

# Nevada State Immunization Program



## Nevada Vaccines for Children (VFC) Program 2018 PROGRAM PROTOCOLS

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**This document has been created to help immunization providers follow all components of the Vaccines for Children (VFC) and Nevada State Immunization Programs. If you have any additional questions or need clarification, then please call (775) 684-5900 or e-mail [nviz@health.nv.gov](mailto:nviz@health.nv.gov).**

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## ENROLLMENT & ANNUAL RE-ENROLLMENT

The Vaccines for Children (VFC) Program is a federal entitlement program (CFDA #93.539) which enables State/Territorial immunization programs across the nation to purchase vaccines for VFC eligible children through the CDC contract. These vaccines are distributed, without charge, to provider sites that enroll in the VFC Program. Annually, each provider site must complete the forms listed below and return the completed forms to the Nevada State Immunization Program (NSIP). **The provider must retain a copy of the completed enrollment form for three (3) years per CDC requirement, as well as for personal reference.**

### **Re-Enrolling Providers Are Required To:**

- Complete the “Vaccines for Children (VFC) Program Agreement to Participate” annually;
- Complete the Provider Profile Form annually, or if:
  - The number of children served changes, or
  - The status of the facility changes during the calendar year.
- Complete and have on-site an “Office Vaccine Management Plan” (OVMP)
  - An OVMP Template may be accessed at:  
[http://dpbh.nv.gov/Programs/VFC/dta/Forms/Vaccines\\_for\\_Children \(VFC\) Program - Forms/](http://dpbh.nv.gov/Programs/VFC/dta/Forms/Vaccines_for_Children_(VFC)_Program_-_Forms/).
  - **If the template is not used by your office, then the Medical Director must ensure that the plan developed contains all sections included in the template.**

### **NEW Providers Are Required To:**

- Complete the “Vaccines for Children (VFC) Program Agreement to Participate” initially and annually thereafter;
- Complete the Provider Profile Form (not necessary if brand new practice) initially and annually thereafter;
- **Purchase or be using a standalone freezer-less refrigerator and standalone freezer for VFC vaccine storage;**
- **Purchase one (1) digital temperature monitoring device (data logger). This can be purchased through this website:**  
<http://www.vfcdataloggers.com/all-products/>
- Ensure the clinic is registered in the state’s Immunization Information System, NV WebIZ;
- Ensure all staff who will be designated as the primary and backup vaccine coordinators be trained on data entry and inventory management and reconciliation for the NV WebIZ program. Training can be scheduled through these websites:
  - Northern Nevada  
<http://www.eventbrite.com/o/northern-nv-webiz-trainer-2965132647>
  - Southern Nevada  
<http://www.eventbrite.com/o/southern-nv-webiz-trainers-2965126605>
- Schedule an Enrollment Visit with NSIP staff; and

- Complete and have on-site an “Office Vaccine Management Plan” (OVMP)
  - An OVMP Template may be accessed at:  
[http://dpbh.nv.gov/Programs/VFC/dta/Forms/Vaccines\\_for\\_Children\\_\(VFC\)\\_Program\\_-\\_Forms/](http://dpbh.nv.gov/Programs/VFC/dta/Forms/Vaccines_for_Children_(VFC)_Program_-_Forms/).
  - **If the template is not used by your office, then the Medical Director must ensure that the plan developed contains all sections included in the template.**

**NOTE: PRACTICES WITH MULTIPLE CLINIC SITES MUST ENROLL EACH SITE AS A SEPARATE PROVIDER WITH A UNIQUE VFC PIN.**

## REQUIREMENTS TO PARTICIPATE

**To receive publicly funded vaccines at no cost, the facility’s signing Medical Director agrees to the following conditions on behalf of him or herself and all the practitioners, nurses, and others associated with the enrolling healthcare facility.**

**By enrolling in the Nevada VFC Program, the Medical Director agrees to:**

1. Annually submit a Provider Profile representing the populations served by the facility. The Provider Profile will need to be submitted more frequently if 1) the number of children served changes or 2) the status of the facility changes during the calendar year.
2. Document vaccinations in records as required by the National Childhood Vaccine Injury Act (42 US Code 300aa-25). This law applies to all health care providers that administer vaccines regardless of the age of the individual or the source of funding for the vaccine: <https://www.law.cornell.edu/uscode/text/42/300aa-25>.
  - a. Date of administration;
  - b. Vaccine, manufacturer and Lot Number;
  - c. Name and address, and if appropriate, title of the healthcare provider administering the vaccine; and
  - d. Any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary of the Department of Health and Human Services.
  - e. In addition, the following information must be recorded:
    - i. Publication date of the Vaccine Information Statement(s) provided; and
    - ii. Date the VIS’s were given to the parent/legal guardian.
3. Maintain clients’ immunization records for a period required by **NRS 629.051** and make such records available to the Nevada Department of Health and Human Services and/or the Federal Department of Health and Human Services upon request. Make such records available to the state health authority and/or designee, if requested (per NAC 441A.750). This includes collection of data for “Quality Improvement Assessments.” The law may be viewed here: <http://www.leg.state.nv.us/NRS/NRS-629.html#NRS629Sec051>.
  - a. *#1: Each provider of health care shall retain the health care records of his or her patients as part of his or her regularly maintained records for 5 years after their receipt or production. Health care records may be retained in written form, or by*

*microfilm or any other recognized form of size reduction, including, without limitation, microfiche, computer disc, magnetic tape, and optical disc...Health care records may be created, authenticated and stored in a computer system which limits access to those records.*

- b. #7: A provider of health care shall not destroy the health care records of a person who is less than 23 years of age on the date of the proposed destruction of the records. The health care records of a person who has attained the age of 23 years may be destroyed in accordance with this section for those records which have been retained for at least 5 years or for any longer period provided by federal law.
4. Screen and document VFC eligibility for each child upon each visit prior to administering immunizations (*see next section for greater detail*).
5. Adhere to the current Recommended Childhood Immunization Schedule as approved by the Centers for Disease Control and Prevention (CDC), Advisory Committee on Immunization Practices (ACIP), American Academy of Family Physicians (AAFP), American Academy of Pediatricians (AAP) and the American College of Physicians (ACP); and
  - a. Comply with NSIP guidelines including notices regarding ACIP recommendations, vaccine shortages, restrictions on vaccine use and use of new reporting forms or methods.
6. Maintain all records related to the Nevada VFC Program for a **minimum of three (3) years** and make these records available to public health officials upon request.
  - a. These records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering reports which include the monthly “Vaccine Request and Accountability Reports,” “Nevada State Immunization Program Temperature Log” or the “Log Tag Report,” “Vaccine Incident Reports,” “VTrckS-UPS Pickup Request for Expired/Spoiled Vaccine,” and the packing list received with each vaccine shipment.
7. **Not impose a charge for the cost of the vaccine.**
8. Not collect an administration fee higher than the maximum fee established by the U.S. Centers for Medicare and Medicaid Services (CMS) for the administration of publicly-supplied vaccine. **The maximum fee allowable in Nevada is \$22.57 per dose administered.**
  - a. For Medicaid-enrolled children, the provider agrees to accept the administration fee reimbursement set by Nevada Medicaid or the contracted Medicaid health plan.
9. **Not refuse to administer a publicly-supplied vaccine** to an eligible child (established patient) due to the inability of the child’s parent, guardian, or individual of record to pay the administration fee.
10. Provide the current Vaccine Information Statement(s) (VIS) to the parent/legal guardian of any child each time the child receives an immunization as required by federal law (42 US Code 300aa-25).
  - a. VIS’s may be downloaded from <https://www.cdc.gov/vaccines/hcp/vis/current-vis.html> or <http://www.immunize.org/vis/>.

11. Comply with the requirements for vaccine management and accountability, including:
  - a. Ordering vaccine and maintaining appropriate vaccine inventories;
  - b. **Not storing vaccine in dormitory-style, or combination refrigerator/freezer units at any time.** For program approved vaccine storage units, please refer to the “Acceptable Storage Units under the “Vaccine Storage” section of this protocol;
  - c. Storing vaccine under proper conditions at all times. Refrigerator and freezer storage units and temperature monitoring equipment and practices must meet CDC and NSIP recommendations and requirements, including:
    - i. Use of the NSIP-supplied digital data logger, the LogTag TRED30-7R, for continuous temperature monitoring of VFC vaccine storage units; or if unable to use the state-supplied product, then facility must use a NSIP-approved alternative that is certified by an ILAC MRA signatory body or which meets ISO/IEC 17025 international standards;
    - ii. Document twice daily the vaccine storage units’ temperature and include actions taken for temperatures recorded outside the recommended range(s);
    - iii. Receive approval from NSIP staff before moving publicly-supplied vaccines to new vaccine storage units; and
    - iv. Receive approval from NSIP and follow all current and appropriate guidelines before transporting publicly-supplied vaccines for any reason.
  - d. Return all eligible expired/spoiled vaccines **within six (6) months** using WebIZ inventory return function or the form(s) and instructions provided by the NSIP.
12. Operate within the Nevada VFC Program in a manner intended to avoid fraud and abuse (*see Fraud & Abuse Policy for details*).
13. Participate in compliance site visits, unannounced storage and handling visits, and immunization improvement activities in collaboration with NSIP representatives as requested.
14. Agree to replace vaccine purchased with any public funds (VFC, S-CHIP, 317, STATE) that are deemed non-viable due to provider negligence or non-compliance on a dose-for-dose basis at private cost.
15. For providers with a current, signed “Deputization Memorandum of Understanding” between a FQHC or RHC and the Nevada State Immunization Program to serve underinsured VFC- eligible children, I agree to:
  - a. Include “underinsured” as a VFC eligibility category during the patient’s screening;
  - b. Vaccinate “walk-in” VFC-eligible underinsured children; and
  - c. Report required usage data to the NSIP annually or upon request.

**NOTE:** “Walk-in” refers to any underinsured child who presents requesting a vaccine; not just established patients. “Walk-in” does not mean that a provider must serve non-established, underinsured patients without an appointment. If a provider’s office policy is for all patients to make an appointment to receive immunizations, then the policy would apply to “walk-in” underinsured patients as well.



