



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-
MAKING REVIEW COMMITTEE**

AGENCY: Pharmacy TITLE-SERIES: 15-12

RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No

RULE NAME: 15-12 Immunizations Administered by Pharmacists, Pharmacy Interns, and Pharmacy Technicians

PRIMARY CONTACT

NAME: Krista Capehart

ADDRESS: 1207 Quarrier St 4th Floor Charleston WV 25301
Charleston, WV 25301

EMAIL: krista.d.capehart@wv.gov

PHONE NUMBER: 304-206-5767

CITE STATUTORY AUTHORITY: 30-5-7 and 29A-3-15

EXPLANATION OF THE STATUTORY AUTHORITY FOR THE LEGISLATIVE RULE, INCLUDING A DETAILED SUMMARY OF THE EFFECT OF EACH PROVISION OF THE LEGISLATIVE RULE WITH CITATION TO THE SPECIFIC STATUTORY PROVISION WHICH EMPOWERS THE AGENCY TO ENACT SUCH RULE PROVISION:

HB 2574 added this authority

IS THIS FILING SOLELY FOR THE SUNSET PROVISION REQUIREMENTS IN W. VA. CODE §29A-3-19(e)? No

IF YES, DO YOU CERTIFY THAT THE ONLY CHANGES TO THE RULE ARE THE FILING DATE, EFFECTIVE DATE AND AN EXTENSION OF THE SUNSET DATE? No

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 6/28/2022

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 7/27/2023

COMMENTS RECEIVED: Yes

(IF YES, PLEASE UPLOAD IN THE COMMENTS RECEIVED FIELD COMMENTS RECEIVED AND RESPONSES TO COMMENTS)

PUBLIC HEARING: No

(IF YES, PLEASE UPLOAD IN THE PUBLIC HEARING FIELD PERSONS WHO APPEARED AT THE HEARING(S) AND TRANSCRIPTS)

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?

SUMMARY OF THE CONTENT OF THE LEGISLATIVE RULE, AND A DETAILED DESCRIPTION OF THE RULE'S PURPOSE AND ALL PROPOSED CHANGES TO THE RULE:

1. Adds pharmacy techs to the list of pharmacy immunizers
2. lowers age of pharmacy immunizations to 3 years and up for CDC/ACIP recommended vaccines
3. Removes requirement for a physician prescription

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

1. Adds pharmacy techs to the list of pharmacy immunizers
2. lowers age of pharmacy immunizations to 3 years and up for CDC/ACIP recommended vaccines
3. Removes requirement for a physician prescription

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED LEGISLATIVE RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

0

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

0

C. ECONOMIC IMPACT OF THE LEGISLATIVE RULE ON THE STATE OR ITS RESIDENTS:

0

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2023 Increase/Decrease (use "-")	2024 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services	0	0	0
Current Expenses	0	0	0
Repairs and Alterations	0	0	0
Assets	0	0	0
Other	0	0	0
2. Estimated Total Revenues	0	0	0

E. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

0

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Krista Capehart -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 12
BOARD OF PHARMACY RULES FOR
IMMUNIZATIONS ADMINISTERED BY PHARMACISTS, ~~AND~~ PHARMACY
INTERNS, AND PHARMACY TECHNICIANS

§15-12-1. General.

1.1. Scope. -- To provide the rules for pharmacists, ~~and~~ pharmacy interns, and pharmacy technicians to administer immunizations to patients in this State through joint rulemaking by the West Virginia Board of Pharmacy, Board of Medicine, and Board of Osteopathy.

1.2. Authority. -- W. Va. Code § 30-5-7 and 29A-3-15.

1.3. Filing Date. -- ~~May 11, 2021~~

1.4. Effective Date. -- ~~June 11, 2021~~

1.5. Sunset Date -- This rule shall terminate and have no further force or effect on August 1, 2034.

§15-12-2. Definitions.

2.1 "ACPE" means American Council for Pharmacy Education.

~~2.12.~~ "Board" means the West Virginia Board of Pharmacy.

2.3. "CDC" means the United States Centers for Disease Control and Prevention.

