# Vaccine Management Plan (VMP)

for Immunization Providers NOT currently enrolled in a public vaccine program



Facility Name:	
Initial Implementation Date:	
Responsible Staff Member for Plan Content:	
Name:	-
Title:	
Signature:	

Date Reviewed/Updated*	Signature*

\*Our facility's **Vaccine Management Plan will be up-to-date at all times.** The plan's content will be reviewed and/or updated at least once annually or as changes occur, to ensure information in this plan is the most up to date information.

A "review date" accompanied by the signature of the responsible staff member will be documented above.

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### **Trained Key Staff**

Trained Key Staff will be responsible for ensuring that all vaccines are stored and handled correctly. Facilities should appoint a secondary staff member to serve as an alternate in the event of the primary Key Staff member is absent. This is particularly important in the event of emergencies.

### **Key Staff Responsibilities**

### **Key Staff Responsibilities include, but are not limited to:**

Responsibilities listed below are only recommendations, and can be adjusted to meet the needs of your facility and staff.

- Order vaccines for the patient population served
- Oversee proper receipt and storage of vaccines
- Organize vaccines within the storage units
- Ensure that vaccine storage unit temperatures are recorded from a calibrated data logger thermometer.
- Ensure that vaccine storage unit minimum/maximum (min/max) temperatures are recorded from a calibrated data logger thermometer.
- Download and review data logger data once per week.
- Inspect storage units daily to ensure they are running efficiently and that there are no abnormal issues
- Monitor vaccine expiration dates and ensure that expired vaccine is promptly removed from the storage unit(s)
- Rotate vaccine stock based on expiration dates
- Overseeing proper vaccine transport
- Respond immediately to any temperature excursions and report any out of range temperatures to the appropriate vaccine manufacturer immediately upon discovery Vaccine Manufacturer contact information can be found

- Maintain all documentation regarding vaccine storage and handling and staff training for a minimum of three (3) years
- Maintain storage equipment records, to include any maintenance work/repairs
- Ensure that designated staff is adequately educated and trained in areas related to the Vaccine Storage & Handling Best Practices and Recommendations as described in the Storage & Handling Toolkit. The Storage & Handling Toolkit can be found on the Wyoming Immunization Unit webpage (www.immunizewyoming.com) under Healthcare Professionals>>Vaccine Storage & Handling.
- Staff training is to be documented on the Staff Training Log located in this Vaccine Management Plan (VMP): Appendix A

# **Trained Key Staff Contacts**

Contact	Name/Title	Primary Phone (cell or home)	Alternate Phone (cell or home)	E-Mail Address
Responsible Key Staff (1)				
Responsible Key Staff (2)				
Other Trained Key Staff				
Other Trained Key Staff				
Other Trained Key Staff				

# **Education and Training**

All staff members who handle or administer vaccines, including recording temperatures of vaccine storage units, should receive comprehensive training regarding proper vaccine storage and handling and vaccine administration.

- Proper training should occur:
  - during new staff orientation.
  - when program recommendations and requirements are updated.
  - when new vaccines are added to our facility's inventory.
  - > At least once annually
- Our facility should have competency checks in place to ensure staff members are skilled and proficient.
- Documentation of all training will be retained using the Staff Training Log located in our Vaccine Management Plan (VMP), Appendix A.
- \_\_\_\_\_will ensure training is completed by all (Name of Staff Member) required staff and that the training has been documented.
  - If training assistance and/or resources are needed, please contact the Immunization Unit at 307-777-7952.

# **Vaccine Storage and Handling**

Proper vaccine storage and handling is crucial to maintaining the viability and integrity of vaccines. Guidelines for vaccine storage and handling have been established to help with this process.



### Vaccine Storage Unit Requirements and Recommendations

- Pharmaceutical grade stand-alone refrigerator and freezer units are preferred for storing vaccine. Dormitory style or bar-style combined refrigerator/ freezer units are prohibited for storing vaccines under any circumstances.
- Vaccines will be placed in the center of the storage unit, and stored in their original packaging.

