

STATE OF NEVADA

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Director



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Administrator

TRACEY D GREEN, MD  
State Health Officer

**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES  
HEALTH DIVISION**

Bureau of Child, Family & Community Wellness  
Immunization Program  
4150 Technology Way, Suite 210  
Carson City, Nevada 89706

December 13, 2010

Dear VFC Immunization Provider,

The Centers for Disease Control and Prevention (CDC) requires that you update your Nevada Immunization Program Enrollment annually. To meet the requirements for calendar year 2011, please complete and return the original "2011 Agreement to Participate" via mail by December 31, 2010.

**Print the attached "2011 Agreement to Participate"**

1. **Agreement:** Complete the form, make certain the Physician in Chief has initialed and signed the agreement in the designated areas, and list all providers with prescription writing privileges. **Include a copy of the medical license of all providers with prescription writing privileges as well as a copy of the Physician in Chief's medical license.**
2. **Profile Table:** Complete the table, using information based on patient load (hard data), and not estimates. Do not use billing data nor encounter data (as you are to count each child only once). For the 12-month period from January 1, 2010 through December 31, 2010, count the number of children who received vaccinations at your health facility by age group and by the specific category listed.
3. **Return:** **Return the completed, signed ORIGINAL "2011 Agreement to Participate" via mail along with copies of all the prescriber's medical license by December 31, 2010, to the address above. If the Nevada State Immunization Program does not receive your completed enrollment by this date, the program will be unable to process your February vaccine request. Agreements received by fax will not be processed.**

**New Program Requirements for 2011:**

- Providers must have an acceptable vaccine storage unit-refer to the attached Protocol
- Centers for Disease Control (CDC) will be instituting a new Vaccine Tracking System (VTrckS) which will allow: online provider ordering and automated approvals. This will require all new users to register with CDC's Secure Access Management Services (SAMS) system.
- Provider license numbers must be included for all prescribing providers at the site.

**ATTENTION: The original signed "2011 Agreement to Participate" must be returned to the Immunization Program via mail (faxes will NOT be accepted)**

For questions: contact Linda Platz, RN at 775-684-5913 or Vivian Lawrence at 775-684-4043.

# STATE OF NEVADA HEALTH DIVISION

*Immunization Program • 4150 Technology Way • Suite 210 • Carson City • Nevada • 89706*

## Federal Vaccines for Children (VFC) Program 2011 Agreement to Participate

Facility Name \_\_\_\_\_ (Assigned PIN Number) \_\_\_\_\_

Vaccine Shipping Contact: \_\_\_\_\_  
(Person responsible for the vaccines)

Physical/Shipping Address: \_\_\_\_\_  
Street Address (No Post Office Box) City State Zip Code

Mailing Address: \_\_\_\_\_  
(May be the same as the shipping) City State Zip Code

Direct Phone Number/Ext: \_\_\_\_\_ Back office number: \_\_\_\_\_

Fax Number: \_\_\_\_\_ E-mail address (please include-PRINT CLEARLY): \_\_\_\_\_

**IMPORTANT – Days and times the clinic is open to accept delivery of vaccines:**

DAY OF THE WEEK	OPEN TIME	LUNCH TIME	CLOSED TIME
MONDAY			
TUESDAY			
WEDNESDAY			
THURSDAY			
FRIDAY			

**Notify the Nevada State Immunization Program (in writing) of any changes, i.e. clinic closures or changes in hours of operation**

**To participate in the VFC program and receive federally supplied vaccine provided to my facility at no cost, I agree to the following conditions, on behalf of myself and all the practitioners, and others associated with the medical office, group practice, managed care organization, community/migrant/rural clinic, health department, or health delivery facility of which I am the physician-in-chief or equivalent:**

**Physician in Chief to initial all:**

- \_\_\_\_\_ 1. I will screen (and document) patients at all immunization encounters for VFC and state eligibility and administer *state supplied* vaccine only to children who are 18 years of age or younger who meet one or more of the following categories:
  - Are **federally**(VFC) vaccine eligible
    - Are enrolled in Medicaid (excluding Nevada Check Up)
    - Are an American Indian or Alaska Native
    - Have no health insurance
    - Are underinsured: Children who have commercial (private) health insurance but the coverage does not include vaccines, children whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only), or children whose insurance caps vaccine coverage at a certain amount (once that coverage amount is reached, these children are categorized as underinsured). Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC).
  - Are **state** vaccine eligible
    - Are enrolled in Nevada Check Up.
  
- \_\_\_\_\_ 2. I will adhere to the appropriate immunization schedule, dosage, and contraindications as established by the Advisory Committee on Immunization Practices (ACIP) unless: a) in my medical judgment, and in accordance with accepted medical practice, I deem such adherence to be medically inappropriate; or b) the particular requirement contradicts the law in my state pertaining to religious and medical exemptions (per NRS 432A, 392, 394).

