

2021 Vaccines for Children (VFC)

Maine Immunization Program
Annual Education Requirement



Vaccines for Children Learning Objectives

Learning Objectives

At the conclusion of this training, the participant will be able to:

1. Describe VFC program requirements.
2. Describe VFC billing practices.
3. Describe VFC vaccine management practices.
4. Describe the purpose of VFC-related site visits performed by the Maine Immunization Program

Vaccines for Children Overview

History of the VFC Program

In 1989-1991, a measles epidemic in the United States resulted in tens of thousands of cases of measles and hundreds of deaths. Upon investigation, the Centers for Disease Control and Prevention (CDC) found that more than half of the children who had measles had not been vaccinated, even though many of them had seen a health care provider.

In partial response to that epidemic, Congress passed the Omnibus Budget Reconciliation Act (OBRA) on August 10, 1993, creating the Vaccines for Children (VFC) program. VFC became operational October 1, 1994. Known as section 1928 of the Social Security Act, the VFC program is an entitlement program (a right granted by law) for eligible children age 18 years and younger.

Vaccines for Children Overview

What the VFC Program Does

The VFC program helps provide vaccines to children whose parents or guardians might not be able to afford them. This helps ensure that all children have a better chance of getting their recommended vaccinations on schedule. Vaccines available through the VFC program are those recommended by the Advisory Committee on Immunization Practices (ACIP). The vaccines protect babies, young children, and adolescents from 16 diseases.

Vaccines for Children Overview

How VFC Works

CDC buys vaccines at a discount from vaccine manufacturers and distributes them at no charge to private physicians' offices, public health clinics, and other health care facilities enrolled as VFC providers. VFC providers play the important role of properly storing vaccines and administering them to eligible children at no cost for the vaccines.

VFC Vaccine is NOT Free

Even though VFC vaccine is provided at no cost to enrolled providers and eligible children, it should never be considered “free”. There is a substantial cost involved with purchasing millions of doses of vaccine and making them available to provider offices.

Vaccines for Children Overview

Availability of VFC Vaccine for Children

The VFC program provides vaccines purchased with public funds to eligible children in all states, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands.

Impact of the VFC program

The VFC program:

- Makes available all vaccines recommended for inclusion in the VFC program by the Advisory Committee on Immunization Practices (ACIP) at no cost for the vaccines
- 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 an administration fee based on the child's eligibility

Vaccines for Children Overview

VFC Partners and Collaborating Agencies

Many partners and collaborating agencies work together with the goal of vaccinating VFC-eligible children with viable, properly handled vaccine.

Successful implementation of this program requires close collaboration with people just like you! There are many programs and agencies that also contribute to the program's success:

- Centers for Disease Control and Prevention
- Centers for Medicare & Medicaid Services (CMS)
- State Medical agencies
- Health Resources and Services Administration (HRSA)
- Indian Health Service (HIS)
- National, state and local organizations representing the private health care sector
- State, local, and territorial immunization programs

Knowledge Check

Is the statement below true or false?

VFC vaccine is free.

TRUE

FALSE 

VFC vaccine is purchased by the federal government for distribution and use in VFC-entitled children and, therefore, there is a cost. However, there is no cost for the vaccine for providers enrolled in the program or for eligible children receiving the vaccine.

VFC Provider Enrollment

Enrolling in the VFC Program

All providers enrolling in the VFC program must have an initial VFC enrollment site visit before receiving VFC vaccine.

Representatives from the Maine Immunization Program conduct enrollment visits to ensure providers have access to information needed for implementation of VFC program requirements. Providers must have appropriate resources and processes in place to implement VFC program requirements, including those that support proper vaccine storage units and temperature monitoring equipment.

As of January 1, 2018, all VFC providers are required to use continuous temperature monitoring devices (data loggers) to monitor vaccine that will be administered to VFC-eligible children, including during routine, on-site storage of vaccine, transport of vaccine, and while conducting mass vaccination clinics.

