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**

Drug Administration

- Basic safe practices for medication/vaccine administration, assess and document:

1) **Patient's identity**
2) **Correct medication**
3) **Correct dose**
4) **Correct route**
5) **Appropriate time**

The " Basic Rights" of medication/vaccine administration:

#1 The right patient

You do not want to administer the medication or vaccine dose on your medication or vaccine tray to the wrong patient! Make sure you are administering the right person by verifying the patient's name and date of birth before you administer medication or vaccine to them. And while you are at it, make sure you have screened for contraindications and precautions for that medication or vaccination.

#2 The right vaccine (and diluent) / medication

Errors have occurred administering the wrong vaccine or medication product to a patient. Check the vial label three times to be sure you have chosen the correct vaccine product (and diluent, when applicable). Check the expiration date of the vaccine (and diluent) before using to be sure they are not out of date.

#3 The right dosage

Errors have been made giving a wrong amount of medication or vaccine to a person, such as giving a pediatric vaccine to an adult or vice versa. Medication/Vaccine dosages are usually guided by the patient's age (and are not based on the patient's weight). Check the package insert or an appropriate guidance document (see resources below) to confirm the appropriate dose for your patient's age.

#4 The right route, needle, and technique

Errors are often made administering vaccines or medication using the wrong route, needle, or technique. Be sure you know the appropriate route of administration (oral, intranasal, subcutaneous, intramuscular (IM), or intradermal) for the vaccine you are using. Needle selection should be based on the prescribed route, size of the individual, volume and viscosity of vaccine, and injection technique. Follow CDC guidance to confirm you are adhering to the correct route, needle, and technique. Deviation from recommendations can reduce vaccine efficacy or increase local adverse reactions.

#5 The right time

Sometimes vaccines are not administered according to the official U.S. immunization schedule. They are given to the wrong age patient, or they are administered earlier than they should be. Be sure the patient is the appropriate age for the vaccine you plan to administer and that the appropriate interval has passed since a previous dose of the same vaccine or between two live vaccines. For medication, check the frequency of the ordered medication. Double-check that you are giving the ordered dose at the correct time. Confirm when the last dose was given.

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:

CONTROLLED SUBSTANCE LOG

Medication Name: _____

Provider's DEA number: _____

Dose (mg/ml – mg/tab): _____

Original Quantity (Original number of doses): _____

Date	Patient Name	Dispensed/Given By	Quantity Dispensed	Balance Available

For information on COVID-19 vaccine storage, see the COVID-19 Vaccine Addendum in CDC's *Vaccine Storage & Handling Toolkit* at www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.

Don't Be Guilty of These Preventable Errors in Vaccine Storage and Handling!

Do you see your clinic or practice making any of these frequently reported errors in vaccine storage and handling? Although some of these errors are much more serious than others, none of them should occur. Be sure your healthcare setting is not making any of these ***preventable*** *errors.*

ERROR: Designating only one person, rather than at least two, to be responsible for storage and handling of vaccines

- Everyone in the office should know the basics of vaccine handling, including what to do when a shipment arrives and what to do in the event of an equipment failure or power outage.
- Train at least one back-up person. The back-up and primary persons should be equally familiar with all aspects of vaccine storage and handling, including knowing how to handle vaccines when they arrive, how to properly record refrigerator and freezer temperatures, what to do when an out-of-range temperature occurs, and how to appropriately respond to an equipment problem or power outage.

ERROR: Storing vaccine inappropriately

- Be sure all office staff (especially persons involved in receiving vaccine shipments) understand the importance of properly storing vaccines immediately after they arrive.
- Know which vaccines should be refrigerated and which should be frozen. Storage information is found in the package insert. For quick reference, post IAC's *Vaccine Handling Tips* (www.immunize.org/catg.d/p3048.pdf) on the refrigerator and freezer.
- Always store vaccines (and temperature monitoring devices) in the body of the refrigerator – not in the vegetable bins, on the floor, next to the walls, in the door, or near the cold air outlet from the freezer. The temperature in these areas may differ significantly from the temperature in the body of the unit.
- Don't over-pack the unit. Place the vaccine packages in such a way that air can circulate around the compartment.
- Always store vaccines in their original packaging.

