

COVID-19 Vaccine Management Plan

Vaccine Management Plan that contains the following:

Developing, implementing, and maintaining a COVID-19 vaccine management plan for routine and emergency vaccine management is strongly encouraged. We recommend that the plan be reviewed and updated annually or more frequently if changes occur, such as new employee hire, when key staff change, and/or when there are updates to best practices.

Every provider enrolled in the Washington State COVID-19 Vaccine Program is recommended to have a

	Contact information for current primary and backup coordinators			
	Provider staff roles and responsibilities			
	Documented training related to vaccine management			
	Proper storage and handling practices, and how to handle a temperature excursion			
	Shipping and receiving procedures			
	Vaccine ordering, inventory management, and procedures for handling spoiled or expired vaccine			
	Procedures for monitoring expiration dates and beyond-use dates/times			
	Emergency procedures for equipment malfunctions, power failures, or natural disasters			
Templa	ates for all the recommended Vaccine Management Plan components are available in this document.			
-	Complete and keep these templates near the vaccine storage units in a readily available location to meet this recommendation.			
Is this \	Vaccine Management Plan near the storage unit(s)? ☐ Yes ☐ No			

Provider Information and Contact Page

PIN:		
Facility Name:		
Facility Address:		
plan for routine and eme must designate a primary	rgency situations to and back up vaccin apliance. Any perso	OVID-19 Vaccine Program should maintain a vaccine management protect vaccines and minimize loss due to negligence. Each facility ne coordinator responsible for implementing the plan and nnel changes to the positions below need to be communicated by
Primary Vaccine Coordina	ator Name:	
Telephone:	Email:	
Back-Up Vaccine Coordin	ator Name:	
Telephone:	Email:	
Medical Director Name:	'	
Telephone:	Email:	
Chief Financial Officer Na	ame:	
Telephone:	Email:	

Washington State Department of Health COVID-19 Vaccine Program

(360) 236-3873

covid.vaccine@doh.wa.gov

Training and Annual Review Documentation

We encourage all staff who are involved in the storage, preparation and/or administration of COVID-19 vaccines to receive training regarding vaccine management best practices and the COVID-19 Vaccine Program's Vaccine Management Plan. All staff should sign and date this page once their training is complete.

	Training	Resources:
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- o CDC Training and Education for COVID-19 Vaccination
- o CDC Vaccine Administration Competencies Assessment

All staff should have awareness of the Vaccine Management Plan in the event of an emergency and review the plan yearly.

Employee Name (Print First and Last Name)	Moderna (Date Completed)	Pfizer (Date Completed)	Novavax (Date Completed)	J&J (Date Completed)	Vaccine Management Plan (Date Reviewed)

Vaccine Storage and Handling

Requirements

Thermometers	 Vaccine storage units must have a continuous <u>temperature monitoring device</u>. A temperature monitoring system or digital data logger (DDL) is required. 			
	 One thermometer is required for each refrigerator, freezer and ultra-cold freezer storing vaccine. 			
	 Have at least one backup temperature monitoring device in case a primary device breaks or malfunctions. 			
	☐ Thermometers must be placed in a central area of the storage unit.			
Storage Units	 □ Place a "Do Not Unplug" sign by the electrical outlet used by each storage unit. □ Place a "Do Not Break Circuit" sign on the circuit breaker and include breaker number along with contact name and phone number. 			
	 Food or drinks are not allowed in a storage unit containing publicly supplied vaccine. Do not store vaccine in the door, vegetable bins, floor, or under the cooling vents of a storage unit. 			
	□ Dorm-style storage units are NOT allowed for vaccine storage.			
	 Do not use the thermal shipper for vaccine storage after vaccine arrives at your facility. 			
Temperatures	Pfizer			
	 Stay up-to-date regarding storage and handling recommendations with the most recent <u>EUA for providers</u>. 			
	Refrigerator:			
	☐ Maintain refrigerator temperatures between <u>36° F and 46° F (2°C and 8°C</u>) and set the unit to approximately 40°F (5°C) for the best safety margin.			
	Ultra-cold:			
	☐ Maintain ultra-cold freezer temperatures between <u>- 112° F and -76° F</u> (-80°C and -60°C) and set the unit to -94° F (-70°C) for the best safety margin.			
	Moderna			
	 Stay up-to-date regarding storage and handling recommendations with the most recent <u>EUA for providers</u>. 			
	Refrigerator:			
	☐ Maintain refrigerator temperatures between 36° F and 46° F (2°C and 8°C) and set the unit to approximately 40°F (5°C) for the best safety margin.			
	Freezer:			
	☐ Maintain freezer temperatures between <u>- 58° F and +5° F</u> (<u>-50°C and -15°C</u>) and set the unit to 0° F (-18°C) for the best safety margin.			
	Novavax			
	 Stay up-to-date regarding storage and handling recommendations with the most recent <u>EUA for providers</u>. 			
	Refrigerator:			
	☐ Maintain refrigerator temperatures between 36° F and 46° F (2°C and 8°C) and set the unit to approximately 40°F (5°C) for the best safety margin.			
	Johnson and Johnson (Janssen)			
	 Stay up-to-date regarding storage and handling recommendations with the most recent <u>EUA for providers</u>. 			
	Refrigerator:			

