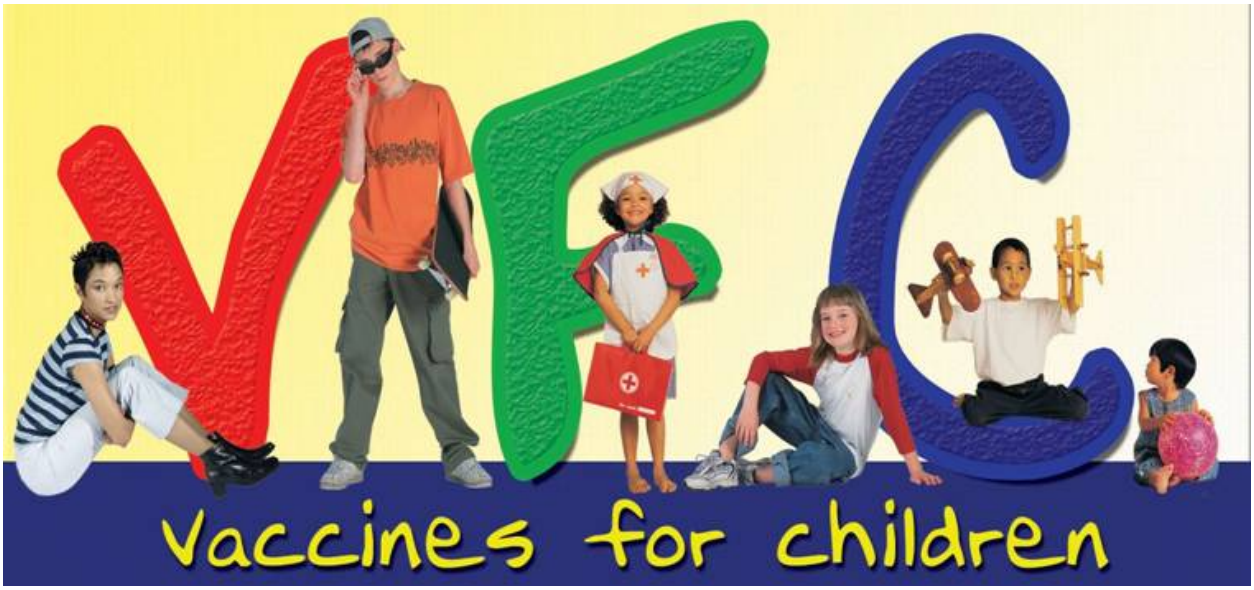
PROVIDER MANUAL

NEW JERSEY



AND

317-FUNDED ADULT PROGRAM

New Jersey Department of Health

Vaccines for Children Program

2018

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INTRODUCTION

PURPOSE

The purpose of this *New Jersey Vaccine for Children Program and 317-Funded Adult Program Provider Manual* is to provide an overview of the VFC and 317 programs and summarize requirements and responsibilities. It is not meant to replace any of the other materials or trainings provided by the VFC program or the CDC.

The New Jersey Department of Health, VFC program appreciates the efforts of providers who administer vaccines and recognizes the vital role providers play in serving the needs of our underserved and at-risk populations. Ensuring that all children, adolescents, and adults are vaccinated in accordance with the ACIP-recommended schedule is the best way to protect individuals and communities against vaccine preventable diseases. The VFC and 317 programs make vaccines available to children, adolescents, and adults who might otherwise go unvaccinated because of an inability to pay for the vaccine. The New Jersey VFC program works to ensure that processes are as streamlined as possible and that providers have timely access to vaccines for their patient populations.

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ACRONYMS

317	317-Funded Adult Program
AAFP	American Academy of Family Physicians
AAP	American Academy of Pediatrics
ACIP	Advisory Committee on Immunization Practices
AFIX	Assessment, Feedback, Incentives, and eXchange
AI/AN	American Indian/Alaska Native
CDC	Centers for Disease Control and Prevention
DDL	Digital Data Logger
DO	Doctor of Osteopathy
EPA	Environmental Protection Agency
FQHC	Federally-Qualified Health Center
MD	Medical Doctor
NCVIA	National Childhood Vaccine Injury Act
NJ	New Jersey
NJDOH	New Jersey Department of Health
NJIIS	New Jersey Immunization Information System
NP	Nurse Practitioner
OSHA	Occupational Safety and Health Administration
PA	Physician Assistant
PIN	Provider Identification Number
STD	Sexually-Transmitted Disease
VAERS	Vaccine Adverse Event Reporting System
VFC	Vaccines for Children
VIS	Vaccine Information Statement

RESOURCES

CDC's Current VIS	https://www.cdc.gov/vaccines/hcp/vis/current-vis.html	Current Vaccine Information Statements
CDC's Guide to Hand Hygiene	http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf	Guide to Hand Hygiene in Healthcare Settings
CDC's Guide to Infection Prevention in Outpatient Settings	https://www.cdc.gov/hai/settings/outpatient/outpatient-care-guidelines.html	Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care

CDC's Guideline for Disinfection and Sterilization	https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines.pdf	Guideline for Disinfection and Sterilization in Healthcare Facilities
CDC's Guidelines for Environmental Infection Control	http://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf	Guidelines for Environmental Infection Control in Health-Care Facilities
CDC's One and Only Campaign	https://www.cdc.gov/injectionsafety/1anonly.html	Injection safety resources
CDC's Storage and Handling Toolkit	https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html	Storage and Handling Toolkit
CDC's Vaccine Resource Library	https://www.cdc.gov/vaccines/hcp/admin/resource-library.html	Educational materials for providers who administer vaccines
CDC's You Call the Shots	https://www.cdc.gov/vaccines/ed/youcalltheshots.html	You Call the Shots Web-based Training Modules
Division of Medical Assistance and Health Services	http://www.state.nj.us/humanservices/dmahs/home/	Administers Medicaid's state-and federally-funded NJ FamilyCare programs for certain groups of low- to moderate- income adults and children.
Immunization Action Coalition	http://immunize.org/	Information about vaccines, temperature log templates, choosing length and gauge of needle for vaccine administration

NJIIS	https://njiis.nj.gov/core/web/index.html#/home	Information about NJIIS, Enrollment and Training, Documents/Forms, Interface Enrollment, Vaccines for Children Program
NJVFC	https://njiis/core/web/index.html#/vfcDocs	VFC Program News, Annual Provider Educational Requirement, VFC Documents, Vaccine Management Template, VFC Newsletters, VFC Program Forms, New Site Enrollment Packages

VFC PROGRAM – AT-A-GLANCE

The VFC Program is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of an inability to pay.

Publicly purchased vaccine for eligible children are supplied at no charge to VFC-enrolled public and private providers in all 50 states and territories.

HOW VFC BENEFITS STATES AND VFC PROVIDERS

- Provides cost-savings to states and territories through bulk purchase of vaccine at lower prices using CDC's contracts, and eliminates state-to-state differences in price.
- Facilitates children remaining within their medical home for vaccination services.
- Saves VFC-enrolled providers out-of-pocket expenses for vaccine.
- Eliminates or reduces vaccine cost as a barrier to immunizing eligible children.

HOW VFC WORKS

- CDC awards federal funding to state health departments and certain local and territorial public health agencies to implement and oversee VFC program activities.
- State, local and territorial public health agencies actively enroll public and private providers into the program to meet the specific needs of the jurisdiction.
- CDC buys vaccines at a discount from manufacturers.
- CDC distributes the vaccines at no charge to registered VFC providers in private physicians' offices and public health clinics.
- CDC has the lead responsibility for policy development, operational oversight, and technical assistance to state, local and territorial public health agencies.
- State, local and territorial public health agencies manage and implement the VFC program within their jurisdictions.

VFC VACCINES AND THE ACIP

The ACIP is a federal advisory committee that was established in 1964 to provide guidance on the most effective means to prevent vaccine-preventable diseases. In 1993, Congress gave the ACIP unique legal authority to determine recommendations for routine administration of vaccine to children and adults in the civilian population. Major functions of the ACIP are as follows:

- Develops technical recommendations on vaccine use and immunization practices.
- Approves vaccines to be provided through the VFC program.
- Recommends immunization schedules that are harmonized with recommendations of other advisory groups, such as the AAP and the AAFP.

After approval, ACIP recommendations are published in Morbidity and Mortality Weekly Report (MMWR), a scientific periodical prepared by the CDC and become the standard for administering the applicable vaccines. Once a new or amended recommendation is published, the ACIP approves it for inclusion in the VFC program by passing a VFC Resolution. VFC Resolutions determine what vaccines are available through the VFC program, including dosage, schedule, and contraindications.

317-FUNDED ADULT PROGRAM – AT-A-GLANCE

The 317 program is a federally funded program that provides vaccines at no cost to adults who might not otherwise be vaccinated because of an inability to pay. In New Jersey, the program is operated by the VFC Program and has many of the same requirements and recommendations as the VFC Program.

Publicly-purchased vaccine for eligible adults are supplied at no charge to 317 program enrolled Not-for-Profit Organizations, Public Health Departments, or FQHCs.

HOW 317 BENEFITS STATES AND 317 PROGRAM PROVIDERS

- Provides cost-savings to states and territories through bulk purchase of vaccine at lower prices using CDC's contracts, and eliminates state-to-state differences in price.
- Facilitates adults receiving ACIP-recommended vaccines.
- Facilitates responses to outbreaks and other public health emergencies.
- Saves 317 program providers out-of-pocket expenses for vaccine.
- Eliminates or reduces vaccine cost as a barrier to immunizing eligible adults.

HOW 317 PROGRAM WORKS

- CDC awards federal funding to state health departments and certain local and territorial public health agencies to implement and oversee 317 program activities.
- State, local and territorial public health agencies actively enroll providers into the program to meet the specific needs of the jurisdiction.
- CDC buys vaccines at a discount from manufacturers.
- CDC distributes the vaccines at no charge to registered 317 providers in Not-for-Profit Organizations, Public Health Departments, or FQHCs.
- CDC has the lead responsibility for policy development, operational oversight, and technical assistance to state, local and territorial public health agencies.
- State, local and territorial public health agencies manage and implement the 317 programs within their jurisdictions.

317 PROGRAM VACCINES AND THE ACIP

The ACIP is a federal advisory committee that was established in 1964 to provide guidance on the most effective means to prevent vaccine-preventable diseases. In 1993, Congress gave the ACIP unique legal authority to determine recommendations for routine administration of vaccine to children and adults in the civilian population. Major functions of the ACIP are as follows:

- Develops technical recommendations on vaccine use and immunization practices.
- Approves vaccines to be provided through the VFC program.

- Recommends immunization schedules that are harmonized with recommendations of other advisory groups, such as the AAP and the AAFP.

After approval, ACIP recommendations are published in Morbidity and Mortality Weekly Report (MMWR), a scientific periodical prepared by the CDC and become the standard for administering the applicable vaccines. Once a new or amended recommendation is published, the ACIP approves it for inclusion in the VFC program by passing a VFC Resolution. VFC Resolutions determine what vaccines are available through the VFC program, including dosage, schedule, and contraindications.

MODULE 1 – VFC ELIGIBILITY

OVERVIEW

VFC is an entitlement program that requires screening and documentation of eligibility status (by category) for all patients from birth through 18 years of age.

PURPOSE

The purpose of this module is to describe VFC eligibility and provide information on how to determine which eligibility category applies in various situations.

VFC ELIGIBILITY CATEGORIES

In order for children to receive vaccines through the VFC program, **eligibility screening and documentation must take place at each immunization visit prior to immunization**. All providers and their staff must fully understand the VFC eligibility categories and perform this basic program requirement.

The only factors that can be considered when screening for VFC eligibility are age and whether the child meets the definition of at least one of the VFC categories described below.

Children through 18 years of age (under 19) who meet at least one of the following criteria are eligible to receive VFC vaccine:

- Medicaid-eligible: A child who is eligible for the Medicaid program (For the purposes of the VFC program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are used interchangeably and refer to children who have health insurance covered by the state Medicaid program.) Children who are enrolled in NJ FamilyCare Plan A are eligible for VFC vaccine.

- Uninsured: A child who has no health insurance coverage.

- AI/AN: As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603).

- Underinsured*:
    - A child who has health insurance, but the coverage does not include vaccines, or
    - A child whose insurance does not cover all ACIP-recommended vaccines. This child would be eligible to receive those vaccines not covered by the insurance.

*Underinsured children are eligible to receive VFC vaccine only through a FQHC in New Jersey.

Children whose health insurance covers the cost of vaccinations are not eligible for VFC vaccines. This applies even when a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible has not been met.

WHEN A CHILD QUALIFIES FOR MORE THAN ONE VFC ELIGIBILITY CATEGORY

Occasionally, children may be VFC-eligible for more than one eligibility category.

A provider must select **and document** the VFC eligibility category that will require the least amount of out-of-pocket expenses to the parent/guardian for the child to receive necessary immunizations. For example: Children that are both AI/AN and Medicaid, either eligibility may be documented, although Medicaid should be used for the administration fee as it is the least out of pocket expense.

QUICK VIEW OF VFC ELIGIBILITY AND INSURANCE STATUS

VFC ELIGIBILITY SCENARIO: CHILD IS INSURED AND…	INSURANCE STATUS	IS CHILD VFC-ELIGIBLE?
Has not yet met plan's deductible or met copays for other services received at visit	**Insured**	**No**
Grandfathered plan that does not cover all ACIP-recommended vaccines	**Underinsured**	**Yes, at FQHC - only for vaccines not covered by plan**
Enrolled in separate Children's Health Insurance Program (CHIP) **– NJ FamilyCare Plans B, C, and D**	**Insured**	**No**
Enrolled in Medicaid-expansion Children's Health Insurance programs – **NJ FamilyCare Plan A**	**Medicaid-eligible**	**Yes**
Seeking contraceptive or STD services at school-based clinic or facility whose main services are primary or acute care, and wants to be immunized but does not want to access insurance	**Insured**	**No**
Seeking contraceptive or STD services at family planning clinic and wants to be immunized but does not want to access insurance or doesn't know status	**Uninsured**	***Yes**
Incarcerated child where the state does not supply vaccine for incarcerated individuals, and the child cannot access health care through a health insurance plan because of incarceration	**Uninsured**	**No**

*Provision of vaccine to unaccompanied minors must be in compliance with the states consent laws as they pertain to minors

LOCATION OF SERVICE

In general, where vaccine services are delivered is not a factor in determining VFC eligibility. However, there are some locations and provider types that require consideration when offering VFC vaccine:

- School-Based and Mass Vaccination Clinics:
  Children who receive vaccines in a school-based or mass vaccination clinic must not automatically be considered VFC-eligible; all children must be screened and their eligibility documented prior to administering VFC vaccine.
- Receiving Health Care in a Bordering State:
  Providers who administer VFC vaccine to Medicaid-eligible child from a neighboring state, the provider must be a Medicaid-enrolled provider for the state where the Medicaid VFC-eligible child resides in order to receive reimbursement for the administration fee from the neighboring state's Medicaid program.
- STD, Family Planning Clinics, and Juvenile Detention Facilities:
  Guidance on children under 19 years of age presenting at family planning clinics and juvenile detention centers is provided in the table below.

STD CLINICS, FAMILY PLANNING CLINICS, AND JUVENILE DETENTION FACILITIES		
POPULATION	**INSURANCE STATUS**	**VFC ELIGIBILITY UNINSURED**
Minors under 19 years of age	**Do not know their insurance status and who present at family planning clinics for contraceptive services or STD treatment**	**Considered uninsured for the purposes of the VFC program**
A person under 19 years of age	**May have insurance, but because of the confidential circumstances of seeking services in a family planning clinic, does not have access to that insurance coverage**	**Considered uninsured for the purposes of the VFC program**
Juveniles under the age of 19 years who are incarcerated in detention facilities	**Loses access to his or her health insurance because of the incarceration**	**Considered uninsured and VFC-eligible**

CDC defines a family planning clinic as a clinic or provider whose purpose is to prescribe contraceptives and/or treat sexually transmitted diseases. School-based clinics or any VFC-enrolled provider whose main services are primary or acute care services do not meet CDC's definition of a family planning clinic and cannot use this VFC eligibility category.

INSURED EXCEPTIONS

AI/AN WITH HEALTH INSURANCE THAT COVERS IMMUNIZATION

AI/AN children are always VFC-eligible. However, VFC is an entitlement program and participation is not mandatory for an eligible child. The family may be responsible for the vaccine administration fee if they have the vaccines delivered through the VFC program. Therefore, if the child has private insurance or is enrolled in Medicaid or CHIP programs, it would result in less out-of-pocket costs for them to receive immunizations through those programs than through the VFC program as there would be no cost-sharing.