Enrolling in the VFC Program (continued)

Each VFC provider must complete two enrollment forms:

- Provider Profile
- Provider Agreement

These forms must be completed and submitted to the Maine Immunization Program at the time of enrollment and on an annual basis.

The Provider Profile

The provider profile captures the number of VFC-eligible children and non-VFC-eligible children served by VFC providers. It supports providers in determining how much vaccine to order for each population served. The data collected in the provider profile also assists the Maine Immunization Program in determining overall vaccine need and are used when reviewing and approving provider vaccine orders.

The provider profile captures the number of children who received vaccines from all providers at the facility during the previous 12 months by age group and program eligibility status.

All VFC providers must complete the provider profile annually. However, providers must submit this form more frequently if the:

1. Number of children served changes or
2. Status of facility changes resulting in an increase or decrease in the amount of vaccine that will be needed during the calendar year

VFC Provider Enrollment

The Provider Agreement

The provider agreement describes VFC program requirements and is used to document the provider's agreement to comply with the requirements. It must be signed annually by the medical director (or equivalent) in a group practice.

The official VFC-registered health care provider signing the agreement must be a practitioner authorized by state law to administer pediatric vaccines. This provider must have the authority to sign on behalf of the organization or practice and ensure that all VFC requirements are met as outlined in the provider agreement.

The Provider Agreement (continued)

In addition to the medical director (or equivalent) in a group practice, the following individuals must be listed on the provider agreement:

- All licensed health care providers (MD ,DO ,NP ,PA , pharmacist) at the facility who have prescribing authority
- VFC Coordinator (individual with the primary responsibility for managing the VFC program at the facility or practice level)
- VFC Backup Coordinator

Knowledge Check

Is the statement below true or false?

The purpose of the provider profile is to provide a listing of VFC program requirements that each provider will follow during the current enrollment cycle.

TRUE

FALSE



The VFC provider agreement provides a listing of all VFC requirements that each provider must follow. The provider profile captures the number of VFC-eligible children and non-VFC-eligible children served by VFC providers. It supports providers in determining how much vaccine to order for each population served.

Knowledge Check

Is the statement below true or false?

The purpose of the provider agreement is to assist the Maine Immunization Program in determining the amount of vaccine supplied through the VFC program.

TRUE

FALSE




The purpose of the provider agreement is to document the provider's agreement to comply with the requirements of the VFC program.

Knowledge Check

Determine the correct answer.

Who signs the provider agreement?

- The VFC Coordinator
- The medical director or equivalent 
- All providers within the practice

The official VFC-registered health care provider signing the agreement must be a practitioner authorized by state law to administer pediatric vaccines. This person is responsible for ensuring that all VFC requirements are met as outline in the provider agreement.

VFC Eligibility Categories

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

- Medicaid-eligible (MaineCare): a child who is eligible for the Medicaid program (for the purposes of the VFC program the terms “Medicaid-eligible” and “Medicaid-enrolled” are used interchangeably and refer to children who have health insurance covered by a state Medicaid program)
- Uninsured: a child who has no health insurance coverage
- American Indian or Alaskan Native (AI/AN): as defined by the Indian Health Care Improvement Act (25 U.S.C. 1603)
- Underinsured:
 - A child who has health insurance, but the coverage does not include vaccines or
 - A child whose insurance does not cover all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) (the child would be eligible to receive those vaccines not covered by the insurance)

VFC Eligibility Categories (continued)

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

State Vaccine Eligibility

Maine is a Universal Vaccine State, which means the Maine Immunization Program provides vaccines to health care providers at no cost for ALL children.

Children age birth through 18 years (or those under age 19) who meet the following criteria are eligible to receive state-eligible vaccine:

- The child does not meet any of the VFC-eligibility categories
- The child is a Maine resident

Provider Responsibility to Screen for VFC Eligibility and Document Eligibility Status

Screening to determine VFC eligibility and documenting the current VFC eligibility category must take place at each immunization visit prior to administering vaccines. Screening results must be documented at each immunization visit even if there is no change in eligibility status.

