PCP:	
SECTION: Clinical Services	
POLICY AND PROCEDURE: Pharmaceutical Services	Approved date: _____ Approved by: _____ Effective date: _____ Revised date: _____ Revised date: _____

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

PROCEDURE:

A. Drugs and medication supplies are maintained secure to prevent unauthorized access.
   1. All drugs (including sample and over-the-counter), medication supplies, prescription pads and hazardous substances are securely stored in a lockable space (room, closet, cabinet, drawer) 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 2, Division 3, Section 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 drugs (including sample and over-the-counter), medication supplies, prescription pads and hazardous substances must be securely locked.

   2. 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 Substances 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, Sections 11053-11058.

   3. A dose-by-dose controlled substance distribution log in maintained, including:
      A. Date
      B. Provider's DEA number
      C. Name of controlled substance
      D. Original quantity of controlled substance
      E. Dose administered, Number of remaining doses
      F. Name of patient receiving controlled substance
      G. Name of authorized person dispensing controlled substance

B. Drugs are handled safely and stored appropriately.

1. Preparation:
   - Drugs are prepared in a clean area, or "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, Section 351).
2. 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 for external use are stored separately from drugs for internal use.
   - 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, Section 211.142). Room temperature where drugs are stored does not exceed 30°C (86°F) (Title22, Section 75037(d)).
3. 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 2°- 8°C, or 35°- 46°F (at time of visit). [MMR and varicella are protected from light at all times, and kept cold]. Oral polio vaccine (OPV), MMR, MMRV and varicella vaccines are stored in a freezer maintained at -15°C, or 5°F, or lower (at time of visit). Failure to adhere to recommended specifications for storage and handling immunobiologics could make these products impotent.
   - Refrigerator and freezer temperatures must be checked at least once a day and documented (U.S. Pharmacopeial Convention Regulations and Recommendations). However, the CA ~~DHS~~DHCS Immunization Branch recommends checking temperatures twice a day, first thing in the morning and last thing at night. (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 www.cdc.gov/nip/publications/VIS or by calling the CDC Immunization Hotline at 800-232-2522.
4. 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 residues 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 words, 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. Proper disposal is via the site's contracted/licensed medical waste hauler.

C. Drugs are dispensed according to State and Federal drug distribution laws and regulations.

1. 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 drugs not bearing the expiration date are deemed to have expired.
   - If a drug is reconstituted at the time of dispensing, its label must contain expiration information for both the reconstituted and unconstituted drug.
   - Site has a procedure to check expiration date of all drugs (including vaccines and samples), and infant and therapeutic formulas. Must be done AT LEAST monthly. A log is preferred, but it is acceptable to clearly mark the outside of the drug packages with the expiration date.
2. Prescription Labeling
   - All stored and dispensed prescription drugs are appropriately labeled with:
     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
3. Drug Dispensing and Administration

- Each prescription medication is dispensed in a container that is not cracked, soiled or without secure closures (Title 22, CCR, Section 75037 (a)).
- 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, Section 4193).
- Drugs are dispensed **ONLY** by a physician, pharmacist or other persons (i.e. NP, CNM, RN, PA) lawfully authorized to dispense medications upon the order of a licensed physician or surgeon. Personnel, such as medical assistants, office managers, and receptionists, **DO NOT DISPENSE DRUGS**.
- 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, Sections 4170,4171).
- Administration of medications ordered by the licensed practitioner may be completed by the MA using the following procedures:
    - Prepare Medication in a clean area
    - 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.
        - Showing the checking practitioner the bottle or vial and medicine cup or syringe,
        - If the practitioner checking the medication is not the practitioner that ordered the drug show the checking practitioner the patient's chart with the original order.
        - Administer to the patient only after a licensed practitioner has checked the prepared medication.

    Note: No MA may administer any anesthetic agent or any medication mixed with an anesthetic agent (e.g. Rocephin diluted with Xylocaine).

4. Vaccine Information Statements (VIS)
    - Since 1994, the National Childhood Vaccine Injury Act, Section 2126 of the Public Health Service 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 DTaP, Td, MMR, IPV, Hep B, Hib, Varicella and Pneumococcal Conjugate. VISs for other vaccines are available through the CDC website referred to previously.
    - VISs 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.

5. 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.

*****Note: All site review survey deficiencies related to Pharmaceutical Services REQUIRE a corrective action plan. *****

Attachments: Temperature Log for Vaccines (Fahrenheit)
Temperature Log for Vaccines (Celsius)
Vaccine Storage Troubleshooting Record

Temperature Log for Vaccines (Celsius)

Month/Year:_____ **Days 1–15**

***Instructions:** Place an "X" in the box that corresponds with the temperature. The hatched zones represent unacceptable temperature ranges. If the temperature recorded is in the hatched zone: 1. **Store the vaccine** under proper conditions as quickly as possible, 2. **Call the vaccine manufacturer(s)** to determine whether the potency of the vaccine(s) has been affected, 3. **Call the immunization program at your local health department** for further assistance: (_____) _____, and 4. **Document the action taken** on the reverse side of this log.

Day of Month	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Exact Time																														
°C Temp	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm
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Refrigerator temperature

Freezer temp

Take immediate action if temperature is in shaded section*

Take immediate action if temperature is in shaded section*

Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health

www.immunize.org/news.d/celsius.pdf • Item #P3039A (11/05)

Vaccine Storage Troubleshooting Record

Date	Time	Storage Unit Temp	Room Temp	Problem	Action Taken	Results	Initials

Temperature Log For Vaccines (Celsius)

Month/Year:_____ **Days 16–31**

***Instructions:** Place an "X" in the box that corresponds with the temperature. The hatched zones represent unacceptable temperature ranges. If the temperature recorded is in the hatched zone: 1. **Store the vaccine** under proper conditions as quickly as possible, 2. **Call the vaccine manufacturer(s)** to determine whether the potency of the vaccine(s) has been affected, 3. **Call the immunization program at your local health department** for further assistance: (_____) _____, and 4. **Document the action taken** on the reverse side of this log.

Day of Month		16		17		18		19		20		21		22		23		24		25		26		27		28		29		30		31	
Exact Time																																	
°C Temp		am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm
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Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health

Vaccine Storage Troubleshooting Record

Date	Time	Storage Unit Temp	Room Temp	Problem	Action Taken	Results	Initials

Temperature Log for Vaccines (Fahrenheit)

Month/Year:_____ **Days 1–15**

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Room temp																														
Staff Initials																														

Refrigerator temperature

Freezer temp

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Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health

www.immunize.org/catg.d/p3039.pdf • Item #P3039 (11/05)

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