16. Utilize Nevada WebIZ, the state’s immunization information system (SIIS), to record all administered vaccinations for children and adults (per **NRS 439.265** and corresponding NAC):
  - a. NRS: <http://www.leg.state.nv.us/Division/Legal/LawLibrary/NRS/NRS-439.html#NRS439Sec265>;
  - b. NAC: <http://www.leg.state.nv.us/Division/Legal/LawLibrary/NAC/NAC-439.html#NAC439Sec870>;
  - c. NV WebIZ: [http://dpbh.nv.gov/Programs/WebIZ/dta/Policies/WebIZ - Policies/](http://dpbh.nv.gov/Programs/WebIZ/dta/Policies/WebIZ_-_Policies/).
17. Notify the NSIP in writing on facility letterhead to terminate participation in the Nevada VFC Program.
18. Notify the NSIP of all changes immediately as they occur, including, but not limited to:
  - a. Change of address;
  - b. Change of shipping hours;
  - c. Change in Primary or Back-Up Vaccine Coordinator;
  - d. Change of telephone, fax number or e-mail addresses;
  - e. Additions/deletions of physicians, PA’s and nurse practitioners.

### **Additional Pharmacy Requirements**

- Administer publicly supplied vaccine to eligible children only under protocol from a board-licensed prescribing physician;
- Provide the Nevada State Immunization Program with a copy of the written protocol agreement between the pharmacy facility and a board-licensed prescribing physician;
- Provide a Certificate of Achievement for each registered pharmacist that will be administering publicly-supplied vaccine at this location as proof that they have completed a Pharmacy-Based Immunization Delivery Program from the American Pharmacists’ Association (APhA); and
- NEVER dispense vaccine to a patient, only administer vaccine on site;
- Vaccinate all “walk-in” VFC-eligible children; and
- Do not refuse to vaccinate VFC-eligible children based on a parent/legal guardian’s inability to pay the administration fee.

**NOTE:** “Walk-in” refers to any underinsured child who presents requesting a vaccine; not just established patients. “Walk-in” does not mean that a facility must serve non-established, underinsured patients without an appointment. If a facility’s policy is for all patients to make an appointment to receive immunizations, then the policy would apply to “walk-in” underinsured patients as well.

## ELIGIBILITY CRITERIA FOR VFC VACCINES

### VFC ELIGIBILITY

Only VFC-eligible children can receive VFC vaccines. Children from birth through 18 years of age who meet at least one of the following criteria are eligible to receive VFC vaccines:

1. **Medicaid-eligible** – A child who is eligible for the Medicaid program. For purposes of the Nevada VFC Program, Medicaid eligible and Medicaid enrolled are used interchangeably and refer to children who have health insurance through Nevada Medicaid;
2. **Uninsured** – A child who has no health insurance coverage;
3. **American Indian/Alaska Native (AI/AN)** – As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603); or
4. **Underinsured (should be diminishing)**
  - a. A child who has private health insurance coverage, but the coverage does not include vaccines; OR
  - b. A child whose insurance does not cover all ACIP-recommended vaccines. The child would be eligible to receive the vaccines not covered by their insurance through a VFC Provider.

**NOTE:** Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC), or under an approved deputization agreement. Private providers who have current “Delegation of Authority” from the NSIP may continue to vaccinate the underinsured children in their office. **Delegation will not be assigned to new providers.**

### STATE VACCINE ELIGIBILITY

Children enrolled in the Nevada Check-Up (NCU) Program can continue to receive publicly-supplied vaccines. **The VFC Provider MUST document that the child is enrolled in the NCU Program in:**

- The patient’s medical record;
- Nevada WebIZ; and

**All children must be screened and have their VFC eligibility documented at each immunization visit, prior to immunizing. In addition to updating the VFC Eligibility field on the patient’s demographic screen in Nevada WebIZ, VFC screening must be documented in the medical record in one of the following ways:**

- By completing a Patient Eligibility Screening Record. If this is the option the office chooses, then the screening record must be maintained for at least three (3) years and is bound by the privacy protection of Federal Medicaid law;
- By making a copy of the child's Medicaid card. The copy must be dated and initialed as current at each immunization visit and filed in the patient’s record. This documentation must be maintained for at least three (3) years and is bound by the privacy protection of Federal Medicaid law, or;

- By using a provider-developed screening form that contains the same elements as the CDC-approved form.

## VACCINE REQUESTS & ACCOUNTABILITY

The Nevada State Immunization Program processes enrolled provider vaccine requests monthly. Monthly request deadlines are provided each month in the e-mailed “VFC Monthly Memo”; providers are generally given the first two weeks of each month to order vaccine. **The amount of vaccine approved is based on the individual provider’s reported monthly usage and a constant 60-day supply is recommended.** VFC provider sites are required to update their inventory in NV WebIZ and close the reconciliation monthly, indicating vaccine doses used and doses remaining in physical inventory. Enrolled providers must use NV WebIZ to order vaccines electronically.

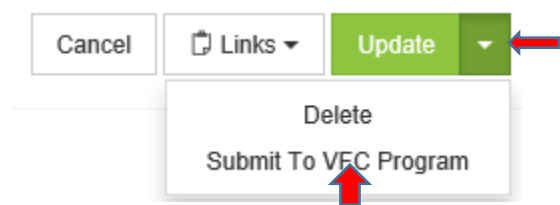
### Provider Staffing Requirements:

- VFC providers must designate one staff member to be the primary vaccine coordinator. This individual is responsible for providing oversight for all vaccine management within the office and for ensuring all vaccines are stored and handled correctly.
- A back-up or alternate vaccine coordinator must also be designated who can assume oversight responsibilities in the absence of the primary vaccine coordinator.
- **The primary or backup vaccine coordinator must be the person that completes the inventory management and reconciliation each month in NV WebIZ and completes the vaccine requests and return requests through NV WebIZ.**
- **Providers must notify the NSIP when there are any changes in key VFC vaccine management staff utilizing the [“Vaccine Coordinator Change Form.”](#) Fax the completed form to the NSIP at (775) 684-8338 whenever staffing changes occur.**

### Monthly On-Line Vaccine Accountability Requirements and Ordering by Enrolled Providers:

- **Primary and back-up vaccine coordinators must have attended or attend (new staff) “in-person training class” for inventory management and reconciliation before they can complete on-line ordering! To sign up for data entry and or inventory management and reconciliation, go to the following links that pertain to your area:**
  - Browse training classes in Northern Nevada:  
<http://www.eventbrite.com/o/northern-nv-webiz-trainer-2965132647>
  - Browse training classes in Southern Nevada:  
<http://www.eventbrite.com/o/southern-nv-webiz-trainers-2965126605>

- The primary vaccine coordinator or back-up vaccine coordinator will log into NV WebIZ and complete their monthly inventory management and reconciliation on the last day of each month or the first day of the following month.
- The primary or back-up coordinator must insure the reconciliation is balanced and closed. If any discrepancies occur, fix any issue that is keeping it from closing. This is a requirement for online orders to be completed.
- VFC enrolled provider offices transmitting information from their Electronic Health Record system (EHR) through HL7 to NV WebIZ must have an inventory in NV WebIZ for your federally funded vaccines. The primary or back-up vaccine coordinator must complete and monthly reconciliation as well but they will use aggregate dose reporting by entering the number of doses for each type of vaccine by lot number given over the previous month. Then complete the doses of vaccine remaining in inventory prior to closing the reconciliation.
- **Reconciliation of the prior month’s inventory and closure of that reconciliation must be completed monthly whether more vaccine is ordered or not.**
- On-line ordering will be completed by clicking on the vaccine ordering module and confirm:
  - Primary Shipping Contact is correct;
  - Shipping address is correct;
  - Delivery information (times for accepting vaccine shipments) is correct.
- Once all vaccines have been entered on the ordering module, click the green “Update” button at the top right margin of the page. This saves the order in the event editing needs to be made prior to sending the order to the NSIP. **This does not send the order to the Immunization Program!**
- To send the order, click on the green arrow button next to the “Update” button. A pull down menu appears showing “Delete”or Submit to VFC Program.” Click on the submit link. The order “status” will change to Submitted.



### Digital Data Loggers for Continuous Temperature Monitoring

The NSIP provides all enrolled offices with a thermometer product called the LogTag TRED 30-7R. This continuous temperature monitoring device, or data logger, provides 24-hour recorded monitoring. The following protocol reviews the procedure for using this product to monitor VFC vaccine storage units.

- Data loggers must be physically checked twice daily. During the morning check, minimum and maximum temperatures must be reviewed;
  - Leaving the probe plugged into the unit, review the min/max temperatures:
    - Press the “Review” button to obtain the maximum temperature recorded for the past 24 hours;
    - Press the “Review” button again to obtain the minimum temperature recorded for the past 24 hours;
    - Press the Start/Clear/Stop button to refresh the display and show current temperatures;
    - Initial, date and record the room temperature and time on the NSIP Temperature Log;
- **If there was an out-of-range temperature recording in the past, the word “ALARM” will be present on the screen above the current temperature display. Take immediate action if this occurs:**
  - **STOP VACCINATING PATIENTS!!**
  - Move the vaccine to proper storage conditions as quickly as possible keeping it separate from other vaccines and mark it “Do Not Use”;
  - Stop the recorder by holding the “Stop” button until the word “Stopping” quits flashing. Once the “stop” button is released and the screen goes blank, unplug the probe;
  - Open the LogTag program and place the LogTag recorder in the USB interface to download the information; **\*\*The LogTag program must be configured for the person who is doing the down loads, and they must be the ones signed into the computer the program is on! \*\*** The LogTag will not down load properly if this is not followed.
  - Send the data to [nviz@health.nv.gov](mailto:nviz@health.nv.gov) and notify the Vaccine Manager;
  - Call the vaccine manufacturer(s) to determine the viability of the vaccine;
  - Document the “Disposition” per manufacturer on the “[Vaccine Incident Report](#)”; and
  - Fax the completed report to (775) 684-8338.
- Providers are required to purchase one (1) backup data logger to use as the clinic’s backup thermometer. It is suggested that the VFC 400 data logger be purchased from Control Solutions, LLC since the LogTagTred30-7R and VFC 400 utilize the same software/interface. Control Solutions website is: <http://www.vfcdataloggers.com/>

### **Documentation of Vaccine Storage Unit Temperature Monitoring**

- Complete all heading information:
  - VFC PIN;
  - Facility Name – official name of the facility (do not abbreviate or use the physician’s name unless that is the legal name of the practice); and
  - Current Month and Year;
- Write in the time, date, room temperature, and initials of the person checking the min/max temperatures and the room temperature for the appropriate day of the month.

- This form must be kept for three (3) years.

