

# PROVIDER MANUAL

For clinics participating in the Washington State Adult Vaccine Program



DOH 348-640. July 2022

**Questions?** Contact the Department of Health at 360-236-2829 or WAAdultVaccines@doh.wa.gov

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## **Definitions**

#### **Administration Fee**

The amount that may be charged for the administration of an adult vaccine. The administrative fee cap is \$23.44.

## **Adult Vaccine Program (AVP)**

The Washington 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. Providers may request vaccine during a limited timeframe once or twice a year (usually in January and July).

## **Immunization Information System (IIS)**

The Washington State Immunization Information System (IIS) is a statewide, lifetime immunization registry that tracks immunization records for people of all ages. The IIS is a secure, free, webbased tool that provides a user-friendly way to keep immunization records up-to-date and know which vaccines a patient may need.

#### Insured

A person with insurance which includes vaccine benefits, 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 an inventory count is taken.

#### **Underinsured**

A person who has health insurance, but the coverage benefit does not include vaccine, or a person whose insurance covers only selected vaccines. – 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 is returnable for excise tax credit to the program. A vaccine return is initiated in the IIS. If the vaccine loss is greater than \$2,500, the Vaccine Loss Log (Appendix A) must be submitted.

# **Adult Vaccine Program (AVP)**

The Washington State Adult Vaccine Program (AVP) provides vaccine to participating provider locations for uninsured and underinsured adults 19 years of age and older. The program is funded using 317 federal funding and allows participating providers to receive vaccine at no cost for administration according to program requirements.

Section 317 vaccine is a limited national resource to 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. Funding is received in October and prioritized for outbreak response throughout the year. Any remaining funding is used for providers to place vaccine requests.

Providers may request available vaccines during a limited timeframe once or twice a year (typically vaccine requests are in January and July of each year). The vaccines available may change from year to year. Information regarding vaccine request opportunities is sent in the Adult Vaccine Program Updates newsletter. Typically, there are one or two vaccine order cycles each year. A typical vaccine order cycle goes as follows:

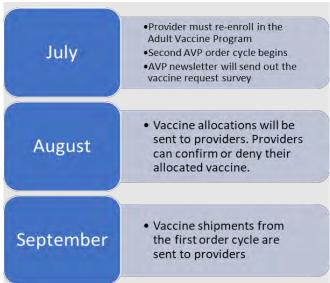
- Vaccine Request form is announced via the Adult Vaccine Program newsletter
- Provider completes Vaccine Request Form by the due date and ensures all required documentation is submitted to the program, including a completed Adult Vaccine Program Provider Agreement.
- Providers requesting doses are contacted by the program if any required documentation is missing.
- Providers requesting doses are sent an allocations spreadsheet. Providers can confirm or deny their acceptance of allocated doses.
- Providers are sent their allocated vaccine.

Refer to the Adult Vaccine Program newsletter for any changes in this process and for exact deadlines.

## January- March Order Cycle:

# February • First AVP order cycle begins • AVP newsletter will send out the vaccine request survey • Vaccine allocations will be sent to providers. Providers can confirm or deny their allocated vaccine. • Vaccine shipments from the first order cycle are sent to providers.

## **July- September Order Cycle:**



# **Adult Vaccine Program Updates Newsletter**

Provider locations are notified of program initiation, changes, requirements, and deadlines through the Adult Vaccine Program Updates newsletter. If interested in receiving the newsletter, please send an email to <a href="mailto:wAAdultVaccines@doh.wa.gov">wAAdultVaccines@doh.wa.gov</a>. It is the facility's responsibility to ensure email addresses are correct and updated when there is a change in staff to ensure communication is received. Having multiple contact email addresses added to the distribution list will help ensure coverage when updates are sent.

# **Program Enrollment**

Program enrollment occurs annually. To enroll in the Adult Vaccine Program:

- 1. Sign and submit a completed <u>Provider Agreement</u>. Follow the <u>Provider Agreement Instructions</u>.
- 2. Obtain appropriate vaccine storage and temperature monitoring equipment
- 3. Complete CDC's You Call the Shots: Vaccine Storage and Handling module
- 4. Ensure all required reporting is complete and submitted (if previously enrolled)
- 5. Submit Adult Vaccine Program vaccine request when available.

Providers who miss the opportunity to request adult vaccine doses can contact the program regarding surplus dose availability. Once enrollment is approved, you will be added to the distribution list and informed of any available surplus doses.

Providers are only eligible for vaccine if their provider agreement is approved, all accountability reports are submitted, and a completed vaccine request is received when available.

## **Vaccine Coordinators**

Each facility must designate one staff member to be the primary vaccine coordinator. This person is responsible for providing oversight for all vaccine management within the office and ensuring all vaccines are stored and handled correctly. Each facility must also designate at least one back-up vaccine coordinator who can assume oversight responsibilities in the absence of the primary vaccine coordinator.

Providers are required to notify the program when there are changes in key vaccine staff (e.g., the primary vaccine coordinator) and update their provider agreement to reflect the changes.

## **Annual Training**

All vaccine primary and back-up coordinators are required to complete the CDC You Call the Shots Training module Vaccine Storage and Handling annually. Training must be completed for the current year and documented as part of the annual enrollment process.

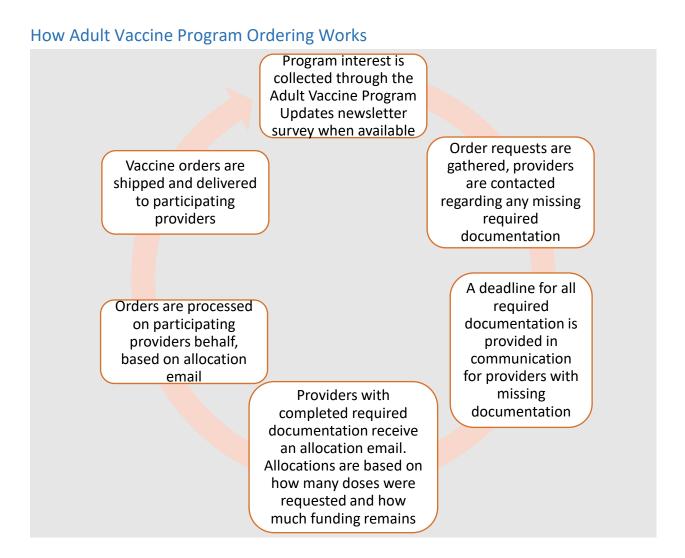
# **Vaccine Ordering**

Adult Vaccine Program vaccine orders are <u>not</u> placed in the Immunization Information System. This program is available based on limited funding. Order requests typically occur only once or twice each year. A link to the Vaccine Request form is sent via the Adult Vaccine Program (AVP) Updates newsletter to submit a vaccine request (typically January and July).

Based on funding a vaccine allocation is created for each provider. The allocation may not match the number of doses requested. Providers are notified of the number of doses for each vaccine allocated to them and must notify the program if they do not want all their allocated doses (typically in March and September of each year). Vaccine orders are processed, based on confirmed allocation amounts and shipped to providers in one shipment (typically in March and September of each year). Providers must have all required enrollment documents and accountability reports submitted to receive a vaccine allocation.

## **Vaccine Ordering Steps**

Receive	Adult Vaccine Program Updates newsletter
Complete	Provider Agreement     Request survey provided in the newsletter
Submit	Any responses required regarding the order request
Allocation	Number of doses provider will receive based on available funding is created (that met all program requirements)
Order	Placed for providers based on allocation



# **Vaccine Storage and Handling**

# Receiving a vaccine delivery

# **Accept all AVP shipments**

Do not reject a vaccine package



A Refusing a vaccine delivery can compromise the viability of the vaccine and result in wastage.

