



Policy: PA.5202
Title: **Labeling and Clinic Storage of Medications**
Department: CalOptima Health PACE
Section: Not Applicable

CEO Approval: /s/ Michael Hunn 06/20/2024

Effective Date: 04/01/2015

Revised Date: 06/01/2024

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

I. PURPOSE

This policy outlines the process for the labeling and storing of medications at the CalOptima Health Program of All-Inclusive Care for the Elderly (PACE) Center.

II. POLICY

- A. The CalOptima Health PACE contracted pharmacy shall clearly and appropriately label, store, and document all medications stored on-site in accordance with state and federal laws.
- B. CalOptima Health PACE clinic employees shall ensure Participants receive the correct medication and that medications are not tampered with or adulterated.

III. PROCEDURE

- A. CalOptima Health PACE will ensure that the contracted pharmacy will follow labeling guidelines as outlined below:
 - 1. The label of each Participant's individual medication pack shall clearly indicate:
 - a. Participant's full name;
 - b. Prescription number;
 - c. Provider's name;
 - d. Name and strength of each medication;
 - e. Manufacturer of each medication;
 - f. Date of issue;
 - g. Directions for use;
 - h. Expiration date;

- i. Quantity of the medication; and
 - j. Name, address, and telephone number of the pharmacy issuing the medication, and dispensing pharmacist's initials.
2. The medication pack label shall also clearly indicate:
 - a. Physical description or identification of each drug product contained in the medication pack;
 - b. Medications contained in each bubble; and
 - c. Any special instructions required for proper use of the medication, as well as any cautionary statement.
3. CalOptima Health PACE Center shall not use medication containers with soiled, damaged, incomplete, illegible, or makeshift labels.
4. Under no circumstances shall any person other than a pharmacist alter any prescription label.
5. If the prescriber changes the directions for use of a drug, the CalOptima Health PACE contracted pharmacy shall repackage the medication in accordance with the provider's order. The CalOptima Health PACE clinic Nurse shall notify the Participant and/or caregiver of any changes in medication dosage or directions.
6. Manufacturer's labeled directions for use must be followed by all CalOptima Health PACE employees. If the bottle is labeled "not to be reused," "dispose of unused portion," "single use container," or with words of similar meaning, the solution must not be stored or be used more than twenty-four (24) hours after opening.

B. CalOptima Health PACE clinic storage of all medications

1. CalOptima Health PACE shall store each Participant's medication individually and locked in a medication cabinet, or cart, except those approved by the Interdisciplinary Team (IDT) for self-administration by the Participant.
 - a. Only authorized CalOptima Health PACE personnel shall have access to the medication cabinet/cart keys.
2. CalOptima Health PACE shall store each Participant's medication in the containers in which they were dispensed.
 - a. Transferring between containers is forbidden; and
 - b. Empty containers, when empty, will be discarded by the CalOptima Health PACE Nurse.
3. CalOptima Health PACE shall store all medications at appropriate temperatures as follows:
 - a. Medication requiring room temperature shall be stored in a place maintained between 15°C (59°F) and 30°C (86°F); and
 - b. Medication requiring refrigeration shall be stored in a refrigerator maintained between 2°C (36°F) and 8°C (46°F).

- c. Medication shall not be stored in a refrigerator that is also used for food storage.
 - d. Medication requiring freezing shall be stored in a freezer maintained between -50°C (-58°F) and -15°C (5°F).
 - e. Medication refrigerator and freezer temperatures are monitored and recorded twice a day in the Clinic Refrigerator and Clinic Freezer Temperature Logs. In the event that a recorded temperature is outside the normal range:
 - i. The employee recording the temperature immediately notifies the Clinic Manager, Nursing Supervisor, or designee.
 - ii. The Clinic Manager, Nursing Supervisor, or designee takes steps to ensure the viability of medications and vaccines. Steps shall include, but are not limited to, visually inspecting medications/vaccines, and moving of medications/vaccines to a different storage unit which is maintained at the proper temperature.
 - iii. The Clinic Manager, Nursing Supervisor, or designee documents actions taken in the Clinic Refrigerator and Clinic Freezer Temperature Logs.
 - 4. CalOptima Health PACE shall store drugs for external use in liquid, tablet, capsule or powder form separately from drugs for internal use.
 - 5. CalOptima Health PACE shall store laboratory specimens, test reagents, germicides, disinfectants, and other household substances separately from all medications.
- C. CalOptima Health PACE clinic employee shall administer Controlled Substances as follows:
- 1. Only CalOptima Health PACE providers, dentists, licensed Nurses, and pharmacists shall have access to Controlled Substances (including Controlled Substances in the emergency supply, Participant's supply, and drugs awaiting destruction).
 - 2. At the start and end of each clinic day, two (2) Nurses, one (1) of whom shall be an RN, shall conduct a count of the Controlled Substances, kept in a double-locked storage system.
 - a. All Controlled Substances are to be counted and documented using the CalOptima Health PACE approved Narcotic Record Form. Documentation must include the following items:
 - i. Date and time of count;
 - ii. Amount on hand, amount received, amount given, and amount remaining; and
 - iii. Signatures of two (2) Nurses, one (1) of whom shall be an RN.
 - 3. If there is a discrepancy in the count that cannot be resolved, the Nurses will immediately notify the CalOptima Health PACE Medical Director Clinic Manager, or their designee.
 - a. Employee must stay at the CalOptima Health PACE Center until the discrepancy is addressed or until released by the CalOptima Health PACE Medical Director Clinic Manager, or their designee.
 - b. The CalOptima Health PACE Medical Director Clinic Manager, or their designee, shall notify, complete, and submit a medication report to the CalOptima Health PACE Quality Improvement Department.

- i. Further investigation will occur by the CalOptima Health PACE Medical Director, Clinic Manager, or their designee, as appropriate, for pattern analysis, corrective action, and prevention.
 4. CalOptima Health PACE shall retain a Controlled Substance narcotic count record for a period of ten (10) years.
- D. CalOptima Health PACE oversight on medication
 1. On a monthly basis:
 - a. The CalOptima Health PACE Clinic RN Manager shall audit the Clinic Refrigerator and Clinic Freezer logs to ensure that documentation is accurate and timely and that any out-of-range temperatures have been reported and documented.
 - b. The CalOptima Health PACE Pharmacist shall review and compare the log and inventory of Controlled Substances for accurate inventory records.
 - c. The CalOptima Health PACE Pharmacist shall review monthly reports of the contracted pharmacy.

IV. ATTACHMENT(S)

- A. Clinic Freezer Temperature Log
- B. Clinic Refrigerator Temperature Log
- C. Individual Participant Narcotic Record

V. REFERENCE(S)

- A. CalOptima Health PACE Contract with the Department of Health Care Services for the PACE Program
- B. CalOptima Health PACE Policy PA.5204: Emergency Medication
- C. CalOptima Health PACE Program Agreement
- D. Title 21, Code of Federal Regulations (C.F.R.), Part 1300-1399
- E. Title 22, California Code of Regulations (C.C.R.), §75037, 75039, and 78317

VI. REGULATORY AGENCY APPROVAL(S)

None to Date

VII. BOARD ACTION(S)

None to Date

VIII. REVISION HISTORY

Action	Date	Policy	Policy Title	Program(s)
Effective	04/01/2015	PA.5202	Labeling and Clinic Storage of Medication	PACE
Revised	05/01/2016	PA.5202	Labeling and Clinic Storage of Medication	PACE
Revised	04/01/2017	PA.5202	Labeling and Clinic Storage of Medication	PACE
Revised	09/01/2018	PA.5202	Labeling and Clinic Storage of Medication	PACE

Action	Date	Policy	Policy Title	Program(s)
Revised	05/01/2019	PA.5202	Labeling and Clinic Storage of Medication	PACE
Revised	10/01/2021	PA.5202	Labeling and Clinic Storage of Medication	PACE
Revised	08/01/2022	PA.5202	Labeling and Clinic Storage of Medication	PACE
Revised	06/01/2023	PA.5202	Labeling and Clinic Storage of Medications	PACE
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IX. GLOSSARY

Term	Definition
CalOptima Health PACE Center	The location designated by CalOptima Health PACE at which Participants shall receive PCP services.
Controlled Substance	A drug or other substance, or immediate precursor included in Schedule I, II, III, IV, or V of the Federal Controlled Substances Act.
Interdisciplinary Team (IDT)	<p>A team composed of members qualified to fill, at minimum, the following roles, in accordance with 42 CFR 460.102. One individual may fill two separate roles on the interdisciplinary team where the individual meets applicable state licensure requirements and is qualified to fill the two roles and able to provide appropriate care to meet the needs of Participants:</p> <ol style="list-style-type: none"> 1. Primary Care Provider; Primary medical care must be furnished to a Participant by any of the following <ol style="list-style-type: none"> a. A primary care physician. b. A community-based physician. c. A physician assistant who is licensed in the State and practices within his or her scope of practice as defined by State laws with regard to oversight, practice authority and prescriptive authority. d. A nurse practitioner who is licensed in the State and practices within his or her scope of practice as defined by State laws with regard to oversight, practice authority and prescriptive authority. 2. Registered Nurse; 3. Master's – level Social Worker; 4. Physical Therapist; 5. Occupational Therapist; 6. Recreational Therapist or Activity Coordinator; 7. Dietician; 8. CalOptima Health PACE Center Manager; 9. Home Care Coordinator; 10. Personal Care Attendant or his or her representative; and 11. Driver or his or her representative
Nurse	A person licensed by the California Board of Nursing as a Registered Nurse (RN) or Licensed Vocational Nurse (LVN).
Participant	An individual enrolled in the CalOptima Health PACE program.