- Non-pharmaceutical grade refrigerators should have water bottles marked "Do Not Drink" or water filled plastic containers placed in the door, on the floor, on the top shelf, and along the walls.
- It is further recommended that pharmaceutical grade vaccine storage refrigeration units also have water bottles placed inside the unit. (UNLESS the unit manufacturer indicates that the water bottles negatively impact the functionality of the unit).
- Frozen water bottles or frozen water filled plastic containers will be placed in the freezer. Vaccine boxes are **not to touch** or be placed directly on any frozen water filled container.
- Food and/or drinks will **not** be stored in the vaccine refrigerator or freezer.
- All drawers/bins will be removed from the storage unit. If the drawers/bins cannot be removed, they will not be used and will be marked "DO NOT OPEN" to avoid accidently being left open causing the door of the unit to not close properly.
- Storage units will be plugged directly into a wall electrical outlet; storage units will not be plugged into a surge protector or power strip.
- "DO NOT DISCONNECT" signs will be placed by the electrical outlet of the storage unit(s) and on the circuit breaker. Include the circuit breaker number of the storage unit(s) as well as the name and after hour contact number of who to contact in an emergency situation.



### Refrigerator and Freezer Temperature Monitoring

- Refrigerator and freezer temperatures will be read from a calibrated data logger thermometer and recorded on the Monthly Temperature Log twice daily.
- Minimum and maximum temperatures are to be read from a calibrated data logger thermometer, once daily in the morning, and recorded on the Monthly Temperature Log.
- The most current version of the Monthly Temperature Log can be found at:
   <u>www.immunizewyoming.com</u> → Healthcare Professionals → Provider Portal

   → Forms and Reports.
- Temperature data from the data logger thermometer will be downloaded and reviewed weekly, preferably Monday.

•		will record temperatures
	( Trained Key Staff)	



### Vaccine Viability – Proper Vaccine Temperatures

- Refrigerators used to store vaccines should maintain temperatures between 2° C & 8° C. (1.9°C and below is too cold & 8.1°C and above is too warm)
- Freezers used to store vaccines should maintain temperatures between -15°
   C & -50° C.

(-14.9°C and above is too warm)

- **DO NOT** administer the vaccines if it is found that the vaccine(s) has been exposed to temperatures below 2° C or above 8° C, for the refrigerator or above -15° C for the freezer and **immediately** take the following actions:
  - Immediately store vaccines at proper temperatures.
    - If the storage unit temperature is currently in range, the vaccines can remain in the unit.
    - If the storage unit temperature is currently out of range, relocate the vaccines to the location listed on your facility's Emergency Plan. All vaccines exposed to out of range temperatures will be quarantined by placing vaccines in a bag marked DO NOT USE.
    - Immediately call the appropriate vaccine manufacturer.
- Document any action taken when responding to any storage and handling issue on the bottom of the Monthly Temperature Log in the comments section.



### **Emergency Plan**

Our Emergency Plan will be up-to-date at all times. The plan's content will be reviewed and/or updated at least once annually or as changes occur, by the responsible staff member.

A "review date" accompanied by the signature of the responsible staff member will be documented.

- In the event of refrigerator/freezer malfunction, power failure, natural disaster, or any other emergency that might compromise appropriate vaccine storage conditions, vaccines may need to be transported to an alternate location.
- Written procedures for relocation of vaccines in case of emergency (Emergency Plan) will be posted on all vaccine storage units.

•	will ensure all staff understand
(Name of Staff Member)	
the Emergency Plan and know where	it is located.

# Vaccine Storage and Handling DO's and DONT's

### **When Managing Vaccine Storage and Handling:**

### DO NOT -

- Designate only one person to be responsible for storage and handling of vaccines. At least two (2) Key Staff members should be trained
- Store vaccine in a manner that could jeopardize its quality
- Store food and drinks in the vaccine refrigerator/freezer
- Inadvertently leave the refrigerator or freezer door open or have inadequate seals
- Store vaccine in a dorm-style/bar-style/compact refrigerator/freezer for ANY length of time
- Record vaccine temperatures only once per day
- Fail to report vaccine temperature(s) on a required day(s)
- Record temperatures for only the refrigerator or freezer, rather than both
- Record temperatures from a non-calibrated, non-data logger thermometer
- Document out-of-range temperatures on vaccine temperature logs **without** reporting them to the appropriate vaccine manufacturer
- Discard multi-dose vials 30 days after they are opened.
  - o Use the vaccine package insert to follow specific vaccination discard date
- Fail to contact the appropriate person immediately to report any problem

### DO

- Store Vaccines in proper storage units
- Prepare vaccine storage units appropriately
- Take and report accurate vaccine storage unit temperatures
- Use only calibrated data-logger thermometers for monitoring and recording vaccine temperatures
- Inspect and maintain vaccine storage units regularly
- Report issues or concerns, immediately

# **Vaccine Storage Unit Maintenance**

Regular maintenance is necessary to help ensure that vaccine refrigerators and freezers work properly. If a storage unit is not working properly, appropriate action should be taken.

