



Vaccines for Children

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INTRODUCTION

The purpose of this *New Jersey Vaccines for Children (VFC) & 317-Funded Adult (317) Program Provider Guide* is to provide an overview of these federally-funded programs and summarize the requirements and responsibilities of participating providers. In conjunction with New Jersey VFC, 317, and Centers for Disease Control and Prevention (CDC) trainings, this guide can be used as a reference for providers to understand program guidance and procedures.

New Jersey’s VFC and 317 programs reside within the New Jersey Department of Health’s (NJDOH) Vaccine Preventable Disease Program (VPDP). VPDP works to reduce and eliminate the incidence of vaccine-preventable diseases affecting children, adolescents, and adults by increasing immunization coverage rates of New Jersey residents. The VFC and 317 programs aim to support providers who administer federally-funded vaccines to underserved and at-risk populations. Ensuring that all children, adolescents, and adults are vaccinated in accordance with the Advisory Committee on Immunization Practices ([ACIP-recommended](#)) schedule is the best way to protect individuals and communities against vaccine-preventable diseases.

NJDOH will periodically distribute communications and updates to enrolled providers. For the latest updates, visit the [New Jersey Immunization Information System \(NJIS\)](#). It is the provider's responsibility to ensure the most up-to-date requirements are met.

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VFC & 317 PROGRAMS AT A GLANCE

The [Vaccines for Children \(VFC\) program](#) was established by Congress in 1994 to increase access to vaccination for children who might not get vaccinated because of financial barriers. The VFC program is a Title XIX Medicaid program.

CDC provides funding to 61 state, local, and territorial immunization program awardees to implement and oversee the VFC program. Awardees, including New Jersey, facilitate the distribution of vaccines to participating provider locations to meet the specific needs of eligible populations in jurisdictions.

The Public Health Services Act Section 317 authorizes the federal purchase of vaccines to meet the needs of priority populations. In New Jersey, those priority populations are uninsured and underinsured adults for routine vaccines AND any at-risk populations during an outbreak response.

The Centers for Disease Control and Prevention (CDC) uses federal funds to purchase vaccines and distribute them at no cost to public health clinics and provider locations enrolled in the program.

All VFC providers are required to stock all ACIP-recommended vaccines for their patient population and follow the ACIP schedule. ACIP schedules are updated yearly and can be viewed online or printed: [Immunization Schedules for Healthcare Professionals | CDC](#)

PROVIDER ENROLLMENT

This module describes eligibility, responsibilities, new provider enrollment, re-enrollment, disenrollment, and termination for VFC and 317 providers.

PROVIDER ELIGIBILITY

To be eligible to participate in these programs, providers must:

1. Be a licensed Medical Doctor (MD) or Doctor of Osteopathic Medicine (DO) in the state of New Jersey authorized to administer vaccines to children aged 18 years and younger for VFC, and to adults 19 and older for 317.
2. Be willing and able to follow all VFC and/or 317 program requirements, policies, and procedures, such as participation in site visits and educational opportunities.
3. Have the capacity to order, receive, manage, store, and monitor temperatures of federally-funded vaccines in accordance with CDC, NJDOH, and vaccine manufacturer guidelines.
4. Be open at least four consecutive hours on a day other than Monday to receive vaccine shipments.
5. Ensure that all health care providers (PA, NP, MD, and DO) in the enrolled practice, and corresponding professional license numbers, are listed on the provider profile.¹
6. For 317 Providers Only: Provider represents a local health department, a federally qualified health center (FQHC), or a not-for-profit organization.

¹ 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 or 317 programs. If NJDOH has been notified by the state Medicaid agency that a provider is on the Office of Inspector General's (OIG) List of Excluded Individuals and Entities (LEIE), that provider location is not eligible for enrollment in the VFC or 317 program.

REQUIREMENTS TO PARTICIPATE

In order for eligible providers to receive federally-funded vaccines at no cost, the facility's Medical Director is responsible for ensuring they, as well as all practitioners, nurses, and other professionals associated with the enrolling health care facility, follow all requirements of the VFC and 317 programs.

The Provider Agreement, which is signed at the time of online enrollment in NJIIS and annually at re-enrollment, details program requirements. The annual execution of the Provider Agreement ensures continued understanding and accountability of providers participating in the VFC/317 programs.

VFC and 317 providers must register with NJIIS and enter all doses of federally-funded vaccine administered into NJIIS within 30 days of administration (regardless of the age of the patient).

NEW PROVIDER ENROLLMENT

The New Provider Enrollment module in NJIIS must be completed for all new VFC and 317 providers. Before beginning the application in NJIIS, it is recommended for providers to review and complete the VFC Enrollment Prerequisites (See Figure 1).

Upon submission of the VFC or 317 enrollment module in NJIIS, sites will receive an electronic notification of approval and activation into the associated program.

***ALWAYS INCLUDE A PIN NUMBER IN
THE SUBJECT LINE OF EMAIL
COMMUNICATIONS.***

NJDOH staff will contact the provider to arrange for a new enrollment site visit. All new providers and returning providers (providers that have exited the program and are re-joining) must receive a VFC or 317 enrollment site visit. The purpose of the site visit is to ensure that facility staff are supported and educated on the VFC/317 program requirements and have appropriate resources to implement them. Providers cannot order vaccine until the site visit is completed.

Figure 1: LIST OF PROVIDER ENROLLMENT PREREQUISITES

Staffing

- Medical Director
 - Responsible for ensuring that all VFC/317 policies and procedures are being followed by the facility.
 - Required to designate a Primary and Backup Vaccine Coordinator.
- Primary and Backup Vaccine Coordinators
 - Vaccine coordinators are responsible for:
 - Being the points of contact for the NJDOH VFC/317 program.
 - Being consistently present during normal business hours.
 - Overseeing all vaccine management within the facility, including ensuring and documenting annual vaccine management training for designated staff, as well as training of new staff upon hire.
 - Being the points of contact for receiving vaccine shipments, monitoring storage unit temperatures, managing vaccine inventory, etc.

Required Training

- Vaccine Coordinators are required to complete ALL of the following training courses before appearing in the drop-down selection in the enrollment application:
 - NJIIS Fundamentals training.
 - Vaccine Ordering and Management in NJIIS
 - Registration for training courses can be found on NJIIS at <https://njiis.nj.gov/core/web/index.html#/training>

Required Equipment

- Provider office **MUST** have storage units that meet CDC requirements. Purpose-built or pharmaceutical-grade units are preferred. Household-grade units can be an acceptable alternative to pharmaceutical-grade vaccine storage units. Stand-alone household units are preferred over combination units, however the freezer compartment of household combination units cannot be used to store vaccines, even temporarily.
- Provider office **MUST** have calibrated and certified digital data logging (DDL) thermometers that meet the following criteria for all vaccine storage units:
 - 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.
 - Low-battery indicator.
 - Current, minimum, and maximum temperature display.
 - Uncertainty of +/-0.5° C (+/-1° F) for fridge and freezer ranges.
 - Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures every 30 minutes or less.
- Provider office **MUST** also have backup calibrated and certified DDL thermometers.
 - As a best practice, backup DDLs should have a different calibration retesting date than other DDLs to avoid requiring all DDLs to be sent out for recalibration at the same time.

Required Documents

- Current 2 weeks of temperatures recorded by your DDL thermometers for each storage unit.
- Current 2 weeks of min/max temperatures entered in NJIIS for each storage unit.

For additional information please contact VFC@doh.nj.gov.

Any office location that wants to administer VFC or 317 vaccine must receive its own NJIIS Provider Identification Number (PIN) assigned by NJDOH. Practices located outside of New Jersey cannot enroll.

PROVIDER STAFFING, TRAINING, AND INFORMATION UPDATES

PRIMARY AND BACKUP VACCINE COORDINATORS

During the application process, VFC and 317 provider locations are required to designate both a primary and backup vaccine coordinator for each facility. Primary and backup coordinators must complete the required trainings in order to be designated in the NJIS system as coordinators. To effectively perform the duties, the primary vaccine coordinator and backup coordinator must be fully trained on routine and emergency standard operating procedures (SOPs) for vaccine ordering, storage, handling, transport, and inventory management. The backup vaccine coordinator must be able to assume vaccine management oversight responsibilities in the absence of the primary vaccine coordinator. The vaccine coordinators are responsible for overseeing all vaccine management within the facility, including:

Vaccine coordinators must complete training before providers can complete new provider enrollment on NJIS.

- Developing and maintaining the [Vaccine Management Plan](#)
- Monitoring storage and handling and vaccine administration practices in the facility
- Overseeing vaccine ordering and ensuring vaccines that are nearing the expiration date are transferred to another VFC or 317 providers.
 - *If a provider is unable to identify a VFC/317 provider to transfer vaccines to, the VFC/317 program will assist in identifying active providers within the program*
- Ensuring and documenting annual vaccine management training for designated staff, as well as training new staff upon hire
- Participating in and documenting completion of annual training on VFC and 317 requirements
- Storing all required documentation for three years even in the case of provider retirement or provider location closure

Providers are required to notify the NJDOH VFC and/or 317 programs whenever there is a change in vaccine coordinator staff.

