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TO: California Vaccines for Children (VFC) Program Providers

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SUBJECT: Vaccine Storage Equipment Requirements Effective July 2009

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SUMMARY

This document reviews the 2009 Vaccine Storage Equipment Requirements and Guidelines for providers participating in the California Vaccines for Children (VFC) Program. These requirements were announced to VFC providers in September 2008 (original letter available at www.eziz.org) and will be fully operational and enforced on July 1, 2009.

Providers who will need to purchase new equipment based on these requirements may benefit from the attached document, entitled "You May Need a New Refrigerator ." The trade names and commercial sources in this attachment are for identification purposes only and DO NOT imply endorsement by the California Department of Public Health (CDPH), Immunization Branch (IZB).

BACKGROUND

Since the inception of the VFC Program over 14 years ago, the inventory and cost of recommended vaccines have dramatically increased. Each year the average California VFC provider receives and stores over 2,000 doses of publicly-purchased vaccines worth well over \$100,000, not including any privately purchased inventory.

While vaccine inventories have increased, useable cold storage space in provider offices has not increased, resulting in overcrowding and reliance on outdated units. Poor temperature control weakens

and damages vaccine potency. When this damage goes unrecognized, children are given ineffectual doses. If it is recognized in time, spoiled doses are discarded at great expense. The new requirements and guidelines are designed to ensure that vaccines are properly stored and managed.

IMPLEMENTATION AND TIMELINES

Under the new storage equipment guidelines, providers will replace any refrigerator/freezer combination units with refrigerator-only and stand-alone freezer units for vaccine storage. The replacement units are designed to provide improved temperature control and storage space to protect larger inventories. To reduce the burdens on VFC providers, the prohibition on the use of combination units is being implemented in phases.

Phases	Implementation	Effective Date
First phase	All newly enrolling providers are expected to comply with new requirements. Any enrolled providers experiencing a failure of their current unit are expected to replace it with separate refrigerator-only units and stand-alone freezers.	September 1, 2008
Second phase	All VFC providers are expected to comply with the new equipment requirements (see next Section).	July 1, 2009
Third phase	All providers will use refrigerator-only and stand-alone freezer units.	Date to be determined

Implementation of the new guidelines will be enforced during routine VFC Quality Assurance Review site visits. Failure to comply may result in reductions in vaccine requests or disenrollment from the VFC Program.

VACCINE STORAGE UNIT TYPES AND REQUIREMENTS

Acceptable Vaccine Storage Units

The new equipment requirements depend on the volume of vaccine in each practice. Providers who each year receive:

- **>10,000 doses of vaccine** (Very High volume providers) are required to use "Pharmacy-grade" or "Biologic-grade" refrigerator-only units and either domestic or commercial stand-alone freezers.
- **2,000-10,000 doses of vaccine** (High volume providers) are required to use domestic or commercial refrigerator-only units and stand-alone freezers. Domestic units generally can be purchased locally through major chain retailers and do not require generator back-up.
- **<2,000 doses of vaccine** (Medium or Low volume providers) are strongly recommended (and will in the future, but not currently, be required) to use domestic or commercial refrigerator-only units and stand-alone freezers. The use of household refrigerator/freezer combination units is discouraged but tolerated under certain circumstances. If combination units fail or do not adhere to requirements outlined below, providers will be required to replace them with separate refrigerator-only units and stand-alone freezers and must repay the cost of spoiled vaccines.

- **<500 doses of vaccine** (Low volume providers) are permitted to use “Pharmacy-grade” or “Biologic-grade” under-the-counter refrigerator units or combination units.

Please refer to the enclosed VFC Practice Profile for more details.

Unacceptable Vaccine Storage Units

The following units are unacceptable for vaccine storage at any time or duration, including daily use:

- “Dorm-style” or household-grade under-the-counter units provide poor temperature control and often freeze vaccines that require refrigeration, resulting in immediate and irreversible damage. “Dorm-style” units are defined as small refrigerator/freezer combination units with a single external door and an evaporator plate or cooling coil that forms a small freezer compartment within the unit or is pulled across the internal back wall of the unit.
- Manual defrost (also known as cyclic defrost) refrigerators have significant temperature variations, often freezing and damaging vaccines. These units often have exposed cooling plates, coiling or vertical plates in the interior back wall of the refrigerator. These may be covered with visible frost or ice.
- “Convertible” refrigerator-only units have an internal switch that converts an “all-refrigerator unit” to an “all-freezer” unit.

