



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

eFILED

7/27/2018 12:25:15 PM

Office of West Virginia
Secretary Of State

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-
MAKING REVIEW COMMITTEE**

AGENCY: Pharmacy TITLE-SERIES: 15-15
RULE TYPE: Legislative Amendment to Existing Rule: No Repeal of existing rule: No
RULE NAME: 15-15 Regulations Governing Pharmacy Permits

PRIMARY CONTACT

NAME: Ryan Hatfield
ADDRESS: 2310 Kanawha Blvd East
Charleston, WestVirginia 25311
EMAIL: ryan.l.hatfield@wv.gov
PHONE NUMBER: 304-558-0558

CITE STATUTORY AUTHORITY: WVC 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:

WVC 30-5-7

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 6/21/2018

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 7/22/2018

COMMENTS RECEIVED: No

(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:

This rule governs the licensure and regulations of pharmacies in the State of West Virginia.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

This rule is copy and pasted from 15 CSR 1 in order to better organize our rules.

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		
	2018 Increase/Decrease (use "-")	2019 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost			
Personal Services			
Current Expenses			
Repairs and Alterations			
Assets			
Other			
2. Estimated Total Revenues			

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

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Ryan L Hatfield -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

15CSR15

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 15
REGULATIONS GOVERNING PHARMACY PERMITS

§15-15-1. General.

- 1.1. Scope. -- Licensure and regulations governing pharmacy permits.
- 1.2. Authority -- W. Va. Code §§ 30-5-7.
- 1.3. Filing date --
- 1.4. Effective date --
- 1.5. Sunset Date -- This rule shall terminate and have no further force or effect upon the expiration of five years from its effective date.

§15-15-2. Registration.

- 2.1. A pharmacy shall first secure a registration from the Board and comply fully with W. Va. Code § 30-5-22 before it may lawfully conduct a pharmacy.
- 2.2. The Board shall require and provide for the annual registration of every pharmacy doing business in this state. Any person desiring to operate, maintain, open or establish a pharmacy in West Virginia, shall apply to the Board for a registration to do so. No registration will be issued unless a pharmacy is operated or pharmacist care is provided. Not more than one registration may be issued in any one name in more than one location. Every registered pharmacy shall be under the direct charge of a pharmacist, designated the Pharmacist-in-charge, and shall operate in compliance with the state and federal laws and rules and regulations.
- 2.2.1. The application for a new registration shall be made on a form prescribed and furnished by the Board, which when properly executed shall include, but not be limited to the following information:
- 2.2.1.a. identification of the owner that is applying for the registration;
- 2.2.1.b. the name under which the business will be operated and which will be used in advertising;
- 2.2.1.c. the physical location of the pharmacy including;
- 2.2.1.c.1. Its street number; and
- 2.2.1.c.1. The city and county.
- 2.2.1.d. the mailing address of the pharmacy if different from its physical location;

2.2.1.e. the name and license number of the pharmacist-in-charge;

2.2.1.f. the name and license numbers of other pharmacists regularly employed at the pharmacy;

2.2.1.g. the name and registration numbers of pharmacy technicians and pharmacy technician trainees regularly employed at the pharmacy;

2.2.1.h. the pharmacy's hours of operation; and

2.2.1.i. detailed floor plans for the pharmacy made to scale.

2.2.2. Each pharmacy shall make a separate application and a separate registration shall be issued for each pharmacy.

2.2.3. A pharmacy shall have available in the pharmacy, in either print or electronic media, a current edition of a drug information and reference compendium such as Elsevier Gold Standard/Clinical Pharmacology, Facts & Comparisons, or other appropriate compendium approved by the board, and shall have the necessary equipment to render service dictated by public health, and as required by other sections of this rule.

2.2.4. An initial application for a pharmacy registration shall be accompanied by a fee of \$150.00.

2.2.5. A pharmacy compounding parenteral/enteral drugs shall also apply for a compounding permit as required by section 16 of this rule.

§15-15-3. Issuance of Permit.

3.1. The Board shall issue a registration to conduct a pharmacy to the applicant after a satisfactory inspection of the facility.

3.2. The registration registers the pharmacy to which it is issued and is not transferrable. It is issued on the joint application of the owner and the pharmacist-in-charge, on the sworn statement that it will be conducted in accordance with the provisions of the federal and state laws and attendant Rules and Regulations.

3.3. A registration shall be posted in a visibly conspicuous place. The registration may not be in a location that is out of sight of the dispensing area.

§15-15-4. Renewal of registration.

4.1. The annual renewal of a registration takes place on the first day of July of each year. The fee for the annual renewal is \$75.00. Registrations expire on the thirtieth day of June of each calendar year. Renewal applications shall be completed and submitted to the Board office by the fifteenth day of June to allow time for processing. Pharmacies shall have a grace period for renewal until July 31 of the year in which the permit expires; however, renewal applications received in the Board office after June 30 of the year in which the registration expires shall require the payment of a late fee in the amount of \$75.00 in addition to the application fee of \$75.00, for a total amount of \$150.00.

4.2. If a pharmacy does not make application for renewal by the first day of August each year, to renew an expired registration the Board shall re-inspect the pharmacy and the permittee shall pay the required

renewal fee and late fee totaling \$150.00 for the registration, and \$150.00 for the re-inspection, for a total amount of \$300.00.

§15-15-5. Surrender of registration.

5.1. When a pharmacist-in-charge in whose name a pharmacy registration has been issued leaves the full time employment of that pharmacy; or for any other reason ceases to be in complete and actual charge of the pharmacy, he or she shall immediately notify the Board, in writing, of the termination or change of his or her services, and return the original pharmacy registration to the Board office with the date of the change and the name and registration number of the newly designated pharmacist-in-charge written on the registration in indelible ink. A copy of the registration as modified shall be made and posted in the pharmacy. For the purposes of this subsection 'full time employment' means working at least 30 hours per week, 3 days per week at one pharmacy. If the pharmacist-in-charge fails to notify the Board and return the pharmacy registration the Board may take disciplinary action against the offending pharmacist.

5.2. A pharmacy owner shall notify the Board, immediately and in writing, of the termination of the full time employment of the pharmacist-in-charge; as shown on the registration, or any other action which causes the pharmacist-in-charge to cease being in complete and actual charge of the pharmacy. The pharmacy registration holder shall immediately designate a new pharmacist-in-charge and write the name on a copy of the pharmacy registration in indelible ink and post it in the pharmacy. An interim pharmacist-in-charge may be designated for a period not to exceed sixty days. The Board may permit in its discretion an additional period of time for an interim pharmacist-in-charge based upon a request in writing detailing the circumstances which warrant the extension. The original pharmacy registration shall be returned to the Board office with the date of the change and the name and registration number of the newly designated pharmacist-in-charge written on the original registration in indelible ink. A copy of the registration as modified shall be made and posted in the pharmacy. Until a pharmacist-in-charge is designated and written in indelible ink on the pharmacy registration, the pharmacy shall not operate. Each day of operation in the absence of a designated pharmacist-in-charge is considered a separate offense. The pharmacy registration holder shall notify the Board of the replacement in writing within 30 days upon a form provided by the Board with a fee of \$10.00 for the new registration reflecting the new pharmacist-in-charge. Upon receipt of this notification, the Board shall provide a newly printed registration to the pharmacy. If an interim pharmacist-in-charge is designated who is not the permanent pharmacist-in-charge, the name of the interim pharmacist-in-charge and the period of time that pharmacist served as interim pharmacist-in-charge shall be noted on the form, and a fee will not be charged and a newly printed registration will not be issued until a permanent pharmacist-in-charge is designated. An interim pharmacist-in-charge is not required to be employed the minimum number of hours as is the permanent pharmacist-in-charge.

5.3. A pharmacy that moves to a new address or a different location within the current building shall apply for a new registration and submit the appropriate fees. The Board shall inspect the facility before a new registration may be issued.

5.4. When a pharmacy changes ownership the registration expires, and a new registration must be obtained from the Board.

§15-15-6. Violations.

6.1. The violation of any of these rules shall be considered cause of disciplinary action.

6.2. A pharmacist shall notify the Board immediately, in writing, of any change in employment or change of address. Failure to notify the Board shall be sufficient cause for disciplinary action.

6.3. A person who employs a licensed pharmacist shall notify the Board within 7 days, in writing, of any discharge or termination of the licensed pharmacist or change of the status of the pharmacist-in-charge. A pharmacy registration holder who fails to notify the Board is subject to disciplinary action.

6.4. A person who employs a licensed pharmacist shall immediately notify the Board, in writing, of any complaints registered against a pharmacist regarding the violation of any pharmacy laws or rules.

§15-15-7. Security.

7.1. If a pharmacy is to be operated for a period less than regular business hours of the entire store or institution, the following requirements apply:

7.1.1. The pharmacy area shall be separated from other departments of the store or institution by a floor to ceiling, physical barrier or partition, with entry doors that can be securely locked. The Board may approve plans, on a case by case basis, for non-physical barriers. If the pharmacist is always present when other persons are in the store or institution, the pharmacy area need not to be enclosed by a physical barrier. The barrier shall be designated so that only a pharmacist with a key has access to the area where prescription drugs, dangerous drugs, controlled substances, and other drugs and devices restricted to sales by pharmacists are stored, compounded, prepared and/or dispensed;

7.1.2. Physical barriers may be either of solid material or movable curtain type:

7.1.2.a. If the barrier is of a solid material it shall be of sufficient strength and thickness that it may not be easily removed and must be equipped with keyed locks; or

7.1.2.b. If the barrier is of a movable material it shall be constructed of material strong enough to prevent breakage and shall have openings or interstices small enough to prohibit removal of any items in the protected area and be equipped with keyed locks;

7.2. A device for the detection of breaking and/or entering shall be installed in each prescription department in each pharmacy. The installation and the device shall be based on accepted burglar alarm industry standards, and are subject to the following conditions:

