



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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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: Yes Repeal of existing rule: No
RULE NAME: 15-15 Regulations Governing Pharmacy Permits

PRIMARY CONTACT

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CITE STATUTORY AUTHORITY: 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:

The Board of Pharmacy has the authority to set standards and requirements for a license, permit, and registration

IS THIS FILING SOLELY FOR THE SUNSET PROVISION REQUIREMENTS IN W. VA. CODE §29A-3-19(e)? No

IF YES, DO YOU CERTIFY THAT THE ONLY CHANGES TO THE RULE ARE THE FILING DATE, EFFECTIVE DATE AND AN EXTENSION OF THE SUNSET DATE? No

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 6/27/2023

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 7/27/2023

COMMENTS RECEIVED: Yes

(IF YES, PLEASE UPLOAD IN THE COMMENTS RECEIVED FIELD COMMENTS RECEIVED AND RESPONSES TO COMMENTS)

PUBLIC HEARING: Yes

(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?

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

Requirement of notifications for temporary, emergency and permanent closures

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

Requirement of notifications for temporary, emergency and permanent closures

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

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

0

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

0

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

0

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2023 Increase/Decrease (use "-")	2024 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

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

0

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

Yes

Krista Capehart -- 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.

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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 -- ~~May 2, 2023~~
- 1.4. Effective date -- ~~May 2, 2023~~
- 1.5. Sunset Date -- This rule shall terminate and have no further force or effect on August 1, 2034.

§15-15-2. Registration.

2.1. A pharmacy shall obtain a registration from the Board and comply fully with W. Va. Code § 30-5-22 before it may lawfully conduct a pharmacy.

2.2. A pharmacy shall obtain a registration biennially. 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 completed on a form prescribed and furnished by the Board.

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 applicable current references readily available according to practice setting as required by 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 compounded sterile preparations shall also apply for a compounding permit as required by 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 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, rules and regulations.

3.3. A registration shall be posted in a visibly conspicuous place.

§15-15-4. Renewal of registration.

4.1. The biennial renewal of a registration takes place on the first day of July of each year. The fee for the biennial renewal is \$150.00. 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 \$150.00 in addition to the application fee of \$150.00, for a total amount of \$300.00.

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 \$300.00 for the registration, and \$300.00 for the re-inspection, for a total amount of \$600.00.

§15-15-5. Surrender of registration.

5.1. When a pharmacist-in-charge changes at a pharmacy, both the pharmacist-in-charge and pharmacy must notify the Board in writing within fourteen (14) days. The original permit should be copied and the change in pharmacist-in-charge written on the original and copy of the permit. The copy of the modified permit shall be posted in the pharmacy. The original modified permit should be surrendered to the Board along with a ten-dollar (\$10.00) fee for the new registration reflecting the new pharmacist-in-charge. Upon receipt of the notification, the Board shall provide for the new registration to the pharmacy. An Interim pharmacist-in-charge may be designated for a period not to exceed sixty (60) days. If an interim pharmacist-in-charge is designated who is not the permanent pharmacist-in-charge, the fee shall not be charged, and a new permit shall not be issued until a permanent pharmacist-in-charge is designated.

5.2. 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.

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

§15-15-6. Security.

6.1. A board approved operating plan shall be implemented if a pharmacy is to be operated for a period less than regular business hours of the entire store or institution.

6.2. 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:

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

6.2.2. 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 readily retrievable to the Board; and

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

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

6.3.1. Only licensed pharmacists may possess any keys to the prescription area;

6.3.2. 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 and shall ensure that:

6.3.2.a. drugs are properly labels;

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

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

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

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

6.3.2.f. written policies and procedures are established to implement the patient care provisions of this subdivision.

6.3.3. 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";

6.4. 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;

6.5. 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;

6.6. Dispensing does not occur until the drug is actually picked up by or delivered to the patient or patient's representative. 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

6.7. 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.

§15-15-7. Professional Work Environment.

7.1 A pharmacist, pharmacy intern, and pharmacy technician who works eight continuous hours or longer per day shall take, at a minimum, one thirty-minute uninterrupted meal break during that work period. If such a pharmacist, pharmacy intern, or pharmacy technician is required to work twelve continuous hours per twenty-four hours, at a minimum, the individual qualifies for an additional twenty-minute break. A pharmacist, pharmacy intern, or pharmacy technician, who is entitled to take such breaks shall not be required to work more than five continuous hours, excluding a twenty-minute break, before being given the opportunity to take a thirty-minute uninterrupted meal break.

7.2 A pharmacy shall not require a pharmacist, pharmacy intern, or pharmacy technician to work longer than twelve continuous hours per twenty-four-hour period, inclusive of the required breaks under 7.1.

7.3 A pharmacy shall keep and maintain a complete and accurate record showing its pharmacists' daily break periods.

7.4 In the case of an emergency, as deemed by the professional judgement of the pharmacist, a pharmacist, pharmacy intern, or pharmacy technician may work longer than twelve continuous hours, work without taking meal breaks, or have a break interrupted in order to minimize immediate health risks for patients. The pharmacist must document and date the amount of time worked beyond the twelve hours limit or breaks missed along with the reason and make it available to the Board.

