

Title 10

MARYLAND DEPARTMENT OF HEALTH

Subtitle 34 BOARD OF PHARMACY

10.34.32 Pharmacist Administration of Vaccinations

Authority: Health Occupations Article, §§12-201, 23-102(b), 12-508, and 12-6A-10, Annotated Code of Maryland

.01 Scope

This chapter does not limit or affect the right of an individual to practice a health occupation that the individual is authorized to practice.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

- (1) “Board” means the State Board of Pharmacy.
- (2) “Pharmacist” means an individual who practices pharmacy regardless of the location where the activities of practice are performed.
- (3) “Pharmacy” means an establishment holding a permit under Health Occupations Article, §12-401, Annotated Code of Maryland.
- (4) “Pharmacy permit holder” means a person authorized by the Board to operate a pharmacy while the pharmacy permit is effective.
- (5) “Pharmacy Experiential Program” means a program under the American Council on Pharmacy Education.
- (6) Practice Pharmacy.
 - a) “Practice Pharmacy” means to engage in any of the following activities:
 - i. Providing pharmaceutical care;
 - ii. Compounding, dispensing, or distributing prescription drugs or devices;
 - iii. Compounding or dispensing nonprescription drugs or devices;
 - iv. Monitoring prescriptions and nonprescription drugs or devices;
 - v. Providing information, explanation, or recommendations to patients and health care practitioners about the safe and effective use of prescription or nonprescription drugs or devices;
 - vi. Identifying and appraising problems concerning the use or monitoring of therapy with drugs or devices;
 - vii. Acting within the parameters of a therapy management contract, as provided under Health Occupations Article, Subtitle 6A, Annotated Code of Maryland; or
 - viii. Administering vaccinations in accordance with Health Occupations Article, §12-602, Annotated Code of Maryland.
 - b) “Practice pharmacy” does not include the operations of a person who holds a permit issued under Health Occupations Article, §12-602, Annotated Code of Maryland.
- (7) “Primary care provider” means a health care practitioner who provides an individual’s primary care services and is the primary coordinator of health care services for the individual.
- (8) “Vaccination” means a vaccination:

- a) That is listed in the Centers for Disease Control and Prevention's Recommended Immunization Adult Schedule authorized by Health Occupations Article, §12-508, Annotated Code of Maryland;
 - b) Recommended in the Centers for Disease Control and Prevention's Health Information for International Travel authorized by Health Occupations Article, §12-508, Annotated Code of Maryland;
 - c) Recommended for individuals between 11 years old and 18 years old in the Centers for Disease Control and Prevention's Recommended Immunization Schedule for Persons aged 0 through 18 years old; or
 - d) An influenza vaccination authorized by Health Occupations Article, § 12-508, Annotated Code of Maryland.
- (9) "Vaccine information statement" means the information sheet, produced by the Centers for Disease Control and Prevention that explains both the benefits and risks of a specific vaccine to the vaccine recipient, their parent, or their legal representative.

.03 Requirements to Administer Vaccinations.

A. Registration

- (1) A licensed pharmacist shall submit a registration to the Board on the form that the Board requires.
- (2) The registration form shall include verification from the licensed pharmacist of the following:
 - a) Successful completion of a certification course approved by the Board of Pharmacy that includes the current guidelines and recommendations of the Centers for Disease Control and Prevention regarding vaccinations; and
 - b) Possession of an active certification in basic cardiopulmonary resuscitation obtained through in-person classroom instruction.
- (3) A registration authorizing a licensed pharmacist to administer vaccinations expires with the expiration of the license to practice pharmacy unless the licensed pharmacist has completed:
 - a) Four hours of continuing education credits related to vaccinations; and
 - b) All other requirements for licensure renewal.
- (4) A licensed pharmacist may not administer vaccinations until the licensed pharmacist receives a written confirmation from the Board accepting the licensed pharmacist's registration.

B. A licensed pharmacist may administer an influenza vaccination to an individual who is 9 years old or older in accordance with a protocol that meets the requirements of Regulation .07 of this chapter.

B-1. A licensed pharmacist may only administer a vaccination that is listed in the Centers for Disease Control and Prevention's recommended immunization schedule to an individual who:

- 1) Is between 11 years old and 18 years old; and
- 2) Has a prescription from an authorized prescriber.

B-2. Except as provided in §§ B and B-1 of this regulation, a licensed pharmacist may administer to an adult a vaccination in accordance with a protocol that meets the requirements of Regulation .07 of this chapter that is:

- (1) Listed in the Center for Disease Control and Prevention's Recommended Immunization Schedule; or
- (2) Listed in the Center for Disease Control and Prevention's Health Information for International Travel.
- C. A pharmacist shall report to the ImmuNet Program established under Health General Article, §18-109, Annotated Code of Maryland, a vaccination administered by the pharmacist to an individual.
- D. A pharmacist shall:
 - (1) Have proof of active certification in basic cardiopulmonary resuscitation readily available.
 - (2) Provide the patient with a vaccine information statement issued by the Centers for Disease Control and Prevention;
 - (3) Obtain a signed consent form from the patient or custodial parent; and
 - (4) Observe the patient for a period of at least 15 minutes after administration of the vaccine for adverse effects including syncope.
- E. A pharmacy student in a Pharmacy Experiential Program, who has successfully completed a Board-approved certification course, may administer vaccinations under direct supervision of a licensed pharmacist who meets requirements in §A of this regulation.

.04 Training Program Requirements.

In order to administer vaccinations, the Board shall assure that any course that it approves contains at a minimum the following elements:

- A. Responses to an emergency situation as a result of the administration of a vaccination;
- B. Administration of intramuscular and subcutaneous injections and intranasal vaccination;
- C. Record-keeping and reporting requirements; and
- D. Advisory Committee on Immunization Practices and Centers for Disease Control guidelines for vaccines.

.05 Record Keeping.

- A. The pharmacy permit holder shall maintain documentation in the pharmacy from which the vaccine was administered for a minimum of 5 years that includes:
 - (1) The name, address, and date of birth of the individual receiving the vaccination;
 - (2) The date of administration and route and site of vaccinations;
 - (3) The name, dose, manufacturer's lot number, and expiration date of the vaccine;
 - (4) The name and address of the primary health care provider of the individual receiving the vaccination, as identified by that individual;
 - (5) The name of the pharmacist, pharmacy student, physician, or nurse administering the vaccination;
 - (6) The version of the vaccination information statement provided to the individual receiving the vaccination;
 - (7) The copy of the signed patient consent form of those individuals to whom the vaccine was administered;
 - (8) The nature and outcome of an adverse reaction and documentation that the adverse reaction was reported to:
 - a) The primary care provider; and
 - b) The Vaccine Adverse Event Reporting System.

- (9) At least one effort made by the pharmacist to inform the individual's authorized prescriber that the vaccination has been administered' and
 - (10) If the authorized prescriber is not the individual's primary care provider or if the vaccination has not been administered in accordance with a prescription document, at least one effort made by the pharmacist to inform the individual's primary care provider or other usual source of care that the vaccination has been administered.
- B. The records required in this regulation shall be:
- (1) Readily retrievable;
 - (2) Made available on the request of the Board;
 - (3) Except for records related to minor patients, maintained for a minimum of 5 years; and
 - (4) IN the case of a minor patient, maintained until the patient attains the age of majority plus 3 years or for 5 years after the record is made, whichever is later.
- C. The pharmacist administering a vaccination as an independent provider at a location that is not a pharmacy shall maintain the following documentation for a minimum of 5 years:
- (1) Name, address, and date of birth of the individual receiving the vaccination;
 - (2) Date of administration, and route and site of vaccinations;
 - (3) Name, dose, manufacturer's lot number, and expiration date of the vaccine;
 - (4) Name and address of the primary health care provider of the individual receiving the vaccination, as identified by that individual;
 - (5) Name of the pharmacist or pharmacy student administering the vaccination;
 - (6) Version of the vaccination information statement provided to the individual receiving the vaccination;
 - (7) Copy of the signed patient consent form of those individuals to whom the vaccine was administered;
 - (8) Nature and outcome of an adverse reaction, and documentation that the adverse reaction was reported to:
 - a) The primary care provider; and
 - b) The Vaccine Adverse Event Reporting System.
 - (9) At least one effort made by the pharmacist to inform the individual's authorized prescriber that the vaccination has been administered; and
 - (10) If the authorized prescriber is not the individual's primary care provider or if the vaccination has not been administered in accordance with a prescription document, at least one effort made by the pharmacist to inform the individual's primary care provider or other usual source of care that the vaccination has been administered.
- D. The pharmacist administering a vaccination on behalf of a permit holder at a location that is not a pharmacy shall maintain the following documentation with the permit holder of a minimum of 5 years:
- (1) Names, address, and date of birth of the individual receiving the vaccination;
 - (2) Date of administration, and route and site of vaccinations;
 - (3) Name, dose, manufacturer's lot number, and expiration date of the vaccine;
 - (4) Name and address of the primary health care provider of the individual receiving the vaccination, as identified by that individual;
 - (5) Name of the pharmacist or pharmacy student administering the vaccination;
 - (6) Version of the vaccination information statement provided to the individual receiving the vaccination;
 - (7) Copy of the signed patient consent form of those individuals to whom the vaccine was administered;
 - (8) Nature and outcome of an adverse reaction, and documentation that the adverse reaction was reported to:

- a) The primary care provider; and
 - b) The Vaccine Adverse Event Reporting System.
- (9) At least one effort made by the pharmacist to inform the individual's authorized prescriber that the vaccination has been administered; and
- (10) If the authorized prescriber is not the individual's primary care provider or if the vaccination has not been administered in accordance with a prescription document, at least one effort made by the pharmacist to inform the individual's primary care provider or other usual source of care that the vaccination has been administered.

.06 Patient Information and Consent.

- A. Every patient receiving a vaccination shall be provided with a current vaccine information statement.
- B. Every patient receiving a vaccination shall:
 - (1) Sign a consent form consenting to the administration of the vaccine; and
 - (2) Be given a copy of the consent form for the patient's future reference.
- C. The consent form shall disclose the credentials of the pharmacist administering the vaccination.

.07 Approved Protocols.

- A. A pharmacist shall have and maintain a written protocol for any vaccine to be administered, including influenza vaccination.
- B. The pharmacist shall administer vaccinations in accordance with the written protocol.
- C. The written protocol for each vaccine shall contain at least the following elements:
 - (1) Identity and license number of the participating pharmacist;
 - (2) Vaccine;
 - (3) Precautions to vaccine use;
 - (4) Contraindications to vaccine use;
 - (5) Process to be followed for screening for:
 - a) Indications;
 - b) Precautions;
 - c) Contraindications; and
 - d) Allergies;
 - (6) Process for obtaining and documenting consent;
 - (7) Process for verification of prescription for patients 11-17 years old for vaccinations other than the influenza vaccine;
 - (8) Dose or doses of the vaccine that will be administered;
 - (9) The route or routes and site or sites of administration of the vaccine;
 - (10) The injection or administration procedures;
 - (11) Post-vaccination procedures, including waiting requirements;
 - (12) Process for handling adverse reactions, including but not limited to:
 - a) Acute anaphylactic reactions; and
 - b) Other acute emergencies; and
 - (13) Process for documenting and maintaining a vaccination record including at least:
 - a) Patient:
 - i. Name;

- ii. Date of birth; and
 - iii. Address;
 - b) Vaccination Administration:
 - i. Date;
 - ii. Dose;
 - iii. Site; and
 - iv. Route;
 - c) Vaccine:
 - i. Manufacturer;
 - ii. Lot number; and
 - iii. Expiration date;
 - d) Required Vaccine Information Statement:
 - i. Version; and
 - ii. Provision date;
 - e) Name of the patient's primary care provider or prescriber;
 - f) Documentation:
 - i. Of at least one attempt to inform the patient's primary care provider or prescriber that the vaccination has been administered; or
 - ii. That the patient has no primary care provider
 - g) Documentation of an attempt to inform the patient's primary care provider that the influenza vaccination has been administered may not be required; and
 - h) The name of the vaccinator.
- D. The protocol shall be:
- (1) Signed and dated at least annually by the pharmacist;
 - (2) Available and presented for inspection to the Board of Pharmacy upon request; and
 - (3) Reviewed and updated as necessary.