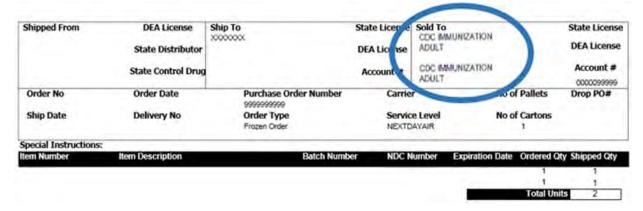
## When vaccine deliveries arrive – unpack vaccines immediately

1. Contact the vaccine coordinator, back-up coordinator, or other staff member to **immediately** receive and store the vaccine shipment appropriately.

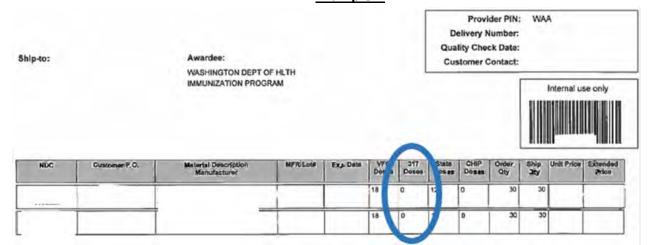
## When receiving a vaccine shipment

- 2. **Examine container and contents for physical damage.** If the package and contents:
  - ARE NOT damaged continue unpacking.
  - ARE damaged *immediately* contact the vaccine distributor, McKesson, at 1-877-836-7123.
     McKesson must be contacted the same day vaccine arrived from the carrier. Also, notify the program at 360-236-2829 or <u>WAAdultVaccines@doh.wa.gov</u>.
- 3. Check the packing list or package insert to determine how long the vaccine was in transit, and the cold chain temperature monitors to ensure temperatures are within the recommended range. If the temperature monitors:
  - ARE within range continue unpacking.
  - ARE NOT within range *immediately* note the date, time and temperature monitor reading, label the vaccine Do Not Use and store under proper conditions. Contact the vaccine distributor, McKesson, at 1-877-836-7123. McKesson must be contacted the same day vaccine arrived from the carrier. Also, notify the program at 360-236-2829 or WAAdultVaccines@doh.wa.gov.
- 4. Store the vaccine at the appropriate temperatures and contact the program the same day at WAAdultVaccines@doh.wa.gov, if you find any discrepancies with vaccine quantities received.
  - Place vaccines in trays or containers for proper air flow
  - o Put vaccines that are first to expire in front
  - Keep vaccines in original boxes with lids closed to prevent exposure to light
  - Separate and label by vaccine type and Adult Vaccine Program supplied vaccine
- Crosscheck contents with the packing slip to ensure delivered items are for the correct number of doses and check expiration dates. The packing slip for program doses will indicate **ADULT** or **317**. The program is funded using 317 federal funding. Examples of packing slips are shown below.

## **Example A**



## **Example B**



6. Enter vaccines received into the Washington Immunization Information System inventory.



# **Shipments-Allocations**

Vaccine allocations will be received in one order; vaccine will not be received at a later date. Program funding is limited and prioritized for outbreak response, if vaccine is compromised in anyway and no longer viable, **there are no replacement doses**.

Your entire allocation will be placed for you

Store vaccine correctly based on packing insert.

There are no replacement doses.

## **Vaccine Depots**

Enrolled facilities <u>cannot</u> function as a vaccine depot for other facilities. Federal policy does not allow one provider to order vaccine with the intent to disperse to other locations. Each facility requesting vaccine must enroll and obtain their own unique Provider Identification Number (PIN). Vaccine requests are specific to each facility and must be shipped to and stored at each location.

# **Storage Units**

Vaccine storage units must maintain recommended vaccine temperatures at all times. Storage units are required to have capacity to store the largest inventory a provider may 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 three to five (3-5) days prior to placing vaccine into the unit. Submit these temperature logs to WAAdultVaccines@doh.wa.gov.

Vaccine storage equipment must maintain recommended temperatures at all times

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.

**2023 Storage Unit Requirement**: Vaccine storage unit requirements are changing and will no longer allow the use of household combination refrigerator/freezer units. **Any enrolled site using the fridge or freezer section of a household combination unit will be required to upgrade to pharmaceutical or stand-alone units by January 1, 2023. This change only affects sites who are still using household combination units to store publicly supplied vaccine. This change will help to prevent vaccine loss resulting in waste of public funds and to help ensure patients receive viable and effective vaccines.** 

## 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 recommended 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. Household combination units will be required to upgrade to pharmaceutical or stand-alone units by January 1st, 2023.

## **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.

## Storage Unit Size

To determine the ideal storage unit size:

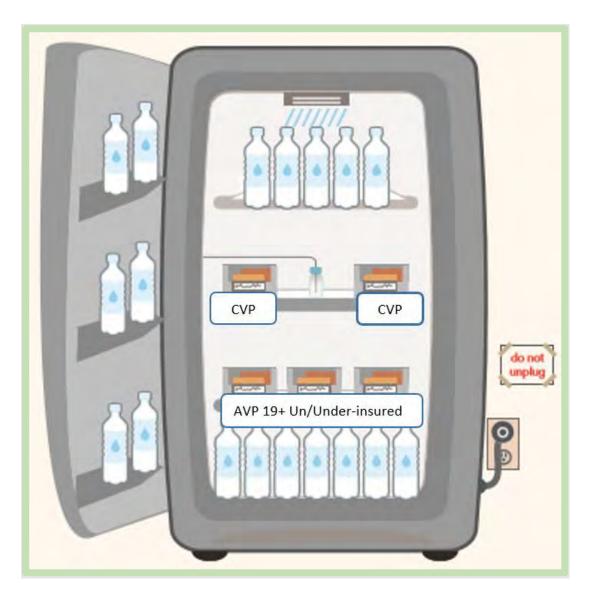
1. Estimate the maximum number of doses of publicly supplied vaccine and privately purchased vaccine (if applicable) to be stored in the unit.

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 clinics needs and meets all Adult Vaccine Program and if enrolled, Childhood Vaccine 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		

## **Labeling Vaccine**

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



## **Temperature Monitoring Equipment**

Vaccines must always be stored at appropriate temperatures. Vaccine manufacturers set the storage temperature requirements. It is important to follow vaccine manufacturer specifications found in the vaccine package insert. The package insert describes the required storage conditions for a particular vaccine.

All AVP providers must monitor vaccine storage temperatures using an approved working thermometer. Approved thermometers must be used in each unit storing publicly-supplied vaccines during routine on-site vaccine storage, during vaccine transport (emergency or non-emergency), and during off-site vaccination clinics. It is the responsibility of the provider to obtain and maintain all thermometers for their facility. Approved thermometers must meet the following requirements:

## 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 30 minutes

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.

Thermometers must be placed in the center of the unit with the vaccines surrounding it. Thermometers must **not** be placed in the unit doors, near or against walls, or close to the floor, ceiling, or air vents. Allowable exemptions include purpose-built or pharmaceutical grade storage units with a built-in

thermometer that meets all program requirements or a dedicated port for placement of the temperature probe.

## **Daily Temperature Monitoring**

Providers storing public-supplied vaccines must follow requirements for reviewing and recording temperature readings in vaccine storage units daily. This helps to identify temperature excursions quickly so corrections can be made to prevent vaccine loss and avoid the need to revaccinate patients. Providers have two options for documenting temperature readings:

Option 1: Handwrite on a paper temperature log (<u>Appendix B</u>). The log should be posted on each vaccine storage unit door or nearby in a readily accessible and visible location and contain the following:

- Twice daily (AM and PM) record current temperatures
- Once daily record the minimum and maximum temperatures of the storage unit(s)

Option 2: Use a continuous temperature monitoring and recording system (TMS) or digital data logger (DDL) that electronically documents temperatures and staff readings. Providers must get pre-approval of reports before using this option to ensure they contain the following information:

- Once daily min/max manual temperature check
- Time and date of reading
- Name or initials of staff member who recorded the reading (manual audit)
- Review digital data logger data weekly to confirm temperatures remained within range

Providers must maintain an ongoing file of all temperature logs or a back-up system of electronic data (both hard copy and electronic copy) for a minimum of three years.

