



**Vaccine Storage and Handling**



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New Jersey Vaccine Preventable Disease Program



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**Outline**

- **Storage & Handling Policies & Procedures**
- **Temperature Excursions**
- **VFC Program Requirements**
- **VFC Program updates**
- **Q&A session**



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**STORAGE AND HANDLING  
POLICIES AND  
PROCEDURES**



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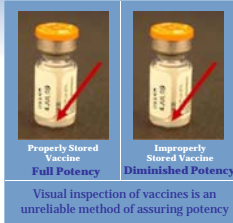
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## Why is Storage & Handling Important?

- Vaccines are very fragile and can lose potency with exposure to excessive heat or cold – leading to potentially severe public health implications
- Cold Chain failure could cost providers thousands of dollars, and/or cause them to have to revaccinate
- Vaccines can be exposed to out of range temperatures yet look normal - visual inspections are unreliable



Properly Stored Vaccine Full Potency

Improperly Stored Vaccine Diminished Potency

Visual inspection of vaccines is an unreliable method of assuring potency




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## Cold Chain

- The vaccine cold chain is a temperature-controlled environment used to maintain and distribute vaccines in optimal condition
- The cold chain begins with the cold storage unit at the manufacturing plant, extends through transport of vaccines to the distributor, delivery to the provider facility, storage of vaccines by the provider, and ends with the administration of vaccines to the patient
- Vaccine potency is reduced every time there is a break in the cold chain and a vaccine is exposed to improper conditions




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## Cold Chain Management

BF1



• Effective cold chain management relies on several elements

- A vaccine management policy that adheres to proper storage and handling procedures
- Well-trained staff
- Reliable cold storage and temperature monitoring equipment




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## Slide 6

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**BF1** Where can providers access this template? Is it on NJIIS? Edit notes accordingly  
Borradaile, Faith, 5/14/2019


## Vaccine Storage Equipment

Pharmaceutical Grade


Household / Commercial Grade (Stainless)

Household / Commercial Grade (Combination)\*


Domestic / Bar Style Combination Unit




Under the counter




Full sized



The CDC does *not* recommend using the freezer compartment of a combination commercial unit



Do not store any vaccine in a domestic style or bar style combination refrigerator/freezer unit under any circumstances



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## Vaccine Cold Storage Preparation and Organization

**Mark the front of unit 'NOT FOR FOOD OR BEVERAGE' and post temperature log sheet**

**Keep vaccines in original packaging**


**Organize vaccines by name in ventilated storage bins**

**Label bins with the vaccine name**

**Separate look alike, sound alike drug names**

**Separate publicly funded vaccines from privately purchased ones**

**Obtain 5 Days of In-range Temps Prior to Storing Vaccines**



**Do not store ice packs in the refrigerator or freezer**

**Label water bottles 'DO NOT DRINK' and place them on the top shelf, along the floor, and in the door racks**

**Bonus: Frozen water bottles can be used in emergency transport containers in the event of a unit malfunction**

**Temperature probe should be located on the center shelf**

**Mark outlet(s) 'DO NOT UNPLUG' and Circuit breakers 'DO NOT STOP POWER TO CIRCUIT BREAKER'**

**Extensions cords and surge protectors create multiple points of failure and should be avoided**

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## Improper Vaccine Placement







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## Proper Vaccine Storage



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## Cold Storage Unit Lock



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## Vaccine Rotations

- All providers are **REQUIRED** to rotate vaccine stock weekly
- Always place vaccines with shorter expiration dates in front of those with longer expiration dates
- Notify New Jersey VFC at least three months in advance if you have vaccines that you will not use before they expires



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## Digital Data Loggers (DDL)

DDLs MUST be NIST certified and calibrated with the following functionality:

- Detachable, buffered probe that best reflects vaccine temperatures
- Alarm for out-of-range temperatures
- Low battery indicator
- Current, minimum (Min), and maximum (Max) temperature display
- Uncertainty of +/-0.5°C (+/-1°F)
- User programmable logging interval (30 minute interval at minimum)



