OKLAHOMA
State Department
of Health

ADULT VACCINE PROGRAM

USER MANUAL

FOR CLINICS PARTICIPATING IN THE
OKLAHOMA STATE ADULT VACCINE PROGRAM

CONTENTS

DEFINITIONS

Administration Fee
The amount that can be charged for the administration of an adult vaccine. The administrative fee cap is $19.58.

Adult Vaccine Program (AVP)
The Oklahoma State Adult Vaccine Program (AVP) provides vaccines for adults 19 years of age and older who are uninsured or underinsured. The program is funded using 317 federal funding.

317 Funding
Section 317 of the Public Health Service Act authorizes the federal purchase of vaccines to vaccinate children, adolescents, and adults. Over its 50 year history, Section 317 purchased vaccine has been directed toward meeting the needs of priority populations; most recently this has included underinsured children not eligible for VFC, and uninsured adults.

Immunization Information System (OSIIS)
The Oklahoma State Immunization Information System (OSIIS) is a statewide, immunization registry that tracks immunization records for people of all ages. OSIIS is a secure, web-based tool for healthcare providers that provides a free and user-friendly way to keep immunization records up-to-date and to know which vaccines patients need.

Insured
A person with insurance that covers the cost of vaccine, even if the insurance includes a high deductible or co-pay, or if 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 had not been met. – *Centers for Disease Control and Prevention (CDC)*

Physical Inventory
The total amount of vaccine that is physically located within a storage unit at the time inventory is taken.

Underinsured
A person who has health insurance, but the coverage does not include vaccines or a person whose insurance covers only selected vaccines. – *Centers for Disease Control and Prevention (CDC)*

Uninsured
A person that does not have health insurance.

Vaccine Order
The number of vaccine doses requested, approved by the program, and delivered to the facility.

Vaccine Return
Any adult vaccine that is returnable. (Vaccines that were purchased using 317 funds which are used for uninsured or underinsured individuals 19 years and older.)

ADULT VACCINE PROGRAM (AVP)

The Oklahoma State Adult Vaccine Program (AVP) provides vaccine to participating provider locations for adults 19 years of age and older who are uninsured or underinsured. The program is funded using 317 federal funding and allows participating providers to receive the vaccine at zero cost to the administer according to program requirements. Section 317 vaccine is a precious national resource that will be used to fill critical public health needs, such as providing routine vaccination for those with no insurance and responding to outbreaks of vaccine-preventable diseases. The vaccines offered may change from year to year. Funding is received in October and prioritized for outbreak response throughout the year.

PROGRAM ENROLLMENT

Program enrollment occurs annually. To enroll in the 317 Program:

1. **Sign and submit a completed Provider Agreement.**
2. **You will need to create an account in TCEO to retrieve and save your training certificates.**
3. **Complete the trainings listed below:**

   You Call the Shots: Vaccine Storage and Handling

   Understanding the Basics: General Best Practice Guidelines on Immunization

   Vaccine Administration

   Learn more about trainings: www.cdc.gov/vaccines/ed/youcalltheshots.html
4. **Ensure all reports are complete and submitted.**

ELIGIBILITY AND BILLING
FOR PUBLICLY FUNDED VACCINES

Patient Status	Eligibility for 317 Vaccine	Eligibility Code	Funding Code	Billing
Medicare Adult Adult is 19 years or older. Enrolled in Medicare. Medicare covers the vaccine.	No	V24 Medicare	PHC70 Privately Funded Vaccine	Contact Medicare for billing guidance.
Un/Under insured Adult seen at facility with 317 Vaccine Adult is 19 years or older, is receiving care at a facility that has 317 vaccine and does not have insurance or has insurance, but the insurance does not cover the vaccine.	Yes	V23 eligible (317)	VXC52 Publicly Funded Vaccine	• Do not bill for cost of vaccine. • Can bill vaccine administration fee up to $19.58 per vaccine dose. • May issue only a single bill within 90 days of service. • Must waive fee if patient is unable to pay. • Cannot refuse to administer vaccine to patients. • Do not send bill to collections for unpaid administration fees.
Private Insured Adult Adult is 19 years or older. Has private insurance that covers vaccine.	No	V01 Not 317 eligible	PHC70 Privately Funded Vaccine	Contact insurance plan for billing guidance.

SCREENING

The Oklahoma State Adult Vaccine Program (317) provides vaccines to participating provider locations for adults 19 years of age and older who are uninsured or underinsured.

Date	Eligible for 317 Vaccine		Not Eligible for 317 Vaccine	
	Has no health insurance, 19 years of age or older.	Health insurance covers no part of vaccine cost; 19 years of age or older.	Has health insurance that covers vaccine(s).	Health insurance deductible or copay not met.

OPTIONS FOR INSURED ADULTS

1. **Work with pharmacies or other community vaccinators to support vaccination needs.**
2. **Contact the vaccine manufacturer or vaccine distributor directly to order vaccine.**

VACCINE STORAGE AND HANDLING

Receiving a Vaccine Delivery

1. **Contact staff responsible for receiving vaccine shipment and storing the vaccine shipment appropriately so that they can unpack the vaccines immediately. Do not let the vaccines sit out for any length of time.**
2. **Examine the container and contents for physical damage. If no damage, continue unpacking.**
3. **Check the packing list to determine how long the vaccine was in transit.**
4. **Check monitoring devices to ensure temperatures remained within range.**
5. **If the temperatures have remained within range, place vaccines in appropriate storage units.**
   - Place the vaccines in storage unit so there is proper air flow.
   - Put vaccines that are first to expire in front.
   - Keep vaccines in original boxes with lids closed to prevent exposure to light.
   - Separate vaccines by vaccine type. Use labels for vaccines.

Immediately Contact the Vaccine Team If:

1. **Temperatures did not remain within range.**
   - Quarantine the vaccine and label it "**DO NOT USE**," storing the vaccine under proper conditions.
   - It is important that viability calls reach the vaccine team the same day that the vaccine was delivered to the provider office.
   - Wait to hear back from the Vaccine Team as to the viability of the vaccine.
2. **There is physical damage to the vaccines themselves.**
3. **There are any discrepancies between the packing slip and the vaccines or vaccine count of shipment.**
4. **The vaccine does not appear in OSIIS to accept into inventory within 24 hours.**

VaccineHelp@health.ok.gov • 405-426-8580

Shipping

Vaccine deliveries are made to each provider's direct location. Vaccine shipments can take five to 10 days, please let us know if there is a clinic set up that needs the delivery in a quick turnaround time. Vaccine shipments cannot be delivered on weekends and can be delayed due to weather and holidays.

VACCINE STORAGE AND HANDLING

Storage Units

Vaccine storage units ***must maintain recommended vaccine temperatures at all times***. Storage units are required to have the capacity to store the largest inventory a provider might have at the busiest point in the year without crowding. If the storage unit is new or repaired, temperatures must be monitored and maintain stable temperatures for five days prior to placing the vaccine in unit.

The use of dormitory or bar-style units is prohibited.

A dorm style unit is a small combination refrigerator/freezer unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.

Vaccine Storage Equipment must maintain recommended temperatures at all times.

Types of vaccine storage units

Pharmaceutical-grade units: A storage unit that is specifically designed to store vaccines.

Stand-alone storage units: A storage unit that operates independently of any other device or system for its desired function. Refrigerator that only functions as a refrigerator. Or freezer that only functions as a freezer.

Household-grade units: A storage unit that is primarily sold for home use. The freezer compartment of this type of unit is not allowed to store vaccines and there may be other areas of the refrigerated compartment that should be avoided as well. If the facility provides frozen vaccine, a separate freezer unit is necessary.

Storage Unit Placement

It is important for good air circulation to be around the outside and inside of the storage unit. Place storage units in well-ventilated rooms, leaving space around the unit. Nothing should be blocking the storage unit.

Determining Storage Unit Size

To determine the ideal storage unit size:

1. **Estimate the maximum number of doses of publicly supplied vaccine and privately purchased vaccine (if applicable) to be stored in the unit.**

(Public Vaccine + Private Vaccine = Total Doses) x 1.25 = Maximum Doses

2. **Match the maximum doses with the minimum cubic feet needed to safely store vaccine in the table below. Purchase a storage unit that is properly sized for your clinic's needs and, if enrolled, meets all Adult Vaccine Program and VFC program requirements. Whenever possible, choose purpose built pharmaceutical grade units.**

Maximum Doses	Minimum Cubic Feet
100 – 399	4.9 – 6.1 cu. ft.
400 – 700	11 – 16.7 cu. ft.
701 – 800	17 – 19.5 cu. ft.
801 – 900	21 – 23 cu. ft.
901 – 1000	36 cu. ft.
1001 – 2000	40 cu. ft.
2000+	May need more than one unit.

