



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: Pharmacy

RULE TYPE: Legislative

TITLE-SERIES: 15-15

RULE NAME: REGULATIONS GOVERNING
PHARMACY PERMITS

CITE AUTHORITY: §§ 30-5-7

The above proposed Legislative rules, following review by the Legislative Rule Making Review Committee, is hereby modified as a result of review and comment by the Legislative Rule Making Review Committee. The attached modifications are filed with the Secretary of State.

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 3, 2024.~~

1.4. Effective date -- ~~May 3, 2024.~~

1.5. Sunset Date -- This rule shall terminate and have no further force or effect on ~~August 1, 2034~~
August 1, 2035.

§15-15-2. Definitions.

2.1. "Board" means the West Virginia Board of Pharmacy.

2.2. "Common carrier" means any person who undertakes, whether directly or by any other arrangement, to transport property including prescription drugs for compensation.

2.3. "Direct-to-patient system" or "DTP system" means any delivery system through which a pharmacy dispenses drugs, devices, or medical equipment to a patient through any means other than:

2.3.1. In-person dispensing to a patient by pharmacy personnel inside a pharmacy, or

2.3.2. In-person dispensing by delivery to a patient's residence or to a health care provider treating that patient, or

2.3.3. Shipping through common carrier to a patient or to a health care provider treating that patient.

2.3.4. Except as provided in this rule or in the exceptions in subdivisions 1-3 of this definition, no person holding any license or permit from the Board shall participate in any arrangement whereby prescriptions may be left at, picked up from, accepted by, or delivered to any other place. The only DTP system allowed are "lockers."

2.4. "Home pharmacy" means the pharmacy responsible for dispensing drugs, devices or medical equipment through a DTP system.

2.5. "Locker" means a secure container in which pharmacy personnel place labeled patient-specific drugs, devices, or medical equipment to be picked up by the patient.

2.6. "Pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacist care.

2.7. "Pharmacist Care" means the provision by a pharmacist of patient care activities, with or without the dispensing of drugs or devices, intended to achieve outcomes related to the cure or prevention of a disease, elimination, or reduction of a patient's symptoms, or arresting or slowing of a disease process and as provided for in West Virginia Code § 30-5-10.

2.8. "Pharmacist-in-charge" means a pharmacist currently licensed in this state who:

2.8.1. Accepts responsibility for the operation of a pharmacy in conformance with all state and federal laws and rules pertinent to the practice of pharmacist care and the distribution of drugs;

2.8.2. Has the responsibility for the practice of pharmacist care, as defined in this rule, at the pharmacy for which he or she is pharmacist-in-charge. The pharmacy permit holder has responsibility for all other functions, administrative and operational, of the pharmacy. The pharmacist-in-charge may advise the pharmacy permit holder in writing of administrative and operational matters. The pharmacist-in-charge is not legally responsible if the permit holder does not follow the written advice;

2.8.3. Work requirements as required in W.Va. §15 CSR 1.2.42.c-d.

~~§15-15-2~~ 15-15-3. Registration.

~~2-23.1.~~ 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.

~~2-23.2.~~ A pharmacy shall obtain a registration ~~biennially~~ annually. 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.

~~2-23.2.1.~~ The application for a new registration shall be completed on a form prescribed and furnished by the Board.

~~2-23.2.2.~~ Each pharmacy shall make a separate application and a separate registration shall be issued for each pharmacy.

~~2-23.2.3.~~ A pharmacy shall have applicable current references readily available according to practice setting as required by this rule.

~~2-23.2.4.~~ An initial application for a pharmacy registration shall be accompanied by a fee of \$150.00.

~~2-23.2.5.~~ A pharmacy compounding compounded sterile preparations shall also apply for a compounding permit as required by this rule.

~~§15-15-3~~ 15-15-4. Issuance of Permit.

~~3-14.1.~~ The Board shall issue a registration to conduct a pharmacy to the applicant after a satisfactory inspection of the facility.

~~3-24.2.~~ 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.

~~3-34.3.~~ A registration shall be posted in a visibly conspicuous place.

~~§15-15-4~~ 15-15-5. Renewal of registration.

~~4-15.1.~~ 4-15.1. The ~~biennial~~ annual renewal of a registration takes place on the first day of July of each year. The fee for the ~~biennial~~ annual renewal is ~~\$150.00~~ \$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 ~~\$150.00~~ 75.00 in addition to the application fee of ~~\$150.00~~ 75.00, for a total amount of ~~\$300.00~~ 150.00.

~~4-25.2.~~ 4-25.2. If a pharmacy does not make application for renewal by the first day of August ~~biennially~~ annually, 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~~ 150.00 for the registration, and ~~\$300.00~~ 150.00 for the re-inspection, for a total amount of ~~\$600~~ 300.00.