### **Submitting Vaccine Requests**

- Vaccine coordinators must download the temperatures from the refrigerator and freezer data loggers at the end of each month (and when there is a temperature excursion) and ensure NSIP receives the downloaded files;
- Complete the vaccine inventory and reconciliation and close that reconciliation. This must be completed and closed every month whether you order vaccines or not;
- Go to the vaccine ordering module and order the vaccines needed. Then, submit the vaccine order to NSIP. If the order is for a special event, write a comment in the provider comment section to alert NSIP. Orders must be sent to NSIP on or before the monthly ordering cutoff date.
- Emergency requests are allowed only during “outbreak” situations.
- Vaccines should arrive within ten (10) days after the Vaccine Request Confirmation is received by the provider.
- **Providers should maintain at least a 60-day supply of public vaccine inventory.**
- If it is necessary for the office to submit a second vaccine request (e.g., you forgot to order a vaccine), place the second order in WebIZ and send it to NSIP. You can only place the second order if you have sent the original order to the immunization program.
- Flu orders during the flu season are separate orders from the main VFC order, and be ordered anytime during the month. There are no cut off dates for flu orders.

## VACCINE BORROWING GUIDANCE

**CDC’s expectation is that VFC-enrolled providers maintain adequate inventories of vaccine to administer to both privately insured and VFC-eligible children. Borrowing of vaccine must be due to unforeseen delays or circumstances surrounding vaccine that has been ordered. Scheduling of a mass immunization clinic without having appropriate amounts of both public and privately purchased vaccine available on-hand for the expected participants would not be considered an unexpected circumstance.**

The “VFC Borrowing Report” can be found on the state website:

[http://dpbh.nv.gov/Programs/VFC/dta/Forms/Vaccines for Children \(VFC\) Program - Forms/](http://dpbh.nv.gov/Programs/VFC/dta/Forms/Vaccines%20for%20Children%20(VFC)%20Program%20-%20Forms/) and completed for all vaccine borrowed in either direction. The “VFC Borrowing Report” must be completed when either:

- Privately-purchased vaccine is administered to a VFC-eligible child, or
- VFC vaccine is administered to a privately-insured child or
- Vaccine exchange occurs to prevent expiration.

The VFC Provider must document:

- Why the vaccine was borrowed, and
- The date the vaccine was replaced and the inventory was made whole.

Borrowing activities must be monitored as part of the VFC Compliance Visit. Questions regarding borrowing have been included in the VFC Compliance Visit Questionnaire. Follow-up and/or corrective actions will be taken when excessive and/or inappropriate borrowing activities are noted by VFC Quality Assurance Coordinators.

- **VFC vaccine cannot be used as a replacement system for a provider’s privately purchased vaccine inventory.**
- VFC vaccine supply must adequately meet the needs of a facility’s VFC-eligible patients. Borrowing of VFC vaccine must not prevent a VFC-eligible child from receiving a needed vaccination because the VFC vaccine was administered to a non-VFC eligible child.

**Borrowing of vaccine between the two vaccine inventories must be a rare, unplanned occurrence. Borrowing can occur only when there is:**

- A lack of private-stock vaccine due to unexpected circumstances such as a delayed vaccine shipment;
- Vaccine spoiled in-transit to provider; OR
- New office staff (at the provider or NSIP level) that calculated ordering time incorrectly.

### **Seasonal Influenza Vaccine Borrowing**

For seasonal influenza vaccine, VFC providers may use private-stock influenza vaccine to vaccinate VFC-eligible children if VFC influenza vaccine is not yet available. Those private stock doses used on VFC-eligible children can later be replaced when VFC stock becomes available.

**This one-directional borrowing exception is unique to seasonal influenza vaccine. VFC influenza vaccine may never be borrowed for administration to a privately insured child.**

### **Borrowing to Prevent Loss Due to Expiration**

This two-way exchange can be used by a VFC-enrolled provider with a patient population that is mostly VFC-eligible. This means the provider has a small number of privately insured children. **Privately purchased vaccine that is short-dated may be administered to a VFC-eligible child, and the dose replaced with a longer-dated VFC dose (or vice-versa).** Document this exchange on the borrowing form.

### **Documentation of Borrowing**

**Providers must document any vaccine borrowing on the Vaccine Borrowing Report regardless of inventory origin (VFC vs. Private).**

- If a provider borrows privately purchased vaccine to administer to a VFC-eligible child because no VFC vaccine is available or if VFC stock is borrowed, then the provider must document that borrowing and replacement activity on the VFC Borrowing Report. This action is to ensure that the private-stock or VFC-stock vaccine is replaced and the appropriate inventory is made whole.
- Once the borrowed vaccine is replaced, the replacement date must be entered on the VFC Borrowing Report.
- The completed borrowing form must be saved and submitted to the NSIP at the end of the month for review and a copy of the invoice proving stock replenishment has occurred must be attached.



## VACCINE STORAGE AND HANDLING

Vaccine storage units must be selected carefully and used properly. **Freezer-less standalone refrigerators and standalone freezers are the only units proven to consistently maintain required temperature ranges for safe vaccine storage.** The Centers for Disease Control and Prevention (CDC) recommends that any refrigerator or freezer being used for vaccine storage must:

1. Be able to continuously maintain required vaccine storage temperatures;
2. Be large enough to hold the year’s largest inventory (think Back-to-School and flu season);
3. Be monitored using an unexpired, calibrated digital data logger; and
4. Be dedicated to the storage of vaccines or other biologics. No food or beverages should ever be stored in a vaccine storage unit.

### IMPORTANT NOTE:

If the NSIP Program Manager, Vaccine Manager, Provider Quality Assurance Manager, and/or the Vaccine Storage & Handling Coordinator has recommended to a VFC-enrolled provider’s Primary Vaccine Coordinator and/or Medical Director that the provider should purchase stand-alone refrigerator and freezer units as a result of reviewing long-term temperature monitoring information, and the office does not purchase the recommended storage unit type, **then the provider WILL be held accountable for replacing all VFC vaccine doses (at private cost) that are spoiled or wasted as a result of temperature excursions in the non-recommended unit.**

**VACCINES SHOULD NEVER BE STORED IN THE DOOR OR CRISPER DRAWERS!!**

For more information, visit: <http://www.cdc.gov/vaccines/recs/storage/default.htm>.

### Unacceptable Vaccine Storage Units

The following units are unacceptable for vaccine storage, even temporarily, **no exceptions**:



- “Dorm-style” units provide poor temperature control and often freezes 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.

**Dorm-Style Units:** Small, single-door combined refrigerator/freezer units **should not be used** for any vaccine storage, even temporary. The freezer compartment in this type of unit is incapable of maintaining temperatures cold enough to store frozen vaccines. If attempts are made to cool the freezer to the appropriate temperature, then the temperature in the refrigerator will fall below the recommended range, potentially freezing the refrigerated vaccines.

- Manual defrost (or cyclic defrost) refrigerators have significant temperature variations, often freezing and damaging vaccines. These units often have exposed cooling plates, coils or vertical plates on the interior back wall of the refrigerator. These may be covered with visible frost or ice.
- Convertible refrigerator-only units that have an internal switch to convert the “refrigerator-only” unit to a “freezer-only” unit.
- Any refrigeration or freezer unit that is over 10 years old.
- Small apartment size (4ft or below) units.
- Any style of combination refrigerator/freezer units as shown below are not acceptable.



## Acceptable Vaccine Storage Units

### **Option 1: Standalone, Under-the-Counter or Full Size Refrigerator and Freezer Units**

Standalone or under-the-counter refrigerators and freezers are excellent choices for vaccine storage. These units allow for the separate storage of frozen and refrigerated vaccines. Freezer-less standalone refrigeration units must be self-defrosting and it is recommended that standalone freezer units be self-defrosting.



The benefits of using standalone units for vaccine storage include:

- **Lower risk of catastrophic inventory loss.** Separate compressors and condensers decrease the risk of total vaccine loss that might occur in a combination style unit.
- **Temperature stability.** Because these units are only required to hold a single set temperature, they are not constantly re-adjusting and circulating cold air between the refrigerator and freezer compartments.
- **No risk of accidentally freezing refrigerated vaccine.** Combined units often use a cold air vent from the freezer to regulate temperatures in the refrigerator compartment. This freezing air blows down on the top shelf of the refrigerator and can quickly freeze any vaccines stored underneath.

Providers have many options for finding affordable, office-appropriate standalone units. **Standalone units can be under-the-counter size as discussed here or full-size.** Office Managers can shop local home improvement stores (Home Depot, Lowes) or go for lab/pharmaceutical grade units (Panasonic, American Biotech Supply, Migali, etc.):

- [www.homedepot.com](http://www.homedepot.com) – search within appliances
- [www.lowes.com](http://www.lowes.com) – search within appliances
- <http://us.panasonic-healthcare.com/preservation/>
- <http://www.americanbiotechsupply.com/>
- <http://www.migaliscientific.com/products/vaccine-storage/>

**Option 2: Standalone, Laboratory Grade Refrigerator and Freezer Units**

Standalone, laboratory grade refrigerators and freezers are considered the gold standard for dedicated vaccine storage; they are considered the most secure. As with most “gold-standard” products, they carry a hefty price tag and are usually reserved for health departments, pharmacies, health laboratories and hospitals. However, many manufacturers also produce an array of refrigerators and freezers that may meet your clinic’s vaccine storage needs at a lower cost. **Be aware that units with glass-front doors do not maintain cold temperatures during power outages as well as units with solid doors.**



*Products and vendors are referenced for informational purposes only; listing in this document does not imply endorsement by the National Immunization Program (NIP) nor the Nevada State Immunization Program.*

**For VFC Providers that were enrolled in the program prior to 2015 and do not have standalone storage units; the current combination unit may be used if:**

- Continuous temperature monitoring proves the unit's temperatures are acceptable;
- The vaccine is not stored on the top shelf of the refrigerator unit; and
- The unit can accommodate the year's largest inventory without vaccine crowding or touching the inside walls.

**However:**

- If the combination unit suffers mechanical failure, then standalone units **MUST** be purchased as replacement.
- If continuous temperature monitoring reveals unacceptable vaccine storage temperatures, then standalone units **MUST** be purchased as replacement.
- If the freezer section of the combination unit endures defrost cycles for longer than thirty minutes, then a standalone freezer **MUST** be purchased.

