



Department of Health and Human Services  
Maine Center for Disease Control and Prevention  
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Augusta, Maine 04333-0011  
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Maine Immunization Program  
Tel. (207) 287-3746  
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## IMMUNIZATION PROVIDER VACCINE AGREEMENT

with

State of Maine \* Maine Centers for Disease Control and Prevention \*  
Maine Immunization Program  
286 Water Street, Key Plaza, 9<sup>th</sup> Floor, 11 State House Station  
Augusta, Maine 04333-0011

Phone (207) 287-3746, 1-800-867-4775

Fax (207) 287-8127, 1-800-437-5743

Individuals or entities that have been placed in non-payment status under Medicare, Medicaid and other Federal health care programs, including the VFC program by the U.S. Department of Health and Human Services, Office of Inspector General (OIG) or through Executive Order by another Executive department (e.g. Department of Transportation, Office of Personnel Management, Department of Justice, Department of Labor, Department of Defense) are not allowed to enroll or participate in the VFC program or receive VFC vaccine. VFC providers are responsible for checking the Office of the Inspector General (OIG) list of excluded Individuals/Entities on the OIG website ([www.oig.hhs.gov](http://www.oig.hhs.gov)) prior to hiring or contracting with any individuals or entities. VFC enrolled provider sites who are found to have a person employed that is on the OIG excluded provider list shall be terminated from the VFC program.

- Please return the completed signature page to the Maine Immunization Program.
- Return can be made by either fax or mail.
- Keep a copy of the agreement on file at your facility.

Thank you for your commitment to keeping the citizens of Maine free of vaccine preventable disease.

## VACCINES FOR CHILDREN PROGRAM PROVIDER AGREEMENT

### FACILITY INFORMATION

Facility Name:			VFC Pin#:
Facility Address:			
City:	County:	State:	Zip:
Telephone:		Fax:	
Shipping Address <i>(if different than facility address)</i> :			
City:	County:	State:	Zip:

### MEDICAL DIRECTOR OR EQUIVALENT

**Instructions:** *The official VFC registered health care provider signing the agreement must be a practitioner authorized to administer pediatric vaccines under state law who will also be held accountable for compliance by the entire organization and its VFC providers with the responsible conditions outlined in the provider enrollment agreement. The individual listed here must sign the provider agreement.*

Last Name, First, MI:	Title:	Specialty:
License No.:	Medicaid or NPI No.:	Employer Identification No.:( <i>optional</i> ):

*Provide Information for second individual as needed*

Last Name, First, MI:	Title:	Specialty:
License No.:	Medicaid or NPI No.:	Employer Identification No.:( <i>optional</i> ):

### VFC VACCINE COORDINATOR

**Primary Vaccine Coordinator Name:**

Telephone:	Email:
Completed annual training: <input type="radio"/> Yes <input type="radio"/> No	Type of training received:

**Back-Up Vaccine Coordinator Name:**

Telephone:	Email:
Completed annual training: <input type="radio"/> Yes <input type="radio"/> No	Type of training received:





## PROVIDER AGREEMENT

*To receive publicly funded vaccines at no cost, I agree to the following conditions, on behalf of myself and all the practitioners, nurses, and others associated with the health care facility of which I am the medical director or equivalent:*

1.	I will annually submit a provider profile representing populations served by my practice/facility. I will submit more frequently if 1) the number of children served changes or 2) the status of the facility changes during the calendar year.
2.	<p>I will screen patients and document eligibility status at each immunization encounter for VFC eligibility (i.e., federally or state vaccine-eligible) and administer VFC-purchased vaccine by such category only to children who are 18 years of age or younger who meet one or more of the following categories:</p> <p>A. Federally Vaccine-eligible Children (VFC eligible)</p> <ol style="list-style-type: none"><li>1. Are an American Indian or Alaska Native;</li><li>2. Are enrolled in Medicaid;</li><li>3. Have no health insurance;</li><li>4. Are 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). Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC) or under an approved deputization agreement.</li></ol> <p>B. State Vaccine-eligible Children</p> <ol style="list-style-type: none"><li>1. In addition, to the extent that my state designates additional categories of children as "state vaccine-eligible", I will screen for such eligibility as listed in the addendum to this agreement and will administer state-funded doses (including 317 funded doses) to such children.</li></ol> <p>Children aged 0 through 18 years that do not meet one or more of the eligibility federal vaccine categories (VFC eligible), are not eligible to receive VFC-purchased vaccine.</p>
3.	<p>For the vaccines identified and agreed upon in the provider profile, I will comply with immunization schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the VFC program unless:</p> <ol style="list-style-type: none"><li>a. 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;</li><li>b. The particular requirements contradict state law, including laws pertaining to religious and other exemptions.</li></ol>

