


VFC Provider Packet

Facility Name:	PIN:
Vaccine Coordinator:	Phone Number:
Backup Vaccine Coordinator:	

In this packet you will find documents necessary for compliance to the Vaccine for Children (VFC) program.

These documents should be made accessible to all staff handling vaccines or utilize the vaccines.



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VFC Program and Highlights

The Centers for Disease Control and Prevention (CDC) buys vaccines at a discount from the manufacturers and distributes them on behalf of awardees at no charge to private physician offices, public health clinics and other healthcare facilities enrolled as VFC providers. VFC providers then administer the vaccine at no cost to eligible children. The VFC program:

- Covers all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP)
- Saves parents and enrolled providers out-of-pocket expenses for vaccine
- Reduces vaccine cost as a barrier to vaccinating eligible children
- Reduces the practice of referring children from the private sector to the public sector for vaccination
- Allows providers to charge a vaccine administration fee.

VFC vaccines are not free. VFC vaccines are purchased with federal funds and provided at no charge to VFC-enrolled providers and eligible children.

Enrolling in the VFC Program

All providers enrolling in the VFC program must have an initial VFC enrollment site visit. Representatives from the VFC program and Statewide Immunization Information System (SIIS) conduct enrollment visits to ensure providers are educated on the VFC program requirements. The providers must also have the appropriate resources to implement the requirements of the program, including proper vaccine storage units and temperature monitoring equipment.

Four forms must be completed by each VFC provider at enrollment:

1. Provider Profile Form
2. Provider Agreement Form
3. VFC Storage Agreement Form
4. VFC Provider Address Form

These forms can be found in Section 2, Provider Enrollment:

https://oepe.wv.gov/immunizations/Pages/vfc_manual.aspx#s6

These forms must be completed and submitted to your immunization program on an annual basis.

Provider Profile Form

The Provider Profile Form requires providers to report the number of VFC eligible children, children enrolled in West Virginia Children's Health Insurance Program (WV CHIP) and non-VFC-eligible children seen in the practice. Data from the Provider Profile Form is used by immunization programs to evaluate vaccine orders and ensure the amount of VFC funded vaccine provided is appropriate for the number of VFC eligible children who receive care from that provider office.



Information supplied on the Provider Profile Form must be based on actual data. Examples of appropriate data sources include:

- Doses administered data
- Benchmarking data
- Medicaid billing data
- Provider encounter data
- Immunization Information System (registry)
- Prior Ordering data
- Vaccine Replacement data

Provider Enrollment Form

The Provider Enrollment Form is the provider's agreement to comply with the requirements of the VFC program. The form describes the requirements of the VFC program and must be signed annually by the medical director or equivalent in a group practice.

The Provider Enrollment Form must list the name and medical license number of all providers within the practice, the name of the VFC Vaccine Manager (individual responsible for managing the VFC program at the facility level), and name of the backup VFC Vaccine Manager. The VFC Vaccine Manager may also be referred to as the VFC Coordinator or VFC Primary Contact.

VFC Eligibility Categories

Children, birth through 18 years of age, 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 equivalent and refer to children who have health insurance covered by a state Medicaid program.
- *Uninsured*: A child who has no health insurance coverage.
- *American Indian or Alaska Native*: A child who meets the definition 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;
 - A child whose insurance covers only selected vaccines (VFC eligible for non-covered vaccines only). These children are eligible when served through a Federally Qualified Health Center (FQHC) and a Rural Health Clinic (RHC), or under an approved deputization agreement (Local Health Departments),
 - A child who has health insurance, but there is a fixed dollar limit or cap for vaccines.

What is an FQHC? An FQHC is a health center that is designated by the Federal Bureau of Primary Health Care (BPHC) of the Health Services and Resources Administration (HRSA) to provide healthcare to a medically underserved population. FQHCs include community and migrant health centers and special health facilities that receive grants under the Public Health Service (PHS) Act. There are also FQHC "look-alikes," which meet the qualifications but do not receive grant funds.



What is an RHC? An RHC is a clinic located in a Health Professional Shortage Area, a Medically Underserved Area, or a Governor-Designated Shortage Area. RHCs are required to be staffed by physician assistants, nurse practitioners, or certified nurse midwives at least half of the time that the clinic is open.

What is deputization? A deputization agreement is a memorandum of understanding within the state that allows local health departments and non-public VFC providers to vaccinate underinsured VFC eligible children. Extending this authority requires approval from Centers for Disease Control and Prevention (CDC) and can only occur in specific circumstances.

Provider responsibility to screen for VFC eligibility: Screening to determine a child's VFC eligibility and documenting the current VFC eligibility status to receive vaccines through the VFC program must take place with each immunization visit. Screening and documentation must be done on all patients from birth through 18 years of age.

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 following categories: Medicaid eligible, uninsured, American Indian/Alaska Native, and underinsured.

Patient eligibility screening records should be maintained on file for a minimum of three years after service.

[The Advisory Committee on Immunization Practices \(ACIP\)](#)

The Advisory Committee on Immunization Practices (ACIP) is a federal advisory committee that was established in 1964. ACIP provides advice and guidance on the most effective means to prevent vaccine-preventable diseases.

The overall goals of ACIP are to provide advice that will assist the U.S. Department of Health and Human Services (DHHS) and the nation in reducing the incidence of vaccine-preventable diseases and to increase the safe use of vaccines and related biological products.

[ACIP's Role in the VFC Program](#)

ACIP's statutory authority includes the authority to determine the vaccines, number of doses, schedule, and vaccine contraindications for the VFC program as well as for the general population. ACIP also approves the specific recommendations for inclusion of a vaccine in the VFC program, which are written in the form of a VFC resolution.

VFC resolutions passed by ACIP form the basis for VFC program policies on vaccine availability and use. After the VFC resolution is in place, CDC must establish a contract for the purchase of the vaccine for availability through the VFC program. These consolidated resolutions are placed on the VFC website after ACIP approval.

VFC vaccines must be administered according to the guidelines outlined by ACIP in the VFC resolutions.

VFC providers must comply with immunization schedules, dosages, and contraindications that are established by ACIP and included in the VFC program unless:

1. In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child.
2. The particular requirements contradict state law, including laws pertaining to religious and other exemptions.

Maintaining Records

VFC providers must **maintain all records** related to the VFC program for a minimum of **three years** and make these records available to public health officials, including the state or U.S. Department of Health and Human Services (DHHS), upon request.

Examples of VFC program records include:

- Temperature logs
- VFC vaccine management training records
- VFC eligibility screening documentation
- Routine and emergency vaccine management plans with standard operating procedures
- Provider Agreements
- Provider Profiles
- Billing Records
- Vaccine ordering records
- Vaccine purchase and accountability records

Vaccine Administration Fees

VFC vaccines must be provided at no cost. Neither patients, Medicaid agencies, nor third-party payers can be billed for the cost of VFC vaccine.

VFC providers can charge a vaccine administration fee. The administration fee is per vaccine and not per antigen within the vaccine (combination vaccines).

- For non-Medicaid, VFC eligible children (American Indian/Alaska Native, uninsured, underinsured), VFC providers cannot charge the eligible child's parent/legal guardian a vaccine administration fee that exceeds the maximum regional charge determined by the Centers for Medicaid and Medicare Services (in West Virginia, **\$19.85**).
- For Medicaid VFC eligible children, VFC providers must accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.

Providers who choose to bill for the vaccine administration fee of a non-Medical, VFC eligible child after the date of service may issue only a single bill within 90 days of vaccine administration. Unpaid administration fees may not be sent to collections, and the provider may not refuse to vaccinate an eligible child whose parents have unpaid vaccine administration fees.



Responsibility to Provide Vaccine

VFC providers cannot deny administration of a federally purchased vaccine to an established VFC eligible patient because the child's parent/guardian/individual on record is unable to pay the administration fee.

The only fee that must be waived is the administration fee. Other visit or office fees may be charged as applicable.

Vaccine Borrowing

VFC enrolled providers are expected to maintain an adequate inventory of vaccine for both their VFC and non-VFC eligible patients.

The borrowing of vaccine from either stock VFC or private is allowed; however, this should occur only on rare occasions, only when unexpected circumstances such as a delayed vaccine shipment, vaccine spoiled in-transit to provider, or new staff that calculated ordering time incorrectly. The reason for borrowing cannot be simply the sake of convenience and routine borrowing is not allowed by this federal program. A Borrowing Report form must be COMPLETELY FILLED OUT for each borrowing occurrence and submitted to the VFC program.

➤ **Check the Printables & Instructions section of this manual for Vaccine Borrowing Template**

Vaccine Information Statements (VIS)

Federal law requires that VIS be provided before certain vaccinations are given. CDC encourages the use of ALL VIS. VIS are increasingly available in electronic formats that patients can read and take away on smart phones and other electronic devices.

All available VIS, including versions in 30 different languages, can be downloaded from the Immunization Action Coalition website at <http://www.immunize.org/vis/> or from CDC's website at <http://www.cdc.gov/vaccines/hcp/vis/index.html>. VIS are updated periodically, and it is the provider's responsibility to ensure that the VIS with the most current publication date is used.

VAERS/National Childhood Vaccine Injury Compensation Act (NCVIA)

The NCVIA requires healthcare providers to report certain adverse events to the Vaccine Adverse Event Reporting System (VAERS) <https://vaers.hhs.gov/>. Adverse events are defined as health effects that occur after immunization that may or may not be related to the vaccine. VAERS data is monitored continually to detect unknown adverse events or increases in known side effects.

VAERS form Information

Information to include:

- Type of vaccine received
- Date and time of vaccination
- Date of onset of the adverse event
- Current illnesses or medications
- History of adverse events following vaccination
- Demographic information about the recipient (age, gender, etc.)

VAERS reports can be submitted online (<http://vaers.hhs.gov/index>) or on a paper VAERS report form.

Fraud and Abuse

When providers enroll in the VFC program, they agree to comply with all the requirements of the program. Not adhering to the program requirements could lead to fraud and abuse of the VFC program. Fraud or abuse can occur in many ways and may be intentional or unintentional.

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.

Some examples of potential fraud and abuse:

- Providing VFC vaccine to non-VFC eligible children.
- 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 vaccine eligible child.
- Denying VFC eligible children VFC funded vaccine because of parents' inability to pay for the administration fee.
- Failing to implement provider enrollment requirements of the VFC program.
- 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 of VFC doses of vaccine.
- Waste of VFC vaccine.

Failure to Comply with VFC Program Requirements

Fraud and abuse by VFC enrolled providers is a result of the VFC-enrolled provider failing to comply with the VFC program requirements outlined in the Provider Enrollment Form.

Non-compliance with program requirements may occur due to an unintentional lack of understanding of the VFC program requirements, or the behavior may be intentional. West Virginia VFC program has specific policies for handling potential fraud and abuse of the VFC program.

Vaccine Coordinator Responsibilities

The Vaccine Coordinator and the Backup Vaccine Coordinator will be responsible for management of the VFC vaccines. Both are responsible for reviewing vaccine storage unit temperatures to ensure they are within the recommended ranges and documenting the temperature on the temperature logs for each storage unit twice a day with pin number on every page. The primary person in charge of vaccines should review and complete this document annually. **Any changes in key staff must be reported to the Immunization Services as soon as the change becomes known in your office.**

- Ordering all ACIP recommended vaccines for the patient population served
- 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 start of each workday
- Ensuring staff are correctly checking and recording vaccine storage unit temperatures per temperature monitoring
- Reviewing and analyzing temperature data at least weekly for any shifts in temperature trends
- Rotating stock at least weekly
- Removing expired vaccine from storage units
- Responding to temperature excursions (out-of-range temperatures)
- Maintaining all documentation, such as inventory and temperature logs
- Ensuring all staff are properly trained and training certificates are maintained
- Monitoring operation of vaccine storage equipment and systems
- Overseeing proper vaccine transport and overseeing temperature excursions (TE)
- Ensuring appropriate handling of vaccines during a disaster or power outage

Vaccine Coordinator responsibilities may be completed by the Coordinator or delegated to appropriate staff. Ensure the Coordinator has trained the delegate(s) and documented competency for the specific task(s) assigned.