7.5 The pharmacist-in-charge or designee shall determine the work schedule for pharmacy technicians based upon prior dispensing records. The pharmacist shall ensure adequate staffing levels based on prior dispensing records and patient care tasks. The pharmacist-in-charge shall have final approval of the work schedule. Any decision overriding such control of the PIC may be grounds for disciplinary action against the pharmacy permit.

7.6 The pharmacist on duty or the pharmacy registrant shall notify the pharmacist-in-charge via telephone, e-mail, or text message whenever a prescription error, loss of drugs, or a violation of any statute or rule occurs and the pharmacist-in-charge is not present.

7.7 A pharmacy shall not use advertisements or make solicitations that may jeopardize the health, safety, or welfare of patients, including, but not limited to, the use of advertisements or solicitations that:

7.7.1 Are false, fraudulent, deceptive, or misleading;

7.7.2 Include any claim regarding a professional service or product or the cost or price thereof that cannot be substantiated by the licensee.

7.8 A pharmacy shall not require a pharmacist to participate in the use or distribution of advertisements.

7.9. A pharmacy shall provide a working environment for all pharmacy personnel that protects the health, safety, and welfare of a patient, which includes, but is not limited to:

7.9.1 employing sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist's ability to practice with competency and safety or creates an environment that jeopardizes patient care as determined by the pharmacist-in-charge or pharmacists based on prior dispensing records and current patient care responsibilities;

7.9.2 Providing appropriate opportunities for uninterrupted rest periods and meal breaks;

7.9.3 Providing adequate time for a pharmacist to complete professional duties and responsibilities, including but not limited to:

7.9.3.a. drug utilization review;

7.9.3.b. immunization;

7.9.3.c. counseling;

7.9.3.d. verification of the accuracy of a prescription;

7.9.3.e. all other duties and responsibilities of a pharmacist as listed in the rules of the Board.

§15-15-8. Notification.

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

8.2. An employer who employs a licensed pharmacist shall notify the Board within fourteen (14) days, in writing, of any discharge or termination of the licensed pharmacist or change of the status of the pharmacist-in-charge.

8.3. A person who employs a licensed pharmacist shall, within three business days from the time of discovery, notify the Board, in writing, of any violations of board rules or laws by the licensed pharmacist.

§15-15-9. Whistleblower protection.

9.1 A permit or license holder of the Board who is found to be in violation of 11 (c) CFR 1977.3 or §6C-1 known as the "Whistle-blower law" may be subject to disciplinary action by the Board.

9.2 Nothing in this Section shall be deemed to diminish the rights, privileges, or remedies of an employee of a pharmacy under any other federal or State law, rule, or regulation or under any employment contract.

§15-15-10 Temporary, Permanent, or Emergency Closure of a Pharmacy.

10.1. For a temporary closure of a pharmacy, the pharmacy shall:

10.1.1. Post notification of closure on each pharmacy entrance as soon as the need to deviate

from the posted hours is known by the pharmacy, but no later than 2 hours after the temporary closure begins. The posting must include:

10.1.1.a. Estimated period of time the pharmacy will be closed; and

10.1.1.b. Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

10.1.2. Post notification of closure on each telephone greeting and pharmacy operated internet (e.g. website, social media, mobile applications) as soon as possible. The posting must include:

10.1.2.a. Estimated period of time the pharmacy will be closed; and

10.1.2.b. Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

10.1.3. If the pharmacy is temporarily closed greater than two consecutive business days or has planned closures greater than two days in a 7-day period deviating from the regular business hours, notify the board office as soon as possible but no later than 72 hours after the temporary closure begins with the date and time the closure began, anticipated date and time of re-opening, and the reason for the temporary closure.

10.2. For a permanent closure of a pharmacy, the pharmacy shall:

10.2.1. Prior to closing, the pharmacy must comply with the following:

10.2.1.a. Provide notification to each patient who has filled a prescription within the previous 12 months. This notification must be made a minimum of 14-calendar days prior to closing and must include:

10.2.1.a.1. The last day the pharmacy will be open;

10.2.1.a.2. Name, address and telephone number of the pharmacy that will take possession of the pharmacy records or the person who will serve as the custodian of records;

10.2.1.a.3. Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and

10.2.1.a.4. The last day a transfer may be initiated.

10.1.2.b. The notification must be made via:

10.1.2.b.1. Distribution by direct mail, electronic mail, phone, text, or written notice with each prescription dispensed; and

10.1.2.b.2. Public notice in a newspaper, online or print, of general circulation, if available, in the area served by the pharmacy; and

10.1.2.b.3. Posting a closing notice at each pharmacy entrance, on each telephone greeting, and pharmacy-operated internet (e.g. website, social media, mobile applications).