## **Required Temperature Log Reporting**

<u>Beginning July 2022</u>, providers are required to begin submitting monthly temperature logs to the Adult Vaccine Program at <u>WAAdultVaccines@doh.wa.gov</u>. Temperature logs are due the first week of the following month. If a provider is enrolled in the Adult Vaccine Program and Childhood Vaccine Program, and vaccines are stored in the same vaccine storage units, the provider does not need to send a duplicate temperature log to the Adult Vaccine Program.



## **Out of Range Temperatures**

Exposure to temperatures outside of the ranges detailed in manufacturers' package insert could affect vaccine viability and ultimately, leave patients unprotected against vaccine-preventable diseases. If vaccine has been exposed to any temperature outside the recommended temperature range, take immediate action to correct.

# Notify

# **Document**

# **Contact**

# Correct

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 details 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 affected vaccines
- Name of the person completing the report

Contact the vaccine manufacturer(s) for guidance

Be prepared to provide the manufacturer with documentation and digital data logger data

Follow manufacturer guidance based on viability of vaccines. If manufacturer guidance is unclear or states that providers can use their discretion to continue to use the vaccine, you must contact the Adult Vaccine Program at WAAdultVaccines@doh.wa.gov. Providers do not have the authority to discard publicly purchased vaccines.

Do not disconnect the alarm until you determined and addressed 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 failed, use your back-up thermometer

Never allow vaccines to remain in a nonfunctioning unit

Complete the Vaccine Loss Form if applicable and notify the program. Please include all documentation including the vaccine manufacturer's guidance.

Manufacturer contacts for excursions	
Merck: 1-800-672-6372	Sanofi Pasteur: 1-800-822-2463
GlaxoSmithKline: 1-888-825-5249	Pfizer: 1-800-438-1985
Seqirus: 1-855-358-8966	Massachusetts Biological Labs: 1-617-474-3000

## Out of Range Temperatures-Still Viable

If the vaccines are determined still viable after contacting 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 to the manufacturer 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:

- Keep the vaccines in the storage unit labeled "do not use"
- Determine if there was any issue with the digital data logger readings

If the doses are determined **not viable** and there is no issue with the digital data logger 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 the IIS to start the vaccine return process. Submit the Vaccine Loss Form if the loss is greater than \$2500.

# Quick Checklist for Vaccine Storage and Handling

Vaccines are stored accordingly to manufacturer's packing insert.			
Vaccine Storage Temperatures are:			
<ul> <li>Refrigerator: Temperatures are between 36°F and 46°F (2°C and 8°C)</li> </ul>			
<ul> <li>Freezer: Temperatures are between -58°F and 5°F (-50°C and -15°C)</li> </ul>			
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 the vaccine. 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.

# Do not discard vaccine



Do not store vaccine at a private residence

## Ways to prepare:

- 1. At a minimum, every facility should have:
  - Back up Temperature Monitoring Device
  - Spare batteries
  - Flashlights
  - Vaccine transport containers and materials
- 2. 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:
- 3. Make sure to have the manufacturer's contact information readily available of your storage units.
  - Manufacturer Name for Refrigerator:
  - Manufacturer Phone for Refrigerator:
- 4. 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.
- 5. Know where you would transfer your vaccines if you have to 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-hours access.
  - Primary alternative vaccine storage address:
  - Primary alternative vaccine storage phone:
  - Secondary alternative vaccine storage address:
  - Secondary alternative vaccine storage phone:

- 6. 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).
- 7. 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.
- 8. Make sure to monitor temperatures from outside the storage unit.

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

Once it is determined the vaccines will be transported make sure to transfer the vaccines properly. Improper packing for transport is as risky for vaccines as a failed storage unit.

## 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 16) and contact the manufacturers to determine viability.

# **Off-Site Clinic guidelines**

Satellite, temporary, and off-site vaccination clinics play an important role in improving vaccination coverage rates and vaccinating hard-to-reach populations. Vaccination clinics held in these settings have unique challenges and providers must follow specific guidelines for managing publicly supplied vaccine in these non-traditional settings. Below is a checklist of requirements, best practices, and reference materials for your off-site vaccination clinic. Review all materials prior to conducting an off-site vaccination clinic.

Off-	site clinic checklist
	Submit your <u>request</u> to the Washington State Adult Vaccine Program for approval before using publicly supplied vaccines for an off-site vaccination clinic.
	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 for transporting and storing vaccine during the clinic.
	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.
	<ul> <li>All remaining pre-drawn doses must be discarded and logged as waste at the end of the clinic.</li> </ul>
	Monitor digital data logger(s) and record temperatures on paper temperature logs hourly, located in <a href="Appendix B">Appendix B</a> .
	After the clinic, download and review digital data logger temperature data.
	If the vaccine went out of temperature range during the off-site clinic, call the manufacturer to
	access viability of the vaccine and notify the Adult Vaccine Program at
	WAAdultVaccines@doh.wa.gov.
	Complete a Vaccine Loss Form for any wasted vaccine doses and submit the loss form to
	WAAdultVaccines@doh.wa.gov.

#### **Transport System Recommendations**

Type of Unit	Emergency	Transfer to another	Off-Site
	Transport	enrolled facility	Clinic
Portable Vaccine Refrigerator or Freezer	Yes	Yes	Yes
Qualified Container and Pack out	Yes	Yes	Yes
Conditioned Water Bottle Transport	Yes	Yes	No
System			
Manufacturer's Original Shipping	Yes (last	No	No
Container	resort only)		
Food/Beverage coolers	No	No	No
Pre-approval required with the Adult	No	Yes	Yes
Program			

# **Managing Adult Vaccines in the IIS**

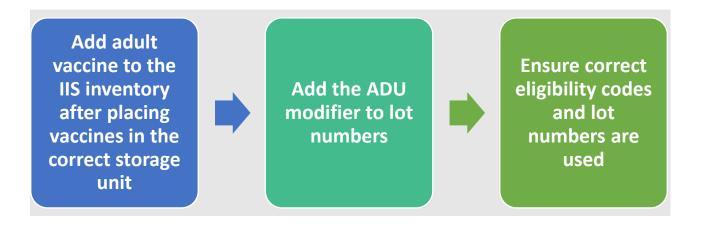
Beginning July 2022, **It is required** that providers use the Immunization Information System (IIS) to manage their adult vaccine inventory. Providers are also strongly encouraged to enter vaccine doses administered to patients into their patient record within the IIS. There are many benefits of using the IIS 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

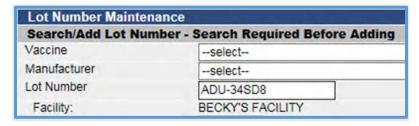
## Adding Adult Vaccines in IIS Inventory/ ADU Modifier

Providers must manually add publicly supplied adult vaccines to the IIS inventory after placing the vaccines in the correct storage unit. When entering adult inventory, **it is required** to add the <u>ADU</u> <u>modifier to the lot number</u> in order to distinguish public adult vaccine doses from public childhood vaccine doses. When adding the ADU modifier to a lot number to differentiate from childhood vaccine stock, make sure the same lot number with ADU modifier is entered in with your Electronic Health Record (EHR). If the lot numbers do not match between the EHR and the IIS, the doses will not decrement from inventory.

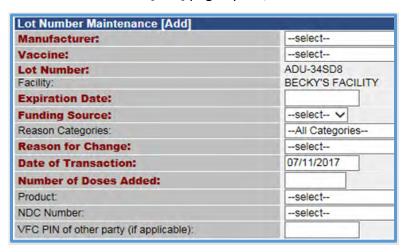


## To add the adult vaccines to the reconciliation page:

- 1. Log into the IIS
- 2. Select Lot Numbers > Search/Add
- 3. On the Lot Number Maintenance page, for the Lot Number field, enter in ADU- and the Lot Number on the vaccine box. For example, if the lot number on the box is 34SD8, then in the Lot Number field, enter ADU-34SD8.



- 4. Select Search
- 5. If no results are found, select Add
- 6. When the Lot Number Maintenance [Add] page opens, add the adult vaccine information.



- 7. Select the appropriate Manufacturer and Vaccine type from the drop downs.
- 8. Enter Expiration Date of the vaccine
- 9. Make sure to select **PUB** in the Funding Source field for adult vaccines.

- 10. Select Reason for Change from the drop down and type in the total Number of Doses your received.
- 11. **Product** and **NDC Number** are required fields. Select the Product first from the dropdown and then the NDC Number.
- 12. After all the information is entered, select Add.
- 13. If you have an interface where your electronic health record sends data to the Immunization Information System (IIS) you will need to ensure that the lot numbers in your EHR include the ADU modifier, so they match the lot numbers in the IIS.

# **Required Accountability Reporting**

Beginning July 2022, providers are required to submit an Inventory Report through the Immunization Information System monthly. Inventory reports are due the first week of each month along with providers temperature logs.

Previously, the program required quarterly reporting through a survey on the AVP webpage. **This is no longer a requirement of the program.** 

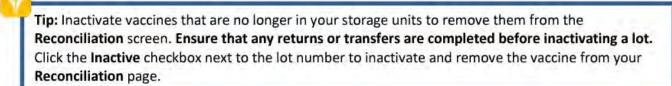
## Reconciling Inventory/ Submitting the Required Monthly Inventory Report

Clinics enrolled in the program are required to reconcile their vaccine inventory and submit their inventory report monthly through the Reconciliation screen in the IIS.

- 1. Click on Lot Numbers heading in the left menu, then click on Reconciliation
- 2. Your inventory will display
- 3. Select the **Print** button at the bottom right of the Reconciliation screen to print the reconciliation worksheet.
  - a. Take the worksheet to your clinic's fridge or freezer and count your physical inventory.
  - b. Write your fridge/freezer counts in the Physical Inventory column.
  - c. Ideally, the Quantity on Hand should match your Physical Inventory. Document any discrepancies on the reconciliation worksheet.
  - d. Use the <u>Vaccine Loss Log</u> to track any wasted, spoiled, or expired vaccine throughout the month. When reconciling inventory in the IIS, account for the doses tracked on this log using the adjustment categories and reasons that match the Vaccine Loss Log documentation.
- 4. If the counts do not match, start by troubleshooting for any doses that did not subtract from your inventory. The Patient Detail Report and the Lot Usage and Recall Report are two helpful troubleshooting reports. See page seven of this guide for additional troubleshooting reports.
  - a. The Patient Detail Report can help identify which patients received doses that did not subtract from your inventory. These <u>instructions</u> describe how to use the report.

- b. The Lot Usage and Recall Report provides a list of patients who received a certain lot number. These <u>instructions</u> describe how to use the report.
- 5. Once you identify doses that did not subtract from your inventory due to documentation errors, you will need to correct those errors (e.g. incorrect lot number or manufacturer) in your electronic health record and/or the IIS. Once you correct any errors, those doses will subtract from your Reconciliation screen.
- 6. If the **Quantity on Hand** in the IIS and your **Physical Inventory** counts still do not match, enter the number of doses from your physical count in the Physical Inventory field, then select a **Category** and **Reason** that best describes what happened to the doses (see the adjustment category and reason descriptions on the next page).
- 7. You can enter in multiple categories and reasons by using the **Add Row (+)** button. Make sure the number in the Adjustment column represents the correct number you want to adjust.





- 8. Adjusting inventory with a Return Category is the first step to submitting an online vaccine return. For more information regarding completing your vaccine return see <u>Vaccine Returns in</u> the IIS.
- 9. When you finish reconciling your inventory, click the **Submit Monthly Inventory** button at the bottom of the screen to submit the inventory report or click the **Save** button to save changes. Selecting **Save** will not submit your inventory report, it will only update your adjusted totals in the Quantity on Hand column of the **Reconciliation** page.



## **Short Dated Vaccine**

Demand for publicly supplied adult vaccine doses is high. Providers with surplus vaccine that cannot be used before expiration are required to contact the program at least 90 days (three months) in advance at <u>WAAdultVaccines@doh.wa.gov</u> so we may assist.

As the program receives notification of surplus doses, providers will be emailed about vaccine availability. These emails will be titled: *Adult Vaccine Program – Additional Doses Available*.

## **Steps for short dated vaccines:**

## Run Reminder/Recall

 Run a Reminder/Recall report to locate patients that are due or past due for the vaccine.

# Ensure proper stock rotation

 Ensure that short-dated vaccines are moved to the front of the storage unit for immediate use.

# Contact us three months in advance

 Contact us at WAAdultVaccines@doh. wa.gov, to arrange a possible transport of vaccine to another enrolled clinic that can administer the vaccine.

## Advertise Vaccine for transfer

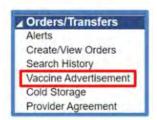
 Advertise soon to expire adult vaccines through the Vaccine Advertisement screen within the IIS.

## **Vaccine Advertisement in the IIS**

In addition to contacting us, providers may also advertise soon to expire adult vaccines on the Vaccine Advertisement Screen in the IIS.

## Advertising Vaccine in the IIS

1. Click on **Orders/ Transfers** heading in the left menu of the IIS. Then click **Vaccine Advertisement** to open the **Vaccine Advertisement** screen.



2. Click circle by **Advertise Vaccine for Transfer**. The first page that comes up will default to the View All Vaccines Advertisements option.



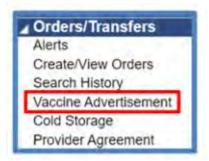
3. Enter the information for the vaccines you would like to advertise for the other Adult vaccine providers to request for transfer. Enter "Adult" in the comments field. Click Advertise.



## Searching for Available Vaccine in the IIS

Providers can look for clinics advertising soon to expire adult vaccines through the Vaccine Advertisement screen within the Immunization Information System (IIS).

1. Click on **Orders/ Transfers** heading in the left menu of the IIS. Then click **Vaccine Advertisement** to open the **Vaccine Advertisement** screen.



2. The first page that comes up will default to the View All Vaccines Advertisements option.



3. To request advertised vaccines, contact the provider listed and ask them to initiate a vaccine transfer request in the IIS.



Tip: You can sort the columns by clicking the up/down arrows

# **Transferring Adult Vaccine**

## **Transfer Requirements**

- 1. Complete Vaccine Transfer Request in the IIS at least 48 hours before each intended movement of vaccine. Vaccine cannot be moved prior to Transfer Request approval from the program.
- **2.** Ensure that receiving facility (where vaccine is being transferred) is a participating AVP provider and is no more than a one (1) hour drive away.
- **3.** Providers must follow vaccine transport guidelines to ensure the cold chain is always maintained during transport.
  - **a.** Follow Vaccine Transport Guidelines located on the Centers for Disease Control and Prevention website, to properly pack vaccine.
  - **b.** Monitor vaccine temperatures during transport with a certified digital data logger.
  - c. Use approved transfer materials.