Education and Training

- A. The Vaccine Coordinator, the Backup Vaccine Coordinator, and all staff members who handle or administer vaccines, including recording temperatures of vaccine storage units are **required** to complete the online CDC Trainings “You Call the Shots” and “Storage and Handling Training” annually, found at:

<https://www.cdc.gov/vaccines/ed/youcalltheshots.html>

These training cover:

- Vaccine Administration
- Vaccines for Children (VFC)
- Vaccine Storage and Handling

To obtain Continuing Education credit, use this website to register:

<https://tceols.cdc.gov/Home/Steps>

- B. Training should occur annually and:
- a. During new staff orientation;
 - b. Annual for all staff involved in immunization and vaccine storage and handling.
 - c. When program recommendations and requirements are updated; and
 - d. When new vaccines are added to your facility’s inventory.
 - Record names of trainings, dates and participants
- C. Competency checks should be in place to ensure staff members are skilled and proficient.
- D. **Train staff on routine vaccine storage and handling, and temperature excursions.** Keep the VFC Vaccine Management Plan near or on vaccine storage units and make sure staff knows where to find them. Document training with dates and participant names.

Vaccine Management Plan

Each VFC provider must have written vaccine storage and handling plans, both for routine storage and handling of vaccines, and for emergency vaccine retrieval and storage. The routine vaccine storage and handling plan should include guidance on routine vaccine management processes and practices.

Emergency vaccine storage and handling plans must include guidance on what to do in the event of refrigerator or freezer malfunctions, power failures, or other emergencies that might compromise appropriate vaccine storage conditions. Emergency plans should be reviewed, tested, and revised annually as needed to ensure the emergency system in place will result in the proper cold chain of the vaccines.

At a minimum, the vaccine management plans must be reviewed and updated annually. Plans must also be updated when vaccine management practices change or when there is a change in staff that has responsibilities specified in the plan.

Your plan should include:

- | | |
|---|---|
| <input type="checkbox"/> Current Vaccine Coordinator and Backup Vaccine Coordinator | <input type="checkbox"/> Staff Training and Documentation on Vaccine Management, Storage and Handling |
| <input type="checkbox"/> Proper Vaccine Storage and Handling Procedures | <input type="checkbox"/> Standing Orders for ALL vaccines in your facility |
| <input type="checkbox"/> Vaccine Receiving Procedures | <input type="checkbox"/> Inventory Control |
| <input type="checkbox"/> Vaccine Wastage Procedures | <input type="checkbox"/> Emergency Plan Procedure |
| <input type="checkbox"/> Review date with signature of reviewer | <input type="checkbox"/> Vaccine Ordering Procedure |
| <input type="checkbox"/> Current Health Alert | |

VFC Compliance Site Visits

A VFC Compliance Site Visit is an opportunity for state or local VFC staff to educate and support VFC providers who immunize VFC eligible children using federally purchased vaccines. The purpose of these visits, as well as other visits performed, is to educate providers about VFC program requirements, including patient screening and documentation of eligibility and proper storage and handling of vaccine.

Each enrolled and active VFC provider will receive a VFC Compliance Site Visit at least every other year. Most providers may receive a VFC Compliance Site Visit every year.

What happens during a VFC Compliance Site Visit?

The VFC program staff will contact the VFC provider to schedule a VFC Compliance Site Visit. The visit involves assessment of provider knowledge regarding program requirements and vaccine storage and handling techniques utilized in the practice. It also provides an opportunity for providers to ask questions while allowing VFC program staff to offer resources to support providers’ efforts in vaccinating children.

VFC Program Areas to be Reviewed During VFC Compliance Site Visits

- Vaccine storage and handling.** This assessment includes a physical inspection of refrigerator and freezer units used for vaccine storage, temperature monitoring devices, and twice-daily temperature documentation. Vaccine accountability, procedures for vaccine retrieval and storage in times of emergencies, and inventory management, including stock rotation to prevent vaccines from expiring, will also be assessed.
- Screening and documentation of VFC eligibility status.** This assessment involves sampling patient records to ensure that appropriate screening for eligibility occurred prior to administering VFC vaccine. Also ensuring documentation of the child’s eligibility status with each immunization visit.
- Documentation and record retention requirements.** This assessment includes reviewing the practice of providing current Vaccine Information Statements prior to immunization and maintaining records in accordance with the http://www.cdc.gov/vaccinesafety/Vaccine_Monitoring/history.html#1
- Compliance with additional VFC program requirements.** This assessment includes not charging for the cost of the vaccine, not charging a vaccine administration fee that is higher than the maximum fee established by the Centers for Medicare and Medicaid Services (CMS) and agreeing not to deny vaccinations because of the parent's inability to pay a vaccine administration fee.

Immunization Record Retention

VFC providers must maintain immunization records that include:

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

Corrective Actions and VFC Compliance Site Visit Follow Up

Overall, VFC Compliance Site Visit results confirm that VFC providers understand and implement the program in their practices successfully. However, on occasion, some issues and educational needs are identified and require additional follow up and communication by the state or local VFC program staff to ensure the provider's success with the program.

Some issues can be corrected during the visit, while other issues may warrant further follow up and communication by the state or local VFC staff. The VFC program staff will work with provider staff to develop a corrective action plan, including follow up steps and a timeframe, to address any non-compliant practices identified.

Unannounced Vaccine Storage and Handling Visits

VFC providers may receive an Unannounced Storage and Handling Visit during the calendar year. These visits serve as "spot checks" for proper vaccine storage and handling practices. The goal of Unannounced Storage and Handling Visits is to offer provider education, support, and resources related to proper vaccine storage and handling to ensure all VFC children are receiving properly managed vaccines.

Vaccine Ordering

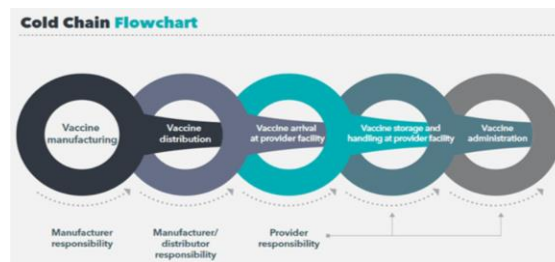
- A. The Vaccine Coordinator or Backup Vaccine Coordinator will be responsible for ordering vaccines and maintaining appropriate vaccine stock. Temperature logs must be sent into the VFC program prior to ordering. Order and administer all ACIP-recommended vaccines based on actual population served. No more than a 3-month supply of vaccine should always be kept unless otherwise arranged with the Immunization Services.
- B. The Vaccine Tracking System (VTrckS) is an information technology system that integrates the publicly funded vaccine supply chain from purchasing and ordering to distribution of the vaccine. West Virginia State Immunization Registry System (WVSIIS) is a confidential, population-based, computerized database that record immunization doses administered by participating providers to persons residing within West Virginia: <https://www.wvimm.org/wvsiis/>
- C. Vaccine will be ordered every month as needed between the 1st and 5th, (regardless of weekends/holidays), using the Vaccine Order Management System (VOMS).

- D. Vaccine inventory will be reconciled every month, prior to placing a vaccine order.
- E. Temperature logs with provider *pin number on each page of the logs* will be submitted to the Immunization Services each month, between the 1st and 5th, by email to Christopher.D.Young@wv.gov or by fax: (304)957-7591.

Vaccine Storage and Handling

This section describes current vaccine storage and temperature monitoring recommendations and covers important vaccine storage and handling requirements.

The system used to maintain and distribute vaccines in optimal condition is called the "cold chain." The cold chain begins with the cold storage unit at the vaccine manufacturing plant, extends through the transfer of vaccine to the distributor and then to the provider's office, and ends with the administration of the vaccine to the patient.



Proper storage temperatures must be maintained at every link in the chain. Recommended temperature ranges are:

- Between 36°F–46°F (2°–8°C) for refrigerated vaccine.
- Between -58°F and +5°F (-50°C and -15°C) for frozen vaccine.
- Refrigerator or freezer thermostats should be set at the factory set or midpoint temperature, which will decrease the likelihood of temperature excursions.

The desired average temperature for refrigerated vaccines is 40°F (5°C). The desired average temperature for frozen vaccines is 0°F (-18°C).

- Keep vaccines in the original box:
 1. Exposure to light may affect the potency of vaccines.
 2. Decreases the potential for medication errors.
- Clearly label each vaccine stored VFC/CHIP or private vaccine.
- Check expiration dates monthly. Rotate vaccine stock so the oldest vaccine is used first.

Monitor and document vaccine storage and handling every day

- **Effective January 1, 2018**, make sure you have certified data loggers in the refrigerator and freezer. Keep certificates of calibration per CDC requirements.

If a cold chain failure is suspected or there is evidence that vaccine has been exposed to temperatures outside the recommended ranges, providers should immediately:

- Store vaccine under correct temperature storage conditions and mark "DO NOT USE." The vaccine should not be administered until a response indicating the vaccine is acceptable for use has been received. **Providers should not discard any vaccine unless directed to do so by the immunization program.**
- Immediately contact the VFC program for guidance.

For comprehensive storage and handling guidance and best practices, please view <http://www.cdc.gov/vaccines/recs/storage/default.htm>

Temperature Ranges

- Refrigerators should maintain temperatures between 2° C and 8° C (36° F and 46° F).
- Freezers should maintain temperatures between -50° C and -15° C (-58° F and +5° F). Refrigerator or freezer thermostats should be set at the factory-set or midpoint temperature, which will decrease the likelihood of temperature excursions.

COVID-19 Vaccines

	Johnson & Johnson	Moderna	Pfizer
Doses	1	2 28 days between doses	2 21 days between doses
Storage	<ul style="list-style-type: none"> ❖ Store vaccine in a refrigerator. ❖ Store vaccine between 2°C and 8°C (36°F and 46°F). ❖ Do not freeze. ❖ Protect from light. 	<ul style="list-style-type: none"> ❖ Frozen vaccine must be thawed before using. ❖ Thaw vaccine in the refrigerator or at room temperature: <ul style="list-style-type: none"> ▪ Refrigerator: Between 2°C and 8°C (36°F and 46°F). ▪ Room temperature: Between 8°C and 25°C (46°F and 77°F). ❖ Amount of time needed to thaw vaccine varies based on temperature and number of vials. <ul style="list-style-type: none"> ▪ In the refrigerator: Up to 3 hours. ▪ Room temperature: Up to 1 hour and 30 minutes. ❖ Do NOT refreeze thawed vaccine. ❖ Use vials in the refrigerator before removing vials from the freezer. 	<ul style="list-style-type: none"> ❖ Frozen vaccine must be thawed before using. ❖ Thaw vaccine in the refrigerator or at room temperature: <ul style="list-style-type: none"> ▪ Refrigerator: Between 2°C and 8°C (36°F and 46°F). ▪ Room temperature (for immediate use): Up to 25°C (77°F). ❖ Do NOT refreeze thawed vaccine. ❖ Use vials in the refrigerator before removing vials from ultracold temperature or freezer storage.
General Information	<ul style="list-style-type: none"> ❖ Each carton contains 10 multidose vials (50 doses). ❖ Each multidose vial contains 5 doses. 	<ul style="list-style-type: none"> ❖ Two multidose vial presentations: <ul style="list-style-type: none"> ▪ Maximum of 11 doses per vial. ▪ Maximum of 15 doses per vial. ❖ Dosage: 0.5 mL. ❖ Do NOT mix with a diluent. ❖ 18 years of age and older. 	<ul style="list-style-type: none"> ❖ Use a new vial every time. ❖ Multidose vial: 6 doses per vial. ❖ Dosage: 0.3 mL. ❖ Vaccine MUST be mixed with diluent before administration. ❖ 5-12 years of age and older.

Receiving Vaccine

When receiving vaccine shipments, providers must:

- Ensure that vaccines are delivered during office hours
- Open vaccine packages immediately
- Store vaccines at the recommended temperatures IMMEDIATELY upon arrival
- Check the temperature monitor reading
- Inspect the vaccine and packaging
- Inspect and document vaccine shipments
- Compare the vaccine received with the vaccine products that show on the packing list
- Check enclosed refrigerator & freezer temperature indicators.
- Check shipment date: interval between shipment date and arrival at your office should be no more than 48 hours.
- Store at appropriate temperatures

If the provider believes that a vaccine shipment is compromised, temperature monitors are out-of-range, or a warm indicator is activated, they should contact the VFC program immediately.