4.	I will maintain all records related to the VFC program for a minimum of three years and upon request make these records available for review. VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records.
5.	I will immunize eligible children with publicly supplied vaccine at no charge to the patient for the vaccine.
6.	<p><u>VFC Vaccine Eligible Children</u></p> <p>I will not charge a vaccine administration fee to non-Medicaid federal vaccine eligible children that exceeds the administration fee cap of \$21.58 per vaccine dose. For Medicaid children, I will accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.</p> <p><u>Non-VFC Vaccine Eligible Children</u></p> <p>I will not charge a vaccine administration fee to non-Medicaid state vaccine eligible children that exceeds the administration fee cap of \$21.58 per vaccine dose.</p>
7.	I will not deny administration of a publicly purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.
8.	I will distribute the current Vaccine Information Statements (VIS) each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
9.	<p>I will comply with the requirements for vaccine management including:</p> <ol style="list-style-type: none"> <li>a. Ordering vaccine and maintaining appropriate vaccine inventories;</li> <li>b. Not storing vaccine in dormitory-style units at any time;</li> <li>c. Storing vaccine under proper storage conditions at all times. Refrigerator and freezer vaccine storage units and temperature monitoring equipment and practices must meet Maine Immunization Program storage and handling recommendations and requirements;</li> <li>d. Returning all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration</li> </ol>

10.	<p>I agree to operate within the VFC program in a manner intended to avoid fraud and abuse. Consistent with "fraud" and "abuse" as defined in the Medicaid regulations at 42 CFR Â§ 455.2, and for the purposes of the VFC Program:</p> <p><b>Fraud:</b> is 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.</p> <p><b>Abuse:</b> provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.</p>
11.	I will participate in VFC program compliance site visits including unannounced visits, and other educational opportunities associated with VFC program requirements.
12.	<p>For pharmacies, urgent care, or school located vaccine clinics, I agree to:</p> <ul style="list-style-type: none"> <li>a. Vaccinate all "walk-in" VFC-eligible children and</li> <li>b. Will not refuse to vaccinate VFC-eligible children based on a parent's inability to pay the administration fee.</li> </ul> <p>Note: "Walk-in" refers to any VFC eligible child who presents requesting a vaccine; not just established patients. "Walk-in" does not mean that a provider must serve VFC patients without an appointment. If a provider's office policy is for all patients to make an appointment to receive immunizations then the policy would apply to VFC patients as well.</p>
13.	I understand this facility or the Maine Immunization Program may terminate this agreement at any time. If I choose to terminate this agreement, I will properly return any unused federal vaccine as directed by the Maine Immunization Program.

***By signing this form, I certify on behalf of myself and all immunization providers in this facility, I have read and agree to the Vaccines for Children enrollment requirements listed above and understand I am accountable (and each listed provider is individually accountable) for compliance with these requirements.***

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Medical Director or Equivalent Name (print):

Signature:	Date:
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Name (print) Second individual as needed:

Signature:	Date:
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## **Attachment A. Vaccine Need - (Current)**

For the 12-month period beginning January 1 estimate the number of patients who will receive vaccinations at your facility, by age group. Only count a patient once for the 12 month period based on the status at the last immunization visit. You may be able to get these numbers from your billing department or VFC Screening Records. These numbers do not affect your ability to receive vaccine in Maine. They do help our program identify appropriate funding sources.