#### **Transport System Recommendations**

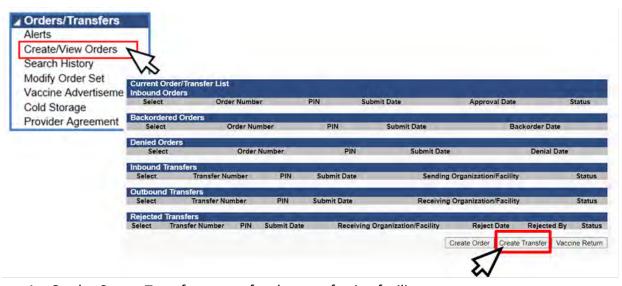
Type of Unit	Emergency	Transfer to another	Off-Site
	Transport	enrolled facility	Clinic
Portable Vaccine Refrigerator or Freezer	Yes	Yes	Yes
Qualified Container and Pack out	Yes	Yes	Yes
Conditioned Water Bottle Transport	Yes	Yes	No
System			
Manufacturer's Original Shipping	Yes (last	No	No
Container	resort only)		
Food/Beverage coolers	No	No	No
Pre-approval required with the Adult	No	Yes	Yes
Program			

# **Transferring Adult Vaccines in the IIS**

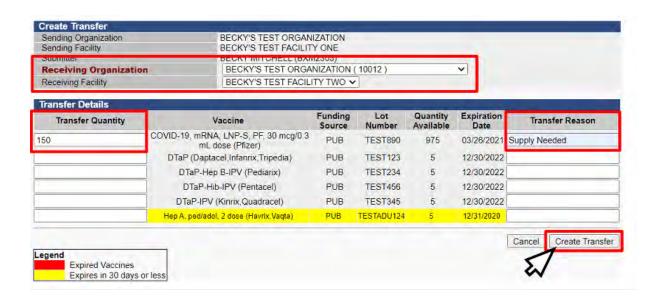
## Transferring Facility (Facility distributing vaccine to other facilities.

Creates a vaccine transfer in the Immunization Information System (IIS):

- 1. Log into the Washington State Immunization Information System (IIS).
- 2. Ensure the correct facility displays at the top of the screen under: Organization/Facility.
- 3. Go to the Orders/Transfers menu in the left menu, select Create/View Orders and then Create Transfer.



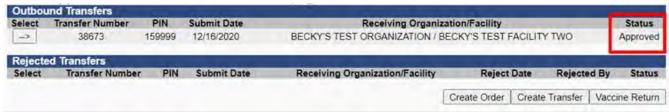
- 4. On the Create Transfer screen for the transferring facility:
  - a. Select the Receiving Organization from the drop-down menu and the Receiving Facility
  - b. Enter the Transfer Quantity (amount of adult vaccine that will be transferred)
  - c. Enter Transfer Reason
  - d. Select Create Transfer



- 5. Once Create Transfer is selected, you will be directed back to the Create/View Orders Page.
- 6. Under the Create/ View Orders page you will be able to view your Outbound Transfers.

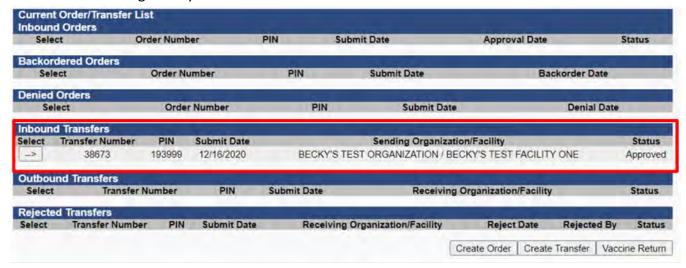


7. Once a transfer is approved by the state, the status will change from In Manual Review to Approved on the Outbound Transfers page.



## Receiving Facility (Facility receiving vaccine from a transferring facility)

1. Once the Transferring Facility's request is approved by the state, the transfer will then appear on the Receiving Facility's Inbound Transfers List.



2. The Receiving Facility will enter the Receipt Quantity and select Receive.

- a. Two things will happen once the transfer is received in the IIS:
  - The vaccine will subtract from the Transferring Facility's reconciliation (inventory)
     page
  - ii. The vaccine will be added to the Receiving Facility's reconciliation page.



# **Vaccine Loss**

A Vaccine Loss Log is required for any vaccine loss greater than \$2500 that cannot be administered. Categories include wasted, expired, and spoiled.

# **Returning Expired or Spoiled Vaccine**

You **must** return adult vaccines that have expired or spoiled to McKesson distribution center (do not discard). To do this:

- 1. Vaccine loss must be properly entered into the IIS. See below section <u>Vaccine Returns in the IIS</u> for instructions on how to submit an online return.
- 2. If the vaccine loss is greater than \$2,500, fill out and submit the Vaccine Loss Log (Appendix A) and email to WAAdultVaccines@doh.wa.gov.
- 3. Please allow for processing time of the return and contact us if you did not receive a return label within three to four weeks of your loss form submission.
- 4. Once your return is processed, you will receive a return shipping label via email from pkginfo@ups.com. Check your junk inbox too as they often go there.
- 5. Print the return label.
- 6. Pack the vaccines to avoid breakage of the vaccine (for example a box with bubble wrap).
- 7. Affix the return label to the container and ship the package.

# **Vaccine Loss Policy**

#### Introduction

Proper vaccine storage, handling, and accountability are vital components to the success of the Washington 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 Washington 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.

## **Expectations of Providers**

- Providers agree to maintain proper storage and handling practices to avoid vaccine loss.
- Providers agree to review vaccine storage temperatures during clinic hours based on program requirements.
- Providers agree to 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.
- Providers agree to report all vaccine loss by completing a Vaccine Loss Form.
- Providers agree to 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 the program three months prior to vaccine expiration to determine vaccine transfer options.
- Not requesting prior approval from the program to transfer vaccine and/or transferring vaccine inappropriately, thereby potentially impairing vaccine viability.
- Failure to follow an emergency response plan.
- 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.
  - o 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 (always 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 Loss Scenarios**

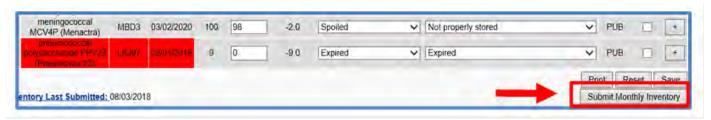
- Provider's first incident within 365 days that is greater than \$2,500.00 but less than \$10,000.00 (A,B,C).
- Provider experiences additional negligent incidents greater than \$2,500.00 within 365 days of their most recent negligent incident (A,B,C,D,E).
- Provider experiences any negligent incident 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

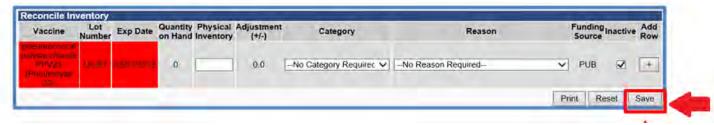
- A. The program may not approve provider vaccine ordering requests until the issue is resolved.
- B. The program will provide an email and resources to educate the provider regarding their incident.
- C. The program will require the provider to submit their <u>Vaccine Loss Form</u> outlining the incident and actions they plan to take to prevent future vaccine loss.
- D. The program will require provider to complete additional training regarding vaccine storage and handling procedures.
- E. The program 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. The provider may be dis-enrolled from the program.

# Vaccine Returns in the IIS

- 1. Ensure pop-up blocker is disabled before completing the vaccine return. If pop-up blocker is enabled in your internet browser, you may submit the return twice or not have access to the vaccine packing slip.
- 2. Log into the Washington State Immunization Information System (IIS).
- 3. Select your facility, if needed.
- 4. Follow inventory reporting procedures in the reconciliation screen.
- 5. During this process, mark any wasted, spoiled, or expired vaccine and click the submit button at the bottom of the reconciliation screen.
  - a. Do not inactivate the vaccine lot number you need to return. Inactivating the lot number at the same time as submitting will not create a vaccine return



6. Once your inventory has been submitted and the vaccine lot number shows zero doses on hand, you may inactivate the vaccine lot number.