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 (MaineCare), uninsured, American Indian/Alaskan Native, or underinsured.


The patient eligibility screening record guides VFC eligibility and provides a method for documenting the eligibility and eligibility category for each child, if VFC-eligible.

Patient eligibility screening records should be kept for a minimum of three years after immunization services are provided.

Knowledge Check

Determine the correct answer.

When should screening for VFC eligibility be conducted?

- At the first immunization visit only
- At every immunization visit 
- Once a year
- Every 6 months

VFC providers must screen all patients age birth through 18 years for VFC eligibility and document eligibility status at each immunization visit.

Knowledge Check

Is the statement below true or false?

VFC providers must document eligibility status at every visit.

TRUE 

FALSE

VFC provider must screen all patients age birth through 18 years for VFC eligibility and document eligibility status at each immunization visit.

ACIP's role in the VFC Program

The Advisory Committee on Immunization Practices

The Advisory Committee on Immunization Practices (ACIP) is a federal committee that was established in 1964.

ACIP's overall goals are to provide guidance to assist the Department of Health and Human Services and the nation in reducing the incidence of vaccine-preventable diseases and increasing the safe use of vaccines and related biological products.

ACIP has the statutory authority to determine the recommended vaccines, number of doses, immunization schedule, and vaccine contraindications for the VFC program, as well as for the general population.

ACIP's role in the VFC Program

The Advisory Committee on Immunization Practices (continued)

ACIP also approves the specific recommendations for including 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 establishes a contract for the purchase of the vaccine through the VFC program.

The consolidated resolutions are posted on the VFC website soon after ACIP approval.

ACIP's role in the VFC Program

Complying with the ACIP Immunization Schedule

VFC providers must offer and make available all ACIP-recommended vaccines included in an approved VFC resolution.

VFC providers must comply with immunization schedules, dosages, and contraindications 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 any law pertaining to religious or other exemptions.

Knowledge Check

Is the statement below true or false?

VFC resolutions passed by ACIP form the basis for VFC program policies on vaccine availability and use.

TRUE 

FALSE


You can view the consolidated resolutions on the CDC website at:

<http://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html>.

Knowledge Check

Determine the correct answer.

VFC providers must comply with which recommendations outlined by ACIP in the VFC resolutions?

- Immunization schedules
- Dosages
- Contraindications
- All of the above 

VFC providers must comply with immunization schedules, dosages, and contraindications 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 any law pertaining to religious and other exemptions.

VFC Record Maintenance

VFC providers must maintain all records related to the VFC program for a minimum of three years and make these records available upon request to public health officials, including the Maine Immunization Program and Department of Health and Human Services Staff.


VFC Program Records

- Vaccine storage unit temperature documentation
- VFC vaccine management training records
- VFC eligibility screening documentation
- Routine and emergency vaccine management plan with standard operating procedures
- Provider Agreements
- Provider Profiles
- Billing records
- Vaccine ordering records
- Vaccine purchase and accountability records

Knowledge Check

Determine the correct answer.

What is the minimum amount of time VFC records must be maintained?


- Three months
- Six months
- One year
- Three years 

VFC providers must maintain all records related to the VFC program for a minimum of three years.

Knowledge Check

Determine the correct answer.

Which of the following are considered VFC program records?

- Vaccine emergency plans and standard operating procedures
- Temperature monitoring documentation
- VFC eligibility screening documentation
- All of the above 

All of the above are VFC program records. If you are unsure what documents are VFC program records, contact the Maine Immunization Program.

VFC-Supplied Vaccine

VFC vaccine must be provided to an eligible child at no cost for the vaccine. Patients, Medicaid agencies, and third-party payers can never be billed for the cost of VFC vaccine.

VFC providers can charge a vaccine administration fee when vaccinating VFC-eligible children. The administration fee is per vaccine and not per antigen within the vaccine (as in combination vaccines).