INSURED AND MEDICAID AS SECONDARY INSURANCE

Situations occur where children may have private health insurance and Medicaid as secondary insurance. These children will be VFC-eligible as long as they are enrolled in Medicaid or FamilyCare Part A. However, the parent is not required to participate in the VFC program. For questions, please consult Medicaid or the Managed Care Organization.

ELIGIBILITY SCREENING

Eligibility screening and documentation must occur at each immunization visit regardless of insurance type.

- Documentation must be maintained for a minimum of 3 years.
- Providers are encouraged to use a standardized process to document the eligibility status of each patient in the medical record. Screening documentation can be completed and maintained electronically or on paper. Providers using paper medical records are encouraged to use the VFC Patient Eligibility Screening Record (IMM-28) available through the NJIIS website.
- Providers must document the patient's eligibility status in NJIIS.
    - Immunizations must be entered into NJIIS within 30 days of administration.
    - Insurance type and Current VFC Eligibility must be indicated in the NJIIS record.

BILLING

There are two costs associated with vaccine – the cost of the vaccine and the administration fee. The billing requirements of the VFC program are defined as follows:

- **Vaccine**
    - Providers must not charge patients, Medicaid, or private insurers for VFC vaccine.
- **Administration Fee**
    - Providers are permitted to charge a vaccine administration fee to non-Medicaid VFC-eligible children. This administration fee cannot exceed the federal administration fee cap of per vaccine dose (not per antigen) as stipulated in the Provider Agreement.

- For Medicaid VFC-eligible children, the provider must accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.
- Providers must not deny access to federally purchased vaccine to an established patient who is unable to pay the administration fee.

MODULE 2 – 317 PROGRAM ELIGIBILITY

OVERVIEW

The 317 program requires screening and documentation of eligibility status (by category) for all patients 19 years of age and older.

PURPOSE

The purpose of this module is to describe 317 program eligibility and provide information on how to determine which eligibility category applies in various situations.

317 ELIGIBILITY CATEGORIES

In order for adults to receive vaccines through the 317 program, **eligibility screening and documentation must take place at each immunization visit prior to immunization**. All providers and their staff must fully understand the 317 program eligibility categories and perform this basic program requirement.

The only factors that can be considered when screening for 317 program eligibility are age and whether the person meets the definition of at least one of the 317 program categories described below.

Adults 19 years of age and older who meet at least one of the following criteria are eligible to receive 317 program vaccine:

- Uninsured: An adult who has no health insurance.
- Underinsured:
    - An adult who has health insurance, but the coverage does not include vaccines, or
    - An adult whose insurance does not cover all ACIP-recommended vaccines. This adult would be eligible to receive those vaccines not covered by the insurance.

Insured adults and children seeking vaccination during identified public health response activities including **(pre-approval must be obtained from the VFC program prior to the use of 317 program vaccine for these activities)**:

- Outbreak response
- Post-exposure prophylaxis
- Disaster relief efforts
- Mass vaccination campaigns or exercises for public health preparedness

Adults whose health insurance covers any of the cost of a vaccine are not eligible to receive the vaccine through the 317 program. This applies even when a claim for the cost of the vaccine and its

administration would be denied for payment by the insurance carrier because the plan's deductible has not been met.

ELIGIBILITY SCREENING

- Eligibility screening and documentation must occur at each immunization visit regardless of insurance type.
- Documentation must be maintained for a minimum of 3 years.
- Providers are encouraged to use a standardized process to document the eligibility status of each patient in the medical record. Screening documentation can be completed and maintained electronically or on paper. Providers using paper medical records are encouraged to use the 317 program Eligibility Screening Record (IMM28-A) available through the NJIIS website at https://njiis/core/web/index.html#/vfcDocs.
- Providers must document the patient's eligibility status in NJIIS.
    - Immunizations must be entered into NJIIS within 30 days of administration.
    - Insurance type and Current 317 program eligibility must be indicated in the NJIIS record.

BILLING

There are two costs associated with vaccine – the cost of the vaccine and the administration fee. The billing requirements of the 317 program are defined as follows:

- **Vaccine**
    - Providers must not charge patients, Medicaid, or private insurers for 317 program vaccines.
- **Administration Fee**
    - Providers are permitted to charge a vaccine administration fee to 317-eligible adults. This administration fee cannot exceed the federal administration fee cap of per vaccine dose (not per antigen) as stipulated in the Provider Agreement.
    - Providers must not deny access to federally purchased vaccine to an established patient who is unable to pay the administration fee.

MODULE 3 – VFC PROVIDER ENROLLMENT

OVERVIEW

The VFC program was created to increase access to immunizations outside of public health department clinics, and to allow eligible children to remain in their medical homes for immunizations to the extent possible. Therefore, maintaining participation of private providers is critical to ensuring that VFC-eligible children have access to vaccines in their medical homes.

VFC providers perform vital functions, such as eligibility screening, vaccine storage and handling, and vaccine administration. It is essential for VFC providers to have a clear understanding of VFC program requirements and how the VFC program works.

PURPOSE

This module describes provider enrollment, the enrollment process, and the VFC program requirements outlined in the Provider Agreement.

PROVIDER ELIGIBILITY

Providers must be eligible to enroll in the VFC program. The following eligibility criteria must apply:

- Provider signing the agreement as the Medical Director has the authority to sign on behalf of the entity and agrees to all program requirements, including participation in site visits and educational opportunities.
- Provider or provider staff are not included on the Office of the Inspector General List of Excluded Providers.
- Provider signing the Provider Agreement has a valid, active Medical License issued by the New Jersey State Board of Medical Examiners and can administer vaccines under state law.
- Provider has the capacity to order, receive, and manage public vaccine, including adhering to the CDC's standards for proper vaccine storage and temperature monitoring.

MEDICAL DIRECTOR RESPONSIBILITIES

The Medical Director will be held accountable for VFC program compliance for the entire organization. The responsibilities include, but are not limited to, the following:

- Annually submit a provider profile representing populations served by the practice/facility. Providers must submit the profile more frequently if the number of children changes, or the status of the facility changes during the calendar year.
- Screen patients and document eligibility status at each immunization encounter for VFC eligibility and administer VFC-purchased vaccine by such category only to children who are 18 years of age or younger who meet the eligibility criteria outlined in **Module 1 – VFC Eligibility**.
- Offer all ACIP-recommended vaccines and comply with the immunization schedules, dosages, and contraindications that are established by the ACIP unless:

    - In the providers medical judgment, **and** in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child.
    - The particular requirements contradict state law, including laws pertaining to religious or other exemptions.
    - The provider has requested to be a "Specialty Provider" and is specifically designated by the VFC program as a "Specialty Provider". A "Specialty Provider" only serves a defined population due to the practice specialty or specific age group within the general population of children ages 0 – 18. Local health departments and general pediatricians are not considered "Specialty Providers".
- Ensure that all records related to the VFC program are maintained and available for production for a minimum of three years.
- Ensure that no charges are billed for publicly supplied vaccine administered to VFC-eligible children.
- Agree to not charge a vaccine administration fee to non-Medicaid federal vaccine-eligible children that exceeds the set administration fee cap per vaccine (not per antigen) and agree to accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.
- Agree to not deny administration of a publicly-purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.
- Ensure that the current VIS is distributed each time a vaccine is administered and maintain record in accordance with the NCVIA, which includes reporting clinically significant adverse events to the VAERS.
- Agree to comply with the requirements for vaccine management, including:
    - Ordering vaccine and maintaining appropriate vaccine inventories.
    - Not storing vaccine in dormitory-style units at any time.
    - Storing vaccine under conditions specified by the CDC at all times. Refrigerator and freezer storage units and temperature monitoring equipment and practices must meet the VFC storage and handling requirements.
    - Returning all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration.
- Agree to participate in VFC program compliance site visits including unannounced visits, and other educational opportunities associated with VFC program requirements.
- Agree to replace vaccine purchased with federal funds that are deemed non-viable due to provider negligence on a dose-for-dose basis. Providers are expected to notify and revaccinate, at their own cost, any child who received compromised or potentially compromised vaccine due to provider negligence.
- Agree to register as a provider with NJIIS and enter all doses of federally-funded vaccines administered into the NJIIS within 30 days of administration (regardless of the age of the patient). In addition, agree to enter all vaccine doses administered into the NJIIS in accordance with N.J.A.C. 8:57-3. All providers administering vaccines to children less than 7 years of age must enter the vaccine doses into NJIIS within 30 days of administration.

- Understand that the provider or the VFC program may terminate the Provider Agreement at any time and that all unused federally-funded vaccine must be returned to the VFC program upon termination.
- Ensure that all healthcare providers (PA, NP, MD, and DO) in the enrolled practice – and their corresponding professional license numbers – are listed on the provider profile. Providers who are on the Office of the Inspector General Exclusion list or employ individuals on the Office of the Inspector General Exclusion List cannot participate in the VFC program.
- Designate, train, and oversee a Primary Vaccine Coordinator and a Backup Vaccine Coordinator (responsibilities of Coordinators are outlined in **Module 5 – Vaccine Management**).
- Submit a "Request to Update Provider Information" (IMM-48) whenever there is a change in the Primary or Backup Vaccine Coordinators or office information (e.g., shipping address, delivery hours, office email address) during the enrollment year.

NEW PROVIDER ENROLLMENT

- Providers wishing to enroll in the VFC program must complete the forms below (*Vaccines for Children Program Provider Enrollment Package Pediatric*) available through the NJIIS website. Forms can be emailed or faxed to the VFC program.
    - **VFC New Provider Enrollment for Pediatric Site (IMM-26)**
      This form captures information about the practice, and the number of VFC-eligible children and non-VFC-eligible children served by providers. It helps the VFC program determine how much vaccine will need to be supplied through the VFC program and compare projected vaccine needs with actual vaccine orders and inventory.
    - **New Provider Agreement for Pediatric Site (IMM-36)**
      This CDC-approved form documents the provider's agreement to comply with the requirements of the VFC program in order to receive VFC-purchased vaccine.
- Providers with more than one office location can associate additional offices by entering the additional locations on the New Provider Enrollment for Pediatric Site (IMM-26) form. Each office location that administers federally-funded vaccine must have a PIN number. A provider cannot transport federally-funded vaccine from one office location to another. Providers with offices outside of New Jersey cannot associate those offices with the New Jersey VFC program. Contact the VFC program in the jurisdiction where your office is located.

WHAT TO EXPECT AFTER SUBMITTING YOUR NEW PROVIDER ENROLLMENT

- Once your paperwork is processed, the VFC program will send a "Welcome Letter" to the email address provided. This letter will include your Provider Identification Number (PIN); a separate PIN will be issued for each office location associated with the Medical Director.
- Providers must complete a New Enrollment Questionnaire for each office location. Providers must:
    - Indicate the names of the Primary and Backup Vaccine Coordinators and the dates that each completed the required NJIIS Fundamental Training AND Vaccine Ordering and Management in NJIIS training available through the NJIIS website.

- Indicate the Certificate/Serial Number of each of the data loggers (and required backup data logger) and the expiration date; Certificates of Calibration must be submitted.
- Indicate the type of storage units in use in the office.
- Ensure the following:
    i. DDL probes are centrally placed in each storage unit.
    ii. The Vaccine Management Policy Template is completed.
    iii. All VISs are current.
    iv. Vaccine temperatures are tracked for each unit for at least two business weeks using the temperature log template found on the Immunization Action Coalition website. DDL must be downloaded prior to the visit so that it can be viewed by the VFC staff at the time of the visit.
    v. Temperatures are saved and submitted in NJIIS for each storage unit.

- Upon receipt and review of your New Enrollment Questionnaire, you will be contacted by VFC staff to arrange for an enrollment site visit. All new VFC providers (first time participating) and returning providers (providers that have exited the program and are re-joining) must receive a VFC enrollment site visit. The purpose of the site visit is to ensure that providers and provider office staff are educated on the VFC program requirements and have appropriate resources to implement the requirements. Providers cannot receive vaccine until the site visit is completed.

ORDERING VACCINE

Enrolled providers are assigned an ordering frequency based on the size of their reported eligible population. Providers must submit their profile representing the population served by the practice/facility over the most recent 12 months. Providers must submit a current profile every 12 months or more frequently if:

- The number of children served changes, or
- The status of the facility changes during the calendar year.

The ordering frequency may be adjusted over time based on the number of administered doses reported in NJIIS, the amount of vaccine that a provider has in inventory, the amount of vaccine ordered, and the amount of vaccine wasted over time. Ordering frequency is assigned as follows:

- Monthly (Large: 2000+ doses/year) – every 30 days
- Bimonthly (Medium: 500 – 1999 doses/year) – every 60 days
    - January, March, May, July, September, November – OR –
    - February, April, June, August, October, December
- Quarterly (Small: 100 – 499 doses/year) – every 120 days
    - January, April, July, October – OR –
    - February, May, August, November – OR –
    - March, June, September, December
- As-is (As-is: 0 – 99 doses/year)

Please note that influenza vaccine can be supplied with your scheduled order or ordered independently in NJIIS during flu season.

The Medical Director is responsible for ensuring that his/her staff is ordering an appropriate amount of vaccine to vaccinate the provider's eligible population until the next scheduled order date. Medical Directors are encouraged to keep vaccine orders at a reasonable interval and level to reduce the risk of vaccine expiration and loss due to storage and handling issues. However, providers are expected to have enough vaccine on hand to cover anticipated and unanticipated delays in vaccine shipment (e.g., natural disasters that might interrupt deliver, holidays, unexpected ordering system outages). It is suggested that provides maintain a "buffer stock" for approximately 14 days.

To expedite the ordering process, providers should:

- Ensure vaccine doses administered are accurately recorded in NJIIS.
- Ensure that vaccine inventory is up-to-date.
- Place an order at the appropriate interval from the last order.
- Ensure accurate assessments of vaccine needs until the next scheduled order.

Providers order vaccines through NJIIS. When an order is placed through NJIIS, there will be a "quantity suggested" for each vaccine being ordered as well as the "inventory" on hand. The "quantity suggested" is based on the number of doses of vaccine administered as correctly recorded by the provider in NJIIS. Each administered dose that is correctly entered into NJIIS – either manually or through an interface with your electronic health record – will automatically decrement your NJIIS inventory. If all the doses administered are not entered correctly into NJIIS, the inventory will be greater than the actual vaccine doses in your storage units.

You can order a greater number of vaccines than the "quantity suggested" to ensure timely vaccination of your eligible population until the next order. However, providers are advised that, if the number of vaccine doses is significantly greater than the "quantity suggested," they indicate the reason for the discrepancy in the comment section. Adding a comment will help expedite the review of these orders by the VFC program. You can view the status of your order at any time through NJIIS.

Providers who face **unanticipated** vaccine shortages between scheduled orders can contact the VFC program by email to request additional vaccine doses. In cases of shortages, it is best to contact the VFC program to place a complete order for all vaccines rather than just the vaccines for which you are facing a shortage. With proper planning and oversight by the Medical Director, requests for additional vaccines between scheduled orders should be rare – particularly for sites that order monthly.

In certain circumstances, the VFC program might reduce or deny orders. Reasons for reducing or denying orders include, but are not limited to:

- Vaccine storage unit temperatures are not current and complete in NJIIS.
- Vaccine storage unit temperatures recorded in NJIIS are noted to be out-of-range.
- There is a large inventory on hand at the time the order is placed.
- There is a national shortage of a particular vaccine.
- Providers have not completed the re-enrollment process.

- Providers have not met requirements of the VFC program.

Figure 1. Example of Order Confirmation from NJIIS

ANNUAL RE-ENROLLMENT FOR EXISTING PROVIDERS

Providers are required to annually re-enroll with the VFC program. The re-enrollment application must be completed by the dates specified in order to remain active in the VFC program. Providers are required to annually:

- Submit their profile representing populations served by the practice/facility over the most recent 12 months. Provider must submit a current profile every 12 months or more frequently if:
  - -The number of children served changes, or
  - -The status of the facility changes during the calendar year.
- Submit the completed CDC-approved Provider Agreement. Providers are encouraged to complete the re-enrollment process as soon as the re-enrollment period opens.

IMPORTANT: Providers are encouraged to complete the re-enrollment process as soon as the re-enrollment period opens. Providers who fail to complete the required re-enrollment process by the designated deadline will be unable to order vaccines.