- \_\_\_\_\_ 3. I will maintain all records related to the VFC program for a minimum of 3 years, and make these records available to public health officials, including the Nevada Department of Health and Human Services and/or Federal Department of Health and Human Services, upon request. These records include (but are not limited to) "Vaccine Request and Inventory and Accountability Report", "Eligibility Report of Doses Administered", "Nevada State Immunization Program Temperature Log", "Vaccine Incident Report", "UPS Pickup Request for Expired/Spoiled Vaccine", "VFC Vaccine Borrowing and Replacement Report", "Packing List" included with the vaccine shipment, and patient/parent/guardian responses on the Patient Eligibility Screening Record form.
- \_\_\_\_\_ 4. I will maintain clients' immunization records for a period specified by **NRS 629.051** "Health care records: Retention; disclosure to patients concerning destruction of records; exceptions; regulations, #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". If requested, I will make such records available to the Nevada Department of Health and Human Services and/or the Federal Department of Health and Human Services. I will make such records available to the health authority and/or designee, if requested (per NAC 441A.750). This includes the collection of data for quality improvement assessments.
- \_\_\_\_\_ 5. I will ensure that parent(s) or guardian(s) or patient(s) will receive the most current and appropriate Vaccine Information Statement(s) (VIS) prior to the administration of any vaccine and immunization records will be maintained in accordance with the National Childhood Vaccine Injury Act. Vaccine adverse events will be reported to the State Immunization Program and/or VAERS ([www.vaers.hhs.gov](http://www.vaers.hhs.gov)), along with any supporting documentation, in accordance with the National Childhood Vaccine Injury Compensation Act (NCVICA) which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System.
- \_\_\_\_\_ 6. I will not impose a charge for the cost of any VFC or other state supplied vaccine which is provided to me at no charge.
- \_\_\_\_\_ 7. I will not charge a vaccine administration fee to non-Medicaid VFC-eligible children that exceeds the administration fee cap of \$16.13 per vaccine dose. For Medicaid VFC-eligible children age 0 through 18 years, I will accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.
- \_\_\_\_\_ 8. I will not deny administration of a state supplied vaccine to a VFC eligible child because of the child's parent/guardian/individual of record's inability to pay the administration fee (per the Federal Registry Vol. 59 No. 190/Monday October 3, 1994).
- \_\_\_\_\_ 9. I will comply with the requirements for vaccine requests, vaccine accountability, and vaccine management per the "Nevada State Immunization Program, Vaccines for Children Program (VFC) Protocol January 2011".
- \_\_\_\_\_ 10. I will participate in site visits and immunization improvement activities in collaboration with program representatives as requested.
- \_\_\_\_\_ 11. I agree to operate within the Nevada State Immunization Program in a manner intended to avoid fraud and abuse.
- \_\_\_\_\_ 12. I will maintain proper storage and handling standards for vaccines as outlined in CDC's Vaccine Storage & Handling toolkit located at: <http://www.cdc.gov/vaccines/recs/storage/default.htm> and in addition as outlined in the following attachments:
- "Acceptable Vaccine Storage Units Required for the Storage of state supplied vaccines"
  - "Vaccine Storage Unit... Things to Consider"
  - "Nevada State Immunization Program, Vaccines for Children Program (VFC) Protocol January 2011"
- \_\_\_\_\_ 13. I will not move state supplied vaccines unless I have prior approval of the Nevada State Immunization Program.
- \_\_\_\_\_ 14. I (the facility) will be financially responsible for the replacement cost of any state-supplied vaccines that are wasted through my failure or the failure of my staff to properly store, handle, account for, or rotate the vaccine.
- \_\_\_\_\_ 15. I will not borrow VFC vaccine to administer to non-VFC eligible patient(s) unless a rare unplanned situation exists and only with prior approval from the Nevada State Immunization Program. In the event an unplanned situation occurs that requires borrowing of VFC vaccine to administer to a non-VFC eligible patient, I will be required to complete the "VFC Vaccine Borrowing Report" to document borrowed and replaced doses.

- \_\_\_\_\_ 16. I will record **all** vaccines that our office administers to children and adults into Nevada's immunization registry (Nevada WebIZ) unless the patient has chosen to not participate in the registry. This requirement is in reference to Nevada Revised Statute (NRS) 439.265 and corresponding Nevada Administrative Code (NAC) R094-09A. Providers with an undue hardship (i.e. no internet access) can comply by completing a WebIZ paper reporting form and mailing to the WebIZ Program. Please contact the WebIZ Help Desk for this form. View these laws at:  
 NRS: <http://www.leg.state.nv.us/NRS/NRS-439.html#NRS439Sec265>  
 NAC: [http://www.leg.state.nv.us/Register/indexes/2009\\_NAC\\_REGISTER\\_NUMERICAL.htm](http://www.leg.state.nv.us/Register/indexes/2009_NAC_REGISTER_NUMERICAL.htm)  
 WebIZ: [http://health.nv.gov/Immunization\\_WebIZ\\_Policies\\_Forms.htm](http://health.nv.gov/Immunization_WebIZ_Policies_Forms.htm)
- \_\_\_\_\_ 17. I understand that the Nevada State Immunization Program may terminate this agreement if it determines that the cost of the unused vaccines due to waste or expiration is in excess of 5 % of the total price of vaccines received in the past year.
- \_\_\_\_\_ 18. I understand that either party may cease participation in this agreement at any time, with written notification. I agree to properly return any unused state-supplied vaccine, if I choose to terminate this agreement.
- \_\_\_\_\_ 19. I will include with this enrollment agreement a copy of each prescribing physician/provider current medical license.
- \_\_\_\_\_ 20. I understand that the Centers for Disease Control (CDC) will be instituting a new Web based Vaccine Tracking System (VTrckS) which will allow online provider ordering. This will require all new users to register with CDC's Secure Access Management Services (SAMS) system.

Therefore I agree to the following:

- 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.

*I certify that I have read and agree to the requirements listed above pertaining to participation in the Nevada State Immunization Program, which includes the federal Vaccines for Children Program.*

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**Printed Name: Physician in Chief (authorized to prescribe vaccines under Nevada State Law)      Medical License #**

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**Signature: Physician in Chief (authorized to prescribe vaccines under Nevada State Law)      Date**

**LIST OF EACH PRESCRIBING PHYSICIAN AND A COPY OF MEDICAL LICENSE MUST BE ATTACHED**

- **Print** the names (in table below) of all providers who possess a medical license and prescription writing privileges.
  - Include **only those** who write prescriptions for the “state supplied” vaccines.
  - It is not necessary to include the names of all staff within this facility that may administer vaccine, but rather only those who possess a medical license or are authorized to write prescriptions.