ERROR: Using the wrong type of equipment

STORAGE UNITS

- CDC recommends storing vaccines in separate, self-contained units that only refrigerate or only freeze. If a combination refrigerator/freezer must be used, only refrigerated vaccines should be stored in the unit, and a separate stand-alone freezer should be used for frozen vaccines.
- Never store vaccines in a "dormitory-style" unit (i.e., a small refrigerator-freezer unit with one exterior door and a freezer compartment inside the refrigerator). These units cannot maintain stable temperatures.

TEMPERATURE MONITORING DEVICES/DIGITAL DATA LOGGERS

- Use only temperature monitoring devices (digital data loggers [DDL] preferred and required for VFC vaccine storage) for continuous temperature monitoring and recordings. Set the DDL to measure and record temperatures no less than every 30 minutes. Be sure the DDL has a current and valid Certificate of Calibration Testing (aka Report of Calibration).
- Buffer the DDL's temperature probe by immersing it in a vial filled with liquid (e.g., glycol, ethanol, glycerin), loose media (e.g., sand, glass beads), or a solid block of material (e.g., Teflon® or aluminum). Use of a buffer ensures you are not just measuring air temperature, which is subject to fluctuation when you open the door.

For more detailed information, see the *Vaccine Storage and Temperature Monitoring Equipment* section of CDC's *Vaccine Storage & Handling Toolkit* (www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html).

ERROR: Inadvertently leaving the refrigerator or freezer door open or having inadequate seals

- Unfortunately, too much vaccine is lost every year because storage unit doors were left open. Remind staff to *completely* close the door every time they open the refrigerator or freezer.
- Check the seals on the doors on a regular schedule, such as when you're taking inventory. If there is any indication the door seal may be cracked or not sealing properly, have it replaced. (This is much less costly than replacing a box of, for example, pneumococcal conjugate or varicella vaccine!)

CONTINUED ON THE NEXT PAGE ▶

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www.immunize.org/catg.d/p3036.pdf ▪ Item #P3036 (8/21)

ERROR: Storing food and drinks in the vaccine refrigerator

- Frequent opening of the refrigerator door to retrieve food items can adversely affect the internal temperature of the unit and damage vaccines. Store only vaccines in the designated units.

ERROR: Inadvertently cutting the power supply to the storage units

- Be sure everyone in your office, including the janitorial staff, understands that very expensive and fragile vaccines are being stored in the refrigerator and freezer.
- Post a *Do Not Unplug* sign (www.immunize.org/catg.d/p2090.pdf) next to electrical outlets for the refrigerator and freezer, and a *Do Not Stop Power* warning label (www.immunize.org/catg.d/p2091.pdf) by the circuit breaker for the electrical outlets.

ERROR: Recording temperatures an insufficient number of times each day

- If using a temperature monitoring device (TMD) (digital data loggers [DDL] preferred and required for VFC vaccine storage) that records minimum/maximum (min/max) temperatures (i.e., this highest and lowest temperature during a specific time period), document min/max and current temperatures *once* each workday, preferably in the morning. If using a TMD that does not record min/max temperatures, document current temperatures *twice,* at the beginning and end of each workday.
- Record the temperatures you observed on an appropriate log. IAC has temperature logs (www.immunize.org/handouts/temperature-logs.asp) available in both Fahrenheit and Celsius formats.
- Record temperatures for ALL units being used to store vaccine. Don't forget to check temperatures for both the refrigerator and freezer.

ERROR: Documenting out-of-range temperatures on vaccine temperature logs but not taking action

- If you find out-of-range temperatures…do something! The viability of your vaccine – and the protection of your patients – is at stake.
- Guidance on what to do may be found on IAC's temperature logs (www.immunize.org/handouts/temperature-logs.asp) and Vaccine Storage Troubleshooting Record (www.immunize.org/catg.d/p3041.pdf).
- Have an Emergency Response Plan and trained staff in place before a problem occurs. For help in developing a plan, see the Checklist For Emergency Vaccine Storage, Handling, and Transport in the *Resources* section of CDC's *Vaccine Storage & Handling Toolkit* (www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html).

ERROR: Discarding temperature logs too soon

Keep your temperature logs for at least 3 years. Why?

- You can track recurring problems as the storage unit ages.
- If out-of-range temperatures have been documented, you can determine how long and how often this has been occurring.
- This can be a great way to demonstrate why you need a new refrigerator or freezer!