VACCINE STORAGE AND HANDLING

Labeling Vaccine

Label Adult Vaccine Program vaccine in your storage unit to distinguish vaccine from VFC or privately purchased vaccine. The image below provides an example of labeling the contents of the storage unit to identify different vaccine programs. For example, labeling Adult Vaccine Program doses, **"AVP 19+ Uninsured/ Underinsured."**

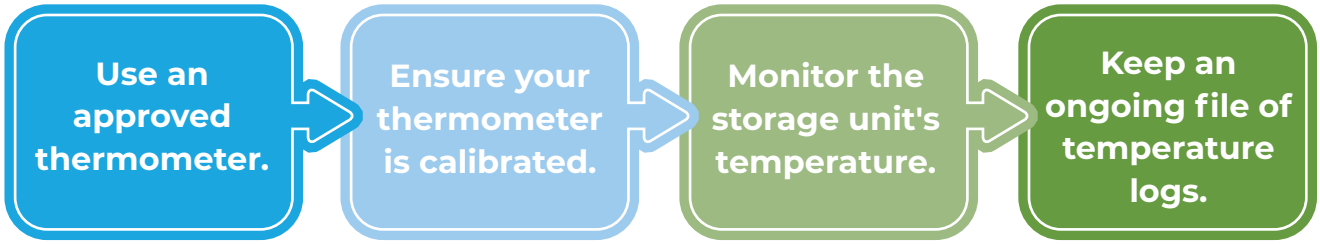
You may want to use these labels that are available at CDC: Vaccine Label Examples-Updated January 12, 2022 (cdc.gov).

Temperature Monitoring

Monitor the storage unit's temperature with an appropriate thermometer. Vaccine viability depends on an approved and currently calibrated thermometer.

A primary and back-up digital data logger or continuous temperature monitoring system with a detachable probe — in a bottle filled with a thermal buffer — is required for each unit storing vaccine. The thermometers must have current certificates of calibration in accordance with National Institute of Standards and Technology (NIST) or the American Society for Testing and Materials (ASTM) standards. Thermometers must be re-certified every year or every other year depending on manufacturer requirements. Review the digital data logger data weekly to confirm temperatures remained within range.

NOTE: An ongoing file of temperature logs is required.



Thermometer Regulations

Requirements

- A detachable, buffered probe.
- An active temperature display that can be easily read from the outside of unit.
- Capacity for continuous monitoring and recording capabilities where the data can be routinely downloaded.
- Low battery indicator.
- Reset feature.
- Current temperature display, as well as minimum and maximum temperatures.
- Must use as primary thermometer for daily temperatures and minimum and maximum readings; cannot use backup device.
- Backup thermometers must also be digital data loggers.
- All storage units used to store Adult Vaccine Program Vaccine must have a thermometer with a current certificate of calibration.
- Alarm for out-of-range temperatures.
- Accuracy of +/- 1°F (0.5°C).
- Memory storage of at least 4,000 readings.
- User programmable logging interval (or reading rate) to measure and record temperatures at least every 15 minutes.

VACCINE STORAGE AND HANDLING

Out of Range Temperatures

Any temperature reading outside recommended ranges listed in the manufacturer's package insert is considered a temperature excursion. Identify temperature excursions quickly and take immediate action.

Notify

Notify the primary and backup vaccine coordinator immediately if you discover a temperature excursion.

Bag the affected vaccines and place a label on them saying, **"DO NOT USE."**

Do not discard the vaccines or remove them from the storage unit.

Document

Document details using the Vaccine Storage Incident Report (VSIR) of the temperature excursion including:

- Date and time.
- Storage unit temperature.
- Minimum and maximum temperatures during the time of the event.
- Room temperature.
- Description of the event.
- Inventory of affected vaccines.
- Name of the person completing the report.

Contact

Contact your IFC and report the incident immediately. You will need to provide the document, digital data logger data and calibration certificates.

Correct

Do not disconnect the alarm until you determine and address the cause.

Check the basics, including:

- **Power Supply**
- **Unit door(s)**
- **Thermostat Settings**

If you believe the storage unit failed, implement your emergency vaccine plan.

If the thermometer has failed, use your back-up thermometer.

Never allow vaccines to remain in a nonfunctioning unit.

If vaccine is determined to be non-viable you will complete a vaccine return in OSIIS.

Out of Range Temperatures – Still Viable

If the vaccines are determined still viable after Immunization Services contacts the manufacturers regarding out-of-range temperatures:

- Retain all information regarding the temperature excursion.
- Keep a record of the lot numbers impacted.
- Mark the vaccine boxes that experienced out of range temperatures.

For example:

Excursion: MM/DD/YY
Determined Viable by Manufacturer
Temperature ranges:
Time out of range:

- All information regarding previous excursions will need to be provided if the vaccine experiences out of range temperatures again.

Out of Range Temperatures – Not Viable

If the doses are determined not viable after contacting the manufacturers regarding out-of-range temperatures:

- Remove the non-viable vaccines from the storage unit.
- Keep them labeled **"do not use"** and away from the storage unit.
- Complete a vaccine return in OSIIS.

Quick Checklist for Vaccine Storage and Handling

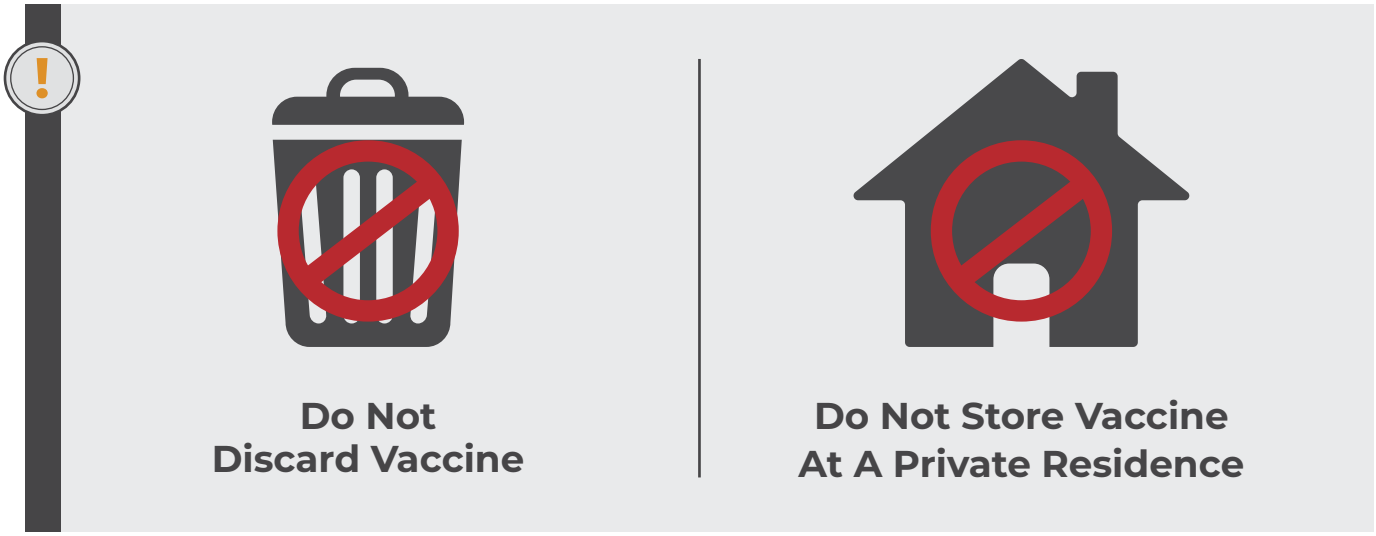
- ❑ Vaccines are stored accordingly to manufacturer's packing insert.
- ❑ Vaccine storage temperatures are:
  - ❍ Refrigerator: temperatures are between 35.6°F and 46.4°F (2°C and 8°C)
  - ❍ Freezer: temperatures are between -58°F and 5°F (-50°C and -15°C)
- ❑ Vaccines are stored in a storage unit that is not a dorm style unit. Dorm Style units are a small combination refrigerator/freezer unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.
- ❑ Vaccines are stored in a storage unit with a digital data logger or temperature monitoring system with current calibration certificates.
- ❑ If temperatures go out of range, label the vaccine **"do not use,"** keep under correct temperature ranges and contact manufacturers to determine viability.
- ❑ If temperatures are out of range and cannot be corrected, the emergency response plan is activated.

EMERGENCY PLANNING

Vaccines should never be allowed to remain in a nonfunctioning unit for an extended period of time.

In the event of a power outage or equipment failure, and power cannot be restored before temperatures go out of range it is important to know what to do with your vaccines. Use the checklist below to help prepare in the event of an emergency. **Do not risk staff safety during an emergency.** Use the following guidance for safeguarding vaccines in the event of an emergency, such as mechanical failure, power outage, natural disaster, or human error.

Learn more about the Routine and Emergency Vaccine Management Plan Worksheet: https://oklahoma.gov/content/dam/ok/en/health/health2/aem-documents/prevention-and- preparedness/immunizations/Oklahoma%20Vaccine%20Management%20Plan.pdf



WAYS TO PREPARE:

At a minimum, every facility should have:

- ☐ Back up Temperature Monitoring Device
- ☐ Spare batteries
- ☐ Flashlights
- ☐ Vaccine transport containers and materials

Make sure to have the power company contact information readily available to check how long an outage will be.