If you have any questions about whether any vaccines have been transported properly, contact:

1. The vaccine manufacturers (privately purchased vaccine).
2. The Division of Immunization Services (DIS) at 800-642-3634 (VFC vaccine).

Refrigerator and Freezer Requirements, Monitoring, and Maintenance

Provider sites are required to have appropriate equipment that can store vaccine, maintain proper conditions, and provide adequate monitoring.

The correct choice of units is either purpose-built or pharmaceutical-grade units designed to either refrigerate or freeze. These units can be compact, under-the-counter style or large.

Purpose-built units, sometimes referred to as “pharmaceutical-grade,” are designed specifically for storage of biologics, including vaccines.

Household grade units are acceptable, however, the freezer compartment of this type of unit **MAY NOT** be used to store vaccines.

Storage Unit Requirements

- Pharmaceutical/purpose-built in.
- Stand-alone refrigerator and freezer units are preferred for storing vaccines.
- Combination (refrigerator/freezer) household units are acceptable alternatives, however:
 - Only use the refrigerator compartment for storing refrigerated vaccines.
 - The freezer compartment for this type of unit is not recommended.
 - Frozen vaccine should be stored in a standalone freezer.
- Separate the VFC vaccines from other public and private supply by identifying the VFC vaccines and placing them in a separate labeled area of the refrigerator and/or freezer. **Do not place all out of the package in one bin.**
- **Store vaccines in their original packaging** (some are light sensitive).

- Place vaccines in the center of the storage unit in the original packaging.
- Store vaccines in the middle of the unit, with space between both the vaccines and the side/back of the unit.
- Do not store vaccines in the doors, vegetable bins, or floor of the unit, or under or near cooling vents
- Place water bottles marked “Do Not Drink” in the door, on the floor, on the top shelf, and in the door racks of the refrigerator and ice packs in the freezer. Place water bottles so they cannot dislodge from the shelf or weigh down the door. The water bottles help to:
 - Stabilize or extend temperatures during a power outage,
 - Mitigate the effects of frequent open/closing door during busy clinic days.
 - Serve as physical blocks preventing the placement of vaccines in areas of the unit that are at higher risk for temperature excursions.
- Rotate vaccines every week or when a new shipment comes in (whichever happens more frequently) so that newer vaccines are stored toward the back of the unit, while those soonest-to-expire are stored in the front and administered first.
- Open only one vial or box of a vaccine at a time to control vaccine use and allow easier inventory control. On each opened vaccine vial, indicate on the label the date and time it was reconstituted or first opened.
- Store vaccine products that have similar packaging in different locations in the storage unit to avoid confusion and medication errors.
- Limit access to the vaccine supply to authorized personnel only.
- Install locks on refrigerators and, if possible, the electrical plug.
- Safeguard public vaccines by providing facility security, such as temperature alarms and restricted access to vaccine storage and handling areas.
- In larger clinics, provide a source of back-up power (generator) and a security system to alert appropriate personnel in the event of a power outage.
- If applicable, test back-up generators quarterly and maintain back-up generators at least annually (check manufacturer specifications for test procedures and maintenance schedules).
- In regular clinics/practices, vaccines should be prepared immediately prior to administration. CDC strongly recommends NOT pre-drawing doses before they are needed.
- Remove all drawers/bins from the storage unit.
 - If the drawers/bins cannot be removed, mark “DO NOT OPEN” to avoid accidentally being left open to alter the door closing
- Plug the refrigerator or freezer directly into the wall electrical outlet.
- Place DO NOT DISCONNECT signs on the circuit breaker box and around the electrical outlet of the storage unit.
- Label fuses and circuit breakers to alert people to not turn off power. Labels should include immediate steps to take if the power is interrupted.
- Plug in only one storage unit per electrical outlet.
- Use a safety-lock plug or an outlet cover to prevent the unit from being unplugged.
- AVOID using:
 - Build-in circuit switches (may have reset buttons)
 - Outlets that may be activated by a wall switch
 - Multioutlet power strips (with or without surge protection)

- Refrigerators used to store vaccines must maintain temperatures between 36° to 46° F or (35°F and below is too cold & 47°F is too warm) 2° C & 8° C (1.9°C and below is too cold & 8.1°C and above is too warm).
- Freezers used to store vaccines must maintain temperatures between 5°F and below -15° C and -50° C. (6°F and above is too warm; -14.9°C and above is too warm).

Storage Unit Monitoring

The VFC Vaccine Coordinator and Backup Vaccine Coordinator are responsible for temperature monitoring and documentation for all vaccine storage units. If additional staff are responsible, those persons must be trained on appropriate temperature monitoring and documentation.

- Digital Data Loggers (DDLs):
 - DeltaTrak
 - DDLs are considered the “gold standard” for monitoring storage temperatures for all vaccines.
 - Ensure temperature excursions are detected, including the **length of time** a temperature is out of range, thus making them one of the most advanced devices to ensure vaccines are stored correctly and protected from unnecessary waste.
 - Provides valuable data that can save vaccine, prevent ineffective vaccine from being administered, and prevent the need to revaccinate affected patients.
 - Post a temperature log on the vaccine storage unit door or nearby in a readily accessible and visible location.
 - Record and assess refrigerator and freezer temperatures twice each day (beginning and end of each clinic day) to ensure refrigerator temperatures are between 35° and 46°F (2° and 8°C) and freezer temperatures are between -58°F and +5°F (-50°C and -15°C).
 - At least one backup data logger thermometer (required January 1, 2018) needs to be available in the event vaccines need to be relocated or if a thermometer in a storage unit stops working.
 - Effective January 1, 2018, make sure you have certified data loggers in the refrigerator and freezer. Keep certificates of calibration per CDC requirements.
 - CDC recommends the use of continuous digital data loggers with detachable probes for temperature monitoring. Check refrigerator and freezer temperatures **twice a day** when the clinic opens and before it closes.
 - Document changes on the temperature log in the comment section. Place Provider pin number on **ALL** temperature log sheets to be processed without delays.
 - Data loggers must be re-calibrated or replaced 2 years from the “Date of Calibration” (Report or Issue Date) that is listed on the calibration certificate. The certificate will expire two years from the date of initial calibration and the data loggers will need to be re-calibrated at that time even if there is an expiration or re-calibration date listed on the certificate with a different date.
 - Certificate of Calibration should include:
 - Model/device name or number
 - Serial number
 - Date of calibration
 - Confirmation that the instrument passed testing
 - **DO NOT** use:
 - Alcohol or mercury thermometers

- Bi-metal stem temperature monitoring devices
- Food temperature monitoring devices
- Chart recorders
- Infrared temperature monitoring devices
- Temperature monitoring devices that do not have a current and valid Certificate Calibration Testing
- Devices sold in hardware and appliance stores are generally designed to monitor temperatures for household or food storage.
- The most current version of the Monthly Temperature Log can be found at one of the following links:
 - [Temperaure log](#) or www.immunize.org.
- Data logger data will be downloaded and reviewed weekly.
- Must be used in any vaccine storage unit(s) and must be calibrated to CDC standards and a current Certificate of Calibration will be kept until expiration.
- Have a detachable probe that best reflects vaccine temperatures
- Have an alarm for out-of-range temperatures
- Have a low battery indicator
- Display current, minimum, and maximum temperatures
- For out of range temperatures, immediately contact the **Division of Immunization Services at 304-558-2188 or 1-800-642-3634** for assistance.
- If your facility relocates any storage unit in your facility or new location or if your office is closed for any length of time, your facility VFC Coordinator or backup will notify the Vaccines for Children Program Assistant Coordinator at Christopher.D.Young@wv.gov or fax at **(304) 356-4244** or the Vaccines for Children Vaccine Manager Jeff Neccuzi at Jeffrey.J.Neccuzi@wv.gov@wv.gov or call **(304) 356-4035**.
- Make sure provider name and **pin number** are on all temperature log sheets. Keep the Certificate of Calibration expiration dates current. Contact the data logger company for a new data logger or to get data loggers calibrated by DeltaTrak. <https://www.deltatrak.com/services/calibration-certificate>
- **The West Virginia immunization program requires submission of temperature logs.**
- **Check the Printables & Instructions section of this guide on how to use the DDL**

Storage Unit Maintenance

Regular maintenance is necessary to ensure vaccine refrigerators and freezers work properly. If the unit remains too warm or too cold after the unit's thermostat is adjusted, or unit is making noises that are not normal or louder than normal, have the unit serviced or replaced.

Refrigerator:

- Clean the storage units once a month.
- Check the door seals and door hinges for gaps.
- Clean the coils and if the unit needs to be unplugged or moved for any reason, relocate the vaccines with the backup data logger thermometer to the backup unit **prior** to doing so.
- Clean the interior of each unit to discourage bacterial and fungal growth. Do so quickly to minimize the risk of temperature excursion.

Freezer:

- If frozen vaccines are stored in a manual defrost freezer it will be defrosted regularly and as

needed to avoid having frost build up in the unit.

- Remove excessive ice buildup.
- During defrost, the vaccines will be moved to the backup storage unit until the unit has been completely defrosted and the unit's temperature is in acceptable range.
- Clean the interior of each unit to discourage bacterial and fungal growth. Do so quickly to minimize the risk of temperature excursion.

Temperature Excursions (TE)

Temperature excursions (TE) are inappropriate storage conditions for any vaccine and require immediate action. Any temperature reading outside the recommended ranges in the manufacturers' package inserts is considered a temperature excursion. **The Vaccine Coordinator needs to call all the manufacturers of the vaccines that are stored and get an email confirmation for administration of the vaccine that have been exposed to a temperature excursion.**

CDC recommends the following steps in the event of a temperature excursion:

1. Any staff who hears an alarm or notices a temperature excursion on the digital data loggers (DDL) should notify the primary or alternate vaccine coordinator immediately or report the problem to their supervisor.
2. Label exposed vaccines "DO NOT USE" and place in a separate container (do not discard).

Temperature Excursion Response Checklist

<input type="checkbox"/>	Follow your Emergency Vaccine Management Plan for instructions on responding to a temperature excursion. Quarantine the vaccine, bagging and labeling it "DO NOT USE."
<input type="checkbox"/>	Call VFC Immunization Services Hotline 1-800-642-3634 or main line at 304-558-2188 to report all excursions to the VFC Immunization Services.
<input type="checkbox"/>	If temperatures do not promptly return to stable ranges, move the vaccine using a DDL and appropriate transport materials to a unit that is monitored according to VFC requirements. See Vaccine Management Plan for Handling excursions and Vaccine Emergencies.
<input type="checkbox"/>	Review the DDL summary report to determine the maximum or minimum temperatures reached and the period the temperatures were out of range.
<input type="checkbox"/>	Download and print DDL report save to attach to excursion report.
<input type="checkbox"/>	Call manufacturers to report the temperatures and time out of range.
<input type="checkbox"/>	Request case number.
<input type="checkbox"/>	Request written documentation/emails
<input type="checkbox"/>	Continue to quarantine vaccine until you get approval from VFC Immunization Services.
<input type="checkbox"/>	Do not discard, use, or transport the vaccine back into the unit until the VFC Immunization Services reviews all documentation and resolves the excursion.
<input type="checkbox"/>	Submit the following documentation to the Vaccines for Children program at or by fax at 304-957-7591 or email excursion documentation to Christopher.D.Young@wv.gov.
<input type="checkbox"/>	Document the Provider PIN Number in the subject line of the email, on the cover sheet of your fax, digital data logger report(s), and all paper temperature log for excursion period.
<input type="checkbox"/>	Acquire the manufacturer written recommendations for affected vaccines.
<input type="checkbox"/>	Complete the Vaccine Storage & Handling Incident Report.
<input type="checkbox"/>	Complete the Vaccine Return Vaccine Form for Vaccine Loss.
<input type="checkbox"/>	It is standard policy to suspend providers from receiving or ordering additional vaccine while the temperature excursion is being evaluated.
<input type="checkbox"/>	For vaccine wastage, please complete the Vaccine Return form and adjust your on-hand inventory in the West Virginia State Immunization Information System (WVSIS).

