Massachusetts Department of Public Health
Immunization Division
State-Supplied Vaccine Program

2024 Guidelines for Compliance with Federal and State Vaccine Administration 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.

A. Appropriate Use of State-supplied Vaccine

A-1. Providers must use state-supplied vaccines only for children and adults determined eligible as defined in the most recent versions of the **Childhood Vaccine Availability Table** and the **Adult Vaccine Availability Table** (available on the MDPH Immunization Division Vaccine Management webpage).

A-2. VFC-only vaccines (see Childhood Vaccine Availability Table) must be offered only to VFC-eligible children. **Children < 19 years of age in the following categories are eligible for VFC vaccine:**

- Enrolled in Medicaid, or
- Without health insurance, or
- American Indian (Native American) or Alaska Native, or
- Underinsured children (insurance coverage does not include vaccines or covers only selected vaccines) seen at federally qualified health centers (FQHC) and rural health centers (RHC).

Note: Children enrolled in sCHIP, or the Children's Medical Security Plan (CMSP) may receive all vaccines on the Childhood Availability Table but are not considered VFC eligible when screening or assessing for VFC eligibility.

A-3. **Providers must screen all children (birth through 18 years of age) at every immunization visit**, as outlined in the Provider Enrollment Agreement, to determine eligibility to receive vaccine purchased with VFC funds. **Providers must document the results of VFC screening at <u>every</u> immunization visit.** Patient eligibility screening for VFC may be recorded electronically if all information requested in the *VFC Patient Eligibility Screening Form* is both recorded and retrievable in the event of a VFC 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.

- This table shows <u>the only options</u> to be selected when documenting VFC eligibility in an EHR in Massachusetts:

Eligibility Categories	**Electronic Health Record Drop-Down Selections**
Medicaid/Mass Health	VFC Eligible - Medicaid
Uninsured	VFC Eligible – Uninsured
American Indian/Alaskan Native	VFC Eligible – American Indian/Alaskan Native
Underinsured	VFC Eligible – Underinsured
Private Insurance	NOT VFC ELIGIBLE

- The use of <u>any other options</u>, including but not limited to *state-specific eligible, local specific eligible, unknown, or* names of other specific programs, is **not acceptable** in Massachusetts.

A-4. Borrowing vaccine is defined as the use of a dose of state-supplied vaccine for a child not eligible for state-supplied vaccines when the privately purchased vaccine is not readily available or vice versa. **Borrowing vaccines 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. Most providers should never run into this situation. **State-supplied vaccines may never be used for someone 19 years of age or older unless eligible per the Adult Vaccine Availability table.** If borrowing does occur, the provider must:

- Assure that state-supplied vaccine inventory is adequate to meet the needs of the provider's state-supplied eligible patients and that borrowing state-supplied vaccine will not prevent an eligible child from receiving a needed vaccination.
- Assure that borrowing occurs only when there is a lack of private-stock vaccine due to unexpected circumstances such as a delayed vaccine shipment, vaccine spoiled in-transit to provider or new staff that calculated ordering time incorrectly.
- Complete the *MDPH VFC Vaccine Borrowing Report Form* whenever a state-supplied vaccine that is available only to a state-supplied eligible child is administered to a non-state-supplied eligible child. **State-supplied vaccines cannot be administered to patients 19 years and older, except as outlined in the Adult Vaccine Availability Table.**
    - The completed form should be kept on file as part of the VFC Program records and made accessible to MDPH staff during VFC site visits.

A-5. Fraud and Abuse: **Improper use of VFC 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 VFC or other state-supplied vaccines.
- Billing a patient or third party for VFC or other state-supplied vaccines.
- Charging more than the established maximum regional charge for administration of a VFC vaccine to a VFC-eligible child. (See section C-2)
- Not providing VFC-eligible children VFC vaccine because of parents' inability to pay for the administration fee.
- Not implementing provider enrollment requirements of the VFC program.
- Failing to screen patients for VFC eligibility.
- Failing to maintain VFC records and comply with other requirements of the VFC program.
- Failing to account for VFC or other state-supplied vaccines fully.
- Failing to receive, store, or use VFC or state-supplied vaccine properly. MDPH may require providers to make restitution for any doses of federal or state-purchased vaccines that have been wasted due to provider negligence/mismanagement. See section A-6 for additional information about the restitution policy. Examples of provider negligence/mismanagement include (but are not limited to):
    - Failure to open vaccine shipments from McKesson or Merck immediately, which results in damage to the vaccines.
    - Failure to rotate vaccine stock, which results in expired vaccine.
    - Allowing vaccines to expire. You must transfer the short-dated (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 Management Unit for assistance at 617-983-6828.
    - Using state-supplied vaccines for unapproved groups.
    - Freezing vaccines meant to be refrigerated. (See section B-2 for more details)
    - Refrigerating vaccines meant to be frozen. (See section B-2 for more details)
    - Refrigerator or freezer left unplugged or electrical breaker switched off by provider staff, contractor, or any other individual resulting in damaged vaccines.

