Policy:	MA.9124
Title:	**CMS Self-Disclosure**
Department:	Office of Compliance
Section:	Regulatory Affairs & Compliance
CEO Approval:	*/s/ Michael Hunn 11/20/2024*
Effective Date:	08/01/2014
Revised Date:	11/07/2024
Applicable to:	☐ Medi-Cal ☒ OneCare ☒ PACE ☐ Administrative

I. PURPOSE

This policy establishes a process for self-disclosing incidences of significant Medicare program non-compliance to CalOptima Health's Centers for Medicare & Medicaid Services (CMS) Regional Account Manager and/or the Department of Health Care Services (DHCS) Contract Manager. This self-disclosing process ensures that corrective actions are taken timely when non-compliance incidents are identified.

II. POLICY

A. CalOptima Health follows the guidelines and regulations set forth by CMS regarding compliance to the Medicare Program and monitoring process for Part C and Part D programs.

B. The Office of Compliance oversees and implements an effective Compliance Program to prevent, detect, and correct Part C and Part D programs non-compliance.

C. This policy encourages internal and external business units to voluntarily identify, disclose, and correct non-compliance incidents to meet the Medicare program guidelines and regulations set forth by CMS.

D. Self–reported non-compliance incidents reported to the Office of Compliance are investigated and Corrective Action Plans (CAPs) issued and responded to, as promptly as the severity level assigned to the non-compliance incident allows, and as described in CalOptima Health Policy HH.2005: Corrective Action Plan.

III. PROCEDURE

A. Submitting a Self-Disclosure

1. The department Director, Manager, or delegate liaison has twenty-four hours (24) hours (once an incident is identified) to Self-Disclose a non-compliance incident to the Office of Compliance. In severe non-compliance incidents impacting and threatening a Member's state of health, the non-compliance Self-Disclosure report must be completed as soon as it is identified.

2. The department Director, Manager, or delegate liaison must document the non-compliance incident and submit the Self-Disclosure to the Office of Compliance. The department Director,

Manager, or delegate liaison may use the attached Non-Compliance Self-Disclosure Form (SDF) to disclose the non-compliance issue to the Office of Compliance.

3. The Self-Disclosure must be submitted electronically.

4. Depending on the severity of the incident being reported, the Office of Compliance will review the submission and respond back within three to five (3-5) business days to the submitting party either accepting, or rejecting, the disclosure.

B. Required Information Related to the Self-Disclosing Incident

1. To Self-Disclose a non-compliance incident to the Office of Compliance, the submitting party must provide the following information in the Self-Disclosure report:

a. Contact information:

i. Submitter contact name, phone number, email, and address (for external submitters), and area of non-compliance (For example: Enrollment, Pharmacy, Customer Service, Sales).

b. A brief description/summary of the identified non-compliance incident, including specific time frames during which the internal or external party might have been out of compliance. Any applicable supporting documentation should be included.

c. A brief description of why the internal or external party believes they are out of compliance with the identified area.

d. Circumstances under which the non-compliance was discovered (For example: Grievance, complaint, Audits, or through a business data analysis), and actions taken, if any, to correct the non-compliance upon discovery of the incident.

e. A root cause analysis and the impact on risks to health, safety, or quality of care posed by the incident disclosed with sufficient information to allow the Office of Compliance to assess the severity of the non-compliance incident or risk, and steps that should be taken to meet compliance.

f. If applicable, the dates, or range of dates, whereby the non-compliance was cured and if any claims or services were, or have been, impacted.

g. Remediating measures taken to prevent future non-compliance of that nature from reoccurring, Monitoring steps and implementation time frames, including proof of remediation. (For example: employee training, enhancing internal control procedures, increased internal Auditing efforts, increased oversight by management, etc.)

h. A description of appropriate Member/Provider notices, if applicable, provided with disclosure of the non-compliance incident.

C. Office of Compliance Investigation & Corrective Action Plan (CAP)

1. Upon receipt of a Self-Disclosure submission, the Office of Compliance will begin its investigation of the disclosed information. The extent of the investigation will depend upon the severity of the incident and evidence, or documentation provided in the Self-Disclosure report.

2. If additional non-compliance incidents are discovered during the investigation process, that incident will be treated as a new non-compliance incident and the self-disclosing party will be required to complete a new Self-Disclosure report for that incident.

3. To facilitate the investigation process, the Office of Compliance will review and request additional information and conduct interviews, if necessary, with the applicable parties/departments. If additional information is requested based on the severity of the incident, the self-disclosing applicable parties/departments shall submit the requested information to the Office of Compliance, in accordance with CalOptima Health Policy HH.2005: Corrective Action Plan.

4. The Office of Compliance shall complete its initial investigation, upon which the self-disclosing department will be provided with initial findings and a request for CAP which must be completed and responded to by the self-disclosing business unit, in accordance with CalOptima Health Policy HH.2005: Corrective Action Plan.

5. If the non-compliance is a result of a Grievance filing, the Office of Compliance will provide the Grievance & Appeals Director with the final resolution for insertion into the Member Grievance file.

D. Findings Report

1. Upon completion of the investigation, the Office of Compliance will submit the Self-Disclosure findings report to the Medicare Compliance Officer (MCO) and Chief Compliance Officer (CCO) for review and sign off.

2. The MCO will review the details of the issue and relay a recommendation to the CCO as to whether the non-compliance is of a level of significance that warrants reporting the issue to the relevant regulators.