ERROR: Not using vaccine with the soonest expiration date first

When unloading a new shipment of vaccine:

- Move vaccine with the shortest expiration date to the front of the unit, making it easier for staff to access this vaccine first.
- Mark the "older" vaccine to be used first.

ERROR: Dealing inappropriately with expired vaccines

- Carefully monitor your usage to ensure viable vaccines don't expire! As discussed above, place vaccines with the shortest expiration dates at the front of the unit.
- If you discover expired vaccines, immediately remove them from the unit so that they are not inadvertently administered.

ERROR: Discarding multidose vials prematurely

- Almost all multidose vials (MDV) of vaccines contain a preservative and can be used until the expiration date on the vial, unless there is actual contamination or the vials are not stored under appropriate conditions. For some vaccines, the manufacturer may specify that once the MDV has been entered or the rubber stopper punctured, the vaccine must be used within a certain number of hours or days. For specific guidance, refer to the package insert (see www.immunize.org/fda).

Temperature Log for Refrigerator – Fahrenheit

DAYS 1–15

For information on storage and handling of COVID-19 vaccines, see the **COVID-19 Vaccine Addendum** in CDC's updated *Vaccine Storage and Handling Toolkit* at www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html.

Month/Year _____ **VFC PIN or other ID #** _____

Facility Name _____

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. If using a temperature monitoring device (TMD; digital data logger recommended) that records min/max temps (i.e., the highest and lowest temps recorded in a specific time period), document current and min/max *once* each workday, preferably in the morning. If using TMD that does not record min/max temps, document current temps *twice*, at beginning and end of each workday.
3. Put an "X" in the row that corresponds to the refrigerator's temperature.
4. If any out-of-range temp observed, see instructions to the right.
5. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range – too warm (above 46°F) or too cold (below 36°F).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the attached "Vaccine Storage Troubleshooting Record."

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Exact Time	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
Min/Max Temp in Unit (since previous reading)															
Danger! Temperatures above 46°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!															
TEMPERATURES 46°F															
45°F															
44°F															
43°F															
42°F															
Aim for 41° 41°F															
ACCEPTABLE 40°F															
39°F															
38°F															
37°F															
36°F															
Danger! Temperatures below 36°F are too cold! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!															
ACTION Write any out-of-range temps (above 46°F or below 36°F) here:															
Room Temperature															

If you have a vaccine storage issue, contact your state or local health department for guidance and complete the attached "Vaccine Storage Troubleshooting Record."

DISTRIBUTED BY THE
IMMUNIZATION ACTION COALITION Saint Paul, Minnesota ▪ 651-647-9009 ▪ www.immunize.org ▪ www.vaccineinformation.org

Adapted with appreciation from California Department of Public Health

www.immunize.org/catg.d/p3037F.pdf ▪ Item #P3037F (8/21)

Temperature Log for Refrigerator – Fahrenheit

DAYS 16–31

For information on storage and handling of COVID-19 vaccines, see the **COVID-19 Vaccine Addendum** in CDC's updated *Vaccine Storage and Handling Toolkit* at www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html.

Month/Year _____ **VFC PIN or other ID #** _____

Facility Name _____

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. If using a temperature monitoring device (TMD; digital data logger recommended) that records min/max temps (i.e., the highest and lowest temps recorded in a specific time period), document current and min/max *once* each workday, preferably in the morning. If using TMD that does not record min/max temps, document current temps *twice*, at beginning and end of each workday.
3. Put an "X" in the row that corresponds to the refrigerator's temperature.
4. If any out-of-range temp observed, see instructions to the right.
5. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range – too warm (above 46°F) or too cold (below 36°F).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the attached "Vaccine Storage Troubleshooting Record."

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																
Exact Time	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
Min/Max Temp in Unit (since previous reading)																
Danger! Temperatures above 46°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
TEMPERATURES 46° F																
45° F																
44° F																
43° F																
42° F																
Aim for 41° 41° F																
ACCEPTABLE 40° F																
39° F																
38° F																
37° F																
36° F																
Danger! Temperatures below 36°F are too cold! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
ACTION Write any out-of-range temps (above 46°F or below 36°F) here:																
Room Temperature																

If you have a vaccine storage issue, contact your state or local health department for guidance and complete the attached "Vaccine Storage Troubleshooting Record."

