VERMONT
DEPARTMENT OF HEALTH

Vaccine Storage and Handling Standard Operating Procedures (SOP)

(Revised January 2025)

Vermont Immunization Providers

This Vaccine Storage and Handling SOP is based on the CDC Vaccine Storage and Handling Toolkit and "You Call the Shots" webinars. It provides information for proper management of publicly-funded vaccine. Use of this template assures that vaccine is managed according to VCVP/VAVP and Vermont Immunization Program requirements. Post these guidelines near your storage unit where they can be easily accessed. All office staff should be aware of this plan.

Date SOP Reviewed	Date YCTS: VFC and S&H Reviewed	Name & Credentials

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Practice Name _____

PIN# _____

Vaccine Coordinators (see page 3)		
Name	**Title (e.g. RN, MA)**	**Home and/or Cell Phone**
Vaccine Coordinator:		
Backup Coordinator:		
2nd Backup Coordinator (*optional*):		

Alternate vaccine storage location (see page 4)	
Location name	
Location address	
Phone	
Primary contact person off-hours	Name: Phone:

Regional Immunization Specialist	
Name	
Phone number	
Email address	

Supplies Needed to Transport Vaccine	
Supplies	**Location on Site**
Hard sided cooler	
Frozen water bottles	
Cardboard and bubble wrap	
LogTag Data Logger (see page 13)	

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Person Completing This Form	
Date of completion	
Your Name	
Title	
Your Signature	

Abbreviations:

ACIP: Advisory Committee on Immunization Practices
BUD: Beyond Use Date
MMR: measles, mumps, and rubella vaccine
MMRV: measles, mumps, rubella, and varicella vaccine
VDH: Vermont Department of Health
VCVP: Vermont Child Vaccine Program
VAVP: Vermont Adult Vaccine Program
VIMS: Vaccine Inventory Management System

To view this document on the web, with a smart phone camera application open, point the lens at the included QR code and click pop-up.

Thank you to all healthcare staff for your unwavering dedication to providing safe and effective vaccines to the communities you serve. Over the last few challenging years, your resourcefulness, creativity, and resilience have been nothing short of inspiring. As we look ahead, we recognize that there may still be difficult times to navigate, but your commitment to the health and well-being of your communities gives us confidence that we can face these challenges together. Please don't hesitate to reach out to our program—your partnership and feedback are vital as we continue this important work.

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I. Rationale

Providers enrolled in the Vermont Children's Vaccine Program (VCVP) and/or Vermont Adult Vaccine Program (VAVP) are entrusted with publicly funded vaccine and must ensure viability. Vaccines that are not stored under required conditions may be ineffective at producing an immune response. In 2024, the value of vaccine distributed to VCVP and/or VAVP enrolled practices in Vermont was valued at more than $26,800,000.

II. Vaccine Emergency Management

A. Temperature excursions

If you experience a temperature excursion, defined as any period outside the recommended temperature range, contact the Immunization Program by phone at 802-863-7638 or email AHS.VDHImmunizationProgram@vermont.gov. This inbox is monitored during regular business hours (7:45 am - 4:30 pm Monday through Friday) outside Vermont State Holidays.

- Label vaccine "Do Not Use" and await guidance.
- Correct obvious problems. For example, if the door is ajar – close it.
- **Do not move the vaccine without approval.**
- Do not make assumptions about vaccine viability.
- Do not adjust the temperature control, add ice packs, or otherwise attempt to cool a refrigerator.
- Once an issue is resolved, acknowledge the alarm in Senso and note all actions taken.

After Hours
802-863-7240
Option 2

If it is after hours and you need to use the vaccine before the next business day, dial the above number to reach an on-call staff member. Otherwise, wait until the next business day.

Failure to seek and follow VDH guidance for vaccine storage & handling or transport may result in vaccine loss.

Contact the Immunization Program before maintenance or repair to monitored units

Never transport vaccine unless authorized by Immunization Program Staff. Vaccine stored in the freezer is NOT usually transported.

B. Alternate storage location

- Alternate locations are used in the event of a mechanical or power failure and must have a generator.
- **Permission from the Immunization Program is always required before moving state-supplied vaccines, even to your alternate storage location.**

Alternate locations must have a backup generator, be enrolled in the state program, and be monitored with a state-supplied device. This location will likely be either your local hospital (if enrolled) or your Local Health Office.

C. Emergency plan for a power outage

NEVER move vaccines to a home, another storage unit, or even an approved location without permission from the Immunization Program. It is often better to leave the vaccine during a power outage than move it. If the building has lost electrical power, check with the building maintenance or the power company to learn if there is an estimate for the restoration of power.