INITIAL AND ANNUAL TRAINING

The VFC/317 programs require that Primary and Backup Vaccine Coordinators complete initial educational training programs. It is the Medical Director's responsibility to ensure that all staff members who receive deliveries, handle, and/or administer vaccines are trained on the storage and handling policies and procedures at the facility and are fully trained to use the equipment at the provider location. NJDOH recommends that policies be accessible to all staff and that providers offer storage and handling training to all staff:

- As part of new employee orientation
- Annually for all staff involved in immunization and vaccine storage and handling activities
- Whenever recommendations for the storage and handling of vaccines are updated

Initial Training Requirement:

Before enrolling as a new VFC or 317 site or requesting a change in Vaccine Coordinators, all new Coordinators are required to take the following [trainings](#):

- NJIS Fundamentals training, and
- Vaccine Ordering and Management (VOM) training.

Annual Education Requirement:

Primary and Backup Coordinators must complete annual training (every 12 months). To satisfy the annual training requirement, Coordinators must complete **one** of the following:

- NJDOH webinar “Understanding VFC & Adult 317 Webinar”
- Both [You Call the Shots](#) - *Vaccines for Children* AND *Vaccine Storage and Handling* modules available through the CDC’s website
- Attend the NJDOH New Jersey Immunization Conference’s Storage and Handling session

All VFC and 317 required training can be accessed on [NJIS](#). Please allow up to two weeks for NJIS to be updated with completion of training. In order to receive credit for the You Call the Shots trainings, certificates of completion must be emailed to the VFC and 317 programs at VFC@doh.nj.gov must be completed prior to provider annual re-enrollment.

INFORMATION UPDATES

An IMM-48 “Request to Update Provider Information” should be submitted whenever there is a change in:

- Office staff including the VFC Vaccine Coordinators
- Office information (delivery address, email address, phone number)
- Delivery days and/or hours
- VFC-eligible or 317-eligible population during the enrollment year. Number of individuals who received vaccinations in the last 12 months

To update the facilities Medical Director submit the following documents:

- [VFC](#): IMM-26 and IMM-36
- [317](#): IMM-18 and IMM 25

The IMM-48 is an electronic form located under VFC/317 tab in NJIS.

ANNUAL RE-ENROLLMENT

Providers are required to re-enroll with the VFC and/or 317 programs each year. 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 placed on a vaccine ordering hold until re-enrollment is complete or they are disenrolled from the program.

The exact dates of re-enrollment will be determined by NJDOH each year. Notice to re-enroll will be posted on the NJIS Bulletin Board and sent to the Vaccine Coordinators as well as the office’s email address on file in NJIS.

PROVIDER DISENROLLMENT

To voluntarily disenroll from the VFC and/or 317 programs, providers will need to complete the “Provider Disenrollment Request” electronic form available on the [NJIS website](#). Email the form to VFC@doh.nj.gov at least two months BEFORE the date of disenrollment. [Vaccines will have to be transferred](#), both physically and electronically, to another participating provider in New Jersey at the time of disenrollment. If a provider is unable to identify a VFC provider to transfer vaccines to, the VFC program will assist in identifying an active provider within the program before the disenrollment form is processed.

TERMINATION

Provider locations that have not placed a core vaccine order of all ACIP-recommended vaccines in over 365 days are considered inactive. A notice will be sent to the provider and if a core order is not placed, the provider will be terminated from the VFC and/or 317 programs. VFC/317 vaccines will need to be transferred to another VFC location at the time of termination.

SOLEY PLACING AN INFLUENZA ORDER DOES NOT SATISFY THE CORE ORDERING REQUIREMENTS.

Providers may also be terminated from the VFC/317 programs due to issues of non-compliance that fail to be remediate within a reasonable timeframe. Depending upon the severity of compliance issues, providers may be referred to external agencies such as the CDC, New Jersey State Board of Medical Examiners, or the Centers for Medicare and Medicaid Services.

VFC-funded vaccines cannot be transferred to an Adult 317 facility and vice-versa.

PATIENT ELIGIBILITY SCREENING AND BILLING

VFC and 317 vaccines can be administered only to eligible populations. For patients to receive vaccines through the VFC or 317 programs, eligibility screening and documentation must take place at each immunization visit prior to immunization.

VFC ELIGIBILITY

Children from birth through 18 years of age (less than 19 years of age) who meet at least one of the following criteria are eligible to receive VFC vaccines:

- **Medicaid-eligible** – A child who is eligible for the Medicaid program. For purposes of the NJ VFC Program, Medicaid eligible and Medicaid enrolled are used interchangeably. Children who have health insurance through NJ Family Care Plan A are eligible Children with FamilyCare Plans B, C, and D are not eligible.
- **Uninsured** – A child who has no health insurance coverage.
- **American Indian/Alaska Native (AI/AN)** – As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603); or
- **Underinsured**- A child who has private health insurance coverage, but the coverage does not include vaccines; or a child whose insurance does not cover all ACIP-recommended vaccines. The child would be eligible to only receive the vaccines not covered by insurance.

Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC). Visit [NJ.gov](https://www.nj.gov) to locate the nearest FQHC.

317 ELIGIBILITY

For adults to receive vaccines through the 317 program, eligibility screening and documentation must take place at each immunization visit prior to immunization.

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 only receive those vaccines not covered by the insurance.

With prior approval from NJDOH, fully insured individuals may also be eligible to receive 317 vaccines during public health response activities including:

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

SCREENING DOCUMENTATION

All individuals must be screened and have VFC/317 eligibility documented at each immunization visit prior to immunization. The [Patient Eligibility Screening Record \(IMM-28\)](#) and [Patient Eligibility Screening Record \(IMM-28A\)](#) are forms that will assist in determining the patient's eligibility for the VFC/317 program. Providers must document the patient's eligibility status and insurance type in NJIS. If the eligibility cannot be documented in the electronic health records (EHR), eligibility may be recorded on the Patient Eligibility Screening Record (IMM-28) and scanned into the EHR or maintained in a paper chart. Paper documentation must be maintained for a minimum of three years and is bound by the privacy protection of Federal Medicaid law. Documentation of eligibility can also be noted on encounter/billing records for all dates of service. These should be readily available for review during a compliance visit.

BILLING FOR VFC VACCINE ADMINISTRATION

Families not covered by Medicaid or Medicaid HMOs may be charged a vaccine administration fee. However, **providers may not refuse vaccine to a VFC-eligible client due to the child's parent/guardian inability to pay an administration fee.** This administration fee should not exceed the maximum regional charge determined by [New Jersey by the Centers for Medicare and Medicaid Services](#). There is no lower limit, so providers have the option to charge what they feel is fair, including not charging a fee.

Providers **may not charge** VFC-eligible patients for the cost of federally funded vaccines provided by the VFC Program. Providers, Medicaid, and Medicaid Health Maintenance Organizations (HMOs) may bill for office visits and vaccine administration fees. Providers that bill for the vaccine administration fee of a non-Medicaid, VFC-eligible child after the date of service may issue only a single bill to the patient within 90 days of vaccine administration. This policy does not apply to vaccine administration fees billed to Medicaid for children who meet the Medicaid eligibility criteria for the VFC program. Unpaid administration fees may not be sent to collections, and the provider may not refuse to vaccinate an eligible child whose parents or guardians have unpaid vaccine administration fees.

VFC SPECIAL SCREENING AND BILLING CONSIDERATIONS

There are certain situations where special screening and billing considerations are applicable. The following situations are common considerations when screening for the VFC program:

- **School-Based Clinics:** Children who receive vaccines in a school-based clinic must not automatically be considered VFC-eligible; all children must be screened, and eligibility documented prior to administering VFC vaccine.
- **Resident of a different state:** Providers who administer VFC vaccine to a Medicaid-enrolled child from a neighboring state must be a Medicaid-enrolled provider for the state where the Medicaid-enrolled child resides to receive reimbursement for the administration fee from the neighboring state's Medicaid program.
- **Medicaid as Secondary Insurance:** The provider can administer VFC vaccines and bill Medicaid for the administration fee or the provider can administer private stock vaccine and bill the primary insurance carrier for both cost of vaccine and administration fee.
- **Medicaid as Secondary Insurance with High Deductible Primary Insurance:** If a child has Medicaid as secondary insurance and the primary insurance is a high-deductible insurance plan requiring the parent to pay out of pocket for vaccines, the child should be considered VFC-eligible if the family has not yet reached its deductible. VFC vaccines should be administered, and the administration fee should be billed to Medicaid until the deductible is reached.

ORDERING VACCINE

Providers order vaccines through NJIIS. See **Table 1** for ordering best practices. 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 reported patient population and the number of doses of vaccine administered and correctly recorded by the provider in NJIIS since the last order. Each administered dose that is correctly entered into NJIIS – either manually or through an interface with an electronic health record – will automatically decrement the NJIIS inventory. If all the doses administered are not entered correctly into NJIIS, the NJIIS inventory will be greater than the actual vaccine doses physically in the storage units.

Enrolled providers are assigned an ordering frequency based on the size of the reported eligible population. Providers must submit a 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 patients 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.

Some vaccine such as COVID-19 and influenza vaccine can be ordered with other VFC/317 vaccines or independently through NJIIS during peak seasons.