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Adapted with appreciation from California Department of Public Health

www.immunize.org/catg.d/p3037F.pdf • Item #P3037F (8/21)

Temperature Log for Freezer – Fahrenheit

DAYS 1–15

For information on storage and handling of COVID-19 vaccines, see the **COVID-19 Vaccine Addendum** in CDC's updated *Vaccine Storage and Handling Toolkit* at www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html.

Month/Year _____ **VFC PIN or other ID #** _____

Facility Name _____

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. If using a temperature monitoring device (TMD; digital data logger recommended) that records min/max temps (i.e., the highest and lowest temps recorded in a specific time period), document current and min/max *once* each workday, preferably in the morning. If using TMD that does not record min/max temps, document current temps *twice*, at beginning and end of each workday.
3. Put an "X" in the row that corresponds to the freezer's temperature.
4. If any out-of-range temp observed, see instructions to the right.
5. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range – too warm (above 5°F) or too cold (below -58°F).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the attached "Vaccine Storage Troubleshooting Record."

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Staff Initials															
Exact Time	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
Min/Max Temp in Unit (since previous reading)															
Danger! Temperatures above 5°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!															
ACCEPTABLE TEMPERATURES **5°F**															
4°F															
3°F															
2°F															
1°F															
0°F															
-1°F															
-2°F															
-3°F															
-4°F															
-58°F to -5°F															
ACTION Write any out-of-range temps (above 5°F or below -58°F) here.															
Room Temperature															

If you have a vaccine storage issue, contact your state or local health department for guidance and complete the attached "Vaccine Storage Troubleshooting Record."

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Adapted with appreciation from California Department of Public Health

www.immunize.org/catg.d/p3038F.pdf ▪ Item #P3038F (8/21)

Temperature Log for Freezer – Fahrenheit

DAYS 16–31

For information on storage and handling of COVID-19 vaccines, see the **COVID-19 Vaccine Addendum** in CDC's updated *Vaccine Storage and Handling Toolkit* at www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html.

Month/Year _____ **VFC PIN or other ID #** _____

Facility Name _____

Monitor temperatures closely!

1. Write your initials below in "Staff Initials," and note the time in "Exact Time."
2. If using a temperature monitoring device (TMD; digital data logger recommended) that records min/max temps (i.e., the highest and lowest temps recorded in a specific time period), document current and min/max *once* each workday, preferably in the morning. If using TMD that does not record min/max temps, document current temps *twice*, at beginning and end of each workday.
3. Put an "X" in the row that corresponds to the freezer's temperature.
4. If any out-of-range temp observed, see instructions to the right.
5. After each month has ended, save each month's log for 3 years, unless state/local jurisdictions require a longer period.

Take action if temp is out of range – too warm (above 5°F) or too cold (below -58°F).

1. Label exposed vaccine "do not use," and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the "Action" area on the bottom of the log.
3. Notify your vaccine coordinator, or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the attached "Vaccine Storage Troubleshooting Record."

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																
Exact Time	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
Min/Max Temp in Unit (since previous reading)	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/
Danger! Temperatures above 5°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
ACCEPTABLE TEMPERATURES **5°F**																
4°F																
3°F																
2°F																
1°F																
0°F																
-1°F																
-2°F																
-3°F																
-4°F																
-58°F to -5°F																
ACTION Write any out-of-range temps (above 5°F or below -58°F) here.																
Room Temperature																

If you have a vaccine storage issue, contact your state or local health department for guidance and complete the attached "Vaccine Storage Troubleshooting Record."

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Adapted with appreciation from California Department of Public Health

www.immunize.org/catg.d/p3038F.pdf ▪ Item #P3038F (8/21)

Emergency Response Worksheet

What to do in case of a power failure or another event that results in vaccine storage outside of the recommended temperature range

Follow these procedures:

1. Close the door tightly and/or plug in the refrigerator/freezer.
2. Ensure the vaccine is kept at appropriate temperatures. Make sure the refrigerator/freezer is working properly or move the vaccines to a unit that is. Do not discard the affected vaccines. Mark the vaccines so that the potentially compromised vaccines can be easily identified.
3. Notify the local or state health department or call the manufacturer (see manufacturers' phone numbers below).
4. Record action taken.