INACTIVATION DUE TO FAILURE TO ORDER VACCINE

Practices that participate in the VFC program are reviewed quarterly to determine activity. Practices that have not placed a vaccine order in over 365 days are considered to be inactive. Inactive practices will receive an email notifying them that they are inactive and will not be able to place any vaccine orders until they complete the following requirements:

- Demonstrate that the Primary and Backup Vaccine Coordinators have completed Vaccine Ordering and Management Training and Understanding VFC and 317 Webinar as a refresher of VFC program requirements, and
- Receive a scheduled storage and handling visit from the VFC program.

Upon completion of the requirements outlined above, practices will once again be able to order vaccine. If the practice remains inactive for an additional 6 months (total of 18 months), it will be terminated from the VFC program. Federally-funded vaccine will be removed from the office by VFC program staff.

PROVIDER DISENROLLEMENT

The VFC program is an at-will program with regard to provider participation and can be terminated by either party at any time, in accordance with the Provider Agreement. Providers wishing to disenroll, must complete the following:

- Complete the “Provider Disenrollment Request” (IMM30) form available through the NJIIS website.
- Ensure that you have entered all doses of federally-funded vaccine administered into NJIIS so that your inventory is up-to-date.
- Contact the VFC program to obtain verbal approval to transfer your vaccine to an approved, active VFC or 317 program provider. If you do not know a provider, the VFC program staff will provide you with a list of providers in the area who you can contact. Once you find a provider who will accept the vaccine, call or email the VFC program.
- Once you have received approval from the VFC program staff, complete the physical transfer of vaccine as well as a transfer from your NJIIS on-line inventory.
- It is the provider’s responsibility to ensure that the cold chain is maintained when transferring vaccines.

MODULE 4 - 317 PROGRAM PROVIDER ENROLLMENT

OVERVIEW

Section 317 of the Public Health Service Act authorizes the federal purchase of vaccines to vaccinate children, adolescents, and adults. Over its 50-year history, Section 317-purchased vaccine has been directed towards meeting the needs of priority populations, including uninsured and underinsured adults.

PURPOSE

This module describes provider enrollment, the enrollment process, and the 317 program requirements outlined on the Provider Agreement.

PROVIDER ELIGIBILITY

Providers must be eligible to enroll in the 317 program. The following eligibility criteria must apply:

- Provider signing the agreement as the Medical Director has the authority to sign on behalf of the entity and agrees to all program requirements, including participation in site visits and educational opportunities.
- Provider or provider staff are not included on the Office of the Inspector General List of Excluded Providers.
- Provider signing the Provider Agreement has a valid, active Medical License issued by the New Jersey State Board of Medical Examiners and can administer vaccines under state law.
- Provider has the capacity to order, receive, and manage public vaccine, including proper vaccine storage and temperature monitoring.
- Provider represents a Not-for Profit Organization, a Public Health Department, or a FQHC.

MEDICAL DIRECTOR RESPONSIBILITIES

The Medical Director will be held accountable for 317 program compliance for the entire organization. The responsibilities include, but are not limited to, the following:

- Annually submit a provider profile representing populations served by the practice/facility. Providers must submit the profile more frequently if the number of adults changes, or the status of the facility changes during the calendar year.
- Screen patients and document eligibility status at each immunization encounter for 317 program eligibility and administer federally-purchased vaccine by such category only to adults who are 19 years of age or older who are 317 eligible as outlined in Module 2.
- Offer all ACIP-recommended vaccines for adults and comply with the immunization schedules, dosages, and contraindications that are established by the ACIP unless:
    - In the providers medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the adult.
    - The particular requirements contradict state law, including laws pertaining to religious or other exemptions.

- Ensure that all records related to the 317 program are maintained and available for production for a minimum of three years.
- Ensure that no charges are billed for publicly supplied vaccine administered to 317 program eligible adults.
- Agree to not charge a vaccine administration fee that exceeds the set administration fee cap per vaccine (not per antigen).
- Agree to not deny administration of a publicly-purchased vaccine to an adult who is unable to pay the administration fee.
- Ensure that the current VIS is distributed each time a vaccine is administered and maintain record in accordance with the NCVIA, which includes reporting clinically significant adverse events to the VAERS.
- Agree to comply with the requirements for vaccine management, including:
    - Ordering vaccine and maintaining appropriate vaccine inventories.
    - Not storing vaccine in dormitory-style units at any time.
    - Storing vaccine under conditions specified by the CDC at all times. Refrigerator and freezer storage units and temperature monitoring equipment and practices must meet the VFC storage and handling requirements.
    - Returning all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration.
- Agree to participate in 317 program compliance site visits including unannounced visits, and other educational opportunities associated with 317 program requirements.
- Agree to replace vaccine purchased with federal funds that are deemed non-viable due to provider negligence on a dose-for-dose basis. Providers are expected to notify and revaccinate, at their own cost, any adult who received compromised or potentially compromised vaccine due to provider negligence.
- Agree to register as a provider with NJIIS and enter all doses of federally-funded vaccine administered into the NJIIS within 30 days of administration (regardless of the age of the patient). In addition, agree to enter all vaccine doses administered into the NJIIS in accordance with N.J.A.C. 8:57-3. All providers administering vaccines to children less than 7 years of age must enter the vaccine doses into NJIIS within 30 days of administration.
- Understand that the provider or the VFC program may terminate the Provider Agreement at any time and that all unused federally-funded vaccine must be returned to the VFC program upon termination.
- Ensure that all healthcare providers (PA, NP, MD, and DO) in the enrolled practice – and their corresponding professional license numbers – are listed on the provider profile.
- Designate, train, and oversee a Primary Vaccine Coordinator and a Backup Vaccine Coordinator (responsibilities of Coordinators are outlined in **Module 4 – Vaccine Management**).
- Submit a "Request to Update Provider Information" (IMM-48) whenever there is a change in the Primary or Backup Vaccine Coordinators or office delivery hours during the enrollment year.

NEW PROVIDER ENROLLMENT

- Providers wishing to enroll in the 317 program must complete the forms (*Vaccines for Children Program Provider Enrollment Package Adult*) below available through the NJIIS website. Forms can be emailed or faxed to the VFC program.
    - **VFC New Provider Enrollment for Adult Site (IMM-18)**
      This form captures information about the practice, and the number of 317 program eligible and non-eligible adults served by providers. It helps the VFC program determine how much vaccine will need to be supplied through the 317 program and compare projected vaccine needs with actual vaccine orders and inventory.
    - **New Provider Agreement for Adult Sites (IMM-25)**
      This CDC-approved form documents the provider's agreement to comply with the requirements of the 317 program in order to receive federally-funded vaccine.
- Providers with more than one office location can associate additional offices by entering the additional locations on the New Provider Enrollment for Adult Site (IMM-18) form. Each office location that administers federally-funded vaccine must have a PIN number. A provider cannot transport federally-funded vaccine from one office location to another. Providers with offices outside of New Jersey cannot associate those offices with the 317 Program. Contact the VFC program in the jurisdiction where your office is located.

WHAT TO EXPECT AFTER SUBMITTING YOUR NEW PROVIDER ENROLLMENT

- Once your paperwork is processed, the VFC program will send a "Welcome Letter" to the email address provided. This letter will include your PIN; a separate PIN will be issued for each office location associated with the Medical Director.
- Providers must complete a New Enrollment Questionnaire for each office location. Providers must:
    - Indicate the names of the Primary and Backup Vaccine Coordinators and the dates that each completed the required NJIIS and Vaccine Ordering and Management in NJIIS training.
    - Indicate the Certificate/Serial Number of each of the dataloggers (and required backup datalogger) and the expiration date; Certificates of Calibration must be submitted.
    - Indicate the type of storage units in use in the office.
    - Ensure the following:
        i. DDL probes are centrally placed in each storage unit.
        ii. The Vaccine Management Policy Template is completed.
        iii. All VIS are current
        iv. Vaccine temperatures are tracked for each unit for at least two business weeks using the temperature log template found at the Immunization Action Coalition website. Datalogger data must be downloaded prior to the visit so that it can be viewed by the VFC staff at the time of the visit.
        v. Temperatures are saved and submitted in NJIIS for each storage unit.

- Upon receipt of your New Enrollment Questionnaire, you will be contacted by VFC staff to arrange for an enrollment site visit. All new 317 program providers (first time participating) and returning providers (providers that have exited the program and are re-joining) must receive an enrollment site visit. The purpose of the site visit is to ensure that providers and provider office staff are educated on the program requirements and have appropriate resources to implement the requirements. Providers cannot receive vaccine until the site visit is completed.

ORDERING VACCINE

Enrolled providers are assigned an ordering frequency based on the size of their reported eligible population. Providers must submit their profile representing the population served by the practice/facility over the most recent 12 months. Providers must submit a current profile every 12 months or more frequently if:

- The number of children served changes, or
- The status of the facility changes during the calendar year.

The ordering frequency may be adjusted over time based on the number of administered doses reported in NJIIS, the amount of vaccine that a provider has in inventory, the amount of vaccine ordered, and the amount of vaccine wasted over time. Ordering frequency is assigned as follows:

- Monthly (Large: 2000+ doses/year) – every 30 days
- Bimonthly (Medium: 500 – 1999 doses/year) – every 60 days
    - January, March, May, July, September, November – OR –
    - February, April, June, August, October, December
- Quarterly (Small: 100 – 499 doses/year) – every 120 days
    - January, April, July, October – OR –
    - February, May, August, November – OR –
    - March, June, September, December
- As-is (As-is: 0 – 99 doses/year)

Please note that influenza vaccine can be supplied with your scheduled order or ordered independently in NJIIS during flu season.

The Medical Director is responsible for ensuring that his/her staff is ordering an appropriate amount of vaccine to vaccinate the provider's eligible population until the next scheduled order date. Medical Directors are encouraged to keep vaccine orders at a reasonable interval and level to reduce the risk of vaccine expiration and loss due to storage and handling issues. However, providers are expected to have enough vaccine on hand to cover anticipated and unanticipated delays in vaccine shipment (e.g., natural disasters that might interrupt deliver, holidays, unexpected ordering system outages). It is suggested that provides maintain a "buffer stock" for approximately 14 days.

To expedite the ordering process, providers should:

- Ensure vaccine doses administered are accurately recorded in NJIIS.
- Ensure that vaccine inventory is up-to-date.

- Place an order at the appropriate interval from the last order.
- Ensure accurate assessments of vaccine needs until the next scheduled order.

Providers order vaccines through NJIIS. When an order is placed through NJIIS, there will be a "quantity suggested" for each vaccine being ordered as well as the "inventory" on hand. The "quantity suggested" is based on the number of doses of vaccine administered as correctly recorded by the provider in NJIIS. Each administered dose that is correctly entered into NJIIS – either manually or through an interface with your electronic health record – will automatically decrement your NJIIS inventory. If all the doses administered are not entered correctly into NJIIS, the inventory will be greater than the actual vaccine doses in your storage units.

You can order a greater number of vaccines than the "quantity suggested" to ensure timely vaccination of your eligible population until the next order. However, providers are advised that, if the number of vaccine doses is significantly greater than the "quantity suggested," they indicate the reason for the discrepancy in the comment section. Adding a comment will help expedite the review of these orders by the VFC program. You can view the status of your order at any time through NJIIS.

Providers who face **unanticipated** vaccine shortages between scheduled orders can contact the VFC program by email to request additional vaccine doses. In cases of shortages, it is best to contact the VFC program to place a complete order for all vaccines rather than just the vaccines for which you are facing a shortage. With proper planning and oversight by the Medical Director, requests for additional vaccines between scheduled orders should be rare – particularly for sites that order monthly.

In certain circumstances, the VFC program might reduce or deny orders. Reasons for reducing or denying orders include, but are not limited to:

- Vaccine storage unit temperatures are not current and complete in NJIIS.
- Vaccine storage unit temperatures recorded in NJIIS are noted to be out-of-range.
- There is a large inventory on hand at the time the order is placed.
- There is a national shortage of a particular vaccine.
- Providers have not completed the re-enrollment process.
- Providers have not met requirements of the VFC program.

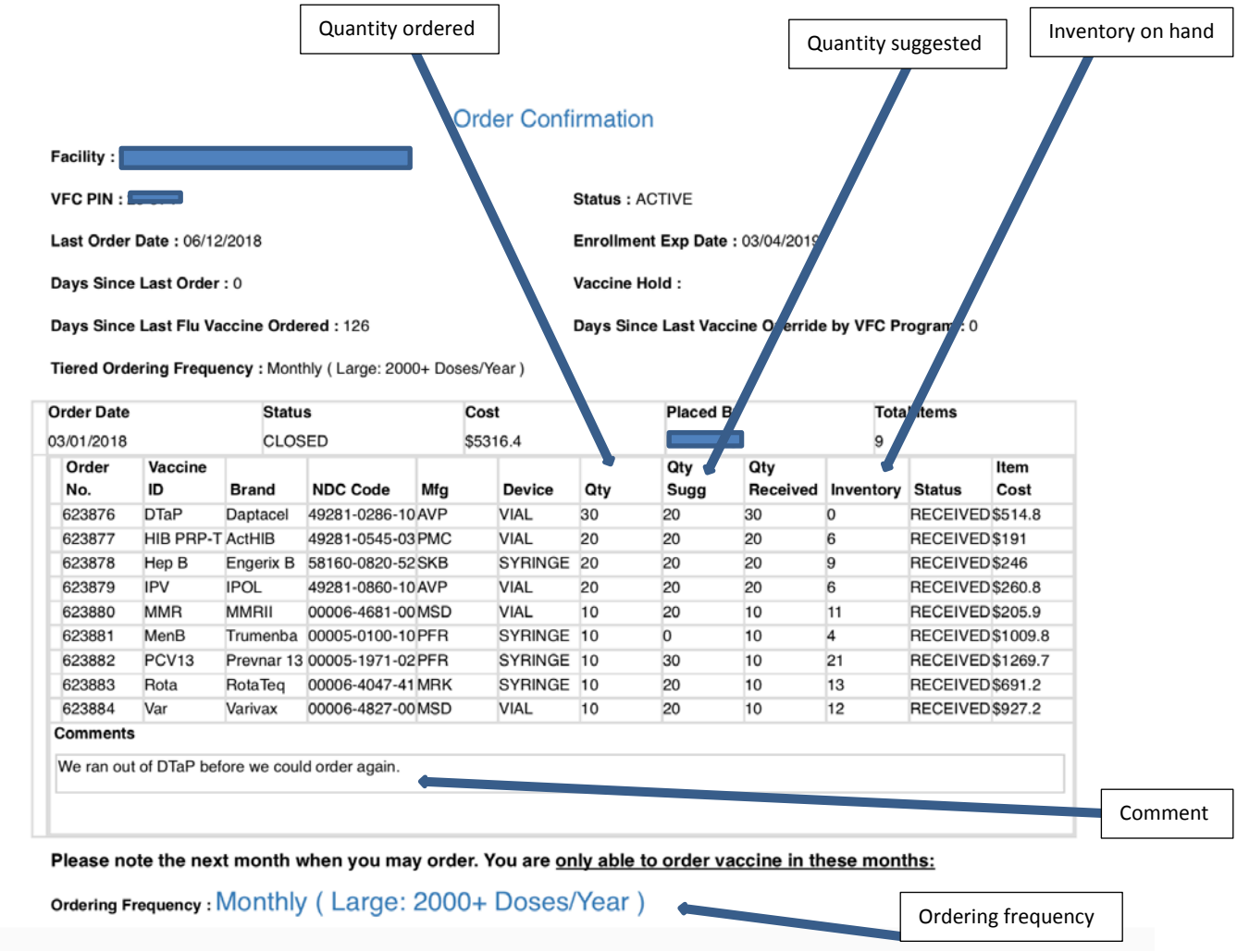


Figure 2. Example of Order Confirmation from NJIIS

ANNUAL RE-ENROLLMENT FOR EXISTING PROVIDERS

Providers are required to annually re-enroll with the 317 program. The re-enrollment application must be completed by the dates specified in order to remain active in the 317 program. Providers are required to annually:

- Submit their profile representing populations served by the practice/facility over the most recent 12 months. Provider must submit a current profile every 12 months or more frequently if:
  - -The number of children served changes, or
  - -The status of the facility changes during the calendar year.
- Submit the completed CDC-approved Provider Agreement. Providers are encouraged to complete the re-enrollment process as soon as the re-enrollment period opens.

IMPORTANT: Providers are encouraged to complete the re-enrollment process as soon as the re-enrollment period opens. Providers who fail to complete the required re-enrollment process by the designated deadline will be unable to order vaccines.