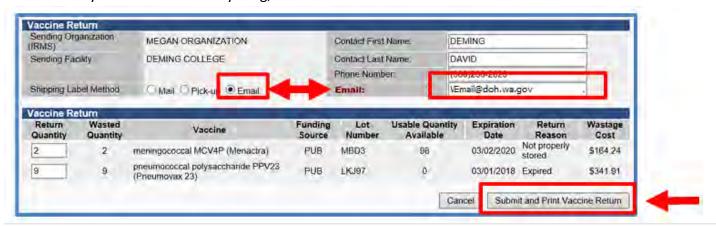
7. Go to the Orders/Transfers menu in the left menu and click on Create/View Orders.



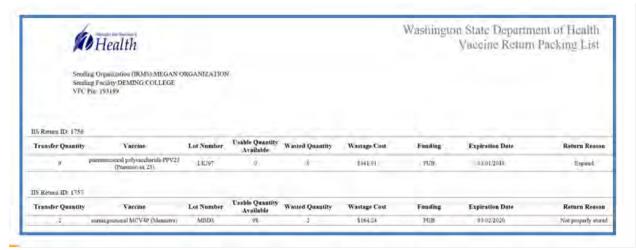
8. On the **Create/View Orders** page, there is a button on the bottom right side of the screen near the Create Order button called Vaccine Return. Select the **Vaccine Return** button.



- 9. The Vaccine Return page will display the vaccines marked as expired/spoiled on the Reconciliation screen. Confirm your clinic information is correct.
- 10. Fill in the vaccine quantity for each vaccine you'd like to return listed under the Vaccine Returns header.
- 11. Make sure your shipping label method is listed as **Email**. Make sure you have a valid email listed on the returns screen to ensure you receive the shipping label for your return.
- 12. Once you've filled out everything, click on the **Submit and Print Vaccine Return** button.



13. The IIS will open a web page showing your Vaccine Return Packing List.



Tip: Print and insert this packing slip in the box with the vaccines you're returning. If you forgot to print the packing slip, you can reprint it by: logging into the IIS, selecting Search History under the Orders/Transfers heading in your left menu. Select the Vaccine Return radio button and click Search.

- 14. After submitting the vaccine return, the State Approvers will review and approve the vaccine return. Once the return is approved, a shipping label will be emailed to you. If you do not receive a shipping label within three weeks, email WAAdultVaccines@doh.wa.gov
  - a. Shipping labels are valid for 30 days after their issued date. Please print as soon as you can as it is time consuming to re-issue return shipping labels.
  - b. Shipping labels will be emailed directly from UPS, pkginfo@ups.com to the email provided in the online vaccine return submitted in the IIS. Please ensure you check your spam/ junk folders as they can go there.
- 15. If you have any issues with the process, please contact the Adult Vaccine Program at <u>WAAdultVaccines@doh.wa.gov</u>

# **Eligibility and Billing for Publicly Funded Vaccines**

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

Patient Status	Eligibility for AVP Vaccine	Eligibility Code	Funding Code	Billing
Medicare Adult Adult is 19 years or older	No	V24 Medicare	PHC70 Privately	Contact Medicare for billing guidance
Enrolled in Medicare  Medicare covers the vaccine		Wicalcure	Funded Vaccine	guidance
Un/Under insured Adult seen at facility with AVP Vaccine Adult is 19 years or older, is receiving care at a facility that has AVP vaccine, and does not have insurance or has insurance but the insurance does not cover the vaccine.	Yes	V23 AVP eligible (317)	VXC52 Publicly Funded Vaccine	<ul> <li>Do not bill for cost of vaccine</li> <li>Can bill vaccine administration fee up to \$23.44 per vaccine dose</li> <li>May issue only a single bill within 90 days of service</li> <li>Must waive fee if patient is unable to pay</li> <li>Cannot refuse to administer vaccine to patients</li> <li>Do not send bill to collections for unpaid administration fees</li> </ul>
Private Insured Adult Adult is 19 years or older Has private insurance that covers vaccine	No	V01 Not AVP eligible	PHC70 Privately Funded Vaccine	Contact insurance plan for billing guidance

# **Eligibility Screening**

	Eligible fo	or 317 Vaccine	Not Eligible for 317 Vaccine		
Date	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 co- pay not met	

## **Outbreak Response**

The Adult Vaccine Program receives a limited amount of Section 317 federal funding each October. Funds are prioritized for outbreak response throughout the year. All outbreak response orders must be received before **September 1st** for allocations to be created for the Adult Vaccine Program based on remaining funding.

Information Needed: For Outbreak Requests	Resources
Completed Adult Vaccine Program Provider Agreement	Provider Agreements are updated yearly and available on the Adult Vaccine Program webpage.
<ul> <li>2. Send a request for vaccine doses by email to WAAdultVaccines@doh.wa.gov that includes: <ul> <li>Provider Identification Number (PIN)</li> <li>Vaccine Type and Brand</li> <li>If the doses are for the Adult Vaccine Program</li> <li>If the doses are for outbreak response</li> <li>If the doses are needed for a scheduled clinic and if so, when that clinic is</li> <li>Quantity of doses (dose quantities requested should be able to be used before the expiration date and be requested for about a couple months' worth)</li> <li>Estimated uninsured and underinsured adult patient population quantity that the doses will be administered to</li> <li>How the facility plans to use the doses requested before the expiration date (by offering additional clinics, reminder recall, etcetera)</li> </ul> </li> </ul>	Adult Vaccine Program webpage.
3. Vaccine deliveries are made to each provider's direct location. Vaccine shipments can take five to ten 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.	

### **Program Disenrollment**

If your facility no longer offers Adult Vaccine Program doses and you currently have a supply of vaccine on hand, please contact us at <a href="www.waa.gov"><u>WAAdultVaccines@doh.wa.gov</u></a>. 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. Additionally, please post vaccine in the <u>IIS Vaccine Advertisement Page</u>.

### **Frequently Asked Questions**

- 1. Is the program limited to providers participating in the Childhood Vaccine Program?

  No. Any provider who serves underinsured and/or uninsured adults may enroll.
- 2. How do providers who are not part of the Childhood Vaccine Program enroll?

  Providers can enroll into the program by completing the Provider Agreement. After the agreement has been approved, a unique PIN will be assigned.
- 3. What sort of <u>reporting requirements</u> will be mandatory for this vaccine?

Providers receiving adult vaccines must managed vaccine inventory in the IIS and submit inventory reports monthly. Additionally, providers must actively monitor temperatures of vaccine storage units and submit temperature logs each month to the AVP inbox at WAAdultVaccines@doh.wa.gov.

Temperature logs are due the first week of the following month. If a provider is enrolled in the Adult Vaccine Program and Childhood Vaccine Program, and vaccines are stored in the same vaccine storage units, the provider does not need to send a duplicate temperature log to the Adult Vaccine Program.

#### 4. What is required when our facility moves locations?

Notify the program immediately to consult on proper vaccine storage and transport throughout the move. Monitor temperatures of storage unit for 3-5 days to ensure it is maintaining stable temperatures before placing vaccine into the unit. Additionally, submit a new Adult Vaccine Program Provider Agreement when there are changes to the vaccine delivery address and delivery times, facility name and address, medical director, and vaccine coordinators.

#### 5. Is there a vaccine administrative fee cap?

Yes. The administrative fee cap is \$23.44.

#### 6. What are the vaccine expiration dates?

Vaccine expiration dates are usually 12-24 months from the date of receipt. The program has no control over the expirations dates shipped from the CDC distribution center (McKesson).

#### 7. What is the difference between uninsured and underinsured?

Uninsured patients do not have health insurance of any kind. Underinsured patients have health insurance with limited or no vaccine coverage benefit in their plan. 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 federal vaccine. It is the individual's responsibility to understand their insurance status and identify in network providers.

#### 8. How does the facility identify a shipment is adult vaccine?

The packing list will identify adult vaccines as **ADULT** or **317**.