- For non-Medicaid VFC-eligible children (American Indian/Alaskan Native), uninsured, underinsured), VFC providers cannot charge the eligible child's parent/legal guardian a vaccine administration fee that exceeds \$21.58 (Maine's regional charge)
- For Medicaid VFC-eligible children (MaineCare), VFC providers must accept the reimbursement for vaccine administration set by the state Medicaid agency or the contracted Medicaid health plans.

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

Knowledge Check

Is the statement below true or false?

Patients, Medicaid agencies, and third-party payers can be billed for the cost of VFC vaccine.

TRUE

FALSE 

Neither patients nor Medicaid agencies or third-party payers can be billed for the cost of VFC vaccine. VFC vaccine is distributed to providers for use in VFC-eligible children at no cost for the vaccine.

Knowledge Check

Is the statement below true or false?

The administration fee is per antigen in the vaccine and not per vaccine.

TRUE

FALSE 

The administration fee is per VFC vaccine and not per antigen. VFC providers can only charge one administration fee per vaccine.

A combination vaccine is considered a single vaccine with one administration fee.

Knowledge Check

Is the statement below true or false?

If a VFC-eligible patient is unable to pay the vaccine administration fee, providers can deny administration of the next dose of VFC vaccine until the administration fee is paid.

TRUE

FALSE 

VFC providers cannot deny administration of a VFC vaccine to an established, eligible patient because the child's parent or guardian of record is unable to pay the administration fee.

Federal Documentation Requirements

Vaccine information statements (VISs) are fact sheets produced by CDC that explain to vaccine recipients both the benefits and risks of vaccines.

Federal law requires health care staff to provide a VIS to a patient, parent, or legal representative before each dose of certain vaccines. The appropriate VIS must be given prior to the vaccination and must be given prior to each dose of a multidose series.

Federal Documentation Requirements

Vaccine Information Statements: Required by Federal Law

Federal law requires that VISs for the following vaccines must be given when vaccinating patients of all ages:

- Diphtheria, tetanus, and pertussis-containing vaccine (DTaP, DT, Td, Tdap)
- Haemophilus influenzae type b (Hib)
- Hepatitis A
- Hepatitis B
- Human papillomavirus (HBV)
- Influenzae (both inactivated and live intranasal vaccines)
- Measles, mumps, and rubella (MMR)
- Meningococcal
- Pneumococcal conjugate (PCV13)
- Polio
- Rotavirus
- Varicella

CDC encourages the use of ALL VISs, whether the vaccine is covered by the law or not. VISs are updated periodically, and it is the provider's responsibility to ensure that the VIS with the most current publication date is used.

Federal Documentation Requirements

Immunization Records

In accordance with federal law, VFC providers must maintain immunization records that include all of the following elements:

- Name of the 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

Federal Documentation Requirements

National Childhood Vaccine Injury Act (NCVIA)

The NCVIA requires health care providers to report certain adverse events to the Vaccine Adverse Event Reporting System (VAERS). Adverse events are defined as health effects that occur after vaccination that may or may not be related to the vaccine. VAERS data are monitored continually to detect unknown adverse events or increased rates of known side effects.

The VAERS form should include the following information:

- 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.)

Knowledge Check

Is the statement below true or false?

The vaccine information statement (VIS) should be provided after the vaccine is administered.

TRUE


FALSE 

The most current VIS should be available to the patient, parent, or legal guardian prior to vaccine administration for each vaccine to be administered during a visit.

Knowledge Check

Determine the correct answer.

In accordance with federal law, VFC providers must maintain immunization records that include which of the following elements?

- 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
- All of the above 

In accordance with federal law, VFC providers must maintain immunization records that include all of the elements listed above.

Knowledge Check

Is the statement below true or false?

Health care providers must report certain adverse events in accordance with the National Childhood Vaccine Injury Act.

TRUE 

FALSE

The NCVIA requires health care providers to report certain adverse events to the Vaccine Adverse Event Reporting System.

