

Nevada State Immunization Program



Hospital/OB Hepatitis B & Cocooning Programs Protocol July 2013

Developed by:

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This document was created to help immunization providers follow all components of the Hospital/OB Hepatitis B & Cocooning Programs. 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

ENROLLMENT.....	3
REQUIREMENTS TO PARTICIPATE.....	4
VACCINE REQUESTS & ACCOUNTABILITY.....	6
PROPER VACCINE STORAGE & HANDLING.....	9
SETTING UP A NEW VACCINE STORAGE UNIT.....	17
RETURNING EXPIRED/WASTED VACCINE.....	18
REQUEST FOR TERMINATION.....	19
VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS).....	20
SAFE INJECTION PRACTICES.....	21
VACCINE ADMINISTRATION.....	22
NSIP COMPLIANCE SITE VISITS.....	23
NON-COMPLIANCE WITH PROTOCOLS.....	24
FRAUD & ABUSE.....	25
VTRCKS.....	31

Enrollment

State supplied vaccines from the Nevada State Immunization Program (NSIP) are distributed, without charge, to hospital and obstetric provider sites that enroll in the NSIP's Hepatitis B & Cocooning Programs. Each provider site must complete and return the completed forms to the NSIP. The provider must retain a copy of the completed enrollment form for three (3) years per federal reporting requirements as well as for future reference.

Re-Enrolling Providers:

- Complete the "Hospital/OB Hepatitis B & Cocooning Programs Agreement to Participate;" and
- Complete and have on site an: "Office Vaccine Management Plan."
 - A template may be accessed at: http://health.nv.gov/Vaccine_VFCProgram.htm

New Providers:

- Complete the "Hospital/OB Hepatitis B & Cocooning Programs Agreement to Participate";
- Schedule an enrollment visit with state staff; and
- Complete and have on site an: "Office Vaccine Management Plan."
 - A template may be accessed at: http://health.nv.gov/Vaccine_VFCProgram.htm

NOTE: PRACTICES WITH MULTIPLE SITES MUST ENROLL EACH SITE AS A SEPARATE PROVIDER

Requirements to Participate

By enrolling in the Hepatitis B & Cocooning Programs, the provider site agrees to:

- 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
 - Date of vaccine administration;
 - Vaccine manufacturer and lot number;
 - Name and address, and if appropriate, the title of the health care provider administering the vaccine; and
 - Any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary of the Department of Health and Human Services.
- In addition the following must be recorded:
 - Publication date of the Vaccine Information Statement (VIS); and
 - Date the VIS was given to the parent, legal guardian, or individual of record.
- 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);
- Comply with NSIP guidelines including notices regarding ACIP recommendations, vaccine shortages, restrictions on vaccine use, and use of new reporting forms;
- Maintain all records related to the NSIP for a **minimum of three (3) years**, and make these records available to public health officials, upon request;
 - These records include (but are not limited to) Special Projects Form 1: "Vaccine Request and Accountability Report;" Special Projects Form 2: "Vaccine Lot Number Inventory Report;" Special Projects Form 3: "Nevada State Immunization Program Temperature Log;" "Vaccine Incident Report;" "VTrckS UPS Pickup Request for Expired/Spoiled Vaccine;" and the "packing list" received with each vaccine shipment.
- 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 "Quality Improvement Assessments."
www.leg.state.nv.us/Division/Legal/LawLibrary/NRS/NRS-629.html#NRS629Sec051
 - *#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.*
 - *#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.*