#### 9. Can the order be "received" in and managed in the IIS?

Adult Vaccine Program doses must be manually entered in IIS inventory. When entering these doses, the <u>"ADU" modifier</u> must be added to the lot number. Once the vaccine has been manually added to the IIS, it can be managed in the same way as childhood vaccine.

#### 10. 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.

#### 11. Do I need to complete my accountability reports to receive my adult vaccine order?

Yes. All required accountability reports (<u>inventory</u> and temperature logs) must be submitted in order to request and receive additional adult vaccine.

#### 12. 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. Additionally, please advertise your adult vaccine in the IIS. See additional information for how to transfer vaccine here.

#### 13. How do I return adult vaccine?

A return request is generated using the Immunization Information System. If the vaccine loss is greater than \$2,500, fill out and submit the Vaccine Loss Form (Appendix A). Once the form is processed you will receive a label by email. Please follow the directions on the shipping label to return the vaccine. See additional information for how to complete a Vaccine Return in the IIS here.

#### 14. Why isn't flu typically offered through the program?

Because of limited funding, the program is only available if we have funding remaining after outbreak response. Flu pre-book is at the beginning of the year and since we will not know how much funding we may have available we cannot pre-book flu doses.

#### 15. 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 <u>Web-based Training Course webpage</u>. The Vaccine Storage and Handling link on the CDC Web-based training course webpage can be accessed <u>here</u>. To complete the training please obtain the certificate by visiting the CDC <u>Web-based Training Course webpage</u>.

## **Appendix A: Vaccine Loss Form**

# Adult Vaccine Program Vaccine Loss Form



Office of Immunization | doh.wa.gov/avp | waadultvaccines@doh.wa.gov



#### **DOH USE ONLY**

Return ID-Expired:

Return ID-Spoiled:

Return ID-Wasted:

## Vaccine Loss Log

#### Month/Year:

Healthcare providers participating in the Washington State Adult Vaccine Program (AVP) are required to report all vaccine loss that results in unusable vaccine.													
Each month, post this log on your storage unit to track vaccine loss and to help complete your monthly inventory report online in the Immunization Information													
System (IIS). At the end of each month, keep this log in your Vaccine Management binder. Providers must submit this log to DOH if:													
1. The provider does not report vaccine loss in the IIS.													
2. The vaccine loss totals \$2,500.00 or more. Use Online Vaccine Returns as needed to determine total cost of vaccine loss.													
Preferred method of receipt is via se	can and email to WAAdultVaccines@doh.	.wa.gov											
PIN:													
Address:		City:		State: WA	Zip:								
Contact Name:	Telephone:		Fmail·										

	Record number of doses, vaccine product details, and reason for vaccine loss in the table below. Use Appendix A as needed for additional NDCs/lot numbers.  *If you have submitted your return online and have your IIS vaccine return ID, only complete the columns indicated below with an asterisk (*).  *IIS Vaccine   Vaccine   *Corrective Action to													
*IIS Vaccine Return ID or Vaccine	Date	Number of Doses	Manufacturer	NDC Number	Lot Number	Expiration Date	Vaccine Loss Codes (see below)	*Corrective Action to Prevent Future Vaccine Loss (use additional pages as needed)	Staff Initials					
Vaccine Loss Cod	des:													
1. Expired				2d. Spoiled: Mechar	nical failure			3c. Wasted: Open multidose via	al					
2a. Spoiled: Natur	ral disaste	r/power outa	age	2e. Spoiled: Other			3d. Wasted: Lost or unaccounted for							
2b. Spoiled: Refri	gerator to	o warm or to	o cold	3a. Wasted: Vaccine	e drawn into sy	ringe but not	administered	4. Misuse: Administered to adu	lt					
2c. Spoiled: Vacc	ine spoile	d in transit		3b. Wasted: Compro	omised vial - b	roken vial, or	lost vial.	5. Recalled vaccine						



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#### **DOH USE ONLY**

Return ID-Expired: Return ID-Spoiled: Return ID-Wasted:

Please answer the questions below as needed based on the vaccine loss logged.										
<ol> <li>Have you already submitted a return or reconciled your inventory for this loss in the Immunization Information System (IIS)?</li> <li>□ NO □ YES</li> </ol>										
2. Were any of the spoiled doses administered to patients?  □ NO □ YES – How many doses?										
3. What type of refrigerator was involved? (Select all that apply)  □ Combination refrigerator / freezer with: □ separate thermostats □ single thermostat □ unknown □ Stand-alone refrigerator – household style □ Stand-alone refrigerator – commercial style □ Stand-alone refrigerator – "purpose-built" for storage of vaccines (e.g. lab or pharmacy grade) □ Type of refrigerator unit is unknown										

In the event of a temperature excursion contact	the manufacturers to determine vaccine viability.
GlaxoSmithKline	MassBiologics (Grifols)
(866) 475-8222	(617) 474-3000
Merck & Co., Inc.	Pfizer Inc.
(800) 444-2080	(800) 505-4426
Sanofi Pasteur	Sequiris
(800) 822-2463	(855) 358-8966

## Adult Vaccine Program AVP

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#### **DOH USE ONLY**

Return ID-Expired: Return ID-Spoiled:

Return ID-Wasted:

#### Appendix A: Use this page to record additional vaccine loss or additional NDCs or lot numbers

*IIS Vaccine Return ID or Vaccine	Date	Number of Doses	Manufacturer	NDC Number	Lot Number	Expiration Date	Vaccine Loss Codes (see below)	*Corrective Action to Prevent Future Vaccine Loss (use additional pages as needed)	Staff Initials			
Vaccine Loss Codes:												
1. Expired	, a o o .			2d. Spoiled: Mechan	ical failure			3c. Wasted: Open multidose via	al			
2a. Spoiled: Natu	ural disaste	er/power outa	age	2e. Spoiled: Other				3d. Wasted: Lost or unaccounted for				
2b. Spoiled: Refr				3a. Wasted: Vaccine	drawn into sy	ringe but not	administered	4. Misuse: Administered to adu				
	. Spoiled: Vaccine spoiled in transit 3b. Wasted: Compromised vial - broken vial, or lost vial. 5. Recalled vaccine											

## **Appendix B: Sample Temperature Log**

# Adult Vaccine Program Sample Temperature Log

			RE	EFRIC	ER	<b>ATOR</b>	TEM	PER	<u>ATL</u>	<u>JRE</u>	MC	<u> INC</u>	<b>TOF</b>	RINC	G L	<u>OG:</u>	Da	ys	<u>1-1:</u>	5							
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## **Appendix C: Off-Site Temperature Logs**

# Adult Vaccine Program Off-Site Temperature Logs



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#### Off-Site Vaccination Clinic Guidelines

Satellite, temporary, and off-site vaccination clinics play an important role in improving vaccination coverage rates and vaccinating hard-to-reach populations. Vaccination clinics held in these settings have unique challenges and providers must follow specific guidelines for managing publicly supplied vaccine in these non-traditional settings. Below is a checklist of requirements, best practices, and reference materials for your off-site vaccination clinic. Review all materials prior to conducting an off-site vaccination clinic.

