



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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**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 and Pharmacy Interns

PRIMARY CONTACT

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CITE STATUTORY AUTHORITY: W. Va. Code §30-5-7

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:

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, and have done so here.

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 6/22/2017

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 7/24/2017

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?

None

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

The rules change set in motion by the Bill Human Papilloma Virus (HPV) to the vaccines permitted to be given to someone over age 18; and would allow for influenza and HPV vaccines to be administered to any person age eleven through eighteen years of age with written informed parental consent, when presented with a prescription from a physician and there are no contraindications to that patient receiving that vaccine.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

House Bill 2518 passed in the 2017 Regular Legislative Session provides for additional rulemaking on pharmacists and pharmacy interns to provide certain immunizations.

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

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

None

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

None

C. FISCAL NOTE DETAIL:

| Effect of Proposal | Fiscal Year | | |
|------------------------------------|--|--|--|
| | 2017 Increase/Decrease (use "-") | 2018 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 |

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

None

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENTS ARE TRUE AND CORRECT.

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

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

§15-12-1. General.

1.1. Scope. -- To ~~amend~~ provide the rules for pharmacists and pharmacy interns licensed in West Virginia 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.

1.3. Filing Date. -- ~~April 16, 2015~~ _____.

1.4. Effective Date. -- ~~May 17, 2015~~ _____.

1.5. Sunset Date -- This rule shall terminate and have no further force or effect upon the expiration of 10 years from its effective date.

§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 licensed pharmacy intern may administer as follows:

2.2.a. to any person eighteen years of age or older, including:

(a) 2.2.a.1. Influenza;

(b) 2.2.a.2. Pneumococcal;

(c) 2.2.a.3. Hepatitis A;

(d) 2.2.a.4. Hepatitis B;

(e) 2.2.a.5. Herpes Zoster;

~~(f)~~ 2.2.a.6. Tetanus, tetanus-diphtheria (commonly referred to as “Td”), or tetanus-diphtheria-and-pertussis (commonly referred to as “Tdap”); ~~and~~

~~(g)~~ 2.2.a.7. Meningococcal; and

2.2.a.8. Human Papilloma Virus (HPV); and

2.2.b. to any person age eleven through eighteen years of age, with written informed parental consent, when presented with a prescription from a physician and there are no contraindications to that patient receiving that vaccine, including:

2.2.b.1. Influenza; and

2.2.b.2. Human Papilloma Virus (HPV)

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~~ as defined by Section 2.2 of this rule provided the pharmacist has met all of the following requirements:

~~(a)~~ 3.1.a. registered with the board to administer immunizations;

~~(b)~~ 3.1.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)~~ 3.1.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)~~ 3.1.d. completed a minimum of 2 hours 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 licensed by the Board may administer immunizations as permitted by this rule provided that:

~~(a)~~ 3.2.a. the licensed 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)~~ 3.2.b. has completed all of the training and current certification required by subsections ~~3.1~~ ~~(b)~~ 3.1.b. and ~~(c)~~ 3.1.c. of this section.

3.3. 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)~~ 3.1. have been met. The application must be submitted along with a required fee of \$10.00. Provided all requirements of Section ~~3(a)~~ 3.1. 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 licensed 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)~~ 3.1.b. and ~~(c)~~ 3.1.c. of this rule. The supervising pharmacist shall maintain this documentation in the pharmacy where the pharmacist and licensed pharmacy intern who administers an immunization is employed or otherwise practicing at the time any immunization is administered by a licensed pharmacy intern.

§15-12-5. Immunizations.

5.1. Immunizations authorized by this rule shall be administered:

~~(a)~~ 5.1.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~~" recommended immunization schedule for adults and children and adolescents, including the footnotes provided for each schedule (available at ~~www.cdc.gov/vaccines/recs/schedules/adult-schedule.htm~~ <https://www.cdc.gov/vaccines/schedules/index.html>); or

~~(b)~~5.1.b. in accordance with a proper order from a properly authorized practitioner, Provided that, for minors age eleven through eighteen, the order must be a prescription from a properly authorized physician.

5.2 Administration must be done in accordance with the training required by Section ~~3.1(b)~~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, and, when done pursuant to a prescription, in accordance therewith;

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 licensed 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. When the immunization is for influenza or HPV for a minor age eleven through eighteen years of age, the questionnaire and consent form must 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 licensed pharmacy intern must document such in the immunization record, and provide a record of the immunization administration to the patient. Such record shall contain the name of the pharmacist, and, where applicable, the name of the licensed 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 or licensed 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 in accordance with 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 or licensed 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 or licensed 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)~~ 8.1.a. basic immunology, including the human immune response;
- ~~(b)~~ 8.1.b. adverse reactions, contraindications, warnings and precautions;
- ~~(c)~~ 8.1.c. response to emergency situations, including administration of epinephrine and diphenhydramine;
- ~~(d)~~ 8.1.d. storage and handling requirements;
- ~~(e)~~ 8.1.e. recordkeeping and reporting requirements, including screening and informed consent documentation;

~~(f)~~ 8.1.f. proper environment for administration and observation;

~~(g)~~ 8.1.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

~~(h)~~ 8.1.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.