**PLEASE ATTACH A COPY OF A CURRENT MEDICAL LICENSE FOR EACH PRESCRIBING PHYSICIAN (MD, DO, PA, NP):**

IS A COPY OF THE CURRENT MEDICAL LICENSE ATTACHED?	LAST NAME	FIRST NAME	MI	MEDICAID NUMBER

(attach another sheet if additional space is needed)

**PROVIDER PROFILE**

PIN: \_\_\_\_\_

**Instructions for completing the Profile:**

Vaccine Need: Please complete the table below in order for the Immunization/VFC Program to calculate your vaccine allowance. The information must be based on patient load (hard data) and not estimates. Please do not use billing data nor encounter data.

For the PAST 12-month period from January 1, 2010 through December 31, 2010 **count the number of children** who received vaccinations at your health facility, by age group and by the specific category listed below.

1. Every **child** who is 0 through 18 years of age and who is **immunized with state supplied or private vaccines** during the period should be entered according to age and insurance status.
2. Do not double count children. **This is a calculation of all your child visits per the year, NOT the number of shots given.**
3. Count each child in one category only. If a child is American Indian or Alaska Native, count that child **ONLY** in the American Indian category. Do not count American Indian or Alaska Native in any other category.
4. **Submit this completed form to the Nevada State Immunization Program along with the “Agreement to Participate”.**

**RETURN THIS COMPLETED FORM WITH WHOLE NUMBERS-NOT TIC MARKS**

STATUS	< 1 Year Old	1 – 6 Years	7 – 18 Years	TOTALS
Enrolled in Medicaid				
No health insurance				
American Indian/Alaska Native				
Underinsured Child has insurance, but the insurance does not pay for the vaccine Note: the child is not considered underinsured if the insurance pays only partially or if the deductible has not been met				
Has private health insurance				
Nevada Check Up				
<b>Total number of children who will receive immunizations in the year 2011</b>	(total of column)	(total of column)	(total of column)	(total of column)

# **Nevada State Immunization Program**



## **Vaccines for Children Program (VFC) Protocol January 2011**

**Developed by:**

**Bureau of Child, Family and Community Wellness  
Immunization Program  
Nevada State Health Division  
Department of Health and Human Services**

**Brian Sandoval**  
Governor

**Michael J. Willden**  
Director

**Richard Whitley, MS**  
Administrator

**Tracey D Green, MD**  
State Health Officer

## **Enrollment/Annual Re-Enrollment**

The Vaccines for Children (VFC) Program is a federal entitlement program (CFDA #93.268) which allows immunization projects across the nation to purchase vaccines for VFC eligible children through a CDC contract. These vaccines are distributed, without charge, to provider sites that enroll in the VFC Program. Annually, each provider site must complete the forms listed below and return the completed forms to the Nevada State Immunization Program. The provider should retain a copy of the completed enrollment form for three (3) years per CDC requirements as well as for future reference.

### **Re-Enrollment Providers:**

- Complete the “Federal Vaccines for Children (VFC) Program Agreement to Participate” annually;
- Complete the Provider Profile Form annually;
- Provide copies of licenses of all prescribing providers; and
- Complete and have on site an: “Office Vaccine Management Plan”. A template may be accessed at: [http://health.nv.gov/Vaccine\\_VFCProgram.htm](http://health.nv.gov/Vaccine_VFCProgram.htm)

### **New Provider Enrollees:**

- Complete the “Federal Vaccines for Children (VFC) Program Agreement to Participate” initially and annually;
- Complete the Provider Profile Form (not necessary if new practice);
- Provide copies of licenses of all prescribing providers;
- Schedule an orientation 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](http://health.nv.gov/Vaccine_VFCProgram.htm)

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

## **Requirements to Participate in the Nevada State Immunization Program**

**By enrolling in the Nevada State Immunization Program, 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):  
[http://www.law.cornell.edu/uscode/html/uscode42/usc\\_sec\\_42\\_00000300--aa025-.html](http://www.law.cornell.edu/uscode/html/uscode42/usc_sec_42_00000300--aa025-.html)
  - the date of administration of the vaccine;
  - the vaccine manufacturer and lot number of the vaccine;
  - the 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.



- In addition the following must be recorded:
  - publication date of VIS; and
  - date VIS given to parent or legal guardian.
- Screen and document the VFC eligibility for each child on each visit prior to immunization;
- Adhere to the current Recommended Childhood Immunization Schedule as approved by the Advisory Committee on Immunization Practices (ACIP), American Academy of Pediatrics (AAP) and American Academy of Family Practice Physicians (AAFP);
- Comply with Nevada State Immunization Program guidelines including notices regarding ACIP recommendations, vaccine shortages, restrictions on vaccine use, and use of new forms;
- Maintain all records related to the VFC program for a **minimum of three (3) years**, and make these records available to public health officials, upon request;
  - These records include (but not limited to) “Vaccine Request and Inventory and Accountability Report” “Eligibility Report of Doses Administered”, “Nevada State Immunization Program Temperature Log” for vaccine storage units, “Vaccine Incident Report”, “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** <http://www.leg.state.nv.us/Division/Legal/LawLibrary/NRS/NRS-629.html#NRS629Sec051>
  - #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.”;
  - 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.”
- Provide current Vaccine Information Statements (VISs) to the parents or legal representative of any child each time the child 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/>;
- Not impose a charge for the cost of the vaccine;
- Not collect an administration fee higher than the maximum fee established by the U.S. Centers for Medicare and Medicaid Services for the administration of publicly procured vaccine. **The maximum fee allowable per administration in Nevada is \$16.13;**
- For Medicaid VFC-eligible children age 0 through 18 years, provider will accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans;
- Not refuse to administer a federally procured vaccine to a child (established patient) due to the inability of the child's parent, guardian, or individual of record to pay the administration fee;

- Comply with the requirements for vaccine requests, vaccine accountability, and vaccine management per the “Nevada State Immunization Program Vaccines for Children Program (VFC) Protocol”;
- Participate in site visits and immunization improvement activities in collaboration with program representatives as requested;
- Operate within the Nevada State Immunization Program in a manner intended to avoid fraud and abuse;
- Utilize Nevada WebIZ, Nevada’s Immunization Information System, to record all administered vaccinations for children and adults as of July 1, 2009 (per **NRS 439.265** and corresponding NAC);
  - NRS: <http://www.leg.state.nv.us/NRS/NRS-439.html#NRS439Sec265>
  - NAC: [http://www.leg.state.nv.us/Register/indexes/2009\\_NAC\\_REGISTER\\_NUMERICAL.htm](http://www.leg.state.nv.us/Register/indexes/2009_NAC_REGISTER_NUMERICAL.htm)
  - WebIZ: [http://health.nv.gov/Immunization\\_WebIZ\\_Policies\\_Forms.htm](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/default.htm> which includes (but not limited to):
  - use of certified calibrated thermometers in vaccine storage units;
    - use of program approved vaccine storage units (no dorm style refrigerators) refer to:
      - **Vaccine Storage Unit...Things to Consider** and
      - **Nevada State Health Division Technical Bulletin dated August 18, 2010 – “Acceptable Vaccine Storage Units Required for the storage of state supplied vaccines”**;
  - document twice daily the vaccine storage unit temperature and include actions taken for temperatures outside the recommended range;
  - receive approval of the Nevada State Immunization Program before transporting state supplied vaccines; and
  - transporting vaccines using CDC handling standards.
- Notify the Nevada State Immunization Program of all changes immediately as they occur including, (but not limited to), the following:
  - change of address;
  - change of vaccine contact person;
  - change of telephone number;
  - change of fax number;
  - change of e-mail address;
  - change in number of VFC eligible children; and
  - additions/deletions of physicians, PA’s and nurse practitioners to the provider site.

#### **Eligibility Criteria Categories for VFC Vaccines:**

- Persons 18 years of age or younger who are either: 1) enrolled in or eligible for Medicaid, 2) are American Indian or Alaskan Native, 3) have no health insurance, or 4) are underinsured;
  - "Underinsured" children, defined as those children whose insurance does not cover immunizations, can receive state supplied vaccines ONLY at Federally Qualified Health Centers (FQHCs) and Rural Health Centers (RHCs), both of which are federally funded through the U. S. Centers for Medicare and Medicaid Services;

- Note: If the provider has chosen the “Delegation of Authority” and has a signed a Letter of Agreement from the Health Division; that provider may vaccinate the “Underinsured” with state supplied vaccine
- A child must be screened for eligibility on each visit prior to immunization. This screening must be documented in one of the following ways:
  - By completing a Patient Eligibility Screening Record. The screening record must be maintained for at least three (3) years and is bound by the privacy protection of Federal Medicaid law;
  - By making a copy of the child's Medicaid card. The copy must be dated and initialed as current at each immunization visit and filed in the patient's record. This documentation must be maintained for at least three (3) years and is bound by the privacy protection of Federal Medicaid law;
  - By completing the Comprehensive Certification Form and submitting it to the Nevada State Immunization Program, if a provider or clinic treats only children on Medicaid. This form eliminates the need to screen VFC program participants individually for eligibility and is available upon request from the Nevada State Immunization Program; and
  - By completing the Comprehensive Certification Form and submitting it to the Nevada State Immunization Program, if a provider or clinic treats only Native American or Alaskan Native children. This form eliminates the need to screen VFC program participants individually for eligibility and is available upon request from the Nevada State Immunization Program office.

## **VTrckS**

The Centers for Disease Control and Prevention’s (CDC) new Vaccine Tracking System (VTrckS) will revolutionize the way the Nevada State Immunization Program currently conducts vaccine management activities and will provide the program with new tools to help the program manage core business functions.

CDC will launch the “Vaccine Tracking System” (VTrckS) in Nevada during 2011. 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 Nevada State Immunization Program visibility and tracking capabilities from vaccine ordering through delivery;
- Reduce time and effort required to order vaccines;
- Enable automated order approvals and order processing;
- Provide 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 in 2011, 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.

## **Vaccine Requests and Accountability**

The Nevada State Immunization Program 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:**

- Vaccine Request and Inventory and Accountability Report
  - Complete all the heading information:
    - Facility Name: (official) name of facility (do not abbreviate nor use physician name unless that is the legal name of the practice)
    - Contact name
    - Direct Phone Line
    - PIN Number
  - Reporting period (always begins the first day of the month and ends the last day of the month);
  - Denote "Beginning Inventory", (this would be the beginning inventory on the 1<sup>st</sup> day of the month and the same as the "End of the Month Refrigerator Count" for the previous month) (do not include private purchase vaccines);
  - Denote "Doses Received", these would be the state supplied vaccines received from the distributor McKesson during the month;
  - Denote "Doses Transferred In", these would be the state supplied vaccines from another enrolled state provider;
  - Denote "Doses Administered", these would from the "Totals" from the "Eligibility Report of Doses Administered";
  - Denote "Doses Transferred Out", these would be state vaccines transferred to another enrolled state provider;
  - Denote "Doses Expired or Wasted", these would be state vaccines expired, spoiled, or wasted (must be returned to the distributor with proper paperwork);