INACTIVATION DUE TO FAILURE TO ORDER VACCINE

Practices that participate in the 317 program are reviewed quarterly to determine activity. Practices that have not placed a vaccine order in over 365 days are considered to be inactive. Inactive practices will receive an email notifying them that they are inactive and will not be able to place any vaccine orders until they complete the following requirements:

- Demonstrate that the Primary and Backup Vaccine Coordinators have completed IMODS and NJIIS as a refresher of program requirements, and
- Receive a visit from the VFC program.

Upon completion of the requirements outlined above, practices will once again be able to order vaccine. If the practice remains inactive for an additional 6 months (total of 18 months), it will be termination from the program. Federally-funded vaccine will be removed from the office by VFC program staff.

PROVIDER DISENROLLEMENT

The 317 program is an at-will program with regard to provider participation and can be terminated by either party at any time, in accordance with the Provider Agreement. Providers wishing to disenroll, must complete the following:

- Complete the “Provider Disenrollment Request” (IMM30) form available through the NJIIS website.
- Ensure that you have entered all doses of federally-funded vaccine administered into NJIIS so that your inventory is up-to-date.
- Contact the VFC program to obtain verbal approval to transfer your vaccine to an approved, active VFC or 317 program provider. If you do not know a provider, the VFC program staff will provide you with a list of providers in the area who you can contact. Once you find a provider who will accept the vaccine, call or email the VFC program.
- Once you have received approval from the VFC program staff, complete the physical transfer of vaccine as well as a transfer from your NJIIS on-line inventory.
- It is the provider’s responsibility to ensure that the cold chain is maintained when transferring vaccines.

MODULE 5 – VACCINE MANAGMENT

OVERVIEW

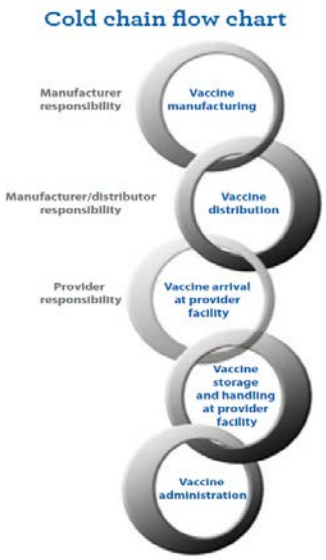
The management of publicly purchased vaccine is one of the most important activities for providers. It is essential for providers to ensure that all staff are educated in proper vaccine ordering, inventory maintenance, and storage and handling practices. Performing proper vaccine storage and handling procedures will ensure the cold chain is maintained at the provider's office. Sound vaccine management practices will minimize vaccine loss and waste, and the potential need to revaccinate patients who received compromised vaccines.

PURPOSE

This module describes the required vaccine management and storage and handling policies of the VFC program, and summarizes the best practices recommended in CDC's Vaccine Storage and Handling Toolkit. For detailed vaccine storage and handling information, please refer to the CDC Vaccine Storage and Handling Toolkit. This document outlines guidance and best practices for all healthcare providers and represents the standards that must be met for all 317 and VFC providers.

INTRODUCTION TO VACCINE MANAGEMENT AND THE VACCINE COLD CHAIN

Vaccine management is a broad term intended to describe the storage and handling practices that should be followed by providers. Providers must understand and must ensure that all staff understand program requirements and best practices for proper vaccine ordering, inventory, and storage and handling.



The Vaccine 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 and delivery to and storage at the provider facility, and ends with administration of vaccine to the patient. Appropriate storage and handling conditions must be maintained at every link in the cold chain.

Too much exposure to heat, cold, or light at any step in the cold chain can damage vaccines, resulting in loss of potency. **While exposure to any inappropriate conditions can affect potency of refrigerated vaccines, a single exposure to freezing temperatures (0°C/32°F or colder) will destroy some.** Liquid vaccines that contain an adjuvant can permanently lose potency when exposed to freezing temperatures. Once lost, potency cannot be restored. Each time vaccines are exposed to improper conditions, potency is reduced further. Eventually, if the cold chain is not properly maintained, potency

will be lost completely, and vaccines will be useless. Vaccine storage and handling requirements and recommendations are in place to ensure the cold chain is maintained.

EDUCATION ON VACCINE STORAGE AND HANDLING AND PROGRAM REQUIREMENTS

The Medical Director will be held accountable for program compliance for the entire organization. The VFC program provides education during the new provider site visit and all subsequent site visits. The VFC program also requires Primary and Backup Vaccine Coordinators to complete educational programs annually. However, it is ultimately the Medical Director's responsibility to ensure that all staff members who receive deliveries and/or handle or administer vaccines are familiar with storage and handling policies and procedures at the facility. Make sure all policies are accessible to staff. Privately purchased vaccines should be handled in accordance with the standards outlined in the manufacturers' instructions and the CDC's Vaccine Storage and Handling Toolkit.

CDC recommends that providers should offer storage and handling training to staff:

- As part of new employee orientation,
- Annually as a refresher for all staff involved in immunization and vaccine storage and handling activities,
- Whenever new vaccines are added to the inventory, and
- Whenever recommendations for storage and handling of vaccines are updated.

It is recommended that you record the names of trainings, dates, and participants. **CDC offers online training modules through their website titled "You Call the Shots."**

VACCINE COORDINATORS

The VFC program requires that providers designate a Primary and Backup Vaccine Coordinator. These Coordinators must be fully trained in routine and emergency policies and procedures. Coordinator responsibilities include:

- Ordering vaccines,
- Overseeing proper receipt and storage of vaccine deliveries,
- Documenting vaccine inventory information,
- Organizing vaccines within storage units,
- Setting up temperature monitoring devices,
- Checking and recording minimum/maximum temperatures at the start of each workday,
- Checking current storage unit temperatures prior to accessing and administering vaccine,s
- Reviewing and analyzing temperature data at least weekly for any shifts in temperature trends,
- Rotating stock at least weekly so vaccines with the earliest expiration dates are used first,
- Removing expired vaccine from storage units,
- Responding to temperature excursions (out-of-range temperatures),

- Maintaining all documentation, such as inventory and temperature logs for a minimum of 3 years,
- Ensuring staff is properly trained,
- Having familiarity with the CDC's Storage and Handling Toolkit,
- Monitoring operation of storage equipment and systems,
- Overseeing proper vaccine transport (when necessary), and
- Overseeing emergency preparations such as tracking inclement weather conditions, and ensuring appropriate handling of vaccines during disasters and power outages.

The Primary and Backup Coordinators, designated by the Medical Director, serve as the liaisons with the VFC program and must be consistently present during normal business hours. The VFC program requires that, at a minimum, the Primary and Backup Coordinators complete annual training (every 12 months). In order to satisfy the annual training requirement, Coordinators must complete:

- Both the "You Call the Shots" - Vaccines for Children AND Vaccine Storage and Handling modules available through the CDC's website; OR
- NJ VFC program "Understanding VFC & Adult 317 Webinar"; OR
- Attend the New Jersey Immunization Conference "Storage and Handling" Workshop.

Coordinators in newly enrolled practices will also need to take the following trainings prior to the initial site visit to the practice:

- NJIIS Fundamentals training, and
- Vaccine Ordering and Management in NJIIS training.

Trainings can be accessed through the NJIIS website.

Proof of completion of the trainings must be emailed to the VFC program.

VACCINE MANAGEMENT POLICY

Providers must develop a Vaccine Management Policy. A template is available through the NJIIS website.

- Customize the template to meet your needs.
- The Vaccine Management Plan should contain plans and information for three major areas:
    - **General information** – include contact information for vaccine manufacturers, equipment service providers, and important facility staff, as well as job descriptions, regularly used forms, and staff training requirements. This section should have:
        - Contact information for:
            - Primary and Backup Vaccine Coordinator,
            - Additional staff to assist in emergencies,
            - VFC program,
            - Vaccine manufacturers,
            - Utility/power company,

        - Vaccine storage unit alarm company,
        - Generator repair company, and
        - Sources for qualified containers and pack-outs.
    - Descriptions of roles and responsibilities of Primary/Backup Vaccine Coordinators.
    - Information for each storage unit, including serial number, link to equipment websites, installation dates, and routine maintenance records.
    - Samples of all vaccine-related forms used in your facility.
    - Protocols for staff education and training.
- **Routine storage and handling policies** – include information for all aspects of vaccine inventory management, from ordering to monitoring storage conditions. This section should include information about:
    - Ordering and accepting vaccine deliveries,
    - Receiving and unpacking deliveries,
    - Managing inventory,
    - Storage requirements,
    - Placing vaccines and diluents in storage units,
    - Handling vaccines prior to administration,
    - Disposing of vaccines and supplies,
    - Monitoring storage unit and temperature,
    - Maintaining storage equipment and DDLs,
    - Responding to storage and handling problems, and
    - Transporting vaccines to off-site clinics.
- **Emergency vaccine storage, handling, and transport policies** – outline steps to be taken in the event of equipment malfunctions, power failures, natural disasters, or other emergencies that might compromise vaccine storage conditions. This section should include the following information:
    - A primary and alternate staff contact for each type of emergency (e.g., power outage, weather conditions, equipment failure), as well as designated drivers for transporting vaccines and transport vehicle information.
    - Name and numbers for companies or private drivers to transport vaccines to alternative vaccine storage facilities.
    - Sources of qualified containers and pack-outs and calibrated DDL.
    - Vaccine storage unit specifications, including brand name, model number, serial number, and maintenance and repair company contract information.
    - A facility floor diagram showing the locations of important elements, including doors, flashlights, spare batteries, keys, locks, circuit breakers, and packing materials.
    - Protocols for:
        - Monitoring vaccines during a power outage,
        - Packing vaccines and diluents for emergency transport,

- Transporting vaccines to and from an alternative vaccine storage facility,
- Assessing whether vaccine can be used after an emergency, and
- Accessing your building and facility after hours.

- Post the policy near your storage units or in a ready accessible area.
- Ensure that all staff members are trained to the policy and understand their role in vaccine management including clerical staff who might sign for packages upon delivery.
- The plan should be reviewed and updated at least annually or any time there is a change in staff responsible for vaccine management or a change in policies.
- The plan must be signed by the Medical Director and the Primary and Backup Vaccine Coordinators.
- The plan must have a "last review date" to verify that the plan was updated within the last 12 months.

STORAGE UNITS (REFRIGERATORS AND FREEZERS)

Refrigerators and freezers typically used for vaccine storage are available in different grades (household and purpose-built) and types (stand-alone and combination refrigerator/freezer). In addition to traditional refrigeration units, there are also purpose-built, auto-dispensing units without doors.

Purpose-built units are sometimes referred to as "pharmaceutical grade" and are designed specifically for storage of biologicals. These units often have:

- Microprocessor-based temperature control with a digital temperature sensor (thermocouple, resistance temperature detector, or thermistor).
- Fan-forced air circulation with powerful fans or multiple cool air vents inside the unit that promote uniform temperature and fast temperature recovery.

CDC recommends (see Figure 1. for acceptable storage units):

- Use of purpose-built units designed to either refrigerate or freeze (can be compact, under-the-counter-style or large units).
- If a purpose-built unit is not available, use a stand-alone household unit.
- If you must use a household-grade, combination refrigerator/freezer unit, only use the refrigerator compartment for storing vaccines. These units have cold spots and temperature fluctuations, and air circulating from the freezer could expose refrigerated vaccines to freezing temperatures. If you are using only the refrigerator section of a household combination unit, leave the freezer on at the factory set or midpoint temperature setting. Use a separate stand-alone freezer unit to store frozen vaccines.
- **Never store any vaccine in a dormitory style or bar-style combined refrigerator/freezer unit under any circumstances.** These units have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment. These units have been shown to pose a significant risk of freezing vaccines, even when used for temporary storage. Not

all small units are dormitory or bar-style units. Compact, purpose-built units for biologicals can be used to store vaccine. See Figure 2. for an unacceptable storage unit.

- Make sure the storage unit has enough space to store the largest inventory you might have at the busiest point in the year (e.g., flu season) without crowding.
- Use safeguards to ensure the doors of the unit remain closed (for example, self-closing door hinges, door alarms).

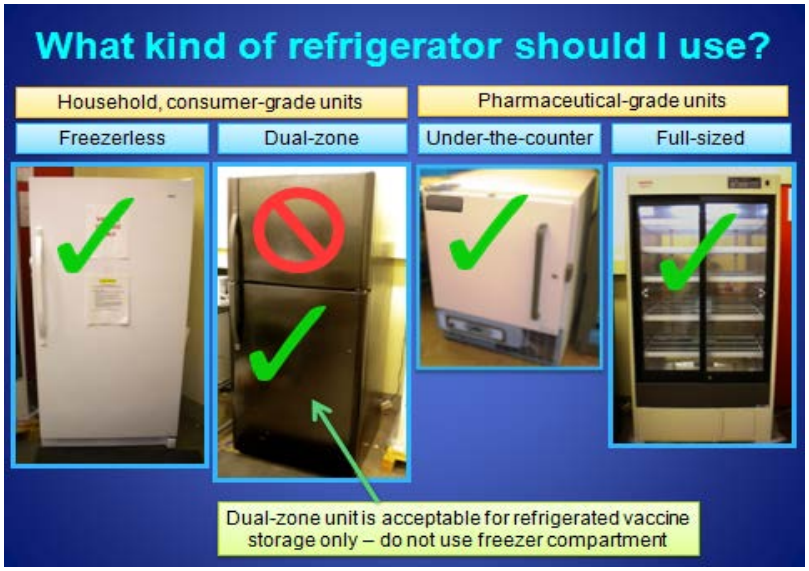


Figure 1. Acceptable Storage Units

Figure 2. Unacceptable Storage Unit

DIGITAL DATA LOGGERS

As of January 1, 2018, the CDC and the VFC program require the use of a specific type of temperature monitoring device known as a DDL for continuous temperature monitoring and recording. Unlike a simple minimum/maximum thermometer, which only shows the coldest and warmest temperatures reached in a unit, DDLs provide detailed information on all temperatures recorded at preset intervals.

An accurate temperature history that reflects actual vaccine temperatures is critical for protecting vaccines. Every vaccine storage unit must have a DDL and investing in a reliable device is less expensive than replacing vaccines wasted due to inaccurate temperature monitoring. Temperatures data from a DDL can be downloaded to a computer or retrieved from a website. Reviewing DDL data is critical for vaccine safety. **The best DDL won't protect vaccines if providers and their staff have not correctly set up the device, do not routinely respond to alarms, do not review the temperature data regularly, and do not act when problems are identified. It is highly recommended that the Medical Director ensures that the staff is using these devices correctly and to their fullest to protect vaccine.**

Your facility must have a DDL for:

- Each storage unit containing federally-funded vaccine,

- Each emergency transport unit (this is particularly important if there are more transport units than storage units), and
- At least one backup DDL in case a primary device malfunctions or is out for calibration testing (make sure the backup device has a different calibration testing schedule than the primary device).

DDLs must have the following features:

- Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon).
- Alarm for out-of-range temperatures.
- An active temperature display that can be easily read from outside the uni.,
- Low battery indicator.
- Current, minimum, and maximum display.
- Accuracy of +/-0.5°C (+/-1°F).
- Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures at set intervals. **The DDL must be set to record the temperatures at least every 30 minutes.**
- Current and valid Certificate of Calibration Testing (also known as Report of Calibration). This certificate must include:
    - Model/device name or number,
    - Serial number,
    - Date of calibration (report or issue date). Units are usually certified for 1 – 2 years and then must be recalibrated; **the expiration date for the calibration certificate must not exceed 2 years from calibration date**,
    - Confirmation that the instrument passed testing, and
    - Documented accuracy of +/-0.5°C (+/-1°F).

  To determine if a Certificate of Calibration Testing (also known as Report of Calibration) was issued by an appropriate entity, check to see if the certificate indicates one or more of the following items about calibration:

    - Conforms to International Organization for Standardization (ISO/International Electrotechnical Commission (IEC) 17025 international standards for calibration testing and traceability,
    - Traceable to the standards maintained by the National Institute of Standards and Technology (NIST),
    - Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 Tolerance Class F (<+/-0.5°C or <+/-1°F),
    - Performed by a laboratory accredited by International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body
        - A list of ILAC/MRA signatories may be found at ILAC.org/ILAC-MRA-and-signatories.

