

The Commonwealth of Massachusetts

Executive Office of Health and Human Services Department of Public Health

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Board of Registration in Pharmacy Drug Control Program Immunization Program

Policy 2023-02: Vaccine Administration

The Massachusetts Department of Public Health ("DPH"), through the Board of Registration in Pharmacy ("Board"), Drug Control Program ("DCP"), and Immunization Program is making vaccines more accessible by authorizing qualified pharmacy personnel to administer certain vaccines and emergency medications as designated by DPH.

For the purposes of this policy, pharmacy personnel are defined as licensed pharmacists, pharmacy interns, and pharmacy technicians, NOT pharmacy technician trainees.

Any pharmacy intern or pharmacy technician administering vaccines pursuant to this policy must have the approval of a licensed pharmacist on duty and be under the direct supervision of a licensed pharmacist who meets all requirements to immunize as outlined in this policy.

Pursuant to a standing order or patient-specific prescription, and using their professional judgement, pharmacists may also dispense a vaccine to a patient/caregiver or a healthcare provider authorized to administer the vaccine.

I. Authorized Vaccines

A. Qualified pharmacy personnel are authorized to administer routine vaccines which are FDA-approved or FDA-authorized vaccines or have been <u>recommended for</u> routine use by the DPH Commissioner.

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- B. The DPH Commissioner may decide to make recommendations for vaccine use in populations or recommend usage schedules that are not listed in the original, FDAapproved or authorized product information. Under these circumstances, qualified pharmacy personnel may administer those vaccines in accordance with the most current <u>DPH Commissioner recommendations</u>, even if the recommendations differ from the manufacturer's FDA-approved or authorized labeling.
- C. Pharmacists engaged in a <u>Collaborative Drug Therapy Management</u> ("CDTM") agreement may administer "travel vaccines" as indicated in <u>CDC's yellow book</u> as well as other indicated "non-routine" vaccines provided that the administration of such vaccines is included in the CDTM agreement. Any other federal / state requirements, including additional training, must also be met. This section does not apply to pharmacists practicing in Board-licensed community or retail pharmacy settings.

II. Vaccine Recipients

Qualified pharmacy personnel may only administer vaccines to individuals who are **5** years of age and older, in accordance with <u>105 CMR 700.004(B)(6)</u>.

III. Training and Other Requirements

- A. All pharmacy personnel administering vaccinations must have a current cardiopulmonary resuscitation ("CPR") certification.
- B. Proof of training and CPR certification for pharmacy personnel administering vaccinations must be kept on file in the pharmacy.
- C. **Pharmacists and pharmacy interns** must also successfully complete an American Council on Pharmaceutical Education ("ACPE") accredited training course prior to administering vaccines.
 - 1. Minimum program requirements:
 - a. 12 contact hours of self-study modules with case studies and assessment exam; and
 - b. 8 contact hours of live seminar with final exam; and
 - c. hands-on assessment of intramuscular and subcutaneous injection techniques appropriate for the patient's age.
 - 2. The goals of training programs must:
 - a. provide comprehensive immunization education and training;
 - b. provide knowledge, skills, and resources necessary to establish and promote a successful immunization service;
 - c. include clinical evaluation of indications and contraindications;

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- d. teach how to identify at-risk patient populations needing immunizations;
- e. teach how to administer immunizations in compliance with legal and regulatory standards;
- f. recognize and treat vaccine reactions; and
- g. include pre-administration patient education and screening, vaccine storage and handling, administration of medication, record-keeping, and reporting of adverse events.
- 3. Pharmacists must obtain at least 1 hour of ACPE-approved, immunization-related continuing pharmacy education every calendar year.
- D. **Pharmacy technicians** must meet the following additional requirements before administering vaccines.
 - 1. Must be licensed as a Pharmacy Technician ("PT") and either:
 - a. be nationally certified (i.e., ExCPT or PTCB); or
 - b. have worked at least 500 hours <u>after</u> being licensed as a PT.

 **Pharmacy Technician Trainees ("PTTs") may NOT vaccinate.
 - 2. Successfully complete an ACPE accredited <u>6-hour</u> training program to include assessment exam(s) and the following minimum requirements:
 - a. at least 2 hours of live training to include instruction and hands-on assessment of intramuscular and subcutaneous injection techniques appropriate for the patient's age; and
 - b. recognition and management of vaccine reactions.
 - 3. Complete at least 2 <u>additional</u> hours of documented on-the-job training with an experienced certified immunizer and completion of a <u>Skills Checklist for Vaccine Administration</u> (or similar).
 - 4. After the pharmacist counsels the patient and selects the vaccine, a pharmacy technician is only authorized to perform the physical act of preparing and administering the vaccine and providing emergency medication to manage a vaccine reaction in accordance with a standing order.
 - 5. At least 2 hours of immunization-related continuing education / updated training must be completed every 2 years.

IV. Requirements for Vaccine Administration

A. A prescription or standing order for the vaccination to be administered is required.

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- B. A prescription or standing order is also required to administer emergency medications to manage any adverse events following vaccination.
- C. Model standing orders for vaccines and emergency medication standing orders for the treatment of adverse events following vaccination can be found here:

http://www.immunize.org/standing-orders/ https://www.mass.gov/lists/vaccine-model-standing-orders

- D. Federal law requires the patient or legal representative to be provided with the appropriate <u>Vaccine Information Statement ("VIS")</u>.
- E. Prior to administering a vaccine other than influenza or COVID-19, the <u>Massachusetts Immunization Information System ("MIIS")</u> must be reviewed to ensure that the requested vaccine has not been administered by another provider.
- F. Prior to administering COVID-19 vaccine doses, it is recommended that vaccinators confirm the formulation of prior COVID-19 vaccine that the individual has received and the dates that the doses were administered. This can be done by reviewing the individual's record in the pharmacy computer system, Electronic Health Record ("EHR"), MIIS, or COVID-19 vaccination card
- G. Pharmacy personnel who administered the vaccine <u>must</u> report the vaccination information to <u>MIIS</u>.

V. Free Pediatric Vaccine Availability

- A. The Immunization Program provides routine childhood vaccines free of charge for administration to individuals under 19 years of age regardless of insurance status.
- B. In order to obtain free vaccines for administration, pharmacies must follow instructions provided here: https://www.mass.gov/resource/vaccine-management
- C. For more information about enrolling in this program, please contact the Vaccine Management Unit at 617-983-6828.

VI. Communications

- A. Notification/record of immunization should be provided to the patient's primary care provider.
- B. If the pharmacy does not utilize free pediatric vaccines through the Immunization Program, the parents/guardians of patients under 19 years of age must be informed of the potential costs and that their primary care provider can provide vaccines at no charge.

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<u>Suggested language</u>: "Please note: the cost of the vaccines your child will be receiving may not be covered by your health insurance, resulting in a significant out of pocket expense. You can avoid this expense by having your child vaccinated at their primary care provider."

C. If the purpose of the visit is for a childhood immunization other than the influenza or COVID-19 vaccine, counseling on the importance of establishing and maintaining a relationship with a pediatric or family practice for ongoing medical and well-child care must be provided. If needed, information about primary care providers in the pharmacy's geographic area should be provided.

VII. Reporting of Adverse Events

The following adverse events must be reported to the Vaccine Adverse Event Reporting System ("VAERS") (https://vaers.hhs.gov/reportevent.html):

- A. Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine; or
- B. any adverse event listed in the <u>VAERS Table of Reportable Events Following Vaccination</u> that occurs within the specified time period after vaccinations.

VIII. Vaccine Storage and Handling

- A. All vaccines must be stored and handled in accordance with Policy 2020-05: <u>Proper Storage of Refrigerated and Frozen Medications.</u>
- B. Drawing up vaccines for future use (i.e., greater than 1 hour) is considered sterile compounding and must be performed under sterile conditions in accordance with <u>USP <797>.</u>

IX. Appendix

Vaccine standing orders must address at least the following:

- Name(s) of the routine vaccine(s) that may be administered or dispensed;
- Timing, route, and specific dose of each vaccine based on age and other factors;
- Inclusion and exclusion criteria to be assessed before administration;
- Post-administration observation and other instructions;

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- Emergency treatment procedures that specify which emergency medications (including dose and route) should be administered and assistance for continued care (i.e., contact 911);
- · Record keeping;
- Specify who may administer (e.g., qualified pharmacy personnel, licensed nurses, etc.);
- Informed consent;
- Vaccine Information Sheet(s);
- Massachusetts Immunization Information System (MIIS) reporting;
- Adverse reaction reporting (i.e., VAERS); and
- Signature of a duly authorized prescriber.

Resources:

- Statewide standing order for COVID vaccines:
 https://www.mass.gov/doc/signed-standing-order-for-dispensing-and-administration-of-covid-2025-2026/download
- Vaccine Information Statements ("VIS") in English and other languages:
 www.immunize.org/vis
- DPH Clinic Operation guidelines: https://www.mass.gov/info-details/vaccine-administration-and-clinical-guidance

Please direct any questions to:

Board of Registration in Pharmacy: Pharmacy.Admin@mass.gov

Vaccine Management Unit: 617-983-6828

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