VFC Vaccine Storage Unit Recommendations

It is essential to ensure vaccines are stored under proper conditions so that they protect the children that receive them. The VFC program recommends the following types of storage units:

- Pharmaceutical-grade stand-alone or combination units
- Household/commercial stand-alone units
- Household/commercial combination using the refrigerator section only

Storage and Handling

VFC Vaccine Storage Unit Requirements

Appropriate storage units must:

- Have enough space to store the largest inventory a provider might have at the busiest point in the year without crowding
- Maintain appropriate temperatures for the vaccines stored within the unit at all times
- Be protected from disconnection from the power source

VFC providers must not use dormitory style refrigerator/freezer units for vaccine storage at ANY time, including for temporary vaccine storage.

- Studies by the National Institute of Standards and Technology (NIST) concluded that dormitory-style or bar-style combination units pose a significant risk of freezing vaccines, even when used for temporary storage.

VFC Temperature Monitoring Equipment Requirements

Routine review of and access to temperature data are critical for determining whether vaccine has been properly stored and for assessing usability of vaccine that was involved in a temperature excursion. All VFC providers must use continuous temperature monitoring devices (data loggers) within storage unity that store vaccines that will be administered to VFC-eligible children.

To meet VFC program requirements, the device must be equipped with:

- A temperature probe (one that best reflects the temperature of the vaccine, such as one that uses a buffering material, is recommended)
- An active temperature display that can be easily read from outside the unit
- The ability to continuously monitor and record data that can be routinely downloaded

VFC Temperature Monitoring Equipment Requirements (continued)

The following are additional characteristics for these devices that are required by the Maine Immunization Program:

- Alarm for out-of-range temperatures
- Current, minimum, and maximum temperature indicator
- Low-battery indicator
- Accuracy of $\pm 0.5^{\circ}\text{C}$ ($\pm 1^{\circ}\text{F}$)
- Memory storage for at least 4,000 readings
- Recommended maximum logging interval (or reading rate) of every 30 minutes that can be programmed by the user

Storage and Handling

Temperature Monitoring Device Calibration Testing

VFC providers must have a working, calibrated, continuous monitoring and temperature recording device with a current and valid Certificate of Calibration Testing issued by an appropriate entity. If you need to determine if a Certificate of Calibration Testing or Report of Calibration was issued by an appropriate entity, check to see if the certificate indicates one or more of the following items about calibration testing:

- Conforms to International Organization for Standardization (ISO/International Electrotechnical Commission (IEC) 17025 international standards for calibration testing and traceability
- Performed by a laboratory accredited by International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body – a list of ILAC/MRA signatories may be found at AC.org/ILAC-MRA-and-signatories/
- Traceable to the standards maintained by the National Institute of Standards and Technology (NIST)
- Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 Tolerance Class F ($< \pm 0.5^{\circ} \text{C}$ or $< \pm 1^{\circ} \text{F}$) or better
- Refers to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points

Storage and Handling

Temperature Monitoring and Documentation

The VFC vaccine coordinator and backup vaccine coordinator are responsible for temperature monitoring and documentation for vaccine storage units. Any additional staff that is responsible must be trained in appropriate temperature monitoring and documentation.

Temperature monitoring and documentation requirements include the following:

- Designated staff must review and record minimum and maximum temperatures for each vaccine storage unit at the beginning of each clinic day before resetting the minimum and maximum temperature readings on the device. This helps to ensure temperature excursions are identified quickly and corrections are made to prevent vaccine loss and to ensure vaccine is viable before use.
- This review must be documented with the date, time, and name and/or initials of the person assessing the temperatures, along with any actions taken if the temperature readings are out of acceptable range:
 - Between 2° C and 8° C (36° F and 46° F) for refrigerators
 - Between -50° C and -15° C (-58° F and 5° F) for freezers

Storage and Handling

Handling Expired Vaccines

When possible Expired vaccines and diluents must be removed from vaccine storage units to prevent inadvertent administration of expired vaccine. If it is not possible to immediately remove the expired vaccine, segregate expired vaccines within the unit preventing them from being administered.