Power Company Name: _____

Power Company Phone: _____

Make sure to have the manufacturer's contact information readily available for your storage units.

Manufacturer Name for Refrigerator: _____

Manufacturer Phone for Refrigerator: _____

If you have a backup generator that will supply power to the storage units or an alternate power source, make sure to keep sufficient fuel on hand. A backup battery power source can also be used in lieu of a generator. Make sure it is tested quarterly and serviced annually.

Know where you will transfer your vaccines if you must implement your emergency vaccine storage, handling, and transport procedures. It is good to have an ongoing agreement with backup locations in the event you will need to transfer vaccine. Having a secondary backup provides quick access to a location if the primary is unable to store your vaccines. Make sure to check in with your backup locations regularly regarding your agreement and make sure you have 24-hour access.

Primary alternative vaccine storage address: _____

Primary alternative vaccine storage phone: _____

Secondary alternative vaccine storage address: _____

Secondary alternative vaccine storage phone: _____

Provide anyone who needs access to vaccine storage units during an emergency with written instructions, a building map, and locations of: spare batteries, flashlights, keys, circuit breakers, packing materials, and after-hour building access and security procedures (including alarm codes).

During a power outage never open the storage unit door until power is restored or it is determined that vaccines need to be packed for transport.

Make sure to monitor temperatures from outside the storage unit.

EMERGENCY PLANNING

THINGS TO DO:

1. Contact the alternative vaccine storage facility before packing any vaccine to confirm they can accept your vaccines for storage.
2. Take inventory of the vaccines.
3. Use appropriate materials for packing. Appropriate materials include:
   - ❑ Portable vaccine refrigerator/freezer units (recommended).
   - ❑ Qualified containers and pack-outs — **do NOT use soft-sided coolers.**
   - ❑ Hard-sided insulated containers.
   - ❑ Coolant materials: properly conditioned frozen water bottles or phase change materials.
   - ❑ Insulating materials: bubble wrap or corrugated cardboard, enough to form two layers per container.
   - ❑ Temperature monitoring devices for each container.
4. Make sure to follow the Vaccine Transport Guidelines located on the Centers for Disease Control and Prevention website, on how to properly pack your vaccine.
5. Do not use frozen gel packs or coolant packs from vaccine shipments to pack refrigerated vaccines.
6. Never freeze diluents.
7. Do not use dry ice, even for temporary storage.
8. Move transported containers directly to a preheated or precooled vehicle.
9. Ensure that you track the temperatures during transport and pack the vaccine appropriately.
10. Record the time vaccines are removed from the storage unit and placed in the container, the temperature during transport, and the time at the end of transport where vaccines are placed in a stable storage unit.
11. Ensure that the backup vaccine storage locations have calibrated digital data loggers or a temperature monitoring system to ensure your vaccine is stored within the appropriate temperatures provided in the manufacturers package insert.
12. If vaccine temperatures go out of range, follow out of range temperature protocol (located on page 13) and contact the manufacturers to determine viability.

VACCINE LOSS POLICY

Introduction

Proper vaccine storage, handling, and accountability are vital components to the success of the Oklahoma State Department of Health's Adult Vaccine Program. This policy outlines processes and repercussions if a vaccine incident or loss were to occur. These may include requiring a provider to complete additional training and/or purchase updated equipment to reduce the risk for future vaccine loss.

Scope

This policy applies to all Oklahoma providers who receive publicly supplied adult vaccine.

Definitions

Provider
An individual, partnership, private organization, or public organization enrolled in the Adult Vaccine Program.

Incident/Vaccine Loss
Expired, spoiled, wasted, or lost/unaccounted for vaccine.

Negligence
Failure to take reasonable action to prevent vaccine loss.

Providers agree to:

- Maintain proper storage and handling practices to avoid vaccine loss.
- Review vaccine storage temperatures manually during clinic hours based on program requirements.
- Take action immediately for temperature excursions or inappropriate storage conditions for any vaccine. Any temperature reading outside the recommended ranges as outlined in the manufacturers' package inserts is considered a temperature excursion.
- Report all vaccine loss by completing an Adult Vaccine Program Vaccine Loss Form located in the Adult Vaccine Program User Manual.
- Retain Adult Vaccine Program documentation for three years.

Reasons of negligence include *but are not limited* to the following:

- Failure to open vaccine shipments immediately, resulting in damaged and non-viable vaccine.
- Failure to rotate vaccine stock, resulting in preventable expired vaccine.
- Failure to alert OSDH three months prior to vaccine expiration to determine vaccine transfer options.
- Not requesting prior approval from OSDH to transfer vaccine and/or transferring vaccine inappropriately, thereby potentially impairing vaccine viability.
- Failure to follow an emergency response plan.

VACCINE ORDERING

Vaccine orders are placed through Oklahoma State Immunization Information System (OSIIS). Providers should order the vaccine in accordance with vaccine demand and avoid stockpiling or build-up of supply. Vaccines provided through the program will be delivered directly to the provider's address.

The CDC recommends smaller, more frequent orders rather than large orders to minimize the amount of vaccine loss if an incident occurs during shipment or in the vaccine storage unit. Storing a larger volume of vaccines than what is needed can increase the risk of wasting vaccines if they expire before they can be used or compromised in some way (e.g., due to mechanical failure of a storage unit). This program is available based on a limited funding amount that typically occurs only once each year.

How the Adult Vaccine Program Ordering Works

All the vaccine orders are submitted through OSIIS.

1. **Login into OSIIS.**
2. **Make sure you are logged in to the correct provider/clinic.**
3. **Navigate to the Vaccine Orders in the left-hand menu.**
4. **Select the Clinic from the dropdown and click next.**
5. **If the clinic has any orders in IN WORK or REJECTED status, the following message displays: "This clinic currently has an open vaccine order. Click OK to continue editing the open order." Click OK to navigate to the open order and complete it or edit and re-submit to VFC program. If a clinic doesn't have any open orders, a screen with shipping information will appear.**
6. **Review all information on the shipping information screen.**
   a. If the information is complete and correct, click Next button.
   b. If any information is missing or incorrect, click cancel and request an update by emailing OSIIS helpdesk: OSIISHELP@health.ok.gov.
   Create the order only after the address and contact information are updated and correct.
7. **Click Order Forecast and select from the dropdown list (Pediatric/Adult).**
   a. This will give you a forecasted order based on information in OSIIS. Please note that vaccine must be ordered in package sizes.
   b. Click add to order.
   c. Select the vaccine from the drop down.
   d. Enter the quantity of packages to order.

8. **If the quantity of packages is larger than recommended, then you will see this message "The quantity of packages does not match the recommended quantity of packages. Please add a comment to note a reason for the discrepancy." Add the comment (back to school/high demand) and click OK.**
   a. Click add to order.
   b. After you add all vaccines you need, click cancel to move back to a screen with vaccine order summary.
9. **Check the appropriate Intent, Fund Type, and Total doses.**
   Since you are ordering 317 funded vaccines, you must indicate that in the Clinic comments.
10. **Click Update to save the order.**
11. **Click the arrow next to Update.**
12. **Select submit to VFC program to submit the order.**
13. **Success message will display.**
14. **Click Cancel to return to the previous screen.**
15. **Vaccine Order Status changes from IN WORK to SUBMITTED FOR APPROVAL.**

Receiving and unpacking the vaccine shipments

Proper vaccine inventory management is essential for appropriate vaccine ordering and management.

Maintaining the cold chain is the first step in vaccine inventory management. Providers must open the vaccine packages **immediately**, check the temperature monitor reading, inspect the vaccine condition, compare the vaccine received with the vaccine products that show on the packaging list, and 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 not activated, they should contact VaccineHelp@health.ok.gov.

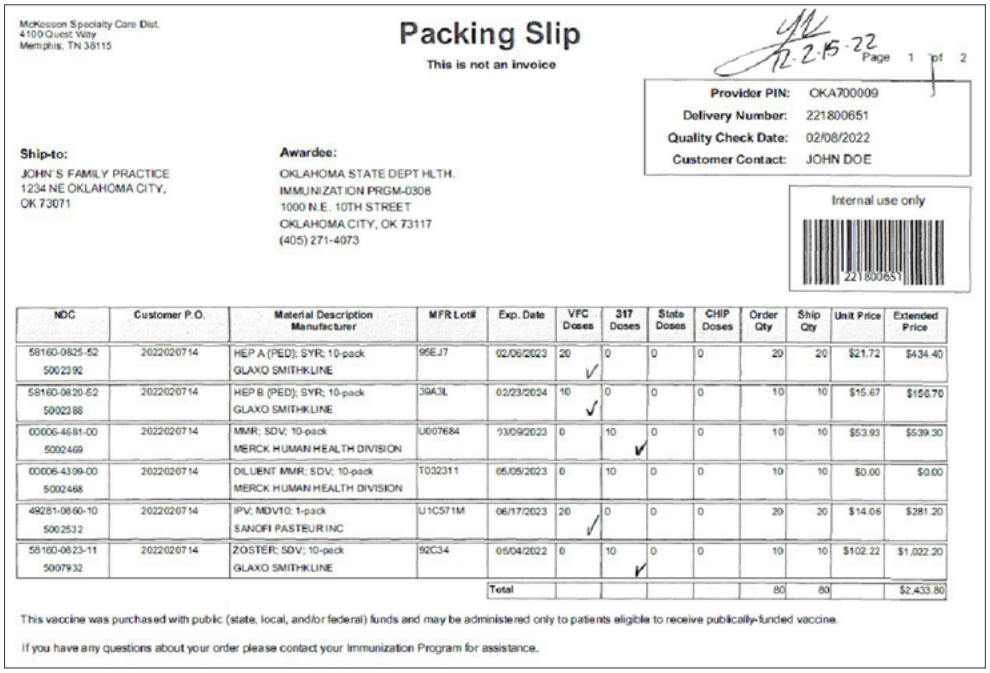
NOTE: It is important that viability calls reach the vaccine team within the same day that the vaccine has arrived at the provider's office as documented by the carrier.

