

## **2024 Agreement to Comply with Federal and State Requirements for Vaccine Administration**

The Vaccines for Children (VFC) Program is a component of the Massachusetts Department of Public Health (MDPH) Immunization Division. To receive vaccine provided by the MDPH Immunization Division and VFC program, I, on behalf of myself and any and all practitioners associated with this medical office, group practice, HMO, health department, hospital, clinic, or other entity of which I am the medical director or equivalent, agree to:

1. Read and comply with the federal and state requirements for vaccine ordering, accountability, management and administration as outlined in the enclosed *Guidelines for Compliance with Federal Vaccine Administration Requirements*.
2. Ensure all communications and standard operating procedures from MDPH regarding immunizations or vaccine preventable diseases are disseminated to and reviewed by all relevant staff within the facility.
3. Administer state-supplied vaccine only to those children and adults determined eligible as defined in the most recent version of the *Childhood Vaccine Availability Table*, the *Adult Vaccine Availability Table* and the *Summary of the Advisory Committee on Immunization Practices Recommended Groups for Vaccination*. (See Section A-1 of the *Guidelines for Compliance with Federal Vaccine Administration Requirements*)
4. Use the Vaccines for Children (VFC) Program eligibility screening form provided to me by the MDPH Immunization Division to determine how many children in my practice are eligible for VFC vaccine. MDPH requires providers to document the results of VFC screening at every 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. Children less than 19 years of age in the following categories are eligible for VFC vaccine: (a) enrolled in Medicaid or (b) without health insurance, or (c) American Indian (Native American) or Alaska Native or (d) underinsured children (has health insurance but the coverage does not include vaccines or only selected vaccines) seen at federally qualified health centers (FQHC). Please note, children who are enrolled in secondary MassHealth insurance should also be screened as VFC Eligible. Children enrolled in sCHIP or the Children's Medical Security Plan (CMSP) are also covered with state funds. (See Sections A-2, A-3 of the *Guidelines for Compliance with Federal Vaccine Administration Requirements*)
5. Properly use VFC vaccine as required by Medicaid regulation 42 CFR §455.2. Improper use of VFC vaccine may constitute fraud and abuse and is punishable by law. VFC vaccines will be kept separate from privately purchased vaccines. (See Section A-5 of the *Guidelines for Compliance with Federal Vaccine Administration Requirements*)
6. Properly complete and submit the Temperature Excursion Reporting Form in the event of an out-of-range temperature in a vaccine storage unit holding state-supplied vaccine. A completed Temperature Excursion Reporting Form must include all pertinent details about the excursion, viability results received directly from the manufacturer and abidance to any and all follow-up actions noted by the Vaccine Management Unit after review.
7. Provide restitution for any doses of federal or state-purchased vaccines that have been wasted due to the provider's failure to properly receive, store, or use vaccines. Restitution would require the provider to privately purchase replacement doses for the vaccines that were wasted. For a list of examples see (Section A-5, A-6 of the *Guidelines for Compliance with Federal Vaccine Administration Requirement*).
8. Follow the manufacturer's specifications and the guidelines established by the MDPH Immunization Division for the storage and handling of vaccines, including having written procedures for vaccine management and vaccine transport that will be reviewed and updated annually. (See Section B of the *Guidelines for Compliance with Federal Vaccine Administration Requirements*)
9. MDPH requires all enrolled practices (any site that administers at least some state-supplied vaccines ) to store ALL refrigerated vaccines in pharmaceutical grade refrigerators at ALL times. (See Section B-2 of the *Guidelines for Compliance with Federal Vaccine Administration*)
  - Stand-alone freezers that are not pharmaceutical grade are acceptable.

- Must use a NIST certified calibrated digital data logger for continuous 24-hour temperature monitoring on all vaccine storage units at all pediatric practices.
  - **The use of any combination refrigerator/freezer unit or dormitory style unit for storage of any vaccines including temporary storage is strictly prohibited.**
9. Maintain all records related to the VFC Program for a minimum of 3 years. These records include the authorized representative's response about a child's eligibility, temperature logs, SOP documentation and receipt of all state provided vaccines. Release of such records will be bound by the privacy protection of Federal Medicaid law. If requested, I will make such records available to the MDPH Immunization Division or the federal Department of Health and Human Services (DHHS). (See Section B-2 and B-4) of the *Guidelines for Compliance with Federal Vaccine Administration Requirements*)
  10. Accurately report to MDPH all required vaccine ordering and usage information, including a complete physical inventory and most recent temperature log when submitting vaccine orders electronically using the MIIS. All expired, damaged or contaminated vaccine must be documented in the New Order Module or the Storage/Handling Problem Module. (See Section B-5, of the *Guidelines for Compliance with Federal Vaccine Administration Requirements*)
  11. All VFC providers are required to maintain inventories of all ACIP recommended vaccines, including COVID-19 vaccines, with the only exception being specialty providers (ie OB/GYN) or flu/COVID-only seasonal providers (ie LBOHs) and make them available to eligible patients 18 years of age and younger.
  12. All state-supplied vaccines must be provided to all eligible patients in accordance with the *Childhood Vaccine Availability Table*, the *Adult Vaccine Availability Table* and section B-9 of the *Guidelines for Compliance with Federal Vaccine Administration Requirements*.
  13. Not impose a charge for the cost of state-supplied vaccine to a patient or a third-party (e.g. insurance company or Medicaid). VFC vaccine will not be given to non-VFC eligible children. (See Section C-1 of the *Guidelines for Compliance with Federal Vaccine Administration Requirements*)
  14. 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, 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. (See Section C-2 of the *Guidelines for Compliance with Federal Vaccine Administration Requirements*). **May only issue a single bill to non-Medicaid VFC-eligible patients within 90 days of vaccine administration.**
  15. Not deny state-supplied vaccine 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 vaccine to any VFC-eligible child who presents for immunization services at their facility. (See Section C-2 of the *Guidelines for Compliance with Federal Vaccine Administration Requirements*)
  16. **Not report unpaid vaccine administration fees for non-Medicaid VFC patients to collections. Administration fees must be zeroed out if left unpaid. Providers may not refuse to vaccinate and eligible children whose parents have unpaid vaccine administration fees.**
  17. Provide a copy of the relevant and current edition of the Vaccine Information Statements (VIS) before administering each dose of vaccine and maintain records in accordance with the National Childhood Vaccine Injury Act. (See Section D of the *Guidelines for Compliance with Federal Vaccine Administration Requirements*) This includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting Systems (VAERS). (See Section F of the *Guidelines for Compliance with Federal Vaccine Administration Requirements*)
  18. Properly document vaccine administration information on the permanent medical record (electronic or paper) of the recipient and maintain the documentation according to the regulations of the Commonwealth of Massachusetts. (See Section E of the *Guidelines for Compliance with Federal Vaccine Administration Requirements*)
  19. Understand and agree that MDPH Immunization Division staff is required to make an initial educational site visit when enrolling in the VFC Program for the first time. (See Section G-3 of the *Guidelines for Compliance with Federal Vaccine Administration Requirements*) MDPH Immunization Division staff is also required to

conduct site visits, every other year, to ensure compliance with VFC and other federal requirements in accordance with MDPH guidelines and provide educational follow-up to address any problems in accordance with CDC fraud/abuse guidelines. MDPH staff will perform some unannounced provider visits to check for proper storage and handling practices. (See Section H of the *Guidelines for Compliance with Federal Vaccine Administration Requirements*) The Primary Vaccine Coordinator and their back-up must also participate in an annual educational training/contact. (See Section B-10 of the *Guidelines for Compliance with Federal Vaccine Administration Requirements*)

20. Comply with the appropriate immunization schedule, dosage, and contraindications that are established by the Department of Health and Human Services' Advisory Committee on Immunization Practices (ACIP), unless (a) in making a medical judgment in accordance with accepted medical practice, I deem such compliance to be medically inappropriate or (b) the particular requirement is not in compliance with Massachusetts law, including laws relating to religious or other exemptions.<sup>1</sup> (See Section G of the *Guidelines for Compliance with Federal Vaccine Administration Requirements*)
21. Providers must register for the Massachusetts Immunization Information System (MIIS) by calling (617-983-4335), in order to have access to the MIIS online Vaccine Management Module. The Vaccine Management Module includes provider enrollment, vaccine ordering and inventory management functionality, temperature upload, transfer vaccines and reporting damaged/expired vaccines. Online provider enrollment and vaccine ordering is now required for all pediatric and adult sites. (See Section B-11 of the *Guidelines for Compliance with Federal Administration Requirements*)
22. By law (MGL Chapter 94C, Section 7 and regulations of the Department of Public Health at 105 CMR 700.004), all provider sites who manufacture, distribute, prescribe, administer, dispense or possess controlled substances (including vaccines) must have an active and valid Massachusetts Controlled Substance Registration (MCSR) license. Providers must renew that MCSR license on an annual basis.
23. By law (M.G.L. 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.contactmiis.info](http://www.contactmiis.info).
24. Provide, with this agreement, a list of all physicians, physician assistants, nurse practitioners and nurse-midwives at this facility who prescribe vaccines, along with their medical license numbers and Medicaid numbers, where applicable. (See Section G-2 of the *Guidelines for Compliance with Federal Vaccine Administration Requirements*)
25. I or the Commonwealth may terminate this agreement at any time for personal reasons or failure to comply with these requirements. If I choose to terminate the agreement, I agree to properly return any unused vaccine.

***Medical Director statement: To receive publicly funded vaccines at no cost, I agree to the requirements listed above on behalf of myself and all the practitioners, nurses and others associated with this health care facility of which I am the medical director or practice administrator or equivalent.***

Medical Director's signature: \_\_\_\_\_

Vaccine Provider Site Number \_\_\_\_\_ Date: \_\_\_\_\_

<sup>1</sup> The ACIP immunization schedule is compatible with the AAP and AAFP recommendation