Pharmaceuticals Storage, Handling and Dispensing

PURPOSE: To store and dispense drugs in accordance with State, Federal and Local distribution laws and regulations.

PERSONNEL: Physicians, Non-Physician Practitioners, Nurses, and Medical Assistants

DEFINITIONS:

Drug: Any chemical compound, remedy or noninfectious biological substance, the action of which is not solely mechanical, which may be administered to patients by any route as an aid for the diagnosis, treatment, or prevention of disease or other abnormal condition, for the relief of pain and suffering, or to control or improve any physiological or pathological condition.

Drug Administration: The action, which a single dose of prescribed drug is given to the patient.

Drug Dispensing: The interpretation of an order for a drug, the proper selection, measuring, packaging, labeling and issuance of the drug.

Storage and Handling

1. All drugs will be well organized and stored in specifically designated cupboards, cabinets, closets or drawers.
2. Drugs will be stored under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, purity of the drug product is not affected. Room temperature drugs should not be stored above 86° F (30° C)
3. Prescription, sample, over the counter drugs, prescription pads and hypodermic needles will be securely stored in a lockable space (cabinet or room) within the office/clinic.
4. Keys to locked storage area will be available only to staff authorized by the physician to have access. (During business hours, the drawer, cabinet or room containing drugs or medication supplies may remain unlocked **ONLY** if there is no access to the area by unauthorized persons. Whenever drugs or supplies are unlocked, authorized clinic personnel must remain in the immediate area **at all times**. At all other times they will be securely locked.
5. Drugs will be prepared in a clean area, or "designated clean" area if prepared in a multipurpose room. Vaccines will not be stored in the door of refrigerator or freezer.
6. Drugs for external use in liquid, tablet, capsule or powder form shall be stored separately from medications for internal use.
7. Drugs and immunobiologics requiring refrigeration will be kept in refrigerators that shall be maintained between 2º C (35ºF) and 8º C (46ºF).
8. Drugs and immunobiologics requiring freezing, will be kept in freezers that shall be maintained at 5º F or -15º C, or lower.
9. **Daily** temperature readings of medication refrigerator and medication freezer will be documented. (See Appendix A).
10. Items other than medications in refrigerator/freezer will be kept in a secured, separate compartment from drugs.
11. Drugs must be kept separate from food, lab specimens, and other items that may potentially cause contamination.
12. Tests reagents, germicides, disinfectants and other household substances shall be stored separately from drugs.

Expiration Date Compliance

1. The manufacturer's expiration date must appear on the labeling of all drugs. All prescription drugs not bearing the expiration date are deemed to have expired.
2. If a drug is to be reconstituted at the time of dispensing, its labeling must contain expiration information for both the reconstituted and unconstituted drug.
3. Expired drugs will not be distributed or dispensed.
4. All drugs including stock, vaccine, sample, emergency, controlled, infant and therapeutic formulas will be checked for expiration monthly and written documentation will be maintained. (See Appendix B).

Controlled Substances

1. A dose-by-dose controlled substance distribution log will be maintained, with written records that include: provider's DEA number, name of medication, original quantity of drug, dose, date, name of patient receiving the drug, name of authorized person dispensing drug and number of remaining doses. (See Appendix C, Pages 1&2).
2. Controlled substances will be stored separately from other drugs in a securely locked, substantially constructed cabinet.
3. Controlled substances include all Schedule I, II, III IV, and V substances listed in the CA Health and Safety Code, Sections 11053-11058, and do not need to be double locked.
4. Personnel with authorized access to controlled substances include physicians, dentists, podiatrists, physician's assistants, licensed nurses and pharmacists.