- At least once a month the storage units will be inspected and maintained to include:
  - Cleaning the inside of the refrigerator and freezer by wiping the inside and shelves with disinfectant or antibacterial wipes.
  - If accessible without moving the unit, cleaning the coils on the back of the unit and underneath the unit by using a duster or vacuum to remove any visible dust.
  - Checking the door seals by examining them to make sure that they are not torn or brittle. There should be no gaps between the seals and the body of the unit, when the doors are closed.
  - If frozen vaccines are stored in a manual defrost freezer, it will be defrosted regularly and as needed to avoid having frost build up in the unit.
    - During defrost, the vaccines will be moved to the backup storage unit with the backup data logger thermometer until the unit has been completely defrosted and the unit's temperature is stable and in acceptable range.

\*Do not unplug the unit or remove vaccines from the unit during cleaning. If the unit needs to be unplugged or moved for any reason, relocate the vaccines with the backup data logger thermometer to the backup unit **prior** to doing so.

- A unit may require additional maintenance or repair if:
  - Unit remains too warm or too cold after thermostat has been adjusted
    - All adjustments will be documented on the temperature log associated with the unit.
  - A unit is making noises that are not normal or louder than normal
    - A refrigerator/freezer repair company will be called right away.
    - Repair company contact information can be found on page 10 of our VMP.

# **Important Contacts**

Resource	Contact Person Name/Title	Phone Number	E-Mail/Web Address
Refrigerator Repair Company			
Freezer Repair Company			
Thermometer Company			
Power Company			
Temperature Alarm System Company (if applicable)			
Generator Company (if applicable)			
Vaccine Manufacturer (company name)			
Vaccine Manufacturer (company name)			
Vaccine Manufacturer (company name)			
Vaccine Manufacturer (company name)			
Vaccine Manufacturer (company name)			
Vaccine Manufacturer (company name)			

# **Vaccine Storage Unit Specifications**

Type of Unit (e.g. stand-alone freezer)		
Brand		
Model Number		
Serial Number		
Date of Purchase/Put in Use		
Location at Facility		

# **Data Logger Thermometers**

<b>Unit</b> (e.g. Primary Freezer, Back up Freezer, etc.)	Initial Date of Calibration Certificate	Renewal Date of Calibration Certificate (Two years from the initial date of calibration)	Responsible Facility Contact

# **Inventory Control**

•		will be responsible for managing vaccine inventory.
	(Trained	Key Staff)
•	Α	_supply of vaccine will be kept at all times.
	(# of months)	

- Short-dated vaccines (vaccines close to expiration) will be placed in front of longer dated vaccines and used first.
- If short-dated vaccines are discovered that are not able to be used prior to the expiration date, attempts should be made to avoid vaccine wastage.

# **Vaccine Ordering**

(Trained Key Staff) maintaining appropriate vaccine stock	will be responsible for ordering and a second control of the contr	vaccines and
Vacci	ine Deliveries	
Vaccines shipments are signed for by_	(Name of Staff Member	.1
Staff member responsible for signing r	` , , , , , , , , , , , , , , , , , , ,	•
	for storage*.	

