Massachusetts Department of Public Health
Immunization Division
State Vaccine Program

2026 Guidelines for Compliance with State Vaccine Program Requirements

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The following requirements regarding state-supplied vaccine storage and handling, administration, documentation, reporting, and information are in accordance with Section 317 of the Public Health Service Act, federal vaccine contract terms, the specifications of the National Childhood Vaccine Injury Act (NCVIA) of 1986 (Section 2125, of the Public Health Service Act), the Vaccines for Children Program (VFC) (Section 1928 of the Social Security Act), and the Massachusetts Department of Public Health (MDPH) Immunization Division.

The Vaccine Program, as mentioned throughout the agreement, is comprised of two sub-programs: universal state pediatric vaccine program (including the federal Vaccines for Children (VFC) program) and the limited adult vaccine program. All sites enrolled in the Vaccine Program (including Specialty providers, Respiratory Vaccine-Only providers, or Adult-Only providers) must consider all doses received via the Vaccine Program as state-supplied vaccines and utilized according to the guidelines described below.

A. Appropriate Use of State-supplied Vaccine

A-1. All DPH recommended vaccines provided by the Universal Pediatric Vaccine Program are available to all children 18 years and younger, regardless of insurance status or VFC eligibility, with the exception of Men-B. Providers must administer state-supplied vaccines in accordance with the eligibility criteria defined in the most recent versions of the **Childhood Vaccine Availability Table** and the **Adult Vaccine Availability Table**).

A-2. **Providers must screen all children (18 years and younger) at every immunization visit**, as outlined in the Agreement to Comply document, to determine their VFC eligibility. Patient eligibility screening results must be documented and recorded electronically. If the *VFC Patient Eligibility form* is used, the form must be retrievable in the event of a Compliance site visit. VFC screening information must be retained in the electronic medical record or on file in the office for a minimum of 3 years after service to the patient has been completed.

Children 18 years and younger in the following categories are eligible for VFC vaccine:

Eligibility Categories	Electronic Health Record Drop-Down Selections
Medicaid/Mass Health	VFC Eligible - Medicaid
Uninsured	VFC Eligible – Uninsured
American Indian (Native American) or Alaskan Native	VFC Eligible – American Indian/Alaskan Native
Underinsured*	VFC Eligible – Underinsured

* Underinsured children (insurance coverage does not include vaccines, covers only selected vaccines, or does not provider first-dollar coverage) seen at federally qualified health centers (FQHC) and rural health centers (RHC).

Non-VFC Eligibility Categories	Electronic Health Record Drop-Down Selections
Any category not listed above	NOT VFC ELIGIBLE

The tables above show the only options to be selected when documenting VFC eligibility in an Electronic Health Record (EHR) in Massachusetts. The use of any other options, including but not limited to *state-specific eligible, local-specific eligible, unknown, or* names of other specific programs, is **not acceptable.**

Children enrolled in the Children's Health Insurance Plan (CHIP) or the Children's Medical Security Plan (CMSP) may receive all vaccines on the Childhood Vaccine Availability Table but are NOT considered VFC eligible when screening or assessing for VFC eligibility.

A-3. Adult patients (19 years and older) that are uninsured or underinsured and seen at public provider sites, can receive state-supplied vaccines, as defined by the Adult Vaccine Availability Table. Private provider sites are NEVER able to administer state-supplied vaccines to adult patients, regardless of the patient's insurance status, unless they are enrolled in the Vaccine Program as a Civil Surgeon. Private provider sites with billing capacity should privately purchase vaccines for their adult patients and seek reimbursement from health insurers.

A-4. The practice of borrowing state-supplied Men-B vaccine has been transitioned to a replacement model. The replacement model, defined as the use of a dose of state-supplied Men-B vaccine for a child not VFC eligible for state-supplied Men-B vaccine when the privately purchased vaccine is not readily available or vice versa, will require provider sites to complete a vaccine replacement form. **This situation should be extremely rare** and only occur to avoid a missed opportunity to provide a needed vaccine for a child who might otherwise not receive the vaccine. **State-supplied vaccines may never be used for someone 19 years and older unless eligible per the Adult Vaccine Availability table.** If replacement is necessary, the provider must:

- Ensure that state-supplied and privately purchased Men-B vaccine inventory is adequate to meet the anticipated needs reflected in the provider profile table. The replacement of Men-B vaccine will not prevent an eligible child from receiving a needed vaccination.
- Ensure that Men-B replacement occurs only when there is a lack of private/state vaccine stock due to unexpected circumstances such as a delayed vaccine shipment, vaccine spoiled in-transit to provider office or mechanical failure of storage units leading to loss of vaccine.

A-5. Providers must agree to use state-supplied vaccines only within their own office/clinic setting. They must further agree not to sell or distribute vaccines provided by the Vaccine Program to any other person, clinic, or organization outside of transfers to other enrolled sites. Transferring of state-supplied vaccines may take place between enrolled Vaccine Program providers, with all vaccine

transfer transactions being entered into the MIIS Vaccine Management Module. The receiving site must accept the transfer transaction in the MIIS for the doses to appear in their inventory.

A-6. Fraud and Abuse: **Improper use of state-supplied vaccine may constitute fraud and abuse** and is punishable by law (Medicaid regulation: 42 CFR §455.2 and applicable state law).

Fraud is defined by the Centers for Disease Control and Prevention (CDC) as an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself, herself, or some other person. It includes any act that constitutes fraud under applicable federal or state law.

Abuse is defined by CDC as provider practices that are inconsistent with sound fiscal, business, or medical practices and result in unnecessary cost to the Medicaid program (and/or including actions that result in an unnecessary cost to the Immunization Division, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.

These fraud and abuse parameters apply to all state-supplied vaccines.