**If the office is considering the purchase of a new vaccine storage unit, then call the NSIP Vaccine Manager first at (775) 684-3462. You must obtain 5 days of acceptable temperature readings prior to storing publicly funded vaccine in any new unit. The NSIP will provide a loaner data logger for these 5 days.**

### **Temperature Monitoring Requirements**

VFC Providers are required to purchase at least one back-up digital temperature monitoring device (data logger) that has a current certificate of calibration and have the data logger readily available. This back-up data logger is to be used if the current temperature monitoring system fails or needs to be sent in for recalibration. This data logger must be equipped with the following:

- A temperature probe in buffered solution and can detach from the recording device
- An active temperature display that can be read from the outside of the storage unit. It must be able to read the current temperatures minimum and maximum temperatures.
- It has continuous monitoring and recording and the data can be down loaded routinely.
- Have an alarm (either audible or visual) for out-of-range temperatures.
- Low battery indicator
- Accuracy of +/- 1°F (0.5°C)
- Has a user programable logging interval

The VFC 400 data logger is recommended since it is a new version of the recorder NSIP distributes to our enrolled providers. It can be ordered over the following website:

<http://www.vfcdataloggers.com/>

## Temperature Checks

Refrigerator and freezer temperatures must be checked a minimum of twice daily on business days using one of two methods:

1. Use the LogTag TRED30-7R as provided by the Nevada State Immunization Program. Providers are required to maintain the temperature downloads for at least three (3) years.
2. Minimum/maximum temperature checks must be done twice a day - once in the morning and once prior to leaving the office for the night. Date, time room temperature and initials must be recorded in a data log. Providers are required to maintain temperature logs on file for at least three (3) years.

## Digital Data Loggers for Continuous Temperature Monitoring

**The Nevada State Immunization Program provides all enrolled VFC providers with at least two (2) LogTag TRED 30-7R data logger units.**

This temperature recording device provides continuous temperature readings 24 hours a day, 7 days a week. A detachable probe facilitates downloading temperature data without removing the probe from the storage unit, and simplifies daily use and minimizes operator cause of temperature variability. The digital data logger also includes the following:

- Hi/low alarm for out of range temperatures (visual only)
- Current temperatures as well as min/max temperatures
- Low battery indicator
- Accuracy of +/- 1° F (5° C)
- Memory storage of at 4000 readings, the device cannot rewrite over old data, and stops recording when the memory is full, and;
- Has a user programmable logging interval, (or reading rate).

**IMPORTANT NOTE: Every VFC enrolled provider is required to purchase at least one data logger as their back-up thermometer. It is recommended that provider clinics purchase the VFC 400 data logger from Control Solutions. View the Control Solutions website at: <http://www.vfcdataloggers.com/> . Digital data loggers are also required for all off site vaccination events, and during transport of vaccines.**

It is strongly recommended that clinics that are routinely closed for more than two (2) consecutive days, and do not have office staff that assess/record temperatures when the office is closed, use digital data loggers with continuous monitoring and recording capabilities.

## Biosafe Glycol-Encased Probes

The Centers for Disease Control and Prevention (CDC) **recommend use of a digital thermometer with a biosafe glycol-encased probe that will more closely approximate the measure of liquid temperature.** A temperature buffer enables a thermometer probe to more closely match the temperature changes experienced by liquid vaccine.

Examples of temperature buffers are a probe inserted into a glycol-filled vial or one inserted into glass beads (**glycol-filled vials are more strongly recommended**). The NSIP requires this type of probe because studies by the National Institute of Standards and Technology (NIST) conducted in 2009 showed that compared to probes that measure ambient air temperature, the digital thermometer with glycol-encased probe more accurately reflects the temperature of the vaccine vial and does not register normal air temperature fluctuations which do not significantly impact vaccine temperature.

Because the main factor affecting potency of refrigerated vaccines is exposure to freezing temperatures, it is important that glycol-encased probes be placed among the vaccines in a central part of the vaccine storage unit instead of on a unit's interior wall; and at least for refrigerated vaccines, in the part of the refrigerator where manufacturer recommended vaccine storage temperatures can best be maintained.

In addition to the use of a digital thermometer in a glycol-filled vial, the recommended temperature monitor should also provide continuous data monitoring information in an active display and be placed on the outside of the unit to allow for reading temperatures without opening the unit door.

### **Thermometer Calibration & Temperature Checks**

To ensure validity of temperature measurements, only calibrated thermometers with a certificate of Traceability and Calibration performed by a laboratory accredited by an ILAC-MRA signatory body or an entity that provides documentation showing calibration testing that meets ISO/IEC 17025 international standards should be used. **Using currently calibrated data loggers continues to be a requirement for VFC Providers.**

### **Receiving Vaccine Shipments**

**In order for shippers to deliver vaccines, provider staff must be on site and available to receive vaccine at least one day a week other than Monday, and for four (4) consecutive hours during that day.** All staff in the facility must be trained in vaccine receipt and management (including, but not limited to):

- Front desk staff
- Medical staff
- Purchasing staff
- Security staff, etc.

**All staff who may accept packages for the clinic must be aware that vaccine shipments require immediate attention**

### **Receiving Refrigerated Vaccine:**

- The staff person accepting the shipment must immediately notify the office's primary vaccine coordinator or designated backup;
- The box containing the vaccines must be physically handed to the office's primary vaccine coordinator or designated backup;

- McKesson uses a number of qualified pack-outs to ship vaccine. **For refrigerated vaccine, the approved pack-out designs have the 3M MonitorMark warm temperature indicator directly under the coolant packs and the TransTracker© FREEZEmarker indicator directly with the vaccines.**
  - **McKesson qualified pack-outs do not require that temperature indicators be included with the vaccine shipment.** In fact, many vaccine manufacturers do not use the indicators in product shipments. The CDC has required them with federal shipments only as an added precaution. Providers may receive private-pay vaccine shipments from other distributors/manufacturers which do not contain the temperature indicators.
- Immediately upon shipment receipt, remove both temperature monitors included in the shipment:
  - 3M MonitorMark to determine if the shipment may have been subjected to warmer temperatures; and
  - TransTracker © FREEZEmarker Indicator to determine if the shipment may have been subjected to colder temperatures.
  - Follow the monitor instructions on each card regarding activation and reading; and
  - If you have any questions or concerns when reading the monitor, if the monitor is not activated, or if you see damage to the package, then contact McKesson Specialty Contact Center (MSCC) at 877-836-7123 within 2 hours and notify the Nevada State Immunization Program;
- Check the condition of the vaccines;
- Determine the length of time the vaccine was in transit by looking at the packing list;
- Compare the “packing list” to the actual contents of the shipment. Any discrepancies and/or damage must be reported immediately to the NSIP at (775) 684-5939;
- If there are any discrepancies with the packing slip or concerns about the shipment, then immediately mark the vaccine and diluents as “DO NOT USE” and store them in proper conditions; and
- **Refrigerate the vaccines immediately and place those with the shortest expiration date in the front of the storage unit to be administered first.**

### Receiving Frozen Vaccine

- The staff person accepting the shipment must immediately notify the office’s primary vaccine coordinator or designated backup;
- The box containing the vaccines must be physically handed to the office’s primary vaccine coordinator or designated backup;
- Immediately upon shipment receipt, check the condition of the vaccines and the packaging for damage;
- Compare the “packing list” to the actual contents of the shipment. Any discrepancies and/or damage must be reported immediately to the NSIP at (775) 684-5939;
- Check the condition of the vaccines;
- Determine the length of time the vaccine was in transit by looking at the packing list.



- Contact the Nevada State Immunization Program immediately if there is any damage and/or discrepancies at (775) 684-5939; and
- **Immediately store the vaccines in the freezer with the shortest expiration date in front to be administered first.**

### **Vaccine Storage Guidelines**

**Refrigerated Vaccine** – The temperature of all refrigerated vaccine must remain steady between 36°F and 46°F (2°C and 8°C). **The recommended temperature for refrigerated vaccines is 40°F.** The vaccines are shipped with ice packs and bubble wrap to protect the vaccines from contact with the frozen ice packs.

**Frozen Vaccine** – Frozen vaccines are shipped by the manufacturer (Merck) directly to the provider site. All frozen vaccines must be stored at temperatures between 5°F and -58°F (-15°C and - 50°C) until reconstitution and use. **The recommended temperature for frozen vaccines is 3°F or lower.**

### **Important storage instructions for Varivax® & ProQuad®**

Merck Warehouses have begun using smaller shipping containers for frozen vaccines. Some things that haven't changed are:

- Providers shouldn't treat these shipping containers any different from the previous ones.
- Diluent will still be shipped in the top cover of the container separate from the vaccine.
- Merck's colors and labeling will not be changing.

This new container is qualified for 2 days in transit. The older, larger frozen shipping container is still being used to ship vaccine and is qualified for 4 days in transit. Should you receive a late Varivax/ProQuad shipment, it is important that you check the shipper insert supplied in the box. This insert will let you know how long the product is good for based on the shipment date shown on the packing list. Specific information on frozen product shipments is on the next page.

- **Varivax/Zostavax**
  - Orders of 40 doses or less will be shipped in the small 2-day box, unless they are shipped on a Thursday or Friday, in which case they will arrive in the large 4-day box for delivery on a Monday or Tuesday.
  - Orders of 40 doses or more will ship in the large 4-day box.
- **ProQuad**
  - Orders are viable for only 1 day regardless of shipping container size.

**If the frozen shipping container is received after the time period described above, then contact the Merck Order Management Center immediately for replacement instructions at (800) 637-2579 and notify the Nevada State Immunization Program. Such requests for replacement must be received by Merck within 3 days of receipt of the original shipment.**

- The vaccine is located in the lower compartment of the package – Store the vaccine in a FREEZER immediately. Standalone freezers are preferred and should reliably maintain a temperature between –58°F and +5°F (–50°C to – 15°C).
- Merck does not recommend re-use of shipping materials, including gel packs and shipping containers to further transport vaccine products as improper re-packaging and transportation could impact the stability of the vaccine.
- The gel packs contain water-based non-toxic gel. Please dispose of these gel packs with regular trash.
- Store the diluent (located in the top compartment of the package underneath the cardboard cap) in a refrigerator [36°F to 46°F (2°C to 8°C)] or at room temperature [68°F to 77°F (20°C to 25°C)].