➢ During a short-term power outage

- Do not open the refrigerator or freezer door until the power outage is resolved and the temperature inside the unit is within the normal range.
- If the outage occurs during business hours, note the time of the power failure.
- Once power is restored, note the time and monitor temperatures (until it reaches 2 to 8°C for the refrigerator, -50 to -15°C for the freezer).
- Determine if the temperature has been out of range; if yes, contact the Immunization Program.

Wi-Fi will likely be lost during a power outage, so you are not getting real-time data online. Use paper temperature logs until the data has been downloaded to the cloud and reviewed.

➢ During a long-term power outage

- Do not open the refrigerator or freezer door unless approval is requested and received to transport vaccines to the backup location.
- If instructed to move your vaccines, contact the receiving location to ensure they have storage. If they do not have power or enough space, contact the Immunization Program for assistance.
- Follow the CDC instructions for packing and transporting vaccines

III. Roles and Responsibilities

A. Vaccine coordinators

Designate a Primary Vaccine Coordinator and at least one Backup Vaccine Coordinator to manage all aspects of state-supplied vaccine, as described in this plan. Both contacts should be knowledgeable about vaccine management and capable of fulfilling all vaccine storage and handling requirements.

Updating Vaccine Coordinators: When the Primary Vaccine Coordinator or the Backup is changed, complete the Contact Update Form

- Located on the main VFC/VFA page where you would locate the enrollment forms: Vermont Child Vaccine Program / Vermont Adult Vaccine Program | Vermont Department of Health

Training: The Primary Vaccine Coordinator and Backup Vaccine Coordinator must complete the following training *annually* if they did not receive a VCVP/VAVP compliance site visit for the calendar year or if they were not present for the duration of the site visit.

- You Call the Shots: Module 10, Storage and Handling
- You Call the Shots: Module 16, Vaccines for Children Program (VCVP providers only)

Follow these You Call the Shots to complete the training and obtain the certificate of completion which should be sent to the immunization program.

In the works: The Immunization program is creating Vermont-specific training through a learning management system (LMS) that will replace the CDC You Call the Shots Training. There is no timeline yet for implementation, but communication will be forthcoming, hopefully this calendar year (2025).

B. Other staff

All staff with vaccine storage and handling responsibility should read and sign (on the cover page) this Vaccine Storage and Handling SOP annually *and* when changes are made to the plan.

It is the responsibility of the Primary and Backup contacts of the program to disseminate Immunization Program communication and training opportunities to appropriate staff.

IV. Storage and Handling-Best Practices

A. Unit approval

Prior to storage of vaccine, unit(s) *MUST be inspected by Immunization Program staff and have at least 72 hours of in-range temperatures*, as monitored by a data logger supplied by the Immunization Program.

The CDC strongly recommends stand-alone refrigerators and freezers.

Refrigerators:

- Refrigerator temperature must be maintained **between 2°C and 8°C** (36°F and 46°F).
- Only the refrigerated part may store the vaccine if using a combination unit, stand-alone units are preferred.
- **Never Permitted:** Dormitory combination refrigerator/freezer units outfitted with one exterior door and an enclosed freezer compartment.
- The unit should have enough room to accommodate the largest inventory of the year – typically during respiratory virus season (or back-to-school) – without overcrowding.

Freezers:

- Freezer temperatures must be maintained **between -50°C and -15°C** (-58°F and +5°F).
- **Never Permitted:** Freezers in combination units, all freezers should be stand-alone units.
- Freezers are recommended to be auto-defrosting or self-defrosting.

Use this guide when purchasing a unit: VVP Refrigerator and Freezer Guide

B. Vaccine storage

Do Not Store Vaccine:

- In any unapproved or unmonitored unit.
- In any unit which also stores food.
- In the door, crisper drawers, or space created by removing the crisper bins.
- On the floor of the unit.
- Near a cooling fan or vent.
- Below other biologicals or medications.

Storage Best Practice:

- At least 2-3 inches away from the walls, floor, and cooling coils.
- As centrally as possible.
- In original packaging to protect from light
- With airflow between each large package, block, tray, or bin.
- Organize units with labeling (pediatric/adult, private purchase/state supplies) and mesh-sided containers (for airflow)
- Water bottles marked "Do Not Drink" can be placed in the door or on the floor as a thermal buffer. If possible, condition water bottles before adding them.
    a. Ice packs are not allowed as a thermal buffer and should never be stored in the refrigerator.