- Refrigerator or freezer door left open or ajar by provider staff, contractor, or any other individual resulting in damaged vaccines.
- Vaccines that are left out of the refrigerator and become non-viable – always call the Vaccine Management Unit at 617-983-6828 to determine if vaccines can be identified as viable.
- Power outage in which the provider fails to act according to provider's vaccine standard operating procedures (SOP). (See section B-1)
- Ordering state-supplied vaccine in quantities or patterns that do not match provider profile or otherwise involve over-ordering of VFC or state-supplied vaccine doses.
- Wastage of state-supplied vaccine.
- Refrigerator malfunction in a non-pharmaceutical grade unit that is being used to store pediatric vaccines resulting in damaged vaccines. (See B-2)
- Storing state-supplied vaccines in a household combination unit.
- Failure to notify the Vaccine Management Unit of any temperature excursion.
- Failure to complete the associated Temperature Excursion Reporting Form for any out-of-range temperatures in vaccine storage units.

Any other handling and storage mistakes made by provider staff.

A-6. MDPH 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-5) if:

a. it is the 1st incident, and the total loss is over $25,000, or
b. it is the 2nd incident (or greater) 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.

MDPH will notify the provider in writing concerning the number of doses of each vaccine that must be replaced. Vaccine orders from the provider will not be processed by the Vaccine Management Unit until a copy of the invoice for the replacement vaccine has been received, reviewed, and determined to be adequate by MDPH.

Note: MDPH Immunization Division will only hold providers accountable in situations of provider negligence/mismanagement and will not seek restitution for a vaccine loss that occurred due to a circumstance beyond the provider's control (e.g., an act of nature). Providers will be given due process to dispute cases of avoidable loss. Procedures for appealing a restitution decision will be included in the formal restitution notification given to practices. However, MDPH 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.** The Vaccine Management SOP must be reviewed and updated annually, or whenever there is a change in responsible staff. The SOP must include:

- Designation of a Primary Vaccine Coordinator and staff person who will act as their back up**. Providers must notify the Vaccine Management Unit either by phone 617-983-6828 or email dph-vaccine-management@mass.gov within 10 days when a new Primary or Back-Up Vaccine Coordinator is designated**. All new Primary Vaccine Coordinators are strongly encouraged to accept an in-person VFC and Vaccine Storage and Handling training.
- 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. Provider must complete and upload the Temperature Excursion Reporting Form and associated temperature logs into the MIIS.

All staff 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.

Providers must have a written Vaccine Transport SOP in place for proper vaccine management during transport, transfer and/or mobile clinics. The Vaccine Transport SOP must be reviewed and updated annually, or whenever there is a change in responsible staff, an update to transport protocols or the intention of starting mobile clinics. The SOP must include:

- Details on transport methods and available supplies on site for transport.
- 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.

A template of MDPH's *Vaccine Management SOP* and MDPH's *Vaccine Transport SOP* can be found on the MDPH Vaccine Management website. Copies of both the Vaccine Management SOP and Vaccine Transport SOP must be uploaded into your MIIS Enrollment profile during each re-enrollment period and whenever an update is made to the documents.

B-2. Providers must agree to follow the manufacturer's specifications and the guidelines established by the MDPH Immunization Division for the storage and handling of vaccines.