- Expired vaccines must be placed in a container or bag and clearly labeled “DO NOT USE.”
- Return expired vaccines within six months of expiration and as directed by the Maine Immunization Program. Note: all expired vaccines must be returned to the federal program even if more than six months have passed since expiration.

Knowledge Check

Is the statement below true or false?

Dormitory-style refrigerator/freezer units can be used to temporarily store vaccines in patient rooms during the clinic day.

TRUE

FALSE 

Dormitory-style refrigerator/freezer units **CANNOT** be used to store vaccine at **ANY** time.

Knowledge Check

Determine the correct answer.

What is the recommended temperature range for refrigerators?


- Between 0° C and 5° C (32° F and 41° F)
- Between 2° C and 8° C (36° F and 46° F) ★
- Between 8° C and 12° C (46° F and 54° F)
- Between 10° C and 20° C (50° F and 68° F)

The recommended temperature range for refrigerators is between 2° C and 8° C (36° F and 46° F)

Knowledge Check

Determine the correct answer.

What is the recommended temperature range for freezers?

- Between -75°C and -50°C (-103°F and -58°F)
- Between -60°C and -35°C (-76°F and -31°F)
- Between -50°C and -15°C (-58°F and $+5^{\circ}\text{F}$) 
- Between -30°C and 5°C (-22°F and 41°F)

The recommended temperature range for freezers is between -50°C and -15°C (-58°F and $+5^{\circ}\text{F}$)

Knowledge Check

Is the statement below true or false?

CDC recommends the use of stand-alone refrigerators and stand-alone freezer units.

TRUE 

FALSE

Studies by the National Institute of Standards and Technology (NIST) show that household, single-condenser, combination refrigerator/freezer units are less capable of simultaneously maintaining proper storage temperatures. In addition, NIST studies of combination refrigerator/freezer units demonstrated that the freezer section was incapable of consistently maintaining frozen vaccine storage temperatures.

Knowledge Check

Is the statement below true or false?

Minimum and maximum temperatures should be checked and recorded at least once a day.

TRUE 

FALSE

Designated staff must check and record the minimum and maximum temperatures at the start of each clinic day, and then reset the minimum and maximum temperatures. This helps to ensure temperature excursions are identified quickly and corrections are made to prevent vaccine loss.

Knowledge Check

Is the statement below true or false?

Vaccine storage units used to store VFC vaccines must be able to maintain proper temperatures, be large enough to store the largest inventory at the busiest point of the year without overcrowding, and be protected against loss of power from the designated power source.

TRUE 

FALSE

Appropriate vaccine storage units must meet all of these requirements to safeguard vaccines.

Vaccine Management

Vaccine Inventory Management

VFC providers are expected to maintain an adequate inventory of vaccine for both the VFC and non-VFC-eligible patients they serve.

Proper inventory management practices help to ensure VFC vaccine is used only for VFC-eligible children.

Vaccine Storage and Handling

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.

Vaccine Management

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

- Quarantine and label vaccines, “Do Not Use.”
- Store vaccines in a unit under proper conditions.
- Contact the appropriate vaccine manufacturer(s) to obtain documentation confirming whether the vaccine can be used.
- Contact the Maine Immunization Program if vaccine needs to be wasted.

All actions taken when responding to temperature excursions must be documented.

The vaccines should not be administered until a response has been received from the manufacturers indicating the vaccine is acceptable for use. Providers should not discard any vaccines unless directed to do so by the Maine Immunization Program.

Vaccine Management

When receiving vaccine shipments, providers must:

- Open vaccine packages immediately.
- Inspect the vaccines and packaging for damage.
- Compare the vaccines received with the vaccine products shown on the packing list.
- Immediately store vaccines at appropriate temperatures.
- Check the cold chain monitor (CCM) readings if a CCM is included with the shipment.