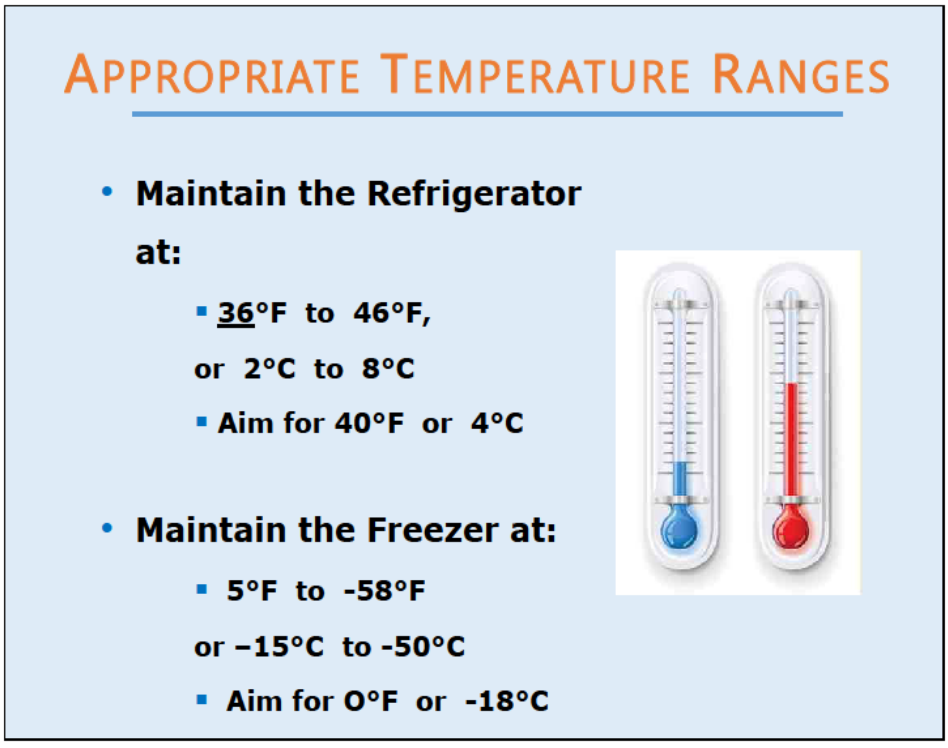
Be sure to check with the manufacturers of your DDL to determine the frequency with which batteries need to be changed. Also, be sure the date and time are updated for daylight savings time.

VACCINE STORAGE TEMPERATURES

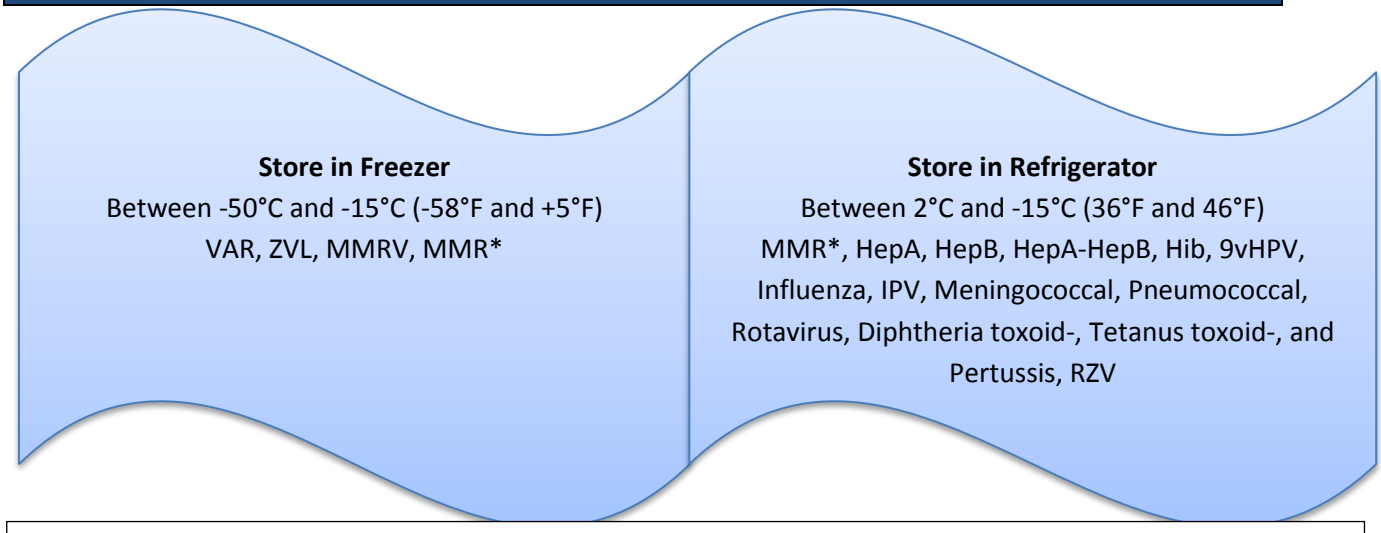
Refrigerated vaccines must be stored at temperatures between 2°C and 8°(36°F and 46°F) and vaccines stored in the freezer between -50°C and -15°C (-58°F and +5°F) at all times.

It is important to follow manufacturer vaccine product specifications found in the package insert. The package insert describes the required storage conditions for a particular vaccine. Manufacturers have access to internal (unpublished) thermostability data concerning the impact of exposures to inappropriate temperatures or light for each vaccine lot.

Providers must contact the manufacturer directly with questions about a specific vaccine storage temperature or temperature excursion. Always request written responses from manufacturers when requesting assistance.



SETTING UP YOUR STORAGE UNITS

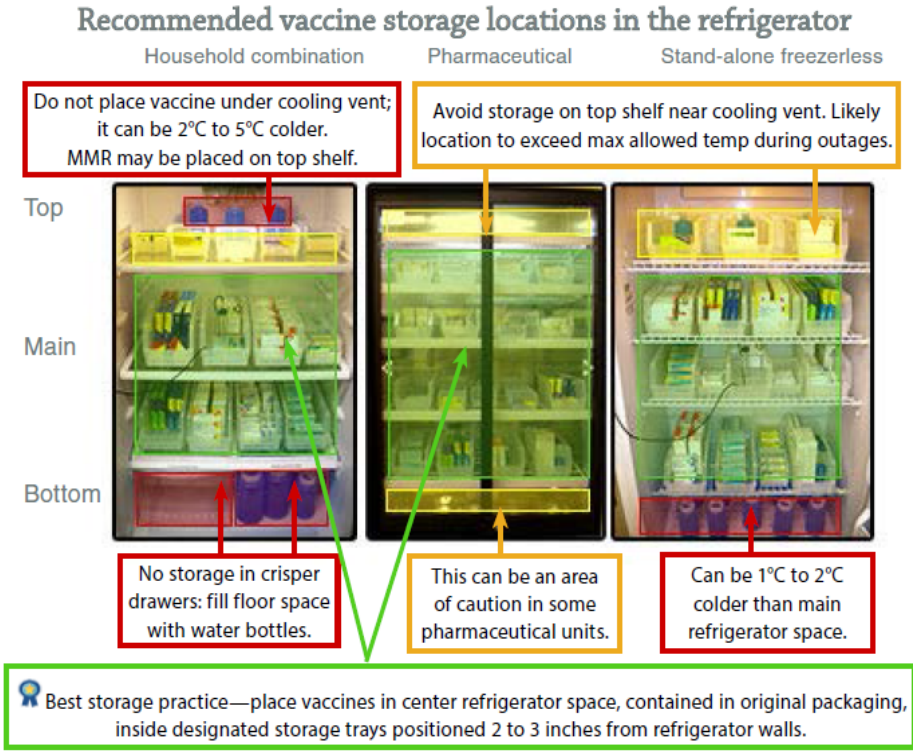


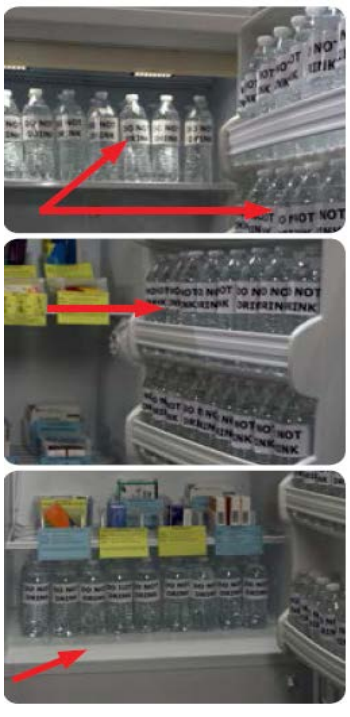
Protect the following vaccines from light: Varivax, Zostavax, ProQuad, MMR, Hiberix, Gardasil9, Afuria, FLUAD, Fluarix, Flublok, Flucelvax, FluLaval, Fluvirin, Flumist, IPOL, Menveo, Bexsero, Rotarix, RotaTeq, Shingrix
*Unreconstituted MMR may be frozen or refrigerated

- The power source of all vaccine storage equipment must be protected by means of warnings on outlets and circuit breakers. **Post "DO NOT UNPLUG" signs to alert staff, custodians, electricians, and other workers not to unplug the unit.** If your building is owned by a third party and you do not have access to circuit breakers, work with your building manager. Units must be plugged directly into an outlet; never plug a unit into a surge protector.
- It takes time for temperatures to stabilize in a new or repaired refrigeration unit. **The VFC Program requires that you have recorded temperatures within the recommended ranges for 5 business days and to submit those temperatures to the VFC program prior to placing vaccine in the unit.**
- Consider purchasing a backup generator for if your facility does not currently have one.
- Remove any deli, fruit, and vegetable drawers from refrigeration units. This provides extra space for water bottles to help maintain stable temperatures and prevents use of the drawers for storing food, beverages, or vaccines.
- Always store vaccines in their original packaging with lids closed until ready for administration. Never store loose vials or manufacturer-filled syringes outside of their packaging.
- Place water bottles on the top shelf and floor and in the door racks. Putting water bottles in the unit can help stabilize temperatures. It also can help prevent vaccines from being stored in areas where there is a greater risk of temperature excursions (such as the top shelf, floor, and door). Label all water bottles "DO NOT DRINK." Pharmaceutical grade units may have specific guidance on the use of water bottles; be sure to check the manufacturers' instructions.
- Whenever possible, store diluent with the corresponding refrigerated vaccine:
    - Some diluents contain antigen or an adjuvant (refer to manufacturer's package insert for guidance on storage and handling.

- Some diluents can be stored at room temperature (no warmer than 25°C (77°F).

- Store each type of vaccine and diluent in a separate container.
- Attach labels to shelves and containers to clearly identify where each type of vaccine and diluent is stored.
- Store vaccines and diluents with similar names (e.g., DTaP and Tdap or Hib and HepB) or with both pediatric and adult formulations on different shelves to minimize the risk of administration errors. Make sure to label the formulation "pediatric" or "adult," if applicable.
- Place vaccines and diluents in the center of the unit, 2 to 3 inches away from walls, ceiling, floor, and door. Avoid storing vaccines and diluents in any part of the unit that may not provide stable temperatures or sufficient air flow, such as directly under cooling vents, in drawers, or in shelves on the door.
- Place vaccines and diluents with the earliest expiration dates in from of those with later expiration dates.
- Do not pack a storage unit too tightly.
- Food and beverages must never be stored in the unit with vaccines.
- If other medications and biological products must be stored in the same unit as vaccines, never store these products in the same container with vaccines. Always store them below vaccines on a different shelf.
- Never store blood, body fluid, stool, or other clinical specimens in the same storage unit as vaccines.





PLACEMENT OF DIGITAL DATA LOGGER

- Place the buffered probe of the DDL in the center of the unit with vaccines surrounding it.
- Place the active digital display on the outside of the unit so temperatures can be checked without opening the door.
- Be sure that your data logger is set to measure and record at least every 30 minutes.

MONITORING STORAGE UNIT TEMPERATURES

- Check and record storage unit minimum and maximum temperatures at the start of each workday. The min/max recorded must be the those obtained since the last workday when the min/max temperatures were reset.
- A temperature monitoring log sheet (available through the Immunization Action Coalition website) should be placed on each storage unit door (or nearby), and **the following information must be recorded daily**:
    - Min/max temperature,
    - Date,
    - Time,
    - Name or initials of person who checked and recorded the temperatures, and
    - Any actions taken if a temperature excursion occurred.

  NOTE: If this information is entered into NJIIS daily, paper logs are not required.

- **Download the DDL data at least once a week, whenever the alarm sounds, and whenever out-of-range min/max or current temperatures are noted.** Review this data carefully along with the recorded daily min/max temperatures. IMMEDIATELY TAKE ACTION IF ANY OUT-OF-RANGE TEMPERATURES ARE NOTED! – even if the current temperature is in range, vaccine in the storage unit at the time of the excursion may have been compromised. You should also look for trends in temperatures - even if all the temperatures are in range. You might want to adjust the storage unit thermostat based on the trends to prevent temperature excursions. (e.g., you note that temperatures of the refrigerator are frequently reaching 36°F. In this case, you might want to adjust the thermostat of the refrigerator to make it a bit warmer. If the temperature reaches below 36°F, then it would be considered out-of-range and might potentially compromise vaccine. Raising the temperature of the unit slightly might prevent the vaccines from being exposed to temperatures below the recommended range.)

HANDLING A TEMPERATURE EXCURSION (OUT-OF-RANGE TEMPERATURE)

Any temperature reading outside ranges recommended by the manufacturers' package inserts is considered a temperature excursion and must be immediately addressed. Temperature excursions or inappropriate conditions for any vaccine require immediate action.

- Any staff member who hears an alarm or notices a temperature excursion on the DDL should notify the Primary or Backup Vaccine Coordinator, the Medical Director, or someone well-trained in vaccine management.
- If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause.
- Label all exposed vaccines, "DO NOT USE," and isolate (quarantine) them from other vaccines in the storage unit. DO NOT DISCARD THESE VACCINES.
- DO NOT USE THE VACCINES UNTIL YOU OBTAIN VIABILITY INFORMATION FROM THE VACCINE MANUFACTURER AND YOU RECEIVE APPROVAL FROM THE VFC PROGRAM.
- The Vaccine Coordinator, Medical Director, or other well-trained individual should begin to document the event with the following information:
    - Date and time of the temperature excursion
    - Storage unit temperature and room temperature, if available (including min/max temperatures during the time of the event, if available)
    - Name of person completing the report
    - Description of the event (some of this information can be gathered after vaccines are safely in a storage unit with temperatures within the recommended range)
        - General description (i.e., what happened)
        - Inventory of affected vaccine including lot numbers
        - If using a DDL, download the data to determine the length of time vaccines may have been exposed to out-of-range temperatures
        - List items in the unit (including water bottles) other than vaccines
        - Any problems with the storage unit and/or affected vaccines before the event
        - Other relevant information
- Implement your facility's policies to evaluate the temperature excursion and bring the unit into the recommended temperature range. Depending on the situation, corrective actions might include, but are not limited to:
    - Ensuring that the door of the unit is closed.
    - Ensuring that the DDL probe is in the center of the vaccines.
    - Ensuring that the storage unit is plugged in and that there is power to the unit.
- Implement your policy for adjusting the storage unit temperatures. Bring the unit into the recommended range of temperatures or move the vaccines to another unit that is operating within the recommended range. Be sure to maintain the cold chain when transporting vaccines.
- Notify the VFC program of the temperature excursion within one business day by calling or emailing the VFC program. You will be provided with the New Jersey Viability Investigation for Federally Funded Vaccines form to complete**.** In addition to the completed form, you will need to provide the VFC program with:
    - Copies of the paper temperature logs if temperatures are not entered into NJIIS daily
    - Downloaded DDL records for 14 days prior to the excursion. Additional information may be required depending on the circumstances.

- Notify the manufacturers of the affected vaccines. In general, the manufacturers analyze information about the magnitude of the temperature excursion and the total amount of time that temperatures were out-of-range, as well as information about the vaccine in question to determine whether a vaccine is likely to still be viable. **Be sure to get their determination in writing as you will need to provide this information to the VFC program.**
- Upon review and confirmation of the manufacturer's determination of viability, the VFC program will give permission to use the vaccines that were marked, "DO NOT USE." In some cases, the manufacturer may issue a new beyond-use date. This means that the vaccine will expire before the date marked on the vial. Be sure to mark the vial with the new beyond-use date and dispose of the vaccine if unused at the close of business on that date.
- A provider's ability to order vaccines is usually suspended when a temperature excursion is discovered until the situation is resolved. Timely submission of all required information will facilitate resolution and decrease the time vaccine ordering privileges are suspended.
- Return to McKesson any vaccine determined to be non-viable by the manufacturers.