The Medical Director is responsible for ensuring that his/her staff is ordering an appropriate amount of vaccine to meet the needs of the provider’s eligible population until the next scheduled order date. Medical Directors are encouraged to keep vaccine orders at a reasonable interval to reduce the risk of vaccine expiration and loss, but also maintain a “buffer stock” of enough vaccines for approximately 14 days 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). Emergency orders can be requested through email; however, emergency orders should be rare and subject to program approval.

Table 1: Best Practices to Expedite The Ordering Process

Ensure vaccine doses administered are accurately recorded in NJIIS.	Input vaccines administered into NJIIS immediately after the dose is given. Providers are expected to enter vaccines administered no later than 30 days after administration.
Ensure that vaccine inventory is up to date.	On-hand inventory should be counted at least monthly and before placing an order. Resolve any inventory discrepancies identified.
Ensure the quantity ordered will maintain sufficient vaccine inventories.	Compare actual inventory counts in storage units with patient population to avoid stockpiling or under-ordering.

Providers are able to request orders that exceed the quantity suggested in NJIIS. However, it is important that providers add a comment that indicates the reason for the larger than expected order. Adding a comment will help expedite the review and approval of these orders.

In certain circumstances, the VFC and 317 programs might update or cancel orders. An automated message is sent if the order is updated or canceled with corrective action steps.

REASONS FOR UPDATING OR CANCELING 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 met requirements of the VFC and/or 317 programs.

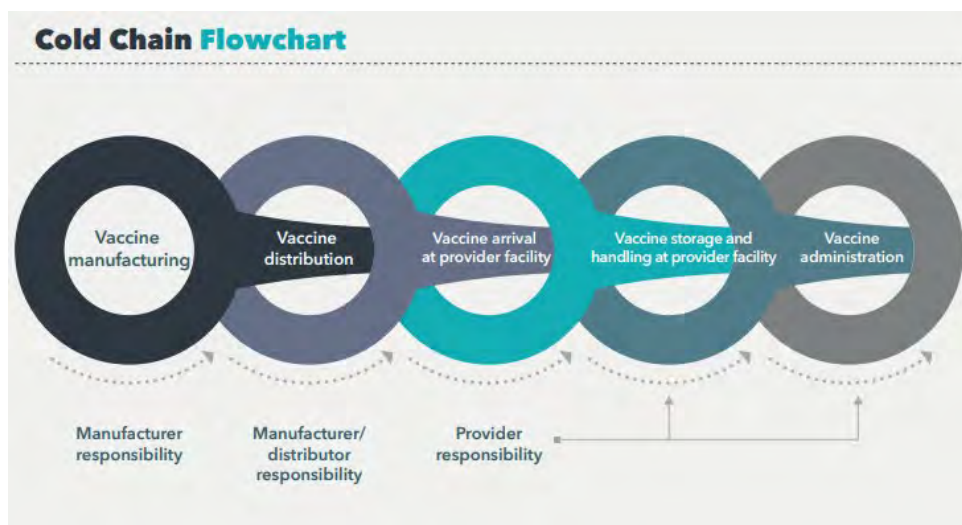
Providers that face unexpected vaccine shortages between scheduled orders can contact VFC@doh.nj.gov to request additional vaccine doses.

VACCINE MANAGEMENT

The management of federally-funded vaccines 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. Proper vaccine storage and handling procedures begin with an effective cold chain. A cold chain (see Figure 2) is a temperature-controlled supply chain that includes all vaccine-related equipment and procedures. Sound vaccine management practices, including maintaining the cold chain, will minimize vaccine loss and waste, and the potential need to revaccinate patients who received compromised vaccines. This section will review the Vaccine Management Plan, Vaccine Storage Unit Selection, Digital Data Loggers, and Storage Unit Set Up.

Providers are encouraged to have all staff responsible for vaccine storage and handling review and apply the practices for proper vaccine storage and handling found on the CDC's website: [Vaccine Storage and Handling Toolkit](#)

Figure 2: Image of Cold Chain Flow Chart



VACCINE MANAGEMENT PLAN

It is a VFC and 317 requirement to keep an updated Vaccine Management Plan. The Vaccine Management Plan Template is available on the [NJIS website](#) to assist providers. Each provider should complete the template to meet specific needs and update the information as needed.

The plan should be posted on or near the vaccine storage unit to be easily accessible for staff to assist in vaccine management response. At a minimum, the plan must be reviewed and updated annually, or any time there is a change in staff with responsibilities specified in the plan. The plan will be reviewed at the VFC and/or 317 compliance visit. It is the Medical Director's responsibility to ensure that all staff members are trained on the policy and understand roles in vaccine management, including clerical staff who might sign for packages upon delivery. The plan must be signed by the Medical Director and the Primary and Backup Vaccine Coordinators. The plan must include the date last reviewed to verify that the plan was updated within the last 12 months.

VACCINE STORAGE UNITS

There are several types of vaccine storage units available (see Figure 3). Purpose-built units are specifically designed to store vaccines and are the preferred for vaccine storage. However, household-grade units are also an acceptable option for vaccine refrigeration under the right conditions. To fully ensure the safety of vaccines, equipment should include a recommended unit with enough space to accommodate maximum inventory during peak seasons without crowding. Providers must document the vaccine storage unit's make and model at the time of enrollment, re-enrollment, and when adding/replacing existing units. It is the Medical Director's responsibility to ensure the vaccine storage units are properly functioning and maintained/serviced in accordance with the manufacturers' recommendations.






Purpose-built units, sometimes referred to as "pharmaceutical-grade," are designed specifically for storage of biologics, including vaccines. These units often have a microprocessor-based temperature control with a digital temperature sensor (thermocouple, resistance temperature detector [RTD], or thermistor) and a fan-forced air circulation with powerful fans or multiple cool air vents promoting uniform temperature and fast temperature recovery from an out-of-range temperature. These units can be compact, under-the-counter style or large.

Household-grade units can be an acceptable alternative to pharmaceutical-grade vaccine storage units. As the name implies, these units are primarily designed and marketed for home use. However, the freezer compartment of a household combination unit cannot be used to store vaccines and there may be other areas of the refrigerated compartment that should be avoided as well. If the facility provides frozen vaccine, a separate freezer unit is necessary.

Doorless/vending style units that are assessed should be identified as such for the type of unit and purpose built for the grade. The immunization program determines which purpose-built units meet VFC and/or 317 program requirements. Please refer to CDC's Vaccine Storage and Handling Toolkit for more information on purpose-built units.

Do not 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 pose a significant risk of freezing vaccines, even when used for temporary storage.

Figure 3: Images Of Vaccine Storage Units

Stand Alone Refrigerator (NO FREEZER COMPARTMENT)	Stand Alone Freezer	Ultra-Low Temperature (ULT) Freezer	Combination Refrigerator / Freezer (VACCINES CANNOT BE STORED IN FREEZER COMPARTMENT)	Doorless/Vending style
				

STORAGE UNIT PLACEMENT

Good air circulation around the outside of the storage unit is important. Place a storage unit in a well-ventilated room, leaving space between the unit, ceiling, and any wall. Nothing should block the cover of the motor compartment. The unit should be firm and level, with the bottom of the unit above the floor. Make sure the unit door opens and closes smoothly and fits squarely against the body of the unit. If not secured properly, unit doors pose a risk to maintaining appropriate internal temperatures of vaccine storage units. Studies find most units work best when placed in an area with standard indoor room temperatures, usually between 20° C and 25° C (68° F and 77° F). Check the manufacturer-supplied owner’s manual for additional guidance on placement and spacing.

STABILIZING TEMPERATURES IN NEW AND REPAIRED UNITS

It may take two to seven days to stabilize the temperature in a newly installed or repaired refrigerator and two to three days for a freezer. After stabilization, providers must send a DDL file with two consecutive days of in-range temperatures to [VFC](#) and add daily minimum and maximum (min/max) temperatures in the NJIIS Temperature Log.