For frozen vaccines, providers should determine the length of time the vaccine was in transit. It is important to check the shipper insert supplied in the box. This insert will let the provider know the acceptable transit time based on the shipment date shown on the packing list.

If the provider believes that a vaccine shipment has been compromised, temperature monitors are out of range, or a warm indicator has been activated, they should contact the customer service center for centralized distribution immediately at 1-877-TEMP123. This telephone number is printed on any temperature monitor that might be placed in a vaccine shipment.

Vaccine Management

VFC Provider Staff

VFC providers must designate one staff member to be the primary VFC vaccine coordinator. This individual may also be referred to as the VFC vaccine manager or primary VFC contact. VFC providers must also designate at least one backup coordinator in the event that the primary coordinator is unavailable.

The VFC vaccine coordinator and backup coordinator are responsible for implementing and overseeing all VFC program requirements in the facility.

Any changes in key staff must be communicated to the Maine Immunization Program as soon as possible.

Vaccine Storage and Handling Standard Operating Procedures

Providers must develop, maintain, and implement plans for routine and emergency vaccine management. These plans should contain clearly written, detailed, and up-to-date storage and handling standard operating procedures (SOPs). These SOPs will help your facility stay organized, serve as a reference and training tool, and assure proper vaccine management. SOPs should also provide guidance for emergency situations such as equipment malfunctions, power failures, or natural disasters. SOPs are a critical component in protecting your vaccine supply and, ultimately, your patients.

At a minimum, the overall vaccine management plan must be reviewed and updated at least annually and include a review date and provider signature. Plans must also be updated when there is a change in the SOPs or in staff that has responsibilities specified in the plan.

Vaccine Storage and Handling Management Plan

The vaccine storage and handling plan must contain standard operating procedures (SOPs) for vaccine management processes and practices and include the following components at a minimum:

- Names of current primary VFC vaccine coordinator and at least one backup VFC vaccine coordinator
- SOPs for vaccine storage and handling practices
 - Receiving vaccine shipments
 - Ordering vaccines
 - Managing inventory (e.g., rotating stock, ordering vaccines, and maintaining appropriate amounts of vaccines at all times)
 - Preventing and reporting vaccine wastage and vaccine returns
 - Documenting staff training on vaccine management and storage and handling
 - Responding to emergency vaccine storage and handling situations

Vaccine Storage and Handling Management Plan (continued)

As part of the overall plan, SOPs must address management of vaccine in an emergency.

The SOPs must include guidance on what to do in the event of:

- Refrigerator or freezer malfunctions
- Power failures affecting vaccine storage units
- Natural disasters or other emergencies that might compromise appropriate vaccine storage conditions

In addition, the SOPs must contain guidance for maintaining the vaccine cold chain during transport to and from and storage at emergency storage locations.

Emergency SOP's should be tested annually, or more frequently as needed, to ensure the emergency system in place will maintain the proper cold chain.

Knowledge Check

Is the statement below true or false?

The vaccine cold chain begins at the vaccine manufacturing plant and ends when vaccine is delivered to the provider's office.

TRUE

FALSE 

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.

Knowledge Check

Is the statement below true or false?

All changes in key staff must be communicated to the Maine Immunization Program one time a year with annual enrollment.

TRUE


FALSE 

All changes in key staff must be communicated to the Maine Immunization Program as soon as they occur.

Knowledge Check

Determine the correct answer.

When should vaccine storage and handling SOPs be updated?

- At minimum, plans should be reviewed once a year
- When one or more standard operating procedures change
- When there is a change in staff that has responsibilities specified in the plan
- All of the above 

At minimum, the overall vaccine management plan must be reviewed, dated and signed annually. Plans must also be updated when there is a change in standard operating procedures or in staff that has responsibilities specified in the plan.

Knowledge Check

Is the statement below true or false?

VFC providers must notify the Maine Immunization Program when a vaccine cold chain failure has occurred and vaccine needs to be wasted.

