

Nevada State Immunization Program



317 Program For Uninsured Adults and Perinatal Hepatitis B Prevention 2016 Protocols

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This document was created to help immunization providers follow all components of the 317 Program. If you have any additional questions or need clarification, please call (775) 684-5900 or email us at nviz@health.nv.gov.

Table of Contents

Contents

ENROLLMENT & ANNUAL RE-ENROLLMENT	1
REQUIREMENTS TO PARTICIPATE	2
ELIGIBILITY CRITERIA FOR 317 VACCINES.....	5
VACCINE REQUESTS & ACCOUNTABILITY	6
Form 1: Vaccine Request and Accountability Report.....	6
Form 2: Vaccine Lot Number Inventory Report	7
Digital Data Loggers for Continuous Temperature Monitoring.....	8
Form 4: Nevada State Immunization Program Temperature Log	8
Submitting Vaccine Requests.....	9
VACCINE BORROWING GUIDANCE.....	10
Seasonal Influenza Vaccine Borrowing	10
Borrowing to Prevent Loss Due To Expiration.....	11
VACCINE STORAGE & HANDLING	12
Unacceptable Vaccine Storage Units.....	12
Acceptable Vaccine Storage Units.....	13
Option 1: Standalone, Under-the-Counter or Full Size Refrigerator and Freezer Units	13
Option 2: Standalone, Laboratory Grade Refrigerator and Freezer Units	14
Temperature Monitoring Requirements	15
Digital Data Loggers for Continuous Temperature Monitoring	16
Biosafe Glycol-Encased Probes	16
Thermometer Calibration Requirements.....	17
Receiving Vaccine Shipments	17
Receiving Refrigerated Vaccine	17
Receiving Frozen Vaccine	18
Vaccine Storage Guidelines.....	19
Important Storage Instructions For Varivax®, ProQuad® And Zostavax®	19
Additional Requirements for Vaccine Storage & Handling	20
Vaccine Exposure to Improper Temperatures	21
Vaccine Restitution Policy.....	21
SETTING UP A NEW VACCINE STORAGE UNIT.....	22
RETURNING EXPIRED/WASTED VACCINES.....	23
The Following Items Should NEVER Be Returned to McKesson.....	23
What Should Be Returned to McKesson?	23

Receiving Return Labels via E-Mail	23
Steps for Returning Expired/Spoiled Vaccine via USPS Mail.....	24
EMERGENCY EVENT STORAGE & HANDLING	25
Short Term Power Outage	25
Long-Term Power Outage	25
Facilities WITH a backup generator	25
Facilities WITHOUT a backup generator.....	25
Mechanical Failure of Unit(s)	26
REQUEST FOR TERMINATION	27
VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)	28
VACCINE ADMINISTRATION	30
317 PROGRAM COMPLIANCE VISITS.....	31
CONSEQUENCES OF NON-COMPLIANCE.....	33
FRAUD & ABUSE POLICY	34
Purpose of the Fraud and Abuse Policy.....	34
Policy Components.....	35
Oversight Personnel.....	35
Examples of Fraud & Abuse.....	36
Wasted Vaccine Definitions	36
Wasted Vaccine Scenarios.....	37
1. Non-Preventable Vaccine Loss	37
2. Preventable Vaccine Loss.....	37
Course of Action for Vaccine Restitution	39
Who Will Investigate?	40
Detection and Monitoring of Fraud and Abuse	40
Failure to Comply with Nevada 317 Program Requirements	41
Appeals Process.....	41

ENROLLMENT & ANNUAL RE-ENROLLMENT

The Federal Section 317 Program provides funding for immunization operations and infrastructure necessary to implement a comprehensive immunization program at the federal, state, and local levels. This funding allows the Nevada State Immunization Program (NSIP) to purchase vaccines exclusively for uninsured and underinsured adults through a CDC contract. However, 317 funds can be used to vaccinate newborns with Hepatitis B vaccine, and can be used to vaccinate children and adults during pandemic exercises such as Point of Dispensing (POD) events.

317-funded vaccines are distributed, without charge, to provider sites that enroll in the Nevada State Immunization Program. Annually, each provider site must complete and return the completed, signed agreement forms to the Nevada State Immunization Program. The provider must retain a copy of the completed enrollment form for three (3) years per CDC requirements as well as for personal reference.

Re-Enrolling Providers Are Required To:

- Complete the “317 Program Agreement to Participate” annually; and
- Complete and have on site an: “Office Vaccine Management Plan” (OVMP)
 - A 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 “317 Program Agreement to Participate” initially and annually thereafter;
- Schedule an Enrollment Visit with NSIP staff; and
- Complete and have on site an: “Office Vaccine Management Plan” (OVMP)
 - A 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 SITES MUST ENROLL EACH SITE AS A SEPARATE PROVIDER WITH A UNIQUE NSIP 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 State Immunization Program, the Medical Director agrees to:

1. Document vaccinations in records as required by the National Childhood Vaccine Injury Act (42 US Code 300aa-25). This law applies to all physicians that administer vaccines regardless of the age of the individual or the source of funding for the vaccine: www.law.cornell.edu/uscode/html/uscode42/usc_sec_42_00000300--aa025-.html
 - a. Date of vaccine administration;
 - b. Vaccine manufacturer and lot number;
 - c. Name and address, and if appropriate, the title of the health care 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 (VIS) provided; and
 - ii. Date the VIS's were given to the parent/guardian or patient of record.
2. 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. Make such records available to the health authority and/or designee, if requested (per NAC 441A.750). This includes the collection of data for the AFIX Quality Improvement Assessments. The law may be viewed here: www.leg.state.nv.us/Division/Legal/LawLibrary/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.*
3. Adhere to the current Recommended Childhood and Adult 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), the

American College of Obstetricians and Gynecologists (ACOG), and the American College of Physicians (ACP); and

- a. Comply with Nevada State Immunization Program guidelines including notices regarding ACIP recommendations, vaccine shortages, restrictions on vaccine use, and use of new reporting forms;
4. Maintain all records related to the Nevada State Immunization 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, 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.
5. **Not impose a charge for the cost of the vaccine;**
6. For adults, not collect an administration fee higher than the maximum fee established by the U.S. Centers for Medicare and Medicaid (CMS) for the administration of publicly-supplied vaccine. **The maximum regional Medicare vaccine administration fee allowed in Nevada is \$21.34 per dose administered.**
7. **Not refuse to administer a publicly-supplied vaccine to an eligible, established patient due to an inability to pay the administration fee;**
8. Provide current Vaccine Information Statements (VISs) to the patient each time the patient receives an immunization, as required by federal law (42 US Code 300aa-25).
 - a. Note: VISs may be downloaded from <http://www.cdc.gov/vaccines/hcp/vis/index.html> or <http://www.immunize.org/vis/>.
9. 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 units at any time.** For program approved vaccine storage units, please refer to the program website under “Vaccine Storage”: [http://dphh.nv.gov/Programs/VFC/dta/Forms/Vaccines_for_Children_\(VFC\)_Program_-_Forms/](http://dphh.nv.gov/Programs/VFC/dta/Forms/Vaccines_for_Children_(VFC)_Program_-_Forms/)
 - 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/wasted 317-funded vaccines **within six (6) months of spoilage/expiration** using the form(s) and instructions provided by the NSIP.
10. Operate within the Nevada State Immunization Program in a manner intended to avoid fraud and abuse; (*see Fraud & Abuse section for details*)
 11. Participate in compliance site visits, unannounced site visits and immunization improvement activities in collaboration with program representatives as requested;
 12. Agree to replace vaccine purchased with any public funds (317, STATE, VFC, S-CHIP) that are deemed non-viable due to provider negligence or non-compliance on a dose-for-dose bases at private cost.
 13. 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: www.leg.state.nv.us/NRS/NRS-439.html#NRS439Sec265
 - b. NAC: <http://www.leg.state.nv.us/Register/2009Register/R094-09A.pdf>
 - c. NV WebIZ: http://dpbh.nv.gov/Programs/WebIZ/dta/Policies/WebIZ_-_Policies/
 14. Notify the NSIP in writing on facility letterhead to terminate participation in the Nevada State Immunization Program;
 15. Notify the Nevada State Immunization Program 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.

ELIGIBILITY CRITERIA FOR 317 VACCINES

317 ELIGIBILITY

317-funded vaccine can only be administered to uninsured and/or underinsured adults aged 19 years and older. Any children aged 0-18 years that meet these eligibility criteria are Vaccines for Children (VFC) Program eligible and should not receive 317-funded vaccine. However, 317 funds can be used to vaccinate newborns with Hepatitis B vaccine, and can be used to vaccinate children and adults during pandemic exercises such as Point of Dispensing (POD) events.

“Underinsured” adults are individuals who are covered by commercial (private) health insurance, but the insurance does not include vaccine coverage; the insurance covers only selected vaccines (individual is eligible for vaccines not covered); or the insurance caps vaccine coverage at a specific amount. Once that coverage amount is reached, the individual is categorized as underinsured. Verbal confirmation from the patient can be used to determine whether a patient or close contact of the newborn is underinsured.

The Nevada State Immunization Program uses 317-funded vaccine to expand immunization services to underserved populations and those at greater risk for under-vaccination and disease.

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 “NSIP 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.** Provider sites are required to submit vaccine inventory and accountability reports monthly indicating vaccine doses used and doses remaining in physical inventory. Enrolled provider sites must use and submit the most current reporting forms each month. For more assistance, please read [Tips for Monthly VFC Reporting](#).

Provider Staffing Requirements:

- 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 vaccine inventory reports each month.**
- **Providers must notify the NSIP when there are any changes in key vaccine management staff utilizing the [“Vaccine Coordinator Change Form.”](#) Fax the completed form to the NSIP at (775) 684-8338 whenever staffing changes occur.**

Completed Forms to be Submitted Each Month by Enrolled Provider:

Form 1: Vaccine Request and Accountability Report

- Complete all heading information:
 - 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);
 - Primary Vaccine Contact (PVC) name;
 - Direct Phone Line to PVC; and
 - 317 PIN
- Reporting period (always begins the first day of the month and ends the last day of the month);
- Denote “Beginning Inventory” (this is the beginning inventory on the 1st day of the month and the same as the “End of the Month Refrigerator Count” for the previous month). Do not include privately purchased vaccines on 317 reporting forms;
- Denote “Doses Received” (these are the vaccines received from the federal distributor McKesson during the month);
- Denote “Doses Transferred In” if applicable (these are vaccines received from another enrolled NSIP provider);
- Denote “Doses Administered” (how many doses of 317/state supplied vaccine the facility administered during the month);

- Denote “Doses Transferred Out” if applicable (these are vaccines the facility transferred to another enrolled NSIP provider);
- Denote “Doses Expired or Wasted” (these are 317/state vaccines that expired or were spoiled/wasted and must be returned to McKesson using the proper paperwork);
- Denote “Ending Inventory” (this is the calculation of adding column #1, plus column #2, plus column #3, minus column #4, minus column #5, minus column #6 and the result is the facility’s ending inventory for the reporting month);
- Denote “End of Month Refrigerator Count” (this is the physical count of 317/state doses in the vaccine storage unit at the end of the month). If the physical vaccine count does not match the “Ending Inventory,” then the accountability paperwork must be reviewed and corrected;
- **Denote the number of DOSES requested (not number of boxes); and**
- **Please note that any discrepancies between the ending inventory calculation and the physical vaccine dose count will be considered “unaccounted for” vaccine and marked as wasted in our records.**

Form 2: Vaccine Lot Number Inventory Report

- Complete all the heading information
 - 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);
 - Primary Vaccine Contact (PVC) name;
 - Direct Phone Line to PVC; and
 - 317 PIN
- Reporting period (always begins the first day of the month and ends the last day of the month);
- **You must report completely and accurately each lot number of publicly-supplied vaccine that you have on hand on the last day of the reporting month;**
- There is room to list up to three (3) lot numbers of any given vaccine on this form; if you have more than three (3) lots of any given vaccine, then you must use another Form 2 page;
- The dose amounts listed in the “Total Inventory” column of Form 2 must match the “End of Month Refrigerator Count” on Form 1.
- **Using the “NV WebIZ Vaccine Inventory Reconciliation Report”**
 - Type 3 NV WebIZ users may use this report in lieu of Form 2 to report vaccine lot numbers and inventory amounts:
 - Complete your inventory count in NV WebIZ;
 - Close your reconciliation;
 - Print these reports and submit with Form 1.
 - The dose amounts listed in the “Ending Balance” column of the reconciliation report must match the “End of Month Refrigerator Count” on Form 1.

Digital Data Loggers for Continuous Temperature Monitoring

The NSIP is providing 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 storage units that hold publicly-supplied vaccines.

- 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 temperature:
 - 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 24 hours, 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, then unplug the probe;
 - Place the LogTag recorder in the USB interface and download the information;
 - Send the data to 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.

Form 4: Nevada State Immunization Program Temperature Log

- Complete all the heading information:
 - NSIP 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);
 - Current Month and Year;
- Use a separate Temperature Log for each vaccine storage unit that holds 317/state supplied vaccine;
- Write in the time of the temperature check;

- Place an "X" in the box that corresponds with the current temperature and time of day (i.e., AM/PM) as well as the initials of the staff member recording the temperature;
 - FOR PRACTICES WITH MIN/MAX THERMOMETERS: During each morning reading place an "O" in the box that corresponds with the max/min temperature reached since the last reset, and then reset the max/min function for the next morning. There are many types of min/max thermometers on the market. If you need assistance resetting the min/max on your thermometer, then please contact the Vaccine Manager.
- Write on the bottom right side of the form the expiration or recalibration date(s) for each thermometer used to monitor a vaccine storage unit that contains 317/state supplied vaccine; and
- **Take immediate action if the temperature recorded is in the shaded zone as this represents an unacceptable temperature range and will damage the vaccines:**
 - **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, then unplug the probe;
 - Place the LogTag recorder in the USB interface and download the information;
 - Send the data to 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.

Submitting Vaccine Requests

- Each month fax to the Nevada State Immunization Program at (775) 684-8338:
 - Form 1: Vaccine Request and Accountability Report;
 - Form 2: Vaccine Lot Number Inventory Report **OR** the NV WebIZ Reconciliation Report; and
 - Form 4: Nevada State Immunization Program Temperature Log **OR** the LogTag temperature download if applicable.
- Incomplete reports will be returned for correction, which could result in the vaccine request being placed on hold.
- 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 are encouraged to maintain a 60 day supply of vaccine inventory.
- If it is necessary for the office to submit a second vaccine request (e.g., you forgot to ask for something, etc.), then you must write "Supplemental" on the margins of Form 1 when you send in the supplemental request. **If you fail to notify us that a request is supplemental to paperwork you have already submitted, then the supplemental request will be discarded.**

VACCINE BORROWING GUIDANCE

CDC’s expectation is that enrolled providers maintain adequate inventories of vaccine to administer to both privately insured and 317-eligible patients. 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 “Borrowing Report” must be specially requested from the Vaccine Manager and completed for all vaccine borrowed in either direction. The “Borrowing Report” must be completed when either:

- Privately-purchased vaccine is administered to a 317-eligible person, or
- 317 vaccine is administered to a privately-insured person or
- Vaccine exchange occurs to prevent expiration.

The 317 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 317/NSIP Compliance Visit. Questions regarding borrowing have been included in the Site Visit Questionnaire. Follow-up and/or corrective actions will be taken when excessive and/or inappropriate borrowing activities are noted by NSIP Quality Assurance Coordinators.

- **317/State vaccine cannot be used as a replacement system for a provider’s privately purchased vaccine inventory.**
- 317 vaccine supply must adequately meet the needs of your 317-eligible patients. Borrowing of 317 vaccine must not prevent a 317-eligible patient from receiving a needed vaccination because the 317 vaccine was administered to a non-eligible person.

Borrowing of vaccine between 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, 317 providers may use private-stock influenza vaccine to vaccinate eligible patients if 317 influenza vaccine is not yet available. Those private stock doses used on 317-eligible patients can later be replaced when 317 stock becomes available. **This one-directional borrowing exception is unique to seasonal influenza vaccine.**

Borrowing to Prevent Loss Due To Expiration

This two-way exchange can be used by a NSIP-enrolled provider with a patient population that is mostly 317-eligible. This means the provider has a small number of privately insured patients. **Privately purchased vaccine that is short-dated may be administered to a 317-eligible patient, and the dose replaced with a longer-dated 317 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 (317 vs. Private).

- If a provider borrows privately purchased vaccine to administer to a 317-eligible patient because no 317 vaccine is available or if 317 stock is borrowed, then the provider must document that borrowing and replacement activity on the NSIP Borrowing Report. This action is to ensure that the private-stock or 317-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 NSIP Borrowing Report.
- The completed borrowing form must be saved and submitted to the NSIP with the monthly paperwork for review and a copy of the invoice proving stock replenishment has occurred must be attached.

VACCINE STORAGE & 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;
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 an 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 publicly-supplied 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 freeze vaccines that require refrigeration, resulting in immediate and irreversible damage. “Dorm-style” units are defined as small refrigerator/freezer combination units with a single external door and an evaporator plate or cooling coil that forms a small freezer compartment within the unit or is pulled across the internal back wall of the unit.

- Manual defrost (or cyclic defrost) refrigerators have significant temperature variations, often freezing and damaging vaccines. These units often have exposed cooling plates, coils or vertical plates in 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/freezer unit that is over 10 years old.
- Small apartment size (4ft or below) units.

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.

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. Under-the-counter refrigerators and freezers are standalone units that allow for the separate storage of frozen and refrigerated vaccines. Standalone refrigeration units must also be self-defrosting and it is recommended that stand-alone freezer units be self-defrosting.



The benefits of using stand-alone 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.):

- <http://www.homedepot.com/> - search within appliances
- <http://www.lowes.com/> - search within appliances
- http://www.panasonic.com/business/healthcare/biomedical/vaccine/?_kk=5ce24da0-8f0d-46d9-a4fc-9e7e44de6fe5&_kt=16601245831
- <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, laboratories and hospitals. However, many manufacturers also produce an array of refrigerators and freezers that may meet your clinic’s vaccine storage needs. **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 317/State 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 of 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 one hour, 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 temperatures prior to storing public vaccine in any new unit. The NSIP will provide you with a loaner data logger for these 5 days.

Temperature Monitoring Requirements

317 Providers are required to purchase at least one back-up vaccine thermometer that has a current certificate of calibration and have it readily available. This back-up thermometer is to be used if the current temperature monitoring system fails or needs to be sent in for recalibration.

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. Document temperatures on the graph-style Form 4: Nevada State Immunization Program Temperature Log. **It is required that providers use a thermometer that includes a minimum/maximum function.** The minimum and maximum temperatures must be recorded on the Temperature Log each morning and reset to be checked the next morning of business. 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 317/State Providers with at least two (2) LogTag TRED30-7R 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).

If your office has not yet been provided a digital data logger from the NSIP, then the thermometer that is used to monitor 317/State vaccine storage units must:

- Have a digital display that can be read without opening the unit doors;
- Have a biosafe glycol-encased probe;
- Have current temperature and min/max temperature review functionality;
- Have an alarm (audible or visual) for out-of-range temperatures;
- Have an accuracy of +/- 1° F (0.5° C); and
- Have a low battery indicator.

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 Requirements

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 thermometers continues to be a requirement for 317 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 the designated backup;
- The box containing the vaccines must be physically handed to the office's primary vaccine coordinator or the 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;
 - 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 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 Nevada State Immunization Program 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 the designated backup;
- The box containing the vaccines must be physically handed to the office’s primary vaccine coordinator or the 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 NSIP 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 35°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® And Zostavax®

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. Any freezer, including frost-free, that has a separate sealed freezer door and reliably maintains a temperature between -58°F and +5°F (-50°C to - 15°C) is acceptable.
- 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 our 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 unit(s) 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 the 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: <http://www.cdc.gov/vaccines/recs/storage/default.htm>.

