

BHS Policies and Procedures

 <p>City and County of San Francisco Department of Public Health San Francisco Health Network BEHAVIORAL HEALTH SERVICES</p>	<p>1380 Howard Street, 5th Floor San Francisco, CA 94103 415.255-3400 FAX 415.255-3567</p>
POLICY/PROCEDURE REGARDING: BHS Clinic Medication Room	
<p>Approved By: David E. Smith, PharmD Director of Pharmacy, Behavioral Health Services</p> <p>Date: September 7, 2021</p> <p> <small>David Smith (Oct 6, 2021 10:27 PDT)</small></p>	<p>Manual Number: 3.01-4</p> <p>References: California Business and Professions Code: Code of Federal Regulations California Code of Regulations</p>

(Technical revision. Replaces version dated May 17, 2016)

PURPOSE:

This policy and procedures is intended to serve as a guideline for compliance with state and federal laws and regulations as well as to ensure medication safety in the clinic setting.

SCOPE:

This policy applies to BHS and BHS-affiliated clinics and to staff working in BHS and BHS-affiliated clinics that store or maintain medications on site.

GLOSSARY: For the purposes of this policy, the following definitions, based on pharmacy law and/or Behavioral Health Services practice environment, will apply:

- a. **Prescription Refill:** The remaining quantity of fills for a particular client prescription at the pharmacy. Prescription refills records are stored on file at a pharmacy. A medication request by the client or clinic must be received by the pharmacy to initiate a refill.
- b. **Medication Request:** A request made by the client or clinic for a particular client medication to be filled by the pharmacy.
- c. **Medication Renewal:** The prescriber issuance of an additional order for a particular client medication once refills of that medication are depleted.
- d. **Medication Dispensing:** The preparation, packaging, labeling, documenting, or transfer of a medication from a bulk supply (e.g. physician supply) by an authorized medical personnel to the client for which the medication was prescribed.
- e. **Medication Distribution:** The distribution of a patient's own medications to the patient. These are medications that were prescribed to the patient, delivered to the clinic by a pharmacy, and stored at the clinic on behalf of the patient. This may include subsequent delivery of the patient's medication to the patient by authorized clinic staff.
- f. **Medication Administration:** The directly observed administration of medications to a client (e.g. orally or via injection) by an authorized medical personnel during the course of a clinic visit.

- g. **Receiving Medications:** The act of accepting a medication delivery from a pharmacy or wholesale distributor. Types of medications being received may be client-specific or may be a physician supply (e.g. for emergency use)
- h. **Medication Room:** A secure location for medication storage of patient's own med, a physician's supply, or a clinic supply that ensures the proper storage and security of medications as outlined in this policy. This definition does not include the mobile storage of emergency medication.

POLICY:

1. RESPONSIBILITY

- a. BHS and BHS-affiliated clinic staff shall be in compliance with this policy and procedure, and with state and federal laws and regulations for medications including the accessing, ordering, receiving, storage, prescribing, dispensing, administration and disposal of medications.
- b. The clinic Medical Director and Program Director have shared responsibility to ensure that the clinic staff and premises are in compliance. The Program Director has responsibility in the general support of the medication room including security and upkeep of the premises, and non-medical staff receiving and distributing/delivering of medications. The Medical Director has responsibility to ensure compliance by medical staff for medication room policies and procedures, and laws and regulations.

2. ACCESS

- a. All prescription medications and medication injection equipment (syringes, needles) will be stored in a securely locked medication room or cabinet with access limited to medical personnel authorized to prescribe, dispense or administer medication. (CCR, Title 9, § 1810.435 (b) (3)) Designated medical staff will be identified in writing by the clinic and posted in the medication room. Non-medical staff may only enter medication rooms when an operational reason exists and when an authorized medical personnel is present.
- b. Keys (keys, key cards, key codes) that open medication rooms and cabinets are issued only to authorized medically licensed personnel assigned to work at these sites. These staff members must secure possession of the keys and must return the keys to the Medical Director when no longer assigned to the clinic. Under no circumstance shall staff members share keys with anyone else. Medical Directors and program managers should maintain an active list of authorized personnel with keys, including name and provider type (e.g. -- physician, psychiatry technician)
- c. Any lost medication room keys must be immediately reported to the Medical Director, who will work with the appropriate program and facilities personnel to ensure only authorized staff will have access.

