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Board of Registration in Pharmacy Drug Control Program Immunization Program

Policy 2020-11: Vaccine Administration

The Massachusetts Department of Public Health ("MDPH" or the "Department"), through the Board of Registration in Pharmacy ("Board"), Drug Control Program, and Immunization Program is making vaccines more accessible by authorizing administration by qualified pharmacy personnel. This policy sets forth the requirements for qualified pharmacy personnel to administer vaccinations and is intended to align with the Secretary of Health and Human Services' August 24, 2020, Declaration under the PREP Act, authorizing qualified pharmacy personnel to vaccinate children as young as 3 years old.

Please note carefully, certain allowances and requirements of this policy will terminate when the emergency declaration under the PREP Act terminates. After termination, policy details will be reevaluated.

Qualified pharmacy personnel, as defined by the PREP Act or MDPH Drug Control Program regulations (<u>105 CMR 700.004 (B)(6)</u>), who have completed a duly accredited training course may administer vaccines and emergency medications to manage any resulting adverse events as designated by the Department.

For the purposes of this policy, qualified pharmacy personnel are defined as pharmacists, pharmacy interns, and qualified pharmacy technicians. <u>Policy 2020-12:</u> <u>Vaccine Administration by Qualified Pharmacy Technicians</u> defines "qualified pharmacy technician".

Any pharmacy intern or qualified 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 pharmacist.

I. Authorized Vaccines

A. FDA authorized vaccines included in the latest recommended immunizations as approved by the Advisory Committee on Immunization Practices ("ACIP") of the Centers for Disease Control and Prevention ("CDC").

The recommended immunization schedule for adults is published here: <u>https://www.cdc.gov/vaccines/schedules/hcp/adult.html</u>

The recommended immunization schedule for persons 18 years of age and younger is published here: https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html

B. COVID-19 vaccines in accordance with <u>Policy 2020-13</u>: <u>Administration of FDA-</u> <u>Authorized, FDA-Licensed, and Investigational COVID-19 Vaccines</u>.

II. Vaccine Recipients

Pharmacists and pharmacy interns are authorized to administer only those vaccines included in the ACIP recommended immunization schedules to individuals **3 years** of age and older.

Qualified pharmacy technicians may only administer vaccines to age groups as authorized in <u>Policy 2020-12</u>: <u>Vaccine Administration by Qualified Pharmacy</u> *Technicians*

III. Training

- A. Pharmacists and pharmacy interns must successfully complete an American Council on Pharmaceutical Education ("ACPE") accredited training course prior to administering vaccines.
 - a. Minimum program requirements:
 - i. 12 contact hours of self-study modules with case studies and assessment exam
 - ii. 8 contact hours of live seminar with final exam
 - iii. Hands-on assessment of intramuscular and subcutaneous injection techniques appropriate for the patient's age
 - b. The goals of training programs must:
 - i. Provide comprehensive immunization education and training.
 - ii. Provide knowledge, skills, and resources necessary to establish and promote a successful immunization service.
 - iii. Include clinical evaluation of indications and contraindications.

- iv. Teach how to identify at-risk patient populations needing immunizations.
- v. Teach how to administer immunizations in compliance with legal and regulatory standards.
- vi. Recognize and treat vaccine reactions.
- vii. Include pre-administration education and screening, vaccine storage and handling, administration of medication, record-keeping and reporting of adverse events.
- B. Qualified pharmacy technician training requirements are outlined in <u>Policy 2020-</u> <u>12: Vaccine Administration by Qualified Pharmacy Technicians</u>
- C. Current cardiopulmonary resuscitation ("CPR") certification is required.
- D. Proof of training and CPR certification must be kept on file in the pharmacy.
- E. <u>All qualified pharmacy personnel</u> who administer vaccines must obtain at least 2 hours of ACPE-approved, immunization-related continuing pharmacy education every 2 years.

IV. Requirements for Vaccine Administration

- A. A prescription or standing order is required.
- B. A standing order is also required to administer emergency epinephrine 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: <u>http://www.immunize.org/standing-orders/</u> <u>https://www.mass.gov/lists/vaccine-model-standing-orders</u>
- 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 booster doses, it is recommended that providers confirm the prior formulation that the individual had received. This can be done by reviewing the individual's record in the pharmacy computer system, Electronic Health Record ("EHR"), MIIS, or COVID vaccination card.
- G. After administration, the vaccination information <u>must</u> be reported to MIIS.

V. Free Pediatric Vaccine Availability

- A. The MDPH Immunization Program provides routine childhood vaccines free of charge for administration to individuals through 18 years of age regardless of insurance status.
- B. In order to obtain free vaccines for administration, pharmacies must follow instructions provided here: <u>https://www.mass.gov/resource/vaccine-management</u>
- 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 MDPH 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.

<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 an immunization is being administered to a person younger than 18 years old, information on primary care providers in the pharmacy's geographic area should be provided.
- D. If the purpose of the visit is for a childhood immunization other than the influenza 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.

VII. Reporting of Adverse Events

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

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</u> <u>Vaccination</u> that occurs within the specified time period after vaccinations.

VIII. Vaccine Storage and Handling

All vaccines must be stored and handled in accordance with Board policy: <u>Proper</u> <u>Storage of Refrigerated and Frozen Medications</u>.

Resources:

- Vaccine Information Statements (VIS) in English and other languages: <u>www.immunize.org/vis</u>
- Centers for Disease Control and Prevention (CDC) website: <u>www.cdc.gov/vaccines</u>
- General Best Practice Guidelines for Immunization from the Centers for Disease Control and Prevention and the Advisory Committee on Immunization Practices: https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- MDPH Clinic Operation guidelines: <u>https://www.mass.gov/doc/guidelines-for-immunization-clinics/download</u>

Please direct any questions to:

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

Vaccine Management Unit: 617-983-6828