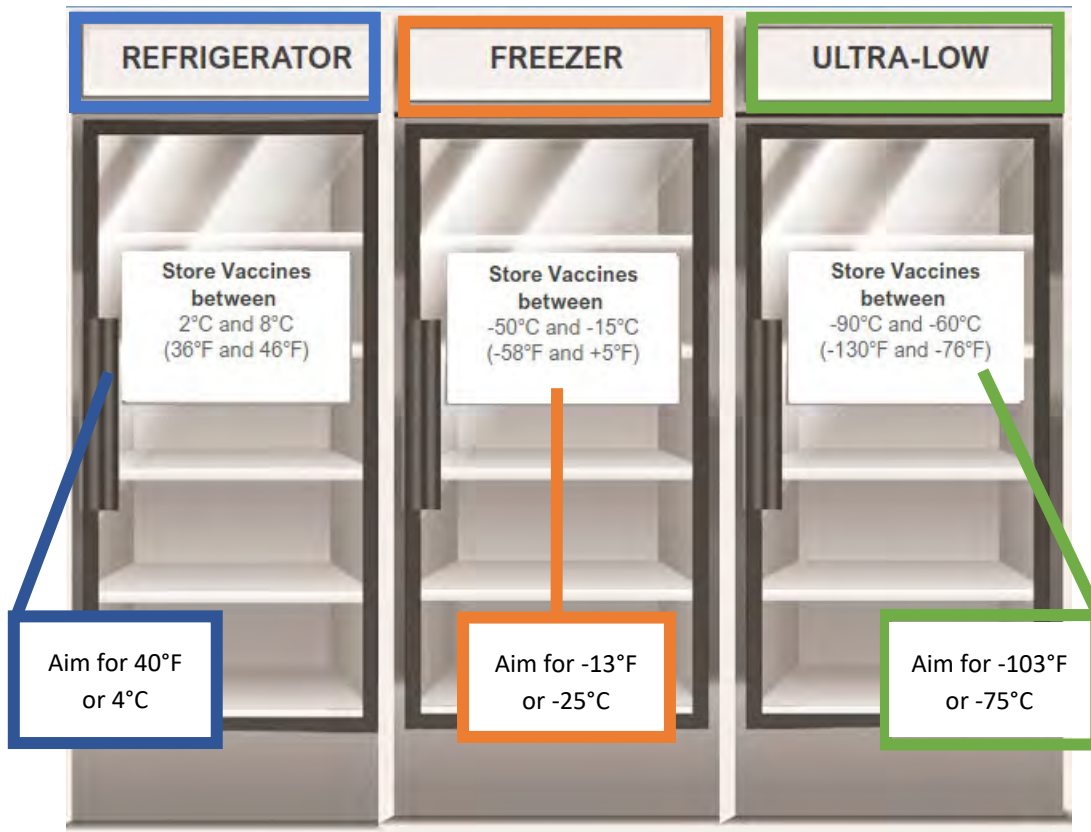
PROVIDERS MUST ENSURE UNITS ARE UPDATED IN NJIIS.

TEMPERATURE RANGES

Refrigerators (see Figure 4) must maintain temperatures between 2° C and 8° C (36° F and 46° F). Freezers must maintain temperatures between -50° C and -15° C (-58° F and +5° F). Ultra-cold freezers must maintain temperatures between -90° C and -60° C (-130° F and -76° F). Refrigerator or freezer thermostats should be set at the factory-set or midpoint temperature, which will decrease the likelihood of temperature excursions.

Consult the owner’s manual for instructions on how to operate the thermostat. Thermostats are marked in various ways and, in general, show levels of coldness rather than temperatures. The only way to know the temperature where vaccines are stored is to measure and monitor it with a temperature monitoring device.

Figure 4: Suggested Temperature Ranges for Refrigerator, Freezer And Ultra-Low Freezer



DIGITAL DATA LOGGERS (DDLs)

Providers are required to have a working and up-to-date DDLs with a Certification of Calibration in each refrigerator and freezer units used for vaccine storage. Only one DDL should be placed in each storage unit. Providers should follow the manufacturer's recommended schedule for recalibration of the certified DDL. It is the Medical Director's responsibility to ensure that staff is trained to use the DDL.

PROVIDER BEST PRACTICE: ONLY ONE DDL SHOULD BE PLACED IN EACH STORAGE UNIT. IT IS RECOMMENDED TO PLACE THE BACKUP PROBE IN THE STORAGE UNIT TO ACCLIMATE. DO NOT PLUG IN THE BACKUP DDL UNLESS THE PRIMARY DDL FAILS.

Recalibration must be performed every 24 months or according to the manufacturer's suggested timeline.

Providers are also required to have at least one back up DDL for each storage unit type with a Certification of Calibration (see Figure 5). For example, if the provider has a dual-probe DDL, the back-up DDL must be either a dual-probe or two single probes. If a provider has a refrigerator-specific DDL and a freezer-specific DDL, refrigerator and freezer back-ups must be available. The back-up digital data logger should have a different Certification of Calibration expiration date than the expiration of the one currently being used in the vaccine storage units.

Each DDL must have the following features:

- Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon®)
- An active temperature display that can be easily read from outside the unit
- Alarm for out-of-range temperatures
- Low-battery indicator
- Current, minimum, and maximum temperature display
- Recommended uncertainty of $\pm 0.5^{\circ}\text{C}$ ($\pm 1^{\circ}\text{F}$)
- Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures at least every 30 minutes

PROVIDER BEST PRACTICE: THE BACKUP DDL SHOULD HAVE A CERTIFICATE OF CALIBRATION EXPIRATION DATE AT LEAST 60 DAYS FROM THE EXPIRATION OF THE PRIMARY DDL.

Battery changes may affect temperature accuracy and may warrant checking against a known, calibrated DDL. Check with the device's manufacturer for specific information on battery changes.

Figure 5: Items for a Certificate of Calibration

Each DDL Certificate of Calibration must include:

Model/device name or number

Serial number

Date of calibration (report or issue date)

Confirmation that the instrument passed testing (or instrument is in tolerance)

Recommended uncertainty of +/- 0.5° C (+/-1° F) or less

To determine if a Certificate of Calibration was issued by an appropriate entity, check to see if the certificate indicates one or more of the following items about calibration testing:

- Conforms to International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 international standards for calibration testing and traceability
- Performed by a laboratory accredited by International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body
- 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 or higher
- Refers to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points



PROVIDER BEST PRACTICE: ENSURE THE CORRECT DATE AND TIME ARE SET ON THE DDL. IT IS IMPORTANT TO KNOW THE CORRECT DATE AND TIME THAT EACH TEMPERATURE RECORDING CORRESPONDS TO.

POWER SUPPLY

Even with appropriate equipment and temperature monitoring practices in place, power disruption can result in destruction of the entire vaccine supply. Precautions should always be taken to protect the storage unit's power supply. Consider purchasing a backup generator if the facility does not currently have one.

- 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 the building is owned by a third party and the provider does not have access to the circuit breakers, work with the building manager. Units must be plugged directly into an outlet; never plug a unit into a surge protector.
- Plug in only one storage unit per electrical outlet to avoid creating a fire hazard or triggering a safety switch that turns the power off.
- Use a safety-lock plug or an outlet cover to prevent the unit from being unplugged.
- Label fuses and circuit breakers to alert people not to turn off power to a storage unit.
- Use caution when using power outlets that can be tripped or switched off and avoid using:
 - Built-in circuit switches (may have reset buttons)
 - Outlets that can be activated by a wall switch
 - Multi-outlet power strips

If built-in circuit switches, Uninterruptible Power Supply (UPS) unit, or power strip surge protection must be used, make sure the device is rated to carry the maximum current as specified by the manufacturer of the refrigerator or freezer. Additionally, consider how the device manages when the power is restored. Whether the device automatically restarts and allows the equipment to run or has to be manually switched on should be considered and represented in Emergency Plans and SOPs. Contact the unit manufacturer for any additional questions or guidance regarding circuit switches, power strips, UPI, or surge protection. If the entire storage unit is affected by a temperature excursion because of a power supply issue or unit malfunction, refer to the facility's emergency SOPs.

PLACEMENT OF DIGITAL DATA LOGGER

- Place the buffered probe of the DDL in the center of the unit with vaccines surrounding it (see Figure 6).
- Place the active digital display on the outside of the unit so temperatures can be checked without opening the door.
- Be sure that the data logger is set to measure and record at least every 30 minutes.
- DDLs should not touch any walls, cooling vents, or doors.

MONITOR STORAGE UNIT TEMPERATURES

Check and record storage unit minimum and maximum (min/max) temperatures at the start of each workday. The min/max recorded must be the temperatures obtained since the last workday when the min/max temperatures were reset. [Temperature monitoring log sheets](#) (examples in Figure 7) should be placed on each corresponding storage unit door (or nearby), and **the following information must be recorded daily**: Min/max temperature (exact temperature with no rounding), date, time, name or initials of person who checked and recorded the temperatures, and any actions taken if a temperature excursion occurred. Temperature Log information must be submitted to NJIIS on the 1st and 15th of every month. The min/max temperatures recorded on your log sheets should be identical to the min/max temperatures entered into NJIIS.

Figure 6: Image of DDL in center of unit



Do not leave vaccines in a storage unit that does not maintain temperatures within the recommended range. If unable to stabilize the temperature in the unit within the required range, or temperatures in the unit are consistently at the extreme high or low end of the range, the vaccine supply is at risk. Use the 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.

If 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. The freezer in a combination storage unit can not be used to store vaccines.

TEMPERATURE EXCURSIONS

Any temperature that falls outside of the CDC and vaccine manufacturer’s recommended ranges is considered a temperature excursion. Monitoring vaccine storage units and temperatures are essential steps to identify temperature excursions quickly and take immediate action to ensure the viability of vaccines and safety of patients. This prevents vaccine waste and the potential need for revaccination of patients. Every vaccine storage unit must have a DDL which provides the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range (referred to as a “temperature excursion”). Temperature data from a DDL can either be downloaded to a computer using special software or retrieved from a website. Routinely reviewing DDL data is critical for vaccine viability and patient safety.