### **Additional Requirements for Vaccine Storage & Handling**

- The provider must have a current “Office Vaccine Management Plan.” A template can be located on the NV State Immunization Program website:  
[http://dpbh.nv.gov/Programs/VFC/dta/Forms/Vaccines\\_for\\_Children\\_\(VFC\)\\_Program\\_-\\_Forms/](http://dpbh.nv.gov/Programs/VFC/dta/Forms/Vaccines_for_Children_(VFC)_Program_-_Forms/)
- Food must not be stored in any units being used for vaccine storage;
- Vaccines must not be stored in the drawers, doors or on the floor of a unit;
- Vaccines must be stored in the refrigerator away from any cool air vents that may be connected to the freezer compartment (combination units only);
- Vaccines must be stacked with at least 2 inches of air space between the boxes and the side/back walls of the unit to allow air circulation;
- Vaccine must be stored in its original box until use;
- Bottles of water should be stored in the lowest compartment of the refrigerator and extra ice packs stored in the freezer to help maintain temperatures in cases of power outage. No ice packs in the doors of the freezer.
- State-supplied vaccine may be stored in the same unit as privately purchased vaccine, but both stocks must be clearly labeled for easy identification by staff;
- Inventory must be rotated to ensure that the shortest dated vaccine is used first and expired vaccine must be removed from the vaccine storage unit;
- State-supplied vaccine with short expiration dates (expiring within 3 months) should be reported to the NSIP if the provider does not anticipate using these vaccines before expiration. When notified that short-dated vaccines will not be used, the NSIP will make every effort to have the vaccines transferred to another enrolled provider for immediate use;
- Post “DO NOT DISCONNECT” signs on the front of each vaccine storage unit, next to the storage units’ electrical outlet (if exposed) and on the breaker switch that supplies power to the vaccine storage unit(s);
- The vaccine storage unit(s) must be plugged directly into an electrical outlet (surge protectors are NOT to be used); and

- Providers are strongly encouraged to have all staff responsible for vaccine storage and handling review and apply the practices for proper vaccine storage and handling found on the CDC’s website: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

### **Vaccine Exposure to Improper Temperatures**

- Immediately place the vaccine into proper storage conditions and label "Do Not Use;"
- **Do not presume that the vaccine has been compromised;**
- Begin completing the “Vaccine Incident Report”;
- Call the manufacturers to assess whether vaccine potency could have been affected;
  - Also contact the NSIP at (775) 684-5939;
- Document viability and disposition per the manufacturer on the “[Vaccine Incident Report](#);”
- Document corrective action steps taken on the “Vaccine Incident Report;” and
- Fax the completed “Vaccine Incident Report” to the NSIP at (775) 684-8338.
- If the vaccines are determined to be non-viable by the manufacturer, then follow the instructions below: “Steps for Returning Expired/Spoiled Vaccine to McKesson.”
- **If the NSIP determines the vaccines were administered after exposure to damaging storage conditions, then the NSIP strongly recommends that patients/parents/guardians of the vaccine recipients be notified by the provider and offered re-vaccination to ensure they are fully immunized.**

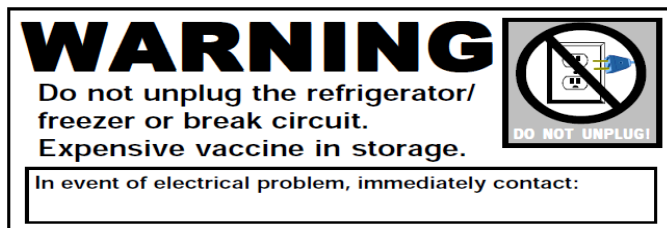
### **Vaccine Restitution Policy**

The Nevada State Immunization Program is authorized to request dose-for-dose reimbursement from an enrolled provider for the value of publicly-supplied vaccines wasted through negligent storage or otherwise non-compliant practices that do not meet federal/state VFC Program requirements. **Dose-for-dose reimbursement means the provider must purchase replacement vaccine using their own private funds at private vaccine cost; additionally, replaced vaccine must be used to vaccinate VFC eligible children only.** The NSIP is NOT authorized to accept financial reimbursement as restitution for wasted/spoiled vaccine.

## SETTING UP A NEW VACCINE STORAGE UNIT

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

- Make arrangements in advance to temporarily store your vaccines in an appropriate, alternate storage unit with unexpired, calibrated data loggers. Monitor the temperature of this temporary unit a minimum of twice daily and maintain stable temperature readings within the target ranges (refrigerator: 40°F and freezer: 5°F or <5°F) until the new unit is approved;
- Five(5) days of acceptable temperatures must be obtained from the new vaccine storage unit before placing vaccines within. Obtain approval from the NSIP prior to transferring vaccines into the new unit;
- The new unit may have colder and warmer areas especially in the refrigerator compartment. A best practice is to check the temperatures in different areas of the compartment prior to vaccine storage in order to determine the most stable area for vaccine storage;
- Plug the new vaccine storage unit directly into a wall or floor outlet. **Never use extension cords or power strips;**
- If the new unit comes with vegetable bins, then fill the bins with full bottles of water. Do not store vaccines in the refrigerator doors, the vegetable bins, or on the floor of the unit;
- Add additional full bottles of water to the shelves inside the refrigerator door and store ice packs in the freezer. These measures will help maintain a stable, cold temperature if the refrigerator or freezer doors are opened frequently or in cases of power failure;
- Place digital unexpired, calibrated thermometers (with glycol-enclosed probes) in the center of each unit close to where the vaccine will be stored. Any thermometer being used, including built-in thermometers in pharmacy and lab-grade units, must have a certificate of calibration proving it has been calibrated to ISO/IEC 17025 standards;
- Set the refrigerator temperature to stabilize around 40°F and set the freezer temperature to stabilize around 3°F or lower. Adjust the temperature in small increments and continue to monitor the units until the target temperatures are reached;
- Carefully label the areas where vaccine will be stored. Identify where state supplied vaccine will be versus where privately purchased vaccine will be stored within the unit;
- Be sure a DO NOT UNPLUG sticker is posted on the front of the unit(s), near the electrical outlet(s), and label the appropriate circuit breaker(s): “Expensive Vaccines, Do Not Disconnect.”



## RETURNING EXPIRED/WASTED VACCINES

### The Following Items Should NEVER Be Returned to McKesson

- Syringes that you filled but did not use;
- Any used syringes with or without needles attached;
- Broken vials; or
- Any multi-dose vial from which some doses have been withdrawn.

**The items listed above should be disposed of according to usual medical biosafety procedures.**

Do not return empty shipping boxes to McKesson Specialty Distribution. Providers are encouraged to recycle the boxes through their local recycling programs. McKesson Specialty Distribution recommends that providers keep one or two boxes on hand for use in returning non-viable (expired, wasted, spoiled) vaccine.

### What Should Be Returned to McKesson?

- Publicly supplied spoiled or expired product in its original vial;
- Unused pre-filled syringes from manufacturers with NDC printed on them; and
- Expired or compromised VFC/CHIP/317/STATE vaccine will be reported to the NSIP through NV WebIZ.

### Receiving Return Labels via E-Mail

- Remove expired/spoiled vaccine from unit as soon as it becomes expired/spoiled and pack the non-viable VFC vaccines in any box for return to McKesson (do not add any private stock vaccines).
- If the expired or spoiled vaccines are in the clinic's NV WebIZ inventory, complete the Vaccine Return Request through the Vaccine Return module in NV WebIZ. Check in WebIZ for the date submitted to VTrckS. No confirmation fax will be sent! Return label will be emailed by UPS to the primary coordinator. If two labels are ordered but only one is used, then the unused shipping label should be enclosed in the box that is being shipped to McKesson. **Do not** photocopy or reprint the label to use at a later time on another shipment.
- If the spoiled/expired vaccines have already been deleted from the inventory in NV WebIZ then complete the "[VTrckS-UPS Pickup Request for Expired/Spoiled Vaccine](#)" (for the products eligible for return) and fax the completed form to (775) 684-8338. Once the NSIP receives the faxed pickup request, McKesson will be contacted to send mailing label(s) via e-mail. The e-mail will go to the person NSIP has on file as the Primary Vaccine Coordinator for the clinic. There are specific guidelines that must followed when receiving the label(s):
  - The e-mail address from which the label arrives is UPS Quantum View [pkginfo@ups.com](mailto:pkginfo@ups.com) and in the subject line it will say "UPS Label Delivery";

- Once NSIP inputs the label request into VTrckS, Tammy Brown will fax your request back with verification that the label was ordered. Once you receive the fax, the return label should arrive in your inbox approximately 30 – 60 minutes later. Check your spam/junk folder if you don't see the label in your inbox within that time.
- If two labels are ordered but only one is used, then the unused shipping label should be enclosed in the box that is being shipped to McKesson;
- **Do not** photocopy or reprint the label to use at a later time on another shipment.
- After printing the return mailing labels, give the box of vaccine to a UPS driver when they come into your office or take the box of vaccine to a UPS store and drop it off. If you call them for pickup, UPS may charge you.

## EMERGENCY EVENT STORAGE & HANDLING

The following procedures should be performed in the event of a power outage:

### Short-Term Power Outage

- Record the time and temperature of the room, refrigerator and freezer using an unexpired, calibrated thermometer;
- If it is determined the power will only be out for a few hours, then tape the unit doors so no one can inadvertently open them and allow cold air to escape;
- When the power resumes, record the time and the temperatures in the refrigerator and freezer. If the temperatures are out of range, then do not use the vaccine; and
- Contact the NSIP Vaccine Manager and the vaccine manufacturers for instructions if VFC/state supplied vaccines are involved.

### Long-Term Power Outage

#### Facilities WITH a backup generator

- Record the time and temperature of the room, refrigerator and freezer using an unexpired, calibrated thermometer;
- Ensure the vaccine storage unit is plugged in an outlet that is supplied by the generator;
- Once the generator is supplying power to the storage unit, record the temperatures in the room, refrigerator and freezer again; and
- If the generator is not functioning, then prepare to transfer the vaccine to a functioning unit.

#### Facilities WITHOUT a backup generator

- Record the time and temperature of the room, refrigerator and freezer using an unexpired, calibrated thermometer;
- Gather cooler boxes, conditioned frozen water bottles, bubble wrap and cardboard to pack the vaccines:
  - Place conditioned frozen water bottles in the bottom of the cooler boxes;
  - Place cardboard and then bubble wrap on top of the conditioned frozen water bottles;
  - Place the refrigerated vaccines on top of the bubble wrap;
  - Place an unexpired, calibrated thermometer probe in the middle with the vaccines;
  - Put another layer of bubble wrap and then cardboard on top of the vaccines;
  - Place another layer of conditioned frozen water bottles on top of the cardboard; and
  - Place the lid of the cooler box on the cooler and secure it with tape. Secure the digital thermometer display on top of the cooler.
- **Frozen vaccines must be placed in a separate cooler box directly on frozen water bottles and surrounded by additional frozen water bottle.**
- **Transport the vaccines to another location that has been coordinated with and not affected by the disaster in the CAB of a vehicle. NEVER transport vaccine in the trunk of a vehicle.**

- Complete a Vaccine Incident Report and fax it to the NSIP as soon as possible at (775) 684-8338.