Fraud and abuse can include (but is not limited to):

- Selling or otherwise misdirecting state-supplied vaccines.
- Billing a patient or third party for state-supplied vaccines.
- Charging more than the established maximum regional charge ($23.29) for administration of a state-supplied vaccine to a non-Medicaid VFC-eligible child. (See section C-2)
- Not providing state-supplied vaccines due to a parents' inability to pay for the administration fee.
- Not implementing provider enrollment requirements of the Vaccine Program.
- Failing to screen patients for VFC eligibility at every immunization visit.
- Failing to maintain Vaccine Program records and comply with other requirements of the Vaccine Program.
- Failing to account for all state-supplied vaccines received.
- Failing to receive, store, or use state-supplied vaccines properly. MDPH may require providers to make restitution for any doses of state-supplied vaccines that have been wasted due to provider negligence/mismanagement. See section A-7 for additional information about the restitution policy. Examples of provider negligence and/or mismanagement include (but are not limited to):
    - Failure to open vaccine shipments from McKesson, Merck or Pfizer immediately, which results in damage to the vaccines.
    - Failure to rotate vaccine stock, which results in expired state-supplied vaccine.
    - Allowing state-supplied vaccines to expire. You must transfer the soon to expire vaccine to another practice 3 months before expiration. If unable to locate a practice within the first two weeks of attempting to transfer vaccines, contact the Vaccine Program for assistance at 617-983-6828.
    - Using state-supplied vaccines out of ordinance with the site's established practice profile and Adult/Childhood Availability Tables.
    - Inappropriately storing fridge vaccines in a freezer unit. (See section B-3 for more details)
    - Inappropriately storing frozen vaccines in a fridge. (See section B-3 for more details)
    - State-supplied vaccines spoil due to a power interruption by either unplugging the fridge or freezer units, storage units plugged into a GFCI, by switching off the sites circuit/electrical

breaker by any party (i.e., provider staff, contractors, etc.) or a failed generator/battery package.

- Refrigerator or freezer unit door left open or ajar by provider staff, contractor, or any other individual at your site, resulting in damaged vaccines.
- State-supplied vaccines that are left out of the storage units and spoil (always contact the vaccine manufacturer to determine if vaccines can be identified as viable).
- Moving state-supplied vaccines during a power outage that results in spoiled doses.
- Ordering state-supplied vaccine in quantities or patterns that do not match provider profile or otherwise involve over-ordering of state-supplied vaccines.
- Wastage of state-supplied vaccine, including a pattern of pre-drawing vaccines resulting in the loss of unused doses.
- Refrigerator malfunction in a non-pharmaceutical grade unit that is being used to store state-supplied vaccines resulting in spoilage. (See section B-3 for more details)
- Storing state-supplied vaccines in a household combination or dormitory style unit.
- Failure to notify the Vaccine Program of any temperature excursion in storage units containing state-supplied vaccine, via the completion and submission of a Temperature Excursion Issue in the MIIS.
- Any other vaccine storage and handling mistake made by provider staff with state-supplied vaccine.

A-7. The Vaccine Program requires providers to make **restitution** by replacing any doses of state-supplied vaccines that have been lost due to the provider's failure to properly receive, store, or use vaccines (as outlined in section A-6) if:

a. it is the 1st incident, and the total loss is over $25,000, or
b. it is the 2nd incident in less than 12-month period and the total loss is over $5,000, or
c. it is the 3rd incident (or greater) in less than 12-month period regardless of the total value, or
d. it is due to a failure to immediately open a vaccine shipment from McKesson or Merck, resulting in damaged vaccine regardless of the total value, or
e. it is due to a failure to store refrigerated vaccines in a refrigerator or store frozen vaccines in a freezer regardless of total value.

The Vaccine Program will notify the provider regarding the number of doses of each vaccine that must be replaced; vaccine must be replaced on a dose per dose basis with privately purchased vaccine. Subsequent vaccine orders from the provider will not be processed by the Vaccine Program until a copy of the vaccine replacement form is received and processed. The Vaccine Program may request copies of the invoice for the privately purchased replacement vaccines if lot numbers match state-supplied vaccine doses in inventory.

The Vaccine Program will only hold providers accountable in situations of provider negligence as outlined above (see section A-6) and will not seek restitution for a vaccine loss that occurred due to a circumstance not in the provider's control (i.e. act of nature). Providers will be given due process to dispute cases of avoidable loss. However, the Vaccine Program retains the right to make final determinations regarding vaccine restitution.

B. Vaccine Management

B-1. **Providers must have written standard operating procedures (SOP) in place for proper vaccine management and vaccine transport.** Both the Vaccine Management and Vaccine Transport SOP must be reviewed, updated and signed in the following situations:

- Annually as part of re-enrollment
- Whenever there is a change in responsible staff (i.e. Vaccine Coordinator or Medical Director)
- Your site intends to start conducting mobile/off-site clinics.

B-1a. The Vaccine Management SOP must include:

- Designation of a Primary Vaccine Coordinator, Back-up Vaccine Coordinator, and Medical Director. **Providers must notify the Vaccine Program either by phone 617-983-6828 or email dph-vaccine-management@mass.gov within 10 days when a new Vaccine Coordinator or Medical Director is designated**. Vaccine ordering will be suspended until compliance trainings are complete, agreement to comply is checked and SOPs are updated.
- Proper storage and handling procedures.
- Vaccine receiving procedures.
- Vaccine relocation procedures in the event of a power or equipment failure.
- Vaccine ordering and inventory control procedures.
- Handling lost or expired vaccine procedures.
- Response procedures for when vaccines are stored out of temperature range and determination of what qualifies as a temperature excursion. In the event of a temperature excursion providers must complete and submit a Temperature Excursion Issue in the MIIS.

Both Vaccine Coordinators and the Medical Director must sign and date the Vaccine Management SOP. Additionally, any staff member responsible for state-supplied vaccines in any way, including monitoring temperatures in vaccine storage units, administering vaccines, or transporting vaccines in an emergency, must acknowledge reading their practice's Vaccine Management SOP by signing and dating the document.