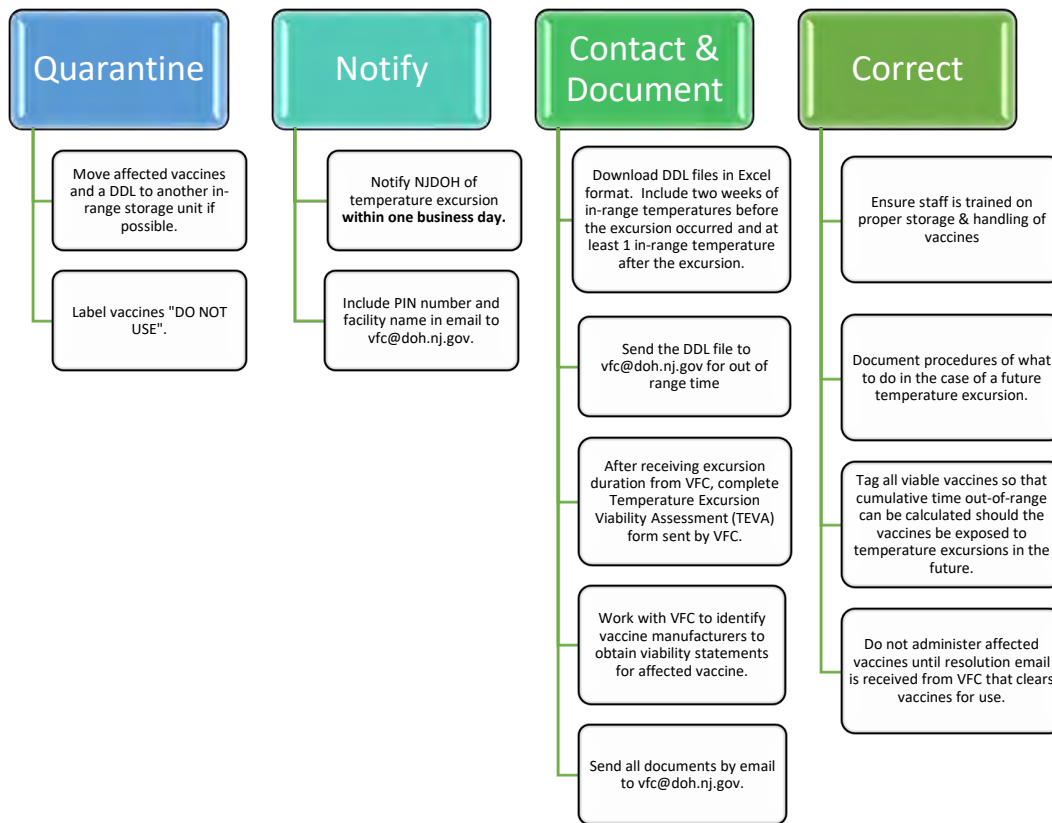
It is important to follow manufacturer vaccine product specifications found in the package insert. The package insert describes the required storage conditions for a particular vaccine. Manufacturers have access to internal (unpublished) thermostability data concerning the impact of exposures to inappropriate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

IMMEDIATELY TAKE ACTION IF ANY OUT-OF-RANGE TEMPERATURES ARE NOTED! (see Figure 8)– Even if the current temperature is in range, vaccine in the storage unit at the time of the excursion may have been compromised. Any out-of-range temperature (e.g., minimum, maximum, current temperature and temperature on DDL downloads) must be reported and investigated.

Providers can contact the manufacturer directly with questions about a specific vaccine storage temperature or temperature excursion. Always request written responses from manufacturers when requesting assistance. For additional training visit [General training for VFC and 317 Providers on Temperature Excursions](#)

PROVIDER BEST PRACTICE: LOOK FOR TRENDS IN TEMPERATURES – EVEN IF ALL THE TEMPERATURES ARE IN RANGE. ADJUST THE STORAGE UNIT THERMOSTAT BASED ON THE TRENDS TO PREVENT TEMPERATURE EXCURSIONS. E.G., NOTE THAT TEMPERATURES OF THE REFRIGERATOR ARE FREQUENTLY REACHING 36°F. ADJUST THE THERMOSTAT TO MAKE IT A BIT WARMER. IF THE TEMPERATURE REACHES BELOW 36°F, IT WOULD BE CONSIDERED OUT-OF-RANGE AND VACCINES MIGHT BE COMPROMISE.

Figure 8: Steps To Take When A Temperature Excursion Occurs



ORGANIZING AND STORING VACCINES

To confirm vaccines are stored correctly (see Figure 9) and to minimize the risk of administration errors, providers should implement the following practices:

- Store each type of vaccine or diluent in its original packaging and in a separate container.
- Position vaccines and diluents 2 to 3 inches from the unit walls, ceiling, floor, and door. If using a household-grade unit, 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 deli, fruit, or vegetable drawers; or on refrigerator door shelves. The instability of temperatures and air flow in these areas may expose vaccines to inappropriate storage temperatures.
- Label shelves and containers to clearly identify where each type of vaccine and diluent is stored.
- Store vaccines and diluents with similar packaging or names or with pediatric and adult formulations on different shelves.
- Whenever possible, store diluent with the corresponding refrigerated vaccine. Never store diluent in a freezer. Only use the diluent provided or recommended by the vaccine manufacturer.
- Avoid placing or storing any items other than vaccines, diluents, and water bottles inside storage units.
 - If other medications and biological products must be stored in the same unit as vaccines, they must be clearly marked and stored in separate containers or bins from vaccines.
 - Potentially contaminated items (e.g., blood, urine, stool) should be properly contained and stored below vaccines due to risk of contamination from drips or leaks.
 - The freezer of a household-grade unit may be used for non-vaccine, medical storage, so long as the use does not compromise the temperature range within the refrigerator compartment where vaccine is stored.
- Arrange vaccines and diluents in rows and allow space between them to promote air circulation.
- Place vaccines and diluents with the earliest expiration dates in front of those with later expiration dates.
- Never reuse single dose vials and syringes.

For certain purpose-built units, it is recommended that vaccine be stored outside of the packaging. If this is the case, follow the manufacturer's guidance for vaccine storage.

Figure 9: Image of Properly Stored Vaccines

How to Store Vaccines

Place water bottles on the top shelf and floor and in the door racks. Putting water bottles in the unit can help maintain stable temperatures caused by frequently opening and closing unit doors or a power failure.

Water bottles are not recommended for use with certain pharmaceutical-grade and purpose-built units. For such units, follow the manufacturer’s guidance.



Food and beverages should never be stored in the unit with vaccines.

If other biologics are stored in the unit, vaccines should be stored on the shelf above them.

HANDLING VACCINE

RECEIVING VACCINES

The Primary or Backup Coordinators should be present or ensure that a trained staff member is available to receive vaccine delivery for at least a four-hour window on a day other than Monday. All staff members who might accept vaccine deliveries must be trained on 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. Vaccines and diluents must be carefully unpacked, stored at recommended temperatures, and documented immediately upon arrival.



Never leave a vaccine shipping container unpacked and unattended.



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.
- 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 products are not expired or soon-to-expire products.
- Check the package's cold chain monitor for any indication of a temperature excursion during transit.
- Verify that vaccines are placed in appropriate storage units based on manufacturers recommended temperature range.

FOR FROZEN VACCINES, THE PACKING LIST WILL SHOW THE MAXIMUM TIME VACCINES CAN BE IN TRANSIT BASED ON SHIPMENT DATE.

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 the delivery.

If there are discrepancies between the contents and the packing list or any other concerns about the contents:

- Place the products in the appropriate storage unit separate from other vaccines.
- Mark **"DO NOT USE"**.
- [Contact VFC@doh.nj.gov](mailto:VFC@doh.nj.gov) immediately.

“BEYOND-USE DATE” (BUD)

EXAMPLES:

Reconstituted vaccines have a limited timeframe for use once the vaccine is mixed with diluent. Be sure to read the package insert carefully.

Multidose vials might have a specific timeframe for use once they have been punctured 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.

Vaccine that is stored in less ideal temperature conditions (for example Pfizer COVID-19 vaccine that is stored in the refrigerator) will have a shorter BUD.

VACCINE EXPIRATION DATES

Understanding expiration dates is a key component of managing 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, see Figure 10. It is important to rotate stock weekly to be sure that products with the shortest expiration dates are being utilized first.

Figure 10: Image of vaccine VIAL expiration dates



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.

Visit [COVID-19 BUD](#) for additional information.

Contact VFC@doh.nj.gov if vaccine stock cannot be used and will expire in 90 days. The program can assist with locating a VFC/317 provider who might be able to use the vaccine if a provider is unable to identify a provider willing to accept the transfer.

VACCINE ACCOUNTABILITY

INVENTORY

VFC/317 programs are supported through federally-funded vaccines. Keeping accurate records of administration and inventory is essential in ensuring vaccine accountability. Providers must account for all doses of federally-funded vaccines received.

BORROWING

“Borrowing” refers to taking a federally-funded VFC/317 vaccine and administering to an ineligible patient. In NJ, VFC/317-enrolled **providers are NOT permitted to borrow vaccines**. In the event that a dose of federally funded vaccine is inadvertently administered to a non-eligible patient, a provider must contact VFC@doh.nj.gov as soon as it is identified.

PROVIDERS WHO HAVE MULTIPLE INCIDENTS OF INADVERTENT ADMINISTRATION OF FEDERALLY FUNDED VACCINES MAY BE SUBJECT TO FURTHER CORRECTIVE ACTION.