Required: A "Do Not Disconnect" notice must be posted next to every outlet where a vaccine freezer or refrigerator is plugged in AND on or near the corresponding circuit breaker. **Stickers are available from the Immunization Program upon request.**

C. Vaccine transport (transfers)

All vaccine transport must be pre-approved by the Vermont Immunization Program

Transport involves vaccine movement over a short time frame and distance between enrolled providers. This transfer refers not to clinics but moving vaccines from practice to practice to reduce waste or in an emergency. Practices should always be prepared for the need to move vaccines with the below supplies.

Don't forget to transport the corresponding diluent

Frozen vaccines should never be transported except in an emergency and with prior approval.

Supplies each practice must have on-site to transport vaccines safely:

- Hard-sided or Styrofoam cooler (do not use soft-sided coolers)
- Backup data logger (see section G)
- Frozen water bottles (these need to be conditioned before packing)
  - Icepacks are not appropriate for transport.
- Insulating materials such as corrugated cardboard and bubble wrap (enough for two layers per container)

Follow instructions on Packing Refrigerated Vaccines for Transport

Instructions for packing/transporting frozen vaccines will be provided during transfer approval from the Vermont Immunization Program.

Never place vaccine directly on conditioned water bottles

D. Offsite clinics

To ensure vaccine viability, you must select a suitable storage option for offsite clinics and monitor the temperatures continuously with a LogTag data logger. **Hard-sided or Styrofoam coolers are not appropriate storage for offsite clinics.**

Frozen only vaccines are **never allowed** at off-site Clinics

Suitable storage includes:

- Vaccine carriers with phase change panels: any location planning an offsite clinic may borrow one of these coolers from the Immunization Program. Request at least 10 business days before your clinic. If interested in learning more, email AHS.VDHImmunizationProgram@vermont.gov.
- Portable vaccine storage units: Portable units are available to purchase privately.

Vaccine Carrier Borrowing Program
Offsite Clinic Guidance
TempArmour Assembly Guide
* These links can all be found on the Vaccine Storage and Handling Page

The total time for transport, including the clinic day, should never extend past 8 hours. *Example:* Clinic location is 1 hour away the clinic day should last a maximum of 6 hours.

E. Temperature monitoring

- **Thermometers:** Storage unit temperatures must be continuously monitored using data loggers purchased and installed by the Vermont Immunization Program.
- **Placement:** The probe in the glycol bottle must be placed centrally in the storage unit.
- **Calibration:** Vaccine thermometers must have a current certificate of calibration. The Immunization Program is responsible for recalibration services.
- **Malfunction:** If a data logger malfunctions, call the Immunization Program immediately.
- **Monitoring:** At the ***start of each clinic day,*** document min/max temperatures
    - If using Senso: log into the SensoScientific cloud system, check off each vaccine storage unit, and click "Audit Node." This action time stamps the min/max and "signs" with the associated login account.
    - If using backup LogTag Data logger: Min/Max, time, and initials must be documented on paper temperature logs.

F. SensoScientific

The Immunization Program provides Senso Scientific devices for any unit permanently storing state-supplied vaccines. Logins are available to any member of your staff who may be tasked with doing daily temperature audits (see Section E: Monitoring) by emailing the main inbox.

Senso Scientific Login: https://cloud.sensoscientific.com/

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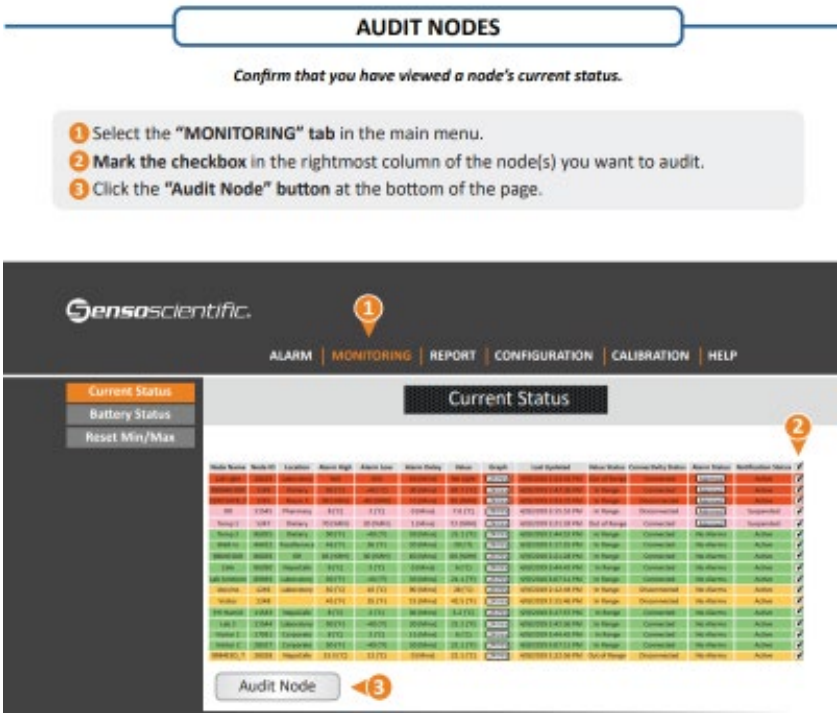
Audit Node: The CDC requires daily documentation of temperatures, even when using a continuous data logger like a SensoScientific device. These checks provide an early indication if problems arise with your unit. Additional safety checks ensure that any temperature excursions recorded by the SensoScientific device are promptly addressed by practice staff.