	☐ Maintain refrigerator temperatures between 36° F and 46° F (2°C and 8°C) and set the unit to approximately 40°F (5°C) for the best safety margin.
Temperature	☐ Record Min/Max temperatures on temperature logs each day, preferably in the
Monitoring	morning.
	 □ If DDL does not display Min/Max temperatures, then record temperatures at the beginning and end of each clinic day. □ Download and review thermometer data at least once a week.

Recommendations and Best Practices

Store vaccine in its original packaging.
Store vaccine in the middle of the storage unit compartment, with space between vaccines and the
side/back of the unit.

- □ Place water bottles and coolant packs in the storage units to help stabilize temperatures, unless otherwise stated by the storage unit manufacturer.
- ☐ Install locks on vaccine storage units, and place covers on electrical outlets to avoid disconnection from power.
- ☐ Allow only authorized personnel access to the vaccine supply.
- $\hfill\Box$ Check the temperature each time vaccines are accessed in the unit.
- □ Plug vaccine storage units directly into an outlet, preferably one storage unit per electrical outlet.
- Avoid using power outlets that can be tripped or switched off, including multi-outlet power strips (unless medical grade), outlets that can be activated by a wall switch, and/or built-in circuit switches (may have a reset button).

Resource

□ CDC Storage and Handling Toolkit

Vaccine Transport

It is critical vaccine potency is always protected by maintaining the cold chain during transport of vaccines. Program guidelines for transporting vaccine and use of proper equipment must be followed when transferring, conducting off-site clinic and emergency transport.

Vaccine Transfer/Transport Equipment			
Type of Unit	Emergency Transport	Routine Transfer	Off-site Clinic
Portable Vaccine Refrigerator or Freezer	Yes	Yes	Yes
Qualified Container and Packout	Yes	Yes	Yes
Conditioned Water Bottle Transport System	Yes	No	No
Hard-sided Cooler	Yes	No	No
Manufacturer's Original Shipping Container	Yes (Last resort only)	No*	No*
Pre-approval Required	No**	Yes	Yes

^{*}The original shipping container for ultra-cold COVID-19 vaccine can be used for transport.

Vaccine Transport Requirements

Use proper vaccine transport equipment (see table).
Place the buffered thermometer probe inside the transport container with the vaccine.
Monitor vaccine temperatures during transport with a digital data logger.
Always stay with the vaccine during transport. Promptly place the vaccine into appropriate storage
units upon arrival.
When transporting vaccines in vehicles, use the passenger compartment and not the trunk.

Vaccine Transfers

Vaccine transfers increase the risk of a temperature excursion and therefore are not a recommended practice. However, for orders smaller than the minimum order size or for large organizations whose vaccine is shipped to a central depot and requires redistribution to additional clinic locations, vaccine redistribution may be allowed with proper documentation and approval.

	Before COVID-19 vaccines can be transferred a CDC Redistribution Agreement must be on file for your
	facility.
	Follow vaccine transport guidelines for transfers (see above).
	Follow the COVID-19 Vaccine Transfer Process which includes instructions to submit and receive on-
	line transfers in the WA State Immunization Information System (IIS).
f-S	ite Vaccination Clinics

Off

Submit your <u>request</u> to the COVID-19 Vaccine Program for approval 24 hours before an off-site
vaccination clinic.
Follow the Off-Site Vaccination Clinic Checklist, which includes requirements, best practices, and
reference material.
Follow vaccine transport guidelines for off-site clinics (see above).

^{**}Transporting vaccine during an emergency (e.g.: power outage) does not require pre-approval

Shipping and Receiving

Vaccine Delivery

Contact the primary coordinator, back-up coordinator, or other individuals responsible for receiving the
vaccine shipment.