- 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).
 - Note: VISs may be downloaded from the Internet at:
<http://www.cdc.gov/vaccines/pubs/vis/> or <http://www.immunize.org/vis/>
- Not impose a charge for the cost of the vaccine;
- For adults 19 years and older, the administration fee should not exceed the regional Medicare vaccine administration fee of \$21.34 per dose administered;
- For children 18 years and younger, the administration fee should not exceed the regional Medicaid vaccine administration fee of \$22.57 per dose administered;
- Not refuse to administer a state supplied vaccine to any individual patient due to inability to pay the administration fee;
- Comply with the requirements for vaccine requests, vaccine accountability, storage and handling, and vaccine management;
- Participate in compliance site visits and immunization improvement activities in collaboration with program representatives as requested;
- Operate within the NSIP in a manner intended to avoid fraud and abuse; (*see Fraud & Abuse section for details*)
- Notify, in writing, the NSIP to terminate participation in the Hospital/OB Hepatitis B & Cocooning Programs;
- Utilize Nevada WebIZ, Nevada's immunization registry, to record all administered vaccinations for children and adults (per **NRS 439.265** and corresponding NAC);
 - NRS: www.leg.state.nv.us/NRS/NRS-439.html#NRS439Sec265
 - NAC: www.leg.state.nv.us/Register/indexes/2009_NAC_REGISTER_NUMERICAL.htm
 - WebIZ: http://health.nv.gov/Immunization_WebIZ_Policies_Forms.htm
- Maintain proper storage and handling standards for vaccines as outlined in CDC's Vaccine Storage & Handling toolkit: <http://www.cdc.gov/vaccines/recs/storage/toolkit/default.htm> which includes (but is not limited to):
 - Use of unexpired, calibrated thermometers that are calibrated to NIST or ASTM standards;
 - Use of program approved vaccine storage units (**no dorm-style units**):
 - http://health.nv.gov/Vaccine_VFCProgram.htm
 - http://health.nv.gov/PDFs/Vaccine/VaccineStorageUnit_ThingstoConsider.pdf
 - Document twice daily the vaccine storage unit temperature and include actions taken for temperatures outside the recommended range;
 - Receive approval from the NSIP before transporting state supplied vaccines;
 - Receive approval from the NSIP before moving state supplied vaccine into a newly purchased refrigerator; and
 - Transport vaccines following CDC standards
 - <http://www.eziz.org/assets/docs/IMM-983.pdf>
- Notify the NSIP of all changes immediately as they occur including, but not limited to:
 - Change of address;
 - Change of shipping hours;
 - Change of vaccine contact person;
 - Change of telephone number;
 - Change of fax number;
 - Change of e-mail address; and
 - Additions/deletions of physicians, PA's and nurse practitioners to the provider site.

Vaccine Requests & Accountability

The NSIP processes enrolled provider vaccine requests monthly per notification in each “Monthly Memo.” The amount of vaccine approved is calculated by the provider’s reported average monthly usage and most often a 60 day supply is allowed. Provider sites are required to submit vaccine inventory and accountability reports on a monthly basis indicating vaccine doses used and vaccine doses remaining in inventory. Enrolled provider sites must use and submit the most current reporting forms each month.

Completed Forms to be Submitted Each Month by Enrolled Provider:

Special Projects Form 1: Vaccine Request and Accountability Report

- Complete all the heading information:
 - Facility Name: official name of the facility (do not abbreviate nor use physician name unless that is the legal name of the practice)
 - Primary Vaccine Contact name
 - Direct Phone Line
 - 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 NSIP reporting forms;
- Denote “Doses Received” (these are the state supplied vaccines received from the distributor McKesson during the month);
- Denote “Doses Transferred In” (these are the state supplied vaccines received from another enrolled state provider);
- Denote “Doses Administered” (how many doses of state supplied vaccine the facility administered during the month);
- Denote “Doses Transferred Out” (these are the state vaccines the facility transferred to another enrolled state provider);
- Denote “Doses Expired or Wasted” (these are the state vaccines that expired, were spoiled or wasted and must be returned to the distributor McKesson using 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 facilities ending inventory for the month);
- Denote “End of Month Refrigerator Count” (this is the actual, physical count of doses in the vaccine storage unit at the end of the month); if the physical 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 vials or boxes);
- **If a discrepancy persists, a MEMO must be sent to the NSIP with an explanation.**

Special Projects Form 2: Vaccine Lot Number Inventory Report

- Complete all the heading information
 - Facility Name: official name of the facility (do not abbreviate nor use physician name unless that is the legal name of the practice)
 - Primary Vaccine Contact name
 - Direct Phone Line
 - 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 state supplied vaccine that you have on hand on the last day of the 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 a second Form 2 sheet;
- The amounts listed in the “Total Inventory” column of Form 2 must match the “End of Month Refrigerator Count” on Form 1: Vaccine Request and Accountability Report.

Special Projects Form 3: Nevada State Immunization Program Temperature Log

- Complete all the heading information:
 - PIN
 - Facility Name: official name of the facility (do not abbreviate nor use physician name unless that is the legal name of the practice)
 - Month and Year
- Use a separate state supplied “Temperature Log” for each vaccine storage unit that holds state supplied vaccine;
- Write in the time you are checking the temperature;
- Place an "X" in the box that corresponds with the current temperature and time of day (i.e.: AM/PM) and initials of staff recording the temperature;
- **FOR PRACTICES WITH MIN/MAX THERMOMETERS:** During each morning reading, you must place an “O” in the box that corresponds with the maximum and minimum temperature reached since the last reset, and then reset the max/min function for the next morning;
- 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 state supplied vaccine; and
- **Take immediate action if the temperature you record is in the shaded zone as this represents an unacceptable temperature range and will damage the vaccines:**
 - Move the vaccine to proper storage conditions as quickly as possible;
 - Begin completing the “Vaccine Incident Report;”
 - Call the vaccine manufacturer(s) to determine the viability of the vaccine;
 - Call the NSIP at (775) 684-5900;
 - Document the “Disposition” per manufacturer on the “Vaccine Incident Report;” and
 - Fax the completed report to the NSIP at (775) 684-8338.

Submitting Vaccine Requests:

- Each month fax to the NSIP at (775) 684-8338:
 - Form 1: Vaccine Request and Accountability Report;
 - Form 2: Vaccine Lot Number Inventory Report;
 - Form 3: The NSIP Temperature Log.
- Incomplete report forms 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.**

Proper Vaccine Storage & Handling

Vaccine Storage and Handling Guidelines:

Vaccine storage units must be selected carefully and used properly. Stand-alone refrigerators and freezers are the only units proven to consistently maintain required temperature ranges for safe vaccine storage. However, a combination refrigerator/freezer unit with two doors and two thermostat controls is acceptable for vaccine storage if only the refrigerator compartment is being used to store vaccine. Combination units do not maintain consistent in-range temperatures for the freezer compartment. The Centers for Disease Control and Prevention (CDC) recommends that any refrigerator or freezer being used for vaccine storage must:

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

General Requirements:

Vaccines that require storage temperatures between **35° and 46°F (2° and 8°C)** must be stored in the refrigerator compartment of a household- or commercial-style refrigeration unit. Vaccines that require storage temperatures of **5°F (-15°C) or colder** must be stored in a stand-alone freezer. Frozen vaccines include MMR-V (Proquad), Varivax and Zostavax. It is recommended that provider offices use separate units for vaccine storage, because stand-alone refrigerators and freezers maintain the required temperatures better than home-style combination units. Whatever type of storage unit is used, the refrigerator and freezer compartments must have separate external doors and separate thermostat controls. The storage unit must have enough room to store the year's largest vaccine order without crowding and without the vaccines touching the back or sides of the unit's interior. It is recommended to store full water bottles in the refrigerator and frozen ice packs in the freezer to help stabilize the temperature and assist in keeping the compartments cold in cases of a power outage.

Reminder: Vaccines are not to be stored in the door of a unit and not in the crisper drawers.

For more information on vaccine storage go to:
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:

The following types of units are accepted by the NSIP:

- Stand-alone refrigerator unit(s) – **recommended type**;
- Stand-alone freezer unit(s) – **recommended type**;
- Combination refrigerator/freezer unit with two doors and **two** thermostat controls;
- Combination refrigerator/freezer unit with two doors and **one** thermostat control, where only the refrigerator compartment is being used for vaccine storage;
- Commercial combination self-defrosting unit with two separate compressors, a thermostat control for each compartment, and no circulating air between the freezer and refrigerator compartments.

Option 1: Stand-Alone, Under-the-Counter Refrigerator and Freezer Units

Stand-alone, under-the-counter refrigerators and freezers are excellent choices for vaccine storage. Under-the-counter refrigerators and freezers are stand-alone units that allow for the separate storage of frozen and refrigerated vaccines. Stand-alone 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 stand-alone units. **Stand-alone 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, Amer Biotech Supply, GemRef):

- <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/Products/Refrigerators/Pharmacy-Vaccine-Basic.aspx>
- http://www.gemref.com/vaccine_refrigerators_freezers.php

Option 2: Home-Style, Combination Refrigerator/Freezer Units

These types of units are most often found in home and appliance stores. Higher-end models are sometimes referred to as “commercial-grade” and are most often used in the food service industry. While not ideal for vaccine storage, many immunization clinics use this type of unit due to its affordability. However, beginning in 2013 all Vaccines for Children providers in Nevada will be required to purchase a stand-alone freezer for storage of frozen vaccines. It is important for providers to choose an appropriate household model for storage of refrigerated vaccines. The unit must incorporate the characteristics detailed in the next paragraph.

Essential features for a combination unit:

- Refrigerator and freezer compartments must have separate external doors;
- Refrigerator and freezer compartments must each have a dedicated thermostat control;
- The shelves should be adjustable; and
- There should be enough room to store vaccine on the middle shelves (away from cool air vents).



Recommended features for a combination unit:

- Outside door locks (manufacturer installed only);
- Separate compressor units for each compartment;
- Automatic condensate removal, no drain lines;
- Forced air circulation;
- Door alarm if left open or ajar; and
- Battery back-up (in cases of power failure).

