Policy:	GG.1422
Title:	**Notification Regarding Medication Recalls**
Department:	Medical Management
Section:	Pharmacy Management
CEO Approval:	*/s/ Michael Hunn 10/31/2024*
Effective Date:	01/01/2011
Revised Date:	10/01/2024
Applicable to:	☒ Medi-Cal ☐ OneCare ☐ PACE ☐ Administrative

I. PURPOSE

This policy describes the process by which CalOptima Health notifies Members, and prescribers of medication recalls and Market Withdrawals.

II. POLICY

A. CalOptima Health pharmacists shall monitor the U.S. Food and Drug Administration (FDA) Enforcement Report to obtain information on actions taken in connection with agency regulatory activities regarding medication recalls and Market Withdrawals.

B. When the medication recall is not limited to specific medication batches or lot numbers, CalOptima Health's Pharmacy Management Department shall notify Members and prescribers, in writing, when there is a Class I or Class II Medication Recall, or when a medication is withdrawn from the market.

C. Member notification shall be in accordance with CalOptima Health Policy DD.2002: Cultural and Linguistic Services.

D. On an annual basis, the CalOptima Health Pharmacy Management Department shall review the medication recall and Market Withdrawal notification procedures.

III. PROCEDURE

A. Medication recalls and Market Withdrawals

1. On a weekly basis, the FDA publishes and posts the FDA Enforcement Report on the FDA Website: www.fda.gov.

2. CalOptima Health pharmacists shall review the FDA Enforcement Report for medication recalls and Market Withdrawals.

3. CalOptima Health pharmacists shall review pharmacy claims data to identify Members and prescribers potentially affected by an FDA medication recall or a Market Withdrawal.

a. In the event the FDA issues a Class I Medication Recall, CalOptima Health pharmacists shall:

i. Identify affected Members and prescribers through pharmacy utilization reports within five (5) calendar days of the FDA medication recall announcement;

ii. Notify affected Members, in writing via U.S. mail, as soon as the Members are identified, but no later than five (5) calendar days from the date of the FDA medication recall announcement;

iii. Notify affected prescribers, via facsimile, as soon as the prescribers are identified, but no later than five (5) calendar days from the date of the FDA announcement; and

iv. In instances where the recalled medication may cause serious adverse health consequences or death to Members, CalOptima Health may place a prior authorization restriction on the medication.

b. In the event the FDA issues a Class II Medication Recall, or a manufacturer withdraws a medication from the market, CalOptima Health pharmacists shall:

i. Identify affected Members and prescribers through pharmacy utilization reports within ten (10) calendar days of the FDA medication recall announcement or a manufacturer Market Withdrawal;

ii. Notify affected Members, in writing via U.S. mail, as soon as the Members are identified, but no later than thirty (30) calendar days from the date of the FDA medication recall announcement or Market Withdrawal;

iii. Notify affected prescribers, via facsimile, as soon as the prescribers are identified, but no later than thirty (30) calendar days from the date of the FDA medication recall announcement or Market Withdrawal; and

iv. In instances where the medication may cause serious adverse health consequences or death to Members, CalOptima Health may place a prior authorization restriction on the recalled or withdrawn medication.

4. CalOptima Health's Pharmacy Management Department shall track, and report medication recalls and manufacturer Market Withdrawals to CalOptima Health's Pharmacy and Therapeutics (P&T) Committee quarterly. The Committee shall determine the need for additional action and shall initiate changes to the physician administered drug Prior Authorization required list (PAD PA List) as deemed necessary.

IV. ATTACHMENT(S)

A. Member Notification Form
B. Prescriber Notification Form
C. Template for reporting recalls and withdrawals to Pharmacy & Therapeutics Committee

V. REFERENCE(S)

A. 2024 NCQA Health Plan Accreditation-UM Standards
B. CalOptima Health Contract with the Department of Health Care Services (DHCS) for Medi-Cal

C. CalOptima Health Policy DD.2002: Cultural and Linguistic Services
D. U.S. Food and Drug Administration (FDA) Enforcement Reports at www.fda.gov

VI. REGULATORY AGENCY APPROVAL(S)

Date	Regulatory Agency	Response
03/27/2014	Department of Health Care Services (DHCS)	Approved as Submitted
08/22/2022	Department of Health Care Services (DHCS)	Approved as Submitted

VII. BOARD ACTION(S)

None to Date

VIII. REVISION HISTORY

Action	Date	Policy	Policy Title	Program(s)
Effective	01/01/2011	GG.1422	Notification Regarding Medication Recalls	Medi-Cal
Revised	01/01/2013	GG.1422	Notification Regarding Medication Recalls	Medi-Cal
Revised	01/01/2014	GG.1422	Notification Regarding Medication Recalls	Medi-Cal
Revised	01/01/2015	GG.1422	Notification Regarding Medication Recalls	Medi-Cal
Revised	06/01/2016	GG.1422	Notification Regarding Medication Recalls	Medi-Cal
Revised	05/01/2017	GG.1422	Notification Regarding Medication Recalls	Medi-Cal
Revised	10/01/2018	GG.1422	Notification Regarding Medication Recalls	Medi-Cal
Revised	08/01/2019	GG.1422	Notification Regarding Medication Recalls	Medi-Cal
Revised	08/01/2020	GG.1422	Notification Regarding Medication Recalls	Medi-Cal
Revised	09/01/2021	GG.1422	Notification Regarding Medication Recalls	Medi-Cal
Revised	08/01/2022	GG.1422	Notification Regarding Medication Recalls	Medi-Cal
Revised	11/01/2023	GG.1422	Notification Regarding Medication Recalls	Medi-Cal
Revised	10/01/2024	GG.1422	Notification Regarding Medication Recalls	Medi-Cal

IX. GLOSSARY

Term	Definition
Class I Drug/Medication Recall	A situation in which there is a reasonable probability that the use of or exposure to a product will cause serious adverse health consequences or death.
Class II Drug/Medication Recall	A situation in which use of or exposure to a product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
Market Withdrawals	A manufacturer's removal or correction of a distributed product that involves a minor violation which would not be subject to legal action by the Food and Drug Administration (FDA).
Member	A Medi-Cal eligible beneficiary as determined by the County of Orange Social Services Agency, the California Department of Health Care Services (DHCS) Medi-Cal Program, or the United States Social Security Administration, who is enrolled in the CalOptima Health program.