

2025 Agreement to Comply with State Vaccine Program Requirements

The Vaccine Program, as mentioned throughout the agreement, is comprised of three sub-programs: universal state pediatric vaccine program, federal vaccines for children (VFC) program and, 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 utilize according to the [Guidelines for Compliance with State Vaccine Program Requirements](#).

To receive vaccines provided by the Vaccine 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 Vaccine Program requirements for vaccine ordering, accountability, management and administration as outlined in the [Guidelines for Compliance with State Vaccine Program Requirements](#).
2. 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 Sections A-1 and A-3 of the [Guidelines for Compliance with State Vaccine Program Requirements](#))
3. Screen and document VFC eligibility with every immunization administered to patients 18 and under. The Vaccine Program requires providers to document the results of VFC screening at every immunization visit. Patient eligibility screening for VFC eligibility 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 compliance visit. Children less than 19 years of age in the following categories are VFC eligible: (a) enrolled in Medicaid or (b) without health insurance, (c) American Indian (Native American)/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, that children enrolled in secondary MassHealth insurance should also be screened as VFC Eligible. However, children enrolled in the State Children's Health Insurance Program (sCHIP) or the Children's Medical Security Plan (CMSP) are not considered VFC eligible. (See Section A-2 of the [Guidelines for Compliance with State Vaccine Program Requirements](#))
4. Proper use of state-supplied vaccine is required by Medicaid regulation 42 CFR §455.2. Improper use of state-supplied vaccine may constitute fraud and abuse and is punishable by law. The vaccines should be marked or identified so that state-supplied and privately purchased vaccine can be differentiated (See Sections A-6 and B-3a of the [Guidelines for Compliance with State Vaccine Program Requirements](#))
5. State-supplied vaccines can only be administered within your own office/clinic setting. Providers 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. Sister sites and/or other associated sites, must be enrolled in the Vaccine Program in order to receive a transfer of state-supplied vaccine. (See Section A-5 of the [Guidelines for Compliance with State Vaccine Program Requirements](#))
6. 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). (See Section C-2a of the [Guidelines for Compliance with State Vaccine Program Requirements](#))
7. Follow the manufacturer's specifications and the guidelines established by the Vaccine Program for the storage and handling of vaccines. Always store ALL state-supplied refrigerated vaccines in stand-alone pharmaceutical grade refrigerators. State-supplied frozen vaccines are not required to be stored in pharmaceutical grade units, but the freezer must be stand-alone. The use of any combination refrigerator/freezer unit or dormitory style unit for storage of any state-supplied vaccines, including

temporary storage, is strictly prohibited. All state-supplied vaccine must be monitored with a National Institute of Standards and Technology (NIST) certified calibrated digital data logger device at all times for continuous 24-hour temperature monitoring. (See Section B-3 of the *Guidelines for Compliance with State Vaccine Program Requirements*)

8. Accurately report to the Vaccine Program all required vaccine ordering and usage information, including a complete physical inventory and most recent temperature log when submitting vaccine orders in the MIIS. Determination of ordering quantities should be based on remaining inventory and anticipated need over the subsequent 6 weeks. All expired, damaged, or contaminated vaccine must be documented via a Storage and Handling Issue. (See Section B-4 of the *Guidelines for Compliance with State Vaccine Program Requirements*)
9. Properly complete and submit a Temperature Excursion Issue via the MIIS for any out-of-range temperature (regardless of duration) in a vaccine storage unit holding state-supplied vaccine. A submitted Temperature Excursion Issue must include all pertinent details about the excursion and viability results received directly from the manufacturer for the submission to be reviewed and closed by the Vaccine Program. Providers must promptly abide to any and all follow-up actions noted by the Vaccine Program upon submission review. (See section A-6 and B-3d of the *Guidelines for Compliance with State Vaccine Program Requirements*)
10. Provide restitution for any doses of state-supplied 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. Additionally, restitution may be requested for any state-supplied data logger that is lost due to neglect or rendered non-functional due to mishandling/improper placement. Data logger restitution would require the provider to privately purchase a comparable data logger device. (For a list of examples see section A-7 and B-3d of the *Guidelines for Compliance with State Vaccine Program Requirements*)
11. Ensure all Vaccine Program communications, the [2025 Vaccine Management SOP](#) and [2025 Vaccine Transport SOP](#) are disseminated to, reviewed, and signed by all staff who interact with state-supplied vaccine at your facility. (See Section B-1 of the *Guidelines for Compliance with State Vaccine Program Requirements*)
12. 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. (See Section C-2b of the *Guidelines for Compliance with State Vaccine Program Requirements*)
13. Maintain all records related to the Vaccine Program for a minimum of 3 years. These records include the authorized representative's response about a child's VFC eligibility, temperature logs, SOPs, borrowing forms, replacement forms, temperature excursion issues, and packing slips. Packing slips for Merck & Co., Inc. must be provided to the Vaccine Program, via an email to dph-vaccine-management@mass.gov, immediately upon receipt of the vaccine. Release of Vaccine Program records will be bound by the privacy protection of Federal Medicaid law. If requested, I will make such records available to the Vaccine Program or the federal Department of Health and Human Services (DHHS). (See Section B-2 and C-2c of the *Guidelines for Compliance with State Vaccine Program Requirements*)
14. Provide 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 C-3 of the *Guidelines for Compliance with State Vaccine Program Requirements*)
15. Understand and agree that Vaccine Program Quality Assurance staff are required to make an initial enrollment site visit when enrolling in the Vaccine Program for the first time. Vaccine Program Quality Assurance staff are also required to conduct Compliance site visits, every 12-24 months, to ensure compliance with Vaccine Program requirements and provide educational follow-up to address any problems in accordance with CDC fraud/abuse guidelines. Sites enrolled as adult-only or respiratory-only are excluded from Compliance site visits. Additionally, Vaccine Program Quality Assurance staff will perform some unannounced provider visits to

- check for proper storage and handling practices. (See Section C-4 of the *Guidelines for Compliance with State Vaccine Program Requirements*)
16. Designate a Primary and Backup Vaccine Coordinator for my practice and ensure the designated Primary and Backup Vaccine Coordinators complete the current annual Vaccine Program Storage and Handling training. (See Section C-3 of the *Guidelines for Compliance with State Vaccine Program Requirements*)
 17. I have the discretion to approve continued use of vaccines in the case of the manufacturer being unable to confirm viability due to insufficient data. Additionally, have the authority to decide whether or not to re-vaccinate in the event non-viable vaccines are administered to patients. (See Section C-5 of the *Guidelines for Compliance with State Vaccine Program Requirements*)
 18. All Vaccine Program providers are required to maintain inventories of all Department of Health and Human Services' Advisory Committee on Immunization Practices (ACIP) recommended vaccines, with the only exception being specialty providers (i.e., OB/GYN), adult-only or respiratory-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. (See Section B-4 and C-6 of the *Guidelines for Compliance with State Vaccine Program Requirements*)
 19. Comply with the appropriate immunization schedule, dosage, and contraindications that are established by the 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.¹ (See Section C-6 of the *Guidelines for Compliance with State Vaccine Program Requirements*)
 20. Do not impose a charge for the cost of state-supplied vaccine to a patient or a third-party (e.g. insurance company or Medicaid). (See Section D-1 of the *Guidelines for Compliance with State Vaccine Program Requirements*)
 21. Sites 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. 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 D-2 of the *Guidelines for Compliance with State Vaccine Program Requirements*)
 22. May only issue a single 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. After 90 days, any outstanding balance related to the administration of the vaccine to a non- Medicaid must be written off. 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. (See Section D-3 of the *Guidelines for Compliance with State Vaccine Program Requirements*)
 23. Properly document vaccine administration information in 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 F of the *Guidelines for Compliance with State Vaccine Program Requirements*)
 24. 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 E of the *Guidelines for Compliance with State Vaccine Program Requirements*) This includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting Systems

(VAERS) or Medwatch (when nirsevimab is not co-administered with another vaccine). (See Section G of the *Guidelines for Compliance with State Vaccine Program Requirements*)

25. I or the Vaccine Program 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 or replace any unused vaccine.**

Medical Director statement: To receive state-supplied 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: _____

¹ The ACIP immunization schedule is compatible with the AAP and AAFP recommendation