Risk of freezing vaccine – Never store freeze-sensitive vaccines near the cold air vent in the refrigerator compartment; cold air from the freezer will often blow down on the vaccine and freeze it, resulting in irreparable damage and wasted vaccine.

Single thermostat units – Home-style, combination refrigerators with a single thermostat are strongly discouraged. This type of unit is only acceptable if storing vaccine in refrigerator compartment only. A single thermostat makes it difficult to maintain recommended temperatures in both compartments. **If you are thinking of purchasing a new unit – do not purchase a single thermostat unit!!**

Option 3: Stand-Alone, Laboratory Grade Refrigerator and Freezer Units

Stand-alone, 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.**



Refrigerated Vaccines:

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.

Temperature Checks:

Refrigerator and freezer temperatures must be checked a minimum of twice daily on business days and documented on the graph-style Form 4: "Nevada State Immunization Program Temperature Log." It is strongly recommended that providers be using a thermometer that includes a minimum/maximum function. If the provider is using a min/max thermometer, then 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.

Reimbursement/Restitution:

The NSIP may request financial or dose-by-dose reimbursement from an enrolled provider for the value of vaccines wasted through negligent storage practices that do not meet program requirements.

Additional Requirements for Proper Vaccine Storage and Handling:

- The provider must have a current "Office Vaccine Management Plan." A template can be located on our website, http://health.nv.gov/Vaccine_VFCProgram.htm
- Food must not be stored in any refrigerator(s) or freezer(s) being used for vaccine storage;
- Vaccines must not be stored in the drawers, doors, or floor;
- Vaccines stored in the refrigerator must be far enough away from the air venting from the freezer compartment to avoid freezing the vaccines;
- Vaccines must be stacked with at least 2 inches of air space between the boxes and the side/back walls of the storage unit to allow air to circulate around the vaccine;
- 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 case of a 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 must be labeled for easy identification by office staff;
- Inventory must be rotated to ensure that the shortest dated vaccine is used first;
- State supplied vaccine with short expiration dates (expiring within 3 months) should be reported to the NSIP if the provider site does not anticipate using these vaccines before they expire. When notified that short-dated vaccines will not be used before expiration, 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 must be plugged directly 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 Vaccine Storage and Handling Website:
<http://www.cdc.gov/vaccines/recs/storage/default.htm>

Receiving Vaccine Shipments:

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 Vaccines:

- The staff person accepting the shipment must immediately notify the office's vaccine manager or the designated backup;
- The box containing the vaccines must be physically handed to the office's vaccine manager or the designated backup;
- 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 C FREEZE marker 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 NSIP;
- Check the condition of the vaccines;
- Compare the "packing list" to the actual contents of the shipment. Any discrepancies and/or damage must be reported immediately to the NSIP at (775) 684-5939.
 - If there are any discrepancies with the packing slip or concerns about the shipment, then immediately mark the vaccine and diluents as "DO NOT USE" and store them in proper conditions.
- Refrigerate the vaccines immediately and place those with the shortest expiration date in front to be administered first.

If Vaccines Have Been Exposed to Improper Temperatures at Provider's Location:

- 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;
- 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.
- 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.

Checklist for Safe Vaccine Handling and Storage

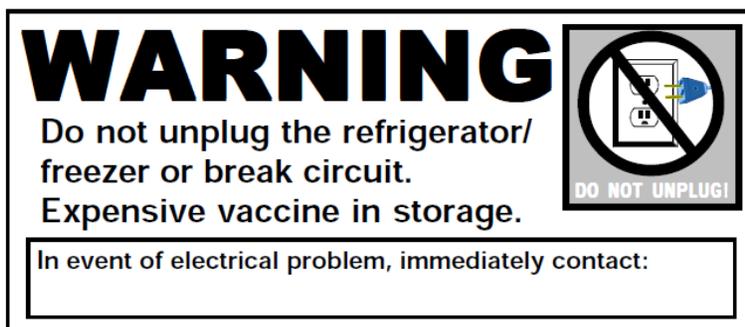
Here are the 20 most important things you can do to safeguard your vaccine supply. Are you doing them all?
Reviewing this list can help you improve your clinic's vaccine management practices.