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.**

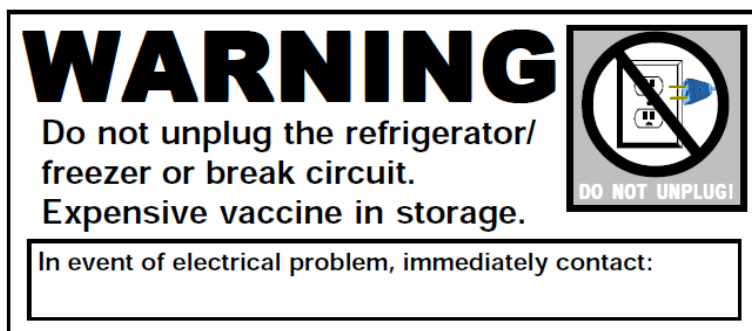
Vaccine Restitution Policy

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 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 eligible patients 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 simple steps to ensure success:

- Make arrangements in advance to temporarily store your vaccines in an appropriate, alternate storage unit with calibrated thermometers. 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 for vaccine storage;
- Monitor the temperature of the new unit twice daily for five (5) business days before placing vaccines within. Obtain approval from the Nevada State Immunization Program prior to transferring vaccines into the new unit;
- Your 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 them 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 (in 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 you will be storing vaccine. Identify where state supplied vaccine will be stored 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?

- 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 must be reported to the NSIP using the appropriate forms (Vaccine Request and Accountability Report).

Receiving Return Labels via E-Mail

- 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;
- Pack the non-viable VFC vaccines in any box for return to McKesson (do not add any private stock vaccines);
- Once the NSIP receives the pickup request, we will contact McKesson to send you mailing label(s) via e-mail. The e-mail will go to the person NSIP has on file as the Primary Vaccine Coordinator for your clinic. There are specific guidelines you must follow when receiving the label(s):
 - The e-mail address from which the label arrives is uoltsupport@usp.com and in the subject line it will say “UPS Shipping API”;
 - 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 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.
 - **One label will arrive per e-mail.** If you have two boxes of vaccine to return, then you will receive two separate e-mails with one label per e-mail;
 - If you ordered two labels but only use one, then you must put the unused shipping label in the box that is being shipped to McKesson;
 - You cannot photocopy or reprint the label to use at a later time on another shipment.
- After printing the return mailing labels, contact a UPS driver for pickup.

Steps for Returning Expired/Spoiled Vaccine via USPS Mail

- 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;
- Pack the non-viable VFC vaccines in any box for return to McKesson (do not add any private stock vaccines);
- Once the NSIP receives the pickup request, we will contact McKesson to send you mailing label(s) via normal mail (below is an example of the envelope for mailing labels that you will receive at your office); and
- After your office receives the mailing labels, contact a UPS driver for pickup.
- Keep a copy of all vaccine return paperwork for up to three (3) years.



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 317/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 water bottles in the bottom of the cooler boxes;
 - Place cardboard and then bubble wrap on top of the conditioned 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 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 ice packs and surrounded by additional ice packs.**
- **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
- 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;
 - Complete 5 business days of temperature monitoring on the affected or new unit; then
 - Fax the Temperature Log or transmit the Log Tag information to the Nevada State Immunization Program to obtain permission to return 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 “Temperature Log”

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. A copy of the VAERS report form can be found at <http://vaers.hhs.gov/esub/index>.

VAERS encourages the reporting of any significant adverse event that occurs after the administration of any vaccine licensed in the United States. You should report clinically significant adverse events, 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 specified time period after vaccination. A copy of the Reportable Events Table can be found at: [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 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;
- Visit the VAERS Website: <http://vaers.hhs.gov/index>;
- 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 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: 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/vac-admin.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: <http://www.cdc.gov/vaccines/schedules/index.html>

317 PROGRAM COMPLIANCE VISITS

All enrolled providers/clinics/facilities must be reviewed periodically as a condition of continued enrollment in the Nevada State Immunization Program. Compliance site visits are performed to evaluate provider compliance with Federal and State Protocols and address any deficiencies. NSIP staff or its representatives will contact the providers/clinics for scheduling of the compliance site visit. 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 formal request; delays in submitting a corrective action plan may result in temporary suspension of vaccine shipments.

AFIX = Assessment, Feedback, Incentives and eXchange; this is a quality improvement methodology created by the CDC that helps Immunization Programs to assess immunization coverage rates at the individual provider/clinic level. This methodology is well-established for providers serving children and is now being expanded to include assessment of adult population coverage rates. More information about the AFIX methodology can be found at <http://www.cdc.gov/vaccines/programs/afix/index.html>.

