Title 10

MARYLAND DEPARTMENT OF HEALTH

Subtitle 34 Board of Pharmacy

10.34.32 Pharmacist Administration of Vaccinations

Authority: Health Occupations Article, §§12-101, 12-102, 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" means to engage in the activities set forth in Health Occupations Article, §12-101(x)(1), 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*) "Secretary's recommendations" means the recommendations for immunizations, screenings, and preventative services issued by the Secretary of Health and published on the Maryland Department of Health website pursuant to Health-General Article, §18-112, Annotated Code of Maryland.

(*9*) "Vaccination" means:

(a) A vaccination that is listed in the Centers for Disease Control and Prevention's Recommended Immunization Adult Schedule;

(b) A vaccination recommended in the Centers for Disease Control and Prevention's Health Information for International Travel;

(c) A vaccination recommended for individuals between 7 years old and 18 years old by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices for Persons aged 0 through 18 years old;

(d) An influenza vaccination;

(e) A COVID vaccination; or

(f) A vaccination approved or authorized by the U.S. Food and Drug Administration.

(*10*) "Vaccine information statement" means the information sheet, produced by the Centers for Disease Control and Prevention, or, for a vaccine recommended exclusively under the Secretary's Recommendations for which no Centers for Disease Control and Prevention vaccine

information statement exists, a comparable patient information document, 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) That the pharmacist has completed a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education and included education *that includes:*

(i) Hands-on injection techniques;

(ii) Clinical evaluation of indication and contraindications of vaccines;

(iii) The recognition and treatment of emergency reaction to vaccines; and

(iv) Applicable vaccine guidance and recommendations.

(b) Possession of an active certification in basic cardiopulmonary resuscitation obtained through in-person classroom instruction based upon *Basic Life Support and American Heart Association standards*. Certification in basic cardiopulmonary resuscitation may be obtained through hybrid instruction where:

(i) Didactic instruction is provided remotely; and

(ii) Practical instruction is provided in-person.

(3) A registration authorizing a licensed pharmacist to administer vaccination expires with the expiration of the license to practice pharmacy unless the licensed pharmacist has completed:

(a) Two 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 order *a vaccination* or administer a vaccination in accordance with a protocol that meets the requirements of Regulation .06 of this chapter to an individual who is at least 3 years old provided that:

(1) The vaccine is:

(a) An influenza vaccine;

(b) A COVID vaccine; or

(c) Used in response to a public health emergency; and

(2) If the vaccination is administered to an individual under the age of 18 years, the pharmacist shall:

(a) Inform the child vaccination patient and the adult caregiver who is accompanying the child of the importance of well-child visits with a pediatric primary care provider; and

(b) Refer the child vaccination patient to a pediatric care provider when appropriate.

C. Requirements.

(1) A pharmacist may order and administer a vaccination in accordance with a protocol that meets the requirements of Regulation .06 of this chapter to an individual who is at least 7 years old provided that:

(a) The vaccine:

(i) Is recommended by the Center for Disease Control and Prevention Advisory Committee on Immunization Practices; or

(ii) Approved or authorized by the U.S. Food and Drug Administration; *or*

(iii) Recommended by the Secretary of Health in accordance with the Secretary's Recommendations issued under Health-General Article, § 18-112, Annotated Code of Maryland and

(b) If the vaccination is administered to an individual under the age of 18 years, the pharmacist shall:

(i) Inform the child vaccination patient and the adult caregiver who is accompanying the child of the importance of well-child visits with a pediatric primary care provider; and

(ii) Refer the child vaccination patient to a pediatric care provider when appropriate.

D. A licensed pharmacist may order and administer to an adult a vaccination in accordance with a protocol that meets the requirements of Regulation .06 of this chapter that is listed in the Centers for Disease Control and Prevention's Health Information for International Travel.

E. A pharmacist shall report *all vaccinations administered or ordered by the pharmacist* to the ImmuNet Program established under Health-General Article, §18-109, Annotated Code of Maryland.

F. A pharmacist shall:

(1) Have proof of active certification in basic cardiopulmonary resuscitation readily available.

(2) Provide the patient with a vaccine information statement *defined in Regulation .02 of this chapter for each vaccine ordered or administered*;

(3) Obtain a signed consent form from the patient or custodial parent *for each vaccine ordered or administered;* and

(4) *If the vaccination is administered*, 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 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, does, 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 ordering the vaccination;*

(6) The name of the pharmacist, pharmacy student, *pharmacy technician,* physician, or nurse administering the vaccination;

(*7*) The version of the vaccination information statement provided to the individual receiving the vaccination;

(*8*) The copy of the signed patient consent form ;

(*9*) 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.

(*10*) At least one effort made by the pharmacist to inform the individual's authorized prescriber that the vaccination has been administered; and

(*11*) 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 pharmacist ordering the vaccination;

(6) Name of the pharmacist, pharmacy technician, or pharmacy student administering the vaccination;

(*7*) *Version of the vaccination information statement provided to the individual receiving the vaccination*;

(8) Copy of the signed patient consent form;

(*9*) 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.

(*10*) At least one effort made by the pharmacist to inform the individual's authorized prescriber that the vaccination has been administered; and

(*11*) If the authorized prescriber is not the individual's primary care provider or if the vaccination has not been administered in accordance within 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 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 pharmacist ordering the vaccination;

(6) Name of the pharmacist, pharmacy technician, or pharmacy student administering the vaccination;

(7) Version of the vaccination information statement provided to the individual receiving the vaccination;

(8) Copy of the signed patient consent form;

(9) 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.

(*10*) At least one effort made by the pharmacist to inform the individual's authorized prescriber that the vaccination has been administered; and

(*11*) 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.

.05 Patient Information and Consent.

A. Every patient receiving a vaccination shall be provided with a current vaccine information sheet.

B. Every patient receiving a vaccination shall:

(1) Sign a consent form consenting to the *ordering or* 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 ordering or administering the vaccination.

.06 Approved Protocols.

A. A pharmacist shall have and maintain a written protocol for any vaccine to be *ordered or* administered, including influenza vaccination.

B. The pharmacist shall *order or* administer vaccinations in accordance with the written protocol.

C. The written protocol for each vaccine shall *be vaccine-specific and shall* contain at least the following elements, *as applicable*:

(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 allowed for screening for:

(a) Indications;

(b) Precautions;

(c) Contraindications; and

(d) Allergies;

(6) Process for obtaining and documenting consent;

(7) Dose or doses of the vaccine that will be administered;

(*8*) The route or routes and site or sites of administration of the vaccine;

(*9*) The injection or administration procedures;

(*10*) Post-vaccination procedures, including waiting requirements;

(*11*) Process for handling adverse reactions, including but not limited to:

(a) Acute anaphylactic reactions; and
(b) Other acute emergencies; and
(*12*) 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 *ordered or administered* may not be required;
(h) The name of the vaccinator; *and*
(i) Documentation that vaccination ordered or administered has been reported to Immunet.

D. The protocol shall be:
(1) Reviewed and updated as necessary
(2) Signed and dated at least annually by the pharmacist; and
(3) Available and presented for inspection to the Board of Pharmacy upon request.

.07 Fees.

Fees charged for the administration *of each* vaccination may not exceed $50, in addition to the cost of each vaccination.

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