YES	NO	
		1. We have a designated person in charge of the handling and storage of our vaccines.
		2. We have a back-up person in charge of the handling and storage of our vaccines.
		3. A vaccine inventory log is maintained that documents: <input type="checkbox"/> Vaccine name and number of doses received <input type="checkbox"/> Date the vaccine was received <input type="checkbox"/> Arrival condition of vaccine <input type="checkbox"/> Vaccine manufacturer and lot number <input type="checkbox"/> Vaccine expiration date.
		4. Our refrigerator for vaccines is either household-style or commercial-style, NOT dormitory-style. The freezer compartment has a separate exterior door and separate thermostat control. Alternatively, we use two storage units: a free-standing refrigerator and a separate, free-standing freezer.
		5. We do NOT store any food or drink in the refrigerator or freezer.
		6. We store vaccines in the middle of the refrigerator or freezer, and NOT in the door.
		7. We stock and rotate our vaccine supply so that the newest vaccine of each type (with the longest expiration date) is placed behind the vaccine with the shortest expiration date.
		8. We check vaccine expiration dates and we first use those that will expire soonest.
		9. We post a sign on the refrigerator door showing which vaccines should be stored in the refrigerator and which should be stored in the freezer.
		10. We always keep an unexpired calibrated thermometer in the refrigerator.
		11. The temperature in the refrigerator is maintained at 35°F to 46°F (2°C and 8°C).
		12. We keep extra containers of water in the refrigerator to help maintain cold temperatures.
		13. We always keep an unexpired, calibrated thermometer in the freezer.
		14. The temperature in the freezer is maintained at 5°F to -58°F (-15°C and -50°C).
		15. We keep ice packs and other ice-filled containers in the freezer to help maintain cold temperatures.
		16. We post a temperature log on the refrigerator door on which we record the refrigerator and freezer temperatures twice a day – first thing in the morning and at clinic closing time – and we know whom to call if the temperature goes out of range.
		17. We have a “Do Not Unplug” sign on the vaccine storage unit and/or next to the refrigerator’s electrical outlet.
		18. In the event of a refrigerator failure, we take the following steps: <input type="checkbox"/> We assure that the vaccines are placed in a location with adequate refrigeration <input type="checkbox"/> We mark exposed vaccines and separate them from undamaged vaccines <input type="checkbox"/> We note the time and the refrigerator or freezer temperature and contact the vaccine manufacturer or state health department to determine how to handle the affected vaccines <input type="checkbox"/> We follow the vaccine manufacturer’s or health department’s instructions as to whether the affected vaccines can be used, and, if so, we mark the vials with the revised expiration date provided by the manufacturer or health department.
		19. We have a detailed written policy for general and emergency vaccine management.
		20. If all above answers are “YES,” we are patting ourselves on the back. If not, we have assigned someone to implement needed changes!

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 NSIP 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 your 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 bottles) in the center of each unit/compartment 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 NIST or ASTM 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 an NDC printed on them; and
- Expired or compromised state supplied vaccine must be reported to the NSIP on Form 1: "Vaccine Request and Accountability Report" in column 4: "Doses Expired/Wasted."

Steps For Returning Expired/Spoiled Vaccines to McKesson:

- Fill out the "VtrckS UPS Pickup Request for Expired/Spoiled Vaccine" (for the non-viable vaccines that can be returned to McKesson) and fax the completed form to the NSIP at (775) 684-8338;
- Pack the non-viable vaccines in any box for return to McKesson;
- Put a copy of the "VtrckS UPS Pickup Request for Expired/Spoiled Vaccine" in the box;
- Keep a copy of all paperwork for up to three (3) years;
- The NSIP will schedule a UPS pickup and will notify you when the pick-up has been scheduled; and
- UPS will bring the shipping label when they pick up the box.

Request for Termination

An enrolled provider may request to become inactive 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 number,
 - expiration date,
 - number of doses; and
 - Current “Temperature Log.”

Upon receipt of this notification, the NSIP will deactivate 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 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: <http://vaers.hhs.gov/resources/vaersmaterialspublications>.
- 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 at: <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

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.



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

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

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

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

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

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

Vaccine Administration

How to Administer Vaccines:

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

- Immunization Action Coalition
 - www.immunize.org/handouts/administering-vaccines.asp
- Pink Book
 - Appendix D
 - www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/appdx-full-d.pdf
- EZ IZ Website
 - <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 can be found on the CDC website at:

<http://www.cdc.gov/vaccines/schedules/index.html>

NSIP Program Compliance Site Visits

All enrolled providers/clinics/facilities must be reviewed periodically as a condition of continued enrollment in the Nevada State Immunization Program:

Site visits are performed to evaluate provider compliance with the NSIP Protocols and address any deficiencies. Nevada State Immunization Program staff or its representatives will contact the providers/clinics for scheduling of the site visit and review. If requested by the reviewer, the provider may need to respond to areas of non-compliance with the NSIP with a written corrective action plan. This corrective action plan is normally due within two weeks of the request; delays may result in temporary suspension of vaccine shipments.