VACCINE ORDERING

Packing Slips for Delivered Vaccine

Review the packing slip to ensure delivered items are for the correct number of doses and ensure expiration dates. The packing slip for Adult Vaccine Program doses will indicate ADULT or 317. The program is funded using 317 federal funding.

Examples of packing slips are shown below.



McKesson Specialty Care Dist.
4100 Quest Way
Memphis, TN 38115

Packing Slip

This is not an invoice

12.15.22

Page 1 of 2

Provider PIN: OKA700009
Delivery Number: 221800651
Quality Check Date: 02/08/2022
Customer Contact: JOHN DOE

Internal use only

221800651

Ship-to:
JOHN'S FAMILY PRACTICE
1234 NE OKLAHOMA CITY,
OK 73071

Awardee:
OKLAHOMA STATE DEPT HLTH.
IMMUNIZATION PRGM-0306
1000 N.E. 10TH STREET
OKLAHOMA CITY, OK 73117
(405) 271-4073

NDC	Customer P.O.	Material Description Manufacturer	MFR Lot#	Exp. Date	VFC Doses	317 Doses	State Doses	CHIP Doses	Order Qty	Ship Qty	Unit Price	Extended Price
58160-0825-52 5002392	2022020714	HEP A (PED); SYR; 10-pack GLAXO SMITHKLINE	95EJ7	02/06/2023	20 ✓	0	0	0	20	20	$21.72	$434.40
58160-0820-52 5002388	2022020714	HEP B (PED); SYR; 10-pack GLAXO SMITHKLINE	39A3L	02/23/2024	10 ✓	0	0	0	10	10	$15.67	$156.70
00006-4681-00 5002469	2022020714	MMR; SDV; 10-pack MERCK HUMAN HEALTH DIVISION	U007684	03/09/2023	0	10 ✓	0	0	10	10	$53.93	$539.30
00006-4309-00 5002468	2022020714	DILUENT MMR; SDV; 10-pack MERCK HUMAN HEALTH DIVISION	T032311	05/05/2023	0	10	0	0	10	10	$0.00	$0.00
49281-0860-10 5002532	2022020714	IPV; MDV10; 1-pack SANOFI PASTEUR INC	U1C571M	06/17/2023	20 ✓	0	0	0	20	20	$14.06	$281.20
58160-0823-11 5007932	2022020714	ZOSTER; SDV; 10-pack GLAXO SMITHKLINE	92C34	05/04/2022	0	10 ✓	0	0	10	10	$102.22	$1,022.20
				Total					80	80		$2,433.80

This vaccine was purchased with public (state, local, and/or federal) funds and may be administered only to patients eligible to receive publically-funded vaccine.

If you have any questions about your order please contact your Immunization Program for assistance.

Make sure to retain all program related materials for three years, this includes the packing slip.

Type of Unit	Emergency Transport	Transfer to another enrolled facility	Off-Site Clinic
Portable vaccine refrigerator or freezer	Yes	Yes	Yes
Qualified container and pack out	Yes	Yes	Yes
Conditioned water bottle transport system	Yes	Yes	Yes
Manufacturer's original shipping container	Yes (last resort only)	No	No
Food/beverage coolers	No	No	No
Pre-approval required with the Adult Program	No	Yes	No

Opportunities for Vaccine Loss

- **Using publicly supplied adult vaccine for unapproved populations.**
- **Freezing vaccine intended to be refrigerated and/or refrigerating vaccine intended to be frozen.**
- **Failure to maintain proper refrigeration and/or freezer temperatures.**
  - Refrigerator or freezer left unplugged.
  - Electrical breaker switched off by provider staff, contractors, or any other individual.
  - Refrigerator or freezer door left open or ajar by staff, contractors, or any other individual.
  - Any power outage in which the provider fails to act according to their vaccine storage back up plan.
  - Not having correct/certified thermometers and/or incorrect placement in each vaccine refrigerator and freezer compartment.
  - Failure to read and record refrigerator and freezer temperatures, and/or failure to take immediate corrective action when temperatures are determined to be out of range.
- **Vaccine left out of the storage unit for 30 minutes or more will result in a VSIR (the Program will call the vaccine manufacturer to determine vaccine viability).**
- **Failure to notify the program when provider office hours change or the provider address changes, resulting in vaccine not being delivered and consequently becoming non-viable.**
- **Discarding non-expired vaccine prior to stated expiration date.**
- **Routinely pre-drawing (pre-filling) syringes that go unused resulting in non-viable vaccine. Pre- drawing vaccines for later use, even if kept within temperature requirements so the vaccine stays viable, is not acceptable. Routinely pre-drawing syringes is not a best practice and is against state and federal vaccine requirements. Pre-drawing is acceptable if done following CDC guidelines for mass immunization clinics.**
- **Failure to use continuous temperature monitoring devices (data loggers) and required back-up thermometers to monitor vaccines during routine onsite storage of vaccine, during transport of vaccine, and during mass vaccination clinics.**
- **Any other preventable incidents made by provider.**

VACCINE ORDERING

Vaccine Loss Scenarios

- Provider's first incident within 365 days that is greater than $2,500.00 but less than $10,000.00 (A,B,C).
- Provider experiences additional negligent incidents greater than $2,500.00 within 365 days of their most recent negligent incident (A,B,C,D,E).
- Provider experiences any negligent incident greater than $10,000.00 (A,B,C,D,E).
- Provider continues to have negligent incidents (A,B,C,D,E).
- Provider fails to comply with the Vaccine Loss Policy (A,F).

Vaccine Loss Repercussion Key

A. Department may not allow provider to order vaccine until the issue is resolved.

B. Department will provide an email and resources to educate the provider regarding their incident.

C. Department will require the provider to submit their Vaccine Loss Form outlining the incident and actions they plan to take to prevent future vaccine loss.

D. Department will require provider to complete additional training regarding vaccine storage and handling procedures.

E. Department may require the provider to purchase or update equipment to reduce the risk for future incidents. (i.e., digital data loggers, remote monitoring data loggers, or pharmaceutical grade storage units)

F. Department may dis-enroll the provider from the program.

MANAGING ADULT VACCINES IN OSIIS

The Adult Vaccine Program requires providers to enter vaccine administrations in the Oklahoma State Immunization Information System (OSIIS) and manage inventory using the registry. There are many benefits of using OSIIS for managing adult vaccines acquired through the Adult Vaccine Program.

Benefits include:

- Help ensure patient's records are accurate.
- Allows other providers to identify patient's vaccination needs.
- Help visually manage your vaccine stock.
- Complete vaccine returns online.
- Run reports, including patient recall.
- Immunization forecasting
- The OSIIS public portal

Adult Vaccines and Decrementing

If your clinic has an interface and adult vaccines are being added in the OSIIS, ensure the information is correct when entering adult inventory and please add the identifier 317 to the lot number in order to distinguish adult vaccine doses from Vaccine for Children doses. While adding the 317 extensions to a lot number to differentiate from VFC, make sure the lot number is the same, matching with your Electronic Health Record (EHR). If the lot numbers do not match between the EHR and OSIIS, the doses will not decrement from inventory.

If managing vaccines through OSIIS, make sure to accept/add the vaccines into inventory after placing the vaccines in the correct storage unit, and ensure everything was entered correctly (expiration date, manufacturer, lot number, dose quantity). This will help ensure that doses are decrementing properly.

MANAGING ADULT VACCINES IN OSIIS

Adding Adult Vaccines to OSIIS Inventory

Accepting Shipments in OSIIS

Providers with an active OSIIS account can use OSIIS to help manage their adult vaccines. The clinic's primary contact person will receive an email and a notification in OSIIS when their order is approved, and the vaccine is shipped out from McKesson.

1. Login into OSIIS.
   a. Make sure you are logged into the correct provider/clinic.
2. Navigate to the *Vaccine Inventory On-Hand* screen by selecting **Inventory > Vaccines > On-Hand** from the left-hand menu.
3. Click on **Pending VTrckS Shipments** link.
4. Verify all auto-populated data fields contain the correct values. Check if the NDC, Lot number and quantity shipped matches with the vaccines received as well as on the packing slip. These values can be changed if necessary.
5. Click the Receive button next to the vaccine for it to be added to inventory on-hand.