Unit Requirements

All refrigerators must:

- Maintain required vaccine storage temperatures (35°F- 46°F) year-round, preferably set at 40°F.
- Be automatic defrost (frost-free) and free of any frost, ice, or water or coolant leaks. Manual defrost (cyclic defrost) refrigerators with visible cooling plates/coiling in the internal back wall of the unit are unacceptable.
- Have sufficient usable space to store the largest number of doses expected at one time (including influenza season), without overcrowding. Bins and drawers should be removed from the unit or used to store temperature stability water bottles. Vaccines stored in combination refrigerator/freezer units should NEVER be stored in areas directly underneath air vents, in deli-crispers/vegetable bins, or in the doors.
- Be used only for vaccine storage unless there is adequate space for storage of other medications. However, these products must be stored below the vaccines on a different shelf.
- Combination units must have separate temperature controls (thermostats) for the refrigerator and freezer.
- Be reliable, with a quiet compressor/motor, and have not needed frequent repairs. Units over 10 years old often will need to be replaced.
- Have doors that seal tightly and close properly.
- Have a minimum capacity of 11 cubic feet, unless unit is a Pharmacy-grade or Biologic-grade under-the-counter unit in a Low Volume VFC provider’s office.
- Have a working thermometer placed centrally in the unit. Thermometers must be certified in accordance with National Institute of Standards and Technology (NIST) or the American Society for Testing and Materials (ASTM) standards.

All Freezers must:

- Maintain required vaccine storage temperatures (5°F or below) year-round.
- Provide space to store your vaccines and sufficient frozen cold packs.

- Have an automatic defroster. (Manual defrosters are acceptable only if the office has an alternate place to store vaccines when defrosting the freezer.)
- Have a working thermometer placed centrally in the unit. Thermometers must be certified in accordance with National Institute of Standards and Technology (NIST) or the American Society for Testing and Materials (ASTM) standards.
- Have doors that seal tightly and close properly.
- Be used only for vaccine storage.

NEW VACCINE STORAGE UNIT PURCHASE

Vaccine storage units are critically important. The protection of your patients depends on the protection of your expensive vaccine inventory. Therefore, when selecting and buying a new unit, keep in mind that you will be making a long-term investment for your practice.

We encourage you to carefully review equipment specifications requirements outlined in this letter to select the appropriate unit for your practice. We advise that you research available options and consult with local refrigeration specialists before making your purchase, especially if buying a commercial unit. For more details, please refer to the enclosed document entitled "VFC Provider: You May Need a New Refrigerator."

Cost

Your new unit will cost a tiny fraction of the vaccine it stores over its lifetime. Domestic or commercial refrigerator-only units cost from \$400-\$4,000. Biologic and Pharmacy-grade units are sold by specialty distributors and cost from \$3,000-\$9,000.

Some of your cost will be offset by the improved energy efficiency. A typical, new 18.5-cu.-ft. refrigerator can use between 30-40% less electricity than a 10-year-old unit.

Unit Size

As a first step in your search for the right unit, determine your storage needs. Calculate the inventory of the public and private doses currently stored in your unit, remembering to include an estimated number of doses to be stored during high peak seasons, such as flu season or back-to-school. The attached worksheet can help in your calculations.

For many providers, 11 cubic feet will be the minimal acceptable size of a refrigerator-only unit. Low Volume providers may use smaller Pharmacy-grade or Biologic-grade under-the-counter refrigerator units. Refrigerator-only units seldom have "deli-crispers" or "vegetable bins," which are unacceptable areas for vaccine storage.

Proper Placement of Your Vaccine Units—Make Sure It Fits!

The number-one reason new refrigerators are returned is that they do not fit in the designated space! Make sure your new equipment will fit in your office. If you are replacing a refrigerator/freezer combination unit, you will now need space for two units: a new refrigerator-only unit and a small freezer-only unit.

Pay close attention to the depth, width, and height measurements of your model before your purchase. You will need extra 4 inches from the wall and ceiling to ensure good air circulation around the unit. This is essential for proper heat exchange and cooling functions on the unit. The unit's location is also important. It must be placed away from direct sunlight and in a well-ventilated area.

IMPORTANT: Never stack a vaccine storage unit on top of another, unless the manufacturer or retailer has approved the configuration.

Product Choices

Refrigerator-only units are commonly used by restaurants, flower shops, and drugstores to keep perishables at a narrow temperature range of 35°-46°F. Many units have temperatures preset at 40°F. They are sold by large pharmaceutical and biological refrigerator retailers and by retailers in the food, beverage, and flower industries.

When buying your units, particularly when using the Internet, make sure to carefully review the unit specifications, and speak with a knowledgeable representative who can answer your questions. Before you buy, clarify the delivery timing and charges, unit warranty, and possible recycling programs to dispose of your old unit.