Record this information*:

1. Temperature of refrigerator: current_____ max._____ min._____
2. Temperature of freezer: current_____ max._____ min._____
3. Air temperature of room where refrigerator is located:_____
4. Estimated amount of time the unit's temperature was outside normal range:
   refrigerator _____ freezer _____
5. Vaccines in the refrigerator/freezer during the event (use the table below)

* Using a recording thermometer is the most effective method of tracking the refrigerator and freezer temperatures over time. Visually checking thermometers twice a day is an effective method to identify inconsistent or fluctuating temperatures in a refrigerator and freezer.

Vaccines Stored in Refrigerator

Vaccine, manufacturer, and lot #	Expiration date	# of doses	# of affected vials	Action taken

Vaccines Stored in Freezer

Vaccine, manufacturer, and lot #	Expiration date	# of doses	# of affected vials	Action taken

Other Conditions

1. Prior to this event, was the vaccine exposed to temperatures outside the recommended range? Y N
2. Were water bottles in the refrigerator and ice packs in the freezer at the time of this event? Y N
3. Other: _____
   _____
   _____

Manufacturers

Crucell Vaccines Inc.	(800) 533-5899
CSL Biotherapies, Inc.	(888) 435-8633
GlaxoSmithKline	(888) 825-5249
MedImmune, Inc.	(877) 633-4411
Merck & Co., Inc.	(800) 672-6372
Novartis Vaccines	(800) 244-7668
Pfizer Inc.	(800) 438-1985
sanofi pasteur	(800) 822-2463

Other Resources

Local health department phone number _____ State health department phone number _____

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

Technical content reviewed by the Centers for Disease Control and Prevention, October 2010.

www.immunize.org/catg.d/p3051.pdf • Item #P3051 (10/10)

Vaccine Storage Power Outage / Disaster Recovery Plan

*** All VFC Providers are required to complete this document ***

Clinic Name:	**County:**
Person Completing Form:	**Date:**

If you have any questions about vaccine transportation or stability call: [1-877-243-8832] (CA Vaccines for Children Program)

In advance of an emergency power outage, providers should:

1. Identify and have an agreement with an alternative storage facility that has refrigerated storage that meets VFC criteria (i.e.: hospital, health department, fire department, etc.) with backup power (generator) where the refrigerated vaccine can be properly stored and monitored for the interim.
2. Insure the availability of staff to pack and transport the vaccine.
3. Maintain the appropriate packing materials (coolers, gel packs, dry ice for Varicella, etc.)
4. Insure a means of transport for the vaccine to the secure storage facility.

NOTE: Whenever possible, providers should anticipate the possibility of a power disruption and suspend vaccine activities **before** the onset of emergency conditions to allow sufficient time for packing and transporting vaccine.

Emergency Procedures

A. List emergency phone numbers, alternate storage facilities, and points of contact for:

Designated person(s) shall be responsible for:

- Monitoring the operation of the vaccine storage equipment and systems daily.
- Tracking inclement weather conditions. Set up and maintain a monitoring/notification system during times of inclement weather or other conditions that would create a shutdown in power. An alarm/notification system is recommended for practices with an inventory of $5,000 or more.
- Assuring the appropriate handling of the vaccine during the disaster or power outage.

Name of Employee	Title of Employee	Work Phone	Home Phone
Primary			
Backup			

Determine if your refrigerator is having a mechanical failure (no lights in the refrigerator, no fan noise, etc.) or if the building has lost electrical power. Check with the building maintenance to ensure that the generator is operational and has been activated. If a timeframe for the restoration cannot be determined, implement the following procedures.

