

**WEST VIRGINIA  
SECRETARY OF STATE  
NATALIE E. TENNANT  
ADMINISTRATIVE LAW DIVISION**

Form #2

Do Not Mark In This Box

FILED

2014 JUN 25 P 4:36

WEST VIRGINIA  
SECRETARY OF STATE

**NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE**

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

RULE TYPE: Legislative CITE AUTHORITY: 30-5-7

AMENDMENT TO AN EXISTING RULE: YES  NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 12

TITLE OF RULE BEING AMENDED: Immunizations Administered By Pharmacists

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: \_\_\_\_\_

TITLE OF RULE BEING PROPOSED: \_\_\_\_\_

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON July 26, 2014 AT 12:00 noon EST ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

WV Board of Pharmacy  
Attn: Series 12 Comments  
2310 Kanawha Blvd East  
Charleston, WV 25311

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.

David E. Potters  
Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

**BRIEF SUMMARY OF AND STATEMENT OF CIRCUMSTANCES  
WHICH REQUIRE THE PROPOSED LEGISLATIVE RULE**

**Immunizations Administered By Pharmacists  
Title 15, Series 12**

**Summary and Statement of Circumstances:** HB 3056, passed during the Regular Session, 2008, and duly enacted into law, permits pharmacists to administer immunizations to patients in this State. This provision was amended in 2013 to allow for pharmacist interns to administer immunizations under appropriate pharmacist supervision. West Virginia Code Section 30-5-7(d) and (e) requires rulemaking by the Board of Pharmacy with the advice and consent of the Board of Medicine and Board of Osteopathy for pharmacist administration of any immunizations beyond the influenza and pneumonia vaccines. The three boards have continued to work together over the past several years to amend the rules in Series 12 to provide for additional immunizations through joint rulemaking.

The modifications proposed here, if approved, would allow for pharmacist interns to administer immunizations under “personal” supervision of the immunizing pharmacist, and would add meningococcal vaccine to the list of approved immunizations which may be given by pharmacists or supervised pharmacy interns. Finally, in addition to requiring pharmacists to report any adverse events with administration to the CDC’s national Vaccine Adverse Events Reporting System (VAERS), with a copy the Board of Pharmacy, it would now also require a copy to the West Virginia Department of Health and Human Resources Bureau for Public Health, Office of Epidemiology and Prevention Services, Division of Immunization Services, and to the patient’s primary care physician or other licensed health care provider as identified by the person receiving the immunization.

**For Further Information:** Copies of the proposed rule may be obtained from the website of the West Virginia Secretary of State at [www.wvsos.com](http://www.wvsos.com), or interested parties may call the Administrative Law Division of the Office of the Secretary of State at (304) 558-6000.

Further information may be obtained by contacting the West Virginia Board of Pharmacy, 2310 Kanawha Boulevard East, Charleston, West Virginia, 25311, telephone (304) 558-0558.

**Note:** This is a modification of the Series, such that changes are reflected by strike-throughs and underlining in the proposed rule.

TITLE 15  
LEGISLATIVE RULE  
WEST VIRGINIA BOARD OF PHARMACY

FILED  
2014 JUN 25 P 4: 36

SERIES 12  
Board of Pharmacy Rules Regarding  
Immunizations Administered By Pharmacists

OFFICE OF THE CLERK  
WEST VIRGINIA  
SECRETARY OF STATE

§15-12-1. General.

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

1.2. Authority. -- W. Va. Code §~~30-5-30~~ 30-5-7.

1.3. Filing Date. -- April 4, 2012 \_\_\_\_\_.

1.4. Effective Date. -- April 4, 2012 \_\_\_\_\_.

§15-12-2. Definitions.

2.1. "Board", unless otherwise specifically indicated, means the West Virginia Board of Pharmacy.

2.2. "Immunizations" means, for the purpose of this rule, the vaccines specifically listed in this subsection which a pharmacist or pharmacy intern may administer to any person eighteen years of age or older, including:

(a) Influenza;

(b) ~~Pneumonia~~ Pneumococcal;

(c) Hepatitis A;

(d) Hepatitis B;

(e) Herpes Zoster; and

(f) Tetanus, tetanus-diphtheria (commonly referred to as "Td"), or tetanus-diphtheria-and-pertussis (commonly referred to as "Tdap"); and

(g) Meningococcal.

2.3. "Personal supervision" means the supervising immunizing pharmacist is physically present in the room during the administration of a vaccine.

**§15-12-3. Qualifications.**

3.1. A pharmacist licensed by the Board may administer immunizations to any person eighteen years of age or older provided the pharmacist has met all of the following requirements:

(a) -registered with the board to administer immunizations;

(b) successfully completed the American Pharmacists Association's (APhA) immunization training program, or such other immunization training course as may be approved by the Board, which courses must be based on the standards established for immunization training by the Centers for Disease Control and Prevention in the public health service of the United States Department of Health and Human Services;

(c) maintains current certification in basic life-support training, including basic cardiopulmonary resuscitation (CPR), offered by the American Heart Association or the American Red Cross; and

(d) completed a minimum of ~~two (2)~~ 2 hours annually of continuing pharmacy education related to immunizations each licensing year for a total of 4 hours each renewal period. The continuing education must be by a provider approved by the Accreditation Council for Pharmacy Education (A.C.P.E.).

3.2. A pharmacy intern registered by the Board may administer immunizations as permitted by this rule provided that:

(a) the pharmacy intern is under the personal supervision by a pharmacist who is registered with the board to administer immunizations as required by this rule; and

(b) has completed all of the training and current certification required by subsections 3.1 (b) and (c) of this section.

~~3-23.3.~~ It is unprofessional conduct for a pharmacist or pharmacy intern to administer an immunization, who is not in compliance with this rule.

**§15-12-4. Registration.**

4.1. 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 3(a) have been met. The application must be submitted along with a required fee of \$10.00. Provided all requirements of Section 3(a) have been

met and the required fee is received, the Board shall issue a registration to administer immunizations. Registrations shall expire bi-annually on June 30 of year in which the pharmacist's license to practice pharmacy expires.

4.2. A pharmacist may not administer an immunization unless currently registered with the Board to do so under this rule. Further, such registration must be posted conspicuously at any location at which the registered pharmacist is doing any administration.

4.3 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 3.1 (b) and (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 given by the pharmacy intern.

#### **§15-12-5. Immunizations.**

5.1. Immunizations authorized by this rule shall be administered:

(a) 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, CDC's "Recommended Adult Immunization Schedule, by Vaccine and Age Group" and "Recommended Adult Immunization Schedule, by Vaccine and Medical and Other Indications", including the footnotes provided for each schedule (available at [www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm](http://www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm)); or

(b) in accordance with a proper order from a properly authorized practitioner.

5.2 Administration must be done in accordance with the training required by Section 3.1(b) of this Series, 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;

5.3. Administration must include implementation of the CDC's recommended appropriate observation for an adverse reaction of an individual following an immunization.

5.4. Under no circumstances may a pharmacist delegate his or her authority to administer immunizations to any other person, including but not limited to, any pharmacy technician, except as otherwise provided herein for a properly trained pharmacy intern who is administering under the direct supervision of the pharmacist.

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

**§15-12-6. Record-keeping and reporting.**

6.1. An immunization questionnaire and consent form shall be completed for each person receiving an immunization. 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~~pharmacist or pharmacy intern must document such in the immunization record, and provide a record of the immunization administration to the patient. Such record shall also contain the name of the pharmacist, and, where applicable, the name of the pharmacy intern, administering the immunization.

6.2. In addition, the pharmacist must 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.

6.3. The immunization questionnaire and 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 (5) 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~~pharmacist or pharmacy intern who administered the immunization is employed or otherwise practicing at the time the immunization is given.

6.4 Pharmacists 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 per subsection 6.1. 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>.

**§15-12-7. Emergencies.**

7.1. A ~~pharmacist~~pharmacist or pharmacy intern 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 for such situations.

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

#### **§15-12-8. Immunization Training Programs.**

8.1. The Board must approve a course or program in immunization administration for that course to be used to meet the qualification requirement of section 3.1(b). In order to be approved by the Board, the course or program, at a minimum, must include practical training and instruction on the following:

- (a) basic immunology, including the human immune response;
- (b) adverse reactions, contraindications, warnings and precautions;
- (c) response to emergency situations, including administration of epinephrine and diphenhydramine;
- (d) storage and handling requirements;
- (e) recordkeeping and reporting requirements, including screening and informed consent documentation;
- (f) proper environment for administration and observation;
- (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
- (h) policies and procedures for establishing and implementing appropriate immunization treatment guidelines.

8.2. Any course approved by the Board must include a minimum of 15 hours of didactic and practical based components of instruction and training, including self study and live instruction. The live instruction must be a minimum of six (6) hours, and shall include documented and supervised instruction on physical administration of vaccinations.

APPENDIX B

***FISCAL NOTE FOR PROPOSED RULES***

Title 15 Series 12 "IMMUNIZATIONS ADMINISTERED BY PHARMACISTS"

Rule Title: \_\_\_\_\_

Type of Rule:  Legislative  Interpretive  Procedural

Agency: WV Board of Pharmacy, jointly with Board of Medicine and Board of Osteopathy

Address: 2310 Kanawha Boulevard East  
Charleston, West Virginia 25311

Phone Number: 304-558-0558 Email: david.e.potters@wv.gov

**Fiscal Note Summary**

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

This should have no fiscal impact on state government. It is revenue neutral.

**Fiscal Note Detail**

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

FISCAL YEAR			
Effect of Proposal	Current Increase/Decrease (use "-")	Next Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0.00	0.00	0.00
Personal Services	0.00	0.00	0.00
Current Expenses	0.00	0.00	0.00
Repairs & Alterations	0.00	0.00	0.00
Assets	0.00	0.00	0.00
Other	0.00	0.00	0.00
2. Estimated Total Revenues	0.00	0.00	0.00

Title 15, Series 12 "IMMUNIZATIONS ADMINISTERED BY PHARMACISTS"

Rule Title: \_\_\_\_\_

Rule Title: \_\_\_\_\_

**3. Explanation of above estimates (including long-range effect):**

Please include any increase or decrease in fees in your estimated total revenues.

There are no fee changes and no discernable impacts on board resources. The rules are simply changes in requirements to allow interns to immunize under the supervision of a training pharmacist, and to require some additional minimal reporting.

**MEMORANDUM**

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

None. There are no fee changes and no discernable impacts on board resources. The rules are simply changes in requirements to allow interns to immunize under the supervision of a training pharmacist, and to require some additional minimal reporting.

Date: June 25, 2014

Signature of Agency Head or Authorized Representative

David E. Potters