<b>Category</b>	<b>Number of Patients Less than 1 year old</b>	<b>Number of Patients 1 through 6 Years of Age</b>	<b>Number of Patients 7 through 18 Years of Age</b>	<b>Number of Patients Over 18 Years of Age</b>	<b>Total</b>
<b>VFC Eligible</b>					
Enrolled in Medicaid					
S CHIP					
Without Health Insurance					
American Indian or Alaskan Native					
<b>Non-VFC Eligible</b>					
Insurance - Private and Medicaid					
Non-Insured					
<b>Total Vaccine Need by Age Group - (Current)</b>					
	<b>&lt;1 year</b>	<b>1-6 years</b>	<b>7-18 years</b>	<b>&gt;18 years</b>	<b>*Total</b>

**\*Maine legislation requires private health insurance companies to cover the cost of ACIP recommended vaccines for those individuals, up to age 19, who are under their health plan.**

## Attachment B. Hours of Operation

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Hours of office operation:	Day	From	To	From	To	Closed?
	<b>Monday:</b>					
	<b>Tuesday:</b>					
	<b>Wednesday:</b>					
	<b>Thursday:</b>					
	<b>Friday:</b>					

### Type of Facility (please check only one box):

- A. Public Health Department - 10 (A state, district, county or city public health clinic)
- B. Federally Qualified Health Center (FQHC) - 15 (Primary care clinics funded by the Bureau of Primary Health Care (BPHC/HRSA) as well as FQHCs and "look-alikes" not funded by BPHC)
- C. Rural Health Clinic (RHC) - 15 (A clinic located in a shortage area as designated by HCFA)
- D. Other Public Health - 16 (Any other public funded clinic which provides immunizations, for example Indian Health Service/Tribal Health Clinic, public school or state, district, county, city public outpatient clinic) Please designate:  
\_\_\_\_\_
- E. Private Practice (Individual or Group) - 20
- F. Private Hospital - 22
- G. Other Private Facility - 24 (For example, Nursing Homes, Long Term Care, Manufacturers)

### Age Cohort Summary (please check only one box):

- 0-18 years       19-99+ years       0-99+ years

The information contained in this agreement should be kept up to date throughout 2016. Please notify the Maine Immunization Program at 287-3746, within 10 days of a change of information, to update the contents of this agreement.
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## **Attachment C. Vaccine Storage, Handling and Accountability Plan**

**Vaccine Storage, Handling and Accountability Plan:** Practices must have a written vaccine routine and emergency storage and handling plan, in accordance with CDC™’s Vaccine Storage and Handling Toolkit (<http://www2a.cdc.gov/vaccines/ed/shtoolkit/>). This plan must address storage, handling and accountability of vaccine during emergency situations (times the office may be closed and there is a power outage) and during regular business hours. This plan will be reviewed by MIP staff during VFC site visits. You may develop your own written routine and emergency storage and handling plan or use the storage and handling plan template below. If you choose to develop your own plan, all of the following information and questions must be addressed.

### **Keep a copy to post on Refrigerator and/or Freezer**

Practice Name: (required)		PIN: (required)
Primary Position Responsible for vaccine and name of person currently in position: (required)		Phone: (required)
Secondary Position Responsible for vaccine and name of person currently in position: (required)		Phone: (required)
Person with 24-hour access: (required)		Phone: (required)

**During a Power Outage:** (The following questions are to identify the steps that will be taken by your facility personnel to ensure temperatures of the vaccine will be maintained appropriately at all times. This includes periods of time when power outages occur, both when the facility is open and closed.)

**1. How will you be notified when a power outage occurs at your facility when your practice is closed?** (required)

2.  This Facility has a back-up Generator. (Go to Question 2)

If you do not have a generator, identify at least one location with a generator (hospital, 24-hour store, etc.). Before transporting, call the back-up location site to ensure that their generator is working.

The **location, contact name and phone #** of an alternative location to store vaccines during a power outage is **REQUIRED** if Facility does not have a back-up Generator.

