

Vaccine Management Plan (VMP)

For Immunization Providers currently enrolled in a public vaccine program

Why?

When?

Who?

How?

What?

Where?

Facility Name: _____

Initial Implementation Date: _____

Responsible Staff Member for Plan Content:

Name: _____

Title: _____

Signature: _____

Date Reviewed/Updated*	Signature*

Our facility's **Vaccine Management Plan must be up-to-date at all times. The plan's content must 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 must be documented above.

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Vaccine Coordinators & Trained Key Staff

**Our facility is required to have at least two Vaccine Coordinators who are responsible for the management of the Public Vaccine Program(s).*

**Any changes in Vaccine Coordinators or key staff as it relates to the vaccine program will be reported to the Immunization Unit.*

Vaccine Coordinator Responsibilities

Responsibilities of Vaccine Coordinators include, but are not limited to:

- Order all Advisory Committee on Immunization Practices (ACIP) recommended 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 a minimum of twice each day, except weekends, state holidays, and office closures communicated to the Immunization Unit
- Ensure that vaccine storage unit minimum/maximum (min/max) temperatures are recorded from a calibrated data logger thermometer. This must be done once per day, in the morning, except weekends, state holidays, and office closures communicated to the Immunization Unit
- Download and review data logger data once per week; preferably Monday morning
- Inspect storage units daily to ensure they are running efficiently and that there are no abnormal issues such as doors left ajar, item(s) blocking unit air circulation vent(s), placement of data logger probe within unit
- Rotate vaccine stock based on expiration dates
- Monitor expiration dates and ensure that expired vaccine is promptly removed from the storage unit(s)
- Respond immediately to any temperature excursions and reporting any out of range temperatures to the Immunization Unit immediately upon discovery at 307-777-7952

- Oversee proper vaccine transport
- Maintain all documentation regarding vaccine storage and handling and staff training for a minimum of 3 years
- Maintain records, including public vaccine program eligibility screening and documentation for a minimum of 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 Program and that the training is documented on the Staff Training Log located in the VMP: Appendix A
- Reporting any changes in key staff to the Immunization Unit as soon as the change is known

Vaccine Coordinator Contacts

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

Education and Training

Both Vaccine Coordinators are required to be trained on Public Vaccine Program requirements including proper storage and handling of vaccines at least annually.

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

- 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 accidentally 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: www.immunizewyoming.com → 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
(Vaccine Coordinator or 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:
 - Quarantine exposed vaccine by placing vaccine in a bag marked “Do Not Use”.
 - 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, using your backup data logger thermometer to document vaccine temperatures.
 - Immediately call the Immunization Unit at 307-777-7952 for further instructions.
- 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.
- _____ is required to ensure all
(Name of Staff Member)

Staff understand 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. Each facility should have at least two (2) Vaccine Coordinators.
- 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 Immunization Unit.
- Discard temperature logs at the end of every month instead of keeping them for three (3) years.
- Discard multi-dose vials 30 days after they are opened.
 - 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
- Document 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
- Keep Temperature Log records for no less than three (3) years
- 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
 - Thermostat should only be adjusted when directed by Immunization Unit Staff.
 - All adjustments must 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 must 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 <i>(if applicable)</i>			
Generator Company <i>(if applicable)</i>			
Other:			

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

Unit (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.
(Vaccine Coordinator or Trained Key Staff)
- A three (3) month supply of vaccine will be kept at all times, unless otherwise arranged with the Immunization Unit.
- Vaccine inventory must be reconciled and submitted every 30 days AND, prior to placing a vaccine order or transfer.
- 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 transfer vaccines to another Public Vaccine Program provider for use to avoid vaccine wastage. For further guidance contact the Immunization Unit at 307 777-7952.

Vaccine Ordering

- _____ and _____ will be responsible for ordering vaccines and maintaining appropriate vaccine stock.
(Vaccine Coordinator) (Vaccine Coordinator)
- Providers are required to place vaccine orders in the WylR using the Vaccine Order Management System (VOMS). Vaccine can be ordered every month as needed between the 1st and 5th (regardless of weekends/holidays).
- Temperature logs will be submitted to the Immunization Unit each month, between the 1st and 5th, by email: wdh.pvpreporting@wyo.gov or by fax: 307-777-2913.
 - Vaccine orders will not be reviewed or approved until our Temperature Log has been submitted to the Immunization Unit.

Vaccine Deliveries

- Vaccines shipments are signed for by _____
(Name of Staff Member)
- Staff member responsible for signing receipt of vaccine will immediately take vaccines to _____ for storage*.
(Vaccine Coordinator or Trained Key Staff)

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

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 Immunization Unit.**
 3. Determine if the shipping Temp Monitor was triggered and showing any signs of the vaccine temperature going out of range
- The Vaccine Coordinator or other trained staff member 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.

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 must 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 chain¹. 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.
- 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

¹ *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 must be maintained at every link in the cold chain.

- 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 an **approved** 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.
 - Any out of range temperatures must be reported to the Immunization Unit immediately.

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 www.immunize.org.

- 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 Immunization Unit immediately at 307-777-7952.**
- 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, you must use the vaccine 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	307-777-5960
Immunization Unit	Main Line	307-777-7952

Staff Training Log

This log sheet can be used to track required annual training for Vaccine Coordinators and other key staff.*

Facility Name: _____

PIN: _____

Name of Person who Completed the Training	Date of Training	Name/Type of Training (e.g. Site Visits, Vaccine Coordinator Training Program(VCTP) Online Modules, Training w/ Immunization Unit Staff, CDC training, or any additional training as it relates to public vaccine program requirements)	Name of Person or Organization that Conducted the Training

**Both Vaccine Coordinators are required to be trained on VFC Program Requirements including proper storage and handling of vaccines at least annually. All staff members who handle or administer vaccines, including recording temperatures of vaccine storage units, should also receive comprehensive training regarding proper vaccine storage and handling and vaccine administration at least annually.*