B-1b. The Vaccine Transport SOP must include:

- Details on transport methods and transport supplies on-site.
- Steps on how to move vaccines to another location or clinic.
- Steps on how to ensure vaccines are viable upon arrival.
- Overall plan for mobile clinics, including staff assignment, frequency, purpose, and methods.
- Overall plan for vaccines at mobile clinics, including administration, wastage, and storage.

Both Vaccine Coordinators and the Medical Director must sign and date the Transport SOP. Also, all staff responsible for state-supplied vaccines in any way, related to the Transport of the Vaccines, must acknowledge reading their practice's Vaccine Transport SOP by signing and dating the document.

B-2. All vaccines, with the exception of Varicella, MMRV and Pfizer COVID-19 vaccines will be shipped to you by McKesson Specialty Distribution. Varicella and MMRV vaccine will be shipped to you by Merck & Co., Inc. Varicella and MMRV doses are always shipped separately and may not arrive on the same day as their associated diluent. Pfizer COVID-19 vaccines will be shipped to you by Pfizer. Diluent for the Pfizer 6m-4y product may not arrive on the same day as the vaccine.

Providers must provide the Vaccine Program with all packing slips for direct ship vaccines from Merck & Co., Inc. (MMRV & Varicella). Failure to provide packing slips may result in a temporary suspension from vaccine ordering. Ensure the shipped doses quantity is equal to the ordered

doses quantity for both the vaccine product and the associated diluent. **All sites must initial and date every packing slip received**.

In order for shippers to be able to deliver vaccines, providers must be on site with appropriate staff available to receive vaccines at least one day per week other than Monday and for at least four consecutive hours during that day.

- **Upon arrival, open the box of vaccine immediately.**
    - For shipments from McKesson, check the two transit temperature monitors. The Vaccine Program must be contacted on the day of receipt if temperature monitors indicate a possible temperature excursion during transit.
    - For direct ship vaccines from Merck, check the shipment date located on the packing slip and check the shipper insert supplied in the box. Shipments of MMRV are always delivered within 24 hours. Varicella can be shipped in a 2-day or 4-day box. Contact the Vaccine Program if the date received is later than the indicated date on the shipper insert, on the day of receipt.
- Check to see if the packing slip matches your vaccine order. If there are any problems or inconsistencies between your order and the vaccine received, contact the Vaccine Program.
    - Providers may find that some packing slips are being divided between VFC, State, CHIP and 317- this is solely for funding purposes, and this distinction should be ignored. Treat all vaccines received from the Vaccine Program as state-supplied vaccine.
- Contact the Vaccine Program immediately if vaccines are delivered outside of your listing shipping hours. Please note you will also be asked to provide a picture of both the shipment box and the shipping label in these instances.

B-3. Providers must agree to follow the manufacturer's specifications and the guidelines established by the Vaccine Program for the storage and handling of vaccines.

B-3a. Vaccine Storage Best Practices

- Store all vaccines in the original manufacturer's packaging.
- All vaccine stock must be rotated, so the vaccine with the shortest shelf life is used first.
- Inventory must be clearly marked or identified so that state-supplied and privately purchased vaccine can be differentiated. Vaccine that has been short-dated or is subject to a beyond use date due to being stored in secondary storage conditions, must be labeled with the updated date of spoilage.
- Any state-supplied vaccines that are due to expire before being administered should be transferred to another enrolled practice at least three months prior to expiration. If unsuccessful in the first two weeks of attempting to transfer vaccines, contact the Vaccine Program for assistance with locating potential sites.
- Storing frozen water bottles in the freezer unit is also a component of your emergency preparedness. Ideally, sites should always keep at least eight 12-16oz frozen water bottles in their freezer. Frozen water bottles for vaccine transport can also be stored in an additional freezer not used for vaccine storage.
- If the temperature of the vaccine storage unit need adjusting, it should be done only after vaccines have been removed and stored in a temporary storage unit. Contact the Vaccine Program for consultation before attempting to do this.

B-3b. Temperature Requirements

- All vaccines, with the exception of Varicella, MMRV, Merck's MMR vaccine, Moderna's COVID-19 vaccine and Mpox, must be stored refrigerated between 2°C and 8°C (35°F and 46°F).
- Varicella and MMRV vaccine must be stored frozen between -50°C and -15°C (-58°F and 5°F). DO NOT store the diluent in the freezer; the diluent for these vaccines may be stored either in the refrigerator or at room temperature.
- Merck's MMR vaccine can be stored between -50°C and 8°C (-58°F and 46°F) according to package insert instructions per manufacturer. DO NOT store the diluent in the freezer; the diluent may be stored either in the refrigerator or at room temperature. GSK's MMR vaccine must be stored in a refrigerator unit between 2°C and 8°C (35°F and 46°F) and **cannot be frozen**.
- Pfizer's Comirnaty 5y-11y COVID-19 vaccine formulation can either be stored in an ultra-cold freezer storage unit (colder than -60°C) until its labeled expiration date or in a vaccine refrigerator between 2°C and 8°C for a maximum of 10 weeks. Pfizer Comirnaty 5y-11y COVID-19 product stored in a refrigerator should be labeled with their 10-week Beyond Use Date. Pfizer Comirnaty 12+ must be stored in a vaccine refrigerator between 2°C and 8°C and may be stored in refrigeration until its labeled expiration date. Pfizer COVID-19 products can never be stored in a regular vaccine freezer.
- Moderna's Spikevax COVID-19 vaccines can either be stored in a freezer storage unit (colder than -15°C) until its labeled expiration date or in a vaccine refrigerator between 2°C and 8°C for a maximum of 60 days. Moderna Spikevax COVID-19 products stored in a refrigerator should be labeled with their 60-day Beyond Use Date.
- Sanofi's Nuvaxovid COVID-19 vaccine must be stored in a vaccine refrigerator between 2°C and 8°C and may be stored in refrigeration until its labeled expiration date. Nuvaxovid COVID-19 products can never be stored in a regular vaccine freezer.
- Mpox vaccines can either be stored in a freezer storage unit (colder than -15°C) until its labeled expiration date or in a vaccine refrigerator between 2°C and 8°C for a maximum of 4 weeks. Mpox products stored in a refrigerator should be labeled with their 4-week Beyond Use Date.

B-3c. Storage Units

- All practices enrolled in the Vaccine Program are required to store **all** refrigerated vaccines in pharmaceutical-grade or purpose-built refrigerators at **all** times. **The use of any household combination refrigerator/freezer unit or dormitory style unit for storage of any state-supplied pediatric vaccines, including temporary storage, is strictly prohibited.**
- Stand-alone freezers that are not pharmaceutical grade are acceptable. These units can vary in size from a compact, under the counter style, to a large stand-alone unit.
- The size of the refrigerator or freezer must be able to accommodate your largest vaccine supply (typically during respiratory season), allowing for sufficient air circulation between rows of vaccine boxes or bins, shelving units, and walls.
- Characteristics of pharmaceutical grade refrigerators include:
    - Internal overhead fans to disperse cold air throughout the unit, eliminating cold pockets of air
    - Adjustable wire shelves to allow better airflow
    - No storage bins or shelves on the door
    - Micro Processor Temperature Controller
    - Electronic Digital Thermometer
    - Typically, pharmaceutical-grade refrigerators have a narrow operating range (less than 2°C or 3°F)

- "DO NOT DISCONNECT" signs must be placed on all storage unit electrical outlets and circuit breakers.
- **Refrigeration units must be plugged directly into a wall outlet.** DO NOT plug refrigeration units into a power strip, surge protector, extension cord, a ground fault circuit (GFC) interrupter outlet (outlets with RESET/TEST buttons), generator, or battery packs. Always contact the Vaccine Program PRIOR to moving storage units to a new location, new outlet, or disconnecting from power for any reason.
    - *Exception*: Generators and battery packs can be utilized if they are wired directly into the circuit breaker of the building. This would result in the storage unit still being plugged directly into the wall outlet.
- Food or beverages must **not** be stored in vaccine storage units with the exception of water bottles per CDC recommendations.

B-3d. Transport Materials

- All providers must maintain their necessary vaccine transport materials on site at all times. Please note that sites whose transport materials are stored at a sister site or neighboring site will be found out of compliance. Sites must have enough transport materials to safely move their entire inventory at one time. Necessary transport materials include:
    - Vaccine transport cooler
        - Providers who have a powered Portable Storage Unit or Qualified Container/Pack Out Cooler may use those units in emergencies. All other sites must follow the CDC Emergency Transport Guide.
    - Phase change materials/frozen water bottles for transport cooler conditioning
    - Packaging materials (i.e. bubble wrap, cardboard, etc.)
    - Backup digital data logger device
- Providers that conduct mobile or off-site clinics as part of their regular daily duties are required to have vaccine transport materials for all mobile/transport storage units. In clarification, mobile provider sites must have a digital data logger device for each mobile transport cooler, each main storage unit and one additional backup digital data logger device per unit type (i.e. fridge).

B-3e. Digital Data Loggers (DDL)

- The Vaccine Program requires the use of NIST-certified calibrated digital data loggers (DDL) for continuous 24-hour temperature monitoring on all state-supplied vaccine storage units at all enrolled practices.
    - **Minimum, maximum and current temperatures should be physically acknowledged at least twice daily for all vaccine storage units**, at the start of the workday and at the end of the workday.
    - Providers are required to have a calibrated back-up DDL device available for use if their primary DDL device is not functioning. If receiving state-supplied DDL devices, additional backup DDL devices (other than if primary DDL malfunctions) or DDL devices used solely for transport purposes will not be provided by the Vaccine Program and must be privately purchased. Back-up DDL devices must have a different calibration date than the primary DDL devices.
- Temperature reports or logs must be reviewed for completeness (no missing temperature readings) and out-of-range temperatures. **Immediate** action must be taken if out-of-range temperatures meet the definition of an excursion, as described below.
    - Staff must be comfortable interpreting temperatures and durations of out-of-range instances in order to communicate information to vaccine manufacturers so that viability can be determined.

        - If an out-of-range temperature lasts a cumulative 30 minutes (within a 24-hour period) sites must contact the Vaccine Program immediately via the submission of a Temperature Excursion Issue in the MIIS, as this is considered a temperature excursion. Shorter out-of-range temperatures do not require reporting to the Vaccine Program, as viability data indicates that the vaccines will remain viable.
    - Providers must submit current temperature logs or reports for all vaccine storage units (refrigerators and freezers) with every routine vaccine order by uploading them into the MIIS.
    - Providers must ensure current temperature logs or reports for all vaccine storage units (refrigerators and freezers) are uploaded within the last 30 days for respiratory vaccine orders to be processed.
    - **Handwritten temperature logs are no longer accepted**. Submitted temperature logs must be generated reports from DDL devices that meet the criteria described below. Temperature logs from out of calibration DDL devices will no longer be accepted in any instance.
    - Sites must ensure a complete record of temperature data for all storage units containing state-supplied vaccine is uploaded in the MIIS. Depending on the capabilities of the DDL device in use, some sites may have to upload temperature logs monthly to ensure no temperature data is lost.
    - Uploading temperature logs into the MIIS meets the VFC requirement for maintaining temperature logs for at least 3 years.
- Any newly and returning providers enrolling in the Vaccine Program will be required to acquire their own privately purchased DDL devices for any unit that will be storing state-supplied vaccines. Every enrolled site will also be responsible to acquire a back-up DDL that is dually calibrated, with a different calibration date than the primary DDL. All devices must abide by the requirements as stated below.
- **PLEASE NOTE:** Starting in 2028, the Vaccine Program will no longer provide DDL devices. Enrolled provider sites who have a state-supplied calibrated DDLs may continue to utilize them until they reach their expiration date. Once the state-supplied DDL device is past calibration, providers must utilize privately purchased devices. The Vaccine Program may require providers to provide restitution (transitioning to a privately purchased device of comparable value and functionality) for any broken or lost state-supplied devices if:
    - the device is rendered non-functional due to mishandling or improper placement
    - the device is not returned to the Vaccine Program upon un-enrolling
    - The device is lost or disposed of due to site neglect
        - Note: The Vaccine Program will not seek restitution for a state-supplied DDL devices that are rendered non-functional or lost due to a circumstance not in the provider's control (i.e. act of nature). Providers will be given due process to dispute cases of avoidable loss. However, the Vaccine Program retains the right to make final determinations regarding digital data logger device restitution.
- All privately purchased DDLs must abide by the following requirements:
    - NIST certified calibration with an associated Calibration Certificate that includes model/device number, serial number, date of calibration (report or issue date), confirmation that instrument passed testing (instrument in tolerance)
    - Capacity for continuous monitoring and routine recording of data, with an accuracy of +/- 1°F (0.5°C)
        - Review the calibration certificate to determine if the device meets the standard accuracy requirements

- Active temperature display that can be easily read from outside the storage unit
- Easily identifiable alarm for out-of-range temperatures and low battery indicator
- Detachable buffered temperature probe with glycol, glass beads, sand or Teflon, that best reflects the temperature of the vaccine
- Logging interval (or reading rate) that is programmable to record temperatures at a maximum of 15-minute intervals with at least 4,000 readings storage capacity
- Ability to acknowledge and document electronically, within the data logger system, maximum and minimum temperatures at least twice daily
- Ability to generate a PDF output report, that clearly indicates daily maximum/minimum temperatures, alarms, and acknowledgment of twice daily temperature checks
    - The PDF output report must include either a graph or daily summary of maximum/minimum temperatures that can be easily reviewed for out-of-range temperatures
- Ability to generate an ad-hoc comprehensive temperature report that displays temperature readings at a maximum of 15-minute intervals
- In the event of a power outage, the device will continue to record temperatures that are accessible for staff review

- Each site must maintain at least one (1) backup Digital Data Logger (DDL) to ensure temperature monitoring continuity in the event of vaccine transport or malfunctioning of the primary DDL in use.
    - If the available DDL is NOT dually calibrated for freezer or refrigerator use, the site must maintain one DDL per type of storage unit they have (e.g., one DDL for refrigerated vaccine use and one DDL for freezer vaccine use).
    - The backup DDL must always be calibrated, and its calibration date must differ from the calibration date of the primary DDL/s assigned to the unit/s.
    - The use of a non-calibrated DDL for backup purposes or vaccine transport is strictly prohibited. Sites found using non-calibrated or expired DDLs may be held responsible for any vaccine damage resulting from improper temperature monitoring and may be asked for restitution.

B-3f. Power Outages

- In the event of a power outage, providers should **NEVER** move their vaccines offsite or to a backup location. It is best practice to keep the vaccines in their storage units with the door closed, being monitored by a digital data logger device. Vaccines should only be moved to an offsite/backup location if the storage unit itself is malfunctioning. Restitution may be requested if providers move vaccines during a power outage and that transport results in vaccine spoilage. Vaccine providers will not be asked for restitution if vaccines spoil during a power outage after being left in the unit with the door closed and monitored with a digital data logger device.

B-4. Inventory Management

- All Vaccine Program providers are required to maintain inventories of all DPH recommended routine vaccines, with the only exception being specialty providers (i.e., OB/GYN), adult-only or respiratory-only seasonal providers (i.e. LBOHs). All DPH recommended routine vaccines must be made available and provided to all eligible patients at the site in accordance with the Vaccine Availability Tables. Provider sites that do not regularly stock respiratory vaccines (i.e. COVID, Flu, RSV), must have a written plan in their Vaccine Management SOP to direct interested patients to another non-pharmacy provider in their area that offers the vaccine. All plans must include guidance/recommendations for interested patients of any age.

- All providers must maintain an accurate record of vaccines received from the Vaccine Program and document this inventory electronically using the MIIS Vaccine Management Module. This record must include:
  - Type of Vaccine
  - Manufacturer
  - Lot Number
  - Expiration Date
  - Number of Doses Received
- Mishandled, expired, or damaged vaccines must not be administered. All expired, damaged, or contaminated vaccine must be promptly removed from the storage unit, clearly labeled as "expired/damaged, do not use" and documented in the MIIS Storage/Handling Problem Module. Please refer to the Vaccine Storage/Handling Problem Mini-Guide for step-by-step directions.
- Determination of ordering quantities should be based on remaining inventory and anticipated need over the subsequent 6 weeks. For most practices ordering routine vaccines, orders should ideally be placed on a monthly basis, however, orders can be placed at any time. Depending on the quantity of vaccine the practice administers during the year, vaccine orders could be as frequent as every couple of weeks or as infrequent as a couple times a year. Once the Vaccine Program processes an order, CDC has up to 2 weeks to ship to provider sites.

C. Responsibilities of the Medical Director

Non-compliance with any of the below shall be cause to exclude the provider from continued participation in the Vaccine Program.

C-1. The Medical Director is responsible for the following Vaccine Program agreements:

C-1a. Responsibilities of the Medical Director.

- The Medical Director, on behalf of themselves and all practitioners associated with the entity, is responsible for ensuring that state-supplied vaccines are administered in compliance with federal requirements for the administration of vaccines. Failure to comply with federal requirements as outlined in this document may constitute fraud and abuse and may be punishable by law (Medicaid regulation: 42 CFR §455.15). The Medical Director must ensure that all communications from the Vaccine Program regarding immunizations or vaccine-preventable diseases are disseminated to all relevant staff within their facility. Providers must stay subscribed to Vaccine Program Constant Contact communications.

C-1b. Documentation Requirements

- Within the MIIS, the Medical Director is responsible for electronically signing the online *Agreement to Comply with State Vaccine Program Requirements*, physically signing the *Vaccine Management SOP* and *Vaccine Transport SOP*, providing the Vaccine Program with an accurate *Practice Profile* and providing the names of all physicians, physician assistants and nurse practitioners in the practice/clinic with their corresponding medical license number, NPI and Medicaid number where applicable.

C-2. The Medical Director is responsible for the following Vaccine Program regulations:

C-2a. Reporting Immunizations

- By law (M.G.L. Chapter 111, Section 24M), all licensed health care providers practicing who administer immunizations shall report and record immunization, immunization history and any data related to immunization as the Immunization Division determines is

necessary for disease prevention and control to the Massachusetts Immunization Information System (MIIS). Providers must ensure that doses are accurately accounted for within the MIIS by reporting administration data via HL7 connection or manual patient record entry, timely reporting of vaccine wastage/expiration within the MIIS and routine review of the Inventory Decrementing Tool so that all administered doses are accurately decremented by the system.

C-2b. Provider Massachusetts Controlled Substance Registration Liscense

- **By law (MGL Chapter 94C, Section 7 and regulations of the Department of Public Health at 105 CMR 700.004), require all provide sites who manufacture, distribute, prescribe, administer, dispense or possess controlled substances (including vaccines) to have a valid Massachusetts Controlled Substance Registration (MCSR) license.** In order to enroll and/or re-enroll in the Vaccine Program, sites must have a valid facility or individual MCSR license on file in the MIIS.

C-2c. Billing NPI Number

- A billing NPI number is required to enroll and/or re-enroll in the Vaccine Program. The Billing NPI may be a group level, practice level or individual level NPI number, as whichever NPI is utilized for billing purposes, should be the NPI number included in enrollment submissions.

C-2d. Maintaining Documentation

- Providers must maintain all records, documentation and temperature logs related to the Vaccine Program for a minimum of 3 years. The release of such records will be bound by the privacy protection of Federal Medicaid law. If requested, the provider must make such records available to the Vaccine Program or the Federal Department of Health and Human Services (DHHS).

C-3. The Medical Director is responsible for the staff who order, store, administer, and report on vaccine usage. A list of all physicians, physician assistants, nurse practitioners and nurse-midwives who prescribe vaccines, along with their medical license numbers and Medicaid numbers, must be updated annually in the MIIS during re-enrollment.

C-3a. Designation of Primary and Back-up Coordinators

- **The Medical Director is responsible for designating a Primary and Back-up Vaccine Coordinator.** The Vaccine Coordinators are responsible for oversight of all vaccine storage and handling, including vaccine ordering, inventory management and acting as the vaccine shipping contact. They are also responsible for communicating vaccine policy, vaccine availability, updates, and alerts to all pertinent staff. Any change in the Primary or Back-up Vaccine Coordinator must be reported to the Vaccine Program within ten (10) days. Sites must have a Primary and Back-up Vaccine Coordinator identified at all times.

C-3b. Designation of Primary and Back-up Coordinators

- **The Primary and Back-up Vaccine Coordinator must complete the current annual Vaccine Program Storage and Handling training.** This training will cover all program requirements, including proper storage and handling of state-supplied vaccines. This requirement may be met by completing one of the following:
    - Vaccine Program Storage and Handling Webinar training
    - Onsite training session conducted by a member of the Vaccine Program
    - Compliance Site Visit with formal training component

- In-person training events held by the Immunization Division

C-4. The Medical Director is responsible for following all site visit requirements:

C-4a. Enrollment Visits

- **Enrollment site visits must be completed by the Vaccine Program Quality Assurance Analyst (QAA) staff for any newly enrolled or returning provider to the program. All sites returning to the program after leaving and requiring an enrollment visit and new sites looking to enroll into the program will be required to have a calibrated DDL that meets the program requirements.** The enrollment visit ensures that the provider and office staff are educated on the Vaccine Program requirements and have appropriate resources to implement these requirements.

C-4b. VFC Compliance Site Visits

- **The Medical Director understands and agrees that Vaccine Program QAA staff are required to make Compliance site visits every 12 to 24 months to evaluate vaccine handling and storage, VFC screening, and record keeping.** Sites enrolled as Respiratory-Only or Adult-Only are excluded from this requirement.

C-4c. Compliance Visit Follow-ups

- If any problems are identified with programmatic compliance, the provider will receive follow-up contact and education, in accordance with CDC guidelines. The Medical Director is responsible for guaranteeing that outstanding non-compliance findings are addressed and resolved as part of completing site visits.

C-4d. Unannounced Storage and Handling Visits

- **The Medical Director understands and agrees that the Vaccine Program QAA staff will perform unannounced provider visits to check for proper storage and handling practices.** Providers who have had prior storage and handling compliance issues may be prioritized for such visits. Unaddressed outstanding follow-ups from unannounced site visits may result in the inability to order state-supplied vaccines until the issue is resolved.
    - Unannounced site visits are a **requirement** of the Vaccine Program and may not be rescheduled. If both Primary and Backup Vaccine Coordinator are not present during your site's hours of operating, another staff member must be appointed responsibility of overseeing your site's Vaccine Program operations.

C-4e. Scheduling Site Visits

- Failure to respond to scheduling of compliance site visits and/or completion of follow-ups identified during visits could result in suspension and an inability to order state-supplied vaccines until the identified issue is resolved.

C-5. Temperature Excursions Reporting Requirement

- In the event of a temperature excursion, it is at the discretion of your site's Medical Director to approve continued use of vaccines in the case of the manufacturer being unable to confirm viability due to insufficient data. It is also at the discretion of your site's Medical Director to decide whether or not to re-vaccinate in the event non-viable vaccines are administered to patients.

C-6. The Medical Director is responsible for assuring that:

- Immunization policies and practices are in compliance with the General Best Practice Practices for Immunization.
- The immunization schedule, dosage, and contraindications followed are in compliance with those established by the CDC's Advisory Committee for Immunization Practices or by the DPH Commissioner as outlined by the DPH recommended guidance for vaccines.
- All routinely-recommended vaccines are supplied, except if the practice is designated as a "Specialty Provider" during the enrollment process. A "Specialty Provider" is defined as a provider that only serves (1) a defined population due to the practice specialty (e.g., OB/GYN, asthma/allergy) or (2) a specific age group within the general population. "Specialty Providers" must indicate which state-supplied vaccines are offered during enrollment.
- Vaccine Administration Resources:
  - DPH Recommended Guidance for Vaccines
  - CDC Vaccines & Immunizations webpage
  - CDC Vaccine Administration webpage
  - CDC Pink Book Education Webinar Series
  - Immunize.org

D. Billing and Charging for State-supplied Vaccine

D-1. Providers may not impose a charge for the cost of a state-supplied vaccine to a patient or a third-party (e.g., an insurance company or Medicaid).

D-2. Providers may charge an administration fee of up to **$23.29** per dose for non-Medicaid (uninsured, underinsured, or who are American Indian or Alaskan Native) VFC-eligible patients. For Medicaid VFC-eligible children, providers must accept the reimbursement for vaccine administration set by the Massachusetts Medicaid agency or the contracted Medicaid health plans. Providers may bill administration fees to third party payers in accordance with the terms of their contracts. Providers may not deny state-supplied vaccines to an established patient due to the inability of the child's parent/guardian/individual of record to pay the administration fee. "Established patient" applies only to private providers. FQHCs must administer state-supplied vaccines to any VFC-eligible child who presents for immunization services.

D-3. Effective January 1, 2020, providers who choose to bill for the vaccine administration fee of a non-Medicaid, VFC-eligible child after the date of service may issue only a single bill to the patient within 90 days of vaccine administration. This policy does not apply to vaccine administration fees billed to Medicaid for children who meet the Medicaid eligibility criteria for the VFC program. **Unpaid administration fees may not be sent to collections**, and the provider may not refuse to vaccinate an eligible child whose parents has unpaid vaccine administration fees.

E. Vaccine Information Statements (VIS) and Consent

E-1. All Vaccine Program providers must provide a copy of the relevant and current edition of the Vaccine Information Statement (VIS) produced by the CDC before administering each dose of vaccine (NCVIA: 42 USC Section 300aa-26). Please see subsection E-3 for more detail.

VISs provide risk-benefit information. VISs must be given for all vaccines and toxoids covered by the NCVIA, whether the vaccine was state-supplied or privately purchased. Each patient or parent/legal representative receiving vaccines must receive a copy of the VIS prior to the administration of vaccines. There are additional requirements relating to the use of VISs in school-based or other programs, where the parent or legal representative is not likely to be present at the time of immunization. Please see subsection E-4 below.

E-2. VISs must be used for the vaccines specified in the NCVIA: measles, mumps, and rubella containing vaccines (MMR, MMRV); diphtheria, tetanus, and pertussis containing vaccines (DTaP, DT, Td, and Tdap); inactivated polio virus vaccine (IPV); hepatitis B vaccine (HBV); *Haemophilus influenzae* type B vaccine (Hib); varicella vaccine (VAR); pneumococcal conjugate 20-valent vaccine (PCV20); hepatitis A vaccine (HAV); trivalent influenza vaccine (both inactivated influenza vaccine [IIV] and live, attenuated influenza vaccine[LAIV]); respiratory syncytial virus vaccine (RSV); rotavirus vaccine(RV); meningococcal ACWY vaccines; serogroup B meningococcal (Men B) and human papillomavirus vaccine (HPV); COVID-19.

With some exceptions, there aren't VISs for combination vaccines. Instead, providers should provide a separate VIS for each vaccine component in the combination (e.g., DTaP-IPV-HepB or DTaP-IPV/Hib). There is a combined VIS (the multi-vaccine VIS) that can substitute for any or all of the routine vaccines given from birth–6 months (DTaP, IPV, Hib, PCV and HepB vaccines).

For the vaccines not covered under the National Childhood Vaccine Injury Act (i.e., adenovirus, anthrax, cholera, COVID-19, Japanese encephalitis, Mpox, pneumococcal polysaccharide, rabies, shingles, typhoid, and yellow fever), providers are not required by federal law to use VISs unless they have been purchased under CDC contract. However, CDC recommends that VISs be used whenever these vaccines are given. Visit the National Vaccine Injury Compensation Program webpage for more information.

E-3. **All providers must maintain copies of the most up to date VISs in their office.** All VISs are available in print and audio formats in many languages. We recommend that someone in every provider office is assigned as the VIS coordinator. Copies of the most recent VISs (including translations in many foreign languages) are available online and can be downloaded from the Immunize.org website or on the CDC VIS webpage and can be downloaded directly into a personal mobile device. Providers are encouraged to subscribe for email notifications when a VIS is updated or a new VIS becomes available, by clicking on "Get Email Updates" on the CDC VIS website.

Prior to vaccination, VIS may be:

- Provided as a paper copy
- Offered on a permanent, laminated office copy
- Downloaded by the recipient (parent/legal representative) to a smartphone or other electronic device (VISs have been specially formatted for this purpose)
- Made available to be read before the office visit, e.g., by giving the patient or parent a copy to take home during a prior visit or telling them how to download or view a copy from the Internet. These patients must still be offered a copy in one of the formats described previously to read during the immunization visit as a reminder.

Regardless of the way the patient is given the VIS to read, providers must still offer a copy (which can be an electronic copy) of each appropriate VIS to take home following the vaccination. However, the vaccinee may decline.

For patients who are not proficient in speaking, reading, or understanding the English language, the law requires that providers ensure all patients (parents/legal representatives) receive a VIS, regardless of their ability to read English. To obtain VISs in other languages, visit the Immunize.org website. Providers can supplement VISs with visual presentations or oral explanations as needed. VISs on the CDC VIS webpage are screen-reader accessible.

E-4. **In school-based programs or other programs where the parent or legal representative is not likely to be present at the time of immunization, the parent or legal representative may:**

- Sign an individual consent form for the administration of each dose of vaccine, which includes acknowledging receipt of the VIS prior to each dose; or

- Sign a single consent form for the administration of an entire vaccine series (e.g., hepatitis B vaccine), if permissible by the institution's legal counsel. Single signature consent forms must:
    - Have a place for the parent/legal representative to acknowledge the receipt of the VIS and give permission for their child to be vaccinated with the complete series.
    - Describe the future process whereby the VIS shall be sent home prior to each subsequent dose.
    - State that a "*Withdrawal of Permission Form*" will be sent home with the VIS prior to each subsequent dose. This statement notifies the parent or legal representative that, based on their earlier permission, the next dose will be given on (list the date), unless the parent or legal representative signs the "*Withdrawal of Permission Form*."

In school-based programs or other programs where the parent or legal representative is not likely to be present at the time of immunization, the provider must:

- Establish procedures for responding to questions from the parent or legal representative by telephone or mail.
- Maintain, in the patient's medical record, the original consent signature(s), any "*Withdrawal of Permission Forms*" and dates the VISs were sent home to the parent or legal representative.
- Consult with the institution's legal counsel about any policies or requirements specific to the institution regarding consent and consent forms.

E-5. There is no federal or state requirement that providers, public or private, obtain the signature of patients, parents, or legal representative acknowledging the receipt of the VIS. However, providers may choose to obtain these signatures.

Regardless of the setting or whether you are vaccinating children or adults, all providers are encouraged to consult with their legal counsel and/or follow their institution's policies regarding consent.

F. <u>Documentation of Vaccine Administration</u>

F-1. **Providers must ensure that the permanent medical record (electronic or paper) of the recipient contains all the required documentation for immunizations. This documentation shall consist of the following:**

- Date of administration of the vaccine
- Vaccine manufacturer and lot number of the vaccine
- Name and credentials of person administering the vaccine
- Address of clinic where the vaccine was given
- The address of the facility where the permanent record will reside (if appropriate)
- Edition date printed on the appropriate VIS, and
- The date the VIS was given to the vaccine recipient or the parents/legal representative.

We also recommend that the vaccine type, dose, site, route of administration, and vaccine expiration date be documented, and any vaccine refusal (if appropriate).

Failure to document the information listed above on every patient record could result in suspension and an inability to order state-supplied vaccines until the identified issue is resolved.

For those sites maintaining paper copies, the initials of the vaccinator may be recorded in place of the full name and title, as long as the patient's vaccine administration record contains a legend that has the full name and title and its corresponding initials.

Copies of vaccine administration records that can be used in your office are available by visiting MDPH's Vaccine Administration and Clinical Guidance webpage.

F-2. Requirements for retention of written documentation vary and depend on licensing requirements:

- Clinics and hospitals: Must retain documentation for a period of *20 years* after the discharge or final treatment of the patient. State law includes a requirement for providers to notify MDPH before destroying records. (105 CMR: 140.302C, 105 CMR: 130.370A, MGL c111, s70).
- All other facilities (e.g., doctor offices, Boards of Health, Visiting Nurse Associations, nursing homes, etc.): Must retain documentation for a period of *10 years* following the end of the calendar year in which the documentation occurred (NCVIA 1986).

State regulations regarding record retention and destruction (including new regulations pertaining to clinics/hospitals) can be found at the Division of Health Care Facility Licensure and Certification website by selecting "Regulations."

An additional requirement applies to all categories of providers. If a notice of a claim or lawsuit has been made, the VIS, *Provider Enrollment Agreement,* and other types of approved documentation pertaining to the matter must be retained until a final disposition of the claim or litigation (including appeals) has been made.

G. Vaccine Safety

G-1. Healthcare providers are required by law to report to the **Vaccine Adverse Events Reporting System (VAERS)**:

- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccinations.
- Any adverse event listed by the vaccine manufacturer as a contraindication to further doses.

Healthcare providers are strongly **encouraged** to report to VAERS:

- Any clinically important adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event.
- Vaccine administration errors (e.g., wrong route, wrong dose, and wrong age).

All providers should report directly by going to the VAERS website and either:

1. Fill out the online reporting tool; or
2. Complete a fillable VAERS PDF form and upload it onto the VAERS website.

Accommodations will be made for persons unable to submit reports electronically. Additional assistance is available via email at **info@vaers.org** or by phone at 1-800-822-7967.

G-2. Healthcare providers are strongly encouraged to report to the MedWatch website any instances where nirsevimab is not co-administered with other vaccines **and**:

- Any clinically important adverse event that occurs after the administration of nirsevimab, whether it is or is not clear that a vaccine caused the adverse event.
- Vaccine administration errors (e.g., wrong route, wrong dose, and wrong age).

G-3. Each vaccine recipient or the vaccine recipient's parent/legal representative must be furnished with a personal immunization record listing the type, dosage, and date (month, day, and year) of each vaccination. This can be generated from the MIIS or a provider's electronic health record (EHR). Information on the required immunization schedules, the vaccine injury compensation program, and claim filing should also be made available.

G-4. The vaccine safety requirements contained in these guidelines must be communicated to any other health care personnel administering vaccines under the supervision of your site's listed Medical Director.