VACCINE TRANSFER

Federally-funded vaccines may be transferred from one VFC/317 provider to another. Vaccine transfers can only occur between VFC to VFC providers, or 317 to 317 providers. 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. NJIIS has a new feature that notifies providers when a vaccine is set to expire within 90 days, 30 days, and a week prior to the expiration date in NJIIS.

Vaccine transfer process:

Step 1: [Contact VFC@doh.nj.gov](mailto:VFC@doh.nj.gov) to obtain approval to transfer vaccine to an approved, active VFC/317 program provider. It is important that both the sending and receiving providers have up-to-date temperature logs before a transfer is requested.

- If a provider is not identified for transfer, the VFC program staff will provide a list of providers in the county for possible transfer.

Step 2: Once approval has been received from the VFC program staff, prepare the vaccines to ensure that the cold chain is maintained during transport, including the use of a DDL and a qualified container and packout or portable refrigerator/freezer.

Step 3: Complete the physical transfer of vaccine as well as the electronic transfer in NJIIS.

Step 4: Review DDL file from transport and ensure temperature documentation is available validating that the vaccine has not been exposed to out-of-range temperatures.

VACCINE TRANSPORT CONTAINERS AND MATERIALS

For safe transport and storage of vaccines, proper supplies are essential. Transport packing methods differ between 1) emergency transport and 2) planned transport such as for off-site clinics, satellite facilities, or re-location of stock. In either case, a portable refrigerator/freezer or qualified container and packout are always the preferred method. All transport must be done using a digital data logger that meets CDC specifications. Be sure packouts are maintained in the conditioned state so they can be used for emergency transport.

Emergency transport requires either portable vaccine storage units (portable vaccine refrigerator/freezer), qualified containers and pack-outs, or the conditioned water bottle transport system (See Table 2).

- For step-by-step guidance on packing a cooler for emergencies using the conditioned water bottle method, see CDC’s [Packing for Emergency Transport](#).

Planned transport requires either portable refrigerators/freezers or qualified containers and pack-outs. The conditioned water bottle method **should not be used for planned transport**.

- Follow instructions specific to the portable refrigerator/freezer or qualified container/pack-out used.

Table 2: Emergency Versus Planned Transport Requirements

Transport Method	Emergency Transport	Planned Transport
Portable Vaccine Storage Unit	Yes	Yes
Qualified Container and Packout	Yes	Yes
Conditioned Water Bottle Transport System	Yes	No
Manufacturer’s Shipping Container	Yes <i>(last resort only)</i>	No
Food/Beverage Coolers	No	No

Note: 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.

Facilities must have a sufficient supply of materials needed for emergency vaccine transport of the largest annual inventory. Keep these available at all times and details of use within in your Vaccine Management Plan.

Appropriate materials include:

- Portable vaccine refrigerator/freezer units
- Qualified containers and packouts
- 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
- Insulating materials such as bubble wrap or corrugated cardboard – enough to form two layers per container
- A DDL with current Certificate of Calibration for each container
- Printed out guidance on [Packing for Emergency Transport](#)
- Printed out [transport temperature log](#) and pen for temperature documentation before, during, and after transport

If any temperature excursions are identified during transport, providers must notify VFC.

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.

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, maintaining an updated Vaccine Management Plan and making preparations in advance to retrieve and/or protect vaccines as quickly as possible can prevent vaccine loss.

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 the 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 there is backup equipment or a generator available, it is strongly recommended that a working agreement be established with at least one 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. It is best practice to use a facility that has 24 hour access and [purpose-built storage units](#).

If an alternative vaccine storage facility within a reasonable distance is not identified, use qualified containers and packouts to store vaccines temporarily.

Always place a DDL with the vaccines.

OFF-SITE VACCINE ADMINISTRATION

Vaccines that will be used at an off-site clinic should be transported using a portable vaccine refrigerator or qualified container and packout, with a DDL placed with the vaccines. Transport only the amount of vaccine needed for the workday as leftover vaccines cannot be left off-site overnight. The total time for transport and workday should be a maximum of eight hours the manufacturer specifies otherwise. Transport vaccines inside the passenger compartment – not the trunk.

PROVIDER BEST PRACTICE: REFER TO THE CDC GUIDANCE ON [PLANNING VACCINATION CLINICS](#) AND UTILIZE THE [OFF-SITE VACCINATION CLINIC CHECK LIST](#).

Immediately upon arrival at an off-site/satellite facility, vaccines should be stored in an appropriate storage unit with a DDL. Keep the container closed as much as possible, and check and record temperatures at least hourly.

LOSS AND NON-COMPLIANCE

NJDOH, CDC, VFC, and 317 providers work together to ensure that all eligible patients receive immunizations. It is important that providers account for and store federally-funded vaccines appropriately to avoid loss of vaccine due to expiration, storage and handling issues, administration, and inventory accounting errors.

Providers must ensure accountability for federally-funded vaccines and comply with VFC and 317 program requirements outlined in the Provider Agreement.

Any vaccine that cannot be used is considered a vaccine loss, including expired vaccine, vaccines past the BUD, spoiled vaccine, wasted vaccine or vaccine which is unaccounted for (See Table 3).

Vaccine that is determined to be a loss due to provider negligence or non-compliance may be required to be replaced as restitution on a dose-for-dose basis and/or the provider may be placed into a Corrective Action Plan.

Table 3: Types of Vaccine Loss

<p>Expired - vaccine that is past its expiration date.</p>	<p>Spoiled - any vaccine that exceeds the limits of approved cold chain procedures (temperature excursions) or is pre-drawn and not used within acceptable timeframes (an opened multi-dose vial is not spoiled until the expiration date has passed), or vaccine that has been delivered in non-viable condition.</p>
<p>Wasted - vaccine in an open vial, drawn into a syringe, or compromised because its container was dropped or broken. Wasted vaccines cannot be returned and should be disposed of following state and local disposal requirements.</p>	<p>Unaccounted for vaccine – vaccine for which the physical vaccine vial or syringe is missing.</p>

When managing expired, spoiled, and wasted vaccine:

- Remove the vaccines from any storage unit that stores viable vaccines.
- Label vaccines “[Do Not Use.](#)”
- Report and record the incident, including the reason and number of doses lost.
 - The reason for the loss must be added into NJIIS.
- Return spoiled and expired vaccines to McKesson within six months of the spoilage or expiration date.
- Remove expired, spoiled, and wasted doses from NJIIS inventory.

PREVENTABLE AND NON-PREVENTABLE LOSS

There are two different categories for vaccine loss, preventable and non-preventable. Non-preventable vaccine loss is when vaccine loss occurs and is not the fault of the provider. Preventable vaccine loss often occurs when providers do not follow vaccine management policies, procedures, and best practices.

Non-Preventable Vaccine Loss: No action will be taken to enforce dose-for-dose restitution if NJDOH determines the vaccine loss was not due to negligence or non-compliance on the part of the provider.

Examples of **non-preventable** loss include but are not limited to:

- A vial is dropped or broken.
- 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 or the manufacturer of vaccines that ship directly from the manufacturer immediately if this occurs.

However, any calls received by McKesson after the day of delivery might result in provider liability and need for replacement.

- A provider, in anticipation of an impending storm, moves vaccine to a location with a secure power source as documented in the Emergency Vaccine Retrieval and Storage Plan, but power is lost at that location.
- Vaccine that is drawn up at the time of the visit but is not administered due to parental or patient refusal or a change in physician orders.

Preventable Loss: This is vaccine loss due to provider negligence or non-compliance. Below is a list of situations that may require dose-for-dose restitution. Situations that occur which are not listed here will be considered on a case-by-case basis by the VFC Coordinator and/or the Vaccine Manager

Examples of preventable loss include, but are not limited to:

- Loss was due to a failure to establish and follow the Vaccine Management Plan.
- Ordering habits that lead to overstocking, resulting in expiration or excessive waste.
- Failure to maintain alarm/alert devices properly.
- Vaccines determined to be non-viable due to preventable and/or unreported temperature excursions.
- Storage unit door was left open or ajar by the provider, provider's staff, or contractor.
- Inability to account for federally funded vaccines.
- Administration of vaccine to VFC and/or 317 -ineligible individuals or drawing up vaccine prior to eligibility screening.
- Relying solely on electronic temperature monitoring and not recording and acting upon min/max temperatures.

NON-COMPLIANCE

If an enrolled VFC or 317 provider is found to be non-compliant with administration and management of federally-funded vaccines or the program requirements outlined in the Provider Agreement, then steps will be taken to correct deficiencies. Failure to adequately correct serious deficiencies, such as those that jeopardize vaccine effectiveness, can result in Corrective Action Plans, restitution, and/or removal of the provider from active participation in the NJ VFC and/or 317 programs.

CORRECTIVE ACTION PLANS (CAP)

Corrective Action Plans (CAP) are provider-specific plans, signed by the Medical Director and the Vaccine Coordinators, that assist providers in better managing aspects of the federally-funded vaccine programs such as VFC and 317. Plans are meant to educate and empower providers to manage vaccines more effectively. If provider negligence in vaccine management is discovered, a provider-specific CAP is developed.