2.4 "CPR" means cardiopulmonary resuscitation.

2.5. "Direct supervision" means the supervising immunizing pharmacist is physically present and readily and immediately available during the administration of an immunization.

~~2.26.~~ "Immunizations" means the action of making a person immune to infection, typically by inoculation.

2.7. "VAERS" means vaccine adverse event reporting system which is the national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) and is available at <http://vaers.hhs.gov/index>.

~~2.3. "Personal supervision" means the supervising immunizing pharmacist is physically present in the room the administration of an immunization.~~

§15-12-3. Immunizations.

~~—3.1 A licensed pharmacist or pharmacy intern may administer immunizations in accordance with definitive treatment guidelines for immunizations promulgated by the latest notice from the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), including, but not limited to, the CDC's recommended immunization schedule for adults, children, and adolescents.~~

~~—3.2. A licensed pharmacist may order and a licensed pharmacist, or pharmacy intern, or pharmacy technician may administer immunizations in accordance with definitive treatment guidelines for immunizations promulgated by the latest notice from the CDC, including, but not limited to, the CDC's recommended immunization schedule for adults, children, and adolescents to a person age 11 through 17 with written informed parental consent when presented with a prescription from a physician and there are no contraindications to that patient receiving that vaccine.~~

§15-12-43. Qualifications.

~~43.1 A licensed pharmacist may immunize order and administer immunizations as provided permitted by this rule in section three provided that the pharmacist has met all of the following requirements:~~

~~43.1.a. is registered with the board to administer immunizations;~~

~~43.1.b. has successfully completed the American Pharmacists Association's (APhA) immunization training program or Board-approved training program, as provided in section 98, which courses shall be based on the standards established for immunization training by the Centers for Disease Control and Prevention (CDC) in the public health service of the United States Department of Health and Human Services;~~

~~43.1.c. maintains current certification in basic life-support training, including basic cardiopulmonary resuscitation (CPR), from the American Heart Association, or the American Red Cross or other Board-approved course; and~~

~~43.1.d. completed a minimum of two hours of continuing pharmacy education related to immunizations each licensing year for a total of 4 four hours each renewal period. The continuing education shall be by a provider approved by the Accreditation Council for Pharmacy Education (ACPE).~~

~~43.2. A pharmacy intern licensed by the Board may administer immunizations as permitted by this rule provided that the pharmacy intern:~~

~~43.2.a. the pharmacy intern is under the personal direct supervision by of a pharmacist who is registered with the board to administer immunizations; and~~

~~43.2.b. has completed all of the training and current certification required by subsections 43.1.b. and 4.1.c. of this section.~~

~~43.3. A pharmacy technician licensed by the Board may administer immunizations as permitted by this rule provided that the pharmacy technician:~~

~~43.3.a. is registered with the Board to administer immunizations;~~

43.3.b. is under the direct supervision of a pharmacist who is registered with the Board to administer immunizations; and

43.3.c. has successfully completed a practical training program approved by the ACPE and the Board. This training must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines; and

43.3.d. maintains current certification in basic life-support training, including basic CPR, from the American Heart Association, or the American Red Cross or other Board-approved course; and

43.3.e. complete a minimum of two hours of continuing pharmacy education related to immunizations each licensing renewal period. The continuing education shall be by a provider approved by the ACPE.

~~43.34.~~ It is unprofessional conduct for a pharmacist, ~~or pharmacy intern, or pharmacy technician~~ to administer an immunization, ~~who is not in compliance with~~ in violation of this rule.

~~§15-12-54.~~ Registration.

~~54.1.~~ Prior to administering immunizations, a pharmacist shall submit an application supplied by the Board for review and approval of the Board, providing that all of the requirements of section ~~43.1.~~ have been met. The application shall be submitted along with a required fee of \$10.00. Provided all requirements of section ~~43.1.~~ have been met and the required fee is received, the Board shall issue the pharmacist a registration to administer immunizations. Registrations shall expire biennially on June 30 of year in which the pharmacist's license to practice pharmacy expires.

~~54.2.~~ The registration shall be posted conspicuously at ~~any~~all locations at which the pharmacist ~~is administering~~ an immunization.

~~54.3.~~ Prior to administering immunizations, a pharmacy intern shall provide to his or her supervising pharmacist documentation that the pharmacy intern has completed all of the training and current certification required by subsections ~~43.1.b.~~ and ~~43.1.c.~~ of this rule. The supervising pharmacist shall maintain this documentation in the pharmacy where the pharmacist and pharmacy intern who administers an immunization is employed or otherwise practicing at the time any immunization is administered by a pharmacy intern.

~~54.4~~ Prior to administering immunizations, a pharmacy technician shall submit an application supplied by the Board providing that all of the requirements of Section 3.3 have been met. Providing all requirements of Section 3.3 have been met, the Board shall issue a registration to administer immunizations. Registrations shall expire biennially on June 30 of the year in which the pharmacy technician's license expires.

~~§15-12-65.~~ Immunizations.

~~5.1.~~ A licensed pharmacist may order and a licensed pharmacist, pharmacy intern or pharmacy technician may administer immunizations in accordance with this rule.

~~65.42.~~ Immunizations authorized by this rule shall be administered:

5.2.a. in accordance with a prescription order from a healthcare provider for a person age 3 years and up; or

65.42.a.b. in accordance with definitive treatment guidelines for immunizations promulgated by the latest notice from the U.S. Department of Health and Human Services, CDC, including, but not limited to, CDC's recommended immunization schedule for adults and children and adolescents, including the footnotes provided for each schedule, available at <https://www.cdc.gov/vaccines/> or a successor webpage created for the same purpose; or Such immunizations administered to a person age three to seventeen years shall be given only:

5.2.b.1. with parental written, informed consent;

5.2.b.2. provided there are no contraindications to that person receiving that vaccine; and

5.2.b.3. after informing the patient and the adult caregiver accompanying the patient of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and referral for patients as appropriate.

~~6.1.b. in accordance with an order from a properly authorized practitioner for minors age eleven through eighteen, the order shall be a prescription from an authorized physician~~

~~65.23.~~ Administration shall be done in accordance with the training required by section 43.1.b. including, but not limited to indications, contraindications, route of administration, sanitary environment for administration, specifics regarding administration, and storage requirements for each specific immunization authorized by this rule, and, when done pursuant to a prescription, in accordance therewith;

~~65.34.~~ Administration shall include implementation of the CDC's recommended appropriate observation for an adverse reaction of an individual following an immunization.

~~65.45.~~ Under no circumstances may a pharmacist delegate his or her authority to administer immunizations to any other person, except as otherwise provided herein for a properly trained pharmacy intern who is administering under the personal supervision of the pharmacist. A pharmacist may not delegate the authority to administer immunizations to any other person, unless administered by a licensed pharmacy intern or registered pharmacy technician under the direct supervision of a pharmacist of whom the pharmacist, the pharmacist technician and intern have successfully completed all required training.

~~65.56.~~ A current Vaccine Information Statement, as provided by CDC, shall be provided to each person receiving an immunization for each immunization administered.

§15-12-76. Record-keeping and reporting.

~~76.1.~~ An immunization questionnaire and consent form shall be completed for each person receiving an immunization. When the immunization is for influenza or HPV for a minor age ~~eleven~~ three through eighteen-seventeen years of age, the questionnaire and consent form shall include written informed parental consent for the minor. ~~A record of the immunization administration shall be forwarded to the primary care physician or other licensed health care provider as identified by the person receiving the immunization, within not more than 30 days of the date of the~~

~~administration. In the event that the patient affirmatively indicates in writing that he or she does not have a primary care physician or other health care provider to whom to forward the report, the pharmacist or pharmacy intern shall document such in the immunization record, and provide a record of the immunization administration to the patient. The record shall contain the name of the pharmacist, and, where applicable, the name of the pharmacy intern administering the immunization.~~

6.2. A record of the immunization administration shall be forwarded to the primary care physician or other licensed health care provider as identified by the person receiving the immunization, within ~~not more than~~ 30 days of the date of the administration. In the event that the patient affirmatively indicates in writing that he or she does not have a primary care physician or other health care provider to whom to forward the report, the pharmacist, pharmacy intern, or pharmacy technician shall document such in the immunization record and provide a record of the immunization administration to the patient. The record shall contain the name of the pharmacist, and, where applicable, the name of the pharmacy intern or pharmacy technician administering the immunization.

~~76.23.~~ The pharmacist shall report the administration of the patient immunization to the West Virginia Statewide Immunization Information (WVSII) database in the format and containing such information as may be required by the WVSII within ~~not more than~~ 30 days of the date of the administration.

~~76.34.~~ The immunization questionnaire, consent form and record of the immunization administration shall be filed in the pharmacy in a manner that will allow timely retrieval and shall be kept on file for a time period not less than five years from the date of the immunization. All such records shall be maintained in the pharmacy where the immunization is administered. In the event it is administered off-site, then the records shall be maintained in the pharmacy where the pharmacist, ~~or pharmacy intern, or pharmacy technician~~ who administered the immunization is employed or otherwise practicing at the time the immunization is given.

~~76.45.~~ A pharmacist shall report all adverse events to the Vaccine Adverse Events Reporting System (VAERS), and promptly provide a copy of all reports to the Board; the West Virginia Department of Health and Human Resources Bureau for Public Health, Office of Epidemiology and Prevention Services, Division of Immunization Services; and the patient's primary care physician or other licensed health care provider as identified by the person receiving the immunization in accordance with subsection ~~76.21.~~ ~~VAERS is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) and is available at <http://vaers.hhs.gov/index>.~~

~~§15-12-87.~~ Emergencies.

~~87.1.~~ A pharmacist, ~~or pharmacy intern, or pharmacy technician~~ authorized to administer immunizations under this rule may administer epinephrine and diphenhydramine in the management of an acute allergic reaction to an immunization following guidelines issued by CDC.

~~87.2.~~ A pharmacist, ~~or pharmacy intern, or pharmacy technician~~ shall have a readily retrievable emergency response plan as outlined by the CDC and maintain a readily retrievable emergency kit to manage an acute allergic reaction to an immunization administered.

~~§15-12-98.~~ Immunization Training Programs.

98.1. The Board shall approve a course or program in immunization administration for pharmacists and pharmacy interns ~~or that course~~ to be used to meet the qualification requirement of section 43.1.b. In order to be approved by the Board, the course or program, at a minimum, shall include practical training and instruction on the following:

- 98.1.a. basic immunology, including the human immune response;
- 98.1.b. adverse reactions, contraindications, warnings and precautions;
- 98.1.c. response to emergency situations, including administration of epinephrine and diphenhydramine;
- 98.1.d. storage and handling requirements;
- 98.1.e. recordkeeping and reporting requirements, including screening and informed consent documentation;
- 98.1.f. proper environment for administration and observation;
- 98.1.g. legal and regulatory issues, including, but not limited to, state law and regulations, OSHA compliance, biohazard control, and such other relevant and applicable standards; and
- 98.1.h. policies and procedures for establishing and implementing appropriate immunization treatment guidelines.

98.2. A course approved by the Board for pharmacists and pharmacy interns shall include a minimum of fifteen hours of didactic and practical based components of instruction and training, including self-study and live instruction. The live instruction shall be a minimum of six hours and shall include documented and supervised instruction on physical administration of vaccinations.

98.3 The Board shall approve a course or program in immunization administration for pharmacy technicians to be used to meet the qualification requirement of section 4.3.c. In order to be approved by the Board, the course or program, at a minimum shall include practical training and instruction on the following:

- 98.3.a. proper technique of drawing up and administering immunizations;
- 98.3.b. commonly used vaccines and their corresponding routes of administration;
- 98.3.c. proper needle length selection based on vaccine, patient age, and patient size;
- 98.3.d. proper vaccine storage requirements;
- 98.3.e. safety measures to avoid accidental needle stick injuries; and
- 98.3.f. appropriate actions to take in emergency situations.

98.4 A course approved by the Board shall include a self-study component combined with a practical component that teaches hands-on immunization techniques.