3. RECEIVING MEDICATIONS

- a. The clinic shall only receive medication deliveries when authorized medical staff is present. Medications delivered to the clinic must be received by authorized personnel, then promptly and appropriately stored in the medication room.

- b. If medications are received by non-medical staff, such as front desk clerk, the front desk clerk shall immediately notify authorized medical staff so that medications are promptly stored in the medication room. Packages shall never be left unattended. Every clinic that receives and stores medications must keep records of their acquisition and disposition (*B&P Code 4081.4105,4180*). A chain of custody chronologically documenting the receipt, dispensing, administration, and/or disposal of all medications shall be maintained.
- c. Clinics must log the receipt of all client medications (*CCR, Title 22 73361*). Copies of the pharmacy's delivery log may serve as the receipt log. The records shall be retained for at least 3 years. (*CCR, Title 22 73361*). Incoming client medication logs must contain all the following information:
 - i. Medication name
 - ii. Strength and quantity
 - iii. Name of the client
 - iv. Date ordered (date medication request made to pharmacy)
 - v. Date received
 - vi. Name of issuing pharmacy
- d. To document "date ordered" for the receipt of client medications, facilities shall do one of the following:
 - a. Retain copies of medication requests sent to the pharmacy or
 - b. Print and retain OrderConnect medication lists, noting date and requested medications or
 - c. Record medication requests using the Client Medication Request Log (Attachment 1)
- e. Clinics must log the receipt of all physician's own use medications (*CCR, Title 22 73361*). A copy of delivery log sent with the delivery, may serve as the receipt log. The records shall be retained for at least 3 years. Incoming medication logs must contain all of the following information:
 - i. Medication name
 - ii. Strength and quantity
 - iii. Name and signature of person receiving medication delivery
 - iv. Date ordered
 - v. Date received
 - vi. For prescription medications, name of ordering physician
 - vii. Name of issuing pharmacy
- g. Client medications received at a clinic from a pharmacy must be properly labeled with (*CA B&P Code 4076*):
 - i. Name of the client
 - ii. Name and strength of the medication; if generic name, include name of manufacturer
 - iii. Description of the medication (color, shape, any identification code)
 - iv. Directions for use
 - v. Condition or purpose of the medication, if indicated
 - vi. Date of issue.
 - vii. Medication quantity
 - viii. Expiration date of the medication
 - ix. Name of the prescriber
 - x. Initials of the dispensing individual
 - xi. Name, address and phone number of the dispensing pharmacy
 - xii. FDA side effects statement label (*21 CFR 209*)

xiii. Any applicable auxiliary labels

h. Prescription labels may be altered only by persons legally authorized to do so.