Disposal and Dispensing

1. Drugs will be disposed of appropriately. Drugs may be returned to the manufacturer or disposed of in medical waste. (See disposal of controlled substances below).
2. Drugs will be dispensed only by a physician, pharmacists or other persons (e.g.; NP, CNM, RN, PA) lawfully authorized to dispense medications, upon the order of a licensed physician or surgeon.
3. Personnel such as medical assistants, office managers, and receptionists will not dispense drugs.
4. Drugs will not be offered for sale, charged or billed to Medi-Cal members.
5. All drugs that are dispensed will be labeled and will include the following:

   Provider's name, patient's name, drug name, dose, frequency, route, quantity dispensed, and manufacturer's name and lot number.

   Dispensing containers will not be cracked, soiled or without secure closures. California Pharmacy Law *does not* prohibit furnishing a limited quantity of sample drugs if dispensed to the patient in the package provided by the manufacturer and no charge is made to the patient.

   All pre-filled syringes must be individually labeled with date, medication name, and dosage.
6. All drugs that are administered or dispensed will be recorded in the medical record.
7. Disposable of Controlled Substances:

   - The DEA requires providers to maintain documentation of disposal of all controlled substances.
   - Provider may return the controlled drugs to the drug manufacturer.
   - Controlled drugs may be sent to a DEA registered disposal firm (reverse distributor) for destruction.
   - Providers may conduct their own drug destruction if the DEA had previously authorized them to do so. Those authorizations will remain in effect until rescinded, revoked, or procedures are changed.

Source: www.ccah-alliance.org/FReview/Clinical_Services/1_**Pharmaceuticals**

SECTION	Approval date:	
Clinical Services	Approved by:	
POLICY AND PROCEDURE	Effective date:	
Pharmaceutical & Vaccine Services	Revision date:	

POLICY:

The site shall maintain competent, efficient, and ethical Pharmaceutical Services according to state and federal statutes for the health and safety of its patients.

PROCEDURE:

I. Drugs and medication supplies are maintained secure to prevent unauthorized access:

A. All drugs (including sample and over the counter), medication supplies, prescription pads, and hazardous substances are securely stored in a lockable space (e.g., a room, closet, cabinet, drawer, etc.) within the office/clinic (CA B&P Code, §4051.3). Keys to the locked storage area are available only to staff authorized by the physician to have access (16 CCR, Chapter, Division 3, §1356.32).
- During business hours, the lockable space may remain unlocked ONLY if there is no access to this area by unauthorized persons and authorized clinic personnel remain in the immediate area at all times. At all other times, all prescription pads and hazardous substances must be securely locked.

B. Controlled drugs are stored separately from other drugs, in a secured, lockable space accessible ONLY to authorized personnel (including physicians, dentists, podiatrists, physician assistants, licensed nurses and pharmacists) (Control Substance Act, CFR §1301.75). There is no need for the controlled substances to be double locked
- Controlled Substances include all Schedule I, II, III, IV, and V substances listed in the CA Health and Safety Code, §§11053-11058.

C. A dose-by-dose controlled substance distribution log shall be maintained to include the following:
    a. Date
    b. Provider's DEA number
    c. Name of controlled substance
    d. Original quantity of controlled substance
    e. Dose administered, Number of doses remaining
    f. Name of patient receiving controlled substance
    g. Name of authorized person dispensing controlled substance

II. Drugs are handled safely and stored appropriately.

A. Preparation:
- Drugs are prepared in a clean area, or a "designated clean" area if prepared in a multipurpose room.
- Drugs or medication supplies are considered "adulterated" if it contains any filthy, putrid, or decomposed substance, or if it has been prepared, packed, or held under unsanitary conditions (21 USC §351).

B. Storage:

- Items other than medications in refrigerator/freezer are kept in a secured, separate, compartment from drugs, as these items may potentially cause contamination.
- Drugs are stored separately from test reagents, germicides, disinfectants, and other household substances.
- Drugs are stored under appropriate conditions of temperature, humidity, and light, so that the identity, strength, quality, and purity of the drug product are not affected (21 CFR, §211.142). Room temperature where drugs are stored does not exceed 30ºC (86ºF) (Title 22, §75037(d)).