Vaccine Waste

Notify VFC Immunization Services of a vaccine cold chain failure/wastage incidents involving publicly funded vaccines after discovery of the incident. Immediately upon the VFC Immunization Services finalizing a cold chain investigation where vaccine is deemed non-viable, remove it from the storage unit, place it in a bag or box marked DO NOT USE. Expired vaccines must be removed from the unit and marked DO NOT USE as soon as they expire. All returnable vaccine must be returned in its original packaging, vial, or manufacturer pre-filled syringe.

- Returning expired or wasted vaccines to the distributor must be reported by a Vaccine Return Form. This form is located at:
https://oepe.wv.gov/immunizations/documents/vfc/manual/7/vaccine_return_form.pdf
- Non-returnable vaccine will be reconciled out of the West Virginia Statewide Immunization Information System (WVSIS) inventory and disposed of properly.
- Short-dated vaccines (vaccines closest to expiration) will be placed in front of longer dated vaccines and used first.
- If short-dated vaccines are discovered that are not able to be used prior to the expiration date and you would like to transfer them to another provider, please contact Vaccine Manager/VFC Coordinator Jeffrey.J.Neccuzi@WV.org for guidance.

McKesson restrictions:

The following items should NEVER be returned to McKesson:

- Used syringes, with or without needles
- Broken vials
- Wasted products such as a syringe that was drawn up but not used
- Any multidose vial from which some doses have been withdrawn
- Diluent (expired or not expired)
- Private-purchased vaccine

The items listed above should be disposed of according to usual medical biosafety procedures as well as **medical waste** syringe within 6 months of the expiration date.

Transporting Vaccines

When transporting vaccine from the office to an off-site clinic, temperatures must be monitored using a calibrated data logger thermometer. These data logger files must be emailed to the Immunization Services with the monthly temperature logs at the end of the month. Any out of range temperatures must be reported to the Division of Immunization Services immediately.

- All vaccine transfers must be pre-approved by Immunization Services.
- CDC discourages regular transport of vaccines. Proper management of vaccine plays a major role in preventing the need to transport vaccines.
- Shipping vaccines is strictly prohibited.
- It is critical that vaccine viability is protected by maintaining proper vaccine storage temperatures during any vaccine transport.
- Use properly insulated containers to transport vaccine. These containers should be validated to ensure they can maintain the vaccine at the correct temperatures. Alternatively, hard-sided, plastic, insulated containers/coolers or styrofoam coolers with at least 2-inch thick walls may be used, as well as portable refrigerator/freezer units.
- Temperatures must be monitored using a calibrated data logger thermometer with a valid calibration when transporting vaccines.
- Pack enough refrigerated/frozen packs to maintain the cold chain. Do not use loose, bagged, or dry ice. The number and placement of refrigerated/frozen packs inside the container will depend on container type, size, and outside temperature.
- Place an insulating barrier (e.g., bubble wrap, crumpled brown packing paper, styrofoam peanuts, or exam table paper) between the refrigerated/frozen packs and the vaccines to prevent accidental freezing.
- The contents of the container should be layered as follows, starting from the bottom:
 - a. refrigerated/frozen packs
 - b. barrier
 - c. vaccine
 - d. calibrated data logger thermometer
 - e. barrier
 - f. refrigerated/frozen packs
- Pack vaccines in their original packaging on top of the barrier. Do not remove vaccine vials from boxes or pre-fill syringes in advance.

Transporter Vaccine Protocol

Hard-sided coolers or styrofoam vaccine shipping containers

- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers; do NOT use soft-sided collapsible coolers.

Conditioned frozen water bottles

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container; they increased risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.

Insulating material — you will need two of each layer

- **Insulating cushioning material** – Bubble wrap, packing foam, or styrofoam for a layer above and below the vaccines, at least 1 inch thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- **Corrugated cardboard** – Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.

Temperature monitoring device -- Digital data logger (DDL) with buffered probe. Accuracy of +/-1°F (+/- 0.5°C) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used if there is a device to measure temperatures for many remaining vaccines.

Varicella, Proquad and Zostavax should be transported only in a portable freezer

Varicella-Containing Vaccines - Special Instructions for Transport

CDC and the vaccine manufacturer do not recommend transporting varicella-containing vaccines. If varicella-containing vaccines must be transported, CDC recommends transport with a portable freezer unit that maintains the temperature between -58°F and +5°F (-50°C and -15°C). Portable freezers may be available for rent in some places. If varicella containing vaccines must be transported and a portable freezer unit is not available, complete the following actions: Varicella-containing vaccines may be transported at refrigerator temperature (36°F to 46°F, 2°C to 8°C) for up to 72 continuous hours prior to reconstitution.

1. Place a calibrated thermometer in the container used for transport as close as possible to the vaccine.
2. Record:
 - a. The time the vaccine was removed from the storage unit and placed in the container.
 - b. Temperature during transport.
 - c. Document the time and temperature at the beginning and end of transport.
3. According to the vaccine manufacturer, **immediately** upon arrival at the alternate storage facility:
 - a. Place **the vaccine in the freezer between -58°F and +5°F (-50°C and -15°C)**. Any freezer that has a separate sealed freezer door and reliably maintains a temperature between -58°F and +5°F (-50°C and -15°C) is acceptable for storage of Varicella-containing vaccines.
 - b. Document the time the vaccine was removed from the container and placed in the alternative unit.
 - c. Note that this is considered a temperature excursion (TE) and contact the manufacturer for further guidance, 1-800-637-2590 for the Merck National Service Center.
 - d. Do not discard vaccine without contacting the manufacturer and Division of Immunization Services for guidance. Use of dry ice is not recommended. Dry ice may subject Varicella-containing vaccines to temperatures colder than -58 °F (-50 °C).

Vaccine Viability

In the event of an excursion, the below vaccine variability process needs to be followed:

- If temperatures are found below 2° C or above 8° C, for the refrigerator or above -15° C for the freezer, DO NOT administer the vaccines and immediately take the following actions:
 - Immediately store vaccines at proper temperatures. If the storage unit temperature is currently in range, the vaccines can remain in the unit. If the storage unit temperature is currently out of range, follow the facility's Vaccine Management Plan for Vaccine Relocation to relocate the vaccines to the backup storage unit.
 - Cross-check the contents of the shipment with the packing slip to be sure they match, determine if the shipping time was less than 48 hours (no more than 4 days for Varicella-containing vaccines), and call the Division of Immunization Program within 2 hours of receipt of shipment if there are any problems with the vaccine shipment.
 - a. Quarantine all vaccines exposed to out of range temperature and mark as DO NOT USE.
 - b. Immediately call the Division of Immunization Services at **304-558-2188** for further instruction.
 - c. If you are currently using a data logger thermometer: download and review the data logger data; do not print the data logger file. The file will need to be emailed or fax to the Division of Immunization Services Assistant Coordinator Christopher.D.Young@WV.org .
- Always document any action taken when responding to any storage and handling problem on the bottom of the Monthly Temperature Log.
- Place the vaccines in the proper storage unit making sure vaccines with shorter expiration dates are placed in front of vaccines with longer expiration dates.
- All vaccine packing slips must be kept for **3 years**.
- A trained staff member must be available to receive vaccine at least one day a week other than Monday, and for at least four consecutive hours during that day.

Vaccine Emergency Plan

In the event of refrigerator/freezer malfunction, power failure, natural disaster, or any other emergency that might compromise appropriate vaccine storage conditions, vaccines may need to be transported to an alternate location. Your clinic should establish the below protocol before an emergency occurs. The Emergency Plan must be reviewed and/or updated at least annually or more frequently if changes occur and all information must always be up to date. A “review date” is required with an accompanying signature of the person responsible for the plans content. All staff are required to understand the Vaccine Emergency Plan for vaccine relocation and know where it is located.

Follow the process below:

- Designate personnel who have 24-hour access to location where the vaccines are stored.
- Set up a system to notify designated personnel during power outages.
- Identify steps to assure proper storage and handling of vaccines during an emergency.
- Identify an alternate power source (generator) if your clinic does not have one or alternate storage units or facilities (nearby hospital, pharmacy, other provider’s office). Identify procedures that allow access to alternate facilities.
- Keep a cooler in the office; place a copy of the Vaccine Emergency Plan Worksheet in the cooler.
- Follow and complete the Vaccine Emergency Plan and Worksheet.
- **DO NOT** automatically discard the vaccine that has been compromised.
- Mark exposed vaccine and store separately from undamaged vaccines, storing appropriately in a refrigerator/freezer.
- **Call all vaccine manufacturers and/or Division of Immunization Services for further instructions.**

If a power outage occurs:

- Freezers and refrigerators should not be opened until power is restored, except to transport vaccine to an alternative storage location.
- Temperatures and duration of power outage must be monitored.
- Vaccine should not be discarded or administered until the situation has been discussed with public health authorities.
- Written procedures for relocation of vaccines in case of emergency (Vaccine Emergency Plan) will be posted on all vaccine storage units.

Vaccine Preparation

- Prepare vaccines in a designated area away from any space where they may come in contact with potentially contaminated items.
- Only prepare vaccines when you are ready to administer them.
- Always check expiration dates and confirm the correct vaccine is selected.
- Only administer vaccines you have prepared.

Administering Vaccines

Lyophilized Vaccine (Freeze-Dried)

- A. A lyophilized vaccine may be a powder or a pellet that must be reconstituted with a diluent prior to administration. After a vaccine is reconstituted its shelf life varies by product. Refer to the FDA's package inserts found at www.immunize.org.
- B. Diluents vary in volume and type. They are designed to meet the volume, pH, and chemical needs of each vaccine.
- C. Diluents are NOT interchangeable unless specified by the manufacturer.
- D. Use only the specific diluent provided by the manufacturer of the vaccine you are reconstituting.
- E. Reconstitute vaccine immediately prior to administration.
- F. Check expiration dates on both the vaccine and the diluent.
- G. After reconstitution, observe the vaccine for color and appearance. If the vaccine cannot be suspended or does not look as described in the product information, label the vial DO NOT USE, and store it under appropriate conditions separate from other vaccines. Immediately call the Immunization Services for further guidance.
- H. Administer the vaccine soon after reconstitution to minimize the risk of reduced potency.

Single-Dose and Multi-Dose Vaccine Vials

- A. Do not open a single-dose vial until you are ready to use it.
- B. A single-dose vial (SDV) contains ONE dose and should only be used ONE time or ONE patient. Do not combine leftover vaccine from one SDV with another to obtain dose.
- C. Once the cap is removed from a single-dose vial, it should be used by the end of the clinic day.
- D. Single-dose vials do not contain a preservative to help prevent the growth of microorganisms.
- E. Always check the vial to make certain that the correct vaccine has been selected before removing the protective cap.
- F. Remove the cap and draw up the vaccine immediately before administration.
- G. DO NOT pre-draw vaccines before they are needed.
- H. Multi-dose vials contain preservatives that prevent bacterial growth. Once opened they can be used through their expiration date, unless the product information specifies a time frame for use after opening that is different from the expiration date on the label.
- I. Only withdraw the number of doses indicated in the manufacturer's package insert from the vial.
- J. After the maximum number of doses has been withdrawn, the vial should be discarded, even if there is residual vaccine and the expiration date has not been reached.
- K. Mark each multi-dose vial with the date it was first opened (when the protective cap was removed).
- L. Never use partial doses from two or more vials to obtain a full dose of vaccine.

Pre-Drawing Vaccines (Immunization Clinics)

- A. There may be rare instances when the only option is to predraw vaccine.
- B. If vaccine must be predrawn:
 - a. Set up a separate administration station for each vaccine type to prevent medication errors.
 - b. Do not draw up vaccines before arriving at the clinic site.
 - c. Each person administering vaccines should draw up no more than one MDV, or 10 doses, at one time.
 - d. Monitor patient flow to avoid drawing up unnecessary doses.
 - e. Discard any remaining vaccine in predrawn syringes at the end of the workday.
 - f. Do not predraw reconstituted vaccine into a syringe until you are ready to administer it.
 - i. If not used within 30 minutes of being reconstituted, follow manufacturer guidance for storage conditions and time limits.
 - ii. Never transfer predrawn reconstituted vaccine back into a vial for storage.