~~§15-15-5~~ 15-15-6. Surrender of registration.

~~5-16.1.~~ 5-16.1. 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.

~~5-26.2.~~ 5-26.2. 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.

~~5-36.3.~~ 5-36.3. When a pharmacy changes ownership the registration expires, and a new registration shall be obtained from the Board.

~~§15-15-6~~ 15-15-7. Security.

~~6-17.1.~~ 6-17.1. 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.

~~6-27.2.~~ 6-27.2. 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:

~~6-27.2.1.~~ 6-27.2.1. The device shall be maintained in functioning order and shall have an auxiliary source of power;

~~6-27.2.2.~~ 6-27.2.2. 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

~~6.27.2.3.~~ This subsection does not apply to pharmacies which are open and staffed by pharmacists ~~twenty-four (24)~~ hours a day;

~~6.3.7.3.~~ The door keys and alarm activation and de-activation codes to the prescription areas are subject to the following:

~~6.3.1.7.3.1.~~ Only licensed pharmacists may possess any keys to the prescription area;

~~6.3.2.7.3.2.~~ 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:

~~6.3.27.3.2.a.~~ ~~4~~ Drugs are properly labels;

~~6.3.27.3.2.b.~~ ~~o~~ Only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements;

~~6.3.2.7.3.2c.~~ ~~w~~ Whenver access to the cabinet occurs, written practitioner's orders and proof-of-use are provided;

~~6.3.27.3.2.d.~~ ~~a~~ All drugs in the cabinet are inventoried no less than once per week;

~~6.3.27.3.2.e.~~ ~~a~~ A complete audit of all activity concerning the cabinet is conducted no less than once per month; and

~~6.3.27.3.2.f.~~ ~~w~~ Written policies and procedures are established to implement the patient care provisions of this subdivision.

~~6.3.37.3.3.~~ 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";

~~6.4.7.4.~~ 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;

~~6.57.5.~~ Except as provided in Title 15, Series 14, for central prescription filling, and this rule for direct-to-patient delivery systems, 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;

~~6.67.6.~~ 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, direct-to-patient delivery systems operated in accordance with this rule, or to transfers of prescription drugs by a retail pharmacy to alleviate a temporary shortage; and

~~6.7.7.~~ 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.

~~§15-15-715-15-8.~~ **Professional Work Environment.**

~~7.18.1.~~ A pharmacist, pharmacy intern, and pharmacy technician who works eight continuous hours or longer per day shall take, at a minimum, one ~~30~~^{thirty}-minute uninterrupted meal break during that work period. If such a pharmacist, pharmacy intern, or pharmacy technician is required to work ~~twelve~~ 12 continuous hours per ~~twenty-four~~ 24 hours, at a minimum, the individual qualifies for an additional ~~twenty~~ 20-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 ~~20~~^{thirty}-minute break, before being given the opportunity to take a ~~thirty~~³⁰-minute uninterrupted meal break.

~~7.28.2.~~ A pharmacy shall not require a pharmacist, pharmacy intern, or pharmacy technician to work longer than ~~twelve~~ 12 continuous hours per ~~twenty-four~~ 24-hour period, inclusive of the required breaks under 7.1.

~~7.38.3.~~ A pharmacy shall keep and maintain a complete and accurate record showing its pharmacists' daily break periods.

~~7.48.4.~~ 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~~ 12 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~~ 12 hours limit or breaks missed along with the reason and make it available to the Board.

~~7.58.5.~~ 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.

~~7.68.6.~~ 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.

~~7.78.7.~~ 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:

~~7.78.7.1.~~ Are false, fraudulent, deceptive, or misleading;

~~7.78.7.2.~~ Include any claim regarding a professional service or product or the cost or price thereof that cannot be substantiated by the licensee.

~~7.88.8.~~ A pharmacy shall not require a pharmacist to participate in the use or distribution of advertisements.

7.98.9. 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:

7.98.9.1. ~~e~~ 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;

7.98.9.2. Providing appropriate opportunities for uninterrupted rest periods and meal breaks;

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

7.98.9.3.a. ~~d~~ Drug utilization review;

7.98.9.3.b. ~~f~~ Immunization;

7.9-8.9.3.c. ~~e~~ Counseling;

7.98.9.3.d. ~~v~~ Verification of the accuracy of a prescription;

7.98.9.3.e. ~~a~~ All other duties and responsibilities of a pharmacist as listed in the rules of the Board.

~~§15-15-8~~15-15-9. Notification.

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

8.29.2. 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.

8.39.3. 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~~15-15-10. Whistleblower protection.

9.110.1. 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.