Senso Scientific Alarms:

Signal Alarm

Lost internet connection, No action is required for short time frame it will reconnect and upload information. If out for more than 4 hours, use paper temperature logs and contact the immunization program.

Data Alarm

Temperatures are out of range mark all vaccines in the unit "Do Not Use" and call the immunization program to work on viability

Battery Alarm

Batteries in the senso are running low, the senso should be plugged into the wall and not running off the battery, contact your regional specialist.

Do not confirm the alarm until the issue has been resolved or the maximum 3-alarm notification will start again flooding your inbox/call/text with additional notifications.

G. LogTag data loggers – Back-up

Backup LogTag data loggers are required for the following:

- When a Senso device malfunctions
- All vaccine transport
- Offsite vaccination clinics.

The Vermont Immunization Program provides backup data loggers to all VCVP/VAVP enrolled practices, and the second page of this document should have the device location documented. For additional data loggers, contact the Immunization Program.

- Ensure at least one computer has the current logtag software – Cannot be downloaded to an Apple device such as a MacBook.
- For more information, see the LogTag Data Logger Device User Guide.

Backup data logger setup before use:

1. Condition the glycol bottle to the appropriate temperature by placing it in the fridge/freezer.

Tip: if space allows, leave the glycol bottle in the fridge, so it is always ready for use.

2. Once in range, you may package the vaccine according to instructions.
3. Transport the vaccine.
4. If the data logger stays in range for the entire length of transport or clinic, no further communication with the program is needed.

If the data logger goes out of range during transport OR it was never able to get into proper range due to time constraints, you **MUST contact the program** and report this as a temperature excursion.

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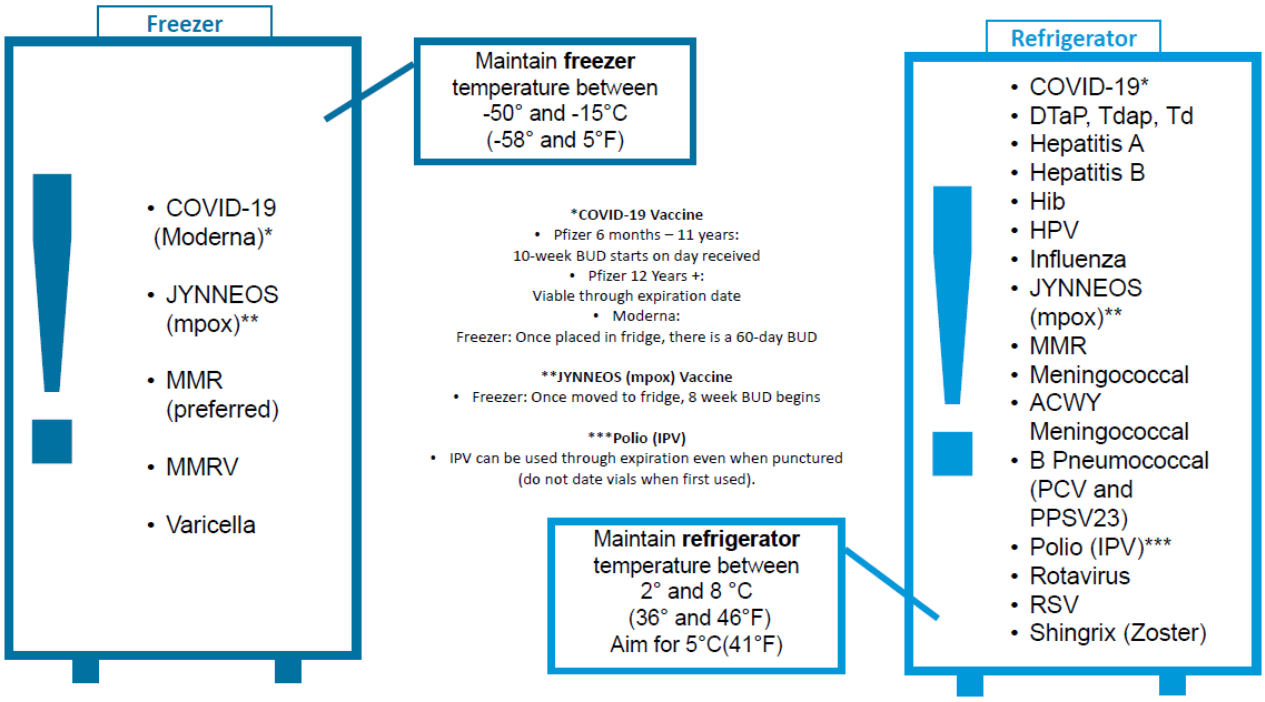
H. Permanent Storage Temperatures



