducting Compliance Investigations	Medi-Cal OneCare PACE

IX. GLOSSARY

Term	Definition
Abuse	<p><u>Medi-Cal</u>: Practices that are inconsistent with sound fiscal and business practices or medical standards, and result in an unnecessary cost to the Medi-Cal program, or in reimbursement for services that are not Medically Necessary or that fail to meet professionally recognized standards for health care. It also includes Member practices that result in unnecessary cost to the Medi-Cal program.</p> <p><u>OneCare</u>: A Provider practice that is inconsistent with sound fiscal, business, or medical practice, and results in an unnecessary cost to CalOptima Health and the OneCare program, or in reimbursement for services that are not Medically Necessary or that fail to meet professionally recognized standards for health care. It also includes Member practices that result in unnecessary cost to CalOptima Health and the OneCare program.</p>
Centers for Medicare & Medicaid Services (CMS)	The federal agency under the United States Department of Health and Human Services responsible for administering the Medicare and Medicaid programs.
Code of Conduct	The statement setting forth the principles and standards governing CalOptima Health's activities to which Board Members, Employees, FDRs, and agents of CalOptima Health are expected to adhere.
Compliance Committee	This CalOptima Health committee consists of executive officers, managers of key operating divisions, and legal counsel and oversees the implementation of CalOptima Health's Compliance Program.
Compliance Program	<p><u>Medi-Cal</u>: The program including, without limitation, the Compliance Plan, Code of Conduct, and CalOptima Health policies, developed and adopted by CalOptima Health to promote, monitor, and ensure that CalOptima Health's operations and practices and the practices of its Board Members, employees, contractors, and providers comply with applicable law and ethical standards.</p> <p><u>OneCare</u>: A comprehensive program that incorporates the fundamental elements identified by the state and federal governments and CalOptima Health as necessary to prevent and detect violations of ethical standards, contractual obligations, and applicable laws and the involvement of CalOptima Health's governing body and executive staff. Elements of the Compliance Program include standards, oversight, training, reporting, monitoring, enforcement, and remediation. The Compliance Program applies to CalOptima Health's Board of Directors, employees, and contractors including delegated entities, providers, and suppliers.</p>
Confidential	Entrusted with private or personal information that is confined to a person or group as opposed to the public.
Designee	A person selected or designated to carry out a duty or role. The assigned Designee is required to be in management or hold the appropriate qualifications or certifications related to the duty or role.
Downstream Entity	<u>Medi-Cal</u> : Any party that enters into a written arrangement, acceptable to DHCS and/or CMS, with persons or entities involved with a CalOptima Health Program benefit, below the level of arrangement between CalOptima Health and a First Tier Entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

Term	Definition
	<u>OneCare</u> : Any party that enters into an acceptable written arrangement below the level of the arrangement between a Medicare Advantage (MA) organization (and contract applicant) and a First Tier Entity. These written arrangements continue down to the level of the ultimate provider of health and/or administrative services.
Employee	For purposes of this policy, any and all employees of CalOptima Health, including all senior management, officers, managers, supervisors and other employed personnel, as well as temporary employees and volunteers.
First Tier, Downstream, and Related Entities (FDR)	First Tier, Downstream or Related Entity, as separately defined herein. For the purposes of this policy, the term FDR includes delegated entities, contracted providers, Health Networks, physician groups, Physician Hospital Consortia, and Health Maintenance Organizations.
First Tier Entity	<u>Medi-Cal</u> : Any party that enters into a written arrangement, acceptable to DHCS and/or CMS, with CalOptima Health to provide administrative services or health care services to a Member under a CalOptima Health Program. <u>OneCare</u> : Any party that enters into a written arrangement, acceptable to CMS, with an MAO or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare eligible individual under the MA program or Part D program.
Fraud	An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable Federal or State law, in accordance with Title 42 Code of Federal Regulations section 455.2, Welfare and Institutions Code section 14043.1(i).
Governing Body	The Board of Directors of CalOptima Health.
Health Insurance Portability and Accountability Act (HIPAA)	The Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, enacted on August 21, 1996. Sections 261 through 264 if HIPAA require the Secretary of the U.S. Department of Health and Human Services to publicize standards for the electronic exchange, privacy and security of health information, as amended.
Protected Health Information (PHI)	Has the meaning given such term in Section 160.103 of Title 45, Code of Federal Regulations. Individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. This information identifies the individual or there is reasonable basis to believe the information can be used to identify the individual. The information was created or received by CalOptima Health or Business Associates and relates to: <ol style="list-style-type: none"> 1. The past, present, or future physical or mental health or condition of a Member. 2. The provision of health care to a Member; or 3. Past, present, or future Payment for the provision of health care to a Member.
Related Entity	Any entity that is related to the Medicare Advantage organization by common ownership or control and: <ol style="list-style-type: none"> 1. Performs some of the Medicare Advantage organization's management functions under contract or delegation;

Term	Definition
	<p>2. Furnishes services to Medicare enrollees under an oral or written agreement; or</p> <p>3. Leases real property or sells materials to the Medicare Advantage organization at a cost of more than two-thousand five-hundred dollars (\$2,500) during a contract period.</p>
Retaliation	Includes, but not limited to, coercion, threats, intimidation, discrimination, and other forms of retaliatory action against individuals.
Sanction	An action taken by CalOptima Health, including, but not limited to, restrictions, limitations, monetary fines, termination, or a combination thereof, based on an FDR's or its agent's failure to comply with statutory, regulatory, contractual, and/or other requirements related to CalOptima Health Programs.
Waste	<p><u>Medi-Cal</u>: The overutilization or inappropriate utilization of services and misuse of resources.</p> <p><u>OneCare</u>: The overutilization of services, or other practices that, directly or indirectly, result in unnecessary costs to a CalOptima Health Program.</p> <p>Waste is generally not considered to be caused by criminally negligent actions but rather the misuse of resources.</p>