How to add inventory manually into OSIIS

Sometimes you might not receive a shipping notification in OSIIS, and you may have to add the inventory manually into OSIIS.

1. Login into system
   a. Make sure you are logged into the correct provider/clinic.
2. On the left side of the screen – select "Inventory"
   a. Select "Vaccines"
   b. Select "On-Hand"
3. At the top of the screen – click on "Add New Inventory".
4. Enter date and time.
5. Select Inventory Location from the dropdown menu.
6. Select Vaccine|Mfg|NDC|Brand from the dropdown menu paying special attention to ensure you are selecting the correct vaccine.
7. Enter the vaccine lot number.
8. Enter the vaccine expiration date.
9. Select the funding source from the dropdown menu (317).
10. Enter the number of doses to be added to inventory.
11. Click "Create"

Returning Expired or Spoiled Vaccine

You **must** return adult vaccines that are expired or spoiled. To do this:

1. Once you have a list of expired vaccines, in the left-hand menu click on vaccine returns.
2. On the vaccine returns screen, select return date range and click search to check that you do not have any In-Work (not submitted) returns. Select a wide date range.
3. If there is already an In-Work return, go ahead and open, edit and submit the return.
4. If there are no In-Work returns, go ahead and click on add new vaccine return.
5. Select clinic from the dropdown menu and click on Next.
6. On the pre-check page, verify all the information on the screen. If any of that information is incorrect, contact OSIISHelp@health.ok.gov to request a change. Proceed with the return only after the information is updated.
7. Select the return type — return only, select the return reason from the drop-down menu, select a label shipping method and enter the number of shipping labels.
8. Begin typing the vaccine name in the field and select the appropriate vaccine. You cannot return opened multi-dose vials.
9. Enter the number of doses being returned and click on add return. When you are done adding all the vaccines, click on create and then submit to VFC program.
10. Please allow for processing time of the return and contact us if you did not receive a return label within two weeks after you submitted the return.
11. Once your return is processed, you will receive a return shipping label via email from UPS if you selected the email method or through mail if you chose to receive the label to be shipped to you.
12. Print the return label.
13. Pack the vaccines to avoid breakage of the vaccine (for example, a box with bubble wrap).
14. Affix the return label to the container and ship the package.

To prevent wastage, please contact us at least three months before the vaccine expires, this way we can see if providers enrolled are interested in the doses and could administer them before the expiration. Open vials cannot be transferred to another provider or clinic.

OFF-SITE CLINIC GUIDELINES

An off-site clinic is a temporary location to administer vaccines. Vaccines may be properly transported to another location for administration with the intent to return vaccines to the original location where they were received.

Off-site clinic checklist	
☐	Ensure you have a working digital data logger with a current certification of calibration for use at your clinic. **This digital data logger must be in addition to the digital data logger that is recording your storage unit temperatures.**
☐	Use a digital data logger that meets state and CDC guidelines for public vaccine.
☐	Ensure you have all necessary materials to pack and transport the vaccines for the off-site clinic.
☐	Use a portable storage unit or certified pack-out.
☐	Follow the vaccine transport guidelines for packing vaccines.
☐	Here is a checklist for off-site vaccination clinic. https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/vaccination-clinic-supply- checklist.html
☐	Keep record of the temperatures during transport along with the quantity of doses and the lot number transferred.
☐	An off-site clinic cannot exceed eight hours, including transport time.
☐	Ensure the cold chain is always maintained during transport and throughout the clinic.
☐	Providers may pre-draw up to 10 doses of vaccine at a time during an off-site clinic.
☐	All remaining pre-drawn doses must be discarded and logged as waste at the end of the clinic.
☐	Monitor digital data logger(s) and record temperatures on paper temperature logs hourly.
☐	After the clinic, download and review digital data logger temperature data.
☐	If the vaccine went out of temperature range during the off-site clinic, submit a Vaccine Storage Incident Report to the Adult Vaccine Program and your IFC.
☐	Complete a Vaccine Return in OSIIS for any wasted vaccine doses.

PROGRAM DISENROLLMENT

If your facility no longer offers Adult Vaccine Program doses and you currently have a supply of vaccines on hand, don't hesitate to get in touch with us at OSIISHelp@health.ok.gov.

Provide the following information in your email:

- Current inventory quantities.
- Date the facility will no longer offer the vaccine.

The program will contact enrolled facilities in the area to see if they can use the vaccine.

This publication was issued by OSDH, an equal opportunity employer and provider. A digital file has been deposited with the Publications Clearinghouse of the Oklahoma Department of Libraries in compliance with section 3-114 of Title 65 of the Oklahoma Statutes and is available for download at documents.ok.gov. | Issued October 2023

FREQUENTLY ASKED QUESTIONS

1. **Is the vaccine limited to providers participating in the Vaccine for Children Program?**
   No. Any provider who serves the target population of underinsured or uninsured adults may enroll.

2. **What sort of reporting requirements will be mandatory for this vaccine?**
   Providers receiving adult vaccines must submit doses administered and inventory reports. For more information regarding reporting please see page 20 of this manual.

3. **What is required when our facility moves locations?**
   Notify the program immediately and submit a new Adult Vaccine Program Provider Agreement when there are changes to the following: vaccine delivery address and delivery times, facility name and address, medical director, and vaccine coordinators.

4. **Is there an administrative fee cap?**
   Yes. The administrative fee cap is $19.58.

5. **What are the vaccine expiration dates?**
   Vaccine expiration dates are usually 12-24 months from the date of receipt.

6. **What is the difference between uninsured and underinsured?**
   Uninsured patients do not have insurance of any kind. Underinsured patients have insurance with limited or no vaccine coverage. Providers are not required to verify insurance status.

   Underinsured (in the context of publicly supplied adult vaccine) is defined by whether the health plan includes the vaccine as part of the coverage plan. Because the program is for underinsured and uninsured adults 19 and older, if a patient's insurance does cover the vaccine, they would not be eligible for publicly supplied adult vaccine. Even if there's a cost deficit, if the vaccine is covered by their insurance, the patient would not be considered underinsured.

   It is the provider's responsibility to conduct diligent screening to ensure fully insured individuals are not receiving 317 vaccines. It is the individual's responsibility to understand their insurance status and identify in-network providers.

7. **How does the facility identify a shipment is adult vaccine?**
   The packing list will identify adult vaccines as ADULT or 317.

8. **Can the order be "received" in and managed in OSIIS?**
   Adult vaccines can be ordered and managed in OSIIS just like VFC vaccines. Once the vaccine is shipped, you will receive a shipping notification in OSIIS. You will have to accept the vaccines into your inventory in OSIIS after the vaccine is delivered to you.

9. **I completed a provider agreement last year, do I need to fill out a new form this year?**
   Yes. All providers wishing to participate in the program will need to complete a provider agreement each year.

10. **Do I need to complete my reports to receive my adult vaccine order?**
    Yes. All required reports must be submitted in order to request and receive additional adult vaccine.

11. **What do I do if I have adult vaccine I cannot use?**
    Contact the program at least three months before your vaccine expires. We will facilitate transferring the vaccine to other clinics enrolled in the program that could potentially use the vaccine before the expiration date.

12. **How do I return adult vaccine?**
    Vaccines can be returned through OSIIS. You will need to create and submit a vaccine return. Once it is processed, you will receive a label either through email or mail depending on your choice. Please follow the directions on the shipping label to return the vaccine. Please refer to page 20 for step-by- step instructions for vaccine returns.

13. **What is the You Call the Shots, Vaccine Storage and Handling training?**
    The Centers for Disease Control and Prevention (CDC) You Call the Shots, Vaccine Storage and Handling training module can be located on the CDC Web-based Training Course webpage. The Vaccine Storage and Handling link on the CDC web-based training course can be accessed here. To complete the training please obtain the certificate by visiting the CDC Web-based Training Course webpage.

TEMPERATURE LOGS
OFF-SITE TEMPERATURE LOGS

OKLAHOMA State Department of Health

Oklahoma AVP Monthly Refrigerator Temperature Log

Month/Year: _____/_____ **Refrigerator Location/ID:** _____

AVP Pin: _____ **Clinic:** _____

Date	Time	Staff Initials	≥36°F Min	≤46°F Max	Actual Temp PM	*Take action immediately if temperature is too high or low! Alarm/Action Taken
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

Instructions for completing the monthly temperature log.