ADJUSTING STORAGE UNIT TEMPERATURES

Storage unit temperatures will likely need to be adjusted over time.

- Thermostat adjustments should only be made by well-trained persons (Primary or Backup Coordinator, or the Medical Director) based on information from the DDL and temperature monitoring log.
- Post a warning sign on all storage units stating, "Do NOT adjust temperature controls. Notify (name of responsible person) if adjustment is necessary.
- The storage unit's owner's manual should be readily accessible.
- Routine temperature adjustments should not be done during a busy workday when the unit door is being frequently opened and closed. If there is a temperature excursion, the adjustment must be made immediately.

Remember that temperatures within any storage unit will vary at least slightly, even with normal use. Therefore, before making any adjustment:

- Confirm the unit is securely plugged into the power source.
- Check the temperature of the storage unit.
- Wait 30 minutes, without opening the door, to allow the temperature to stabilize and check it again to verify if the thermostat should be adjusted. If you believe there could be an issues with your data logger itself, use your backup device to confirm the temperature.

If you confirm that an adjustment is needed:

- Refer to the owner's manual for detailed instructions.
- Turn the thermostat knob slowly to avoid going outside the correct temperature range and make a small adjustment toward a warmer or colder setting as necessary.
- Allow the temperature inside the unit to stabilize for 30 minutes without opening the door.
- Recheck the temperature.

- Repeat the steps as needed until the temperature has stabilized.
- Consider placing additional water bottles in the unit to help improve temperature stability.

If you are using a combination storage unit, please note that adjustments to the freezer temperature can adversely affect the refrigerator compartment temperature, possibly resulting in frozen vaccines.

Do not leave vaccines in a storage unit that does not maintain temperatures within the recommended range. If you are unable to stabilize the temperature in your unit within the required range, or temperatures in the unit are consistently at the extreme high or low end of the range, your vaccine supply is at risk. Use your emergency storage and handling plan and policies to identify an alternative unit with appropriate temperatures and sufficient storage space until the primary unit can be repaired or replaced.

RECEIVING AND UNPACKING VACCINE SHIPMENTS

The Primary or Backup Coordinators should be present for all vaccine deliveries. All staff members who might accept vaccine deliveries must be aware of the importance of maintaining the cold chain. They should be trained to immediately notify the Vaccine Coordinator when deliveries arrive so that vaccines can be unpacked and stored quickly.

Never leave a vaccine shipping container unpacked and unattended. Vaccines and diluents must be carefully unpacked, stored at recommended temperatures, and documented immediately upon arrival. Never place an unopened and/or unpacked shipment box in vaccine storage unit.

When unpacking deliveries:

- Examine the shipping container and vaccines for signs of physical damage.
- Check the contents against the packing list to be sure they match.
    - For frozen vaccines, the packing list will show the maximum time vaccines can be in transit based on shipment date.
    - If the shipment includes lyophilized vaccines, make sure they came with the correct type and quantity of diluents.
- Check both vaccine and diluent expiration dates to ensure you have not received any expired or soon-to-expire products.
- Check the package's cold chain monitor for any indication of a temperature excursion during transit.
- If there are no concerns, place the products in the appropriate storage units:
    - Store VFC vaccine, 317 program vaccine, and private vaccine separately from each other
    - Claim the shipment in NJIIS after making sure the information in NJIIS matches your delivery
- If there are discrepancies between the contents and the packing list or any other concerns about the contents, put the products in the appropriate storage unit separate from other vaccines, mark "DO NOT USE," and call the VFC program immediately.

VACCINE EXPIRATION DATES

Understanding expiration dates is a key component of managing your vaccine inventory. Vaccine and diluent expiration dates indicate when the product must be discarded if it has not been used. These dates are printed on vials, manufacturer-filled syringes, and packages.

- When the expiration date has only a month and year, the product may be used up to and including the last day of the month. If a day is included with the month and year, the product may only be used through the end of that day.
- Sometimes vaccines must be used before the expiration date – by an earlier date known as the "beyond-use date" (BUD). The BUD is calculated based on the date the vial is first entered and the storage information in the package insert. The BUD replaces the expiration date and should be noted on the label along with the initials of the person making the change. Examples include:
    - Reconstituted vaccines have a limited time frame for use once the vaccine is mixed with diluent. Be sure to read the package insert carefully.
    - Multidose vials might have a specific time frame for use once they have been entered with a needle. If the package insert for a vaccine does not indicate an earlier BUD, the vial can be used until the expiration date indicated on the vial.
    - Manufacturer-shortened expiration dates may apply when a vaccine is exposed to out-of-range temperatures. The manufacturer might determine the vaccine can still be used, but with a shortened expiration date.
- Rotate your stock weekly to be sure that you are using the products with the shortest expiration dates first.
- **Notify the VFC program if you have stock that you cannot use that will expire in 90 days. The VFC program can assist you with locating a provider who might be able to use the vaccine.**

VACCINE ACCOUNTABILITY

Providers must account for all doses of federally-purchased vaccines that they receive. Providers must:

- Enter all doses of federally-purchased vaccines into NJIIS within 30 days of administration. Contact your NJIIS trainer with questions regarding the appropriate documentation of doses administered to patients who declined participation in NJIIS.
- Ensure that the NJIIS on-line inventory accurately reflects all doses of vaccine transferred to another provider, wasted, spoiled, or expired.

BORROWING NOT PERMITTED

CDC's expectation is that providers maintain adequate inventories of both privately-purchased and federally-funded vaccines. In NJ, VFC/317-enrolled **providers are NOT permitted to borrow vaccines**. That means that providers cannot knowingly administer a dose of federally-purchased vaccine to a privately insured patient with the intention of "paying back" the dose at a later time. Every effort should be made to ensure that the provider confirms eligibility to receive federally-funded vaccine prior to vaccine administration. In the event a dose of federally-funded vaccine is inadvertently administered to a non-eligible patient, a provider must contact the VFC program. The provider must document the following information:

- Vaccine type administered
- Patient name
- Patient date of birth
- Date the dose was inadvertently administered
- Reason the dose was inadvertently administered
- Corrective action instituted to prevent future inadvertent administration
- The vaccine type, lot number, and expiration date of the privately purchased vaccine dose that will replace the inadvertently administered dose in the provider's inventory

Providers who have multiple incidents of inadvertent administration of federally-funded vaccines might be subject to further corrective action.

VACCINE TRANSFER

On occasion, even with proper inventory management, a provider might experience a situation where they have stock close to expiring. Vaccine that will expire within 3 – 6 months should be transferred to another provider if the vaccine cannot be used prior to expiration. Short-dated vaccine can be transferred to other VFC/317 providers only under the following conditions:

- The transferring provider can ensure that a process is in place to maintain the cold chain during transport.
- Temperature documentation is available validating that the vaccine has not been exposed to out-of-range temperatures impacting usage of the vaccine and the documentation is included with the transported vaccines.

In order to transfer vaccine:

- Contact the VFC program to obtain verbal approval to transfer your vaccine to an approved, active VFC/317 program provider. If you do not know a provider, the VFC program staff will provide you with a list of providers in the area who you can contact. Once you find a provider who will accept the vaccine, call or email the VFC program.
- Once you have received the approval from the VFC program staff, complete the physical transfer of vaccine as well as transfer from your NJIIS on-line inventory.

TRANSPORT CONTAINERS AND MATERIALS

For safe transport and storage of vaccines, proper supplies are essential. Your facility should have a sufficient supply of materials needed for emergency vaccine transport of your largest annual inventory. Appropriate materials include:

- Portable vaccine refrigerator/freezer units,
- Qualified containers and pack-outs,
- Hard-sided insulated containers or Styrofoam,
- Coolant materials: frozen 16.9-or 8-ounce water bottles that can be conditioned or 4°C to 5°C phase change materials,
- Insulating materials such as bubble wrap or corrugated cardboard – enough to form two layers per container, and
- DDL for each container.

Do not use soft-sided coolers. Most commercially available soft-sided coolers are poorly insulated and likely to be affected by room or outdoor temperatures.

Coolant materials:

Frozen water bottles can be used as coolant packs if they are properly conditioned, which should take only a few minutes:

- Hold the bottles under running tap water or submerge them in a sink filled with tap water until you can easily see a layer of water forming near the surface of the plastic.
- Once the ice block inside the bottle can spin freely, the bottle is ready to be used for packing. The inner block of ice will continue to melt while maintaining a constant temperature in the cooler.
- Use appropriate insulating materials, such as bubble wrap, to protect vaccines from direct contact with the water bottles.

Phase change materials can also be purchased to maintain proper temperatures. Follow the manufacturer's instructions for use to reduce the risk of freezing during transport.

DO NOT USE FROZEN GEL PACKS OR COOLANT PACKS FROM VACCINE SHIPMENTS TO PACK REFRIGERATED VACCINES. NEVER USE ICE PACKS, ICE CUBES, OR DRY ICE DURING TRANSPORT.

The manufacturer does not recommend transporting frozen vaccines (VAR, MMRV, and ZVL). If these vaccines must be transported during an emergency, CDC recommends using a portable vaccine freezer unit (available for rent in some areas) or qualified container and pack-out that maintains temperatures between -50°C and -15°C (-58°F and +5°F).

The CDC does not recommend using only cold chain monitors during transport since they provide limited data on temperature excursions that may occur.

Transport diluents with their corresponding vaccines to ensure there are always equal amounts of vaccines and diluents for reconstitution. Follow the manufacturers' instructions. Some diluents that contain antigens or an adjuvant must be refrigerated and should be transported with the corresponding lyophilized component.

If diluents that are stored at room temperature between 20°C and 25°C (68°F and 77°F) are going to be transported with refrigerated vaccines, they should be refrigerated in advance as long as possible so they do not raise the container temperature when placed with refrigerated vaccines. Place an insulating barrier between the diluents and conditioned water bottles or phase change materials.

NEVER FREEZE DILUENTS – NOT EVEN DURING TRANSPORT.

MANAGEMENT OF EXPIRED, SPOILED, AND WASTED VACCINE

Expired or spoiled vaccine is nonviable vaccine in its original container (vial or syringe) that is able to be returned for excise tax credit. This includes expired vaccine or vaccine that is spoiled as a result of the following:

- Natural disaster/power outage,
- Refrigerator too warm or too cold,
- Failure to store properly upon receipt,
- Vaccine spoiled in transit,
- Mechanical failure,
- Spoiled – other, and
- Recall.

- Vaccine drawn into the syringe but not administered,
- Vaccine in open vial but doses not administered, and
- Compromised vial (e.g., due to drop causing damage to vial integrity or sterility), broken vial, or lost vial.

Lost or unaccounted for vaccine are a third type of vaccine loss.

Providers are required to do the following when they identify expired, spoiled, or wasted vaccine:

- Remove expired, spoiled, or wasted vaccine from storage units with viable vaccine to prevent inadvertent administration (this includes wasted, spoiled, and expired diluents). IMPORTANT: Do not remove vaccines in quarantine from storage unit until viability is assessed. Vaccines in quarantine are those vaccines that were exposed to a temperature excursion but viability has not yet been determined.
- Label all expired, spoiled, and wasted vaccine: "DO NOT USE".

- Report vaccine storage and handling incident that result in vaccine loss, reasons for loss, and the number of doses involved in loss to the VFC program.
- Spoiled and expired vaccines should be returned to the centralized distributor within six months after their spoilage or expiration date. Providers should not wait to make returns. However, vaccines that have expired more than six months previously will still be accepted. Providers must properly dispose of all vaccine designated as waste.
- Provider must update their NJIIS on-line inventory to reflect the expired, spoiled, or wasted vaccine.

EMERGENCIES

Emergencies usually happen without warning. Various situations – equipment failure, power outages, severe weather conditions, or natural disasters - may compromise vaccine storage conditions. Vaccines must never be allowed to remain in a nonfunctioning unit for an extended period of time. Therefore, making preparations in advance to retrieve and/or protect vaccines as quickly as possible during a potentially compromising situation could save your facility costly vaccine lost. You might want to check with your insurer to see the circumstances during which vaccine loss might be covered.

Emergency Backup Options

- **Backup equipment**
  - Backup DDL
  - Spare batteries
  - Flashlights
  - Vaccine transport containers and materials
- **Generators and Backup Battery Power Sources**
  An on-site generator can prevent having to transport vaccine to an alternative storage facility during a power outage. Keep sufficient fuel on hand to continuously run the generator for at least 72 hours. A battery power source can also be used in lieu of a generator. If your facility has a backup battery power source, it should be tested quarterly and serviced annually (check the manufacturer's guidance).
- **Alternative Vaccine Storage Facility**
  Even if you have backup equipment or a generator, you should establish a working agreement with at least on alternative storage facility with a backup generator where vaccines can be appropriately stored and monitored in an emergency. Hospitals, long-term care facilities, fire stations, and commercial pharmacies are some facilities that might assist you. Make sure you have 24 hours access to the facility.

  If you cannot find an alternative vaccine storage facility within a reasonable distance, you can use qualified containers and packouts to store vaccines temporarily at your facility. Always place a DDL with your vaccines.

OFF-SITE VACCINE ADMINISTRATION

Vaccines that will be used at an off-site facility should be delivered directly to that facility. If that is not possible, transport or vaccines should be done using a portable vaccine refrigerator with a DDL placed with the vaccines. If this is not available, qualified containers and pack-outs can be used with a DDL. If you must transport vaccines, transport only what is needed for the workday. The total time for transport and workday should be a maximum of 8 hours. If you must transport vaccines in non-commercial vehicles, use the passenger compartment – not the trunk.

Immediately upon arrival at an off-site/satellite facility, vaccines should be stored in an appropriate storage unit with a DDL. If the vaccines cannot be stored in an on-site storage unit, they should be kept in the portable refrigerator or qualified container during an off-site clinic:

- Place a DDL as close as possible to the vaccines, check and record temperatures a least hourly.
- Keep the container closed as much as possible – temperature display should be on the outside of the unit.
- Remove only 1 multiple use vial or 10 doses at a time for preparation and administration by each person administering vaccines.

MODULE 6 – FRAUD AND ABUSE

OVERVIEW

As vaccines become more expensive and immunization programs more complex, the VFC program becomes more vulnerable to fraud and abuse. It is important that providers and their staff understand what constitutes fraud and abuse and ensure that they have sound policies and procedures in place to avoid potential fraud and abuse. State and territorial VFC programs are tasked by the CDC with ensuring that providers are good stewards of federally-funded vaccines.

PURPOSE

This module defines fraud and abuse terms as they apply to the VFC program. In addition, this module provides examples of potential fraud and abuse and describes CDC requirements for managing and preventing fraud and abuse.

FRAUD AND ABUSE

Federal fraud and abuse laws apply to the entire VFC program. In addition, for those portions of the VFC program involving state funds, state fraud and abuse/consumer protection/medical licensure laws may also apply. A working understanding of what constitutes fraud and abuse is critical for all persons involved with the VFC program including the provider and all of the provider's staff involved with vaccine management.

Consistent with "fraud" and "abuse" as defined in the Medicaid regulations at 42 CFR § 455.2, the following definition will be used:

- **Fraud:**
  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:**
  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 healthcare. Abuse also includes recipient practices that result in unnecessary cost to the Medicaid program.

EXAMPLES OF FRAUD AND ABUSE

Examples of fraud and abuse include, but are not limited to:

- Providing VFC vaccine to non-VFC-eligible children.

- Selling or otherwise misdirecting VFC vaccine.
- Billing a patient or third party for VFC-funded vaccine.
- Charging more than the established maximum regional charge for administration of a VFC-funded vaccine to a VFC-eligible child.
- Denying established VFC-eligible children VFC-funded vaccine because of parents' inability to pay for the administration fee.
- Failing to implement the requirements specified in the Provider Agreement.
- Failing to screen for and document eligibility status at every visit.
- Failing to maintain VFC records and comply with other requirements of the VFC program.
- Failing to fully account for VFC-funded vaccine.
- Failing to properly store and handle VFC vaccine.
- Ordering VFC vaccine in quantities or patterns that do not match the provider's profile or otherwise over-ordering VFC doses of vaccine.
- Waste of VFC vaccine.
- Using single dose vials or syringes of vaccine for more than one patient.
- Relabeling or otherwise altering the vaccine manufacturer's label.
- Knowingly recording incorrect information in NJIIS or the patient's medical record concerning vaccine doses administered (e.g., recording a different lot number than that on the vaccine manufacturer's label for the dose received).