Providers are also required to have at least one additional DDL as a back-up thermometer




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## Temperature Monitoring and Min/Max

Staff must be well trained to use the DDL and must:

- Ensure that the probe is placed correctly within the vaccine storage unit
- Ensure that the alarms are set correctly
- Ensure the device is set to record the temperatures at least every 30 minutes
- Understand the display features:
  - Current temperature
  - Min temperature
  - Max temperature
- Download the DDL data at least weekly, whenever the alarm sounds, and whenever there is an out-of-range min/max temperature

MIN/MAX MUST BE RESET AT THE START OF BUSINESS EACH DAY UNLESS DEVICE HAS AN AUTOMATIC RESET




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## Temperature Documentation

CDC recommends that providers:

- Check and record storage unit Min/Max temperatures at the start of each workday
  - The Min/Max temperatures recorded should be those obtained since the last workday when the Min/Max temperatures were reset. **If you have a manual Min/Max reset, be sure to reset the device after recording the temperature!**
- Check the current temperature each time vaccines are accessed
- Place temperature monitoring log sheet on each storage unit door (or nearby), and record the following information
  - Min/Max temperatures
  - Date
  - Time
  - Name or initials of person who checked and recorded temperatures
  - Any actions taken if a temperature excursion occurred
- Review storage unit temperature readings and review downloaded DDL files weekly to look for any trends

MAINTAIN TEMPERATURE DOCUMENTATION AT LEAST 3 YEARS




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# TEMPERATURE EXCURSIONS




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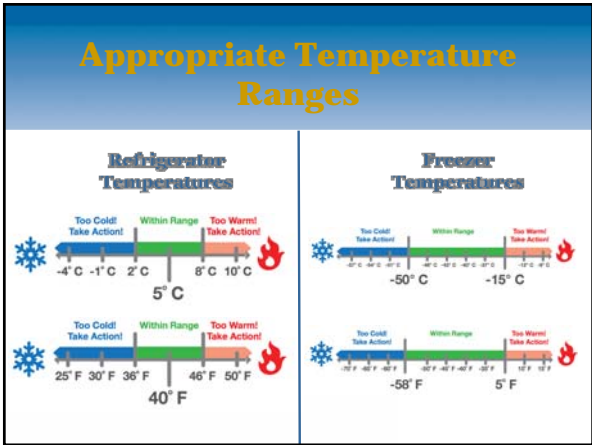
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## Temperature Excursions

**What is a temperature excursion?**

- Any temperatures that fall outside of the CDC and vaccine manufacturer's recommended ranges are considered temperature excursions
- Temperature excursions require **IMMEDIATE ACTION**
- In general, manufacturers analyze information about the magnitude of the temperature excursion, total amount of time temperatures were out of range, and information about each vaccine exposed to determine vaccine viability

**MINIMUM TEMPERATURE OUT OF RANGE**



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## Temperature Excursion Response

**FOLLOW THESE STEPS WHENEVER THERE IS A TEMPERATURE EXCURSION**

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### Excursion Response: Notification

- Notify the primary or alternate vaccine coordinator immediately or report the problem to a supervisor
- Quarantine the vaccines and notify staff by labeling the exposed vaccines, "DO NOT USE." Place them in a separate container apart from other vaccines in the storage unit. This will ensure that vaccines will not be administered until instructed by the VFC Program
- Do not discard these vaccines

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### Excursion Response: Documentation

**Document details of the temperature excursion:**

- Date and time
- Storage unit temperature (including min/max during the time of the event)
- Room temperature, if available
- Name of the person completing the report
- General description of the event (i.e., what happened)
- Download the DDL to determine the length of time vaccines may have been exposed to out-of-range temperatures
- Inventory of affected vaccines including lot numbers and expiration dates
- List of items in the unit other than vaccines (including water bottles)
- Any problems with the storage unit and/or affected vaccines before the event (previous excursions)
- Other relevant information

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## Excursion Response: Contact

- Call the vaccine manufacturers to assess the viability of the vaccines that were exposed to the temperature excursion
- Be prepared to report all the information that you documented
- Be sure to get written documentation from the manufacturers

VFC PROVIDERS  
MUST NOTIFY THE VFC PROGRAM  
OF AN EXCURSION WITHIN  
1 BUSINESS DAY




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## Excursion Response: Correct

- If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause
- Check the basics, including
  - Power supply
  - Unit door(s)
  - Thermostat settings
- Refer to your storage unit manufacturers' instructions and the CDC's Vaccines Storage and Handling Toolkit
- Adjust thermostat in the storage unit to ensure temperatures return to an acceptable range. If this is not possible, immediately move the vaccines to a storage unit that can maintain acceptable temperatures
- If you believe the storage unit has failed and cannot maintain the acceptable temperatures, institute emergency procedures to relocate vaccines. Never allow vaccines to remain in a non-functioning unit

BE SURE TO  
TRANSPORT  
VACCINES WITH A  
DDL. YOU MUST  
BE ABLE TO  
DOCUMENT THAT  
THE COLD CHAIN  
WAS MAINTAINED




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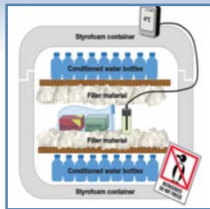
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## Emergency Vaccine Transport

- Keep DDL with vaccines at all times
- DDL must be placed in each vaccine transport container when vaccines being transported to another site
  - Be sure to have enough DDLs to monitor vaccine transport in an emergency
- Packing essentials for emergency vaccine transport
  - Hard-sided cooler or Styrofoam vaccine shipping container
  - Conditioned frozen water bottles
  - Insulating filler material (2 layers of each)
  - Corrugated cardboard
  - Digital Data Logger




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## Temperature Excursion Resolution

After obtaining all the manufacturers' viability determinations for the vaccines in quarantine within your storage unit:

- Wait for a final determination from the VFC Program before using or disposing of any VFC vaccine that was exposed to out-of-range temperatures
- Remove non-viable vaccines from the vaccine storage unit and label them "DO NOT USE"
- Tag all viable vaccines so that cumulative time out-of-range can be calculated should the vaccines be exposed to temperature excursions in the future




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## Preventing Temperature Excursions

- Develop a culture where vaccine storage and handling is a priority
- Be sure everyone in the office understands the importance of vaccine storage and handling
- Be sure that all staff are well trained and that they have ample time/support to perform duties
- Invest in appropriate equipment – vaccine storage units and DDLs
- Record min/max temperatures daily, check current temperature whenever accessing unit, download DDL files weekly – assess temperatures for trends
- Optimize processes to minimize potential for temperature excursions
  - Do not keep the door of a vaccine storage unit open for long periods during stocking and inventory checks



MANY TEMPERATURE EXCURSIONS CAN BE PREVENTED BY BEING PROACTIVE!




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## Reporting Waste

Vaccines are wasted if they are spoiled as a result of a temperature excursion, expired, broken, or drawn up but never administered

- Wasted vaccines must be reported to the VFC Program via a transaction in the NJIIS Inventory within 6 months



Inventory	Lot Number	NDC Code	Brand	Manufacturer	Date Recd	Shots Recd	Shots Admin	Total Recd
Inventory	100000	40201-0001-00	Parke-D	AMGEN/AMGEN/AMGEN	10/13/2014	10	40	50
Inventory	100000	40201-0001-00	Parke-D	AMGEN/AMGEN/AMGEN	10/14/2014	20	5	25

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## VFC Program Eligibility: Medicaid as Secondary

Situations occur where children may have private health insurance AND Medicaid as secondary insurance

- Providers may administer VFC vaccines to the patient and treat the patient as VFC-eligible
- Providers must select and document the eligibility category that will require the least amount of out-of-pocket expenses to the parent/guardian for the child to receive the necessary immunizations



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## 317 Program Eligibility

Eligible patients are those who:

- Are 19 years of age and older with no insurance coverage for the ACIP-recommended vaccines needed
  - If the adult has private insurance, Medicare, or Medicaid, check if the insurance pays for a portion of the vaccine. If the insurance pays any portion of the vaccine costs, the adult is not eligible to receive vaccine under the 317 program
- Are privately-insured individuals of any age seeking vaccines during public health response activities including:
  - Outbreak response
  - Post-exposure prophylaxis
  - Disaster relief efforts

Please note: Prior approval from the 317 program must be obtained before program vaccines are used in public health response activities



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## Eligibility Screening and Documentation

- Eligibility must be verified before each immunization visit
- Documentation of eligibility must include:
  - Patient's eligibility category
    - Example: no insurance or Plan A
  - Date eligibility was checked



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## Annual Re-enrollment

- **Must submit each year using the online form**
- **Communication from the New Jersey VFC program will be sent indicating the need and timeframe to re-enroll**
- **Failure to re-enroll by the specified deadline will result in suspension from the program**
- **Continued failure to re-enroll may also result in the removal of VFC vaccines from your office**




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## Vaccine Ordering Minimum Requirements

- **Every provider who receives federally-funded vaccines must place a core vaccine order at least once every 365 days**
  - **Flu vaccine is not considered core vaccine and therefore flu-only orders do not satisfy the minimum ordering requirements**
- **If you fail to order vaccines each year, your office will become inactive. Your office will not be allowed to order any vaccines until key staff are retrained on New Jersey VFC policies and procedures and a new enrollment site visit has been successful completed**




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## Recommendations from the Advisory Committee for Immunization Practices

- **VFC and 317 providers must offer all Advisory Committee for Immunization Practices (ACIP) recommended vaccines to their patient population**
- **Providers are required to follow the appropriate ACIP-recommended immunization schedules**

<http://www.cdc.gov/vaccines/hcp/acip-recs/>




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## Record Retention

- Office must maintain ALL VFC records for a minimum of 3 years
- All active patients, must have a up-to-date vaccine administration record in their medical chart



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## Vaccine Administration Documentation

By federal law, each vaccination record within a medical chart must contain ALL the below elements:

- Address of clinic where vaccine was administered
- Name of vaccine administered
- Date vaccine was administered
- Date VIS was given
- Publication date of VIS
- Name of vaccine manufacturer
- Lot number
- Name and title of person who administered the vaccine



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## Reimbursement



- VFC & 317 providers are NOT allowed to charge patients for federally-funded vaccine
- Administration fee
  - Medicaid, Medicaid Managed Care, and Family Plan A patients: contact your Medicaid/Managed Care representative for current reimbursement schedules
  - Uninsured and underinsured patients: Providers may charge patients up to \$24.23 per vaccine (regardless of number of antigens)
  - Physicians are NOT permitted to withhold VFC/317 vaccines due to the patient's inability to pay the administrative fee
- If a provider gives a VFC/317 patient one of their private vaccines they will not be reimbursed. It is the provider's responsibility to ensure proper stock for VFC/317 patients



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## Vaccine information Statement (VIS)

- **What is a VIS?**
  - A VIS is a document, produced by CDC, that informs vaccine recipients - or their parents or legal representatives - about the benefits and risks of a vaccine they are receiving.
- **Distribution of VIS is required by law**
  - All vaccine providers, public and private, are required by the National Vaccine Childhood Injury Act (NCVIA - 42 U.S.C. § 300aa-26[2 pages]) to give the appropriate VIS to the patient (or parent or legal representative) prior to every dose of specific vaccines.
- **The appropriate VIS must be given prior to the vaccination, prior to each dose of a multi-dose series, and regardless of the age of the recipient.**

For more information visit <http://www.cdc.gov/vaccines/hcp/vis/>




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## Vaccination Adverse Event Reporting System (VAERS)

### Two Ways to Submit an Online Report to VAERS



#### Option 1 - Report Online to VAERS (Preferred)

Submit a VAERS report online. The report must be completed online and submitted in one sitting and cannot be saved and returned to at a later time. Your information will be erased if you are inactive for 20 minutes; you will receive a warning after 15 minutes.