I've included this graph to provide the most current information available. However, please note that it is subject to change, and it is your responsibility to stay updated on all relevant details.

Diluent

- Diluents that are packaged with their vaccines (e.g. ACTHIB, Rotarix) must be stored in the refrigerator and should not be separated from the vaccine with which they are packed.
- Diluents that are packaged separately from their vaccines may be stored at room temperature or in the refrigerator, *not in the freezer.* This includes diluents for MMR, MMR-V, and Varicella.

Note: Although the IPOL vaccine is a multi-dose vial, it should be used through the manufacturer's expiration date printed on the vial, even after puncture.

Beyond Use Date: The date a vaccine is viable through, once removed from permanent storage.

- BUDs should be marked on the box
- BUDs are not documented in VIMS and are tracked solely by the practice.

V. Inventory Management and Ordering Vaccine

A. Avoid administration errors

- Label each basket/tray with the vaccine type. Labels are available for printing.
- Separate and label privately-purchased vaccines vs. state-supplied vaccines.
- Separate and label adult vs. pediatric vaccine. * Can be located in VIMS
- If applicable, mark the appropriate Beyond Use Date (BUD) or expiration date.
- Conduct a weekly inventory to ensure the rotation of vaccines. Short-dated vaccines must be used first, and if unused removed promptly upon expiration.
- Report vaccine administration errors to VAERS, or MedWatch for Beyfortus that is not co-administered, and contact the Immunization Program for further guidance.
- Do not pre-draw vaccines as this error could result in a patient receiving the wrong vaccines and increase waste as most syringes are designed for immediate administration. Prefilling syringes is also a violation of medical administration guidelines.

B. Vaccine ordering schedule

- Each practice is assigned an ordering frequency with a 2-week window of time.
- All practices are expected to reconcile their entire inventory monthly. VIMS will send out automated emails if this does not occur.
    a. Reconciling is required 7 days before placing and order

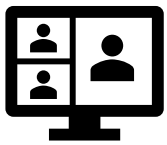
- If there isn't sufficient space in your refrigerator or freezer to store the vaccine, as outlined in this document, the unit is too small. Ask for more frequent orders and explore acquiring a unit capable of accommodating the largest expected inventory.
- If the ordering frequency is not working, please reach out to the immunization program to request a change.

C. VIMS and vaccine ordering

- VIMS is accessed through the Vermont Immunization Registry (IMR) .
  - Users who do not have IMR access should contact IMR support at 888-688-4667.
  - Once logged in, Select "Vaccine Inventory Management System (VIMS)" from the left navigation menu.
  - VIMS access is available only to your Primary and Backup contacts.
- A step-by-step VIMS User Guide
- The Immunization Program reviews all vaccine orders. Should adjustments be necessary, you will be contacted. Use the Practice Comments section of the order to convey reasons for ordering outside of the recommended quantities.
- The View History link can check an order's status and tracking information. Shipment tracking and carrier information is added to a VIMS Order Request the morning after it is shipped by the distributor.

VIMS Tutorials (Approximately 7 minutes each)

Adjustment Request (Vaccine Waste/Return)
Inventory Reconciliation Request
All-Vaccine Order Request
COVID-only Order Request



D. Receipt of vaccine shipments

- Although products can be ordered together in your VIMS Order Request, they may be shipped from various locations and arrive separately through different delivery companies.
  - Most vaccines are shipped from McKesson Specialty Distribution using FedEx.
  - Freezer stable vaccines (varicella and MMR-V) are shipped by the manufacturer, Merck using UPS.