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10.1.2.e. Provide any new patients filling prescriptions during the 14-calendar day period prior to the pharmacy closing with written notification that includes:

10.1.2.c.1. The last day the pharmacy will be open;

10.1.2.c.2. Name, address and telephone number of the pharmacy to which pharmacy records will be transferred or the person who will serve as the custodian of pharmacy records;

10.1.2.c.3. Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and

10.1.2.c.4. The last day a transfer may be initiated.

10.2.1.d. Notify DEA of any controlled substances being transferred to another registrant as specified in 21 CFR 1301.52.

10.2.2. On the date of closing or up to 24 hours after the permanent closure begins, the pharmacist-in-charge must comply with the following:

10.2.2.a. Complete and document an inventory of all controlled substances.

10.2.2.b. If the pharmacy dispenses prescriptions:

10.2.2.b.1. Transfer the prescription drug order files, including refill information, and patient medication records to a West Virginia licensed pharmacy who will serve as the custodian of records;

10.2.2.b.2. Update the pharmacy operating status with each electronic prescribing vendor; and

10.2.2.b.3. Remove all signs and symbols indicating the presence of the pharmacy including pharmacy-operated internet (e.g. website, social media, mobile applications).

10.2.2.c. Notify the Board of the closing of the pharmacy.

10.2.3. After closing, Within 30 calendar days after the closing of the pharmacy, the pharmacist-in-charge must:

10.2.3.a. Complete and document an inventory of all non-controlled drugs and devices.

10.2.3.b. Remove all prescription and non-prescription drugs, devices, and related supplies from the pharmacy by one or a combination of the following methods:

10.2.3.b.1. Return to manufacturer or supplier (credit or disposal);

10.2.3.b.2. Transfer to a licensed healthcare professional or outlet who is legally authorized to possess drugs; or

10.2.3.b.3. Destroy and document the destruction by two Board licensees. For controlled substances, the registrant must comply with 21 CFR 1304.21, 21 CFR 1304.22, 21 CFR 1317.05, 21 CFR

1317.90 and 21 CFR 1317.95.

10.2.3.c. Provide the board a written notice of the closing on a Board prescribed form which includes the following information:

10.2.3.c.1. Date of closing to the public and discontinuance of the business;

10.2.3.c.2. Date and time the inventory of all prescription drugs and devices was conducted;

10.2.3.c.3. Name, address, phone number and applicable registration number where all legend and controlled substances possessed by the pharmacy were transferred or disposed;

10.2.3.c.4. If drugs were destroyed, name and license numbers of individuals that who witnessed the destruction;

10.2.3.c.5. If the pharmacy is registered to possess controlled substances, confirmation that the pharmacy complied with all applicable federal requirements in 21 CFR 1301.52 for discontinuing operation as a pharmacy that dispenses controlled substances.

10.2.3.c.6. The name, address and phone number of the pharmacy that took possession of the pharmacy records or the licensed pharmacist who is serve as the custodian of pharmacy records which must be maintained according to W.Va. CSR §15-4 et seq.;

10.2.3.c.7. Confirmation all pharmacy labels and blank prescriptions were destroyed;

10.2.3.c.8. Confirmation all signs and symbols indicating the presence of the pharmacy including pharmacy-operated internet (e.g. website, social media, mobile applications) have been removed; and

10.2.3.c.9. Confirmation that each registration certificate issued to the pharmacy by the Board has been mailed to the board office.

10.2.3.d. Once the pharmacy has notified the Board that the pharmacy is permanently closed, the license may not be renewed.

10.2.3.e. Unless a registration has expired, the registration will remain active until the board has notified the registrant that the notice of permanent closure has been received and the registration has been lapsed.

10.2.3.f. The pharmacist-in-charge may be permitted, by written permission from the Board, an extension for compliance with Section 10.2.3 if the requestor shows good cause for the extension.

10.3. Emergency closing. If a pharmacy is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, inclement weather, or other emergency circumstances and the pharmacist-in-charge cannot provide notification as required in subsection 10.1, the pharmacist-in-charge must comply with the provisions of subsection 10.1 as far in advance or as soon after the closing as allowed by the circumstances.

10.4. Non-resident pharmacies are exempt from subsections 10.1, 10.2, and 10.3 and must follow laws and rules in the pharmacy's state of residence pertaining to temporary, permanent and emergency

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closures. The non-resident pharmacy must provide the Board a written notice of the closing within 30 calendar days on a form prescribed by the board which includes the following information:

10.4.1. Date of closing to the public and discontinuance of the business;

10.4.2. If the pharmacy dispenses prescriptions, the name, address and phone number of the pharmacy or licensed pharmacist who will serve as the custodian of records for West Virginia patients to which the prescriptions, including refill information, and patient medication records were transferred; and

10.4.3. Confirmation that each registration certificate issued to the pharmacy by the Board has been mailed to the board office.

10.5. The Board may conduct an inspection to verify all requirements in this subsection.