#1. Location \_\_\_\_\_ Contact Name \_\_\_\_\_ Ph# \_\_\_\_\_

#2. Location \_\_\_\_\_ Contact Name \_\_\_\_\_ Ph# \_\_\_\_\_

3. **If your emergency back-up location is more than 30 minutes away and you have a large quantity of vaccine, consider renting a refrigerated truck to transport your vaccine.**

Refrigeration Company \_\_\_\_\_ Ph# \_\_\_\_\_

4. **Other Resources:**

\_\_\_\_\_ Ph# \_\_\_\_\_

\_\_\_\_\_ Ph# \_\_\_\_\_

5. **Who is responsible for training new staff on the Storage and Handling Policy and Procedures for this facility at this site?**

6. **Describe your procedure for monitoring refrigerator/freezer temperatures twice daily including steps to be taken if temperatures are out of recommended range.**

Procedure should include, at a minimum:

- Checking temperatures for each storage unit at least twice a day (morning and evening) and recording those temperatures on temperature log.
- Recording minimum and maximum temperatures for the prior 24 hrs. daily on days when the office is open.
- Adjusting the thermostat of the storage unit(s), when necessary, to bring temperature back in range. Note: When adjusting the thermostat does not bring temperatures back in range, it is recommended to move vaccine to a stable environment until temperatures in the storage unit can be maintained at appropriate levels.
- When the temperatures were outside the recommended range, provider must document all action taken, including but not limited to moving the vaccine to another location until temperatures in storage unit can be stabilized. This can be done on the back of the temperature log or on a separate page attached to the log with the date that the temperature was out of range. IMMPACT users can provide documentation of actions taken using the Comments text box on the temperature log screen. Notify MIP when vaccine has been involved in a cold chain failure.
- If temperatures are outside appropriate range, practice will contact Vaccine Manufacturer for guidance on viability of vaccine(s) and fill out vaccine wastage worksheet (**Attachment B**)

I have read and agree to follow the above storage and handling requirements.

Please use the space below to describe any additional steps your practice will take. Please include the name of the responsible person if different from primary vaccine position.

**7. Describe your procedure to ensure vaccines are immediately unpacked and stored at recommended temperatures upon receiving shipment. Include maintenance of the cold-chain prior to vaccine administration.**

Procedure should include, at a minimum:

- When vaccines arrive at practice, immediately notify appropriate staff (identify who this is and all backup personnel for times primary is unavailable).
- The vaccines will immediately be unpacked and cold chain monitor checked for activation. MIP will be notified if cold chain monitor was activated.
- The vaccines will be checked against the packing list for matching names/lot numbers.
- Vaccines will immediately be placed in appropriate unit (fridge and/or freezer).
- Practice will not pre-draw vaccines.
- Temperatures will be checked and recorded at least twice a day.
- Minimum and maximum temperatures will be recorded for the prior 24 hrs. daily on days when the office was open.
- Thermometers are inspected to ensure that they are certified and calibrated.
- Storage unit(s) are large enough to allow adequate ventilation/air flow for vaccine ordered/received.
- Storage unit(s) are regularly inspected/maintained to ensure that they work efficiently.

I have read and agree to follow the above storage and handling requirements.

Please use the space below to describe any additional steps your practice will take. Please include the name of the responsible person if different from primary vaccine position.

**8. Identify steps taken to advise maintenance and/or cleaning personnel not to unplug storage units (e.g., safety outlet covers and Do Not Unplug stickers are placed on the unit or near the outlet and circuit breakers. (These stickers are available at no cost from the Maine Immunization Program.)**

Steps should include, at a minimum:

- Do Not Unplug signs or stickers placed on each unit (or near relevant outlets).
- Do Not Unplug signs or stickers placed near relevant circuit breakers.

I have read and agree to follow the above storage and handling requirements.

Please use the space below to describe any additional steps your practice will take. Please include the name of the responsible person if different from primary vaccine position.