1. Complete the top of the form with the month/year, refrigerator id/location, VFC Pin, and name of clinic.
2. Record min/max temperatures daily at opening of the clinic in Fahrenheit with time and initials.
3. Clear min/max temperature daily after recording the temperatures on the temperature log.
4. Download data logger data regularly and save to computer file. Temp logs and data logger information must be kept for 3 years.
5. For out-of-range temperatures refer to the VSIR Decision Tree for guidance and record action to take.
6. **Record Actual temp at end of day.**

Name of person completing form: _____

Signature: _____ **Date:** _____

OKLAHOMA State Department of Health

Oklahoma AVP Monthly Refrigerator Temperature Log

Month/Year: _____/_____ **Refrigerator Location/ID:** _____

AVP Pin: _____ **Clinic:** _____

Date	Time	Staff Initials	≥36°F Min	≤46°F Max	Actual Temp PM	*Take action immediately if temperature is too high or low! Alarm/Action Taken
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

Instructions for completing the monthly temperature log.

1. Complete the top of the form with the month/year, refrigerator id/location, VFC Pin, and name of clinic.
2. Record min/max temperatures daily at opening of the clinic in Fahrenheit with time and initials.
3. Clear min/max temperature daily after recording the temperatures on the temperature log.
4. Download data logger data regularly and save to computer file. Temp logs and data logger information must be kept for 3 years.
5. For out-of-range temperatures refer to the VSIR Decision Tree for guidance and record action to take.
6. **Record Actual temp at end of day.**

Name of person completing form: _____

Signature: _____ **Date:** _____

OKLAHOMA State Department of Health

Oklahoma VFC Monthly Freezer Temperature Log

Month/Year: _____/_____ **Freezer Location/ID:** _____

AVP Pin: _____ **Clinic:** _____

Date	Time	Staff Initials	-50°F Min	≤5°F Max	Actual Temp PM	*Take action immediately if temperature is too high or low! Alarm/Action Taken
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

Instructions for completing the monthly temperature log.

1. Complete the top of the form with the month/year, freezer id/location, VFC Pin, and name of clinic.
2. Record min/max temperatures daily at opening of the clinic in Fahrenheit with time and initials.
3. Clear min/max temperature daily after recording the temperatures on the temperature log.
4. Download data logger data regularly and save to computer file. Temp logs and data logger information must be kept for 3 years.
5. For out-of-range temperatures refer to the VSIR Decision Tree for guidance and record action to take.
6. **Record Actual temperature at the end-of-day.**

Name of person completing form: _____

Signature: _____ **Date:** _____

OKLAHOMA State Department of Health

Oklahoma VFC Monthly Freezer Temperature Log

Month/Year: _____/_____ **Freezer Location/ID:** _____

AVP Pin: _____ **Clinic:** _____

Date	Time	Staff Initials	-50°F Min	≤5°F Max	Actual Temp PM	*Take action immediately if temperature is too high or low! Alarm/Action Taken
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

Instructions for completing the monthly temperature log.

1. Complete the top of the form with the month/year, freezer id/location, VFC Pin, and name of clinic.
2. Record min/max temperatures daily at opening of the clinic in Fahrenheit with time and initials.
3. Clear min/max temperature daily after recording the temperatures on the temperature log.
4. Download data logger data regularly and save to computer file. Temp logs and data logger information must be kept for 3 years.
5. For out-of-range temperatures refer to the VSIR Decision Tree for guidance and record action to take.
6. **Record Actual temperature at the end-of-day.**

Name of person completing form: _____

Signature: _____ **Date:** _____

Temperature Log

when Transporting Vaccine at Refrigerated Temperatures

When transporting refrigerated vaccines, use:

- ❑ A portable refrigerator or vaccine storage container qualified to maintain temperatures between 2°C and 8°C (36°F and 46°F).
- ❑ A digital data logger (DDL) with a thermal buffer and external temperature display (preferred). Place the probe as close as possible to the vaccine.
- ❑ This temperature log to document temperatures and how long the vaccine is in the portable storage container.

Temperature monitoring and transport time frames

- ❑ Most DDLs display minimum/maximum (min/max) temperatures.*
- ❑ Record the time and min/max temperatures:
  - At the start of transport
  - Every time the portable storage container is opened
  - When transport is completed
- ❑ The total time for transport alone or transport plus clinic workday should be a maximum of 8 hours.‡
- ❑ Beyond-use date/time (BUD), if applicable, are included in transport time. For example, if the vaccine may be stored at refrigerated temperature for 120 hours, transport is included in this time frame.

If the temperature is out of range, TAKE ACTION!

1. Do **NOT** discard the vaccine.
2. Label the vaccine **"Do Not Use."**
3. Complete the Vaccine Troubleshooting Record.
4. Contact the manufacturer to determine under what conditions (refrigerated) to store the vaccine as quickly as possible.

Today's date: _____ **Transport start time:** _____ **Transport end time:** _____

Provider name: _____ **Facility name:** _____ **PIN number:** _____

Temperatures measured in (circle one): **Celsius** **Fahrenheit**

Time																
Staff Initials																
Min/Max Temperatures																

Temperatures lower than 2°C (36°F) and higher than 8°C (46°F) are out of range.‡
Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.

Temperature Log

when Transporting Vaccine at Frozen Temperatures

When transporting refrigerated vaccines, use:

- ❑ A portable freezer or vaccine storage container qualified to maintain temperatures below -15°C (5°F).
- ❑ A digital data logger (DDL) with a thermal buffer and external temperature display (preferred). Place the probe as close as possible to the vaccine.
- ❑ This temperature log to document temperatures and how long the vaccine is in the portable storage container.

Temperature monitoring and transport time frames

- ❑ Most DDLs display minimum/maximum (min/max) temperatures.*
- ❑ Record the time and min/max temperatures:
  - At the start of transport
  - Every time the portable storage container is opened
  - When transport is completed
- ❑ The total time for transport alone or transport plus clinic workday should be a maximum of 8 hours.‡
- ❑ Beyond-use date/time (BUD), if applicable, are included in transport time. For example, if the vaccine may be stored at refrigerated temperature for 120 hours, transport is included in this time frame.

If the temperature is out of range, TAKE ACTION!

1. Do **NOT** discard the vaccine.
2. Label the vaccine **"Do Not Use."**
3. Complete the Vaccine Troubleshooting Record.
4. Contact the manufacturer to determine under what conditions (refrigerated) to store the vaccine as quickly as possible.

Today's date: _____ **Transport start time:** _____ **Transport end time:** _____

Provider name: _____ **Facility name:** _____ **PIN number:** _____

Temperatures measured in (circle one): **Celsius** **Fahrenheit**

Time																
Staff Initials																
Min/Max Temperatures																

Temperatures higher than -15°C (5°F) are out of range.‡
Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.

OKLAHOMA
State Department
of Health

VACCINE MANAGEMENT

PLAN TEMPLATE

CONTENTS

CONTACT LIST

Vaccine Coordinators

Vaccine Coordinators (Name/Title)	Phone Number (home, cell)	Alternate Phone Number (home, cell)	Email Address
Primary:			
Secondary:			
Alternate (backup):			

Resources Contact List

Resources	Phone Number	Email Address	
Local Health Department (LHD)			
OSDH Imms Service			
Additional Resources	**Company / Entity Name**	**Phone Number**	**Email Address**
Electric/Power/ Utility Company			
Refrigerator repair			
Freezer repair			
Data logger repair/recalibration			

OKLAHOMA IMMUNIZATION ROUTINE VACCINE STORAGE AND HANDLING PLAN

Instructions: All Oklahoma Immunization enrolled sites are responsible for routine management of vaccine inventory. Once completed, this template will serve as the required ***Routine Vaccine Storage and Handling Plan***.

This plan should be reviewed **annually** or whenever there are changes to the signing clinician, vaccine coordinators, or vaccine storage equipment. The most current ***Routine Vaccine Storage and Handling Plan*** will be reviewed during Oklahoma Immunization Program Compliance Site Visits.

A copy of this plan, along with the *Emergency Vaccine Storage and Handling Plan*, must be posted on or near all refrigerators and freezers that store vaccine.

Clinic Name:	Clinic Address:
PIN:	Email Address:
Telephone number:	Fax Number:
Signing Clinician or Equivalent:	Primary Vaccine Coordinator:
Back-up Vaccine Coordinator:	Alternate Back-up:
Person(s) Responsible for Monthly Vaccine Count:	Person Responsible for Monthly Vaccine Reporting and Ordering:
Person Responsible for Rotating Vaccine Inventory:	Person Responsible for Receiving and Storing Vaccine Shipments:

***Routine Vaccine Storage and Handling Plan* reviewed and updated by:**

Name:	Title:
Signature:	Date of Last Review:

OKLAHOMA IMMUNIZATION PROCEDURES FOR ROUTINE STORAGE AND HANDLING OF VACCINE

Temperature Monitoring

_____ is responsible for monitoring data logger(s) and recording temperatures of all vaccine storage units.

In their absence, _____ is responsible for monitoring and recording temperatures.

- A ***Temperature Log*** must be posted on or near all units storing vaccine.
- Staff are required to record min/max temperatures and current temperature at least once daily, preferably in the morning.
- Results of each temperature check must be documented on the ***Temperature Log***. The time (hour and minute) and the initials of the staff member monitoring/ recording the information must be documented on the form.
- Do not round the temperatures up or down – record only the number to the left of the decimal point.
- If an out-of-range temperature is observed, immediately contact your Immunization Field Consultant and complete “Vaccine Storage Incident Report (VSIR)”.