Plans may be used to address items identified during a compliance site visit, temperature excursion investigation, inventory reconciliation, or other situations. CAPs that are needed for situations below the threshold for restitution will focus on education and providers identifying appropriate corrective actions.

RESTITUTION

Restitution is expected when provider negligence is identified. Two years of vaccine inventory is reviewed when calculating vaccine loss and determining the need for restitution. Providers with greater than 5% annual vaccine loss/waste per year (excluding flu vaccine) will be issued a Restitution Agreement. The Restitution Agreement stipulates that the provider must replace vaccines on a dose-for-dose basis by purchasing private vaccine doses within 90 days of signing the restitution agreement. Vaccine loss/waste might occur due to temperature excursions, overordering, inability to account for doses administered, not rotating stock, etc.

The provider must submit a copy of receipt(s) for all privately purchased vaccines procured to fulfill the restitution agreement. VFC program staff will enter the privately purchased vaccine doses into the provider's NJIIS online inventory under "NJDOH USE ONLY."

The VFC program staff will work with the provider during the restitution process to ensure there is no disruption in the provider's ability to administer all ACIP-recommended vaccines. Failure to fulfill the terms of the restitution agreement may result in disenrollment from the VFC program and possible referral to outside agencies.

There are circumstances when there is vaccine loss despite a provider's best efforts. Vaccine loss under 5% of total doses per year is considered in determining next steps towards restitution.

REVACCINATION

A Notice of Revaccination is issued to a provider when any vaccine doses determined to be non-viable were administered to patients within a provider's practice. The provider is required to submit data logger files with 5 days of in-range temperatures for vaccine storage units prior to the purchase of vaccines for revaccination.

New Jersey VFC program recommends that providers notify all patients or guardians of individuals who received non-viable vaccines and revaccinate all patients. VFC will provide assistance that includes:

- Template notification letter that can be customized and provided to patients and/or guardians.
- Secure spreadsheet that identifies the patients and lot numbers of vaccines deemed non-viable by the manufacturer(s).
- NJDOH Revaccination Help Guide for entering patient revaccination information in NJIIS.

It is NJDOH standard policy that revaccination be completed using privately purchased vaccines when the revaccination is needed because of a preventable temperature excursion or administration past the beyond-use date.

FRAUD AND ABUSE

All compliance visit reports submitted by field staff, including all documented cases of potential fraud and/or abuse (See Table 4), and all compliance visit findings and recommendations will be reviewed by NJDOH and then referred to the Program Manager, as needed, for final action. If the non-compliance appears intentional and/or

the provider has received financial benefits from the behavior, then the situation would require immediate referral to an outside agency for investigation of suspected VFC and/or 317 fraud and abuse.

NJ VFC is not responsible for the official investigation of fraud and/or abuse. Instead, when suspicious activity is documented or reported to the program a review will be conducted. If further investigation is warranted or justified, the case will be referred for formal investigation.

Referral 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.

Table 4: Fraud and Abuse is defined in the Medicaid regulations at 42 CFR § 455.2, the following definitions 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 health care. Abuse also includes recipient practices that result in unnecessary cost to the Medicaid program.

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

- Providing federally-funded vaccine to non-eligible patients.
- Selling or otherwise misdirecting federally-funded vaccine.
- Billing a patient or third party for federally-funded vaccine.
- Altering temperature or DDL data.
- Charging more than the established maximum regional charge for administration of a federally-funded vaccine to eligible patients.
- Denying established eligible patients federally-funded vaccine due to inability to pay 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 records and comply with other requirements of the federally-funded programs.
- Failing to fully account for federally-funded vaccine.
- Failing to properly store and handle federally-funded vaccine.

- Ordering federally-funded vaccine in quantities or patterns that do not match the provider’s profile or otherwise over-ordering VFC doses of vaccine.
- Preventable waste of federally-funded 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).

SITE VISITS

All enrolled providers will be reviewed periodically as a condition of continued enrollment in the New Jersey VFC and/or 317 programs. Providers should expect one or more of the following types of visits during a calendar year.

ENROLLMENT OR RE-ENROLLMENT VISIT–

The purpose of the enrollment site visit is to educate providers on implementing VFC/317 program requirements and supply appropriate resources, as well as to confirm the provider can store and monitor vaccine supply according to program requirements. An enrollment visit includes education about program requirements and recommendations, including proper vaccine storage and handling techniques. This visit is also an opportunity to establish a working relationship with the NJ VFC field representative assigned to the provider’s region. A re-enrollment visit will be made to providers that have: 1) requested to be reactivated in the program after termination, 2) moved into a new facility and/or 3) been delinquent in re-enrolling during the annual re-enrollment period.

VFC COMPLIANCE VISIT –

A compliance visit is a formal review of VFC procedures, practices, and records to confirm provider understanding and implementation of distributing current vaccine information statements (VIS) prior to administration of each vaccine. Compliance visits are performed to evaluate provider compliance with federal VFC protocols and address any noted deficiencies. VFC staff will contact the primary vaccine coordinator for scheduling of the VFC Compliance Visit, which should last between 2.5 and 3 hours. The NJ VFC representative will use CDC’s VFC Compliance Visit Questionnaire to guide the visit. Primary and Backup Coordinators should be available for this visit. It is highly recommended that the Medical Director be present for this visit as well. A review is conducted of a sampling of patient charts for documentation of VFC eligibility and billing, including both VFC and non-VFC eligible children 18 years of age and younger. Vaccine dose documentation will also be reviewed, including (1) name of vaccine administered; (2) date vaccine was administered; (3) date VIS was given; (4) publication date of VIS; (5) name of vaccine manufacturer; (6) lot number; (7) name and title of person who administer the vaccine; and (8) address of clinic where vaccine was administered. Providers are not notified in advance of charts that will be selected for review during site visits. Storage and handling practices/protocols and electronic as well as physical vaccine inventories are also reviewed and assessed.

If the office is using electronic health records, it is expected that someone familiar with the system is available to assist in retrieving any required documentation.

The facility's Medical Director (the person who signed the VFC Provider Agreement) must review compliance visit findings and sign the provided documentation. If requested, the provider may need to respond to areas of non-compliance with a written corrective action plan. This corrective action plan is normally due within two weeks of the request; delays in submitting a corrective action plan may result in a temporary hold on vaccine orders.

Preparation Tips for a Compliance Visit:

- Vaccine Management Plan is up to date, signed and all staff have been trained.
- Update NJIIS inventory.
 - **VFC STAFF WILL COMPARE PHYSICAL INVENTORY WITH REPORTED ON-HAND INVENTORY AS REPORTED IN NJIIS.**
- VFC vaccine storage units are accessible.
- DDLs: have current calibration certificates and DDL downloads (for each storage unit and at least one backup).
- Paper temperature logs are complete and accessible for review.
- [Vaccine Information Statements](#) are current.
- 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.

COMPLIANCE FOLLOW UP–

A compliance follow up is an assurance check of issues of concern that arose from a Compliance Visit. This follow-up may occur within 6 months of the original compliance visit.

STORAGE & HANDLING VISIT –

VFC enrolled providers may receive an unannounced storage and handling visit. The goal of this visit is to provide guidance and education, to protect the vaccine, and to ensure that all VFC-eligible children are receiving properly managed vaccines. This visit will be separate from any other VFC or IQIP visit and will be selected based upon a provider's previous history with storage and handling compliance, time elapsed since last visit and geographic distance from providers receiving VFC compliance visits.

EDUCATION VISIT –

VFC and 317 enrolled providers are offered and may request Vaccine Management Education Visits when circumstances warrant, such as a change in coordinators and other issues for which additional vaccine management education would be beneficial. The topics addressed during an educational visit can cover a specific area of improvement, such as: a review of how to maintain inventory documentation, review and download DDL's, the ACIP schedule, reporting forms or developing written vaccine storage and handling plans.

IQIP VISIT –

The goal of the IQIP visit is to assess immunization coverage rates of VFC providers for children 24 – 35 months of age and adolescents 13 years of age. This visit provides ongoing education regarding methods to increase immunization coverage levels. Methods include the use of tools within IIS, making a strong provider recommendation, and scheduling the next immunization appointment before the patient leaves the clinic. Additionally, this visit helps to analyze clinic flow and identify practices that may be affecting immunization rates and delivery of vaccines services to patients.

IQIP FOLLOW UP–

IQIP follow-up visits are conducted through phone/video calls at two months, six months, and 12 months.

VACCINE INFORMATION STATEMENTS AND VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)

VFC and 317 providers are required to distribute the current VIS each time a vaccine dose is administered and to maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS). Please note, that for FDA authorized products when there is not a VIS available, providers are required to distribute the Fact Sheet for Vaccine Recipients and Caregivers.

VACCINE INFORMATION STATEMENTS

A VIS or Vaccine Information Statement is a document, produced by CDC, that informs vaccine recipients – or parents or legal representatives – about the benefits and risks of a vaccine received. All vaccine providers, public or private, are required by the National Vaccine Childhood Injury Act (NCVIA – 42 U.S.C. § 300aa-26) to give the appropriate VIS to the patient (or parent or legal representative) prior to every dose of specific vaccines.