- Denote “Ending Inventory”, this would be calculated by adding column #1 plus column #2, plus column #3, minus column #4, minus column #5, minus column #6 and the result is the inventory per your accountability paperwork;
  - Denote “End of Month Refrigerator Count, this would be the actual count of doses in the vaccine storage unit (if it does not match the “Ending Inventory” then the accountability paperwork must be reviewed and corrected);
  - **If a discrepancy persists, a MEMO must be sent to the Immunization Program with an explanation;**
  - Denote the number of doses requested (not number of vials or boxes); and
  - Denote the PREFERRED VACCINE CHOICE by checking the corresponding box (vaccine requests lacking choices will not be processed).
- **Eligibility Report of Doses Administered**
    - Complete all the heading information:
      - Facility Name: (official) name of facility (do not abbreviate nor use physician name unless that is the legal name of the practice)
      - Contact name
      - Direct Phone Line
      - PIN Number
      - Reporting period (always begins the first day of the month and ends the last day of the month)
    - Make a blank copy of this report to use as a worksheet. As each dose is drawn, make a tic mark for that dose in the corresponding cell and category;
      - Document similar vaccine doses from different manufacturers into one cell/category/row. There is no need to document all the different doses/manufacturers separately. In addition, there is no need to add any rows to the form;
    - Use the “Not VFC Eligible and Non-Nevada Check Up” only for birth Hep B administered at hospitals, Tdap cocooning projects, and Twinrix;
    - Add the tic marks on the worksheet at the end of the month and place the whole number in each corresponding cell on a blank form for faxing to the Nevada State Immunization Program; and
    - Do not fax to the Nevada State Immunization Program with tic marks.
- **Temperature Log**
    - Complete all the heading information:
      - PIN Number
      - Facility Name: (official) name of 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;
    - Place an "X" in the box that corresponds with the current temperature and time of day (i.e.: AM/PM);
    - Do not cross off holidays or weekends; and
    - **Take immediate action if the temperatures are in the shaded zones as they represent unacceptable temperature ranges and will damage the vaccines**
      - Move the vaccine to proper conditions as quickly as possible;
      - Document on the temperature log action taken;

- Document the action taken on the “Vaccine Incident Report”;
- Call the Nevada State Immunization Program at 775-684-5900;
- Call the vaccine manufacturers(s) to determine the viability of the vaccine(s);
- Document the “Disposition” per manufacturer on the “Vaccine Incident Report”; and
- Fax the completed form to the Nevada State Immunization Program to (775) 684-8338.

### **Submitting Vaccine Requests:**

- Fax the “Vaccine Request and Inventory and Accountability Report” along with “Eligibility Report of Doses Administered” and the Temperature Log to the Nevada State Immunization Program at (775) 684-8338.
- Fax completed forms as a package during the time period designated in each “Monthly Memo” for each month:
  - Vaccine Request and Inventory and Accountability Report;
  - Eligibility Report of Doses Administered; and
  - Nevada State Immunization Program 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 in an “Outbreak” situation.
- Vaccines should arrive within ten (10) days after the confirmation is received via fax.

## **Proper Vaccine Storage and Handling**

Proper storage and handling is required to ensure that vaccines remain potent to effectively protect children from disease. The thermo stability of individual vaccines varies; some vaccines are damaged if kept too cold, while others are damaged only if they are too warm. For example, most refrigerated vaccines, **excluding MMR**, can be compromised rapidly by exposure to freezing temperatures of 0°C or lower (32°F or lower).

### **Minimum requirements for proper vaccine storage and handling:**

- APPROPRIATE appliance units for storage of vaccines;
- Strongly recommended: commercial or laboratory-quality free-standing or combined refrigerator/freezer units with separate compressors for the freezer and refrigerator and no circulating air between the refrigerator and freezer;
- **Household combined refrigerator/freezer unit with separate outside insulated doors and separate thermostats controlling the freezer and refrigerator;**
- A counter-high free-standing freezer is an acceptable size and should maintain at least: -20°C temperatures; and
- Acceptable, but not recommended for purchase: Single thermostat regular size household combined refrigerator/freezer unit, when ONLY one compartment of the unit is used for vaccine storage.

### **NOT ACCEPTABLE (high risk of vaccine wastage):**

- DORM STYLE UNITS NOT ACCEPTABLE

- **If your facility has any of the following unacceptable units, corrections must be made within 30 days. Call 775-684-5913 for technical assistance**
  - Household combined refrigerator/freezer unit with only one thermostat controlling both sections and vaccines stored in both sections.
  - Any small, dormitory style refrigerator unit (with or without a freezer box) for storage of refrigerated or frozen vaccines.
  - Counter high refrigerator only household grades.
  - Four foot high combinations.
  - Refrigerators with freezer units on the inside of the refrigerator (e.g., dormitory style refrigerator/freezer units) are NOT acceptable for the storage of Varicella vaccine. The freezer must have its own outside door and its own thermostat or be a free-standing unit.
  - Any household refrigerator unit over 10 years old

**Program enrollees still using unacceptable units are strongly encouraged to replace such units as soon as possible with recommended units. No provider is permitted to store frozen state supplied vaccine in a freezer box within a dormitory style refrigerator.**

**Certified calibrated thermometers must be used to monitor the temperatures in vaccine storage units:**

- All thermometers are calibrated during manufacturing; however, certified calibrated thermometers undergo a second individual calibration against a reference standard and a certificate is issued with the instrument when purchased. Certified calibrated thermometers can be purchased from most scientific supply companies and are usually certified by the National Institute of Standards and Technology (NIST) or the American Society for Testing and Materials (ASTM). Certified calibrated thermometers are available as bio-safe liquid, continuous graph, and minimum-maximum instruments. The duration of certification varies by manufacturer, up to lifetime certification; recalibration is necessary once the certificate expires. Certificates must be saved and stored with records related to the immunization program.

**Refrigerated vaccines:**

- The temperature of all refrigerated vaccine must stay between 2° and 8° C (35° and 46°F). The vaccines are shipped with ice packs and bubble wrap to protect the vaccines from contact with the frozen ice packs.

**Frozen vaccines:**

- Frozen vaccines are shipped by the manufacturer directly to the provider site with dry ice. The temperature of all frozen vaccines must stay at or below -15°C (5°F) until use.

**Temperature checks:**

- Both refrigerator and freezer temperatures must be checked twice daily on business days and documented on the graph-style Nevada State Immunization Program temperature log provided by the program. The temperature logs are to be kept on file by the provider for at least three (3) years.