C. Immunobiologics:

- Vaccines are placed in a refrigerator or freezer (**not** on the door) immediately upon receipt on site and are stored according to specific instructions in the package insert for each vaccine.
- Vaccines, such as DTP, DTaP, DT, Td, Hep A, Hep B, Enhanced Inactive Polio (E-IPV), and Pneumococcal, are kept in a refrigerator maintained at 2º-8 ºC or 36 º-46 ºF (at time of visit). MMR and varicella are protected from light at all times. Oral polio vaccine (OPV), MMR, MMRV, and varicella vaccines are stored in a freezer maintained at -15 ºC, or 5 ºF, or lower (at time of visit). Failure to adhere to recommended specifications for storage and handling of Immunobiologics could make these products impotent.
- A written plan for vaccine protection in case of power outage or malfunction of the refrigerator or freezer is available on site (see Attachments).
- Site personnel are able to verbalize the procedures in the plan used to promptly respond to out of range temperatures.
- Refrigerator and freezer temperatures are documented at least once a day (required twice daily for VFC providers). CDC recommends use of a continuous temperature monitoring device (data loggers), calibrated at least every 2 years, to monitor vaccine storage unit temperatures. Data loggers should have a minimum accuracy of +/- 1°F (0.5°C), be equipped with buffered probe, an active temperature display outside of the unit, and the capacity for continuous monitoring and recording where the data can be routinely downloaded. A back-up device should be readily available for emergency vaccine transport or when primary data logger is sent in for calibration.

D. Hazardous substances (Substances that are physical or health hazards):

- Safety practices on site are followed in accordance with current/updated CAL-OSHA standards.
- The manufacturer's label is not removed from a container as long as the hazardous material (or residue from the material) remains in the container.
- All portable containers of hazardous chemicals and secondary containers (into which hazardous substances are transferred or prepared) require labeling. Hazardous substances are appropriately labeled with the following information:
  a. Identity of hazardous substance
  b. Description of hazard warning: can be word, pictures, symbols
  c. Date of preparation or transfer

  ******EXCEPTION**:** Labeling is NOT required for portable containers into which hazardous chemicals are transferred from labeled containers, and which are intended only for the immediate use of the individual who performs the transfer.******

- Site has method(s) in place for drug and hazardous substance disposal (see C.5.).

III. Drugs are administered or dispensed according to State and Federal drug distribution laws and regulations.

A. Drug Dispensing and Administration:

- Drug dispensing is in compliance with all applicable State and Federal laws and regulations. Drugs are not offered for sale, charged, or billed to Medi-Cal members (Business and Professions Code, Article 13, §4193).
- Criteria for selecting pharmaceutical manufacturers and suppliers shall be established to ensure that patients receive pharmaceuticals and related supplies of the highest quality.
- The clinic shall govern the activities of manufacturers' representatives or vendors of drug products (including related supplies and devices) within the ambulatory care setting. Representatives should not be permitted access to patient care areas and should be provided with guidance on permissible activities. All promotional materials and activities shall be reviewed and approved by the provider.
- Adequate inventory controls shall be maintained to allow proper inventory levels of medications based on utilization.
- A list of drugs available for dispensing or administration in the clinic shall be maintained (see Attachments).
- Each prescription medication is dispensed in a container that is not cracked, soiled, or without secure closures (Title 22, CCR, §75037 (a)).
- Drugs are dispensed **ONLY** by a physician, pharmacist, or other persons (i.e., NP, CNM, RN, PA) lawfully authorized to dispense medication upon the order of a licensed physician or surgeon. Personnel, such as medical assistants, office managers, and receptionists, **DO NOT DISPENSE DRUGS**.
- A record of all drugs dispensed is entered in the patient's medical record.
- California Pharmacy Law *does not* prohibit furnishing a limited quantity of sample drugs if dispensed to the patient in the package provided by the manufacturer, no charge is made to the patient, and appropriate documentation is made in the patient's medical record (CA Business and Professions Code, §§ 4170-4171).
- Administration of medications ordered by the licensed practitioner may be completed by the MA using the following procedures:
  a. Prepare medication in a clean area
  b. Have the ordering practitioner or another licensed practitioner (i.e., MD, NP, PA, CNM, RN, LVN) verify the medication and dosage prior to administration of the drug by:
     - Showing the bottle or vial and medicine cup or syringe to the verifying practitioner
     - Show the patient's chart and original medication order to another verifying practitioner when the ordering practitioner is not available
     - Administer to the patient only after a licensed practitioner has checked the prepared medication for the correct medication, correct dose, correct route, and the appropriate time; and the patient's identity is verified.
  c. To help reduce the risk of medication errors, staff shall confirm the patient's identity prior to administration by asking the patient/parent to confirm the patient's name and date of birth.
  d. Drugs and vaccines are prepared and drawn only prior to administration.
  e. Unused prefilled syringes shall be discarded if not used within the same day that they are filled. Unused syringes that are prefilled by the manufacturer and activated (i.e.,, syringe cap removed or needle attached) shall be discarded at the end of the clinic day.