CORRECTIVE ACTION PLANS

Whenever the VFC program discovers issues with vaccine management, a provider-specific Corrective Action Plan is developed. Corrective Action Plans may include, but are not limited to:

- Education of providers and their staff.
- Restitution of vaccine on a dose-for-dose basis as stipulated in the Provider Agreement.
- Patient notification and revaccination.
- Replacement of the provider's storage units or temperature monitoring devices.

Corrective actions may be necessary when the VFC program discovers that the provider's actions resulted in the following:

- Expired or Spoiled Vaccine
  This is vaccine that is determined to be non-viable, is in its original container, and can be returned for excise tax credit. This includes vaccine that is expired or has been spoiled as a result of the following:
    - Natural disaster/power outage
    - Refrigeration unit too warm/too cold
    - Failure to store properly upon receipt
    - Vaccine spoiled in transit
    - Mechanical failure
    - Recall

- Wasted Vaccine
  Non-viable vaccine that is not able to be returned for excise tax credit. This includes:
  - Vaccine drawn into a syringe but not administered
  - Vaccine in an open vial that has not been administered
  - Compromised vial
  - Lost or unaccounted for vaccines that are not a result of negligence by the provider
- Negligent Waste
  Non-viable vaccine in which the viability was compromised as a direct result of negligence by the provider
- Ineligible
  Vaccine was administered to non-VFC eligible individuals.

WASTE ASSESSMENT

Providers with ≤ 5% Annual Waste

Providers will be allowed up to 5% Annual Waste (this excludes negligent waste). Providers with a robust vaccine management plan are expected to have little to no waste. However, the VFC program recognizes that there are circumstances when vaccines are wasted despite a provider's best efforts. Therefore, the VFC program has established 5% as its benchmark. Waste, whether self-reported or identified by the VFC program, will be referred to a VFC program staff member for follow-up and provider education. There may be occasions when less that the 5% benchmark requires follow-up based on the circumstances.

- Provider waste reports are reviewed in NJIIS. The VFC program reviews overall waste annually.
- The waste allowance percentage is based on the practice's total number of vaccine doses wasted divided by the total number of vaccine doses shipped, over the prior 12 months. Flu vaccine doses are not counted in these numbers due to the seasonal nature of flu vaccine and the short expiry of the products.
- Once a practice has reached the 5% benchmark, it will need to demonstrate 12 consecutive months without waste before another 5% waste will be permitted without penalty.

Providers with > 5% but < 25% Annual Waste

Providers with > 5% but < 25% Annual Waste will be provided with education concerning methods to reduce waste and improve vaccine accountability.

Providers with ≥ 25% but < 50% Annual Waste

Providers with ≥ 25% but < 50% Annual Waste are required to draft a Corrective Action Plan which must be signed by the Medical Director. The Plan must outline key areas of focus to mitigate waste and improve accountability.

Providers with ≥ 50% Annual Waste

Providers with ≥ 50% Annual Waste are required to draft a Corrective Action Plan which must be signed by the Medical Director. The Plan must outline key areas of focus to mitigate waste and improve accountability, Additionally, the provider is referred to the VFC Vaccine Manager for review and reduction in ordering allowance.

RESTITUTION

According to CDC guidelines, all federally-funded vaccines must be replaced on a dose-for-dose basis by providers who have failed to adhere to the terms of the Provider Agreement. The VFC program understands that not all waste is the result of provider negligence and always takes into account the circumstances under which the vaccine loss occurs to determine if the event was beyond the control of the provider or could have been reasonably predicted by the provider. The Medical Director who signs the Provider Agrement is ultimately responsible for all vaccine management activities at the facility and is therefore responsible for all actions by their staff. The Medical Director must ensure that all people who are involved in vaccine management are trained and following CDC requirements.

The following situations are examples of negligence that might necessitate restitution of vaccine on a dose-for-dose basis:

- Drawing up or administering federally-funded vaccine prior to VFC-eligibility screening.
- Vaccine storage and handling errors by the provider or the provider's staff.
- Vaccine that is left out of the storage unit and becomes non-viable.
- Freezing vaccine that is only meant to be refrigerated.
- Refrigerating vaccine that is only meant to be frozen.
- Storage unit was left unplugged or electrical breaker was switched off.
- Storage unit door was left open or ajar by the provider, provider's staff, or contractor.
- Power outages or other disasters wherein the provider failed to act in accordance with the provider's Emergency Vaccine Retrieval and Storage Plan.
- Situations in which VFC-eligible children must be re-vaccinated due to improper vaccine administration or administration of vaccine subsequently determined to be non-viable.
- Ordering habits that lead to overstocking, resulting in expiration or excessive waste.
- Inability to account for federally-funded vaccines.
- Administration of vaccine to VFC-ineligible individuals.

The following are examples of situations that are considered to be out of the provider's control and, generally, do not require restitution:

- Package is not delivered to the provider in a timely manner or is otherwise damaged or exposed to improper temperatures during transit to the provider. The provider must notify McKesson immediately if this occurs. **Any calls received by McKesson after the day of delivery might result in provider liability and need for replacement.**

- A provider has a contract with an alarm company or has properly installed an alarm, then experiences a storage unit failure, and the alarm does not notify the provider. Documentation is required.
- A provider, in anticipation of an impending storm, moves vaccine to a location with a secure power source as documented in their Emergency Vaccine Retrieval and Storage Plan, but power is lost at that location.
- A provider, in anticipation of upcoming expiration dates, attempted to redistribute vaccine 120 days or more prior to the expiration but the redistribution was unsuccessful. Documentation is required.
- Extraordinary circumstances not listed above deemed by the VFC program to be beyond the provider's control.

Restitution Agreement

This policy has been in effect since January 1, 2013. All incidents requiring restitution are reviewed on a case-by case basis by VFC program management prior to issuance of a Restitution Agreement.

- Providers with < 100 doses of vaccine loss/waste (excluding flu vaccine) will not be required to restitute for the first occurrence.
- The Restitution Agreement stipulates that the provider must replace vaccines on a dose-for-dose basis by privately purchasing the vaccine doses within 60 days of signing the Agreement.
- The provider must submit to the VFC program a copy of the receipt for all privately-purchased vaccine procured to fulfill the Agreement.
- VFC program staff will enter the privately purchased vaccine doses into the provider's NJIIS online inventory under NJDOH USE ONLY.
- Providers must track each dose given to VFC-eligible children.
- VFC program staff will sample charts during a subsequent visit to the provider's office to ensure that vaccines purchased as restitution were appropriately given to VFC-eligible children.
- The VFC program staff will work with the provider during the restitution process to supplement vaccines not included in the Agreement to ensure there is no disruption in the provider's ability to administer all ACIP-recommended vaccines.
- Failure to fulfill the terms of the Provider Agreement may result in disenrollment from the VFC program and possible referral to outside agencies .

REVACCINATION

Whenever potentially compromised vaccine is administered or other vaccination errors occur, the provider must notify patients/guardians of the error and provide counseling to the patient/guardian on the need for revaccination. Providers must sign a Revaccination Plan issued by the VFC program and which includes the following:

- Determine which persons received the compromised or potentially compromised vaccine doses

- Notify the persons (or guardians) of the affected population, preferable in writing, that they received compromised or potentially compromised vaccine. The letter must be reviewed and approved by the VFC program prior to distribution to the affected parties.
- Provide counseling to those individuals.
- Revaccinate those individuals at the provider's cost by privately purchasing vaccine, as appropriate.
- Providers must complete the activities within 180 days of signing the Revaccination Plan.
- Providers are encouraged to follow this same course of action for any privately ensured patients who receive compromised or potentially compromised vaccine.
- Failure to fulfill the terms of the Agreement may result in disenrollment from the VFC program and possible referral to outside agencies.
- If the provider refuses or cannot notify patients (e.g., action is taken against the provider's license by the New Jersey Board of Medical Examiners), the VFC program may conduct the patient notification. Patients will be advised to consult a healthcare provider for counseling and revaccination, as appropriate.

REFERALS TO OTHER AGENCIES

It is the policy of the VFC program to work with providers through Corrective Action Plans to avoid referrals to other agencies. However, the VFC program is tasked with ensuring that all providers are good stewards of federally-funded vaccine. There are times when the VFC program must make referrals to other agencies. These agencies include:

- The New Jersey State Board of Medical Examiners or other appropriate licensing or regulatory agency.
- New Jersey Office of the State Comptroller, Medicaid Fraud Division.
- The New Jersey Division of Medical Assistance and Health Services, Department of Human Services.
- The CDC

MODULE 7 - NATIONAL CHILDHOOD VACCINE INJURY ACT and VAERS

OVERVIEW

The National Childhood Vaccine Injury Act (NCVIA) of 1986 was enacted to provide a cost-effective arbitration and compensation system for vaccine injury claims and reduce the potential liability of vaccine manufacturers. It also created a system for reporting and tracking adverse events related to vaccinations. Healthcare professionals who administer vaccines must adhere to the following NCVIA requirements when administering vaccinations.

PURPOSE

To ensure that providers understand the requirements as outlined in the NCVIA. Please note that these requirements apply to ALL vaccinations administered at your facility, not just those given through the VFC program.

VACCINE INFORMATION STATEMENTS (VIS)

VIS are published by the CDC and provide information to vaccine recipients about the risks and benefits of the vaccine. **Providers must ensure that patients receive a current vaccine-specific VIS to the vaccine recipient or his/her guardian at each vaccination visit.**

VIS are updated periodically, and CDC maintains current print, and foreign language versions on their website.

The CDC VIS webpage offers a “Get email updates” function that notifies you by email when VISs are changed.

VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)

VAERS is a national vaccine safety surveillance program created through the NCVIA and co-sponsored by the CDC and the Food and Drug Administration (FDA). VAERS provides a nationwide system for reporting, analyzing, and publishing information on adverse events related to vaccines.

The NCVIA requires healthcare providers to report to VAERS:

- Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of vaccine.
- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccination.

You may also report any adverse event that occurs after the administration of a vaccine licensed in the U.S., even if you are unsure whether a vaccine was the cause.

VACCINE CHARTING REQUIREMENTS

The NCVIA requires that following information be documented on the patient's paper or electronic medical record or on a permanent office log:

- Name of the vaccine
- The vaccine manufacturer
- The lot number of the vaccine
- The date the vaccine is administered
- The name, office address, and title of the healthcare provider administering the vaccine
- The VIS edition date located in the lower right corner on the back of the VIS. When administering combination vaccines, all applicable VISs must be given and the individual VIS edition dates recorded.
- The date the VIS was given to the patient, parent, or guardian

The federally required information must be both permanent and accessible. Federal law does not require a parent, patient, or guardian to sign a consent form in order to receive a vaccination, providing them with the appropriate VIS(s) and answering their questions is sufficient under federal law. However, you should check your policies and procedures to see what is required at your facility.

MODULE 8 - VACCINE ADMINISRATION, INFECTION PREVENTION AND INJECTION SAFETY

OVERVIEW

For vaccines to be effective, they must be administered correctly. A provider must ensure that all staff involved in vaccine administration are aware of the current ACIP recommended immunization schedule including dosages and routes of administration. It is also important that providers and staff understand the importance of infection prevention in outpatient settings. The CDC recommends that all providers have infection prevention programs in place that extend beyond Occupational Safety and Health Administration bloodborne pathogen training to address patient protection. Most vaccines are administered via injection. Unsafe injection practices put patients and healthcare providers at risk of infectious and non-infectious adverse events and have been associated with a wide variety of procedures and settings. This harm is preventable. Safe injection practices are part of Standard Precautions and are aimed at maintaining basic levels of patient safety and provider protections.

PURPOSE

To ensure providers and their staff understand the importance of having policies and training addressing recommended vaccine administration, infection prevention, and safe injection practices.

HAND HYGIENE

Good hand hygiene, including use of alcohol-based hand runs and handwashing with soap and water, is critical to reduce the risk of spreading infections in outpatient settings. Use of alcohol-based hand rubs as the primary mode of hand hygiene in healthcare settings is recommended by the CDC and the World Health Organization. Soap and water should be used when hands are visible soiled (e.g., blood, body fluids) and is also preferred after caring for a patient with known or suspected *Clostridium difficile* or norovirus during an outbreak.

Complete guidance on how and when hand hygiene should be performed, including recommendations regarding surgical hand antisepsis and artificial nails can be found in the Guide for Hand Hygiene in Health-Care Settings.

Key situations where hand hygiene should be performed:

- Before contact with a patient
- Before performing an aseptic task (preparing vaccine)
- After contact with the patient (including after vaccine administration) or objects in the immediate vicinity of the patient
- After contact with blood, body fluids or contaminated surfaces
- Before and after glove use

ENVIRONMENTAL CLEANING

Outpatient facilities should establish policies and procedures for routine cleaning and disinfection of environmental surfaces as part of their infection prevention plan. Offices that administer vaccines should have policies and procedures in place for routine cleaning and disinfection and procedures for handling spills of blood or other body fluids.

EPA-registered disinfectants or detergents/disinfectants with label claims for use in healthcare should be selected for disinfection. Disinfectant products should not be used as cleaners unless the label indicates the product is suitable for such use. Healthcare professionals should follow manufacturers' recommendations for use of products selected for cleaning and disinfection (e.g., amount, dilution, contact time, safe use, disposal).

Complete guidance for the cleaning and disinfection of environmental surfaces, including cleaning blood or body substance spills, is available in the Guidelines for Environmental Infection Control in Health-Care Facilities and the Guideline for Disinfection and Sterilization in Healthcare Facilities.

Key situations for cleaning and disinfection of environmental surfaces:

- Establish policies and procedures for routine cleaning and disinfection of environmental surfaces in the facility:
    - Policies and procedures should also address prompt and appropriate cleaning and decontamination of spills of blood or other potentially infectious materials.
- Select EPA-registered disinfectants or detergents/disinfectants with label claims for use in healthcare.
- Follow manufacturer's recommendations for use of cleaners and EPA-registered disinfectants (e.g., amount, dilution, contact time, safe use, and disposal.

THE RIGHTS OF VACCINE ADMINISTRATION

Unfortunately, vaccination errors are easy to make. These errors can leave patients unprotected, or even experience adverse events following vaccination. Make sure you know the "Rights of Vaccine Administration."

- Right Patient
  Make sure you are vaccinating the right person by verifying the patient's name and date of birth. And make sure that you've screened for contraindications and precautions for that vaccine.

- Right Time
  Be sure the patient is the appropriate age for the vaccine you plan to administer and that the appropriate interval has passed since the previous dose of the same vaccine or between two live vaccines. Vaccines are not as effective if the minimum age and the minimum interval is not met.

- Right Vaccine (and Diluent)
  Errors have occurred administering the wrong vaccine product to a patient. Check the vial label to be sure you have chosen the correct vaccine product and diluent. Vaccines can look or sound the same (DTaP, Tdap) and sometimes there is both an adult and pediatric version of the same vaccine. Check the expiration date of the vaccine and diluent before using to be sure they are not expired.

- Right Dosage
  Errors have been made giving the wrong amount of vaccine to a person, such as giving a pediatric vaccine to an adult or vice versa. Vaccine dosages are usually guided by the patient's age, not weight. Check the package insert or an appropriate guidance document to confirm the appropriate dose for your patient.

- Right Route, Needle, and Technique
  Errors are often made administering vaccines using the wrong route, needle, or technique. Be sure you know the appropriate route of administration (oral, intranasal, subcutaneous, intramuscular, or intradermal) for the vaccine you are administering. Needle selection should be based on the prescribed route, size of the individual, volume and viscosity of the vaccine, and injection technique. Follow CDC guidance to confirm you are adhering to the correct route, needle, and technique. Deviation from recommendations can reduce vaccine efficacy or increase local adverse reactions. Aspiration is not required before administering a vaccine.

- Right Injection Site
  Errors are often made by administering vaccine at the wrong site. Sometimes injections are given into the wrong part of the arm and not into the thick, central portion of the arm. This can result in injury to the shoulder joint.

- Right Documentation
  Be sure to follow federal law. You must document:
  - Name of the vaccine
  - The vaccine manufacturer
  - The lot number of the vaccine
  - The date the vaccine is administered
  - The name, office address, and title of the healthcare provider administering the vaccine

- The VIS edition date located in the lower right corner on the back of the VIS. When administering combination vaccines, all applicable VISs must be given and the individual VIS edition dates recorded.
- The date the VIS was given to the patient, parent, or guardian

SYRINGE AND NEEDLE SELECTION

A separate needle and syringe should be used for each injection. Occupational Health and Safety and Health Association requires that safety-engineered injection devices be used for injectable vaccination in all clinical settings to reduce risk for injury and disease transmission. Personnel who will be using these devices should be involved in evaluation and selection of these products and should receive training with these devices before using them in the clinical area. Some syringes are packaged with expiration dates.