**Mechanical Failure of Unit(s)**

- Record the time and temperature of the room and the affected storage unit using an unexpired, calibrated thermometer; then
  - Pack the vaccine in a bag and mark it “DO NOT USE”;
  - Place the vaccine in another freezer or refrigerator if the provider has more than one storage unit;
- Call each vaccine manufacturer and follow their directions to determine vaccine viability;
- Complete a Vaccine Incident Report immediately and fax it to the Nevada State Immunization Program. Ensure the report details if your vaccine is viable or spoiled; then
- Return expired/spoiled vaccine through WebIZ Return function or complete the “VTrckS-UPS Pickup Request for Expired/Spoiled Vaccine” and fax to the NSIP at (775) 684-8338 to obtain a mailing label for return;
- Have the affected storage unit repaired or replaced;
  - Obtain 5 business days of acceptable temperatures from the affected or new unit; then;
  - Fax the Temperature Log or transmit the LogTag information to the Nevada State Immunization Program to obtain permission to return the vaccine to the affected unit; and
- Continue to monitor temperatures twice daily to ensure the repaired or new unit stays within the proper temperature ranges for continuous vaccine storage.



## REQUEST FOR TERMINATION

An enrolled provider may request to terminate their Agreement to Participate at any time and must provide:

- Written notification on office letterhead including:
  - Date participation in the NSIP will cease;
  - Reason for termination;
  - Ending inventory of the state supplied vaccines on hand including:
    - Lot Numbers,
    - Expiration Dates,
    - Number of doses; and
    - Current “Log Tag” down loads or a “Temperature Log” if log tags are not installed in your storage units.

Upon receipt of this notification, the NSIP will inactivate the provider as requested and the local health department will transfer any viable vaccines to another enrolled provider.

An inactive provider may request to be re-activated at any time; however, state-supplied vaccines may not be requested by the re-activated provider until re-enrollment paperwork has been completed, a re-enrollment visit has been conducted, and the site is approved as being in compliance with current NSIP Protocols.

## VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)

The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS collects and analyzes information from reports of adverse events following immunization. Adverse events should be reported online at: <https://vaers.hhs.gov/reportevent.html>.

VAERS encourages the reporting of any significant adverse event that occurs after the administration of any vaccine licensed in the United States. Clinically significant adverse events should be reported, even if you are unsure whether a vaccine caused the event. The National Childhood Vaccine Injury Act (NCVIA) requires health care providers to report:

- Any event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine; and
- Any event listed in the Reportable Events Table that occurs within the specific time period after vaccination. A copy of the Reportable Events Table can be found online: [https://vaers.hhs.gov/resources/VAERS\\_Table\\_of\\_Reportable\\_Events\\_Following\\_Vaccination.pdf](https://vaers.hhs.gov/resources/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf)

Both the CDC and the FDA review data reported to VAERS. The FDA reviews reports to assess whether a reported event is adequately reflected in product labeling, and closely monitors reporting trends for individual vaccine lots. The CDC encourages all physicians to report any reaction following vaccination to VAERS, regardless of whether or not the physician believes that the vaccine caused the reaction. Reports sent to the VAERS Program that also make reference to non-vaccine pharmaceutical products are shared with MedWatch, the FDA's drug safety surveillance system.

### To obtain additional information about VAERS:

- Send e-mail inquiries to [info@vaers.org](mailto:info@vaers.org);
- Visit the VAERS website: <https://vaers.hhs.gov/index.html>;
- Call the toll-free VAERS information line at (800) 822-7967; or
- Fax inquiries to the toll-free information fax line at (877) 721-0366.

## SAFE INJECTION PRACTICES

The investigation of four large outbreaks of hepatitis B and hepatitis C virus among patients in ambulatory care facilities in the United States identified a need to define and reinforce safe injection practices. The four outbreaks occurred in a private medical practice, a pain clinic, an endoscopy clinic, and a hematology/oncology clinic. The primary breaches in infection control practice that contributed to these outbreaks were 1) reinsertion of used needles into a multiple-dose vial or solution container (e.g., saline bag) and 2) use of a single needle/syringe to administer intravenous medication to multiple patients.

In one of these outbreaks, preparation of medications in the same workspace where used needle/syringes were dismantled also may have been a contributing factor. These and other outbreaks of viral hepatitis could have been prevented by adherence to basic principles of aseptic technique for the preparation and administration of parenteral medications. These include the use of a sterile, single-use, disposable needle and syringe for each injection given and prevention of contamination of injection equipment and medication. The CDC launched a national education campaign: <http://www.oneandonlycampaign.org/>.

Improper use of syringes, needles, and medication vials during routine healthcare procedures, such as administering injections have resulted in one or more of the following:

- Transmission of blood borne viruses, including hepatitis B and hepatitis C to patients;
- Notification of thousands of patients of possible exposure to blood borne pathogens and recommendation that they be tested for hepatitis B, hepatitis C, and HIV;
- Referral of providers to licensing boards for disciplinary action;
- Malpractice suits filed by patients.

These unfortunate events serve as a reminder of the serious consequences of failure to maintain strict adherence to safe injection practices during patient care. Injection safety and other basic infection control practices are central to patient safety. All healthcare providers are urged to carefully review their infection control practices and the practices of all staff under their supervision. In particular, providers should ensure that staff:

- Never administer medications from the same syringe to more than one patient, even if the needle is changed;
- Do not enter a vial with a used syringe or needle.

Hepatitis B, hepatitis C, and HIV can be spread from patient to patient when these simple precautions are not followed. Additional protection is offered when medication vials can be dedicated to a single patient. It is important that:

- Medications packaged as single-use vials never be used for more than one patient;
- Medications packaged as multi-use vials be assigned to a single patient whenever possible;
- Bags or bottles of intravenous solution not be used as a common source of supply for more than one patient;
- Absolute adherence to proper infection control practices is maintained during the preparation and administration of injected medications.

## VACCINE ADMINISTRATION

### How to Administer Vaccines:

There are several resources available on how to administer vaccinations to persons of all ages. These include:

- Immunization Action Coalition:  
<http://www.immunize.org/handouts/administering-vaccines.asp>
- Epidemiology and Prevention of Vaccine-Preventable Disease (Pink Book)
  - Appendix D
  - <http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>
- EZ IZ: <http://eziz.org/eziz-training/>

### Immunization Schedule:

The NSIP requires all enrolled providers to follow the Advisory Committee on Immunization Practices (ACIP) schedule. Alternative immunization schedules are not allowed unless for a specific medical circumstance.

ACIP schedules are updated yearly and can be viewed, downloaded and printed online:

<https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>

## VFC PROGRAM COMPLIANCE VISITS

All enrolled providers/clinics/facilities must be reviewed periodically as a condition of continued enrollment in the Nevada VFC Program. The Nevada State Immunization Program may conduct one or more of the following types of visits during a calendar year:

- **Enrollment or Re-enrollment Visit** – an enrollment visit includes education about federal and state program requirements and recommendations, including proper vaccine storage and handling techniques. This visit is also an opportunity to establish a working relationship with the Nevada State Immunization Program representative. A re-enrollment visit will be made to providers/clinics that have: 1) requested to be reactivated in the program after termination, 2) moved into a new facility and/or 3) been delinquent in re-enrolling during the annual re-enrollment period.
- **VFC Compliance Visit** – a formal review of compliance with VFC standards for all enrolled providers. Compliance visits are performed to evaluate provider compliance with federal Vaccines for Children (VFC) and Nevada State Immunization Program (NSIP) Protocols and address any noted deficiencies. NSIP staff or designated representatives will contact the primary vaccine coordinator for scheduling of the VFC Compliance Visit. The CDC’s VFC Compliance Visit Questionnaire is completed and a review is conducted of a sampling of patient charts for documentation of VFC eligibility, including both VFC and non-VFC eligible children 18 years of age and younger. **The facility’s Medical Director (the person who signed the VFC Agreement to Participate) must review compliance visit findings with the state/local Quality Assurance Coordinator and sign the provided documentation.** If requested by the reviewer, the provider may need to respond to areas of non-compliance with a written corrective action plan. This corrective action plan is normally due within two (2) weeks of the request; delays in submitting a corrective action plan may result in temporary suspension of vaccine shipments.
  - **VFC Compliance Follow-Up Visit** – an assurance check of issues of concern that arose from the VFC Compliance Visit. This follow-up visit may occur within 6 months of the original compliance visit. The facility’s Medical Director, who signed the enrollment forms, or a designee, is strongly recommended to attend.
- **AFIX Visit** – an assessment of the immunization rates of preschool and/or adolescent patients is completed utilizing immunization data from Nevada WebIZ. A questionnaire will be completed either before or during the visit to identify areas of needed improvement. The provider will be asked to select two (2) areas of quality improvement in order to implement activities that will increase their patient’s immunization rates.
  - **AFIX Follow-Up Visit** – a follow-up to the AFIX visit to document that measures to improve immunization practices and delivery have been implemented. This follow-up visit normally occurs within six (6) months of the original visit. The

facility's Medical Director, who signed the enrollment forms, or a designee, is strongly recommended to attend. A second immunization assessment will be performed prior to this follow-up visit and discussed during the visit.

- **VFC Education Visit** – a visit that occurs when enrolled provider sites undergo significant staff turnover or to assist in a specific area of improvement, such as annual required VFC education, a review of the ACIP schedule, reporting forms or developing written vaccine storage and handling plans. This type of visit may be initiated by a NSIP representative or may be specifically requested by an enrolled provider or their staff.
- **Unannounced Storage & Handling Visit** – a visit that occurs when an enrolled provider site has had a vaccine wastage history of greater than 5% of all doses ordered during the previous calendar year or lack of provider response to NSIP requests for reports. Vaccine storage and handling procedures and historical temperature data will be reviewed with the primary vaccine coordinator and recommendations will be made based on the provider's specific needs.