#### Off-Site Clinic Checklist

Preparation
Submit your request to the Washington State Adult Vaccine Program for approval <b>before</b> using publicly supplied adult vaccines for an off-site vaccination clinic. <b>See Appendix A</b>
Ensure you have a working digital data logger with a current certification of calibration for use at the clinic. This digital data logger must be in addition to the digital data logger that is recording temperatures in your permanent storage unit.
Ensure you have all necessary materials to pack and transport the vaccines for the off-site clinic.
Transport
Vaccines must be transported using a portable vaccine refrigerator or qualified container and pack-out designed to transport vaccines within the temperature range recommended by the manufacturers (i.e., between 2–8° Celsius or 36–46° Fahrenheit for ALL refrigerated vaccines). Coolers available at general merchandise stores or coolers used to transport food are NOT ACCEPTABLE. See CDC's Vaccine Storage and Handling Toolkit for information on qualified containers and pack-outs: <a href="www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf">www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf</a> .
Use a digital data logger that meets state and CDC guidelines for public vaccine.
The person transporting the vaccines confirms manufacturer instructions for packing configuration and proper conditioning of coolants were followed. (Your qualified container and pack-out should include packing instructions. If not, contact the company for instructions on proper packing procedures.)
Ensure the total time for vaccine transport and clinic workday does not exceed 8 hours.
Storage and Handling
Ensure the cold chain is maintained at all times 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 temperatures went out of appropriate ranges, call the manufacturer to assess viability of the vaccine and notify the Adult Vaccine Program at <a href="https://www.wasauto.com/wasauto-notify">WAAdultVaccines@doh.wasauto.com/wasauto-notify</a> the Adult Vaccine Program at <a href="https://www.wasauto-notify">WAAdultVaccines@doh.wasauto-notify</a> the Adult Vaccin
Complete a Vaccine Loss Form for any wasted vaccine doses and submit the loss form to <a href="mailto:wAAdultVaccines@doh.wa.gov">wAAdultVaccines@doh.wa.gov</a> .

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov. DOH xxx-xxx December 2021.







• •		sport for Off-Site ( e-supplied vaccines only)	Clinic	
Date of Request:			PIN:	
Facility Name:				
Contact Person:			Phone Number:	
Email:				
Location of Off-Site Clinic:				
Date of Clinic:				
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Packing material used: Container/packout make/model				
Make, model & calibration expiration date of digital data logger used:				
*A type of container and supplies specifically desig through laboratory testing under controlled condit period of time. (Does not include McKesson or Mer	tions	to ensure they achieve an		
Submit form to Washington State Adult Vacci You will receive notice by email of approval. E throughout the clinic.		• • • • •		
In case of a temperature excursion, call the m	anu			
AstraZeneca (Medimmune) (800) 236-9933			GlaxoSmithKline (	
		Inc. (800) 444-2080   358-8966	Pfizer Inc. (800) 50	J5-442b
Janon i asteur (600) 622 2703 Sequins (	000	1336 6366		
DOH USE ONLY		At	pproved	] Denied

Reviewed by:

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Date:

<sup>\*</sup>Please print additional pages as needed for any upcoming clinics within a three months period.

## Adult Vaccine Program A V P

Office of Immunization | doh.wa.gov/avp | waadultvaccines@doh.wa.gov



		REFRIGERATOR OFF-SITE CLINIC TEMPERATURE MONITORING LOG															
	PROVIDER OFF-SITE L										WH.	ealth					
	Record the mi     Record vaccir     corresponds v     At the end of t     Record min/m	accine after to uring the clinure. temperatures transport fro	ine after transport to off-site clinic.  Ing the clinic by putting an X in the row that  Call the vaccine manufacture properatures reached.  1. Store the vaccine under properature was "Do not complete the vaccine manufacture properatures reached.  2. Call the vaccine manufacture properatures reached.  3. Email WAAdultVaccines@complete.								ORDING IS IN THE SHADED ZONE: r conditions as quickly as possible. Place the affected vaccine in a bag and use." s to determine whether the vaccines are viablewa.gov with the results from manufacturer. a to record the actions taken to correct the problem.						
S	Clinic Hour	Transport	Hour 1	Hour 2	Hour 3	Hour 4	Hour 5	Hour 6	Hour 7	Hour 8	Hour 9	Hour 10	Hour 11	Hour 12	End of Clinic	Transport	
Notes	Exact Time																
Z	Staff Initials																
	≥49°F (9.5°C) 48°F (8.9°C) 47°F (8.4°C)	WARNI	WARNING TOO WARM  Call the manufacturer for vaccine viability  WARNING TOO WARM													ARM	
	46°F (7.8°C)	Max:													Max:	Max:	
ø	45°F (7.3°C)																
ä	44°F (6.8°C)																
rat	43°F (6.2°C)																
be	42°F (5.5°C)											ne viability  e viability  accine Log - Co					
me	41°F (5.0°C)															\	
F	40°F (4.5°C)															1	
to	39°F (3.9°C)																
era	38°F (3.4°C)															\	
ige	37°F (2.7°C)														\	\	
Refrigerator Temperature	36°F (2.3°C)	Min:													Min: \	Min:	
8	35°F (1.7°C)							100,000		4.44							
	34°F (1.1°C) 33°F (0.6°C) ≤32°F (0.0°C)	DANGER!!!  WARNING TOO COLD  Call the manufacturer for vaccine viability  WARNING TOO COLD														OLD	
-	Please list any steps	DATE	°F /°C	Action Ta	ken: Fridg	e control	adjusted,	notified		Was	sted Vacc	ine Log - C	omplete r	eturn in t	he IIS & paper i	ncident form	
	you've taken to	you've taken to 1/1 33 1 °F DOH etc								Vaccine 7			# Doses Wasted Reason			Initials	
S	address temperature or storage unit issues										7,1						
ge	<b>.</b>																
Changes																	
2																	

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			FF	REEZE	R OFF-	SITE C	LINIC	TEMPE	RATU	RE MO	NITOR	RING LO	OG					
	PROVIDER PIN:OFF-SITE LOCATION:						DATE OF CLINIC:  CLINIC HOURS:						F°/C°		W Health			
	Write your initials     Record the min/m     Record vaccine to with the storage to the storage to the storage of the stor	me of Temp". ite clinic.  X in the row that corresponds  2. Ca 3. En			Store the va mark the Call the v Email WA	TEMPERATURE RECORDING IS IN THE SHADED ZONE: e the vaccine under proper conditions as quickly as possible. Place the affeark the vaccine as "Do not use." all the vaccine manufacturers to determine whether the vaccines are viable. mail WAAdultVaccines@doh.wa.gov with the results from manufacturer. Ise the Changes tracking area to record the actions taken to correct the pro-						ffected vaccine in a bag and						
S	Clinic Hour	Transport	Hour 1	Hour 2	Hour 3	Hour 4	Hour 5	Hour 6	Hour 7	Hour 8	Hour 9	Hour 10	Hour 11	Hour 12	<b>End of Clinic</b>	Transport		
Notes	Exact Time																	
ž	Staff Initials																	
	8°F (-13.4°C)							DA	NGEF	SIII								
	7°F (-13.9°C)	WARN	ING TO	O WAI	RM								_ UM	ARNIN	IG TOO W	ARM		
	6°F (-14.4°C)					call th	e mar	nutact	urer t	or vac	cine v	<i>y</i> iabilit	У					
	, ,	\Max:													Max:	Max:		
	4°F (-15.6°C)																	
o)	3°F (-16.1°C)															1		
'n	2°F (-16.7°C)														\	1		
rat	1°F (-17.2°C)														\	\		
)ei	0°F (-17.8°C)																	
E	-1°F (-18.3°C)	\_													1	N		
Temperature	-2°F (-18.9°C)	\													\	\		
	-3°F (-19.4°C)	\													1	\		
Freezer	-4°F (-20.0°C)	\														\		
re	-5°F (-20.6°C)	\													\	\		
-	-6°F (-21.1°C)	\													\	\		
	-7°F to -57°F	Min:													Min:	Min:		
	≤-58°F (-50°C)							DA	NGER	RIII								
		WARN	ING T	00 C	OLD) (	Call th	e mar				cine v	iabilit	WA	RNING	TOO CO	LD		
	Please list any steps									Wasted Vaccine Log - Complete return in the IIS & paper incident form								
	you've taken to address	1/1	33.1 °F DOH, etc.							Vaccine	11-14-1-1-1-1-1	Number	- CANADA CANADA	Wasted	Reason	Initials		
S	temperature or storage										. , , = = = = = =		,,					
ge	unit issues																	
an																		
Changes										l								
										<b>—</b>								