Vaccine Storage

- Clinics enrolled in the Oklahoma Immunization VFC Program are required to have the appropriate equipment to store vaccine that will maintain proper temperatures.
- Refrigerator/freezer units must be large enough to hold VFC and private vaccine during back-to-school or flu season without crowding.

Vaccine Storage *(continued...)*

- **In order of preference, OSDH recommends the use of a:**
  1) pharmaceutical, purpose-built unit;
  2) stand-alone refrigerator and stand-alone freezer; or
  3) house-hold combination unit, using only the refrigerator section unless the refrigerator and freezer compartments have separate thermostat controls (they must have separate exterior doors). A stand-alone freezer must be used when using a combination unit for refrigerated vaccine.

Small combination refrigerator-freezer units outfitted with a single external door (dorm-style) are never allowed for the storage of vaccine.

- The refrigerator compartment must maintain temperatures between 36°F and 46°F (2°C and 8°C) for vaccine viability.
- The freezer compartment must maintain temperatures between -58°F and +5°F (-50°C and -15°C).

Water Bottles

- Place water bottles **(labeled "Do Not Drink")** on the top shelf, under the cold air vent, on the floor of the unit, in the door, along both sides of the walls, and at the back of the refrigerator.

  Water bottles are not recommended for certain pharmaceutical and purpose-built units. Follow the manufacturer's guidance in those instances.
- Place frozen water bottles along both sides of the walls, at the back, on the floor, and in the door of the freezer.

- The ultra-cold freezer must maintain temperatures between -112°F and -76°F (-80°C and -60°C).
- Diluents that are not packaged with vaccine may be stored outside of the storage unit or in the door of the refrigerator. **DO NOT freeze diluent.**
- Do not store food or drinks in the same refrigerator or freezer as vaccine.
- Do not store lab specimens on the same shelf or above vaccine. Store specimens below vaccine or in a separate storage unit.
- Refrigerators and freezers storing vaccine must be plugged directly into a wall outlet with a plug guard installed. Multi-strip outlets are not allowed.

Vaccine Shipping and Receiving Procedures

_____ is responsible for receiving and storing vaccine shipments.

In their absence, _____ is responsible for receiving and storing vaccine shipments.

- Staff must ensure that an accurate shipping address and delivery hours are entered into the Oklahoma State Immunization Information System (OSIIS).
- Staff must always accept vaccine shipments in a timely manner. Never refuse or return vaccine shipments without specific instructions from OSDH.
- Oklahoma Immunization Unit recommends all sites have a protocol to ensure the vaccine is stored immediately and appropriately upon arrival. The following steps must be taken when a vaccine shipment arrives:
  - Check the vaccine received against the packing list to verify all vaccines have been received.
  - Verify the packing list against the order placed in OSIIS once the vaccine has been properly stored. Receive the order in OSIIS.
  - Ensure adequate diluent is included for vaccines requiring reconstitution.

    IMMEDIATELY contact the OSDH if vaccine or diluent was ordered and not received. Frozen vaccines, MMRV and Varicella will be shipped directly from the manufacturer.
  - Place vaccine in the appropriate storage unit immediately.
  - Ensure vaccines with longer expiration dates are stored behind shorter- dated vaccines. This ensures short-dated vaccine is used first.
  - If the data logger or temperature monitoring strip in the package indicates or if staff suspect that the cold chain has been compromised, staff should immediately:

    Place the back-up data logger probe in the shipment, near the vaccine, and put the lid back on it, to gain the current temperature. Check it frequently to see when the temperature stabilizes.

    Store questionable shipments appropriately, and immediately contact OSDH at 405-426-8580. A determination will be made is vaccine is viable.

Vaccine Ordering Procedures

_____ is responsible for ordering vaccine.

- All vaccine orders are submitted in OSIIS.
- Staff are required to enter in OSIIS all vaccines received, doses transferred, expired/ wasted vaccine, doses administered, and a physical count of all VFC vaccines in their inventory each month regardless of whether an order is placed.
- Staff are responsible for contacting OSDH/IFC to update provider information, including delivery address, days and hours available to receive vaccine shipments, and primary and back-up contact information.

Inventory Control including stock rotation

_____ is responsible for managing VFC vaccine inventory.

_____ is responsible for reporting VFC vaccine received, vaccine transferred, vaccine loss, and physical count in OSIIS each month.

- Vaccine with the shortest expiration date must be used first.
- Staff should notify their IFC 60-90 days prior to the vaccine expiration date.

Vaccine Loss (expired, spoiled, and wasted vaccine)

Staff are required to follow the procedures listed below when a vaccine loss occurs:

_____ is responsible for completing and submitting the Vaccine Return or adjustment in OSIIS.

- Remove expired/spoiled vaccine from the other vaccine in the storage unit immediately. Label **“DO NOT USE”** and complete a vaccine return in OSIIS.
- If vaccine is lost to a storage incident then the completed VSIR must be printed and signed by the signing clinician who signed the Oklahoma Immunization Agreement or a prescribing authority that is listed on the Oklahoma Immunization Agreement and sent to your IFC for viability determination for the vaccine.

Vaccine Loss (expired, spoiled, and wasted vaccine)

Staff are to follow these procedures for returning expired or spoiled vaccine:

_____ is responsible for returning expired or spoiled vaccine.

- Complete the VSIR as indicated above and submit to your IFC for spoiled vaccine.
- Once the return is processed, your primary vaccine coordinator will receive a shipping label via email.
- Staff must ensure that only vaccines listed on the VSIR or on a vaccine return are included in the box for return.
- A copy of the packing slip must be included in each box when returning expired or spoiled vaccine.
- Shipping/Return labels expire after 30 days. If UPS has not picked up the package within 30 days, another shipping label must be requested.
- Do not return broken vials or syringes and do not return syringes with exposed needles. Do not return open multi-dose vials.
- You must wait until UPS returns to your office with the next delivery to return the box with the expired or spoiled vaccines; otherwise, charges may be incurred.

OKLAHOMA IMMUNIZATION EMERGENCY VACCINE STORAGE AND HANDLING PLAN

Instructions: All Oklahoma VFC Immunization enrolled sites are responsible for accurate management of their vaccine inventory in the event of an emergency. Once completed, this template will serve as the recommended ***Emergency Vaccine Storage and Handling Plan***.

You should review and update this plan **annually** or more frequently if there are any changes to the plan, or changes in staff responsible for vaccine management, storage and handling. The most current ***Emergency Vaccine Storage and Handling Plan*** will be reviewed during VFC Immunization Compliance Site Visits.

A copy of this plan, along with the *Routine Vaccine Storage and Handling Plan*, must be posted on or near all refrigerators and freezers that store VFC vaccine.

Clinic Name:	Clinic Address:
VFC PIN (if applicable):	Email Address:
Telephone number:	Fax Number:
Signing Clinician or Equivalent:	Primary Vaccine Coordinator:
Back-up Vaccine Coordinator:	Alternate Back-up:
Person(s) Responsible for Monthly Vaccine Count:	Person Responsible for Monthly Vaccine Reporting and Ordering:
Person Responsible for Rotating Vaccine Inventory:	Person Responsible for Receiving and Storing Vaccine Shipments:

***Emergency Vaccine Storage and Handling Plan* reviewed and updated by:**

Name:	Title:
Signature:	Date of Last Review:

Location vaccines will be transferred to in case of emergency:

Location Name:	Contact Person at Receiving Location:
Address:	Telephone Number:
VFC PIN (if applicable):	Second Person at Receiving Location:
Is there a Temperature Monitoring device for the Refrigerator and Freezer? ◯ Yes ◯ No	Is there adequate space to store the vaccine during an emergency? ◯ Yes ◯ No
Is there a generator? ◯ Yes ◯ No	Date of Agreement:

***Emergency Vaccine Storage and Handling Plan* reviewed and updated by:**

Name:	Title:
Signature:	Date of Last Review:

OKLAHOMA IMMUNIZATION PROCEDURES FOR EMERGENCY STORAGE AND HANDLING OF VACCINE

Identify a responsible person and a responsible back-up person who will enact the ***Emergency Vaccine Storage and Handling Plan***. Include contact information, such as home, office, and cell phone numbers for each person.

The person responsible for enacting the ***Emergency Vaccine Storage and Handling Plan*** is _____.

The back-up person responsible for enacting the ***Emergency Vaccine Storage and Handling Plan*** is _____.