## CONSEQUENCES OF NON-COMPLIANCE

If an enrolled provider is found to be non-compliant with federal Vaccines for Children (VFC) Program or Nevada State Immunization Program Protocols, then vaccine shipments to the provider may be suspended until a corrective action plan is submitted and/or other necessary steps are taken to correct deficiencies. **Failure to adequately correct serious deficiencies, such as those that jeopardize vaccine effectiveness, can result in removal of the provider from active participation in the Nevada VFC Program.**

**The following actions may be taken and special provider status assigned:**

### Suspended from Vaccine Ordering

1. Vaccine integrity cannot be assured because the temperature in the refrigerator was recorded as 32°F or 0°C, or lower, at any given time without documented immediate corrective action; no thermometer in vaccine storage unit; no documentation of daily temperature checks for vaccine storage unit. **When vaccine storage problems cause vaccine to be compromised, shipments may be suspended until the practice provides a one-week temperature data from the storage unit, proving that it is capable of sustaining appropriate storage temperatures.** Once reactivated, practices may need to provide weekly temperature data to evaluators for up to two (2) months to ensure that vaccine storage problems have been resolved.
2. Refusal to cooperate with NSIP staff requests for compliance visits, reports, information or corrective action plans needed to satisfy program requirements.

### Not Active (INACTIVE)

1. The provider requests in writing to withdraw from program participation;
2. The provider is unwilling or has refused to comply with program requirements; or
3. The provider refuses to meet reasonable “standard of care” expectations by not adhering to the current ACIP Recommended Immunization Schedules.

## FRAUD AND ABUSE POLICY

The NSIP Fraud & Abuse Policy provides guidance in the monitoring, detection and prevention of fraud and/or abuse of VFC and/or State-supplied vaccines. This policy is consistent with standards established in the policy on fraud and abuse by the U.S. Centers for Disease Control and Prevention (CDC) located at <http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/fraud.html>. This policy applies to any fraud, abuse, and/or waste of federal and/or state supplied vaccines involving Nevada State Immunization Program enrolled providers.

### **Background**

The Federal VFC Program was created as part of the Omnibus Budget Reconciliation Act, Section 1928 of the Social Security Act in August 1993. The goal of this federally funded program is to improve vaccine availability nationwide by providing vaccines at no cost to VFC-eligible children through public and private providers enrolled in the program. Learn more by visiting this site: <http://www.cdc.gov/vaccines/programs/vfc/index.html>. The VFC Program is operational in all 50 states, D.C., and eight (8) territories including the U.S. Virgin Islands, Puerto Rico and Guam.

Nevada began its VFC Program in 1994 as part of the President's Childhood Immunization Initiative. The VFC Program is a Title XIX Medicaid program. Children who are VFC eligible are those who are under 19 years and are: Medicaid-eligible, uninsured, underinsured and seen at a Federally Qualified or Rural Health Center, or are American Indian/Alaska Native. These children are entitled to receive low to no-cost pediatric vaccines that are recommended by the CDC's Advisory Committee on Immunization Practices (ACIP).

Nevada Check-Up (S-CHIP) is a non-Medicaid managed care program operated by the State of Nevada. Effective October 1<sup>st</sup> 1998, children enrolled in Nevada Check-Up began receiving vaccines from the Nevada State Immunization Program that are distributed in the same manner as vaccines for VFC-eligible children but which are purchased with funds from the Nevada Division of Health Care Financing and Policy.

### **Purpose of the Fraud and Abuse Policy**

The purpose of this policy is to provide a standard operating procedure for prevention, detection, investigation and resolution of all suspected cases of provider fraud and/or abuse. All VFC providers are required to be enrolled and to re-enroll in the Nevada VFC Program annually. The facility's Medical Director or equivalent must sign the *VFC Agreement to Participate* which specifies the Nevada VFC Program requirements (more information online: [http://dpbh.nv.gov/Programs/VFC/VFC\\_-\\_Home/](http://dpbh.nv.gov/Programs/VFC/VFC_-_Home/)). Federal fraud and abuse laws apply to the entire VFC Program. In addition, providers who use Nevada Check-Up, "317"-funded or Nevada Cocooning Program vaccines are also subject to this Fraud and Abuse Policy.

Suspected fraud and/or abuse will be identified by several mechanisms, which may include, but will not be limited to:



- Vaccine Request and Accountability Report or the electronic equivalent;
- Eligibility Report of Doses Administered;
- VFC compliance or VFC education visits;
- Responses to high priority questions on the CDC VFC Compliance Visit Questionnaire;
- Responses to high priority questions on the CDC Unannounced Visit Questionnaire;
- Verbal or written reports from provider staff;
- Verbal or written complaints from patients;
- Inconsistencies in reporting of vaccines in the state’s immunization system (Nevada WebIZ); and
- Any other information provided to the Nevada State Immunization Program that is deemed valid.

**\*\*Reports of suspected fraud and/or abuse will be investigated immediately\*\***

**For the purposes of this Fraud and Abuse Policy, the following definitions will be used:**

**Fraud:** defined in the Code of Federal Regulations, Title 42, Part 455, Section 455.2 (42 CFR 455.2) as an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

**Abuse:** defined in 42 CFC 455.2 as provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid Program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid Program.

**Policy Components**

All suspected cases of fraud and/or abuse will be reviewed by the following Immunization Program staff: Program Manager, Provider Quality Assurance Manager, Vaccine Manager, and other staff assigned to assist. Available data and complaints will be reviewed. If staff believes that intentional fraud and/or abuse is occurring, then the case will be reported to the Centers for Medicare & Medicaid Services (CMS) - Medicaid Integrity Group with a copy to the CDC. CMS will then refer the suspected case to the Nevada Division of Health Care Financing and Policy (Nevada Medicaid) who will conduct the investigation following the Federal Regulatory scheme at [42 CFR section 455.15](#). The Nevada State Immunization Program will track all suspected cases of fraud and/or abuse in a database to monitor and document all actions taken on allegations related to fraud and/or abuse, including actions taken to address identified situations.

**Oversight Personnel**

The Nevada State Immunization Program’s Health Program Manager II will serve as the primary position which has the authority to:

- a) Determine if a situation requires immediate referral or if educational intervention and follow-up are adequate;
- b) Make decisions to refer the case to the Medicaid Integrity Group and the Nevada Division of Health Care Financing and Policy;
- c) Make the referral(s); and
- d) Notify appropriate governmental agencies (e.g., CDC) of actions taken.

The Nevada State Immunization Program’s Provider Quality Assurance Manager and Vaccine Manager will serve as the first and second back-up oversight positions respectively. Finally, if necessary, the Administrator for the Division of Public and Behavioral Health and the Bureau Chief for Child, Family and Community Wellness may become involved.

**Examples of Fraud and Abuse**

1. Examples of actions that might constitute potential fraud and/or abuse:
  - a. Providing VFC vaccine to non VFC-eligible children. If the provider administers immunizations to fully-insured children, then that vaccine must be privately purchased;
  - b. Selling or otherwise misdirecting VFC/CHIP vaccine;
  - c. Billing a patient or third party for the cost of VFC/CHIP vaccine;
  - d. Charging more than the established maximum regional charge for administration of a VFC vaccine to a non-Medicaid enrolled VFC-eligible child;
  - e. Denying VFC-eligible children any VFC vaccine because of the parent/legal guardians’ inability to pay the administration fee;
  - f. Abusing Delegation of Authority privilege – this includes allowing fully insured patients to be categorized as “underinsured;”
  - g. Failing to implement the VFC Program enrollment requirements;
  - h. Failing to screen and document patients’ VFC eligibility status at every immunization visit;
  - i. Failing to maintain VFC records or to comply with any other program requirement;
  - j. Failing to fully account for VFC/CHIP vaccine;
  - k. Failing to properly store and handle VFC/CHIP vaccine resulting in excessive expired/spoiled vaccine;
  - l. Ordering VFC/CHIP vaccines in quantities or patterns that do not match the provider’s profile or otherwise involve over-stocking; and
  - m. Wasting of VFC/CHIP vaccines due to provider negligence or non-compliance.

2. All cases of intentional fraud and/or abuse situations will be examined by the Nevada State Immunization Program and referred to the Centers for Medicare and Medicaid Service (CMS), Medicaid Integrity Group (MIG).

### **Wasted Vaccine Definitions**

Wasted vaccine is listed above under *Examples of Fraud and Abuse*. Any vaccine that cannot be used is considered “wasted,” including *expired vaccine, spoiled vaccine, or vaccine which is unaccounted for*. **Wasted vaccine that is determined by the Nevada State Immunization Program to have been wasted due to provider negligence or non-compliance may be required to be replaced on a dose-for-dose basis; the provider must replace the vaccines using private funds. Providers will have to submit receipt of purchase of the vaccine within 90 days demonstrating that all doses were replaced appropriately. Finally, replaced doses can then only be administered to VFC-eligible children.**

1. **Expired** – vaccine that is past its expiration date.
2. **Spoiled** – any vaccine that exceeds the limits of approved cold chain procedures or is pre-drawn and not used within acceptable time frames (an opened multi-dose vial is not spoiled until the expiration date has passed), or vaccine that has been delivered in non-viable condition.
3. **Unaccounted For** – any vaccine that has been lost in transit by the distributor or manufacturer, or vaccine not accounted for by monthly usage and inventory reports. This can be reflected by usage data or inventory discrepancies that reflect unaccounted for vaccine.

### **Wasted Vaccine Scenarios**

This list includes, but is not limited to the following scenarios:

#### **1. Non-Preventable Vaccine Loss**

No action will be taken to enforce dose-for-dose restitution if the NSIP determines the vaccine loss was not due to negligence or non-compliance on the part of the provider.

- a. The carrier (UPS, FedEx, etc.) does not deliver the vaccines in a timely manner. Before making the determination that the vaccine is non-viable, the provider must first contact the vaccine manufacturers.
- b. An alert/alarm company does not notify the provider of a vaccine storage unit malfunction.
- c. Power is interrupted or discontinued due to a [storm, earthquake, etc.] natural or man-made disaster.
- d. Vaccine is moved to a nearby facility due to anticipated inclement weather, the facility experiences a power failure and the vaccine is later deemed to be non-viable.
- e. A vial is accidentally dropped/broken.
- f. Vaccine that is drawn at the time of the visit, but is not administered due to parental refusal or a change in physician orders.

- g. Extraordinary situations not listed above which the NSIP deems to be beyond the provider's control.