The NSIP staff may conduct one or more of the following types of visits:

- **The NSIP Enrollment or Re-Enrollment Visit:** An enrollment visit includes education about the NSIP guidelines, including proper vaccine storage and handling techniques. This visit is also an opportunity to establish a working relationship with the NSIP representative. A re-enrollment visit will be made to providers/clinics that have: 1) requested to be reactivated in the program, 2) moved into a new facility, and/or 3) been delinquent in re-enrolling during the annual re-enrollment process.
- **The NSIP Compliance Site Visit:** A formal review of compliance with 317 standards for all 317 enrolled providers. The site visit questionnaire is completed. A review is conducted of a sampling of patient charts for documentation of vaccine administration.
- **The NSIP Follow-Up Visit:** An assurance check of issues of concern that arose from the 317 Site Visit. This follow-up visit normally occurs within four (4) weeks of the original visit. The medical director or senior physician, who signed the enrollment forms, or a designee, is strongly recommended to attend.
- **Educational Visit:** A visit that occurs when provider sites undergo significant staff turnover or to assist in an area for improvement, such as a review of the ACIP schedule, or developing written vaccine storage and handling plans.

Non-Compliance with Protocols

If an enrolled provider is found to be non-compliant with The NSIP Protocols, 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. 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 program.

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 temperature checks of 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 months to ensure that vaccine storage problems have been resolved; or
- Refusal to cooperate with The NSIP requests for site visits, records, information, or corrective action plans needed to meet program requirements.

Not Active (Inactive):

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

Fraud & Abuse

The NSIP Fraud & Abuse Policy provides guidance in the monitoring and prevention of fraud and/or abuse of 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/downloads/vfc-op-guide/14-module-10.pdf>.

This policy applies to any fraud, abuse, and waste of state supplied vaccines involving Nevada State Immunization Program enrolled providers.

Purpose of the Fraud and Abuse Policy:

The purpose of the Nevada State Immunization Program's Fraud and Abuse 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 hospitals and obstetric providers are required to be enrolled provider must sign the Hospital/OB Hepatitis B & Cocooning Programs *Agreement to Participate* which specifies the NSIP requirements (available at http://health.nv.gov/Vaccine_VFCProgram.htm).

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

- Vaccine Request and Accountability Reports;
- NSIP in compliance site or NSIP education visits;
- Responses to high priority questions on the CDC Site Visit Questionnaire;
- Verbal or written reports from provider staff;
- Verbal or written complaints from patients;
- Inconsistencies in reporting of vaccines in the immunization registry (Nevada WebIZ); and
- Any other information provided to the NSIP that is deemed valid.

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

The NSIP's Fraud and Abuse policy is to ensure that vaccine loss and wastage is minimized.

For the purposes of this NSIP 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.

Fraud and Abuse 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 fraud and/or abuse is suspected then further examination will take place.

The NSIP 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.

The Accounting Assistant in collaboration with the Program Manager will serve as the primary person to: a) make the referral; and b) notify appropriate governmental agencies. The Vaccine Manager and Provider Quality Assurance Manager will serve as the first and second back-up referral positions.

Examples of Fraud & Abuse:

1. Examples of actions that might constitute potential fraud and/or abuse:
 - Selling or otherwise misdirecting state supplied vaccine;
 - Billing a patient or third party for state supplied vaccine;
 - Charging more than the established maximum regional charge for administration of a state supplied vaccine;
 - Denying an eligible patient state supplied vaccine because of inability to pay the administration fee;
 - Failing to implement provider enrollment requirements of the NSIP;
 - Failing to maintain records and comply with other requirements of the NSIP;
 - Failing to fully account for state supplied vaccine;
 - Failing to properly store and handle state supplied vaccine;
 - Ordering state supplied vaccine in quantities or patterns that do not match the provider's profile or otherwise involve over-ordering of state supplied vaccine; and
 - Wasting of state supplied vaccine due to negligence or non-compliance.
2. All cases of intentional fraud and/or abuse situations with NSIP Providers will be examined by the NSIP.
3. Based on 1 and 2 above, the CDC Non-Compliance Algorithm will be used to respond to specific allegations of fraud or abuse. The Algorithm can be viewed here:
<http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/nc-vfc-algorithm-fall08.pdf>

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 NSIP to have been wasted due to negligence or non-compliance on the part of the provider may be subject to financial recapture.

1. **Expired:** Vaccine that is past the 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

- a. The carrier (UPS, FedEx etc ...) does not deliver in a timely manner. Before making the determination that the vaccine is non-viable, the provider must first contact the NSIP and vaccine manufacturers
- b. An alert/alarm company does not notify the provider of a refrigerator or freezer malfunction
- c. Power is interrupted or discontinued due to a [storm, earthquake] 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 that is accidentally dropped or broken
- f. Vaccine that is drawn at the time of visit, but 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 financial restitution. Situations that occur which are not listed here will be considered on a case-by-case basis by the NSIP.

- a. Failure to establish and follow your "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 months before the vaccine's expiration date
- c. Pre-drawing vaccine before screening patients
- d. Leaving vaccine out of the refrigerator/freezer so it becomes non-viable
- e. Vaccine stored improperly (example - refrigerating vaccine that should have been frozen, or freezing vaccine that should have been refrigerated, or storing any vaccine in a dormitory-style refrigerator, even for day use)
- f. Leaving a refrigerator or freezer unplugged or an electrical breaker switched off. (A "Do not unplug the refrigerator/freezer or break circuit. Expensive vaccine in storage" sticker is required at each outlet and circuit breaker)
- g. Leaving a refrigerator or freezer door open or ajar, whether by staff, contractors, or guests
- h. Improper maintenance of recommended refrigerator and freezer temperatures resulting in vaccine spoilage, including prolonged storage of vaccines when out of range temperatures are recorded. (*Note: Temperatures recorded on temperature logs will be considered official in 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 your facility's office vaccine management plan in a power outage

- j. Transporting/shipping vaccine in a manner that does not maintain the cold chain appropriately at all times
- k. Failure to notify the NSIP when provider office hours change or the practice moves, resulting in vaccines being undeliverable and consequently spoiled
- l. Failure to maintain alarm devices properly
- m. Relying solely on electronic temperature monitoring and not manually checking and documenting temperatures twice daily
- n. Failure to be available to receive and properly store vaccine shipments per the established office hours
- o. Failure to use approved vaccine storage units. Dorm style units are no longer acceptable. Approved vaccine storage units can be found on our website:
http://health.nv.gov/Vaccine_VFCProgram.htm
- p. Failure to use digital unexpired, calibrated thermometers that are certified to NIST or ASTM standards.

Loss Due to Non-Compliance: State supplied 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. Examples include:

- a. Failure to document vaccine usage or inaccuracy in reporting vaccine usage or inventory received on:
 - I. Vaccine Request and Accountability form; or
 - II. Vaccine Lot Number Inventory Report form

- b. Accepting reimbursement from insurance companies or patients for state supplied vaccine as evidenced by:
 - I. Administering state supplied vaccine to a patient and subsequently billing the patient's insurance for the cost of the vaccine;
 - II. Charging the patient for the cost of the vaccine; and/or
 - III. Charging a Medicaid recipient any fee at all.

Non-Preventable Loss: No action will be taken for recapture if the NSIP determines the loss was not due to negligence or non-compliance on the part of the provider.

Loss Due to Negligence: Action may be taken by the NSIP to financially recapture vaccine loss if it is determined the loss was due to negligence on the part of the provider. The reimbursement will be determined by the current CDC Vaccine Price List:

<http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html>.

Loss that is determined by the NSIP to be negligence on the part of the provider may also be subject to financial recapture.

Loss Due to Non-Compliance: Action may be taken by the NSIP to financially recapture vaccine loss if it is determined the loss was due to non-compliance on the part of the provider. The reimbursement will be determined by the current CDC Vaccine Price List:

<http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html>.

Loss that is determined by the NSIP to be due to non-compliance on the part of the provider may also be subject to financial recapture.

Providers are encouraged to have insurance policies in place to cover the cost of wasted vaccine.

Course of Action for Financial Recapture of Wasted Vaccine:

The NSIP 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. Anything above this may be due to negligence or non-compliance and therefore the provider may be subject to pay the cost to replace the vaccine.

Who Will Investigate?

The Nevada State Immunization Program will examine all suspected fraud and/or abuse cases involving NSIP Providers. When the NSIP identifies suspicious activity via data or written or verbal reports, then the program will review the case. If the NSIP determines that further investigation is warranted or justified, then the case will be analyzed by program staff and a determination will be made.

Criteria that will be considered during a fraud and/or abuse investigation include:

- Past NSIP compliance by the provider up to the time of the incident;
- Proper vaccine storage compliance by the provider;
- How the incident was reported/identified;
- Length of time the situation was occurring;
- Inadvertent financial gain of the provider;
- The amount of money lost by the NSIP;
- The provider's willingness to replace dose for dose the lost state supplied vaccine with privately purchased vaccine; and
- The provider's willingness to participate in the education visit referral and post-education follow-up.