**9. Describe your plan for ordering vaccines, controlling inventory and ensuring required accountability paperwork is submitted monthly.**

Plan should include, at a minimum:

- Order vaccine in accordance with actual vaccine need; avoid stockpiling or build-up of more than six week supply.
- Submit monthly temperature logs when MIP supplied vaccine is stored.
- Submit monthly usage reports when MIP supplied vaccine is in inventory.

I have read and agree to follow the above storage and handling requirements.

Please use the space below to describe any additional steps your practice will take. Please include the name of the responsible person if different from primary vaccine position.

**10. Describe your plan for minimizing vaccine wastage (e.g. check and rotate stock to assure shortest dated vaccine is used first; transferring short dated vaccine to another Maine Immunization Program participating provider, etc.)**

Plan should include, at a minimum:

- Short-dated vaccines are stored in the front of unit and used first (stock rotated). On a weekly basis, expiration dates are checked to ensure proper placement.
- Vaccines are not stored in vegetable/fruit bins, deli drawers, or door of storage units.
- Vaccines are properly placed in storage units with air space between the stacks and side/back of the unit to allow cold air to circulate around the vaccine.
- Transfer short dated vaccine to another MIP participating Provider.
- Practice will not pre-draw vaccines.

I have read and agree to follow the above storage and handling requirements.

Please use the space below to describe any additional steps your practice will take. Please include the name of the responsible person if different from primary vaccine position.

**11. Vaccine Storage Equipment: Please indicate the type of unit(s) currently being used by your practice to store vaccines. Identify each unit below by providing corresponding name as shown on your ImmPact temperature log(s) report.**

**Unit 1:** Name \_\_\_\_\_ Style:

Refrigerator

Freezer

**Unit 2:** Name \_\_\_\_\_ Style:

Refrigerator

Freezer

**Unit 3:** Name \_\_\_\_\_ Style:

Refrigerator

Freezer.

The information supplied in this Storage and Handling Plan may be verified by the State during a visit and/or in the event of a cold chain incident.

\_\_\_\_\_  
Vaccine Coordinator

\_\_\_\_\_  
Medical Director Or Equivalent

**Reminder:** A copy of the Storage and Handling Plan must be submitted with the Provider Agreement. Keep a copy of this Plan in a location easily accessible by all staff and on your storage units.

The following are the provider enrollment requirements that each provider **must agree to follow to participate in the VFC program and receive vaccine from the Maine Immunization Program.** Failure to adhere to these requirements may result in enrollment in a non-compliance resolution process. **Do Not** return this section with the provider agreement. This Attachment is for your files.

**(1) Eligibility Screening:**

Screen all patients at every immunization encounter to determine VFC eligibility.

a. VFC eligibility categories are listed below:

- Are American Indian or Alaska Native
- Are enrolled in Medicaid
- Have no health insurance

b. Non-VFC eligibility categories are listed below:

- \*health insurance (including underinsured)

\*Maine legislation requires private health insurance companies to cover the cost of ACIP recommended vaccines for those individuals, up to age 19, who are under their health plan

**(2) ACIP Schedule:** Comply with immunization schedule, dosage, and contraindications that are established by the ACIP and included in the VFC program unless:

- a. In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate;
- b. The particular requirements contradict state law, including those pertaining to religious and other exemptions.

**(3) Retain Records:**

- a. maintain all records (order forms, usage reports, temperature logs, VFC screening records, Provider Agreement and Site Visit Reports) related to the VFC program for a minimum of three years and
- b. make these records available to public health officials including the State or Department of Health and Human Services (DHHS) upon request.



- (4) **No Charge for Vaccine:** Immunize eligible children with VFC-supplied vaccine at no charge to the patient for the vaccine.
  
- (5) **Maximum Administration Fee:**
  - a. For Medicaid VFC-eligible children, accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.
  - b. Do not charge a vaccine administration fee to non-Medicaid VFC-eligible children that exceeds the regional fee cap. The Centers for Medicare and Medicaid Services (CMS) has set the regional fee cap in Maine at **\$21.58** per vaccine dose.
  
- (6) **Access to Vaccine:** Do not deny administration of a federally purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.
  