9.210.2. 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~~15-15-11. Temporary, Permanent, or Emergency Closure of a Pharmacy.

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

10.111.1.1. 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~~ two hours after the temporary closure begins. The posting must include:

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~~40:411.1.1.a.~~ Estimated period of time the pharmacy will be closed; and

~~40:411.1.1.b.~~ Options for prescription pick-up (e.g., another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

~~40:411.1.2.~~ 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:

~~40:411.1.2.a.~~ Estimated period of time the pharmacy will be closed; and

~~40:411.1.2.b.~~ Options for prescription pick-up (e.g., another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

~~40:411.1.3.~~ If the pharmacy is temporarily closed greater than two consecutive business days or has planned closures greater than two days in a ~~seven~~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.

~~40:211.2.~~ For a permanent closure of a pharmacy, the pharmacy shall:

~~40:211.2.1.~~ Prior to closing, the pharmacy must comply with the following:

~~40:211.2.1.a.~~ Provide notification of the closing to each patient who has filled a prescription at that pharmacy within the previous 12 months. This notification must be made a minimum of 14 calendar days prior to closing and must include:

~~40:211.2.1.a.1.~~ The last day the pharmacy will be open;

~~40:211.2.1.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;

~~40:211.2.1.a.3.~~ Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and

~~40:211.2.1.a.4.~~ The last day a transfer may be initiated.

~~40:211.2.1.b.~~ The notification must be made via:

~~40:211.2.1.b.1.~~ Distribution by direct mail, electronic mail, phone, text, or written notice with each prescription dispensed; and

~~40:211.2.1.b.2.~~ Public notice in a newspaper, online, or print, of general circulation, if available, in the area served by the pharmacy; and

~~40:211.2.1.b.3.~~ Posting a closing notice on each pharmacy entrance, on each telephone greeting, and pharmacy-operated internet (e.g., website, social media, mobile applications).

~~40:211.2.1.c.~~ Provide any new patients filling prescriptions during the 14-calendar day period prior to the pharmacy closing with written notification that includes:

~~40:211.2.1.c.1.~~ The last day the pharmacy will be open;

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~~40:211.2.1.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;

~~40:211.2.1.c.3.~~ Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and

~~40:211.2.1.c.4.~~ The last day a transfer may be initiated.

~~40:211.2.1.d.~~ Notify DEA of any controlled substances, as defined by W. Va. Code 60A-2.201 *et seq.*, being transferred to another registrant as specified in 21 CFR 1301.52.

~~40:211.2.2.~~ On the date of closing or up to 24 hours after the permanent closure begins, the pharmacist-in-charge must comply with the following:

~~40:211.2.2.a.~~ Complete and document an inventory of all controlled substances.

~~40:211.2.2.b.~~ If the pharmacy dispenses prescriptions:

~~40:211.2.2.b.1.~~ Transfer the prescription drug order files, including refill information, and patient medication records to a licensed pharmacy pursuant to W.Va. 15 CSR 15-2 *et seq.* who will serve as the custodian of records;

~~40:211.2.2.b.2.~~ Update the pharmacy operating status with each electronic prescribing vendor; and

~~40:211.2.2.b.3.~~ Remove all signs and symbols indicating the presence of the pharmacy including pharmacy-operated internet (e.g., website, social media, mobile applications).

~~40:211.2.2.c.~~ Notify the Board of the closing of the pharmacy.

~~40:211.2.3.~~ After closing. Within 30 calendar days after the closing of the pharmacy, the pharmacist-in-charge must:

~~40:211.2.3.a.~~ Complete and document an inventory of all non-controlled drugs and devices.

~~40:211.2.3.b.~~ Remove all prescription and non-prescription drugs, devices, and related supplies from the pharmacy by one or a combination of the following methods:

~~40:211.2.3.b.1.~~ Return to manufacturer or supplier (credit or disposal);

~~40:211.2.3.b.2.~~ Transfer to a licensed healthcare professional or outlet who is legally authorized to possess drugs; or

~~40:211.2.3.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.

~~40:211.2.3.c.~~ Provide the board a written notice of the closing on a Board prescribed form available at www.wvbop.com which includes the following information:

~~40:211.2.3.c.1.~~ Date of closing to the public and discontinuance of the business;

~~40:211.2.3.c.2.~~ Date and time the inventory of all prescription drugs and devices was

conducted;

~~40-211.2.3.c.3.~~ Name, address, phone number, and applicable registration number where all legend and controlled substances possessed by the pharmacy were transferred or disposed;

~~40-211.2.3.c.4.~~ If drugs were destroyed, name and license numbers of individuals that who witnessed the destruction;

~~40-211.2.3.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.