If an instance of fraud and/or abuse is determined to result from an excusable lack of knowledge or understanding of the NSIP Hospital/OB Hepatitis B & Cocooning Programs, 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 NSIP. The provider will be temporarily suspended by the NSIP pending the outcome of a more in-depth review.

If an enrolled provider is not compliant with NSIP 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 site 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 Hospital/OB Hepatitis B & Cocooning Programs or in the case of suspected fraud, referral for criminal prosecution or civil resolution.

Detection and Monitoring of Fraud and Abuse:

All provider site visits will include the examination and analysis of Section I of CDC's Site Visit Questionnaire. All site visit reports submitted by field staff, including all documented cases of potential of fraud and/or abuse, all site findings and site recommendations, will be reviewed by the Provider Quality Assurance Manager and, if appropriate, by the Vaccine Manager and then referred to the Program Manager.

Failure to Comply with Hospital/OB Hepatitis B & Cocooning Programs Requirements:

All NSIP providers must enroll into the Hospital/OB Hepatitis B & Cocooning Programs Program. This includes completing the Hospital/OB Hepatitis B & Cocooning Programs *Agreement to Participate* form. This form includes all mandatory components of the NSIP that providers must comply with.

Consequences:

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

- Replacement cost of vaccines;
- Termination from the Hospital/OB Hepatitis B & Cocooning Programs; and
- Other consequences deemed appropriate by the Nevada State Health Division.

Collections:

The NSIP has the right to invoice providers who are found guilty of fraud and/or abuse. Providers who have received an invoice for payment from the NSIP will have up to 60 days from invoice date to submit their payment. If payment is not received within 60 days of invoice date, then the case will be submitted to the Nevada State Controller's Office.

Appeals Process:

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

Per Nevada Revised Statutes (NRS) 439.200, 233B.130, and corresponding regulations Nevada Administrative Code (NAC) 439.300 – 439.395, providers have the right to appeal decisions made by the NSIP in regards to termination from the Hospital/OB Hepatitis B & Cocooning Programs or financial responsibility to replace vaccines.

If the NSIP has made the decision to invoice a provider for loss of vaccine or terminate a provider from the Hospital/OB Hepatitis B & Cocooning Programs, the provider will receive a notice of disciplinary action from the program. If the provider wishes to appeal the notice, the provider has 10 days to submit an appeal to dispute the notice. If an appeal is not received within 10 days of notice the decision is final.

If an appeal is received within 10 days of the notice, the Nevada State Health Division's 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 off of evidence provided by both the NSIP 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.

VTrckS

The Centers for Disease Control and Prevention's (CDC) new Vaccine Tracking System (VTrckS) will revolutionize the way the NSIP currently conducts vaccine management activities and will provide the program with new tools to help manage core business functions. The NSIP went live in VTrckS in November 2012.

The Vaccine Tracking System (VTrckS), is a critical component of CDC's Vaccine Management, and will be a centralized, integrated system designed to support tens of thousands of grantee-approved and enrolled health care providers and 64 grantees covering all states and territories of the United States. VTrckS will integrate the entire publicly-funded vaccine supply chain which includes vaccine ordering, vaccine forecasting, budget management, and contract management for CDC, grantees, and providers.

VTrckS Will:

- Improve CDC's and the NSIP's visibility and tracking capabilities from vaccine ordering through delivery;
- Reduce time and effort required to order vaccines;
- Provide the CDC with better allocation capabilities for handling routine vaccine needs, as well as respond to shortages and crises; and
- Facilitate easier enrollment and management of provider information from a central location.

In preparation for the upcoming implementation of VTrckS, the Provider must agree to the following in the "Agreement to Participate:"

- Should my staff, representative, or I access VTrckS, I agree to be bound by CDC's terms of use for interacting with the online ordering system. I further agree to be bound by any applicable federal laws, regulations or guidelines related to accessing a CDC system and ordering publically funded vaccines.
- In advance of any VTrckS access by my staff, representative or myself, I will identify each member of my staff or representative who is authorized to order vaccines on my behalf. In addition, I will maintain a record of each staff member who is authorized to order vaccines on my behalf. If changes occur, I will inform CDC within 24 hours of any change in status of current staff members or representatives who are no longer authorized to order vaccines, or the addition of any new staff authorized to order on my behalf. I certify that my identification is represented correctly on this provider enrollment form.