- ☐ Inspect the container and contents for damage.
 - If the package and contents **ARE NOT** damaged continue unpacking.
 - If the package or contents **ARE** damaged *immediately* contact the vaccine distributor.
 - ✓ Label the vaccine **Do Not Use** and store under proper conditions.
- ☐ Open the package immediately and check the temperature indicators or shipping insert.
 - Vaccines ship with temperature indicators. Read the indicators to determine if vaccines were exposed to out of range temperatures.
 - If the indicators or shipping insert **ARE** within range/time continue unpacking and store under proper conditions.
 - If the indicators or shipping insert **ARE NOT** within range/time *immediately* contact the vaccine distributor.
 - ✓ Note the date, time, and temperature monitor reading.
 - ✓ Label the vaccine Do Not Use and store under proper conditions.
 - For additional information on specific delivery instructions for COVID-19 Vaccines see the <u>CDC</u>
 Storage and Handling Toolkit: pg.52
 - ✓ Pfizer Pg. 59
 - ✓ Moderna Pg. 60
 - ✓ Janssen Pg. 63
- ☐ Crosscheck package contents and expiration dates with the packing slip.
- □ Report any identified issues *immediately*. The vaccine distributors for the COVID Vaccine Program must be contacted the same day the vaccine arrived from the carrier.

McKesson Specialty	1-877-836-7123		
COVID-19 Vaccine Program	360-236-3873 or COVID.Vaccine@doh.wa.gov		

Receive Vaccine

☐ Enter all vaccine inventory into the IIS by receiving vaccine shipments through the Inbound Order Screen. <u>Vaccine Ordering & Receiving Guide</u>

Staff Responsible for Vaccine Receiving			
Primary			
Back up			
Other			

Ordering, Inventory Management, Reporting and Wastage

Accurate inventory management assures vaccine is available for patients when needed and prevents vaccine waste.

Ordering and Tracking Inventory

Ordering Vaccine	□ Vaccine Ordering and Receiving Guide	
Ordering Vaccine	vaccine Ordering and Necelving Guide	
Inventory	☐ Rotate stock every time an inventory is conducted so vaccine doses closest to	
Management	expiration are used first.	
	☐ Expired vaccines and diluents must be removed immediately from storage units	
	to avoid inadvertently administering them.	
	□ Vaccine Lot Number and Expiration Date Look-up Tool	
	☐ Beyond Use Date Tracking Labels	
	o <u>Pfizer</u>	
	o <u>Moderna</u>	
Inventory Capture vaccine administration data in the WAIIS within 24 hours o		
Reporting	vaccine.	
	 Reconcile your inventory in the WAIIS daily. 	
	☐ Report vaccine inventory to <u>VaccineFinder</u> weekly.	
	 Report your appointment availability to <u>WA Health</u> as needed. 	
	 Report any suspected adverse events to <u>VAERS</u>. 	
Wasted Vaccine	☐ How to Report Wastage of the COVID-19 Vaccine in the IIS.	
	□ Avoiding COVID-19 Vaccine Waste	
	☐ Remove wasted, expired, and spoiled vaccine from vaccine storage units to	
	prevent inadvertent administration to patients.	
	☐ The COVID-19 Vaccination Provider Agreement states that providers should	
	dispose of COVID-19 vaccine waste in accordance with local regulations and	
	processes currently being used to dispose of regulated medical waste.	

Resource

☐ <u>IIS Training Materials Portal</u>

Vaccine Emergency Plan

Do not risk staff safety during an emergency. Use common sense when attempting to protect vaccines. Use the following guidance for safeguarding vaccines in the event of an emergency, such as mechanical failure, power outage, natural disaster, or human error.

In an emergency, contact the following people in the order listed:

Name	Role/Responsibility	Phone #	Alt Phone #	E-mail Address		
1.						
2.						
3.						
4.						
Does the facility have a g	generator? 🗆 Yes 🗆	No If so, w	here is it located	1?		
It may be necessary to transport vaccines to an alternate storage location (e.g., a local hospital or another provider). Identify alternate location(s) that has vaccine storage units.						
Alternate Facility	Address & City	Conta	act Name	Contact Information		
Do you have a written agreement between you and your back-up facility? ☐ Yes ☐ No						
Location of Back-up Tem Monitoring Device:	Location of Back-up Temperature Monitoring Device:					
Location of Emergency Packing Supplies:						

Useful Emergency Numbers

Service	Name	Phone #	Alt Phone #	E-mail
Utility Company				
Building Maintenance				
Building Alarm Company				
Refrigerator/Freezer Alarm Company				
Refrigerator/Freezer Repair				

During an Emergency

Due to the risk to vaccines from improper packing and transporting, follow these instructions during an emergency to determine whether vaccines should be transported or sheltered in place.

Step	Description				
1.	Do not open the unit.				
2.	Place a "DO NOT OPEN" sign on vaccine storage unit(s) and leave door(s) shut to conserve cold air.				
3.	Notify the emergency contacts.				
4.	Note the time the outage started and document storage unit temperatures (CURRENT, MIN, and MAX).				
5.	Assess the cause of the power failure and estimate the time it will take to restore power.				
6.	 Take appropriate action. In the event of appliance failure: Place vaccines in an approved backup storage unit with a program compliant data logger, or transport vaccines to the designated alternate storage facility. (Refer to Vaccine Transport section for instructions.) 				
	 In the event of thermometer failure: Place backup thermometer in storage unit. Monitor and continually document temperatures until thermometer is reading temperatures within required ranges. 				
	 For power outages: Monitor storage unit temperatures. If temperatures near out of range conditions, or for outages that extend beyond the current business day, transport vaccines to the alternate storage facility. (Refer to Vaccine Transport section for instructions.) Monitor temperatures throughout transport and report any excursions. (Refer to Vaccine Temperature Excursion Guide.) 				
7.	Once power has been restored, follow the steps listed in After an Emergency section.				

Vaccine Management Plan

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After an Emergency

Follow these instructions after vaccine-related emergencies.

Step	Description			
1.	Verify power is restored and storage units are functioning properly.			
2.	Once vaccine storage unit temperatures have stabilized, notify the emergency contacts identified on the vaccine management plan.			
3.	 If vaccines were transported due to an emergency: Follow the same transportation procedures and transfer vaccine back to original storage unit. If vaccines were kept within proper temperature during the power outage, notify supervisor that the vaccines may be used. 			
4.	If vaccines were maintained within required temperatures: Remove the "DO NOT OPEN" sign from storage unit(s). Notify supervisor that vaccines may be used.			
5.	 If vaccines were exposed to out-of-range temperatures: Store vaccine under proper conditions as quickly as possible. Label affected vaccines "Do Not Use." Follow the <u>Vaccine Temperature Excursion Guide</u> and contact vaccine manufacturers to determine whether the vaccines are viable. Report incident to COVID-19 Vaccine Program at <u>COVID.Vaccine@doh.wa.gov</u> as soon as possible. 			

In case of a temperature excursion, contact the manufacturers to determine vaccine viability			
Pfize r: 800-666-7248 Jansse n: 800-565-4008			
cvgovernment@pfizer.com	jsccovidtempexcursion@its.jnj.com		
Moderna: 866-663-3762 Novavax: 844-668-2829			
Moderna Temperature Excursion Tool	www.NovavaxMedInfo.com		

COVID-19 Billing

Enrolled providers must administer COVID-19 Vaccine regardless of the vaccine recipient's ability to pay the administration fee. Providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient, but may not seek any reimbursement, including through balance billing, from the vaccine recipient. Providers cannot accept payment or donations.

Billing for Administration Fees

Medicaid Eligible	☐ Cost of vaccine: Do not bill
	□ Administration Fee: Bill Medicaid
Uninsured	☐ Cost of vaccine: Do not bill
	☐ Administration Fee: Do not bill recipient.*
Underinsured	☐ Cost of vaccine: Do not bill
	☐ Administration Fee: Do not bill recipient.*
Fully Insured	☐ Cost of vaccine: Do not bill
	☐ Administration Fee: Bill insurance, but do not bill vaccine recipient (ex. co-pay,
	balance billing)

^{*}If you have questions about covering the administration costs for patients without insurance, please reach out to covid.vaccine@doh.wa.gov. There may be opportunities for funding available.

Billing Contact Information				
Contact Name:	Phone Number:	Email		
Contact Name:	Phone Number	Email		

COVID-19 Vaccine Transfer Tracking Form

Appendix A

This form can be used as an optional resource for providers and depots during transfer of COVID-19 vaccine. Ensure that the transferring provider has a <u>Redistribution Agreement</u> approved by the Vaccine Program prior to transfer.

rate of Transfer: Courier name:					
IIS Transfer Approval Number:					
Transferring Provider Signature	: :				
Transferring Provider:				PIN	
Contact Person:				Phone Number	
Receiving Provider Signature:					
Receiving Provider:				PIN	
Contact Person:				Phone Number	
Vaccina Dackaged Cafely for Tre					
Vaccine Packaged Safely for Tra					
Vaccine transport supplies us	sed*:				
Vials upright			Ye	s 🗆 No	
Protected from light			Ye	s 🗆 No	
Secure in pack-out			Ye	s 🗆 No	
*Include make/model of qualifie	d packout or po	ortable unit			
COVID-19 Vaccines Transferred	:				
Vaccine Mfg/Presentation Lot Number from Box Beyond-Use Date Number of sup					Ancillary supplies Included
Note: Partially used vials cannot be transferred between providers.					
Vaccine Transport Temperature	s:				
Temp. of vaccine at beginning of transfer: Celsius Fahrenheit					
Temp. of vaccine at delivery: Celsius \square Fahrenheit \square					
Min./Max. during transport: Celsius Fahrenheit Fahrenheit					
Total transport time:					