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OFFICE WEST VIRGINIA
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Form #6

NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

AMENDMENT TO AN EXISTING RULE: YES X 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: ___

THE ABOVE RULE HAS BEEN AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE.

AUTHORIZATION IS CITED IN (house or senate bill number) HB 4139

SECTION 64-9-15, PASSED ON March 10, 2012

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON THE FOLLOWING DATE: Date of Final Filing: April 4, 2012

David E. Potters
Authorized Signature

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State of West Virginia
Board of Pharmacy

David E. Potters,
Executive Director &
General Counsel

Betty Jo Payne,
Asst. Exec. Director

Office
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Charleston, West Virginia 25301

APPROVAL OF FINAL FILING OF RULES

BE IT HEREBY KNOWN that the West Virginia Board of Pharmacy approves the final filing of the following rules with the Secretary of State and the Legislative Rulemaking and Review Committee, as approved by the Legislature in House Bill 4139 during the 2012 Regular Session. each of which were considered and approved for final filing by the Board following at its meeting held on March 26, 2012:

(1) Title 15, Series 2, "RULES OF THE BOARD OF PHARMACY FOR THE UNIFORM CONTROLLED SUBSTANCES ACT", with modification regarding electronic prescribing (per SB 1001, 2007 1st Special Session and subsequent changes in federal law), limiting early refills, and clarifying other provisions;

(2) Title 15, Series 3, "BOARD OF PHARMACY RULES FOR CONTINUING EDUCATION FOR LICENSURE OF PHARMACISTS", modernizing certain language and updating requirements to match national standards;

(3) Title 15, Series 5, "LICENSURE OF WHOLESALE DRUG DISTRIBUTORS", to update language as required by federal law, and clarify requirements for licensing of distributors who maintain title, ownership, or control over their product which is brought into this State by another entity on their behalf; and

(4) 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 26th day of March, 2012,

BY: George Karos
George Karos, President

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 12
Board of Pharmacy Rules Regarding Immunizations Administered By Pharmacists

§15-12-1. General.

1.1. Scope. -- To 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. -- 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 may administer to any person eighteen years of age or older, including:

(a) Influenza;
(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.