The VFC program strongly suggests that pharmacy- or biologic-grade refrigerators or freezers be purchased, installed, and maintained by refrigeration specialists, who should also perform routine maintenance. The units should be connected to a back-up power source, such as an electric generator, to avoid losses during a power failure.

Freezer units with automatic-defrost are preferred over manual defrost units. Manual units require defrosting a few times per year in order to ensure that they continue to seal and function properly. Practices selecting manual defrost units must identify an alternate location to store vaccines during defrosting.

To facilitate your search, the enclosed document entitled "VFC Provider: You May Need a New Refrigerator" includes examples of refrigerators that meet requirements specified in this letter. The California Department of Public Health, Immunization Branch **DOES NOT** endorse or promote the purchase any of the units included in the document. The use of trade names, brands, and models is for identification and education purposes only.

Timing the Purchase and Delivery of Your Unit

The purchase and delivery of your new unit(s) should be carefully coordinated between the person purchasing your new unit and your clinic's vaccine manager. Clinics should purchase their units when vaccine inventory is at its lowest, and should avoid placing a large vaccine request until the new unit has been received and the appropriate temperature has been maintained for at least 3-5 days.

Special Features to Consider

Although NOT required, items below are optimal features to consider while shopping for a new unit:

- Narrow temperature range 35-46°F; preset temperature at 40°F
- Visible temperature displays or built-in National Institute of Standards and Technology (NIST)-certified temperature gauge
- "Negative pressure self-closing doors" (doors that close automatically)
- Security locks
- Glass doors
- Wire racks
- Pharmacy- or biologic-grade units should be backed-up by an electric generator
- Consider a maintenance contract.

SETTING-UP YOUR NEW UNIT

Before placing vaccines in your new unit, follow these simple steps to ensure success:

- Plug your vaccine storage units directly into the outlets. Never use extension cords.
- If your unit comes with vegetable bins or deli-crispers, remove them from the unit, or fill them with bottles of water.
- Carefully label the areas where you will be storing each vaccine type.
- Place certified thermometers in the center of each unit.
- Set refrigerator temperatures to 40°F.
- Prior to placing vaccines in your unit, record temperatures twice a day for at least 3-5 days. Vaccines should be temporarily stored in an alternate unit until the temperature in the new unit is stable within the recommended range.
- Once your new unit maintains appropriate temperatures for 3-5 days, you may store vaccines in it.
- Installation of pharmacy- or biologic-grade refrigerators should be done professionally by refrigeration specialists. They will level the unit and identify the coldest and warmest zones in the device. They will also determine when the unit is ready for use and provide training to staff on the unit.

Please review the Vaccine Storage Guide at www.eziz.org for additional information on setting up your new vaccine storage unit.

DISPOSAL OF YOUR OLD UNIT

Check with your local utility company about rebates for removal of your old unit. Please dispose of your old unit safely to avoid the risk of entrapment to children.

OFFICIAL VFC REPRESENTATIVES

If you have any questions about the new guidelines, or this communication, please contact your VFC Representative or VFC Customer Service at 1-877-243-8832. A listing of Official VFC representatives is included with this mailing. Please be advised that VFC Program Representatives do not endorse or promote any refrigerator or freezer. No other company, person, or retailer should use the term "VFC Representative" without any official affiliation to the California Department of Health Services, Immunization Branch.

Encl: VFC Provider: You May Need a New Refrigerator Guide
VFC Program Practice Profile
VFV Program Representative Listing

cc: American Academy of Family Physicians
American Academy of Pediatrics, California Region IX
California Medical Association
California Local Health Officers
Immunization Branch Field Representatives
Immunization Coordinators
Gloria Merk, Program Administrator, Child Care Program Office,
California Department of Social Services
CDPH Immunization Branch Field Representatives
Local Health Officers
Local Health Department Immunization Coordinators
Vanessa Baird, Chief, Medi-Cal Managed Care Division, CDHS
Marian Dalsey, M.D., Chief, Children Medical Services Branch, CDHS
Michael Farber, M.D., Chief Medical Officer, Medi-Cal Managed Care, CDHS
Shabbir Ahmad, DVM, MS, PhD., Acting Chief, Maternal, Child and Adolescent
Health/Office of Family Planning Branch, CDPH
Villita Lewis, Deputy Director, Benefits and Quality Monitoring, MRMIB
Marcia Ehinger, M.D., Medi-Cal Benefits Branch, CDHS
Kathy Chance, M.D., Children Medical Services Branch, CDHS