Proper vaccine storage and handling include:

- Store all vaccines in the original manufacturers packaging.
- All vaccines, with the exception of varicella, MMRV, Merck's MMR vaccine and Moderna's COVID-19 vaccine, 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 COVID-19 vaccines 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 COVID-19 products stored in a refrigerator should be labeled with their 10-week Beyond Use Date. Pfizer COVID-19 products can never be stored in a regular vaccine freezer.
- Moderna's 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 30 days. Moderna COVID-19 products stored in a refrigerator should be labeled with their 30-day Beyond Use Date.
- Inventory must be clearly marked or identified so that providers can differentiate between state-supplied (which includes VFC vaccine) and privately purchased vaccine. Vaccine that has been short-dated due to an excursion or is subject to a beyond use date due to being stored in secondary storage conditions, must also be labeled with the updated date of spoilage.
- MDPH requires all enrolled practices (not limited to Pediatric Vaccine Program sites as previously required, but also extending to Adult-Only and Flu/COVID-Only sites) 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 flu 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 refrigerator/freezer 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. Vaccine Storage Units cannot have cords/plugs that offer ground fault protection (plugs that have RESET/TEST Buttons).
- Food or beverages must **not** be stored in vaccine storage units with the exception of water bottles per CDC recommendations.
- Using a National Institute of Standards and Technology (NIST) certified, calibrated, biosafe glycol-encased probe thermometer (product temperature thermometer), **temperatures should be physically acknowledged at least twice daily for all vaccine storage units**, preferably at the start of the workday and at the end of the workday.
  - It is required for all enrolled practices to monitor the minimum and maximum temperatures daily.
  - Temperature reports or logs must be reviewed for completeness and out-of-range temperatures. Immediate action must be taken if temperatures are out of range. **It is required that the Vaccine Management Unit is notified of every out-of-range temperature even if it does not result in an alarm.** 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.
  - **Report all vaccine storage and handling issues to the Vaccine Management Unit by uploading the associated temperature logs and completed Temperature Excursion Reporting Form into the MIIS.**
- MDPH requires the use of NIST-certified calibrated digital data loggers (DDL) for continuous 24-hour temperature monitoring on all vaccine storage units at all enrolled practices. These data loggers should have a biosafe glycol-encased detachable temperature probe.
  - Even if digital data loggers are used, providers must still read and acknowledge the minimum and maximum temperatures.
  - Providers are required to have a back-up DDL available for use if their primary DDL is not functioning.
  - If receiving state-supplied DDLs, additional backup DDLs (other than if primary DDL malfunctions) or DDLs used solely for transport purposes will not be provided by the State Vaccine Program.
- **Providers must submit current temperature logs or reports for all vaccine storage units (refrigerators and freezers) with every vaccine order by uploading them into the MIIS.** State-supplied Fridge Tag2L data loggers store temperatures for 56 days. You must upload your temperature logs monthly if you do not order monthly so as not to

lose data. Uploading temperature logs into the MIIS meets the VFC requirement for maintaining temperature logs for at least 3 years.

- Sites utilizing the state-supplied Site-L data loggers must monitor vaccine storage unit temperatures daily via the online SmartView system. The SmartView system will store temperature data for 5 years, thus monthly uploads into the MIIS to avoid losing data are not required. Providers still must submit current temperature logs for all vaccine storage units (refrigerators and freezers) with every vaccine order by uploading them into the MIIS, if utilizing the Site-L data loggers.
- Providers that receive only influenza vaccine from MDPH must submit their temperature logs to the Vaccine Management Unit on a monthly basis starting in August and ending when they exhaust their supply of flu vaccine for the season. Temperature logs should be submitted by uploading directly into the MIIS Vaccine Management Module. Temperature logs must be uploaded within the past 30 days for flu vaccine orders to be processed.
- All vaccine stock must be rotated, so the vaccine with the shortest shelf life is used first.
- All inventory must be checked at least monthly for short-dated (2–3-month shelf life) products that might not be used before expiring. This product must be transferred to another facility that is enrolled to receive state-supplied vaccines so that the vaccine is not wasted, and restitution is not requested. Call the Vaccine Management Unit at 617-983-6828 if you need help facilitating this process. Providers must enter all vaccine transfer transactions into the MIIS Vaccine Management Module.
- Stabilize refrigerator and freezer temperatures by placing water bottles on the floor of the unit where there is empty space.
  - Refrigerator units will hold regular water bottles whereas freezer units will hold frozen water bottles. Make sure to **pre-freeze** the water bottles prior to putting them into the freezer units.
  - When placing the water bottles in the units, place them in increments and watch the temperatures to avoid a potential temperature excursion.
- Store frozen water bottles in the freezer as part of your emergency preparedness in case the need arises to transport vaccines during an emergency. Ideally, you need enough frozen water bottles for two layers in both of the coolers.
- Should 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. Please call the Vaccine Management Unit for consultation before attempting to do this.

B-3. Most state-supplied vaccines will be shipped directly to providers by a third-party distributor. There may be times when some state-supplied vaccine might be transferred to another facility. In such circumstances, providers must follow their established Vaccine Transport SOP. Please consult with the Vaccine Management Unit for additional guidance on vaccine transport. Transferring providers must enter all vaccine transfer transactions 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.

B-4. The provider must maintain an accurate record of vaccines received from the MDPH Immunization Division. This record must include:

- Type of vaccine
- Manufacturer

- Lot number
- Expiration date
- Number of doses received

Please note: In the MIIS Vaccine Management Module, this requirement is fulfilled automatically.

B-5. Providers must accurately report to MDPH, through the MIIS Vaccine Management Module, all required vaccine ordering and usage information, including a complete physical inventory and most recent temperature log(s) when submitting vaccine orders. Temperature reports or logs must be uploaded to the MIIS Vaccine Management Module using the upload temp log function. (Temperature Log Upload Mini Guide)

Handwritten temperature logs are no longer accepted as official temperature tracking for storage units holding state-supplied vaccine. Submitted temperature logs must be generated reports from approved digital data logger devices.

B-6. 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. Please note that Varicella and MMRV doses are always shipped separately and must be stored in the freezer upon arrival in your facility. Pfizer COVID-19 vaccines will be shipped to you by Pfizer.

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.

B-7. Providers must complete a physical inventory of all state-supplied vaccines, including verification of expiration dates prior to submitting vaccine orders, and document this inventory electronically using the MIIS Vaccine Management Module.

- All expired, damaged, or contaminated vaccine must be documented in the MIIS Storage/Handling Problem Module. Please refer to the Storage/Handling Problem Mini-Guide for directions.
- All expired or damaged vaccines must be removed from refrigerator or freezer units promptly and clearly labeled as “expired/damaged, do not use.”
- Mishandled, expired, or damaged vaccine must not be administered.
- Determine vaccine ordering levels for each vaccine so that orders for all vaccines are placed at the same time. For most practices ordering non-seasonal vaccines, orders should ideally be placed on a monthly basis, however, exceptions can be made in certain circumstances or with seasonal vaccines (i.e., Influenza and COVID-19). Depending on the quantity of vaccine the practice administers during the year, vaccine orders could be as frequent as every couple of weeks for extremely large busy practices or as infrequent as a couple times a year for very small practices. Expect order delivery no later than 14 days after the order is processed by the Vaccine Management Unit.
- **Upon arrival, open the box of vaccine immediately.**
    - For shipments from McKesson, check the two transit, temperature monitors. McKesson Specialty must be contacted at 877-836-7123 by the end of the day of receipt of vaccines if temperature monitors indicate a possible temperature variation.

- For direct ship vaccines from Merck, check the shipment date located on the packing list 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 Merck Order Management Center at 800-637-8579 if the date received is later than indicated by the shipper insert.
- For direct ship vaccines from Pfizer, the packing list will appear as a sticker on the inside of the box flap. Providers must take a picture of the packing slip and save with Vaccine Program documentation for a minimum of 3 years.

- Check to see if the packing list matches your vaccine order. If there are any problems or inconsistencies between your order and the vaccine received, contact the Vaccine Management Unit immediately at 617-983-6828.

B-8. 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 MDPH Immunization Division to any other person, clinic, or organization. Transferring of state-supplied vaccines may take place between enrolled MDPH providers, but the transaction must be entered into the MIIS Vaccine Management Module.

B-9. All VFC providers are required to maintain inventories of all ACIP recommended vaccines, including COVID-19 vaccines, with the only exception being specialty providers (i.e., OB/GYN) or flu/COVID-only seasonal providers (i.e. LBOHs). All ACIP recommended vaccines must be made available and provided to all eligible patients at the site in accordance with the Vaccine Availability Tables.

B-10. Providers must maintain all records related to the VFC Program for a minimum of 3 years. These records must include the authorized representative's response about a child's eligibility, temperature logs, and receipt of all state provided vaccines (see section B-2 and B-4). 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 MDPH Immunization Division or the Federal Department of Health and Human Services (DHHS).

B-11**. The Primary and Back-up Vaccine Coordinator at each VFC provider site must receive annual VFC and Vaccine Storage and Handling training.** This training must cover all VFC requirements, including proper storage and handling of state-supplied vaccines. This requirement may be met by one of the following: VFC compliance site visit with a formal training component, webinar training, or an in-person presentation (e.g., Immunization Update seminar, specified break-out session at MIAP).

B-12. Providers must register for the MIIS at www.miisresourcecenter.com in order to have access to the MIIS Vaccine Management Module. The Vaccine Management Module includes provider enrollment, temperature log upload, vaccine transfer, vaccine ordering, and inventory management functionality and reporting damaged/expired vaccine. **Note: Online provider enrollment and vaccine management using the MIIS is required for all provider (pediatric and adult) sites**. Contact the MIIS help desk at 617-983-4335 or miishelpdesk@mass.gov with any questions regarding registration. Each facility should have at least 2 staff registered in the MIIS.

B-13. **By law (MGL Chapter 111, Section 24M), all licensed health care providers practicing who administer immunizations shall report to the immunization registry** such data related to immunizations as the department determines is necessary for disease

prevention and control. For more information and to initiate the onboarding process with the MIIS, go to www.miisresourcecenter.com/.

B-14. **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 or re-enroll in the Universal Vaccine Program, sites must have a valid facility or individual MCSR license on file in the MIIS.

C. Billing and Charging for State-supplied Vaccine

C-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).

C-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.

C-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 have unpaid vaccine administration fees.

D. Vaccine Information Statements (VIS) and Consent

D-1. All providers, including public clinics and private offices, 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). See D3 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 item D-4 below.

D-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 13-valent vaccine (PCV13) Pneumococcal 15-valent (PCV15); hepatitis A vaccine (HAV); trivalent or quadrivalent influenza vaccine (both inactivated influenza vaccine [IIV] and live, attenuated influenza vaccine[LAIV]); rotavirus vaccine(RV); meningococcal ACWY vaccines; serogroup B meningococcal (Men B) and human papillomavirus vaccine (HPV); COVID-19.

If there is not a single VIS for a combination vaccine, use the VISs for all components as appropriate.

For the vaccines not covered under the National Childhood Vaccine Injury Act (i.e., adenovirus, anthrax, cholera, Japanese encephalitis, 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. Information about the National Vaccine Injury Compensation Program can be found at https://www.hrsa.gov/vaccine-compensation/index.html.

D-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 Immunization Action Coalition website (www.immunize.org/vis) or on the CDC website (https://www.cdc.gov/vaccines/hcp/vis/current-vis.html) and can be downloaded directly into a personal mobile device. Providers are encouraged to subscribe for email notification when a VIS is updated, or a new VIS becomes available at the same website (https://www.cdc.gov/vaccines/hcp/vis/current-vis.html), click on "Get Email Updates" and enter your email address.

Prior to vaccination, VIS may be:

- Provided as a paper copy
- Offered on a permanent, laminated office copy
- Downloaded by the vaccinee (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 don't read or speak English, 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 Immunization Action Coalition website at www.immunize.org/vis. Providers can supplement VISs with visual presentations or

oral explanations as needed. VISs on the CDC website are screen-reader accessible and can be found at https://www.cdc.gov/vaccines/hcp/vis/current-vis.html.

D-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.

D-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.

E. Documentation of Vaccine Administration

E-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 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.

E-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 visiting https://www.mass.gov/orgs/division-of-health-care-facility-licensure-and-certification, and then 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.

F. Vaccine Safety

F-1. Healthcare providers are required by law to report to the **Vaccine Adverse Events Reporting System (VAERS)** (https://vaers.hhs.gov/):

- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination (https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf) 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 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)

Online reporting is encouraged. Please report clinically important adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event.

All providers should report directly by going to the VAERS website (https://vaers.hhs.gov/reportevent.html), 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.

F-2. 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.

F-3. The requirements contained in these guidelines must be communicated to any other health care personnel administering vaccines under the supervision of the physician signing this agreement.

G. Responsibilities of the Medical Director

G-1. The Medical Director, on behalf of himself or herself and all practitioners associated with the entity, is responsible for ensuring that state-supplied vaccines, including VFC 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 MDPH regarding immunizations or vaccine-preventable diseases are disseminated to all relevant staff within his or her facility. MDPH

recommends that each practice or agency have a communication plan and identify a person responsible for disseminating information.

G-2. Within the MIIS, the Medical Director is responsible for electronically signing the online *Provider Enrollment Agreement* and *Agreement to Comply with Federal and State Requirements for Vaccine Administration*, providing the MDPH Immunization Division 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 and Medicaid number where applicable.

G-3. **MDPH Immunization Division staff are required to make an initial educational site visit to a provider who is enrolling in the VFC Program for the first time or returning to the program after an extended leave.** The enrollment visit ensures that the provider and office staff are educated on the VFC Program requirements and have appropriate resources to implement these requirements.

G-4. **The Medical Director understands and agrees that MDPH Immunization Division staff are required to make site visits every 12 to 24 months to evaluate vaccine handling and storage, VFC screening, and record keeping.** MDPH staff will also conduct unannounced visits to some providers to check for proper storage and handling practices.

- The Medical Director is responsible to guarantee that outstanding non-compliance findings are addressed and resolved as part of completing site visits.

G-5. The Medical Director is responsible for the staff who order, store, administer, and report on vaccine usage. Any change in Medical Director must be reported to the MDPH Immunization Division within ten (10) days by calling the Vaccine Management Unit at 617-983-6828.

G-6. **The Medical Director is responsible for designating a Primary and Back-up Vaccine Coordinator.** The Primary Vaccine Coordinator is responsible for oversight of all vaccine storage and handling, including vaccine ordering and acting as 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 MDPH Immunization Division within ten (10) days by calling the Vaccine Management Unit at 617-983-6828. Sites must have a Primary and Back-up Vaccine Coordinator identified at all times.

G-7. The Medical Director is responsible for assuring that:

- Immunization policies and practices are in compliance with the *General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)*. https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html and
- The immunization schedule, dosage, and contraindications followed are in compliance with those established by the Advisory Committee on Immunization Practices (ACIP). ACIP recommendations and link to the Immunization Schedules can be found at https://www.cdc.gov/vaccines/hcp/acip-recs/index.html
- All ACIP-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 vaccines are offered during enrollment.

Non-compliance with any of the above shall be cause to exclude the provider from continued participation in the MDPH Immunization Division/VFC Program.

Vaccine Administration Resources:

- CDC Vaccines & Immunizations webpage: https://www.cdc.gov/vaccines/index.html
- CDC Vaccine Administration webpage: https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html
- CDC Vaccine Administration e-learn: https://www2.cdc.gov/vaccines/ed/vaxadmin/va/ce.asp
- CDC Pink book webinars: https://www.cdc.gov/vaccines/ed/webinar-epv/index.html
- Immunization Action Coalition: www.immunize.org

H. Site Visits

H-1. Providers must be assessed for compliance with VFC and other federal requirements in accordance with MDPH guidelines every 12 to 24 months.

H-2. If any problems are identified with VFC compliance, the provider will receive follow-up contact and education, in accordance with CDC guidelines.

H-3. MDPH will perform some 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.

H-4. 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.

I. Additional Guidance

Injection Safety for Patients and Health Care Personnel

(American Practitioners of Infection Control, World Health Organization, CDC)

I-1. Healthcare workers should follow the principles of injection safety. This includes the practice of one needle, one syringe, only one time, meaning using a needle and syringe only once, only on one patient.

In addition, hazards to healthcare workers must be minimized. By meeting the requirements of the federal Occupational Health and Safety Administration (OSHA) Bloodborne Pathogen Standard and MDPH regulations, the risk of needle stick injury is reduced. All needles used to attach to prefilled syringes or to use to administer vaccines should have built-in sharps injury prevention features.

I-2. Providers should ensure that any used needles are disposed of immediately and appropriately in sharps containers that are rigid, puncture-proof, and can be closed, preventing needles from spilling out. The containers must contain the appropriate labels for biohazardous waste.

I-3. **The person who prepares the vaccine for administration should be the same person who administers the vaccination.** CDC strongly recommends providers prepare vaccines only at the time of administration to ensure the cold chain is maintained and vaccines are not inappropriately exposed to light. Do not pre-draw vaccines before they are needed.

I-4. The OSHA requires all employers to have an exposure control plan that delineates procedures for the management of needle stick injuries and other potential exposures to bloodborne pathogens. An example can be found at https://www.mass.gov/doc/sample-exposure-control-plan-annotated/download

I-5. **In the event of a needle stick injury or exposure to blood or body fluids:**

- Wash needlesticks and cuts with soap and water
- Flush splashes into the nose, mouth, or skin with water
- Irrigate eyes with clean water, saline, or sterile irrigants
- Report the incident to your supervisor
- Immediately seek medical evaluation and possible treatment
- See CDC emergency Needle Stick Information: https://www.cdc.gov/niosh/topics/bbp/emergnedl.html
- Questions about appropriate medical treatment for occupational exposures, 24-hour assistance is available from the clinicians' Post Exposure Prophylaxis Hotline (PEPline) at 1-888-448-4911.www.nccc.ucsf.edu.