4. STORAGE

- a. The medication room/storage area shall be located on premises.
- b. The medication room/storage area shall be secure, clean, and orderly. Drugs are organized in a manner that prevents crowding and confusion. The facility shall have a schedule or procedure for cleaning and upkeep of the premises.
- c. Controlled substance floor stock or physician supply medications must be stored in a separately locked cabinet in the medication room. CCR, Title 22, §73367(a)
- d. Medications labeled and intended for external-use only (topical) shall be stored separately from oral and injectable medications. Germicidals, cleaning agents and test reagents are stored separately from all drugs.
- e. Drugs stored at room temperature are kept between 59° and 86°F. (CCR, Title 9, §1810.435(b) (3)) Room temperatures shall be logged each working day on the Room Temperature Log form (Attachment 2). For any out-of-range temperatures, contact CBHS Pharmacy immediately for instructions and document actions taken on the Room Temperature Log form. Room temperature logs shall be retained for at least 3 years.
- f. Drugs requiring refrigeration are stored in a refrigerator between 36° and 46°F. (CCR, Title 9, §1810.435(b) (3)) Refrigerator temperatures shall be logged each working day on the Refrigerator Temperature Log form (Attachment 3). Contact CBHS Pharmacy immediately for instructions for any out-of-range temperatures and document actions on the Refrigerator Temperature Log form. Refrigerator temperature logs shall be retained for at least 3 years.
- g. Drugs shall not be stored in a refrigerator with any food or lab specimens. (CCR, Title 9, §1810.435 (b) (3))
- h. Vaccines: vaccine storage, use, and documentation must be in compliance with Center for Disease Control Guidelines, and in alignment with other applicable programs supplying the vaccine (e.g. Vaccine for Children).
 1. If any vaccines are stored in refrigerators, refrigerator temperatures must be logged at the beginning and end of each working day. Vaccines cannot be stored in dormitory-style refrigerators which have a combined refrigerator and freezer in the same compartment.
 2. Vaccines in multidose vials that do not require reconstitution can be administered until the expiration date printed on the vial or vaccine packaging if the vial has been stored correctly and the vaccine is not visibly contaminated, unless otherwise specified by the manufacturer.
- i. Multiple dose injectable medications will be initialed and have the expiration date recorded on the label when opened, with the exception of certain vaccines,. Once opened, multiple dose vials expire in 28 days. Any open vial that appears to be contaminated or discolored shall be discarded and not used.
- j. Drug containers shall not be cracked, soiled or without secure closures.
- k. Expired, contaminated, or deteriorated prescription medications, Over-The-Counter (OTC) medications, and/or medical supplies are not available for use and shall be properly disposed of.

- l. Medication expiration dates will be checked and documented on a monthly basis by a designated person with legal access to the medication room. The Monthly Expired Medication Review form (Attachment 4) may be used to document completion. Records shall be retained for at least 3 years.
- m. Medication samples and drug vouchers are not allowed in clinics.
- n. Paper prescription pads are stored in a secure location inaccessible to clients.

5. HANDLING OF CLIENTS' OWN MEDICATIONS

- a. Clients' own prescription medications that have been dispensed by a pharmacy may be stored in the clinic medication room, if necessary to support the client's wellness and recovery, and be supported by documentation, e.g. – documented medication order or in the medical record,
- b. Clients' own medications are properly stored, clearly labeled, and with internal use medications separated from external use.
- c. No more than an 8-week supply of client's own medications should be stored in the clinic medication room.
- d. If a client does not claim his or her medications within 8 weeks of receipt by the clinic, they may be considered as medications abandoned by the client.
- e. Abandoned, expired, or discontinued medications shall, if possible, be first sent back to the dispensing pharmacy for the billing to be reversed. If the issuing pharmacy does not accept returned dispensed medications, medications shall be disposed of as hazardous medication waste.
- f. Clients' own medications shall only be distributed to the specific client for whom it was prescribed and labeled. Client's own medications shall not be administered or "shared" with other clients.
- g. Re-packaging of client's own medications (e.g. - specialty packaging, such as bubble packs) can only be performed by a pharmacy or the client. (BPC code 4052.7)
- h. "Automatic medication refills" (i.e. refills sent by the pharmacy automatically without needing to be requested) shall not be utilized for client's medications stored in the clinic medication room in compliance with CMS requirements mandating member consent for all prescription deliveries, new or refill. (2014 Call Letter) (42 CFR §423.504)
- i. Delivering medication: this refers to staff handing an unaltered bubblepack, bag or vial of medication delivered from the pharmacy, along with any medication information, to a patient who had their medication delivered to the clinic's address. This is the equivalent of handing a patient any other items that are mailed to the clinic, and is within the scope of any healthcare worker at the clinic.

6. PHYSICIAN'S SUPPLY MEDICATIONS

- a. "Physician's Supply Medications" refers to a physician's supply of medications for the physician's use in clinic (*B&P Code 4119.5 and 4170*).
- b. A physician's own supply of medications may be stored in the medication room. Medications should be prescribed by the physician, and use should be limited to acute or emergency need of medications. Prescribers should use a local community pharmacy to provide non-acute, standard medications to clients.
- c. Usage shall be documented on the Physician's Supply Medication Log sheet. (Attachment 6).