The NSIP may conduct one or more of the following types of 317 Compliance 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 more than one (1) year of inactive status, 2) moved into a new facility and/or 3) been delinquent in re-enrolling during the annual re-enrollment period.
- **317 Compliance Visit:** a formal review of compliance with federal and state standards for all 317-enrolled providers. Compliance visits are performed to evaluate provider compliance with federal and state policies/protocols and address any noted deficiencies. NSIP staff or designated representatives will contact the primary vaccine coordinator for scheduling of the 317 Compliance Visit. A CDC questionnaire is completed and a sample review may be conducted of adult (19 years +) patient charts to ensure 317 eligibility screening is occurring in required settings and situations. **The facility's Medical Director (the person who signed the 317 Agreement to Participate) must review compliance visit findings with the NSIP representative and sign the provided documentation.**
 - **317 Compliance Follow-Up Visit:** an assurance check of issues of concern that arose from the 317 Compliance Visit. This follow-up visit may occur within 1 to 3 months of the original compliance visit. The facility's Medical Director or senior physician, who signed the enrollment forms, or a designee, is strongly recommended to attend.

- **Adult AFIX Visit:** age-based assessments of the immunization rates of adult patients are completed utilizing immunization data exported from Nevada WebIZ. A questionnaire will also 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 or senior physician, 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 the results discussed.
- **317 Educational Visit:** a visit that occurs when enrolled provider sites undergo significant staff turnover or to assist in a specific area of improvement, such as a review of the ACIP schedule, vaccine inventory reporting 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.

CONSEQUENCES OF NON-COMPLIANCE

If an enrolled provider is found to be non-compliant with Federal or Nevada State Immunization Program (NSIP) 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 NSIP.**

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

Temporarily Inactive

- 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 log from the storage unit, proving that it is capable of sustaining appropriate storage temperatures.** Once reactivated, practices may need to provide weekly temperature logs to evaluators for up to two (2) months to ensure that vaccine storage problems have been resolved.
- Refusal to cooperate with NISP staff requests for compliance site visits, records, information or corrective action plans needed to satisfy program requirements.

Not Active (Inactive):

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

FRAUD & ABUSE POLICY

The NSIP Fraud & Abuse Policy provides guidance in the monitoring, detection and prevention of fraud and/or abuse of 317-funded 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 Section 317 Program provides funding for immunization operations and infrastructure necessary to implement a comprehensive immunization program at the federal, state, and local levels. This funding allows the Nevada State Immunization Program to purchase 317-funded vaccines for administration to:

- Uninsured and/or underinsured adults aged 19 years and older;
- Newborns under the “universal” Perinatal Hepatitis B Prevention Program, meaning the NSIP supplies the vaccine for both insured and VFC-eligible newborns; and
- Children and adults during approved pandemic exercises or emergency responses (e.g., Point of Dispensing (POD) events to combat influenza).

These vaccines are distributed, without charge, to provider sites that enroll in the Nevada State Immunization Program. The Nevada State Immunization Program uses 317-funded and other state-supplied vaccines to expand immunization services to underserved populations and populations at greater risk for under-vaccination and disease.

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 317 providers are required to be enrolled and to re-enroll in the Nevada 317 Program annually. The facility’s Medical Director or equivalent must sign the *317 Agreement to Participate* which specifies the Nevada 317 Program requirements (more information online: [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/)). Federal fraud and abuse laws apply to the entire 317 Program. In addition, providers who use Vaccines for Children (VFC), Nevada Check-Up or Nevada Cocooning Program vaccines are also subject to this Fraud and Abuse Policy.