3. If the recommendation is made that the issue is to be disclosed to the pertinent regulators, the MCO will report the details of the issue to the appropriate CalOptima Health senior management. The CCO will report the issue to the CEO and the Board of Directors.

4. Once the above steps have been completed, and an accepted CAP (if applicable) has been submitted, the MCO, or Designee, will submit the non-compliance incident to CalOptima Health's CMS Regional Account Manager and/or the Department of Health Care Services (DHCS) Contract Manager including any steps taken to correct the non-compliance, immediately, but no later than ten (10) calendar days.

5. CalOptima Health shall report the incident to CMS as soon as possible after its discovery and sufficient details have been obtained.

6. The MCO, or Designee, may also submit the final, signed Non-Compliance Self-Disclosure Form outlining the course of actions that included the accepted CAP, and continued monitoring efforts to the CCO or Executive Director, and Director of the business unit and applicable Committees.

IV. ATTACHMENT(S)

A. Non-Compliance Self-Disclosure Form

V. REFERENCE(S)

A. CalOptima Health Contract with the Centers for Medicare & Medicaid Services (CMS) for Medicare Advantage
B. CalOptima Health PACE Program Agreement
C. CalOptima Health Compliance Plan
D. CalOptima Health Policy HH.2005: Corrective Action Plan
E. "CMS Consideration of Self-Disclosure by Plan Sponsors of Non-Compliance Conduct in the Determination of Compliance Actions," Health Plan Management System, Issued 02/27/2013.
F. Medicare Managed Care Manual, Chapter 21
G. Medicare Prescription Drug Benefit Manual, Chapter 9
H. Title 42, Code of Federal Regulations **(**C.F.R.), §§422.503(b)(4)(vi)(G)
I. Title 42, Code of Federal Regulations (C.F.R.), §§423.504(b)(4)(vi)(G)

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	08/01/2014	MA.9124	CMS Self Disclosure	OneCare
Revised	12/01/2014	MA.9124	CMS Self Disclosure	OneCare
Revised	09/01/2015	MA.9124	CMS Self Disclosure	OneCare OneCare Connect
Revised	12/01/2016	MA.9124	CMS Self Disclosure	OneCare OneCare Connect
Revised	12/07/2017	MA.9124	CMS Self-Disclosure	OneCare OneCare Connect
Revised	12/06/2018	MA.9124	CMS Self-Disclosure	OneCare OneCare Connect PACE

Action	Date	Policy	Policy Title	Program(s)
Revised	12/05/2019	MA.9124	CMS Self-Disclosure	OneCare OneCare Connect PACE
Revised	12/03/2020	MA.9124	CMS Self-Disclosure	OneCare OneCare Connect PACE
Revised	12/20/2021	MA.9124	CMS Self-Disclosure	OneCare OneCare Connect PACE
Revised	12/31/2022	MA.9124	CMS Self-Disclosure	OneCare PACE
Revised	09/01/2023	MA.9124	CMS Self-Disclosure	OneCare PACE
Revised	11/07/2024	MA.9124	CMS Self-Disclosure	OneCare PACE

IX. GLOSSARY

Term	Definition
Audit	A formal, systematic, and disciplined approach designed to review, evaluate, and improve the effectiveness of processes and related controls using a particular set of standards (e.g., policies and procedures, laws and regulations) used as base measures. Auditing is governed by professional standards and completed by individuals independent of the process being Audited and normally performed by individuals with one of several acknowledged certifications
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.
Compliance Program	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.
Corrective Action Plan (CAP)	A plan delineating specific identifiable activities or undertakings that address and are designed to correct program deficiencies or problems identified by formal Audits or monitoring activities by CalOptima Health, the Centers for Medicare & Medicaid Services (CMS), Department of Health Care Services, or designated representatives. FDRs and/or CalOptima Health departments may be required to complete CAPs to ensure compliance with statutory, regulatory, or contractual obligations and any other requirements identified by CalOptima Health and its regulators.
Department of Health Care Services (DHCS)	OneCare: The single State Department responsible for administration of the Medi-Cal program, California Children's Services (CCS), Genetically Handicapped Persons Program (GHPP), Child Health and Disabilities Prevention (CHDP), and other health related programs. PACE: The single State Department responsible for administration of the federal Medicaid (referred to as Medi-Cal in California) Program.
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.
Grievance	OneCare: An expression of dissatisfaction with any aspect of the operations, activities or behavior of a plan or its delegated entity in the provision of health care items, services, or prescription drugs, regardless of whether remedial action is requested or can be taken. A grievance does not include, and is distinct from, a dispute of the appeal of an organization determination or coverage determination or an LEP determination.

Term	Definition
	PACE: A complaint, either written or oral, expressing dissatisfaction with service delivery or the quality of care furnished, as defined by the federal PACE regulation 42 CFR Section 460.120.
Member	A beneficiary enrolled in a CalOptima Health Program.
Provider	Any Medicare provider (e.g., hospital, skilled nursing facility, home health agency, outpatient physical therapy, comprehensive outpatient rehabilitation facility, end-stage renal disease facility, hospice, physician, non-physician provider, laboratory, supplier) providing Covered Services under Medicare Part B. Any organization, institution, or individual that provides Covered Services to Medicare members. Physicians, ambulatory surgical centers, and outpatient clinics are some of the providers of Covered Services under Medicare Part B.
Self-Disclosure	The act of voluntarily notifying the compliance governing body of a non-compliance incident.