- d. Each medication use shall be logged separately with a running inventory of the quantity used and quantity remaining for that particular medication. The records shall be retained for at least 3 years. Logs must contain all of the following information:
 - i. The date and time the medication was administered
 - ii. The source of the medication
 - iii. The expiration date, lot and/or vial number of the medication
 - iv. The name of the client receiving the medication
 - v. The name, dosage and quantity of the medication given
 - vi. The route of administration for medication (if other than oral)
 - vii. The signature of authorized staff who administered the medication
- e. Requests for Physician's Supply Medications shall be placed using the BHS Drug and Supply Request form (Attachment 5). Orders shall be placed by designated medical staff, and need to include a copy of the Physician's Supply Medication Log sheet for proof of use or expiration of the medication requested.
- f. For Controlled Substances, medication quantities must be reconciled at least daily on the Physician's Supply Medication Log (Attachment 6) and shall be retained for at least three years. Controlled Substances are stored separate from non-controlled medications and locked.

7. STORAGE OF MEDICATIONS FOR PUBLIC HEALTH BENEFIT

- a. County-sponsored or State-sponsored programs may provide medications for clinics to distribute for public health benefit. For example, the DHCS-sponsored Nasal Distribution Project provides nasal naloxone, a life-saving medication, to assist in the opiate epidemic. (https://www.dhcs.ca.gov/individuals/Pages/Naloxone_Distribution_Project.aspx)
- b. On-site storage of medication obtained through these programs are permitted after review and approval by the clinic Medical Director and the BHS Pharmacy Director. These medications are not required to be stored within a medication room. However, if stored in a medication room, they must be stored separately from other medications and must follow any additional guidelines set out by the sponsoring program.

8. MEDICATION ADMINISTRATION

- a. Medications may only be administered to clients by authorized personnel upon an order by a lawfully authorized prescriber. BHS personnel who are authorized to administer medications under their scope of practice include: physicians, physician assistants, nurse practitioners, registered nurses, licensed vocational nurses, licensed psychiatric technicians and pharmacists.
- b. Authorized personnel administering a medication are responsible for:
 - i. Knowing a drug's usual dosage range, indications, side effects, toxicity, stability, expiration date and the client's hypersensitivity or allergies.
 - ii. Ensuring that the fundamentals of medication administration are followed: right client, right drug, right dose, right route, and right time.

- c. Prior to drug administration, establish the client’s identity by using two distinct client identifiers (e.g. asking the client to state their name and date of birth).
- d. For injectable medication administration:
 - i. Use universal and bloodborne pathogen precautions
 - ii. Use safety needles
- e. Documentation by the person administering the medication(s) shall be in compliance with Medical Records Policy 3.10-02, (CCR, Title 22 § 73313(f), 73351, 73353) and include:
 - i. Medication, dosage, frequency and route
 - ii. Date and time of administration
 - iii. Site/location of any injection
 - iv. The lot and/or vial number if medication was dispensed from a multi-dose container
 - v. Any unusual or adverse response to the medication
- f. Client medications shall not be “shared” or utilized as floor stock medications under any circumstance. Client medications shall only be administered to the specific client for whom it was prescribed and labeled.