PRINTABLES & INSTRUCTIONS

Important Contacts

Resource	Contact Person Name	Phone Number	Email Address and/or Website
VFC Program Manager and Vaccine Ordering	Jeff Neccuzi	304-352-6258	Jeffrey.J.Neccuzi@wv.gov
VFC Assist. Cord. and Return labels-temp logs	Christopher Young	304-352-6265	christopher.d.young@wv.gov
Division of Immunization Services		304-558-2188 1-800-642-3634	
VFC Quality Assurance Manager	Tiffany Kotalic	304-352-6284 (o) 304-541-4162 (c)	Tiffany.a.kotalic@wv.gov
VFC, COVID, & IQIP Field Visits	Cindy Chapman	304-352-6259 (o) 304-546-2068 (c)	Cindy.a.chapman@wv.gov
	Matt Hill	304-545-3243	Matthew.p.hill@wv.gov
	Dana Schrack	304-221-2175 304-541-1094 (c)	Dana.L.Schrack@wv.gov
	Malissa Teter	304-538-2391 ext. 12018 304-546-1896 (c)	malissa.d.teter@wv.gov
	Noah Davis		noah.j.davis@wv.gov
	Jennifer Wentz	304-419-1994	jennifer.l.wentz@wv.gov
	Allison Toler		allison.d.toler@wv.gov
	Christina Spickler		christina.m.spickler@wv.gov
WV Statewide Immunization Information Services (WVSIIS)	Carolyn Smith	304-352-6262	Carolyn.j.smith@wv.gov
	Becky Pierson	304-352-6261	Becky.l.pierson@wv.gov
Refrigerator Repair Company			
Freezer Repair Company			
Thermometer Company			
Power Company			
Temperature Alarm System Company			
Generator Company (if applicable)			
Other			



Quality Assurance Provider Checklist

For Site Visit Preparation

Yes	Can we answer 'Yes' to all of the questions? If so, we are ready for out site visit?
<input type="checkbox"/>	Our Vaccine Management Plan has been reviewed, updated, and signed by each administrator of vaccines.
<input type="checkbox"/>	The VFC Provider and back-up have participated in the annual VFC training, and the training has been properly documented. ("You Call the Shots")
<input type="checkbox"/>	All Vaccine Information Statements (VIS) are up to date. Only the most current VIS is provided to parents. VIS are provided to parents at each immunization visit.
<input type="checkbox"/>	Each immunization record has the following documented: date given, parent's consent (signature), type of vaccine, manufacturer name, lot number, publication date of the VIS, date VIS provided to parent; and he name and title of the person administering the vaccine.
<input type="checkbox"/>	Staff can clearly describe all VFC eligibility categories.
<input type="checkbox"/>	I know how my clinic screens and documents VFC eligibility, and I am able to clearly describe the process.
<input type="checkbox"/>	Our clinic's vaccine administration fee for non-Medicaid VFC eligible children is \$ _____. Our staff knows how to properly bill for vaccines and the administration fee.
<input type="checkbox"/>	VFC vaccines are clearly labeled and separated from our private vaccine.
<input type="checkbox"/>	Our thermometers are properly placed in the central area of each vaccine storage unit.
<input type="checkbox"/>	We have the thermometer calibration certificates for all our thermometers, and they are available for review.
<input type="checkbox"/>	Staff knows where our back-up thermometer located is. Is it readily available to use, if necessary.
<input type="checkbox"/>	We have replaced expired thermometers and calibration certificates.
<input type="checkbox"/>	All temperature logs for each refrigerator and freezer unit used to store VFC vaccine are available for review. All temperature logs are completed as required by the VFC program.
<input type="checkbox"/>	Our digital data loggers are properly placed on the middle shelves of each vaccine storage unit that stores VFC vaccines.
<input type="checkbox"/>	Check calibration certificate dates. Fridge calibration date: ____-____-____ Freezer calibration date: ____-____-____ Back-up thermometer calibration date: ____-____-____
<input type="checkbox"/>	All temperature logs are completed twice a day with exact time (i.e. 8:04 am) temperatures are taken, temperatures to the tenths place (i.e. 40.2°F), Fahrenheit or Celsius are circled and the initials of the person taking the temperatures as required by AIPO. The minimum temperatures and maximum temperatures of the units storing VFC vaccines are recorded on the temperature log once a day in the morning for the previous 24 hours as required by AIPO.
<input type="checkbox"/>	If we had any out of range temperatures reported on our temperature logs, we document the actions taken, and that documentation is available for review.
<input type="checkbox"/>	Our vaccines with the shortest expiration dates are placed in front of those with the longer expiration dates.
<input type="checkbox"/>	Our vaccines are stored in the center of the unit, away from the cold air vent, away from the walls; not stored in refrigerator or freezer doors, not on the floor, and not stored in the crisper drawers.
<input type="checkbox"/>	The Division of Immunization Services was notified of any temperature excursions/incidents. Please ensure any documentation regarding temperature excursions/incidents is available for review.
<input type="checkbox"/>	There are water bottles located near the air vents and on the bottom of the storage unit, to prevent vaccines from being stored there. There are ice packs in the freezer unit, leaving adequate space for vaccine storage.
<input type="checkbox"/>	We are able to locate the breaker box to view the VFC "do not disconnect" sign with the site reviewer.
<input type="checkbox"/>	We are aware that failure to be ready will not postpone the site visit.

Vaccine Storage Units

Refrigerator:

Type of Unit	Brand	Model Number	Serial Number	Date of Purchase/Put in Use	Location at Facility

Freezer:

Type of Unit	Brand	Model Number	Serial Number	Date of Purchase/Put in Use	Location at Facility

Emergency Vaccine Plan

The following section includes space for information and necessary actions to take in the event of an emergency such as unit malfunction, power outage, human error, etc.

POST THIS PLAN ON THE VACCINE UNIT OR OTHER PROMINENT LOCATION

Emergency Contacts and Backup Location

Name	Phone
Primary Emergency Contact	
Backup Emergency Contact	
Contact with 24-hour Access to Backup Location	
LHD VFC Contact	

All VFC Providers must identify an appropriate backup unit/location even if a generator is on-site. This is to ensure there is a location for vaccine storage if the actual unit fails and vaccine must be re-located.

Reminder: Test your emergency plan to ensure it works when needed!

Backup Location	Address	Phone

In Case of an Emergency

Follow the below protocol in the event of an emergency.

1. Power Outage:
 - a. Contact the Power Company. Name and phone number:

 - b. Determine the anticipated length of outage:

 - c. If over _____ hours, relocate the vaccine to: (facility address, contact, and phone number)

2. If there is not an area wide power outage:
 - a. Check all power sources: (breaker box, outlet...)
 - b. Make necessary corrections.
 - c. Implement new signs (Do Not Unplug...)
3. Check all Data Loggers (DDLs)
 - a. If DDLs are damaged or not accurate, replace them and monitor for correct temperatures.
 - i. Document your actions in the temperature log.
 - b. If DDLs are accurate, move to the next step.
4. Remove vaccine and place in appropriate storage.
 - a. Adjust refrigerator or freezer temperature.
 - b. Recheck every 30 minutes until temperature returns to the correct range.
5. If unable to adjust temperature, connect with the emergency contact person
 - a. Emergency Contact Person _____
 - b. Or call the Division of Immunization Services 1-800-642-3634

Emergency Response Worksheet

Utilize this worksheet to track transported vaccines or vaccines exposed to out-of-range temperatures. Document temperature information and decision on viability when calling manufacturers.

Excursion Discovered	Time at Discovery:	Temp at Discovery:
Review Details	Total time out-of-range:	Max temp reached:
If Transport occurs	Time at start of transport:	Temp at start of transport:
	Time at end of transport:	Temp at end of transport:

Excursion Follow up: Utilize this for vaccine transported or exposed to out-of-range temperatures.

Vaccine	VFC or Private	Lot	# of Doses	Manufacturer Decision

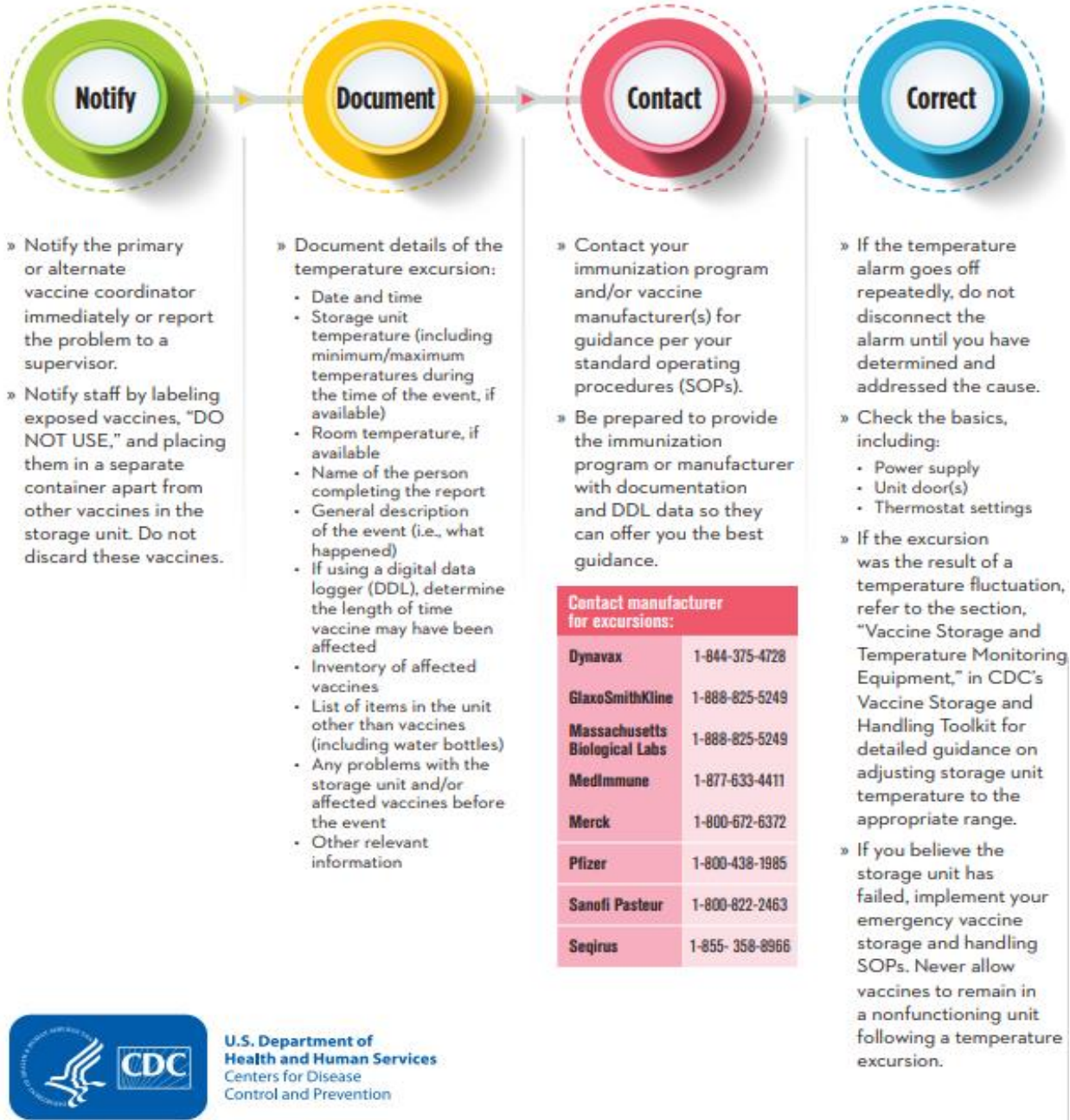
Contact Division of Immunization Services 1-800-642-3634 to report TE (Temperature Excursion)

Contact each vaccine manufacturer to determine viability. You will need: lot numbers, expiration dates, temperature log, and occurrence information.