The appropriate VIS must be given prior to the vaccination and must be given prior to each dose of a multi-dose series. It must be given regardless of the age of the recipient. If a vaccine is FDA authorized and not approved, the EUA Fact Sheet for Vaccine Recipients and Caregivers will serve as the VIS.

Suggested ways to give a VIS:

- Paper copies of the VIS can be printed and given to patients prior to vaccination.
- Permanent, laminated office copies may be given to patients to read prior to vaccination.
- Patients may view VISs on a computer monitor or other video display.

Patients may read the VIS on phones or other digital device by downloading the pdf file from CDC's website.

Patients may be given a copy of a VIS during a prior visit, or told how to access it through the internet, so it can be read in advance. These patients must still be offered a copy to read during the immunization visit, as a reminder.

Patients must still be offered a copy of the VIS to take away following the vaccination. The patient may decline.

In addition to distributing VISs, as described above, providers are required to record specific information in the patient's medical record which can include an electronic medical record or paper chart:

- The edition date of the VIS (found on the back at the right bottom corner)
- The date the VIS is provided (i.e., the date of the visit when the vaccine is administered).
- The office address and name and title of the person who administers the vaccine.
- The date the vaccine is administered.
- The vaccine manufacturer and lot number.



VACCINE ADVERSE EVENT REPORTING SYSTEM

The Vaccine Adverse Event Reporting System (VAERS) is a national early warning system to detect possible safety problems in vaccines used in the United States. VAERS accepts and analyzes reports of adverse events (AEs) after a person has received a vaccination. Anyone can report an adverse event to VAERS. Health care professionals are required to report certain adverse events and vaccine manufacturers are required to report all adverse events that come to attention.

Health care providers are **required by law** to report to VAERS:

- Any adverse event listed in the [VAERS Table of Reportable Events Following Vaccination](#) that occurs within the specified time period after vaccinations
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine. Health care providers are strongly **encouraged** to report to VAERS:
- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event
- Vaccine administration errors

To report an adverse event visit [VAERS](#). For further assistance with reporting to VAERS, please email info@VAERS.org or call 1-800-822-7967.

GLOSSARY

Abuse (related to Fraud): Provider/provider location practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program (also includes actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient), or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. Also includes program recipient practices that result in unnecessary cost to the Medicaid program.

Advisory Committee on Immunization Practices (ACIP): Consists of 15 medical and public health experts selected by the Department of Health and Human Services secretary to provide advice and guidance to the secretary, assistant secretary for health, and CDC on the control of vaccine-preventable diseases. The committee develops recommendations for the routine administration of vaccines to children and adults in the civilian population, including guidance on age for vaccine administration, number of doses and dosing intervals, and precautions and contraindications.

American Indian or Alaska Native (AI/AN): As defined by the [Indian Health Care Improvement Act \(25 U.S.C. 1603\)](#):

- “Indians” or “Indian,” unless otherwise designated, means any person who is a member of an Indian tribe, as defined in subsection (d) of this section, except that, for the purpose of sections 1612 and 1613 of this title, such terms shall mean any individual who (1) irrespective of whether he or she lives on or near a reservation, is a member of a tribe, band, or other organized group of Indians, including those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member, or (2) is an Eskimo or Aleut or other Alaska Native, or (3) is considered by the Secretary of the Interior to be an Indian for any purpose, or (4) is determined to be an Indian under regulations promulgated by the Secretary.

- (d) “Indian tribe” means any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or group or regional or village corporation as defined in or established pursuant to the [Alaska Native Claims Settlement Act \(85 Stat. 688\)](#) [43 U.S.C. 1601 et seq.], which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

Beyond-use date (BUD): The date or time after which a vaccine should not be administered, stored, or transported. The BUD should never exceed the manufacturer’s original expiration date.

Digital data logger (DDL): An electronic device that records data digitally over time or in relation to location either with a built-in or external instrument or sensor

Diluent: A diluting agent (e.g., a liquid) added to reconstitute lyophilized vaccine before administration. Manufacturers of these vaccines also supply the matching diluent

Expiration Date: The last date on which a vaccine may be used; expired vaccine includes vaccine that is past the manufacturer expiration date on the vial or expiration date after reconstitution, depending on the vaccine and according to manufacturer instructions.

Fraud (related to Abuse): An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or another person. Includes any act that constitutes fraud under applicable federal or state law.

Minimum/maximum temperature: A vaccine storage unit’s coldest and warmest temperature readings during a set period of time.

Portable vaccine storage unit: A type of powered refrigerator or freezer unit specifically designed for use during vaccine transport. These are passive units that require a power source to function. Please note that some active units are “qualified” to maintain desired temperatures for a set amount of time in the event of a power loss.

Qualified container and packout: A type of container and supplies specifically designed for use when packing vaccines for transport. They are passive containers that do not require a power source and are “qualified” through laboratory testing under controlled conditions to ensure they achieve and maintain desired temperatures for a set amount of time.

Temperature excursion: Any temperature reading that is outside the recommended range for vaccine storage as defined in the manufacturer’s package insert.

Vaccine: For the purposes of the VFC program, the term ‘vaccine’ is defined as any FDA-authorized or licensed, ACIP-recommended product for which ACIP approves a VFC resolution for inclusion in the VFC program.

Vaccine Funding Source: One of three types of funding awardees use to purchase vaccines:

- VFC funds: Federal entitlement funds used to purchase vaccines for administration to VFC- eligible children
- Section 317 funds: Federal funds provided through an annual appropriation that support 64 state and local awardee immunization programs. Federal 317 funds also support the purchase of vaccines for certain eligible populations.
- State funds: State-contributed funds used to purchase vaccine for children who are not VFC-eligible or to support immunization program operations.

APPENDIX

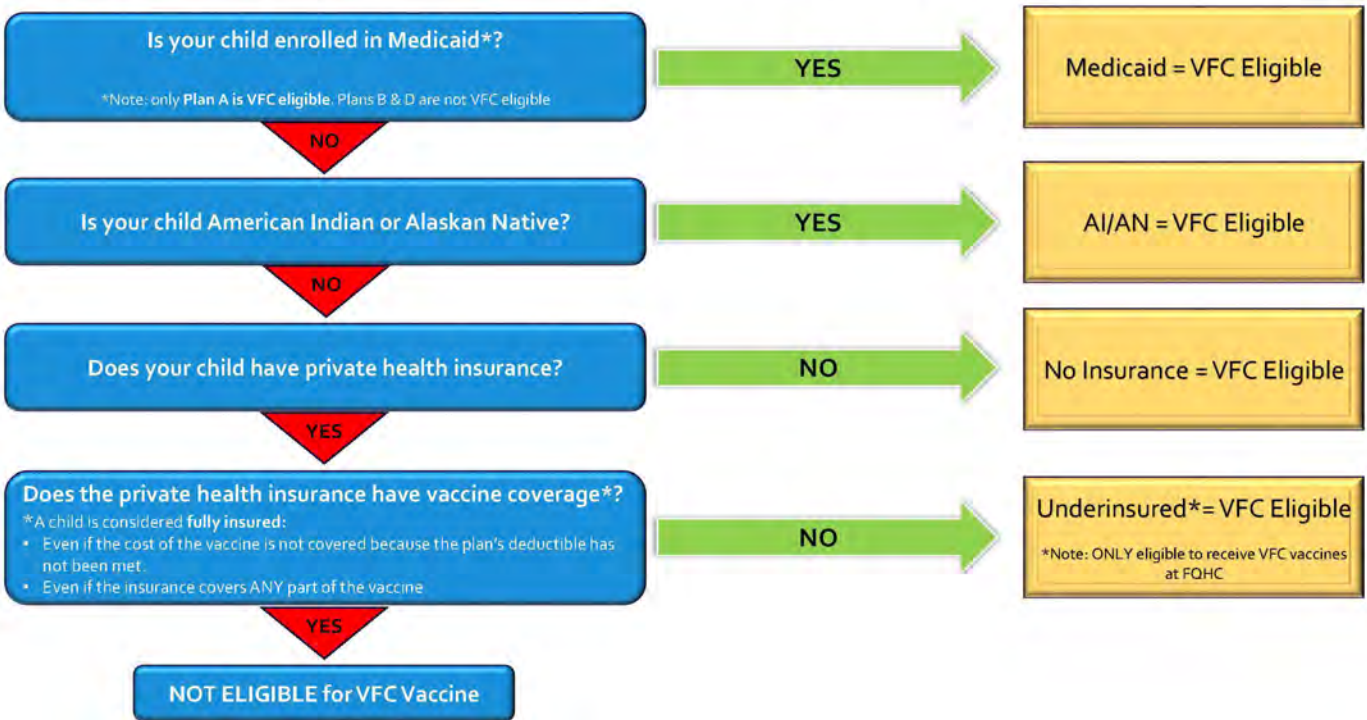
COVID-19 BUD LABELS BEYOND USE LABELS

Pfizer	Moderna	Novavax
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“DO NOT USE” LABEL



VFC Patient Eligibility Screening Flowchart (Birth Through 18 Years of Age)



317 Patient Eligibility Screening Flowchart (19+ Years of Age)