## 2. Preventable Vaccine Loss

**Loss Due to Negligence:** Below is a list of situations that may be considered "provider negligence" and may require dose-for-dose restitution. Situations that occur which are not listed here will be considered on a case-by-case basis by the NSIP Program Manager and/or the Vaccine Manager. Action may be taken by the NSIP to enforce dose-for-dose restitution if it is determined that vaccine loss was due to negligence on the part of the provider. Loss that is determined by the Nevada State Immunization Program to be negligence on the part of the provider may also be subject to replacement on a dose-for-dose basis at the provider's expense. Providers must submit receipt of purchase to NSIP within 90 days demonstrating that all doses were replaced appropriately. Replaced vaccine can then only be administered to VFC-eligible children.

- a. Failure to establish and follow an "Office Vaccine Management Plan."
- b. Failure to rotate or transfer vaccine that results in expired vaccine, and the NSIP was not notified at least three (3) months before the vaccine's expiration date.
- c. Pre-drawing vaccine before screening patients.
- d. Leaving vaccine out of the vaccine storage unit so it becomes non-viable.
- e. Vaccine stored improperly (e.g., refrigerating vaccine that should be frozen or freezing vaccine that should be refrigerated, etc.).
- f. Leaving a vaccine storage unit unplugged or an electrical breaker switched off. A "DO NOT UNPLUG" sticker is required at each outlet and circuit breaker that is powering a vaccine storage unit.
- g. Leaving a vaccine storage unit door open or ajar, whether by staff, contractors or guests.
- h. Improper maintenance of recommended temperatures resulting in vaccine spoilage, including prolonged storage of vaccines when out of range temperatures are recorded.  
*NOTE: Temperatures recorded on NSIP Temperature Logs will be considered official when making vaccine viability decisions. Also, a thermometers margin of error will not be considered when temperatures are recorded at or below 35°F / 2°C or above 46°F / 8°C.*
- i. Failing to act according to the Office Vaccine Management Plan during a power outage or other emergency situation.
- j. Transporting VFC/CHIP vaccines in a manner that does not maintain the cold chain appropriately at all times.
- k. Shipping publicly supplied vaccine at any time (shipping is different from "transporting").
- l. Failure to notify the NSIP when office hours change or the practice moves, resulting in vaccines being undeliverable and consequently spoiled.
- m. Failure to maintain alarm/alert devices properly.
- n. Relying solely on electronic temperature monitoring and not manually checking and documenting temperatures twice daily.

- o. Failure to be available to receive and properly store vaccine shipments per established office hours.
- p. Failure to use approved vaccine storage units. **Dorm style units are NOT acceptable.**

**Loss Due to Non-Compliance:** VFC/CHIP vaccine not accounted for by monthly usage and inventory reports. This can be reflected by usage data or inventory discrepancies that reflect lost vaccine supply. Action may be taken by the NSIP to enforce dose-for-dose restitution if it is determined that vaccine loss was due to non-compliance on the part of the provider. Loss that is determined by the Nevada State Immunization Program to be negligent or intentional on the part of the provider may also be subject to replacement on a dose-for-dose basis at the provider's expense. Providers must submit receipt of purchase to NSIP within 90 days demonstrating that all doses were replaced appropriately. Replaced vaccine can then only be administered to VFC-eligible children. Examples include:

- a. Failure to document vaccine usage or inaccuracy in reporting vaccine usage or inventory received on the:
  - i. Vaccine Request and Accountability Report,
  - ii. Vaccine Lot Number Inventory Report, or
  - iii. Eligibility Report of Doses Administered.
- b. Knowingly administering VFC/CHIP vaccine to ineligible children, includes:
  - i. Administering VFC/CHIP vaccine to patients over 18 years of age;
  - ii. Administering VFC/CHIP vaccine to every patient in the practice whether they are eligible or not (e.g., a VFC enrolled provider discontinues purchasing private stocks of vaccine for administration to fully insured patients);
  - iii. Administering VFC/CHIP vaccine because the reimbursement rate of the child's private insurance is low;
  - iv. Administering VFC/CHIP vaccine to a child who is fully insured, including a child whose parents have not met their deductible (high deductible plan still means the child is fully insured and therefore is not VFC-eligible);
  - v. Administering VFC/CHIP vaccine to a child even though the insurance company provides a flat rate of coverage for immunizations for the year (upon exhaustion of the flat rate coverage, the child becomes VFC-eligible).
- c. Accepting reimbursement from insurance companies or patients for VFC/CHIP vaccine as evidenced by:
  - i. Administering VFC/CHIP vaccine to a child and subsequently billing the patient's insurance for the cost of the vaccine;
  - ii. Charging the patient for the cost of the vaccine; and/or
  - iii. Charging a Medicaid recipient any fee at all.

**\*\*Providers are encouraged to have insurance policies in place to cover the cost of wasted/spoiled vaccine\*\***

### **Course of Action for Vaccine Restitution**

The Nevada State Immunization Program allows for up to a 5% vaccine wastage loss on an annual basis. This means that if a provider received 100 doses annually, up to 5 doses may be allowable in wastage, with no consequences. Anything above this threshold may be due to negligence or non-compliance and therefore the provider may be subject to replace the vaccine on a dose-for-dose basis using the most current vaccine pricing available on the CDC's website: <http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html>. Providers must submit receipt of purchase to NSIP within 90 days demonstrating they have all doses replaced appropriately.

The Vaccine Manager and Provider Quality Assurance Manager in tandem will be responsible for analyzing the wasted vaccine doses and determining which providers should be investigated. The Program Manager will send out the formal correspondence, and the program's Accounting Assistant will be responsible for collecting/filing the receipts/packing slips from charged providers. Should restitution be enforced, then the Vaccine Manager will be responsible for reviewing monthly vaccine administration records to ensure the replacement vaccine is being administered to VFC-eligible children; tracking may occur on paper or in Nevada WebIZ.

### **Who Will Investigate?**

The NSIP is not responsible for the official investigation of fraud and/or abuse within the VFC Program. Instead, when the NSIP identifies suspicious activity via electronic data or written/verbal reports the program will only review the case. If the NSIP determines that further investigation is warranted or justified, then the case will be reported to the CMS - Medicaid Integrity Group with a copy to the CDC. The VFC Program, as a component of each state's medical assistance plan, is considered a Title XIX Medicaid Program. All suspected cases of VFC fraud and/or abuse are referred to the CMS Medicaid Integrity Group for further referral – usually the state Medicaid agency (Nevada Division of Health Care Financing and Policy), which will then formally investigate the case.

### **Criteria that will be considered during a fraud and abuse investigation:**

- Past program compliance by the provider up to the time of the reported incident;
- Compliance to vaccine storage and handling requirements;
- How the incident was reported/identified;
- Length of time the situation was/has been occurring;
- Inadvertent or purposeful financial gain by the provider;
- The amount of VFC/CHIP vaccine that is wasted/spoiled;
- The provider's willingness to replace dose for dose the lost VFC/CHIP vaccine with privately purchased vaccine; and
- The provider's willingness to participate in the education visit referral and post-education follow-up.

Non-compliance with program requirements may occur due to an unintentional lack of understanding of the program requirements. If an instance of fraud and/or abuse is determined to result from an excusable lack of knowledge or understanding of the Nevada State Immunization VFC Program, then secondary education and a corrective action plan will be implemented. If an instance of fraud and/or abuse is determined to be intentional and the provider has received financial benefits from the behavior, then the situation will require immediate referral to CMS - Medicaid Integrity Group with a copy to the CDC. The provider will be temporarily suspended by the Nevada State Immunization Program pending the outcome of a more in depth investigation.

If a VFC-enrolled provider is not compliant with VFC Program Protocols or fraud and/or abuse is suspected or reported, then vaccine shipments to the provider may be suspended until a corrective action plan is submitted or other necessary steps are taken to correct deficiencies. Corrective actions may include more frequent follow-up visits and monitoring of records or replacement of vaccine damaged through provider negligence at provider expense. Failure to adequately correct serious deficiencies may result in enrolling the provider into a formal education process, termination of provider participation in the VFC Program or in the case of suspected fraud, referral for criminal prosecution or civil resolution.

### **Detection and Monitoring of Fraud and Abuse**

All VFC Compliance Site Visits will include completion of Section I of CDC’s VFC Compliance Visit Questionnaire. All compliance visit reports submitted by field staff, including all documented cases of potential fraud and/or abuse, and all compliance visit findings and recommendations will be reviewed by the State Provider Quality Assurance Manager and, if appropriate, by the Vaccine Manager, and then referred to the Nevada State Immunization Program Manager for final action. If the non-compliance appears intentional and the provider has received financial benefits from the behavior, then the situation would require immediate referral to an outside agency for investigation of suspected VFC fraud and abuse.

### **Failure to Comply with Nevada VFC Program Requirements**

On an annual basis, all VFC providers must re-enroll into the VFC Program. When providers enroll in the Nevada VFC Program, they agree to comply with all the requirements of the program. Lack of adherence to the Nevada VFC Program requirements by an enrolled provider could lead to fraud and/or abuse of the VFC Program. Failure to comply with VFC requirements is defined in the VFC Operations Guide as “not maintaining the federal requirements listed within the VFC Compliance Site Visit Questionnaire.” Failure to comply may be identified by Nevada State Immunization Program staff, the enrolled provider’s staff or a third party.

### **Consequences**

Any provider found guilty of fraud and/or abuse will be subject to:

- Dose-for-dose restitution of VFC/CHIP vaccines at private market cost;
- Termination from the Nevada VFC Program;
- Loss of Delegation of Authority; and/or
- Other consequences deemed appropriate by the Nevada Division of Health Care Financing and Policy.

**Appeals Process**

For decisions and findings rendered by the Nevada State Immunization Program a provider must follow guidance for the appeals process.

Per Nevada Revised Statutes (NRS) 439.200, 233B.130, and corresponding regulation in Nevada Administrative Code (NAC) 439.300 – 439.395, providers have the right to appeal decisions made by the Nevada State Immunization Program in regards to termination from the VFC Program or financial responsibility to replace vaccines.

If the Nevada State Immunization Program has made the decision to invoice a provider for loss of vaccine or terminate a provider from the VFC Program, then the provider will receive a notice of disciplinary action from the program. If the provider wishes to appeal the notice, then the provider has 10 days to submit an appeal to dispute the notice. If an appeal is not received within 10 days of notice, then the decision is considered final.

If an appeal is received within 10 days of the notice, then the Nevada State Division of Public and Behavioral Health Administrator will assign a hearing officer for a formal proceeding. A formal hearing will be set and a decision will be made by the hearing officer based on evidence provided by both the Nevada State Immunization Program and the provider. All decisions made by the hearing officer are final unless either party wishes to seek judicial review in a court of law.