\*The staff member responsible for placing the vaccines in the storage unit will also need to:

(Trained Key Staff)

- 1. Examine the shipping container and vaccines for signs of damage
- 2. Cross-check the contents of the shipment with the packing slip to be sure they match
  - For frozen vaccines, the packing list will show the maximum time vaccines can be in transit based on shipment date.
  - If there are discrepancies between the contents and the packaging list or other concerns about the contents, immediately notify the vaccine manufacturer.
- 3. Determine if the shipping Temp Monitor was triggered and showing any signs of the vaccine temperature going out of range
- The Key Staff Member receiving the delivery will place vaccines in the proper storage unit making sure vaccines with shorter expiration dates are placed in front of vaccines with longer expiration dates.
  - Check both vaccine and diluent expiration dates to ensure you have not received any expired or soon-to-expire products.
    - If the shipment includes lyophilized (freeze-dried) vaccines, make sure they came with the correct type and quantity of diluents. (Diluents for varicella-containing [frozen] vaccines are stored in a separate compartment in the lid of the shipping container and should be stored separately in the refrigerator).

### **Vaccine Waste**

	(how your office will discard non-viable or expired vaccine)
	will be
	storage unit(s), place it in a bag or box marked DO NOT USE. Non-viable or expired vaccine
•	Immediately upon determining that vaccine is non-viable or expired, remove it from the

# **Transporting Vaccines**

### **Vaccine Transport:**

- Vaccine transports cannot exceed two (2) hours total one-way.
- CDC discourages regular transport of vaccine. Proper management of vaccine inventory plays a major role in preventing the need to transport vaccines.
- Shipping vaccine is strictly prohibited.
- It is critical that vaccine viability is protected by maintaining proper vaccine storage temperatures at all times during any vaccine transport.
- Use properly insulated containers to transport vaccine. These containers should be validated to ensure they are capable of maintaining the vaccine at the correct temperatures. Alternatively, hard-sided, plastic, insulated containers with at least 2-inch thick walls may be used, as well as portable refrigerator/freezer units.
- Temperatures will be monitored using a calibrated data logger thermometer with a valid certificate of calibration when transporting vaccines.
- Pack enough refrigerated/frozen conditioned water bottles to maintain the cold chain<sup>1</sup>. Do
  not use loose or bagged ice or dry ice. The number and placement of refrigerated/frozen
  water bottles/water filled plastic containers inside the insulated container will depend on
  container type, size, and outside temperature.

<sup>&</sup>lt;sup>1</sup> The vaccine cold chain is a temperature-controlled environment used to maintain and distribute vaccines in optimal condition. The cold chain begins with the cold storage unit at the manufacturing plant, extends through transport of vaccines to the distributor and delivery to and storage at the provider facility, and ends with administration of vaccine to the patient. Appropriate storage and handling conditions will be maintained at every link in the cold chain.

- Place an insulating barrier (e.g., bubble wrap and corrugated cardboard) between the refrigerated/frozen conditioned water bottles/water filled plastic containers and the vaccines to prevent accidental freezing.
- The contents of the container should be layered as follows, starting from the bottom:
  - 1. refrigerated/frozen conditioned water bottles/water filled plastic containers
  - 2. barrier
  - 3. vaccine
  - 4. calibrated data logger thermometer buffered probe
  - 5. barrier
  - 6. refrigerated/frozen conditioned water bottles/ water filled plastic containers
- Pack vaccines in their original packaging and place on top of the barrier. Do not remove vaccine vials from boxes or pre-fill syringes in advance.
- If you must transport vaccines in a personal vehicle (non-commercial) rather than a vehicle used only for the purpose of transporting(commercial), use the passenger compartment—not the trunk.
- When transporting vaccine from the office, temperatures must be monitored using a
  calibrated data logger. It is recommended that you review the temperatures once per hour
  at a minimum to ensure the temperatures are within appropriate range the vaccine is safely
  stored in a vaccine storage unit.
  - When using an on-site vaccine storage unit with your back-up data logger, temperatures should be read and recorded a minimum of 2 times during the workday.
  - If vaccines cannot be stored in an on-site storage unit, temperatures must continue to be reviewed hourly to ensure the container is maintaining appropriate temperatures.

### **Vaccine Transport Supplies**

Coolers/Packing Materials	Location at Our Facility	Ordering Information (Company Name and Phone Number)
Portable Refrigerator/ Freezer Units		
Insulated Coolers/Containers		
Insulating Barrier (e.g., bubble wrap and corrugated cardboard)		

Conditioned Water Bottles/ Water Filled Plastic Containers	
Frozen Water Bottles/ Water Filled Plastic Containers	
Backup Calibrated Data Logger Thermometer(s)	
Flashlights	
Plastic Storage Bags (baggies)	
Permanent Markers	

# **Administering Vaccines**

### **Lyophilized (Freeze-Dried) Vaccines:**

A lyophilized vaccine may be a powder or a pellet that must be reconstituted with a diluent prior to administration. After a vaccine is reconstituted its shelf life varies by product. Refer to the FDA's package inserts found at <a href="https://www.immunize.org">www.immunize.org</a>.