Complete Return Vaccine Form (RVF) for each vaccine affected. Fax it to Division of Immunization Services 1-304-957-7591

Handling a Temperature Excursion in Your Vaccine Storage Unit

Any temperature reading outside ranges recommended in the manufacturers' package inserts is considered a temperature excursion. Identify temperature excursions quickly and take immediate action to correct them. This can prevent vaccine waste and the potential need to revaccinate patients.



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

Refrigerator and Freezer Temperature Logs can be found at: <https://www.immunize.org/>
Refrigerator: <https://www.immunize.org/catg.d/p3037f.pdf>
Freezer: <https://www.immunize.org/catg.d/p3038f.pdf>

Temperature Excursion (TE)

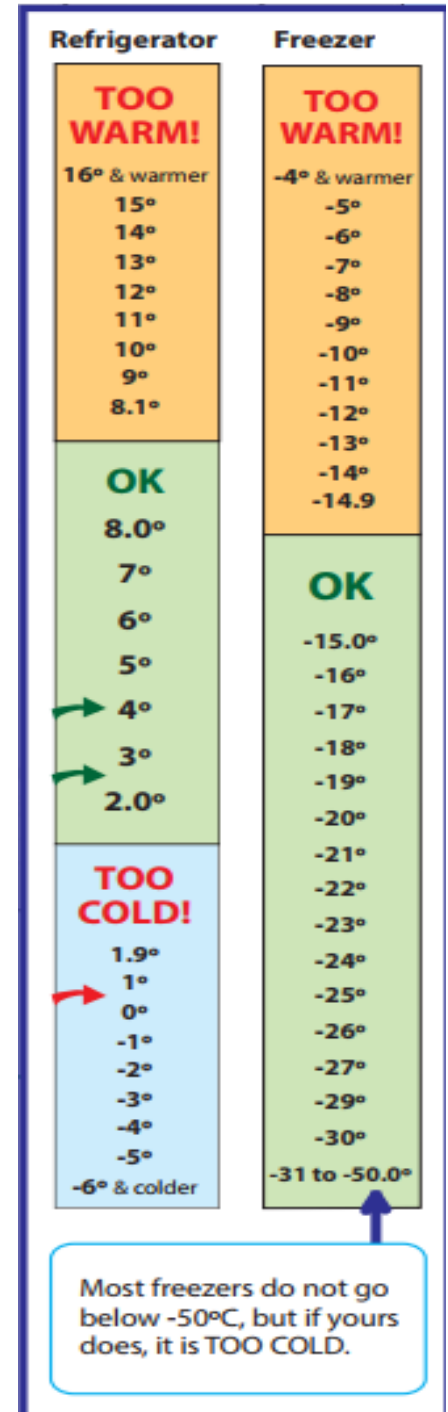
A temperature excursion is any temperature outside the recommended temperature range for a vaccine. The total amount of time a vaccine is stored at an outside temperature range affects the viability of the vaccine.

OUT-OF-RANGE TEMPERATURE:
An out-of-range refrigerator temperature is below 0°C or above 9°C (Celsius) [Below 32°F or above 47°F (Fahrenheit)]
An out-of-range freezer temperature is above -15°C (Celsius) [Above 5°F (Fahrenheit)] but equal or less than 14°F (-10°C)

Corrective Action:

1. Notify the VFC Coordinator, Backup Vaccine Coordinator, or office manager.
2. **Quarantine** exposed vaccine and label as "**DO NOT USE.**" Store vaccines under proper conditions, as quickly as possible.
3. **Download** the report from the digital data logger. Print out and review for when the excursion started and for how long.
4. Document detail of the temperature excursion occurrence: date and time, data logger last temperature recorded and temperature when discovered, room temperature, how long were vaccine exposed according to the data logger report, what vaccines are involved, and a detailed report of the event.
5. **Report Immediately** to the Division of Immunization Services at **1-800-642-3634** or at **304-558-2188**. Do not leave voicemails/ after hours (including weekends, holidays), next business day
6. **Contact Vaccine Manufacturers** and **give details of occurrences and wait for guidance on vaccine use.**
7. **Wait** for advice and further instructions from the Division of Immunization Services regarding the excursion. Do not use or administer any vaccines until instructed by the Division of Immunization Services.

Merck	877-829-6372
Sanofi Pasteur	800-822-2463
Pfizer/Wyeth	800-505-4426



Vaccine Handling Guidelines

1. Vaccines should be ordered monthly by the 5th day of the month.
2. Keep no more than two months of vaccine on hand at any time, keep shortest dated vaccines in front and rotate stock on a monthly basis.
3. Report any wasted or expired vaccine to the Division of Immunization Services. Any vaccines that will be expiring within 3 months that will not be used should also be reported.
4. Protect all light sensitive vaccines including Varicella, HPV, MMR, MMRV, Rotavirus, ActHib, Hiberix, Menactra, Menveo Bexsero and inactivated Flu vaccine.
5. Stack vaccines so that air can circulate around them, do not place vaccines in the door or the crisper, do not store food or drink in refrigerator, place water bottles in refrigerator and ice packs in freezer to stabilize temperature.
6. Always maintain the cold chain with vaccines even when moving or transporting.

Vaccine Transport			
Coolers/Packing Materials	Location at our Facility	Ordering Information (Company)	Phone Number
Portable refrigerator/freezer units			
Insulated Coolers/Containers			
Insulating Barrier (bubble wrap, Styrofoam, peanuts, exam table paper, etc.)			
Cold Packs			
Freezer Packs			
Calibrated Data Logger Thermometer(s)			
Flashlights			
Plastic Storage Bags (baggies)			
Plastic Storage Containers			
Sharpies			

Vaccine Storage

Vaccines			
Refrigerator	Freezer	Light Sensitive	
Diphtheria, Tetanus, and Pertussis (DTaP) Hiberix (Hib) Hepatitis A & B (HepA and HepB) Human papillomavirus (HPV) Inactivated Influenza Vaccine (IIV) Injectable Polio Vaccine (IPV) Live, attenuated influenza vaccine (LAIV) Meningococcal B (MenB) Measles, Mumps, Rubella (MMR) Meningococcal bacteria – A, C, W and Y (MenACWY) Pneumococcal (PCV) Polio Haemophilus B conjugate (PRP-T Hib) Rotavirus (RV) Recombinant Zoster Vaccine (RZV)	Measles, Mumps, Rubella (MMR) Measles, Mumps Rubella, and Varicella (MMRV) Varicella (VAR)	Varicella HPV MMR MMRV Rotavirus	ActHib Hiberix Menactra Menveo Bexsero Inactivated Flu Vaccine
Notes			
NEVER store diluents in the freezer Some diluents must be refrigerated Some diluents may be stored in the refrigerator or room temperature (no warmer than 25°C (77°F)).			

How to Use a Digital Data Logger (DDL)

1. Place the small temperature bottle in the refrigerator or freezer one hour before you connect the Digital Data logger to it, so it cools off.
2. Plug the Digital Data logger into the gel bottle sensor.
3. Press the green button for about 5 to 7 seconds (press hard) till the “START” signal goes off and you see a temperature number display on the screen, it’s now ready to record.
4. Without unplugging the device, you can check temps. You can check temps by pressing the green button for one second and it will give you, **high temp max**. Press it again and it will give you the **low temp max**. Press it again and it will give you the **average temp**.

Checking and recording temps on the computer:

1. Before unplugging the device, **press the red stop button until it stops flashing “STOP”** (around 5 to 7 seconds). Now you can unplug the device and insert it into the computer.
2. You can then look for the “Flashlink” on one of your ports. Here you can download the information in Adobe (PDF) or excel file. (make sure you save the information).
3. Once this is done you only need to send in the 1st page where the information is condensed **as your monthly temperature log submission**.

Reinstalling the device:

1. **Unplug the device from the computer.**
2. **Without plugging the device back into the bottle sensor on the refrigerator**, press both the green and red button at the same time (around 5 to 7 seconds hard) until the odd-looking plus sign stops flashing. You will then see a moon icon indicating it’s ready for re-installment.
3. Plug the device into the sensor cord to start recording again.

NOTE: You can always restart the device by pressing both the red and green buttons if you need to start over.

Changing the parameters of the Digital Data Logger (DDL)

1. Once you have downloaded the software that came with the DDL, go to the “hidden icons” at the bottom of the page (the one you use when you are removing your thumb drive that says it is now safe to remove).
2. Here you should see a “FlashPDF” icon. RIGHT CLICK THIS.
3. Go to “Setup” this will bring up Current Configuration, go to NEXT.
4. Here are **Logging Options** this will let you change the minutes between DDL checks (middle row **Logging interval**).
5. Go to NEXT again. This lets you change the temps and cut off or on alarms. When done go to NEXT ignore **data tags** go to NEXT again, this gives you the parameters you have set. NEXT again. Logger will be configured press OK.

You are finished unless you want to configure another DDL (press no or yes). If you want to configure with the same parameters, unplug the current DDL and plug in a new one. It will set it automatically.

Storage and Handling Errors

A best practice to avoid handling and storage errors is to designate only one person, or at the most two, to be responsible for storage and handling of vaccines

Do Not:

- Store food and/or drinks in the vaccine refrigerator/freezer
- Store vaccine in a manner that could jeopardize its quality
- Leave the refrigerator or freezer door open
- Have inadequate door seals
- Store vaccines in a dorm-style refrigerator
- Record only refrigerator or freezer
- Use an uncalibrated thermometer
- Discard vials if they are expired
- Plug the refrigerator or freezer into a surge protector

Do:

- Record temperatures multiple times a day
- Record both refrigerator and freezer temperatures
- Use a calibrated thermometer
- Report all out of range temperatures
- Keep temperature logs for 3 years
- Have an emergency plan for power outages or natural disasters
- Contact Division of Immunization Services for any problem



Temperature Log for Freezer – Celsius

Days 1-15

Monitor temperatures closely!

1. Write your initials below in “Staff Initials,” and note the time in “Exact Time.”
2. Record temps twice each workday.
3. Record the min/max temps once each workday preferably in the morning.
4. Put an “X” in the row that corresponds to the freezer’s temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month’s log for 3 years, unless state/local jurisdictions require a longer period.

Month/Year _____ VFC PIN or other ID # _____

Facility Name _____

Take action if temp is out of range—too warm (above -15°C) or too cold (below -50°C).

1. Label exposed vaccine “do not use,” and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the “Action” area on the bottom of the log.
3. Notify your vaccine coordinator or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the “Vaccine Storage Troubleshooting Record.”

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Staff Initials																
Exact Time	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Min/Max Temp (since previous reading)																
Danger! Temperatures above -15°C are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
ACCEPTABLE TEMPERATURES	-15°C															
	-16°C															
	-17°C															
	-18°C															
	-19°C															
	-20°C															
	-21°C															
	-22°C															
-50°C to -23°C																
ACTION	Write any out-of-range temps (above -15°C or below -50°C) here.															
	Room Temperature															



Temperature Log for Freezer – Celsius

Days 16-31

Monitor temperatures closely!

1. Write your initials below in “Staff Initials,” and note the time in “Exact Time.”
2. Record temps twice each workday.
3. Record the min/max temps once each workday preferably in the morning.
4. Put an “X” in the row that corresponds to the freezer’s temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month’s log for 3 years, unless state/local jurisdictions require a longer period.

Month/Year _____ VFC PIN or other ID # _____

Facility Name _____

Take action if temp is out of range—too warm (above -15°C) or too cold (below -50°C).

1. Label exposed vaccine “do not use,” and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the “Action” area on the bottom of the log.
3. Notify your vaccine coordinator or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the “Vaccine Storage Troubleshooting Record.”

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)																
Danger! Temperatures above -15°C are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
ACCEPTABLE TEMPERATURES	-15°C															
	-16°C															
	-17°C															
	-18°C															
	-19°C															
	-20°C															
	-21°C															
	-22°C															
ACTION	-50°C to -23°C															
	Write any out-of-range temps (above -15°C or below -50°C) here.															
	Room Temperature															



Temperature Log for Freezer – Fahrenheit

Days 1-15

Monitor temperatures closely!