This policy also exists to ensure that all 317-funded vaccines are only administered to eligible patients and that vaccine loss and wastage is minimized. 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;
- 317 compliance or education visits;
- Responses to high priority questions on the CDC Compliance Visit Questionnaire;

- Verbal or written reports from provider staff;
- Verbal or written reports 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 & Abuse Policy, the following definitions will be used:

Fraud: Fraud is 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: Abuse is defined in 42 CFR 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 & Abuse

1. Examples of actions that might constitute potential fraud and/or abuse:
 - a. Providing 317-funded vaccine to non-eligible patients. If the provider administers immunizations to fully insured adults, then that vaccine must be privately purchased (*except for Perinatal Hepatitis B Prevention Providers*).
 - b. Selling or otherwise misdirecting 317-funded vaccine;
 - c. Billing a patient or third party for 317-funded vaccine;
 - d. Charging more than the established maximum regional charge for administration of a 317-funded vaccine to an eligible patient;
 - e. Denying 317-eligible patients any 317-funded vaccine because of an inability to pay the administration fee;
 - f. Failing to implement 317 Program enrollment requirements;
 - g. Failing to screen and document patients' eligibility status at every applicable immunization visit;
 - h. Failing to maintain 317 Program records or to comply with any other program requirements;
 - i. Failing to fully account for 317-funded vaccine;
 - j. Failing to properly store and handle 317 vaccine resulting in excessive expired/spoiled vaccine;
 - k. Ordering 317-funded vaccine in quantities or patterns that do not match the provider's patient population or otherwise involve over-stocking; and
 - l. Wasting of 317-funded 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 Disease Control and Prevention (CDC) as appropriate.

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 eligible patients (i.e., uninsured adults aged 19 years +).

- 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 317-eligible patients.

- 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 NSIP Temperature Logs will be considered official when making vaccine viability decisions. Also, a thermometer’s 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 publicly-supplied vaccines in a manner that does not maintain the cold chain appropriately at all times.
- k. Shipping publicly-supplied vaccines 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.** Approved vaccine storage units can be found by checking our 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/)

Loss Due to Non-Compliance: 317-funded 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 317-eligible patients. 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, or
 - ii. Vaccine Lot Number Inventory Report
- b. Knowingly administering 317-funded vaccine to anyone not eligible, includes:
 - i. Administering 317-funded vaccine to non-eligible patients under 19 years of age;
 - ii. Administering 317-funded vaccine to fully insured adults (this includes adults covered under a high-deductible insurance plan);
 - iii. Administering 317-funded vaccine because the reimbursement rate of the adult's insurance coverage is low (**Medicaid and Medicare enrolled adult patients are considered insured**).
- c. Accepting reimbursement from insurance companies or patients for 317-funded vaccine as evidenced by:
 - i. Administering 317-funded vaccine to a patient and subsequently billing the patient's insurance for the cost of the vaccine, or
 - ii. Charging the patient for the cost of the vaccine.

****Providers are encouraged to have insurance policies in place to cover the cost of wasted 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 eligible patients only; 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 317 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 CDC for further guidance.

Criteria that will be considered during a fraud and/or 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 317-funded or State-supplied vaccine that is wasted/spoiled;
- The provider's willingness to replace dose for dose the lost 317-funded 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 317 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 review by the Nevada State Immunization Program and possible referral to the CDC's Immunization Services Division. The provider will be temporarily suspended by the Nevada State Immunization Program pending the outcome of a more in depth investigation.

If a 317-enrolled provider is not compliant with 317 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 317 Program or in the case of suspected fraud, referral for criminal prosecution or civil resolution.

Detection and Monitoring of Fraud and Abuse

All 317 Compliance Visits will include completion of Section I of CDC's Compliance Site Visit Questionnaire. All compliance visit reports submitted by field staff, including all documented cases of potential of 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 fraud and abuse of federally supplied vaccines.

Failure to Comply with Nevada 317 Program Requirements

On an annual basis, all 317 providers must re-enroll into the 317 Program. When providers enroll in the Nevada 317 Program, they agree to comply with all the requirements of the program. Lack of adherence to the Nevada 317 Program requirements by an enrolled provider could lead to fraud and/or abuse of the 317 Program. Failure to comply with 317 Program requirements is defined as “not maintaining the federal requirements listed within the CDC Compliance 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 317-funded vaccines at private market cost;
- Termination from the Nevada 317 Program; and/or
- Other consequences deemed appropriate by the Nevada Division of Public and Behavioral Health or the Centers for Disease Control and Prevention (CDC).

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 317 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 317 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.