2026 Agreement to Comply with State Vaccine Program Requirements

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 utilize according to the <u>Guidelines for Compliance with State Vaccine Program Requirements</u>.

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.
- Administer state-supplied vaccine only to those children and adults determined eligible as defined in the most recent version of the <u>Childhood Vaccine Availability Table</u>, <u>Adult Vaccine Availability Table</u> and <u>DPH</u> <u>Recommended Guidance for Vaccines</u>. (See Sections A-1 and A-3 of the <u>Guidelines for Compliance with State Vaccine Program Requirements</u>)
- 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. (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. (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. All storage units holding state-supplied vaccine must abide by the most upto-date version of the <u>Vaccine Storage Unit Checklist</u>. All data logger device monitoring state-supplied vaccine must abide by the most up-to-date version of the <u>Data Logger Requirements</u> document. (See Section B-3 of the <u>Guidelines for Compliance with State Vaccine Program Requirements</u>)
- 8. Accurately report to the Vaccine Program all required vaccine ordering and usage information, including a complete physical inventory and most recent temperature logs for all storage units holding state-supplied vaccine when submitting vaccine orders in the MIIS. 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 <u>qualifying out-of-range</u> temperature that results in an excursion in a vaccine storage unit holding state-supplied vaccine. 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-3e of the *Guidelines for Compliance with State Vaccine Program Requirements*)

- 10. Provide restitution for any doses of state-supplied vaccines that have been wasted/lost 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 transition to a privately purchased data logger device as they would not be receiving a state-supplied replacement. (For a list of examples see section A-7 and B-3e of the *Guidelines for Compliance with State Vaccine Program Requirements*)
- 11. Ensure all Vaccine Program communications (including the Vaccine Program Monthly Update communications), the <u>Vaccine Management SOP</u> and <u>Vaccine Transport SOP</u> are disseminated to, reviewed, and signed (if required) by all staff who interact with state-supplied vaccine at your facility. Providers must stay subscribed to Constant Contact emails sent by the Vaccine Program. (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. Provide a valid Billing National Provider Identifier (NPI) number as part of your annual enrollment information. Providers must provide their Billing NPI every re-enrollment period as part of the State Vaccine Program requirements. (See Section C-2c of the *Guidelines for Compliance with State Vaccine Program Requirements*)
- 14. Maintain all records related to the Vaccine Program for a minimum of 3 years. If requested, providers 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-2d of the *Guidelines for Compliance with State Vaccine Program Requirements*)
- 15. 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*)
- 16. Understand and agree that the Vaccine Program Quality Assurance staff are required to conduct sites visits. Enrollment visits to new and returning providers, Compliance visits every 12-24 months, and Unannounced Storage and Handling. Sites enrolled as adult-only or respiratory-only are excluded from Compliance site visits. (See Section C-4 of the *Guidelines for Compliance with State Vaccine Program Requirements*)
- 17. Designate a Primary and Backup Vaccine Coordinator for the 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*)
- 18. Designated provider Medical Directors 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, Medical Directors have the authority to decide whether 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*)
- 19. All Vaccine Program providers are required to maintain inventories of all DPH recommended 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 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*)
- 20. Comply with the appropriate immunization schedule, dosage, and contraindications that are indicated in the DPH Recommended Guidance for Vaccines, 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. (See Section C-6 of the Guidelines for Compliance with State Vaccine Program Requirements)

- 21. 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*)
- 22. 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. (See Section D-2 of the *Guidelines for Compliance with State Vaccine Program Requirements*)
- 23. 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. **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*)
- 24. 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*)
- 25. 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*)
- 26. 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: