

**WEST VIRGINIA
SECRETARY OF STATE
BETTY IRELAND
ADMINISTRATIVE LAW DIVISION**

Form #2

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2008 JUL 30 PM 3:46

OFFICE 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: WV Code Section 30-5-30 (HB 3056)

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 12

TITLE OF RULE BEING PROPOSED: Pharmacist Administration of Immunizations

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 August 29, 2008 AT 3:00 p.m. ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

West Virginia Board of Pharmacy

Attn: David Potters

232 Capitol Street

Charleston, West Virginia 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

**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. HB3056 directs the West Virginia Board of Pharmacy as set forth in West Virginia Code Section 30-5-30 to promulgate rules, with the advice of the Board of Medicine and Board of Osteopathy, to implement and enforce the provisions of this section. Pharmacists are already administering immunizations in most other states in the United States pursuant to the laws in the various jurisdictions. These proposed regulations set forth the conditions under which a pharmacist in West Virginia may do so, including the training and certifications that must be obtained, continuing education, and standards of practice which must be followed.

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 proposed new series, such that there are no strike-throughs in the proposed rule..

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: 15-12-1, et seq: Pharmacist Administration of Immunizations

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: dpotters@wvbop.com

Fiscal Note Summary

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

The Board of Pharmacy will have to process and issue certifications for pharmacists to administer immunizations, including future renewals. The proposed regulation allows for a \$10.00 fee for application for such a certification which will cover the administrative costs. Thus, while the Board of Pharmacy will realize costs, it will also realized increased revenues through fees received. As such, there should be no net financial impact to the Board. There will be no effect to the State's general revenue.

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	5,000.00	15,000.00	15,000.00
Personal Services			
Current Expenses			
Repairs & Alterations			
Assets			
Other			
2. Estimated Total Revenues	5,000.00	15,000.00	15,000.00

Rule Title: _____

Rule Title: 15-12-1. et seq: Pharmacist Administration of Immunizations

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

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

The Board has approximately 3,000 pharmacists currently actively licensed in the State. The above estimates assume that approximately 1/2 of the licensees will desire to obtain certification to administer immunizations, with approximately 500 applying in the 2008-2009 phiscal year, and approximately 1,500 applying for certification or renewal each phiscal year thereafter.. The Board of Pharmacy will have to process and issue certifications for pharmacists to administer immunizations, including future renewals. This includes costs of providing applications (in other than electronic format), time for Board employees to process applications, costs of producing and mailing certificates, and costs of producing and mailing notices for renewals. The proposed regulation allows for a \$10.00 fee per application for such a certification, which will cover the administrative costs. Thus, while the Board of Pharmacy will realize costs, it will also realized increased revenues through fees received. As such, there should be no net financial impact to the Board. There will be no effect to the State's general revenue.

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.

Date: July 31, 2008

Signature of Agency Head or Authorized Representative

David E. Potters

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§15-12-1. General.

OFFICE WEST VIRGINIA
SECRETARY OF STATE

1.1. Scope. -- To establish rules for pharmacists licensed in West Virginia to administer immunizations to patients in this State.

1.2. Authority. -- W. Va. Code §30-5-30 (HB 3056, 2008 Regular Session), with advice from the Board of Medicine and Board of Osteopathy.

1.3. Filing Date. -- July 30, 2008.

1.4. Effective Date. -- _____.

§15-12-2. Definitions.

2.1. "Immunizations" means, for the purpose of this title, 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.

§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 Title.

§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 Title.

§15-12-5. Immunizations.

5.1. Immunizations authorized by this Title 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; 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, specifics regarding administration, and storage requirements for each specific immunization authorized by this title;

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.

§15-12-7. Emergencies.

7.1. A pharmacist authorized to administer immunizations under this title 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.