- Pfizer Covid products are currently being shipped by Pfizer, using UPS.

- Upon receipt of **refrigerated** vaccines, check the enclosed temperature monitoring card. If an out-of-range temperature occurred during shipping, mark the vaccine "Do Not Use," store it in the refrigerator, and call or email the Immunization Program for guidance that same day it is received for the ordering team to assist.
- **Frozen** vaccines are NOT packed with temperature indicators. Instead, they come with a shipper insert that identifies the allowable shipping time. Check the packing slip's shipping date to determine how long the vaccines were in transit. If the shipment arrives beyond the allowed time, mark the vaccine "Do Not Use", store it in the freezer, then call or email the Immunization Program the same day for the ordering team to assist.
  - The lid of the box contains diluent. Remove the diluent before you discard the box. The diluent can be stored in the refrigerator or at room temperature, but not in the freezer.

- Verify that the packing slip agrees with the content of the shipment. Date and sign the packing slip and keep it for your records. Do not fax it to Immunization Program.
  - If the shipment contents and the packing slip do not match, call or email the Immunization Program *the same day* the shipment is delivered.
- Rotate vaccine stock within storage units to ensure that vaccines with the shortest expiration dates are placed in a position to be used first (Always use the First In, First Out Method).

E. Avoiding wastage due to vaccine expiration

- Conduct a weekly check to ensure that vaccine with the earliest expiration date is used first.
- 60 to 90 days before expiration, if a vaccine is not likely to be used, contact the Immunization Program for assistance redistributing the vaccine to a practice that can use it. Immunization Program permission is required before moving state-supplied vaccines.
  a. Reasons why redistribution would not be recommended:
     i. Contact was made late, and the vaccines are set to expire before a practice would be able to use the vaccine.

ii. Transporting the vaccines is more work than the cost of the vaccine.

iii. If no local practices use that brand of vaccine or have more than enough supply.

- **Remove** the expired or non-viable vaccine from the storage unit immediately and mark "Do Not Use".
- When the expiration date is marked by only a month and year, the vaccines or diluent may be used up to and including the last day of the month indicated on the vial

Always maintain the integrity of your vaccine stock by never swapping or borrowing doses between state-supplied and privately purchased vaccine

F. Handling expired, spoiled, and wasted vaccine

All spoiled, expired, or wasted vaccines must be accounted for and reported to the Immunization Program in VIMS. These doses are documented via an Adjust Request with an Adjustment Type of Return or Waste.

- **RETURN:** Non-viable, unopened, and intact state-purchased vaccine vials and syringes should be returned to McKesson for federal excise tax credit.
  - All expired, or spoiled vaccines must be reported in a VIMS Adjust Request.

  The Immunization Program will review the request and upon approval, UPS will email the shipping label only to the primary vaccine contact.
  - Upon receiving the shipping label, carefully package the vaccine to prevent vial breakage and ship it to McKesson within 1 month of spoilage or expiration. Print your Return Adjustment from VIMS to include as a packing slip.
- **WASTE:** Vaccines are considered wasted if opened or damaged and they cannot be administered to patients. These vaccines may not be returned and should be discarded as medical waste.
  - Reasons for waste include: being drawn into a syringe but not administered, opened in error, error in reconstitution, vaccine whose

sterility has been compromised by the vial being dropped or broken, or open multi-dose vials that have expired.

- All wasted vaccines must be reported in a VIMS Adjust Request.
- Dispose of a wasted vaccine on-site in a sharps container.

Provider Recognition

G. Overview

Our vaccine program is delighted to recognize and celebrate the dedication and hard work of our enrolled providers. The Compliance Champion Award will be presented to all providers who achieve a 100% score during their biannual compliance visits. Each year, the award-winning practices will be featured in an edition of the monthly provider update.

H. Details

The Compliance Champion Award will be determined for each grant cycle (July 1 – June 30). Since compliance visits occur biannually, only about 50% of enrolled providers will undergo a visit in any given year, making it unlikely for providers to receive the award annually.

To qualify for the award, a provider who receives a compliance visit during the grant cycle must complete the visit with no follow-up actions required by the program.

Thank you for everything your office does. We are here to help and support you in any way that we can!

Pictured: The Division of Laboratory Sciences and Infectious Disease.