Alternate Facility	Point of Contact	Work Phone	Emergency Phone

C. **Entering Vaccine Storage Facility:**

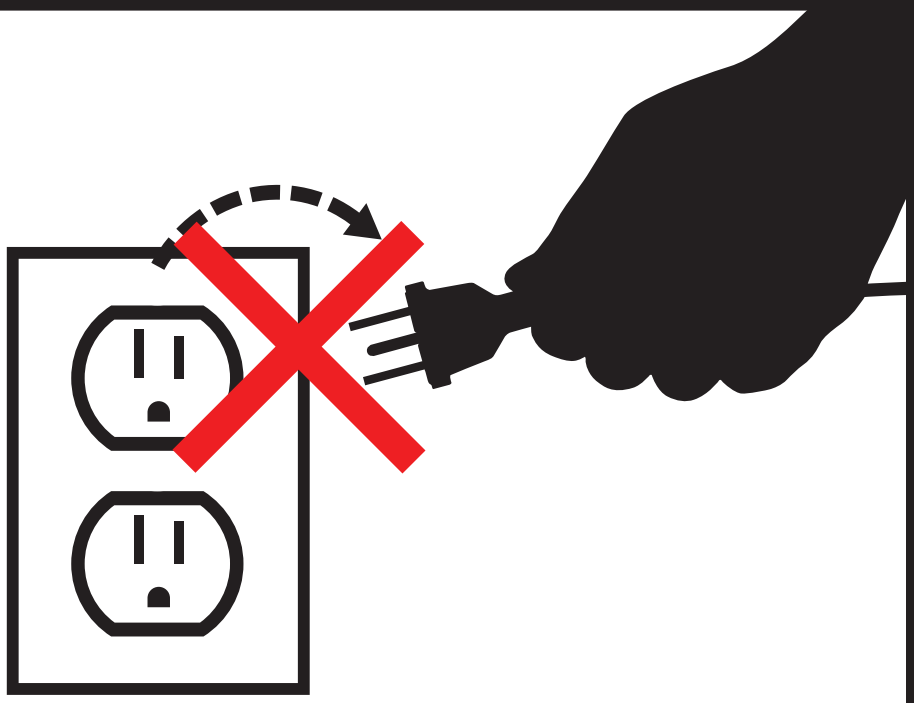
Describe how to enter the building and vaccine storage spaces in an emergency if closed or after hours. Include a floor diagram and the locations of:

Item	**Location**
Doors	
Flashlights	
Spare Batteries	
Light Switches	
Keys	
Locks	
Alarms	
Circuit Breakers	
Packing Materials	

D. Conduct an inventory before you transport the vaccine.

E. Package the vaccine in a well-insulated container with ice packs.
Unpackaged vials of DTaP, IPV, Hib, Hep A, Hep *A/B,* Influenza, PCV7, PPV23, etc., must not directly touch cold packs as the vaccine may be inactivated. It is best to keep vaccines in their original package during transport. MMR is the exception and may be transported directly on cold packs. Remember that Varicella and MMRV must be kept frozen therefore package Varicella and MMRV separately from the other vaccines. Do not expose the other vaccines (except MMR) to freezing temperatures.

F. Move vaccines to back up storage according to pre-arranged plans.
- How to load transportation vehicle
- Routes to take (alternative routes if necessary)
- Time in route.



DO NOT UNPLUG REFRIGERATOR OR FREEZER!

¡No desconecte el refrigerador o congelador!

EXPENSIVE VACCINE IN STORAGE!

¡AVISO! CONTIENE VACUNAS CARAS.

In the event of a problem, immediately contact

Si hay un problema, comuníquese inmediatamente con

.....

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www.immunize.org/catg.d/p2090.pdf ▪ Item #P2090 (10/15)

DO NOT UNPLUG REFRIGERATOR OR FREEZER!

¡No desconecte el refrigerador o congelador!

EXPENSIVE VACCINE IN STORAGE!

¡AVISO! CONTIENE VACUNAS CARAS.

In the event of a problem, immediately contact

Si hay un problema, comuníquese inmediatamente con

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MONTHLY VERIFICATION LOG

YEAR: _____

Month	Date	Medication in Refrig/ Freezer	Locked Meds and/or Controlled Meds	Sample Medications	Emergency Kit (Equipment and Meds)	Oxygen level (at least ¾ full), Mask, Cannula, and tubing	Laboratory (reagents, hemoccult etc.)	Laboratory (vacutainer tubes, culture medium, collection systems, etc)	Other
January									
February									
March									
April									
May									
June									
July									
August									
September									
October									
November									
December									

Instructions:

* Initial each category as you check the items
* An Initial indicates that the items have been checked; expired medications and supplies purged, and properly disposed of.

_____ _____

Initial Print name of person checking

_____ _____

Initial Print name of person checking