1. Write your initials below in “Staff Initials,” and note the time in “Exact Time.”
2. Record temps twice each workday.
3. Record the min/max temps once each workday preferably in the morning.
4. Put an “X” in the row that corresponds to the freezer’s temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month’s log for 3 years, unless state/local jurisdictions require a longer period.

Month/Year _____ VFC PIN or other ID # _____

Facility Name _____

Take action if temp is out of range—too warm (above -15°C) or too cold (below -50°C).

1. Label exposed vaccine “do not use,” and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the “Action” area on the bottom of the log.
3. Notify your vaccine coordinator or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the “Vaccine Storage Troubleshooting Record.”

Day of Month	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15		
Staff Initials																															
Exact Time	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	
Min/Max Temp (since previous reading)	/		/		/		/		/		/		/		/		/		/		/		/		/		/		/		
Danger! Temperatures above 5°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																															
ACCEPTABLE TEMPERATURES	5°F																														
	4°F																														
	3°F																														
	2°F																														
	1°F																														
	0°F																														
	-1°F																														
	-2°F																														
	-3°F																														
	-4°F																														
-58°F to -5°F																															
ACTION	Write any out-of-range temps (above 5°F or below -58°F) here.																														
	Room Temperature																														



Temperature Log for Freezer – Fahrenheit

Days 16-31

Monitor temperatures closely!

1. Write your initials below in “Staff Initials,” and note the time in “Exact Time.”
2. Record temps twice each workday.
3. Record the min/max temps once each workday preferably in the morning.
4. Put an “X” in the row that corresponds to the freezer’s temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month’s log for 3 years, unless state/local jurisdictions require a longer period.

Month/Year _____ VFC PIN or other ID # _____

Facility Name _____

Take action if temp is out of range—too warm (above -15°C) or too cold (below -50°C).

1. Label exposed vaccine “do not use,” and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the “Action” area on the bottom of the log.
3. Notify your vaccine coordinator or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the “Vaccine Storage Troubleshooting Record.”

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																
Exact Time	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Min/Max Temp (since previous reading)																
Danger! Temperatures above 5°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
ACCEPTABLE TEMPERATURES	5°F															
	4°F															
	3°F															
	2°F															
	1°F															
	0°F															
	-1°F															
	-2°F															
	-3°F															
	-4°F															
-58°F to -5°F																
ACTION	Write any out-of-range temps (above 5°F or below -58°F) here.															
	Room Temperature															



Temperature Log for Refrigerator – Celsius

Days 1-15

Monitor temperatures closely!

1. Write your initials below in “Staff Initials,” and note the time in “Exact Time.”
2. Record temps twice each workday.
3. Record the min/max temps once each workday preferably in the morning.
4. Put an “X” in the row that corresponds to the freezer’s temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month’s log for 3 years, unless state/local jurisdictions require a longer period.

Month/Year _____ VFC PIN or other ID # _____

Facility Name _____

Take action if temp is out of range—too warm (above -15°C) or too cold (below -50°C).

1. Label exposed vaccine “do not use,” and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the “Action” area on the bottom of the log.
3. Notify your vaccine coordinator or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the “Vaccine Storage Troubleshooting Record.”

Day of Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Staff Initials																
Exact Time	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Min/Max Temp (since previous reading)																
Danger! Temperatures above 8°C are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
TEMPERATURES	8°C															
	7°C															
	6°C															
	5°C															
ACCEPTABLE	4°C															
	3°C															
	2°C															
Danger! Temperatures below 2°C are too cold! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
ACTION	Write any out-of-range temps (above 8°C or below 2°C) here:															
	Room Temperature															



Temperature Log for Refrigerator – Celsius

Days 16-31

Monitor temperatures closely!

1. Write your initials below in “Staff Initials,” and note the time in “Exact Time.”
2. Record temps twice each workday.
3. Record the min/max temps once each workday preferably in the morning.
4. Put an “X” in the row that corresponds to the freezer’s temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month’s log for 3 years, unless state/local jurisdictions require a longer period.

Month/Year _____ VFC PIN or other ID # _____

Facility Name _____

Take action if temp is out of range—too warm (above -15°C) or too cold (below -50°C).

1. Label exposed vaccine “do not use,” and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the “Action” area on the bottom of the log.
3. Notify your vaccine coordinator or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the “Vaccine Storage Troubleshooting Record.”

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																
Exact Time	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Min/Max Temp (since previous reading)																
Danger! Temperatures above 8°C are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
TEMPERATURES	8°C															
	7°C															
	6°C															
	Aim for 5°C															
	4°C															
ACCEPTABLE	3°C															
	2°C															
Danger! Temperatures below 2°C are too cold! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
ACTION	Write any out-of-range temps (above 8°C or below 2°C) here:															
	Room Temperature															



Temperature Log for Refrigerator – Fahrenheit

Days 1-15

Monitor temperatures closely!

1. Write your initials below in “Staff Initials,” and note the time in “Exact Time.”
2. Record temps twice each workday.
3. Record the min/max temps once each workday preferably in the morning.
4. Put an “X” in the row that corresponds to the freezer’s temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month’s log for 3 years, unless state/local jurisdictions require a longer period.

Month/Year _____ VFC PIN or other ID # _____

Facility Name _____

Take action if temp is out of range—too warm (above -15°C) or too cold (below -50°C).

1. Label exposed vaccine “do not use,” and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the “Action” area on the bottom of the log.
3. Notify your vaccine coordinator or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the “Vaccine Storage Troubleshooting Record.”

Day of Month		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Staff Initials																	
Exact Time		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Min/Max Temp (since previous reading)																	
Danger! Temperatures above 46°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																	
TEMPERATURES	46°F																
	45°F																
	44°F																
	43°F																
	42°F																
	41°F																
ACCEPTABLE	Aim for 40 → 40°F																
	39°F																
	38°F																
	37°F																
	36°F																
Danger! Temperatures below 36°F are too cold! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																	
ACTION	Write any out-of-range temps (above 46°F or below 36°F) here:																
	Room Temperature																



Temperature Log for Refrigerator – Fahrenheit

Days 16-31

Monitor temperatures closely!

1. Write your initials below in “Staff Initials,” and note the time in “Exact Time.”
2. Record temps twice each workday.
3. Record the min/max temps once each workday preferably in the morning.
4. Put an “X” in the row that corresponds to the freezer’s temperature.
5. If any out-of-range temp, see instructions to the right.
6. After each month has ended, save each month’s log for 3 years, unless state/local jurisdictions require a longer period.

Month/Year _____ VFC PIN or other ID # _____

Facility Name _____

Take action if temp is out of range—too warm (above -15°C) or too cold (below -50°C).

1. Label exposed vaccine “do not use,” and store it under proper conditions as quickly as possible. Do not discard vaccines unless directed to by your state/local health department and/or the manufacturer(s).
2. Record the out-of-range temps and the room temp in the “Action” area on the bottom of the log.
3. Notify your vaccine coordinator or call the immunization program at your state or local health department for guidance.
4. Document the action taken on the “Vaccine Storage Troubleshooting Record.”

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																
Exact Time	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM	AM PM
Min/Max Temp (since previous reading)																
Danger! Temperatures above 46°F are too warm! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
TEMPERATURES	46°F															
	45°F															
	44°F															
	43°F															
	42°F															
	41°F															
ACCEPTABLE	Aim for 40°	40°F														
	39°F															
	38°F															
	37°F															
	36°F															
Danger! Temperatures below 36°F are too cold! Write any out-of-range temps and room temp on the lines below and call your state or local health department immediately!																
ACTION	Write any out-of-range temps (above 46°F or below 36°F) here:															
	Room Temperature															



Vaccine Administration Record

Patient Name: _____
 Date of Birth: _____
 Provider Name: _____
 Address: _____
 City, State, Zip: _____

(Providers stamp)

***Site/Route Legend**
 RA=Right Arm
 LA=Left Arm
 RT=Right Thigh
 LT=Left Thigh
 PO=Oral
 IM=Intramuscular
 SQ=Subcutaneous

Circle Vaccine	Date Given M/D/Y	Site/ Route	Vaccine		Vaccine Information Statement (VIS)		Vaccinator (signature or initials & title)	Parent/Guardian Signature	VFC ✓ Yes
			Lot #	MFR.	Date on VIS	Date Given			
DTaP DTaP/Hepb/IPV DT									
DTaP DTaP/Hepb/IPV DT									
DTaP DTaP/Hepb/IPV DT									
DTaP DT									
DTaP DTaP/IPV DT									
Hep A									
Hep A									
Hep B									
Hep B									
Hep B									
Hib HepB/Hib DTaP/Hib/IPV									
Hib HepB/Hib DTaP/Hib/IPV									
Hib HepB/Hib DTaP/Hib/IPV									
Hib DTaP/Hib/IPV									
HPV									
HPV									
HPV									
Influenza									
Influenza									
IPV									
IPV									
IPV									
IPV									
Mengino Conj (MCV4)									
Mengino Conj (MCV4)									
MMR MMRV									
MMR MMRV									
PCV 13									
PCV 13									
PCV 13									
PCV 13									
Pneumococcal Polysaccharide									
Rotavirus									
Rotavirus									
Rotavirus									
Td									
Td Tdap									
Varicella									
Varicella									
Other:									

Vaccine Storage Troubleshooting Record

Use this page to record details of any vaccine storage incident, including the date and time of the last known temperature within appropriate vaccine storage range.

Date	Time	Current Storage Unit Temp	Min/Max	Incident	Action Taken	Results	Initials
1/13/22	7:30am	5C	6C/1C	Refrigerator too cold	Put do not use sign on the fridge. Called the WV Immunization department and explained excursion. At 8am, I changed the thermostat to change the temp. Notified other staff of incident and temp change.	Closely monitored refrigerator temps. Temp stabilized at 5C	AB

In the event of a temperature excursion, call the WV Division of Immunizations at 1-800-642-3634.



Facility Name: _____

Pin #: _____

VACCINE BORROWING REPORT

VFC-enrolled providers are expected to manage and maintain an adequate inventory of vaccine for both their VFC and non-VFC-eligible patients. **Planned borrowing of VFC vaccine including the use of VFC vaccine as a replacement system for a provider's privately purchased vaccine inventory is not permissible.**

VFC-enrolled providers must ensure borrowing VFC vaccine will not prevent a VFC-eligible child from receiving a needed vaccination. Infrequent exchanging between VFC and private stock of a short-dated vaccine dose may be performed if the provider serves a small number of private pay patients, the dose is one month from expiration, or the dose of vaccine cannot be used for the population it is intended for prior to the expiration date.

COMPLETE THIS FORM WHEN:

- A dose of VFC vaccine is administered to a non VFC-eligible child
- A dose of privately-purchased vaccine is administered to a VFC-eligible child

HOW TO COMPLETE THIS FORM:

- Enter information on each dose of vaccine borrowed in a separate row in the Vaccine Borrowing Report Table.
- All columns must be completed for each dose borrowed
- The provider must sign and date at the bottom of this report
- Enter the corresponding reason code in column F of the Borrowing Report Table on page 2.
- Enter details of reason in Column F if an Other code (7Other or 13Other) is entered in the Vaccine Borrowing Report Table.

Reason for Vaccine Borrowing and Replacement Coding Legend

Reason for Borrowing VFC Dose	Code	Reason for Borrowing Private Dose	Code
Private vaccine shipment delay (vaccine order placed on time/delay in shipping)	1	VFC vaccine shipment delay (order placed on time/delay in shipping)	8
Private vaccine not useable on arrival (vials broken, temperature monitor out of range)	2	VFC vaccine not useable on arrival (vials broken, temperature monitor out of range)	9
Ran out of private vaccine between orders (not due to shipping delays)	3	Ran out of VFC vaccine between orders (not due to shipping delays)	10
Short-dated private dose was exchanged with VFC dose	4	Short-dated VFC dose was exchanged with private dose	11
Accidental use of Private dose for VFC eligible child	5	Accidental use of a VFC dose for a child not eligible for the VFC program	12
Replacement of Private dose with VFC when insurance plan did not cover vaccine	6	Other – Describe:	13Other
Other – Describe:	7Other		

WHAT TO DO WITH THIS FORM:

- Completed forms must be retained as a VFC program record and made available to the State/Local or Territorial Immunization Program upon request.



Date Range of Vaccine Reporting (date of first dose borrowed to date of last dose borrowed): / / to / /

VACC [REDACTED] TABLE

A Vaccine Type Borrowed	B Stock Used (VFC or Private)	C Patient Name	D Patient DOB (XX/XX/XXXX)	E Date Dose Administered (XX/XX/XXXX)	F Reason Appropriate Vaccine Stock was not Used (Use legend code on page 1 to mark one reason for each dose borrowed)	G Date Dose Returned to Appropriate Stock (XX/XX/XXXX)

I hereby certify, subject to penalty under the False Claims Act (31 U.S.C. § 3730) and other applicable Federal and state law, that VFC vaccine dose borrowing and replacement reported on this form has been accurately reported and conducted in conformance with VFC provisions for such borrowing and further certify that all VFC doses borrowed during the noted time period have been fully reported on this form.

Provider Name:	Provider Signature:	Date:
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The diagram shows two vertical storage units side-by-side. The left unit is labeled 'REFRIGERATOR' and contains a sign that reads: 'Store vaccines between 2°C and 8°C (36°F and 46°F)'. The right unit is labeled 'FREEZER' and contains a sign that reads: 'Store vaccines between -50°C and -15°C (-58°F and +5°F)'. Both units have three shelves and a door handle on the left side.

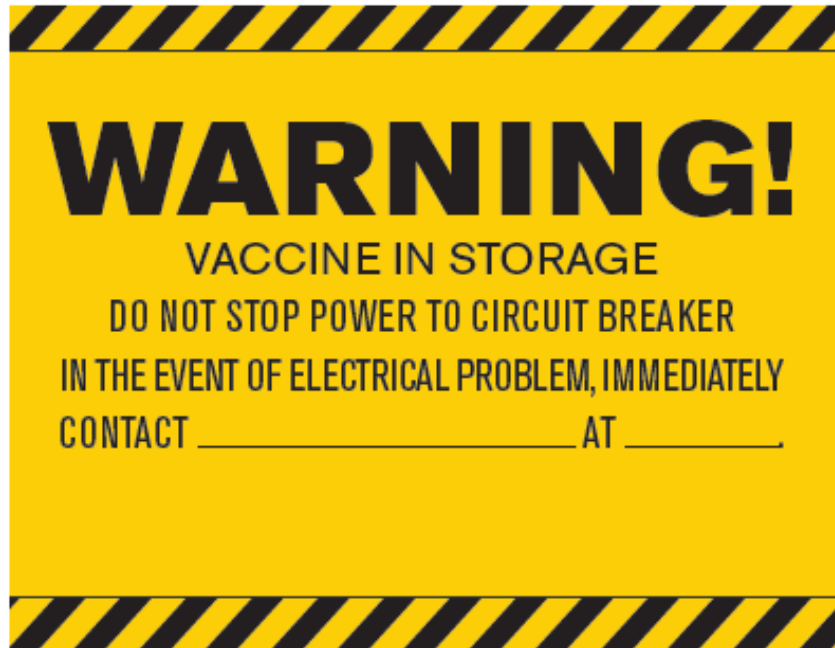
- » Keep your storage units and vaccines within the appropriate temperature ranges.
- » Check and record storage unit min/max temperatures at start of each workday. If your device does not display min/max temperatures, then check and record current temperature a minimum of 2 times (at start and end of workday). Also check current temperature before accessing and administering vaccine.
- » Take immediate action if temperatures are out of range.
- » Keep vaccines in their original packages.
- » Many vaccines should be protected from light (consult manufacturer's product information).
- » Check expiration dates and rotate your vaccine stock to keep most recent expiration dates at the front.

 Do **NOT** adjust refrigerator or freezer temperature controls!

 **Notify**
(insert name/phone number)
if adjustment is necessary.

 ¡ **NO** cambie la temperatura del refrigerador/congelador!

 **Comuníquese con**
(inserte nombre y número de teléfono aquí)
si hay necesidad de cambiar la temperatura.



WARNING!

**DO NOT UNPLUG THE REFRIGERATOR
OR BREAK CIRCUIT.**



VACCINE IN STORAGE.

**IN THE EVENT OF ELECTRICAL PROBLEM, IMMEDIATELY
CONTACT: _____**

(insert name/phone number)

¡AVISO!

**NO DESCONECTE EL REFRIGERADOR
NI CORTE EL CIRCUITO.**



¡CONTIENE VACUNAS!

**SI HAY UN PROBLEMA CON LA ELECTRICIDAD,
COMUNIQUESE INMEDIATAMENTE CON:**

(inserte nombre y número de teléfono aquí)

WARNING!

DO NOT UNPLUG THE FREEZER OR
BREAK CIRCUIT.



VACCINE IN STORAGE.

IN THE EVENT OF ELECTRICAL PROBLEM, IMMEDIATELY
CONTACT: _____

(insert name/phone number)

¡AVISO!

NO DESCONECTE EL CONGELADOR
NI CORTE EL CIRCUITO.



¡CONTIENE VACUNAS!

SI HAY UN PROBLEMA CON LA ELECTRICIDAD,
COMUNIQUESE INMEDIATAMENTE CON:

(inserte nombre y número de teléfono aqui)

REFRIGERATE

UPON ARRIVAL

PERISHABLE

NO DELAY!

DO NOT FREEZE | KEEP FROM HEAT

FREEZE

UPON ARRIVAL

PERISHABLE

NO DELAY!

DO NOT REFRIGERATE | KEEP FROM HEAT







WARNING!
EXPENSIVE VACCINE IN STORAGE!
¡AVISO! Contiene vacunas caras.

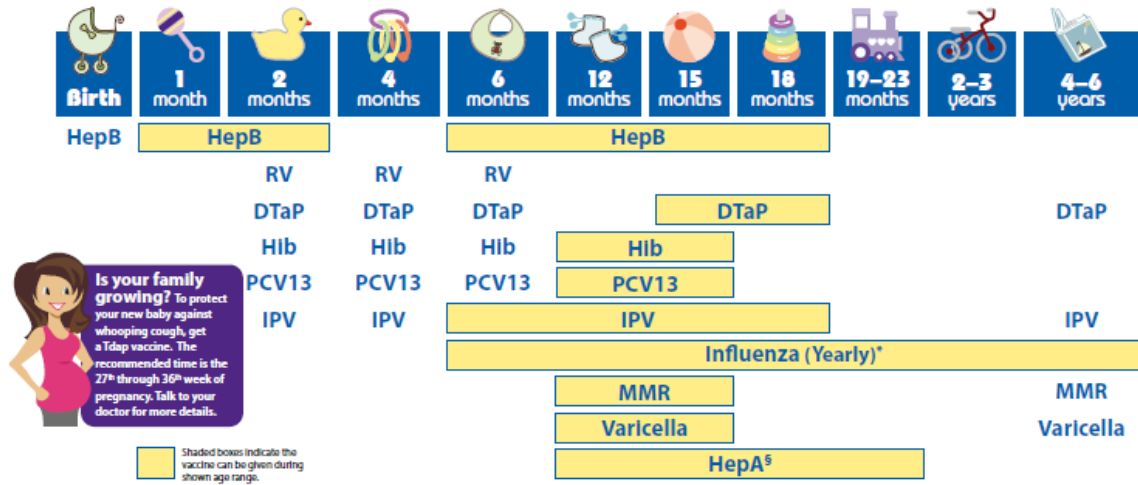
DO NOT TURN OFF CIRCUIT BREAKER #____
No apague el interruptor de circuito #____

In the event of an electrical problem, immediately contact
Si hay un problema con la electricidad, comuníquese inmediatamente con

.....

Recommended Immunization Schedules

2021 Recommended Immunizations for Children from Birth Through 6 Years Old



For more information, call toll-free
1-800-CDC-INFO (1-800-232-4636)
or visit
www.cdc.gov/vaccines/parents



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention



American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN

Vaccine-Preventable Diseases and the Vaccines that Prevent Them

Disease	Vaccine	Disease spread by	Disease symptoms	Disease complications
Chickenpox	Varicella vaccine protects against chickenpox.	Air, direct contact	Rash, tiredness, headache, fever	Infected blisters, bleeding disorders, encephalitis (brain swelling), pneumonia (infection in the lungs)
Diphtheria	DTaP* vaccine protects against diphtheria.	Air, direct contact	Sore throat, mild fever, weakness, swollen glands in neck	Swelling of the heart muscle, heart failure, coma, paralysis, death
Hib	Hib vaccine protects against <i>Haemophilus influenzae</i> type b.	Air, direct contact	May be no symptoms unless bacteria enter the blood	Meningitis (infection of the covering around the brain and spinal cord), intellectual disability, epiglottitis (life-threatening infection that can block the windpipe and lead to serious breathing problems), pneumonia (infection in the lungs), death
Hepatitis A	HepA vaccine protects against hepatitis A.	Direct contact, contaminated food or water	May be no symptoms, fever, stomach pain, loss of appetite, fatigue, vomiting, jaundice (yellowing of skin and eyes), dark urine	Liver failure, arthralgia (joint pain), kidney, pancreatic and blood disorders
Hepatitis B	HepB vaccine protects against hepatitis B.	Contact with blood or body fluids	May be no symptoms, fever, headache, weakness, vomiting, jaundice (yellowing of skin and eyes), joint pain	Chronic liver infection, liver failure, liver cancer
Influenza (Flu)	Flu vaccine protects against influenza.	Air, direct contact	Fever, muscle pain, sore throat, cough, extreme fatigue	Pneumonia (infection in the lungs)
Measles	MMR** vaccine protects against measles.	Air, direct contact	Rash, fever, cough, runny nose, pink eye	Encephalitis (brain swelling), pneumonia (infection in the lungs), death
Mumps	MMR** vaccine protects against mumps.	Air, direct contact	Swollen salivary glands (under the jaw), fever, headache, tiredness, muscle pain	Meningitis (infection of the covering around the brain and spinal cord), encephalitis (brain swelling), inflammation of testicles or ovaries, deafness
Pertussis	DTaP* vaccine protects against pertussis (whooping cough).	Air, direct contact	Severe cough, runny nose, apnea (a pause in breathing in infants)	Pneumonia (infection in the lungs), death
Polio	IPV vaccine protects against polio.	Air, direct contact, through the mouth	May be no symptoms, sore throat, fever, nausea, headache	Paralysis, death
Pneumococcal	PCV13 vaccine protects against pneumococcus.	Air, direct contact	May be no symptoms, pneumonia (infection in the lungs)	Bacteremia (blood infection), meningitis (infection of the covering around the brain and spinal cord), death
Rotavirus	RV vaccine protects against rotavirus.	Through the mouth	Diarrhea, fever, vomiting	Severe diarrhea, dehydration
Rubella	MMR** vaccine protects against rubella.	Air, direct contact	Sometimes rash, fever, swollen lymph nodes	Very serious in pregnant women—can lead to miscarriage, stillbirth, premature delivery, birth defects
Tetanus	DTaP* vaccine protects against tetanus.	Exposure through cuts in skin	Stiffness in neck and abdominal muscles, difficulty swallowing, muscle spasms, fever	Broken bones, breathing difficulty, death

* DTaP combines protection against diphtheria, tetanus, and pertussis.
** MMR combines protection against measles, mumps, and rubella.

Additional Resources

- Immunization Action Coalition
 - Immunization.org
- Immunizations – CDC
 - [cdc.gov/vaccines](https://www.cdc.gov/vaccines)
 - https://www.cdc.gov/coronavirus/2019-nCoV/index.html?ACSTrackingID=USCDC_450-DM76609&ACSTrackingLabel=3%20COVID-19%20Learning%20Opportunities&deliveryName=USCDC_450-DM76609
 - https://www.cdc.gov/training/learning/index.html?ACSTrackingID=USCDC_450-DM76609&ACSTrackingLabel=3%20COVID-19%20Learning%20Opportunities&deliveryName=USCDC_450-DM76609
- DHHR’s Office of Epidemiology and Prevention Services
 - <https://oeps.wv.gov/Pages/default.aspx>