- (7) **VIS Statements:**
  - a. Distribute the most current Vaccine Information Statements (VIS) each time a vaccine is administered and
  - b. Maintain records in accordance with the National Childhood Vaccine Injury Compensation Act (NCVIA) which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).

**NOTE:** It is the sole responsibility of the provider to maintain the integrity of the vaccine as identified in the following items **8 a – i**.

**(8) Vaccine Ordering, Accountability, and Management:** Comply with the requirements for ordering, vaccine accountability, and vaccine management. Agree to operate within the VFC program in a manner intended to avoid fraud and abuse as listed below.

**(a) Designate Vaccine Personnel:**

1. Designate one staff member to be the primary vaccine coordinator and at least one back-up vaccine coordinator who is able to perform the same responsibilities as the primary vaccine coordinator in the event that the primary person is unavailable.
2. These positions will be responsible for some key requirements and provide oversight for all vaccine management within the office.
3. The designated vaccine coordinator and backup must be responsible for the following vaccine management activities:
  - (a) Adjusting the temperature of a vaccine storage unit.
  - (b) Documenting the temperature twice daily on the temperature logs for each storage unit.
  - (c) Recording minimum and maximum temperatures for the prior 24 hrs. daily on days when the office is open.
  - (d) The primary vaccine coordinator should review temperature logs weekly if daily monitoring is being conducted by a backup person to ensure proper temperature recording. The backup staff should monitor the temperature logs if the primary coordinator is recording the daily temperatures.
4. The primary and backup vaccine coordinators are responsible for training other staff that are responsible for administering vaccines or may be required to transport vaccine in an emergency situation based on the vaccine storage and handling plans. A simple log sheet with the staff member's name and date of training should be kept as documentation.
5. Unless otherwise noted, the vaccine coordinator and/or backup should be the VFC contacts for the office

**(b) Storage and Handling Plans:**

1. A Storage and Handling Plan must be submitted with your Provider Vaccine Agreement. You may develop your own written routine and emergency storage and handling plans or use the attached-storage and handling template (Storage and Handling Plan Part C) to reflect your office practice.

### **Storage and Handling Plans (Cont.)**

The routine vaccine storage and handling plan should include details specific to routine vaccine management which include:

- (a) ordering vaccines
  - (b) controlling inventory
  - (c) storing vaccines and monitoring storage conditions
  - (d) minimizing vaccine wastage
  - (e) vaccine shipping including receiving, packing and transporting
2. The emergency vaccine storage and handling plan should include details specifically addressing what to do in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise appropriate vaccine storage conditions. The emergency plan should include:
- (a) Person(s) responsible for preparing and transportation including contact information
  - (b) How this person will be notified that vaccine needs to be moved
  - (c) Location that will receive vaccine
  - (d) How receiving location will be notified of transport
  - (e) How to pack vaccine for transport
3. Worksheet to document vaccine involved in power or equipment failure. (Attachment B)
4. At a minimum the emergency plan must be reviewed and updated (as necessary) on an annual basis or when there is a change in staff that has responsibilities in the emergency plan.

#### **(c) Vaccine Storage Equipment:**

1. Two types of storage units are acceptable: 1) a refrigerator that has a separate freezer compartment with a separate exterior door or; 2) stand-alone refrigerators and freezers.
  - (a) The refrigerator(s) or freezer(s) used for vaccine storage must:
    - (1) be able to maintain required vaccine storage temperatures year-round;