  NOTE: No MA may administer any anesthetic agent or any medication mixed with an anesthetic agent (e.g., Rocephin diluted with Xylocaine).
- All vaccines administered in the clinic shall be reported by the clinic to an immunization registry (i.e., California Immunization Registry or "CAIR")

B. Vaccine Information Statements (VIS):

- Since 1994, the National Childhood Vaccine Injury Act (§2126 of the Public Health Services Act) mandates that parents/guardians or adult patients be informed before vaccines are administered. Health care providers **must** give a copy of the most recent VIS to patients prior to each vaccination dose of ALL vaccines (i.e., DTaP, Td/Tdap, MMR, Influenza, Hepatitis A/B, Pneumococcal, etc.). VIS sheets for all vaccines are available through the CDC website: http://www.cdc.gov/vaccines/pubs/vis/default.htm.

- VIS sheets for distribution to patients are present on site. Site personnel should be able to verbalize standard practices regarding VIS distribution.
- The date the VIS was given and the publication date of the VIS MUST be documented in the patient's medical record. (See Attachments)
- The most current Vaccine Information Statements (VIS) are available from state and local health departments or can be downloaded from the CDC website at http://www.cdc.gov/vaccines/pubs/vis/default.htm or by calling the CDC Immunization Hotline at (800) 232-4636. (800-CDC-INFO).

C. Prescription Labeling:

- All stored and dispensed prescription drugs are appropriately labeled with the following:
  a. Provider's name
  b. Patient's name
  c. Drug name
  d. Dose
  e. Frequency
  f. Route
  g. Quantity dispensed
  h. Manufacturer's name and lot number

D. Pharmacy:

- If there is a pharmacy on site, it is licensed by the CA State Board of Pharmacy, with a licensed pharmacist monitoring drug distribution and current policies/procedures for drug storage and dispensing.

E. Drug Expiration:

- There are no expired drugs on site, as they may not be distributed or dispensed.
- The manufacturer's expiration date must appear on the label of all drugs. All prescription or over the counter (OTC) drugs not bearing the expiration date are deemed to have expired.
- Multi-dose vials (MDV): Per CDC, MDV injectable expire 28 days once opened unless manufacturer recommends a longer or shorter expiration date. Vials must be labeled with date opened. Unlabeled open vials are deemed to have expired.
- Site follows the procedures below to monitor for expiration date and a method of dispose of expired medications/hazardous substances (i.e., sample medications), vaccines, and infant formula. A tracking log is the preferred method of tracking expiration dates (see Attachments).

Frequency of monitoring:	Method of disposal:
☐ Monthly, ☐ Weekly, or ☐ Other:	Prescription & OTC drugs / hazardous substances / infant formula: Vaccines: