

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

Form #2

Do Not Mark In This Box

2011 SEP 14 PM 1:40

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 Rule CITE AUTHORITY: 30-5-30

AMENDMENT TO AN EXISTING RULE: YES ☒ NO ☐

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 12

TITLE OF RULE BEING AMENDED: Board of Pharmacy Rules Regarding 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 October 20, 2011 AT 4:00 p.m. ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

West Virginia Board of Pharmacy
C/o Immunizations Comments
232 Capitol Street
Charleston, WV 25301

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

David E. Potters
Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

Board Members
George Karos, Pres.
Lydia Main, Vice Pres.
Charles Woolcock, Sec.
Martin Castleberry
Rebekah E. Hott
Carl K. Hedrick, Jr.
Sam Kapourales



Board of Pharmacy

David E. Potters,
Executive Director &
General Counsel

Betty Jo Payne,
Asst. Exec. Director

Office

232 Capitol Street
Charleston, West Virginia 25301

Phone (304) 558-0558

Fax (304) 558-0572

APPROVAL OF FILING OF RULES

BE IT HEREBY KNOWN that the West Virginia Board of Pharmacy approves the filing of the following modified rules with the Secretary of State and the Legislative Rulemaking and Review Committee, which were considered and approved for filing by the Board at its regular meetings held on June 17, 2011, and with changes proposed by the Board of Medicine and Board of Osteopathy on July 27, 2011:

Title 15, Series 12, "BOARD OF PHARMACY RULES REGARDING IMMUNIZATIONS ADMINISTERED BY PHARMACISTS", expanding the vaccines permitted to be administered by pharmacists (per West Virginia Code § 30-5-30 requiring joint rulemaking between the Boards of Medicine, Osteopathy, and Pharmacy for expanding the list of immunizations permitted).

Signed this 12 day of September, 2011,

BY: *George Karos*
George Karos, President



STATE OF WEST VIRGINIA
BOARD OF OSTEOPATHY
405 Capitol Street, Suite 402
Charleston, WV 25301

Phone: 304-558-6095
Fax: 304-558-6096

September 2, 2011

RECEIVED

SEP - 8 2011

WV BOARD OF PHARMACY

David Potters, Executive Director
WV Board of Pharmacy
232 Capitol Street
Charleston, WV 25301

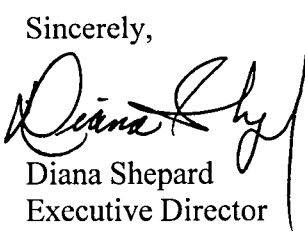
Dear David:

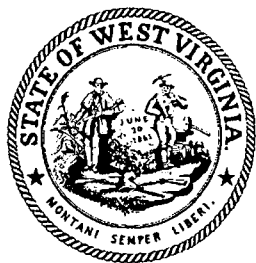
The West Virginia Board of Osteopathy met by conference call on Monday, July 25, 2011, and reviewed the proposed changes to §15-12-1.

After review and discussion of the proposed changes to the administration of immunizations by Pharmacists, the Board approved the changes with the addition of §15-12-6.4 for the reporting of adverse outcomes to the Vaccine Adverse Events Reporting System and to the West Virginia Board of Pharmacy.

The WV Board of Osteopathy appreciates the collaborative effort made in reaching the rule changes and looks forward to a continued close working relationship with the WV Board of Pharmacy.

Sincerely,


Diana Shepard
Executive Director



REV. O. RICHARD BOWYER
PRESIDENT

CATHERINE SLEMP, MD, MPH
SECRETARY

State of West Virginia *Board of Medicine*

101 Dee Drive, Suite 103
Charleston, WV 25311
Telephone 304.558.2921
Fax 304.558.2084
www.wvbom.wv.gov

FILED
SEP 11 2011

WV BOARD OF PHARMACY

MICHAEL L. FERREBEE, MD
VICE PRESIDENT

ROBERT C. KNITTLE
EXECUTIVE DIRECTOR

September 2, 2011

David E. Potters, Esq.
Executive Director and General Counsel
West Virginia Board of Pharmacy
232 Capitol Street
Charleston, WV 25301

Re: Joint Rule proposed by the West Virginia Board of Pharmacy, amendments to 15 CSR 12

Dear Mr. Potters:

I have reviewed the proposed amendments to the above noted rule relating to immunizations which you sent yesterday. The proposed amendments are at 1.1, relating to the scope of the Rule, at 2.1 in the definitions, at 2.2 adding immunizations which may be given by certain pharmacists, and at 6.4, relating to reporting. These amendments were approved by the full West Virginia Board of Medicine at its regular July 11, 2011, meeting. Please feel free to use this letter with the Board of Pharmacy filing with the Legislative Rule Making Review Committee to show the Board of Medicine's involvement in and agreement with this joint project.

For the Board,

Robert C. Knittle

lab



REV. O. RICHARD BOWYER
PRESIDENT

CATHERINE SLEMP, MD, MPH
SECRETARY

State of West Virginia **RECEIVED**
Board of Medicine

JUL 13 2011

WV BOARD OF PHARMACY

101 Dee Drive, Suite 103
Charleston, WV 25311
Telephone 304.558.2921
Fax 304.558.2084
www.wvbom.wv.gov

MICHAEL L. FERREBEE, MD
VICE PRESIDENT

ROBERT C. KNITTLE
EXECUTIVE DIRECTOR

July 12, 2011

David E. Potters
Executive Director and General Counsel
West Virginia Board of Pharmacy
232 Capitol Street
Charleston, WV 25301

Re: 15 CSR 12, Board of Pharmacy Rules Regarding Immunizations Administered by Pharmacists

Dear Mr. Potters:

This will affirm that the Board of Medicine yesterday at its regular meeting endorsed the proposed amendments to the above rule at section 2 that the Board of Pharmacy provided to us last month. As long as a reporting requirement is added to the proposed amendments with respect to adverse reactions, the Board of Medicine is in favor of the filing of the joint rules as contemplated under West Virginia Code § 30-5-30. Our General Counsel is ready to assist you with this and you may contact her at Deborah.Lewis.Rodecker@wv.gov or 304.558.2921 ext. 214.

Best wishes.

Sincerely,

A handwritten signature in black ink that reads "Robert C. Knittle".

Robert C. Knittle

lab

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

Pharmacist Administration of Immunizations

15 CSR 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. West Virginia Code Section 30-5-30 directed the West Virginia Board of Pharmacy to promulgate rules, with the advice of the Board of Medicine and Board of Osteopathy, to implement and enforce the provisions of this section for pharmacist administration of flu and pneumonia vaccines, but required joint rulemaking by the three Boards for any further expansion of the types of immunizations a pharmacist may administer. The Board of Pharmacy prepared and the Legislature approved of the Board of Pharmacy's rules for pharmacists to administer flu and pneumonia vaccines in Title 15, Series 12. Now, after reviewing that process, the West Virginia Board of Pharmacy, Board of Medicine, and Board of Osteopathy have worked together to amend those rules in Series 12 to provide for additional immunizations through joint rulemaking by the three boards. The modification of Series 12, if approved, would add all of the vaccines specifically listed in the statute: Influenza, Pneumonia, Hepatitis A, Hepatitis B, Herpes Zoster, and Tetanus. With regard to tetanus, the rule would follow CDC recommendations and market realities to allow for tetanus-diphtheria (commonly referred to as "Td"), or tetanus-diphtheria-and-pertussis (commonly referred to as "Tdap") as combination vaccines which are preferred by the CDC over tetanus alone. Finally, it would require pharmacists to report any adverse events with administration to the Vaccine Adverse Events Reporting System (VAERS), and provide a copy of all reports to the Board. 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>.

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, 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, David E. Potters, Executive Director and General Counsel, 232 Capitol Street, Charleston, West Virginia, 25301, 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.

FISCAL NOTE FOR PROPOSED RULES

Title 15, Series 12

Rule Title: _____

Type of Rule:

☒ Legislative ☐ Interpretive ☐ Procedural

Agency:

West Virginia Board of Pharmacy

Address:

232 Capitol Street

Charleston, West Virginia 25301

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.

None. This just provides for pharmacists' authority within their scope of practice.

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

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.

None. This just provides for pharmacists' authority within their scope of practice.

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.

This just provides for pharmacists' authority within their scope of practice.

Date: September 14, 2011

Signature of Agency Head or Authorized Representative

David E. Potters

TITLE -15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

FILED
2011 SEP 14 PM 1:40
OFFICE OF THE CLERK
SECRETARY OF STATE

SERIES 12
Board of Pharmacy Rules Regarding
Immunizations Administered By Pharmacists

§15-12-1. General.

1.1. Scope. -- To establish ~~amend~~ the rules for pharmacists 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.

1.3. Filing Date. -- ~~June 9, 2009~~ _____.

1.4. Effective Date. -- ~~July 1, 1009~~ _____.

§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 may administer to any person eighteen years of age or older, including:

- (a) Influenza; and
- (b) Pneumonia;
- (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").

§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) hours annually of continuing education related to immunizations. The continuing education must be by a provider approved by the Accreditation Council for Pharmacy Education (A.C.P.E.).

3.2. It is unprofessional conduct for a pharmacist 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.

§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); 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.

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 must document such in the immunization record, and provide a record of the immunization administration to the patient.

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 who administered the immunization is employed 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. 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 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 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.