#### Option 2 - Report using a Writable PDF Form

Download the Writable PDF Form to a computer. Complete the VAERS report offline if you do not have time to complete it all at once. Return to this page to upload the completed Writable PDF form by clicking here.

If you need further assistance with reporting to VAERS, please email [info@VAERS.org](mailto:info@VAERS.org) or call 1-800-822-7967.

- **National reporting system co-managed by CDC and FDA**
- **Accepts and analyzes reports of adverse events (possible side effects) after a person has received a vaccination**
- **VAERS is a passive reporting system, meaning it relies on individuals to send in reports of their experiences**




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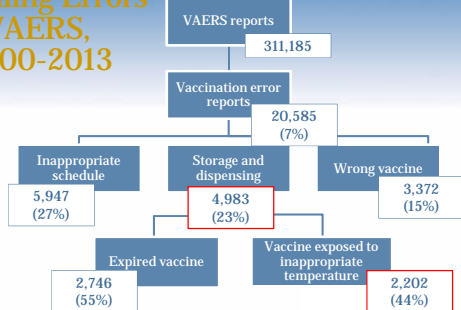
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## Storage and Handling Errors VAERS, 2000-2013




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## Staffing Needs for VFC/317 Providers

- Medical Director
- Vaccine Coordinators
  - Primary and Back-up
  - Must have completed NJIIS trainings:
    - Fundamentals
    - Vaccine Ordering and Management
  - Must complete annual education training
- Any changes in key staff must be reported to the New Jersey VFC Program immediately using:
  - IMM-36\* (VFC) IMM-25\* (317) [Change of Medical Director]
  - IMM-48 [Change of Coordinators]



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## When Will the VFC Program Visit?

- **Compliance Visit** - scheduled visit every 18-24 months to review all VFC Program requirements
  - A 20 Chart Follow-Up Visit may be required if provider does not show compliance during visit
- **Storage and Handling Visit** - unannounced visit focused on the safe handling and storage of vaccines
- **Enrollment Visit** - initial visit for a new or returning VFC site
- **Educational Visit** - visit centered around specific needs of a provider
- **AFIX/IQIP Visit** - quality improvement visit focused on improving a provider's best practices

It is the goal of VFC to see each provider at least once a year through one of the above listed visits



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## NEW JERSEY VFC PROGRAM UPDATES



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## 2018-2019 VFC Program Updates

- **Temperature Excursion Taskforce**
- **Release of VFC and 317 Provider Manual**
- **Support of VPD outbreaks/clusters**
- **2019 Re-enrollment process**



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## New Requirements 2020 and Beyond



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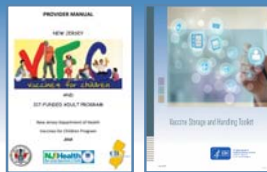
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## Resources



<https://njhs.nj.gov/core/web/index.html#home>  
<https://www.cdc.gov/vaccines/imz/downloads/pdf/317/index.html>  
[https://www.cdc.gov/vaccines/imz/downloads/pdf/317/provider\\_manual.pdf](https://www.cdc.gov/vaccines/imz/downloads/pdf/317/provider_manual.pdf)

NJ Vaccines for Children Program  
Email: [VFC@doh.nj.gov](mailto:VFC@doh.nj.gov)  
Telephone: 609-826-4862  
Fax: 609-826-4868



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Questions?



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