- Doses of diluents that come with lyophilized (freeze-dried) vaccines should be documented on a separate stock record. Quantities of vaccines and their corresponding diluents should be equal at all times.
- Liquid diluents vary in volume and composition, and are specifically designed to meet volume, pH (acid/alkaline balance), and chemical requirements of their corresponding vaccine. Diluents are NOT interchangeable unless specified by the manufacturer. Use only the specific diluent provided by the manufacturer of the vaccine you are reconstituting.
- Even if the diluent is composed of sterile water or saline, use only the diluent supplied with the vaccine to reconstitute it. Never use a stock vial of sterile water or normal saline to reconstitute vaccines.
- Never administer vaccine reconstituted with the wrong diluent.
- Check expiration dates on both the vaccine and the diluent.
  - ➢ If vaccine has already been administered prior to realizing diluent was expired and/or the incorrect diluent was used for reconstitution, contact the appropriate vaccine manufacturer immediately.

- Reconstitute vaccine immediately prior to administration.
- After reconstitution, observe the vaccine for color and appearance. If the vaccine cannot be suspended or does not look as described in the product information, label the vial "DO NOT USE", and store it under appropriate conditions separate from other vaccines. Immediately call the Immunization Unit for further guidance. Administer the vaccine soon after reconstitution to minimize the risk of reduced potency.

### **Single-Dose Vaccine Vials:**

A single-dose vial (SDV) contains ONE dose and should be used ONE time for ONE patient.

- Do not combine leftover vaccine from one SDV with another to obtain a dose.
- Do not open a SDV until ready to use.
- Before you remove the protective cap, always check the vial to make sure you have the correct vaccine.
- Once you remove the cap, vaccine should be used because it may not be possible to
  determine if the rubber seal has been punctured. Discard any unused SDVs without a
  protective cap at the end of the workday.
- DO NOT pre-draw vaccines before they are needed.

#### **Multi-dose Vaccine Vials:**

A multi-dose vial (MDV) contains more than one dose of vaccine. Because MDVs typically contain a preservative to help prevent the growth of microorganisms, they can be entered or punctured more than once.

- Only the number of doses indicated in the manufacturer's package insert should be withdrawn from the vial.
- After the maximum number of doses has been withdrawn, the vial should be discarded, even if there is residual and the expiration date has not been reached.
- MDVs can be used until the expiration date printed on the vial unless the vaccine is contaminated or compromised in some way or there is a beyond use date (BUD) noted in the package insert.
- Never use partial doses from two or more vials to obtain a dose of vaccine.
- Remove the cap and draw up the vaccine immediately before administration.
- Whenever possible use all vaccine in one multi-dose vial before opening another.

#### **Pre-filled Syringes**

A pre-filled syringe (PFS) is prepared and sealed under sterile conditions by the manufacturer. Do not activate a PFS (i.e., remove the syringe cap or attach the needle) until ready to use. PFSs do not contain a preservative to help prevent the growth of microorganisms.

 Once the sterile seal has been broken, the vaccine should be used or discarded at the end of the workday.