Vaccine must reach the desired tissue site for optimal immune response. Use of longer needles has been associated with less redness or swelling than occurs with shorter needles because of the injection into deeper muscle mass. Therefore, needle selection should be based on the prescribed route, size of the individual, and injection technique. A supply of needles in varying lengths appropriate for the facility's patient population should be available to staff. Check to make sure the needle you are using has not reached its expiration date.

Educational material is available through the Immunization Action Coalition website.

PREPARING VACCINES FOR ADMINISTRATION

Vaccine preparation is the final step in the cold chain before administration. Handling vaccines with care is equally as important as storing them properly.

- Vaccines should be prepared in a designated area away from any space where potentially contaminated items are placed.
- Only prepare vaccines when you are ready to administer them.
- Only administer vaccines you have prepared. This is a quality control and patient safety issue and a best practice standard of medication administration. If vaccine is drawn up by one person but administered by another, the person administering the vaccine cannot be sure what is in the syringe and whether it is safe.

Single-Dose Vials

A single-dose vial contains ONE dose and should be used ONE time for ONE patient. Do not combine leftover vaccine from one single-dose with another to obtain a dose. Single-dose vials do not contain a

preservative to help prevent the growth of microorganisms. There have been outbreaks of infections caused by pooling contents and/or storing contents for future use.

Do not open a single-dose vial until ready to use. Before you remove the protective cap, always check the vial to make sure you have the correct vaccine. Once you remove the cap, you must use the vaccine because it may not be possible to determine if the rubber seal has been punctured. Discard any unused single-dose vials without a protective cap at the end of the workday.

Some single-dose vials contain more than the recommended dosage of the vaccine. The entire contents of the vial should be used, even if it is a little more than the recommended dose. Discarding the excess vaccine is not required or recommended. **THE CONTENTS OF A SINGLE DOSE VIAL SHOULD NEVER BE USED FOR MORE THAN ONE PATIENT.**

Multiple-Dose Vials

A multiple-dose vial contains more than one dose of vaccine. Because multiple-dose vials typically contain a preservative to help prevent the growth of microorganisms, they can be entered or puncture d more than once. Only the number of doses indicated in the manufacturer's package insert should be withdrawn from the vial. After the maximum number of doses has been withdrawn, the vial should be discarded, even if there is residual or the expiration date has not been reached.

Multiple-dose vials can be used until the expiration date printed on the vial unless the vaccine is contaminated or compromised in some way or there is a beyond-use date noted in the package insert or due to a temperature excursion. NOTE: This is different than other medications that are supplied in multiple-dose vials; for other medications, the beyond-use date is 28 days from opening unless the manufacturer states otherwise.

Never use partial doses from two or more vials to obtain a dose of vaccine. Never bring a multiple-dose vial of vaccine into the immediate patient treatment area. Always keep and prepare the vial in a clean, medication preparation area.

Manufacturer-Filled Syringes

A manufacturer-filled syringe is prepared and sealed under sterile conditions by the manufacturer. Do not activate a manufacturer-filled syringe (i.e., remove the syringe cap or attach the needle) until ready to use. Manufacturer-Filled Syringes do not contain a preservative to help prevent the growth of microorganisms. Once the sterile seal has been broken, the vaccine should be used or discarded at the end of the workday.

- When using a manufacturer-filled syringe, you do not need to expel the air pocket. It is not wrong to expel the air from the syringes but, typically the amount is so small that the CDC does not believe it to be a problem. This air is absorbed. CDC does, however, recommend that when drawing vaccine from a vial into a regular syringe, the air be expelled because the amount of air is typically larger than the amount in the manufacturer-filled syringe.

Reconstitution

Lyophilized vaccines may be in the form of a powder or pellet that must be mixed with a liquid (diluent) in a process known as "reconstitution" before being administered.

Liquid diluents vary in volume and composition and are specifically designed to meet volume, pH, and chemical requirements of their corresponding vaccine. Some diluents contain antigen or adjuvant.

Diluents are not interchangeable unless specified by the manufacturer. Even if the diluent is composed of sterile water or saline, use only the diluent supplied with the vaccine to reconstitute it. Never use a stock vial of sterile water or normal saline to reconstitute vaccines.

Never administer vaccine reconstituted with the wrong diluent. If the vaccine has already been administered, contact the vaccine manufacturer and the VFC program for guidance on revaccination. Always check expiration dates on both vaccines and diluents before reconstituting them.

Pre-drawing Vaccines

CDC recommends drawing up vaccines only at the time of administration. Once vaccines are inside syringes, it is difficult to tell them apart, which can lead to administration errors. Pre-drawing can also result in vaccine waste if more is drawn up than is needed.

General-use syringes are designed for immediate administration – not for storage. Contamination and growth of microorganisms can occur in syringes with pre-drawn vaccine that does not contain a preservative. In addition, vaccine components may interact with polymers in a plastic syringe over time, potentially reducing vaccine potency.

Vaccine manufacturers do not recommend pre-drawing vaccines in advance of influenza vaccination clinics because no data exist on the stability of vaccines stored in general-use syringes that have been filled by providers.

As an alternative to pre-drawing vaccines, CDC recommends using manufacturer-filled syringes for large immunization clinics.

If vaccine must be pre-drawn:

- Set up a separate administration station for each vaccine type to prevent medication errors.
- Do not draw up vaccines before arriving at the clinic site. Drawing up doses hours or even days before a clinic is not a best practice because general-use syringes are not designed for storage.

- Each person administering vaccines should draw up no more than one multiple-dose vial, or 10 doses, at one time.
- Monitor patient flow to avoid drawing up unnecessary doses.
- Discard any remaining vaccine in pre-drawn syringes
- Do not pre-draw reconstituted vaccine into a syringe until you are ready to administer it. If not used within 30 minutes of being reconstituted, follow manufacturer guidance for storage conditions- and time limits. A manufacturer may specify that an unused reconstituted vaccine can only be stored in the vial for the indicated time.
- Never transfer pre-drawn reconstituted vaccine back into a vial for storage

NONSTANDARD ADMINISTRATION

CDC discourages deviating from the recommended route, site, dosage, or number of doses for any vaccine. Deviation can result in reduced protection and increase the risk of an exaggerated local response. For certain vaccines, the ACIP recommends revaccination if a nonstandard route or site is used. Any vaccination using less than the standard dose should not be counted, and the person should be revaccinated according to age. If a partial dose of a parenteral vaccine is administered because the syringe or needle leaks or the patient jerks away, the dose should be repeated.

MANAGING ACUTE VACCINE REACTIONS

Severe, life-threatening anaphylactic reactions following vaccination are rare. However, staff have to be familiar with procedures for managing a reaction. Epinephrine and equipment for maintaining an airway should be available for immediate use.

INJECTION SAFETY

- Follow proper infection prevention practices and maintain aseptic technique during the preparation and administration of vaccines
- Perform hand hygiene with soap and water or alcohol-based hand rubs before preparing vaccines
- Never administer vaccines from the same syringe to more than one patient, even if the needle is changed
- Never enter a vial with a used syringe or needle
- Do not use medications packaged as single-dose or single-use for more than one patient
- Use a separate sterile alcohol pad to clean each vaccine vial septum – even newly opened vials. Allow the alcohol to dry prior to piercing the vial.
- Cleanse the skin with a sterile alcohol pad and allow the alcohol to dry before piercing the skin. Do not use the same alcohol pad to clean the skin that was used to clean the septum of the medication vial.
- OSHA regulations do not require the wearing of gloves when administering vaccinations, unless the person administering the vaccine is likely to come into contact with potentially infectious body fluids or has an open lesion on their hand. If a healthcare worker chooses to wear gloves,

he or she must change them between each patient encounter and must engage in hand hygiene before donning gloves and after glove removal.

- It is not necessary to change the needle even if it has passed through two stoppers (as with reconstitution vaccine) unless the needle is damaged or contaminated.
- Never carry vaccine vials or syringes in your pocket
- Dispose of used sharps at the point of use in a sharps container that is closable, puncture resistance, and leak proof

MODULE 9 - SITE VISITS

OVERVIEW

To ensure the quality of federally-funded vaccine and the integrity of the VFC and 317 programs, the VFC program is required by the CDC to conduct site visits to enrolled providers. Visits help determine a provider's compliance with program requirements. This includes identifying potential issues with vaccine accountability and determining whether vaccines are being handled, stored, and administered in accordance with the laws and policies governing the federally-funded programs.

The review and evaluation of provider practices involves assessing verbal, written, and visual evidence encountered during the visit to determine if provider sites are following the requirements of the program.

The goals of these site visits are to:

- Identify areas where providers are doing well and areas needing additional follow-up.
- Identify the educational needs of providers in order to support them with meeting program requirements.
- Ensure that eligible individuals receive properly managed and viable vaccine.

Additionally, site visits are critical opportunities to engage providers and their staff and develop and strengthen ongoing relationships.

PURPOSE

To describe the types of visits conducted by the VFC program and outline the expectation of providers at each of these visits.

TYPES OF SITE VISITS

The VFC program conducts different types of site visits to assist providers in identifying compliance with requirements and recommendations. VFC program staff typically focus on CDC-defined priorities during visits. VFC program staff are not expected to evaluate every aspect of a provider's practice as related to vaccines and vaccination policy during the time limited visits. **Therefore, it is important for providers to understand that it is their responsibility to ensure that their vaccine policies and procedures including, but not limited to, storage and handling, administration, and billing are consistent with CDC requirements/recommendations, vaccine manufacturers package inserts, professional guidelines, and applicable laws.**

- **Enrollment Site Visits**
  All newly enrolled and returning providers must receive an enrollment site visit prior to receiving federally-funded vaccines. These visits are scheduled by the VFC program and typically last approximately 1.5 hours. The purpose of this visit is to ensure that the provider and the provider's staff are educated on the program requirements and have appropriate resources to

implement program requirements. It is highly recommended that the Medical Director be present for this visit. Providers cannot receive vaccine shipments before the enrollment site visit is successfully completed, the provider has been trained on how to successfully perform program requirements, and the provider has the appropriate storage and handling equipment in place to receive and store vaccine.

- **Compliance Visits**

  All enrolled and active providers must receive a Compliance Site Visit at a minimum of every 24 months. These pre-scheduled visits typically last approximately 2.5 – 3 hours. Primary and Backup Coordinators should be available for this visit. It is highly recommended that the Medical Director be present for this visit. During the visit, the VFC program staff assess:
  - Day-to-day operations
  - Eligibility screening and documentation policies and procedures
  - Billing policies and practices
  - Storage and handling practices/protocols

  If your office is using electronic health records, it is expected that someone familiar with the system is available to assist in retrieving any required documentation.
  In preparation for the Scheduled Compliance Visits, you should ensure that:
  - Your NJIIS inventory is up-to-date.
  - The federally-funded vaccine storage units are accessible.
  - You have a DDL, meeting program requirements, for each storage unit and at least one backup. Current calibration certificates must be available at the time of the visit.
  - Your paper temperature logs are complete and accessible for review.
  - Documentation concerning any temperature excursions are available.
  - Your VISs are current.
  - Your Vaccine Management Plan is up to date, signed and all staff have been trained to its content.
  - The storage units are plugged directly into the outlet and that outlets and circuit breakers are labeled with a “DO NOT UNPLUG” sticker.
  - A room is available that can accommodate at least one VFC program staff member with a laptop. There should be an area where the provider’s staff can meet with the VFC program staff member.

  Upon completion of the site visit, the VFC program staff discusses the outcomes in a face-to-face meeting with appropriate provider staff and provides a written summary of findings. It is strongly recommended that the Medical Director be present for this meeting. The discussion includes:
  - A review of the visit findings that addresses any required and recommended follow-up for the provider visit.
  - A formal follow-up plan with timeline that addresses any issues of non-compliance or opportunities for improvement.
  - An indication of whether requirements are met.
  - Follow-up actions required of the provider for any issues identified during the visit.

Providers are asked to sign an "Acknowledgement of Receipt" in which they attest to the fact that a site visit was completed, the provider received the results of the visit, and that both the site visit reviewer and the provider understand the non-compliance issues identified and the actions necessary to address them.

- **Storage and Handling Visits**
  These CDC-mandated site visits might be pre-scheduled or unannounced and typically last approximately 1.5 hours.

- **Assessment, Feedback, Incentives, and eXchange (AFIX) Visits**
  These visits are scheduled and can vary in length. The AFIX Program consists of components:
  - **A**ssessment involves generating data reports on a provider's vaccination coverage levels and examining the effectiveness of the provider's immunization delivery practices.
  - **F**eedback provides an opportunity to share with each provider their Assessment results, discuss practice procedures and barriers, and collaborate to develop customized, evidence-based quality improvement strategies.
  - **I**ncentives recognize provider accomplishments and can be powerful motivation for providers to improve vaccination coverage rates.
  - e**X**change is the regular follow-up with providers to monitor their quality improvement progress and offer support through guidance and Incentive.

AFIX serves to assist and support healthcare providers by identifying low immunization rates, determining opportunities for improving immunization delivery practices, and ensuring that providers are:

- Aware and knowledgeable about their immunization rates and missed opportunities to vaccinate.
- Motivated to incorporate changes into their current practices.
- Ready to try new immunization service strategies.

- **Other Visits**
  VFC program staff might conduct an unannounced visit to follow-up on an active issue or investigate other areas of concern. Any complaint against a provider would likely trigger an unannounced visit; these complaint investigations might take longer and might involve outside agencies depending on the allegation against the provider.

FOLLOW-UP

Issues identified during a site visit must be addressed in the specified time frame. Providers who do not complete the corrective actions, might jeopardize their participation in the program and will be referred to VFC program management for further action.

If significant deficiencies are noted during a site visit, a provider's ability to order vaccine might be suspended until the deficiencies are corrected. Timely correction of deficiencies will facilitate a prompt resumption of vaccine ordering privileges.

VFC AND 317 PROGRAM REQUIREMENT SUMMARY

VFC REQUIREMENT BY FREQUENCY
UPON ENROLLMENT AND AS NEEDED
Submit new provider enrollment form and Provider Agreement forms
Receive VFC PIN #
Register with NJIIS and complete training
Complete Vaccine Ordering and Management in NJIIS training
Complete New Enrollment Questionnaire • Designate Primary and Backup Vaccine Coordinator and note their NJIIS and Vaccine Ordering and Management in NJIIS training dates • Note required information regarding DDL and back up datalogger for each storage unit and provide Certificate of Calibration • Indicate the type of storage unit at the facility (Dormitory-style refrigerators are never allowed) • Place dataloggers in each storage unit. Track temperatures for two business weeks and enter them into NJIIS • Complete the Vaccine Management Policy Template • Ensure VISs are the most current
Prepare for initial site visit • Post “Do Not Disconnect” signs on outlets and circuit breakers • Ensure Vaccine Management Policy Template is completed and available • Ensure vaccine storage units meet current requirements Ensure DDL is appropriately placed in the storage units and that data is downloaded. Ensure min/max temperature logs complete and available. Verify that all temperatures are within the recommended ranges.
EVERY VACCINATION VISIT
Screen for VFC/317 eligibility
Distribute current VIS to patients/guardians prior to vaccination
Chart required vaccination information
Bill only allowable administration fee charges
DAILY
Log min/max temperatures on paper temperature log
Address all temperature excursions immediately upon discovery
WEEKLY
Download, review, and save DDL; address any temperature excursions immediately
Review inventory in NJIIS and in storage units to ensure all doses are accounted for in NJIIS (e.g., administered, wasted, spoiled, expired)
Check vaccine expiration dates and rotate stock
Transfer any vaccine that will expire in 3 – 6 months, return expired or wasted vaccine to central distributor within 6 months
YEARLY
Review and update Vaccine Management Plan. Ensure all staff are trained to the plan
Submit re-enrollment paperwork by the date stipulated
Fulfill annual Primary and Backup Vaccine Coordinator Training
BIANNUALLY
Host a scheduled compliance site visit from the NJ VFC program
AS NEEDED
Immediately address and report all temperature excursions
Submit VAERS reports
Update Vaccine Management Plan
Inform NJ VFC program of any changes to staff or provider profile
Host unannounced and educational site visits from the NJ VFC program
Maintain all VFC/317 related records/documents for a minimum of 3 years