9. DRUG AND SHARPS DISPOSAL

- a. General requirements: Every clinic that maintains a stock of drugs must keep records of their acquisition and disposition (*B&P Code 4081.4105,4180*). All medications shall be disposed in accordance to applicable federal, state, and local regulations for disposal of chemicals and potentially dangerous or hazardous substances.
- b. Medications for disposal may include:
 - i. Medications which are not taken with the client upon termination of services
 - ii. Medications abandoned by the client
 - iii. Discontinued medications
 - iv. Expired, contaminated or deteriorated medications
- c. Proper medication disposal
 - i. Clients’ medications may be returned to the dispensing pharmacy for disposal, or disposed of at the clinic through the use of a licensed medical waste disposal service (e.g. -- Stericycle) or destruction container (e.g. -- RxDestroyer).
 - ii. Solid dosage form medications (e.g. -- pills, capsules) are removed from their original containers before disposal.
 - iii. Non-Controlled Substances
 - a. Non-Controlled pharmaceutical waste shall be place in the **white waste container with the blue top** that is puncture resistant and sealable when full. This container is labeled “Pharmaceutical Waste” and shall be stored in the medication room .
 - b. The waste shall be removed by a licensed medical waste disposal company.
 - iv. Controlled Substances
 - a. Controlled substances shall be placed in the “RxDestroyer” which is a white, puncture resistant container with a red top and sealable when full. This container is labeled “RxDestroyer”, and shall be stored in the medication room. RxDestroyer should only be used for destruction of controlled substances. All other pharmaceutical waste must be destroyed by placing in the blue and white pharmaceutical waste container as described above.

- b. Directions for using “RxDestroyer”
 - i. Load medications into the bottle
 - ii. Tightly replace cap
 - iii. Gently shake to mix solution over medications. The bottle contains a solution that will dissolve medications on contact. Active medication ingredients are absorbed or neutralized by activated charcoal.
 - iv. Note that the outer shells of capsules or patch materials will not dissolve
 - v. Bottle is full when contents are 2 inches from the cap. Do not overfill.
 - vi. When full, the full container shall be discarded into regular trash receptacle.
 - v. Personnel conducting disposal
 - a. Only individuals with authorized access to the medication room may dispose of expired or returned medications.
 - b. Disposal and documentation of disposal of non-controlled medications shall be conducted by a pharmacist or registered nurse employed by the facility. In the absence of a pharmacist and registered nurse, by licensed medical staff authorized to access the medication room.
 - c. Disposal and documentation of disposal of controlled medications shall be conducted by both a pharmacist and registered nurse. In the absence of a pharmacist and/or registered nurse, by two licensed medical staff authorized to access the medication room.
 - vi. Disposal shall be documented on a Medication Destruction Log (Attachment 7). The log shall be retained for at least 3 years and include the following information:
 - a. Name of the client
 - b. Medication name and strength
 - c. Quantity destroyed
 - d. Prescription number
 - e. Date of destruction
 - f. Name and signature of witness (two signatures if controlled substance)
- d. Client Confidentiality
 - i. Client identifiers are protected health information (PHI), include the client’s name, medical record number, address, and date of birth. (Refer to San Francisco Department of Public Health Privacy and Data Security Policies)
 - ii. Labels or documents containing PHI are disposed of by placing in confidential waste or by physically removing or fully obscuring with a permanent marker.
- d. Sharps containers:
 - i. Shall be stored in a secure location not accessible to clients. Containers are disposed of in accordance to applicable federal, state, and local regulations for disposal of chemical and potentially dangerous or hazardous substances. The method of disposal may include the use of a contracted medical waste disposal service.

10. MEDICATION ROOM COMPLIANCE CHECKLIST

- a. The Clinic Medical Director will appoint appropriate staff to manage monitoring of medication storage and handling, and to conduct the quarterly Medication Room Audit. The results of the audit shall be reviewed by the clinic Medical Director.
- b. The Medication Room Compliance Checklist (Attachment 8) form shall be used to complete the Medication Room Audit. It must be completed each quarter (every three months) by a pharmacist or other authorized medical staff.
- c. Plans of Correction: Any areas of non-compliance shall be promptly addressed through a plan of correction developed by the clinic Medical Director, who will be responsible for its implementation. BHS Director of Pharmacy may be consulted for questions arising from a plan of correction. Areas of non-compliance should be addressed before the next quarterly audit.
- d. Compliance checklists and any plans of correction shall be retained for at least three years.

Contact Person:

Director, BHS Pharmacy Services

Distribution:

BHS Policies and Procedures are distributed by the Health Information Management Department under the DPH Compliance Office

Administrative Manual Holders

BHS Programs

SOC Managers

BOCC Program Managers

CDTA Program Managers