2. be large enough to hold the year's largest inventory; NOTE: A dormitory-style refrigerator (a small combination refrigerator-freezer unit outfitted with a single external door) is **never acceptable for permanent storage** of VFC vaccines. Permanent storage is defined as having the vaccine supply maintained in the unit 24 hours a day/7 days a week. Dormitory-style refrigerators are not adequate for long-term storage of biological products; they cannot be used to store vaccine on a permanent basis due to their inability to reliably maintain temperatures needed to keep vaccine within required ranges to prevent vaccine loss caused by inappropriate temperature excursions. The primary concern with dormitory-style units is the presence of the freezer compartment co-located inside the refrigerator compartment, which creates an environment that places refrigerated vaccine at high risk for freezing.
3. be dedicated to the storage of vaccines (food and beverages must not be stored in a vaccine storage unit because this practice results in frequent opening of the door and destabilization of the temperature).
  - (b) Thermometers must be certified and calibrated..
    1. have a working thermometer certified in accordance with National Institute of Standards and Technology (NIST) or the American Society for Testing and Materials (ASTM) standards placed in a central area inside each storage compartment (these are available from the Maine Immunization Program)
    - (2) Provider will utilize a digital thermometer with a bio safe glycol encased or similar temperature buffered probe to measure vaccine storage unit temperatures
    - (3) Provider will maintain a set of readily available back up thermometers with valid certificates of calibration.
  - (d) **Vaccine Storage Practices:**
    - a. The following vaccine storage tasks listed below can be the responsibility of the vaccine coordinator or can be delegated to another staff member. If the tasks are delegated, the vaccine coordinator should monitor the activity periodically.
      - (a) **On a weekly basis**, rotate vaccine stock by placing vaccines with shorter expiration dates in front of those with longer expiration dates: check for short-dated vaccine.
      - (b) Store vaccines that require refrigeration in the middle of the refrigerator compartment away from the coils, walls, floor, and cold air vent.
      - (c) Store vaccines that require freezer storage in the middle of the freezer compartment, away from the walls, coils, and peripheral areas.
      - (d) Properly space stored vaccine to allow for cold air circulation around the vaccine

## Appendix A: Provider Requirements

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- (e) Provider will maintain a set of readily available back up thermometers with valid certificates of calibration.
- (f) Redistribute short-dated vaccines you will be unable to administer to MIP participating VFC-providers who are able to administer it before it expires, while maintaining the cold chain. See guidelines: [Maintaining the Cold Chain During Transport](http://www.immunize.org/catg.d/p3049.pdf) (<http://www.immunize.org/catg.d/p3049.pdf>). In cases where you cannot locate a provider to take the short dated vaccine, notify the Maine Immunization Program for assistance.
- (g) Never store food or drink in the storage unit.

### (e) **Temperature Monitoring:**

1. Temperature monitoring should be the primary responsibility of the vaccine coordinator and backup. If other staff must monitor temperatures, those individuals must be trained on how to respond to and document actions taken for temperatures outside the appropriate range.
  - (a) Post a temperature log on the vaccine storage unit door or nearby and readily accessible.
  - (b) Record refrigerator and freezer temperatures twice each day (beginning and end) ensuring that refrigerator temperatures are between 35° – 46° F (2° – 8°C). The freezer temperature should be <5°F (<-15°C). Twice-daily temperature monitoring and recording is required even if a continuous graphing/recording thermometer or a digital data logger is used.
  - (c) Record minimum and maximum temperatures for the prior 24 hrs. daily on days when the office is open.
  - (d) Take immediate action to correct improper vaccine storage conditions, including inappropriate exposure to light and inappropriate exposure to storage temperatures outside the recommended ranges and document actions taken on the temperature log.
  - (e) Maintain an ongoing file of temperature logs, and store completed logs for three years (unless your facility requires retention for a longer period).

### (f) **Vaccine Shipments:**

1. Immediately check vaccine cold chain monitors and document the temperature inside the transport unit when vaccine arrives at office or clinic.
2. Notify the Maine Immunization Program if cold chain monitor was activated. If the provider believes that a vaccine shipment is compromised, temperature monitors are out-of-range, or a heat monitor is not activated (i.e., turned on), the provider should also contact McKesson Customer Service within 2 hours of vaccine shipment delivery time at: 1-877-TEMP123 (1-877-836-7123).