**Reimbursement:**

- The Nevada State Immunization Program may request reimbursement from an enrolled provider for the dollar 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”;
- Food must not be stored in refrigerators or freezers used for vaccine storage;
- Vaccines must not be stored in the drawers, doors, or floor;
- Vaccines stored in the refrigerator unit 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 stacks and side/back of the unit to allow air to circulate around the vaccines;
- Vaccine must be stored in their original boxes until use;
- Bottles of water should be stored in the lowest compartment of the refrigerator and extra ice packs in the freezer to help maintain temperatures in case of a power outage. No ice packs on the doors of the freezer or refrigerator;
- State supplied vaccine may be stored in the same unit as privately purchased vaccine and must be labeled for easy identification by staff members;
- Inventory must be rotated to ensure that the shortest dated vaccine is used first;
- State supplied vaccine with short expiration dates (expiring within 8 weeks) should be reported to the Nevada State Immunization Program, if the provider site does not anticipate using these short-dated vaccines before they expire. When notified that short-dated vaccines will not be used before expiration, the Nevada State Immunization Program will make every effort to have the vaccines transferred to another enrolled provider for use;
- Post "Do Not Disconnect" signs next to the refrigerator's electrical outlet and on the breaker switch that supplies power to the vaccine storage unit;
- The vaccine storage unit must be plugged directly into the electrical outlet (**surge protectors are not to be used**); and
- Providers are strongly urged to have all staff responsible for vaccine storage, monitoring, or handling review and apply the practices for proper vaccine storage and handling found in the CDC Vaccine Storage and Handling Toolkit (provided online at <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.

**Refrigerated vaccines:**

- **The staff person accepting the shipment must immediately notify the vaccine manager or the designated backup;**



- The box containing the vaccines must be physically handed to the vaccine manager or the designated backup;
- Immediately upon shipment receipt, remove both temperature monitors included in the shipment ; and
  - The two temperature monitors included in the shipment:
    - 3M MonitorMark to determine if the shipment may have been subjected to warmer temperatures and
    - TransTracker C 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, contact McKesson at 877-TEMP123 (877-836-7123) within 2 hours and notify the State Immunization Program**
  - 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 Nevada State Immunization Program at (775) 684-5939
  - Refrigerate vaccines immediately placing the ones with the shortest expiration date in front to be used first

#### **Frozen vaccines:**

- **The staff person accepting the shipment must immediately notify the vaccine manager or the designated backup;**
- The box containing the vaccines must be physically handed to the vaccine manager or the designated backup;
- Immediately upon shipment receipt check the condition of the vaccines; and
- 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; and

#### **IMPORTANT STORAGE INSTRUCTIONS**

##### **ABOUT VARIVAX® (VARICELLA Virus Vaccine Live):**

- VARIVAX® is temperature sensitive and is shipped on dry ice to maintain potency during transport.
- VARIVAX™ is packed with dry ice in the shipping container. The quantity of dry ice placed in the container is based on carefully determined guidelines. These Merck guidelines take into account the maximum temperature to which the container will be exposed, the time in transit and the need to keep the temperature of the vaccine at -15°C (+5°F) or colder.
- Store frozen at an average temperature of -15°C (+5°F) or colder prior to reconstitution for injection.
- The vaccine is located in the lower compartment above the dry ice - Store the vaccine in the FREEZER immediately. Any freezer (e.g. chest, frost-free) units that reliably maintain an average temperature of -15°C (+5°F) or colder and have separate sealed freezer door are acceptable.

- The diluents (located in the top compartment) should be stored separately at room temperature (20°C to 25°C [68°F to 77°F]) or in a refrigerator (2°C to 8°C [36°C to 46°F]).
- **IMPORTANT**
  - **Adequate dry ice was placed in this shipment container to maintain the vaccine at proper temperatures for TWO DAYS from the shipment date located on the packing list;**
  - **If the container is received after the time period described above, contact the Merck Order Management Center immediately at 1-800-MERCK RX for replacement instructions. Requests for replacement must be received by Merck within 10 days of the original shipment; and**
  - **Notify the State Immunization Program.**

**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;
- Contact the Nevada State Immunization Program at (775) 684-5939;
- Fill out the "Vaccine Incident Report";
- Call the manufacturers to assess whether vaccine potency could have been affected;
- Document viability and disposition on incident report;
- Document corrective action steps on the "Incident Report"; and
- Fax the completed "Incident Report" to the Nevada State Immunization Program.
  - If the vaccines are determined to be non-viable, follow the instructions below for "Steps for Returning expired/spoiled vaccines to McKesson"
  - If the Nevada State Immunization Program determines the vaccines were administered after exposure to damaging storage conditions, the Nevada State Immunization Program strongly recommends that patients/parents/guardians of the recipients be notified by the provider and offered revaccination to ensure they are fully immunized.

## Returning expired/wasted vaccines



**The following items should NEVER be returned to McKesson:**

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

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

**What should be returned to McKesson:**

- Spoiled or expired product in its original vial or pre-filled syringe;
- Unused pre-filled syringes from manufacturers with an NDC printed on them; and

- Expired or compromised state supplied vaccine must be reported to the Nevada State Immunization Program on “Vaccine Request and Inventory and Accountability Report” under “Doses Expired/Wasted”

#### **Steps for returning expired/spoiled vaccines to McKesson:**

- Fill out the “UPS Pickup Request for Expired/Spoiled Vaccine” (for the non-viable vaccines) and fax the completed form to the Nevada State Immunization Program at (775) 684-8338;
- Pack the non-viable vaccines in any box (without ice packs) for return to the distributor, McKesson;
- Put a copy of the “UPS Pickup Request for Expired/Spoiled Vaccine” in the box;
- Keep a copy of all paperwork for three (3) years;
- The Immunization Program will schedule a UPS pickup and will notify you of the “tracking number”; and
- UPS will bring the shipping label when they pick up the box.

### **Setting up your new vaccine storage unit**

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

- Make arrangements in advance to temporarily store vaccines in an alternate vaccine storage unit with certified thermometers; with temperature monitoring twice daily; and with stable temperature readings at the target temps (refrigerator: 40°F and freezer: 5°F or <5°F) until the new unit is approved for vaccine storage;
- Plug your vaccine storage unit directly into the outlets. Never use extension cords or power strips;
- If your unit comes with vegetable bins, fill them with bottles of water. Do not store vaccines in the vegetable bin space or directly on the floor of the refrigerator;
- Add additional jugs of water to the shelves inside the door and store ice packs in the freezer. This will help maintain a stable, cold temperature if the refrigerator or freezer doors are opened frequently or in case of power failure;
- Place certified/calibrated thermometers in the center of each unit: one in the refrigerator and one in the freezer;
- Set refrigerator unit temperature to 40°F and set freezer unit temperature to 5°F or lower. Adjust the temperature in small increments and continue to monitor until the target temperatures are reached;
- Once temperatures are stable at the target temps and prior to placing vaccines in the unit, record temperatures twice a day for a minimum of 5 working days. Obtain approval from the state prior to transferring vaccines to the new unit; and
- Be sure a DO NOT UNPLUG sticker is posted near the electrical outlet and label the breaker “Expensive Vaccines Do Not Disconnect.”

### **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 the VAERS program:
  - Send e-mail inquiries to [info@vaers.org](mailto: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

## VFC Program 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 Nevada State Immunization Program 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 Nevada State Immunization Program 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.
- Nevada State Immunization Program staff may conduct one or more of the following types of visits:
  - **Nevada State Immunization Program Pre-Enrollment or Re-Enrollment Visit:** A pre-enrollment visit includes education about the Nevada State Immunization Program guidelines, 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 site visit will be made to providers/clinics that have:
    - 1) requested to be reactivated in the program, 2) moved into a new facility or another county, 3) acquired new staff, and/or 4) are delinquent in re-enrolling during the annual re-enrollment process.

- **VFC Site Visit:** A formal review of compliance with VFC standards for all VFC enrolled providers. The VFC site visit questionnaire is completed and a review is conducted of a sampling of patient charts for documentation of VFC eligibility including both VFC and non-VFC eligible children 18 years of age and younger.
- **VFC/AFIX Site Visit:** A formal review of compliance with VFC standards and an assessment of immunization practices and delivery. The VFC site visit questionnaire is completed in conjunction with an assessment of up to 50 patient charts for children born in 2008 to include both VFC and non-VFC eligible children.
- **VFC Follow-Up Visit:** An assurance check of issues of concern that arose from the VFC visit. This follow-up visit normally occurs within (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.
- **AFIX Follow-Up:** A follow-up to the AFIX portion of the combined visit to ensure that measures to improve immunization practices and delivery have been implemented. This follow-up visit normally occurs within 6 months of the original visit. The medical director or senior physician, who signed the Nevada State Immunization Program enrollment forms, or a designee, is strongly recommended to attend.
- **Educational Visit:** A visit to assist in an area for improvement, such as a review of the ACIP schedule, or developing written vaccine storage and handling plan.

### **Non-Compliance with Nevada State Immunization Program Protocols**

If an enrolled provider is found to be non-compliant with Nevada State Immunization Program Protocols, 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 Nevada State Immunization Program requests for site visits, records, information, or corrective action plans needed to meet program requirements.

**Not Active:**

- The provider requests in writing to withdraw from the Nevada State Immunization Program for any reason;
- The provider is unwilling or has refused to comply with Nevada State Immunization Program Protocols; or
- The provider refuses to meet reasonable "standard of care" expectations by not adhering to the current ACIP Recommended Childhood and Adolescent Immunization Schedules.

**Request for Inactivation in the Nevada State Immunization Program**

- An enrolled provider may request to become inactive at any time. The VFC provider must state in writing the date participation in the Nevada State Immunization Program will cease and an inventory of the state supplied vaccines on hand by vaccine type, lot number, expiration date, and number of doses. Upon receipt of this notification, the Nevada State Immunization Program 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 the re-enrollment paperwork has been completed, a re-orientation has been conducted and the site is approved as being in compliance with Nevada State Immunization Program Protocols.

## VACCINE STORAGE UNIT ...Things to Consider!

### New Vaccine Storage Requirements by CDC

Due to the high cost of vaccines and their fragility, CDC no longer permits the use of dorm style storage units. If your facility has this type of unit, it will have to be replaced with an acceptable one. This will assure that your VFC vaccines, as well as your privately purchased vaccines and medications are stored in a manner to assure viability. In addition, certified calibrated thermometers are required.

### In evaluating or choosing your vaccine storage unit look to see that it:

- Is able to maintain required vaccine storage temperatures year-round (35-46° F for refrigerator and 5 F or colder for freezer) ,
- Has one control for the freezer and a separate control for the refrigerator,
- Is large enough to hold the year's largest inventory (without crowding or touching the sides or back of the unit), and
- Is dedicated to the storage of vaccines and medications (no food allowed).

### Reminder: vaccines are not to be stored in the crisper drawers or on the doors

### Acceptable Vaccine Storage Units:



- Commercial or lab styles-these are the most reliable but may be costly.
- Combination refrigerator/freezer unit sold for home use (not apartment size or smaller) are very reliable and moderately priced (\$600-\$700) and are acceptable as long as the refrigerator and freezer compartments each have a separate external door and separate temperature controls.
- Counter high refrigerators are only acceptable if they are lab style.
- Single thermostat units- Household-style refrigerators with a single thermostat are strongly discouraged. This type of refrigerator/freezer is acceptable only if storing vaccine in refrigerator *or* freezer, but not both. A single thermostat makes it difficult to maintain recommended temperatures in both sections. Do not purchase one of these. If you currently have a regular size combination refrigerator/freezer with only one control it may be reliable for refrigerator only storage.

### Unacceptable Vaccine Storage Units Are:

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



- "Dorm-style" or household-grade under-the-counter units provide poor temperature control and often freeze vaccines that require refrigeration, resulting in immediate and irreversible damage.
- "Dorm-style" units are defined as small refrigerator/freezer combination units with a single external door and an evaporator plate or cooling coil that forms a small freezer compartment within the unit or is pulled across the internal back wall of the unit.
- Counter high *refrigerator only* household grades are unacceptable.
- Four foot high combination are not acceptable
- Any household refrigerator unit over 10 years old.