7.2.1. The device shall be maintained in operating order and shall have an auxiliary source of power;

7.2.2. The device shall fully protect the prescription department and shall be capable of detecting breaking and/or entering by any means when activated;

7.2.3. Deactivation of the alarm system for the prescription department shall be restricted to the pharmacists working at the pharmacy, and the system shall be activated whenever a pharmacist is not on duty. The pharmacy registration holder may deactivate the system for security or surveillance purposes as long as the reason for the deactivation, the person deactivating the system, and time and date of deactivation are documented and immediately available to the Board; and

7.2.4. This subsection does not apply to pharmacies which are open and staffed by pharmacists twenty four (24) hours a day;

7.3. The door keys are alarm activation and de-activation codes to the prescription areas are subject to the following:

7.3.1. Only pharmacists practicing at the pharmacy and authorized by the pharmacist-in-charge may possess any keys to the locks on the doors of the prescription area;

7.3.2. The pharmacist-in-charge may place a key and the alarm access code, if required, in a sealed envelope or other container with the pharmacist's signature across the seal in a vault or safe within the store or other secured place;

7.3.3. During times that an institutional pharmacy may be unattended by a pharmacist, arrangements shall be made in advance by the pharmacist-in-charge for provision of drugs to the medical staff and other authorized personnel of the institution by use of night cabinets and, in emergency circumstances, by access to the pharmacy. A pharmacist shall be 'on call' during all absences. In the absence of a pharmacist, drugs shall be stored in a locked cabinet or other enclosure constructed and located outside the pharmacy area, to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons. The pharmacist-in-charge shall, in conjunction with the appropriate committee of the institution, develop inventory listings of those drugs to be included in the cabinets and determine who may have access, and shall ensure that:

7.3.3.a. drugs are properly labels;

7.3.3.b. only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements;

7.3.3.c. whenever access to the cabinet occurs, written practitioner's orders and proof-of-use are provided;

7.3.3.d. all drugs in the cabinet are inventoried no less than once per week;

7.3.3.e. a complete audit of all activity concerning the cabinet is conducted no less than once per month; and

7.3.3.f. written policies and procedures are established to implement the provisions of this subdivision.

7.3.4. Whenever any drug is not available from floor supplies or night cabinets, and the drug is required to immediately treat a life-threatening situation of a patient, the drug may be obtained from the pharmacy by a supervisory nurse in accordance with the requirements of this subdivision. The pharmacist-in-charge shall, in conjunction with the appropriate committee of the institution, designate in writing one supervisory nurse in any given eight hour shift who is responsible for obtaining drugs from the pharmacy during any emergency situation. Removal of any drug from the pharmacy by an authorized nurse shall be recorded on a suitable form showing the patient's name, and location within the institution, the name of the drug, its strength and amount, and date and time, and the signature of the nurse. The form shall be left with the container from which the drug was removed and the supervisory nurse shall contact the pharmacist "on call";

7.4. In the absence of a pharmacist, a sign with a minimum of four (4) inch letters shall be prominently displayed stating: "Pharmacy Closed. No Pharmacist On Duty", and the pharmacist shall secure the pharmacy by implementing any barriers and security devices prior to leaving the pharmacy;

7.5. Except as provided in Title 15, Series 14, for central prescription filling, completed prescription orders shall be bagged and kept in the pharmacy and cannot be removed from the pharmacy unless the pharmacist is present and the removal is for the immediate delivery to the patient, the patient's authorized

designee picking up the prescription for the patient, or person delivering the prescription to the patient at his or her residence or other place designated by the patient or the patient's authorized designee. If the patient or the patient's designee is unknown to the pharmacist then his or her identity shall be established by photo identification card;

7.6. Dispensing has not occurred until the drug is actually picked up by or delivered to the patient or patient's representative. Mobile pharmacy units and remote dispensing are prohibited. Completed prescriptions must be picked up at or delivered from the same pharmacy at which they were prepared, except that this subsection does not apply to a mail order pharmacy licensed by the Board, a central fill pharmacy licensed by the Board, or to transfers of prescription drugs by a retail pharmacy to alleviate a temporary shortage; and

7.7. Emergency facilities to provide pharmaceutical services during emergency conditions or natural disasters may be approved by the Board for a period not to exceed 180 days.

§15-15-8. Professional Work Environment

8.1. No pharmacist may work more than 12 hours within a 24 hour period without at least 8 hours off duty in that 24 hours, except in a case of emergency when a pharmacist calls off work, the pharmacist on duty may work more than 12 hours in order to keep the pharmacy open. The pharmacists would have to document and date an amount of time worked beyond the 12 hour limit along with the reason for the extended hours of work and make it available to the Board.

8.2. Any pharmacy dispensing more than 15 prescriptions per hour on average during a day shall have a registered pharmacy technician assisting the pharmacist. The pharmacist-in-charge shall determine the work schedule for pharmacy technicians based upon prior dispensing records.

8.3. The pharmacist on duty or the pharmacy registrant shall notify the pharmacist-in-charge whenever a prescription error, loss of drugs, or a violation of any statute or rule occurs and the pharmacist-in-charge is not present.