TRUE 

FALSE

If a cold chain failure is suspected or there is evidence that vaccine has been exposed to temperatures outside the recommended temperature ranges, providers should immediately contact the manufacturers to determine whether the vaccine may be used. If vaccine needs to be wasted, the Maine Immunization Program should be notified as soon as possible.

VFC Site Visits and Provider Education

VFC Site Visits

A VFC site visit is an opportunity for Maine Immunization Program staff to educate and support VFC providers who vaccinate VFC-eligible children using federally purchased vaccines. The purpose of these visits is to assess a provider's understanding and implementation of each VFC program requirement. The visit also offers an opportunity to address any changes in program requirements and creates an environment for sharing current information on available immunization resources and proper storage and handling of vaccines.

Each VFC provider will receive a VFC visit at least every 24 months.

VFC Site Visits and Provider Education

What Happens During a VFC Site Visit?

VFC program staff will contact the provider's facility to schedule a VFC site visit. During the visit, VFC program staff will evaluate a provider's understanding and implementation of VFC program requirements. This is done by verifying vaccine ordering and inventory processes, reviewing records of children who have been vaccinated, and assessing vaccine storage and handling practices and implementation of VFC program requirements.

Site visits are also opportunities for providers to ask questions and for VFC program staff to offer resources to support providers' efforts in vaccinating children.

VFC Site Visits and Provider Education

Practices Not Meeting VFC Requirements

Overall, VFC site visit results confirm that VFC providers understand and are successfully implementing the program in their practices. However, on occasion, some issues and educational needs are identified and require additional follow-up and communication with VFC program staff to ensure the provider's success with the program.

VFC program staff will work with the provider to develop a follow-up plan that outlines specific actions that need to be taken to address issues identified during the visit.

VFC Site Visits and Provider Education

Unannounced Vaccine Storage and Handling Visits

Some VFC providers may receive an unannounced storage and handling visit. The goals of unannounced storage and handling visits are to provide education, support, and resources related to proper vaccine storage and handling, thereby ensuring all VFC-eligible children are receiving viable vaccine that protects them from vaccine-preventable diseases.

VFC Site Visits and Provider Education

VFC Provider Education

Vaccine coordinators and back-up coordinators are required to complete training covering all VFC requirements every 12 months.

New primary and secondary coordinators must complete the following:

- Maine Immunization Program online training – Vaccines for Children
- Maine Immunization Program online training – Storage and Handling

Primary and secondary vaccine coordinators who have completed both trainings in the previous year will only need to do one of the following:

- Complete the Maine Immunization Program online training – Storage and Handling
- Attend a VFC regional training presented by the Maine Immunization Program
- Participate in a VFC Compliance Site Visit

Knowledge Check

Is the statement below true or false?

VFC-enrolled providers will only receive a VFC site visit from the Maine Immunization Program if it is requested by the provider.

TRUE

FALSE 

Each VFC provider will receive a VFC site visit at least every 24 months.

Knowledge Check

Is the statement below true or false?

The goals of unannounced storage and handling visits are to provide education, support, and resources related to proper vaccine storage and handling.

TRUE 

FALSE

Unannounced storage and handling visits provide all of the above ensuring that all VFC-eligible children are receiving viable vaccine and are protected against vaccine-preventable diseases.

Knowledge Check

Is the statement below true or false?

VFC providers must complete training covering all VFC requirements every 24 months.

TRUE

FALSE 

All primary and secondary vaccine coordinators must complete training covering all VFC requirements every 12 months.

Post Test and Education Credit

This completes the Maine Immunization Program Vaccines for Children (VFC) online training presentation.

To receive credit for the training you **MUST** complete a post test.

Once you have completed and submitted the test the Maine Immunization Program will be notified and you will be awarded credit for this training. You will also receive notification by email of completion for your records.

Please have your PIN # and email ready before beginning the test. They will be required.

[LINK TO TEST](#)

As always, thank you for helping to keep Maine's children free from vaccine-preventable disease.