- Identify an emergency contact and storage location to take the VFC vaccine for storage. The emergency storage location must have appropriate vaccine storage equipment capable of maintaining temperatures within acceptable ranges, as well as adequate space to accommodate the vaccine inventory at the busiest time of the year (e.g. flu or back-to-school season) without crowding. Temperatures for storage units are required to be monitored and recorded, per OSDH/CDC guidelines. A location with a power generator or other alternate source of power, such as a hospital or pharmacy is preferable.
- Contact the emergency storage location for their approval before including them on your plan. List the contact person(s) and phone number(s) on your plan. Consider locating a back-up location in case the primary emergency storage location is unavailable or unable to store vaccines.
- Using the emergency vaccine storage and handling plan checklist for refrigerated and frozen vaccine:
  - Document the time the emergency/power outage occurs.
  - Document the temperature of the vaccine storage units before removing any vaccine for transportation.
  - Review how refrigerated vaccine should be packed for transport, and pack them using only approved storage units.
  - Insert a certified and calibrated data logger probe in the center of the vaccine storage unit, and note the time and temperature when the vaccine is placed in the transport containers. Before storing the vaccine inside of the receiving emergency storage unit, document the temperature of that storage unit.
  - Conduct an inventory of the vaccine as you move it to the transport container and record the information:

    Lot number,
    Number of doses of each vaccine, and
    Expiration dates

OKLAHOMA IMMUNIZATION PROCEDURES FOR EMERGENCY STORAGE AND HANDLING OF VACCINE

You must follow all guidance provided by VFC/CDC when transferring vaccines in the event of an emergency.

In the table below, provide the information where you will obtain the necessary items for emergency transport of vaccine and the appropriate contact information.

- **Do not use frozen gel packs or coolant packs from vaccine shipments to pack refrigerated/frozen vaccines.**
- **Dry ice is only to be used to transport Pfizer COVID-19 vaccine when in ultra-cold state.**
- **Do not use dry ice to keep normal freezer temperatures for any other vaccine, even if for temporary storage.**

Emergency Needs:	Location in office:
Portable Refrigerator: (Optional)	
Portable Freezer: (Optional)	
Cooler(s):	
Frozen Water Bottles:	
Bubble-wrap / Corrugated cardboard:	
VaxiPac™ w/Bricks:	

EMERGENCY VACCINE STORAGE AND HANDLING PLAN CHECKLIST: REFRIGERATED VACCINE

Contact with OSDH/IFC made prior to transport by:	
Date:	Time: _____ ◯ AM ◯ PM
Person Transporting Vaccine:	

Transport of REFRIGERATED Vaccine

☐	**Assemble packing supplies.** **Container used to transport refrigerated vaccines:** ☐ Portable fridge ☐ Cooler **Other supplies needed if using a cooler:** ☐ Conditioned frozen water bottles* ☐ Certified, calibrated data logger ☐ Packing material (2" of bubble wrap or crumpled paper and two pieces of cardboard that is cut to cooler size) *Frozen water bottles that are not "conditioned" can freeze vaccines. To "condition" frozen water bottles, remove them from the freezer and immerse in a sink of water or under running water until the ice spins freely in the bottle.
☐	Spread a layer of conditioned water bottles at the bottom of the cooler. Cover the conditioned water bottles with a piece of cardboard, cut to the size of the cooler. Cover with a 2" layer of bubble wrap or crumpled paper.
☐	Stack vaccine boxes on the bubble wrap or crumpled paper. Vaccines must not touch the conditioned water bottles in the cooler.
☐	Place the data logger probe with vaccines.
☐	Cover the vaccine with 2'' layer of bubble wrap or crumpled paper. Add a piece of cardboard, cut to the size of the cooler. Add conditioned water bottles to cover the cardboard.
☐	Fill the cooler to the top with bubble wrap or crumpled paper.
☐	Place the data logger display on top of the bubble wrap, crumpled paper, or outside the cooler.

EMERGENCY VACCINE STORAGE AND HANDLING PLAN CHECKLIST: REFRIGERATED VACCINE *(continued...)*

Contact with OSDH/IFC made prior to transport by:	
Date:	Time: _____ ◯ AM ◯ PM
Person Transporting Vaccine:	

☐	**Include a list of the vaccines that are in the container.**
☐	**Record temperatures on a *Temperature Log* prior to transport.** Temperature of **storage unit** when the vaccines are removed: _____ ◯ C ◯ F Time vaccines were removed from **storage unit**: _____ ◯ AM ◯ PM Temperature of **transport container** when the vaccines were placed inside: _____ ◯ C ◯ F
☐	**Record temperatures on a *Temperature Log* upon arrival at the emergency storage location.** Temperature of **transport container** when the vaccines are removed: _____ ◯ C ◯ F Time vaccines were removed from **transport container**: _____ ◯ AM ◯ PM Temperature of **storage unit** when the vaccines were placed inside: _____ ◯ C ◯ F

EMERGENCY VACCINE STORAGE AND HANDLING PLAN CHECKLIST: FROZEN VACCINE

Contact with OSDH/IFC made prior to transport by:	
Date:	Time: _____ ◯ AM ◯ PM
Person Transporting Vaccine:	

Transport of FROZEN Vaccine

☐ **Assemble packing supplies.**

Container used to transport frozen vaccines:

- ☐ Portable freezer
- ☐ VaxiPac™
- ☐ Cooler

Other supplies needed if using a cooler:

- ☐ Frozen water bottles
- ☐ Certified, calibrated data logger (to be used with VaxiPac™ too).
- ☐ Packing material (2" of bubble wrap or crumpled paper and two pieces of cardboard that is cut to cooler size).

DO NOT FREEZE DILUENT DURING TRANSPORT

IF A COOLER IS USED:

☐	Spread a layer of frozen water bottles on the bottom of the cooler. Cover the frozen water bottles with a piece of cardboard, cut to the size of the cooler, and a 2'' layer of bubble wrap or crumpled paper.
☐	Stack vaccine boxes on the bubble wrap or crumpled paper. Vaccines must not touch the frozen water bottles.
☐	Place the data logger probe with vaccines.
☐	Cover vaccine with 2'' layer of bubble wrap or crumpled paper. Add a piece of cardboard, cut to the size of the cooler. Add frozen water bottles to cover the cardboard.
☐	Fill the cooler to the top with bubble wrap or crumpled paper.
☐	Place the data logger display on top of the bubble wrap, crumpled paper, or outside the cooler.

EMERGENCY VACCINE STORAGE AND HANDLING PLAN CHECKLIST: FROZEN VACCINE *(continued...)*

Contact with OSDH/IFC made prior to transport by:	
Date:	Time: _____ ◯AM ◯PM
Person Transporting Vaccine:	

Transport of FROZEN Vaccine (continued...)

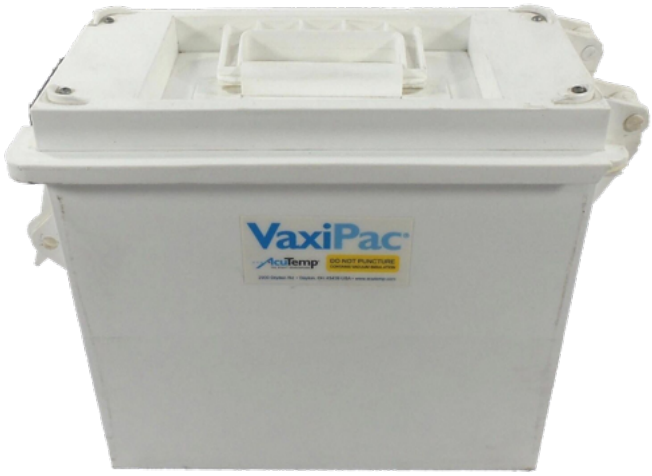
If a VaxiPac™ is used:

☐	**Pack vaccine in accordance with manufacturer instructions (place one freezer brick on the bottom, followed by vaccine and probe, followed by four more freezer bricks).**
☐	**Include data logger probe with vaccines. Place the data logger display outside the VaxiPac™.**

For all transport of frozen vaccine:

☐	**Include a list of the vaccines that are in the container.**
☐	**Record temperatures on a *Temperature Log* prior to transport.** Temperature of **storage unit** when the vaccines are removed: _____ ◯C ◯F Time vaccines were removed from **storage unit**: _____ ◯AM ◯PM Temperature of **transport container** when the vaccines were placed inside: _____ ◯C ◯F
☐	**Record temperatures on a *Temperature Log* upon arrival at the emergency storage location.** Temperature of **transport container** when the vaccines are removed: _____ ◯C ◯F Time vaccines were removed from **transport container**: _____ ◯AM ◯PM Temperature of emergency **storage unit** when the vaccines were placed inside: _____ ◯C ◯F

VAXIPAC™ VACCINE TRANSPORT



Do Not Use dry ice. Most manufacturers do not recommend transporting vaccines on dry ice as it may expose the vaccine to temperatures below -58° F.

A VaxiPac™ is an approved method for transporting frozen vaccine that does not short date the product. The VaxiPac™ can reliably maintain an average temperature between +5°F and -58° F when used with either VaxiSafe™ (-20°C) or VaxiSafe™(-15°C) frozen bricks. Refer to the VaxiPac™ manual for specific instructions.

If vaccine is not transported in a VaxiPac™, then document EXPLICITLY:

1) time storage began; 2) time storage ended; and 3) storage temperatures under which the vaccine was kept for this period of time.

Your IFC should be called before discarding frozen vaccine that has been kept under less than ideal storage conditions.