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3. Develop a policy, complete with protocols and procedures, for maintaining the vaccine cold chain during transport to off-site clinics or emergency storage locations. Guidance for developing a policy and procedures can be found at [Maintaining the Cold Chain During Transport](http://www.immunize.org/catg.d/p3049.pdf) (<http://www.immunize.org/catg.d/p3049.pdf>)

**(g) Vaccine Wastage:**

1. Notify the immunization Program of vaccine cold chain failure/wastage incidents involving publicly funded vaccines promptly after discovery of the incident.
  - (a) Wasted vaccine: a vaccine that cannot be used; includes expired, spoiled, drawn-up but not administered, dropped vial, broken vial, lost vial.
  - (b) Expired vaccine: a vaccine that is past the manufacturer expiration date on the vial or expiration date after reconstitution depending on the vaccine and according to manufacturer instructions.
2. Implement written procedures to report and respond to losses resulting from vaccine expiration, wastage, and compromised cold chain.
3. Remove wasted/expired vaccine from viable vaccine storage to prevent inadvertent administration. Fill out a vaccine wastage worksheet (Attachment B).
4. Return all spoiled or expired vaccines supplied by the Maine Immunization Program for excise tax credit in accordance with Maine Immunization Program procedure.

**(h) Vaccine Preparation:**

1. It is not acceptable clinical practice to pre-draw vaccines into syringes.
2. To ensure that the cold chain is maintained and the vaccine is not inappropriately exposed to light, providers should draw vaccine only at the time of administration.

**(i) Vaccine Ordering and Accountability:**

1. Order vaccine in accordance with actual vaccine need; avoid stockpiling or build-up of more than a six week supply.
2. Submit monthly temperature logs as long as vaccine supplied by the Maine Immunization Program is stored in refrigerator and/or freezer.
3. Submit monthly usage reports, regardless of usage, as long as vaccine supplied by the Maine Immunization Program is in inventory.

**NOTE:** Providers may be responsible for reimbursement of any non-administered vaccine resulting from non-adherence to the above requirements.

- (9) Education Requirement:** Designated provider staff, at a minimum of the primary and secondary vaccine coordinators, will meet the annual provider educational requirement. This may be done through live training, completion of online modules, or other means determined by MIP.

**The Maine Immunization Program may terminate the Provider Agreement at any time for failure to comply with these requirements. The provider may terminate this agreement at will. If the provider chooses to terminate the agreement, he or she agrees to properly return any unused VFC vaccine.**

**Appendix B: Vaccine Wastage Worksheet**

What to do if a power failure occurs, the storage unit door was left open, the temperature was out of range, the power cord was unplugged, or any other situation which would cause improper storage conditions:

1. Close the door and/or plug in the refrigerator/freezer.
2. Record the current temperature of the refrigerator/freezer below.
3. Store the vaccines at appropriate temperatures. Make sure that the refrigerator/freezer is working properly or move the vaccines to a unit that is. Do not automatically throw out the affected vaccine. Mark the vaccine so that the potentially compromised vaccines can be easily identified.
4. **Call all manufacturers of affected vaccine(s) (see table below).**
5. Collect essential data on this sheet and notify the Maine Immunization Program.
6. Maintain this record for internal use and programmatic review.
7. All actions taken when the temperatures were outside the recommended range must be documented and include the date that the temperature was out of range.

1. Current temperature of refrigerator: \_\_\_\_\_ Max/min temperature reached: \_\_\_\_\_
2. Current temperature of freezer: \_\_\_\_\_ Max/min temperature reached: \_\_\_\_\_
3. Amount of time temperature was outside normal range: refrigerator \_\_\_\_\_ freezer: \_\_\_\_\_

**REFRIGERATOR**

DATE	VACCINE AND LOT #	Expiration Date	Amount of Vaccine

**FREEZER**

DATE	VACCINE AND LOT #	Expiration Date	Amount of Vaccine

**CALL ALL MANUFACTURERS(S) OF AFFECTED VACCINE(S):**

Manufacturer/Website	Phone Number
GlaxoSmithKline www.gskvaccines.com	866-475-8222
MedImmune, Inc. www.medimmune.com	877-633-4411
Merck & Co., Inc. www.merckvaccines.com	800-637-2590
Pfizer (Wyeth Vaccines) www.pfizerpro.com	800-438-1985
Sanofi Pasteur www.vaccineshoppe.com	800-822-2463