For more information on vaccine storage go to: <http://www2a.cdc.gov/vaccines/ed/shtoolkit/>  
Before purchasing a new unit contact: Linda Platz RN, 775-684-5913

Rev 8/2010

# Nevada State Health Division Technical Bulletin



Topic: Acceptable Vaccine Storage Units	Bureau/Program: Bureau of Child, Family and Community Wellness/Immunization Program
Bulletin #: BCFCW-IZ-05-10	
Date: August 18, 2010	
To: Immunization Providers	Contact: Linda Platz (775) 684-5913

## Acceptable Vaccine Storage Units Required for the storage of state supplied vaccines

Program enrollees still using unacceptable units **MUST** replace such units **WITHIN 30 DAYS** with recommended units.

### Proper Vaccine Storage and Handling:

Proper storage and handling is required to ensure that vaccines remain potent to effectively protect the recipient from disease. The thermo stability of individual vaccines varies; some vaccines are damaged if kept too cold, while others are damaged if they are too warm. For example, most refrigerated vaccines, can be compromised rapidly by exposure to freezing temperatures of 0°C (32°F) or lower.

### Vaccine Storage & Handling Toolkit:

This toolkit created by Centers for Disease Control will assist your facility in the recommendations and requirements to keep vaccines at a safe and viable state:

<http://www2a.cdc.gov/vaccines/ed/shtoolkit/pages/introduction.htm>

### Not acceptable (high risk of vaccine spoilage):

- a. Any small, dormitory style refrigerator unit (with or without a freezer box) is **not acceptable** for storage of either refrigerated or frozen vaccines
- b. Counter high “refrigerator only” **are not acceptable** unless they are commercial or lab grade
- c. Apartment size or smaller (including four foot tall) combined refrigerator freezer units **are not acceptable**
- d. Refrigerators with freezer units on the inside of the refrigerator compartment (e.g., dormitory style refrigerator/freezer units) **are NOT acceptable** for the storage of vaccine. For the **storage of varicella the freezer must have its own outside door and its own thermostat**, or be a free-standing unit
- e. Any household combined refrigerator/freezer unit with only one thermostat controlling both sections and vaccines stored in both sections **are not acceptable**
- f. Any household unit over 10 years old is **not acceptable**



## Minimum requirements for proper vaccine storage and handling:

### Acceptable appliance units for storage of vaccines:

- a. Commercial or laboratory-quality free-standing or combined refrigerator/freezer units with separate compressors for the freezer and refrigerator and no circulating air between the refrigerator and freezer
- b. Under the counter refrigerator models must be commercial or laboratory grade
- c. Regular size (no apartment size nor four foot tall) household combined refrigerator/freezer unit with separate outside insulated doors and separate thermostats controlling the freezer and refrigerator
- d. Commercial or laboratory grade refrigerator
- e. A counter-high free-standing freezer is an acceptable size and should maintain at least: 5° F (-15°C) or colder
- f. Acceptable, but not recommended for purchase, single thermostat household combined refrigerator/freezer unit, only when one compartment of the unit is used for vaccine storage

VFC providers are strongly urged to have all staff responsible for and trained in vaccine storage, monitoring, and handling. Review and apply the practices for proper vaccine storage and handling found in the CDC Vaccine Storage and Handling Toolkit (provided online): <http://www.cdc.gov/vaccines/recs/storage/default.htm>.

### CAUTION: SETTING UP YOUR NEW UNIT

- Place your newly acquired unit in its permanent location away from direct sunlight and in a well ventilated area.
- Place “DO NOT DISCONNECT” stickers on outlets and circuit breakers associated with the unit. Do not connect the unit to an outlet that depends on a light switch for electricity.
- Place the certified/calibrated thermometers in the center of each section
- **Make certain the temperature is regulated and stable within the recommended range for 7 days before placing vaccines in the unit and continue to monitor and record temperatures twice a day**
- Review “Vaccine Storage and Handling Toolkit” for proper set-up and storage of vaccines.

Call Linda Platz for guidance in selecting your new unit: (775) 684-5913

#### References:

Recommendations & Guidelines - Vaccine Storage & Handling:

<http://www.cdc.gov/vaccines/recs/storage/default.htm>


Vaccine Storage and Handling toolkit: <http://www2a.cdc.gov/vaccines/ed/shtoolkit/>

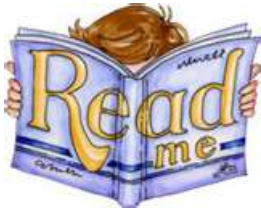
Vaccine Storage Unit... Things to Consider (attached)!

Approved by: \_\_\_\_\_

  
Tracey D Green, MD, State Health Officer

Approved by: \_\_\_\_\_

  
Richard Whitley, MS, Administrator



## **Before mailing the Federal Vaccines for Children (VFC) Program 2011 “Agreement to Participate”**

- ✓ **MAIL** the entire completed **ORIGINAL** “Agreement to Participate” (5 pages)
  - Make sure Numbers 1 thru 20 have been initialed by the Physician in Chief (pages 1 thru 3);
  - Make sure Page 3 has been signed by the Physician in Chief;
  - Make sure that the Provider Profile (page 5) is complete;
- ✓ **MAIL** a copy of each prescribing practitioner’s (MD, DO, PA, NP, etc.) current medical license.

➤ **Submit by MAIL ONLY by December 31, 2010 to:**

Nevada State Health Division  
Immunization Program  
ATTN: Vivian Lawrence  
4150 Technology Way Suite 210  
Carson City NV 89706

- **Faxed “Agreements” will be discarded**
- **Keep a copy of the completed “Agreement to Participate” for your records**
- Vaccine requests for February 2011 will not be filled if “Agreement to Participate” is not received by the due date