### **Pre-drawing Vaccines:**

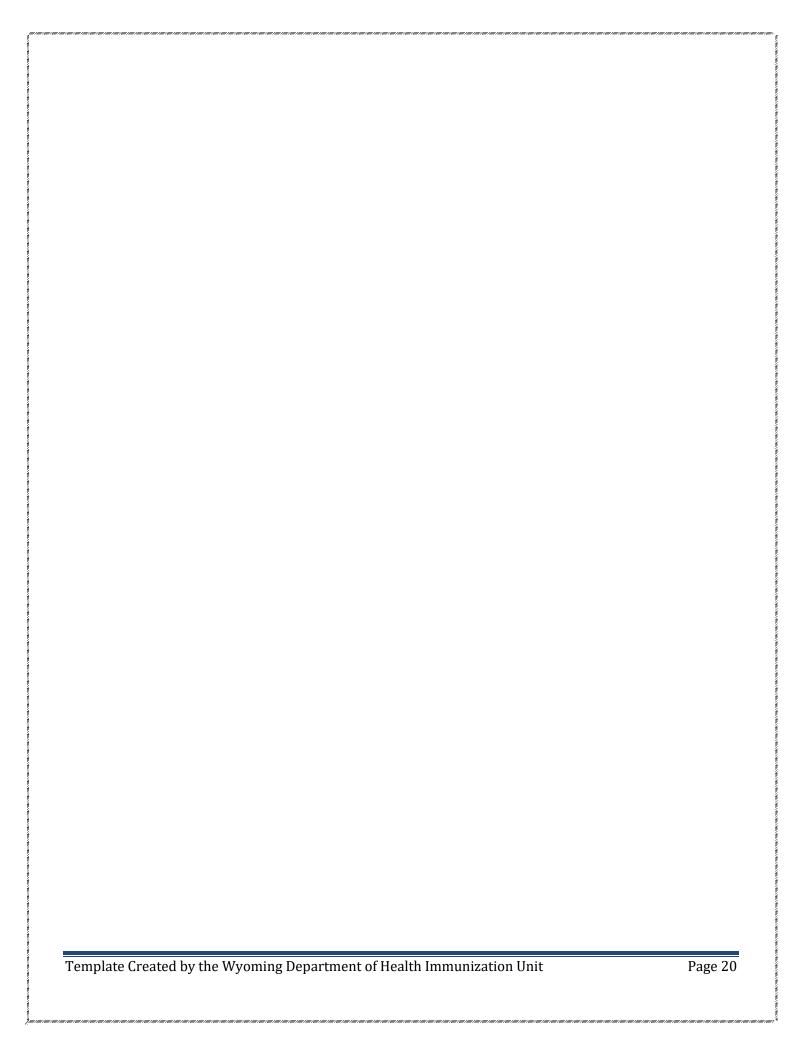
- Pre-drawing vaccines is generally discouraged, however, a limited amount of vaccine doses
  may be pre-drawn in a mass immunization setting IF the following procedures are followed:
  - > Set up a separate administration station for each vaccine type to prevent medication errors.
  - Do not draw up vaccines before arriving at the clinic site. Drawing up doses hours or even days before a clinic is not acceptable.
  - Each person administering vaccines should draw up no more than one MDV, or 10 doses, at one time.
  - Monitor patient flow to avoid drawing up unnecessary doses.
  - Discard any remaining vaccine in pre-drawn syringes at the end of the workday.
  - > Do not pre-draw reconstituted vaccine into a syringe until you are ready to administer it.
    - If not used within 30 minutes of being reconstituted, follow manufacturer guidance for storage conditions and time limits. A manufacturer may specify that an unused reconstituted vaccine can only be stored in the vial for the indicated time.
    - Never transfer pre-drawn reconstituted vaccine back into a vial for storage.

# **Immunization Unit Contacts**

Area	Immunization Unit Contact	Phone Number
Vaccine Storage & Handling	Client Support Specialist	307-777-8503
Public Vaccine Program Enrollment and Changes to Named Staff	Client Management Specialist	307-777-5043
Clinical Services and Information	Clinical Specialist	307-777-8981
Wyoming Immunization Registry (WyIR) and Public Vaccine Program	Immunization Access Manager	307-777-2413
WyIR Interoperability	Interoperability Specialist	307-7775960
Immunization Unit	Main Line	307-777-7952

Material in this guide was referenced from:

U.S. Department of Health and Human Services. Center for Disease Control (2018). Vaccine Storage and Handling Tool Kit.



### **Staff Training Log**

This log sheet can be used to track annual training of  $\underline{\textit{all}}$  staff\*.

Facility Name:

Name of Person who Completed the Training	Date of Training	Name/Type of Training (Training related to Storage & Handling best practices)	Name of Person or Organization that Conducted the Training

<sup>\*</sup> All staff members who handle or administer vaccines, including recording temperatures of vaccine storage units, should receive comprehensive training regarding proper vaccine storage and handling and vaccine administration at least annually.