~~40-211.2.3.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. 15 CSR 4.1 *et seq.*;

~~40-211.2.3.c.7.~~ Confirmation all pharmacy labels and blank prescriptions were destroyed;

~~40-211.2.3.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

~~40-211.2.3.c.9.~~ Confirmation that each registration certificate issued to the pharmacy by the Board has been mailed to the board office.

~~40-211.2.3.d.~~ Once the pharmacy has notified the Board that the pharmacy is permanently closed, the license may not be renewed.

~~40-211.2.3.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.

~~40-211.2.3.f.~~ The pharmacist-in-charge may be permitted, by written permission from the Board, an extension for compliance with Section ~~40~~11.2.3 if the requestor shows good cause for the extension.

~~40-311.3.~~ 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 ~~40-4~~ 11.1, the pharmacist-in-charge must comply with the provisions of subsection ~~40-4~~ 11.1 as far in advance or as soon after the closing as allowed by the circumstances.

~~40-411.4.~~ Non-resident pharmacies, as defined by W.Va. 15 CSR 6-2.2, are exempt from subsections ~~40~~11.1, ~~40~~11.2, and ~~40~~11.3 and must follow laws and rules in the pharmacy's state of residence pertaining to temporary, permanent and emergency 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 available at www.wvbop.com which includes the following information:

~~40-411.4.1.~~ Date of closing to the public and discontinuance of the business;

~~40-411.4.2.~~ 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

~~40-411.4.3.~~ Confirmation that each registration certificate issued to the pharmacy by the Board has been mailed to the board office.

~~40-511.5.~~ The Board may conduct an inspection of the pharmacy and records to verify all requirements in this subsection.

§15-15-12. Direct-to Patient Delivery Systems.

12.1. Any DTP system located within West Virginia (lockers) shall meet the following requirements:

12.1.1. Before any drugs, devices, or medical equipment may be picked up from a DTP system, the home pharmacy shall have been issued a pharmacy permit by the Board.

12.1.2. The home pharmacy shall notify the Board via the form on the website at www.wvbop.com prior to beginning to use any DTP system. The home pharmacy shall notify the Board within 10 days after discontinuing patient use of any DTP system.

12.1.3. Any DTP system shall be located at the physical address of the permitted home pharmacy.

12.1.4. The home pharmacy shall prohibit access to the DTP system and its contents by unauthorized personnel and maintain confidentiality of patient information. The DTP system shall be under the continuous supervision of a pharmacist employed by the home pharmacy or under contract with a licensed pharmacy, which may be satisfied by real-time remote supervision of the pharmacy through video and audio connections.

12.1.5. The home pharmacy shall ensure that there is continuous, recorded video surveillance of the DTP system and any persons using or accessing the DTP system. It shall maintain any recordings for a minimum of 90 days.

12.1.6. The home pharmacy shall develop, maintain, and follow a manual of policies and procedures that includes policies and procedures for:

12.1.6.a. Maintaining the security of the DTP system and the drugs, devices, and medical equipment within the DTP system.

12.1.6.b. Determining and applying criteria regarding which drugs, devices, and medical equipment are appropriate for placement in the DTP system and which patients are eligible to use the DTP system.

12.1.6.c. Maintaining any drugs, devices, and medical equipment at temperatures, humidities and other environmental conditions to ensure that they do not become adulterated and to ensure that they are transported and stored in accordance with manufacturer's specifications, if any, for those items.

12.1.6.d. Removing outdated drugs, devices, and medical equipment from the DTP on a regular basis so that patients do not receive drugs, devices, and medical equipment with a beyond use date during the period when the patient is to use the item.

12.1.6.e. Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filling procedures for the DTP system.

12.1.6.f. Orienting participating patients on use of the DTP system; notifying patients when expected drugs, devices, or medical equipment are not available in the DTP system or when the DTP system is not functioning and notifying them of alternate methods for having those prescriptions filled; and ensuring that patient use of the DTP system does not interfere with the delivery of drugs, devices, and medical equipment to patients.

12.1.6.g. Self-inspection of the DTP system for required compliance with West Virginia Code and the Rules of this Board and all Federal laws and regulations.

12.1.7. The written manual of policies and procedures shall be reviewed and updated annually by the pharmacist-in-charge of the home pharmacy.

12.1.8. The home pharmacy shall comply with any federal and state controlled substance laws and rules before any controlled substances are picked up from any DTP systems. The home pharmacy shall comply with WV Code §60A-3-308.d.2.B in delivering any drugs covered by that statute from a DTP system, and shall visually confirm that the person seeking the dispensation is the same as the person on the government issued photo identification.

12.1.9. Only pharmacy personnel who are licensed with this Board as pharmacists or registered with this Board as pharmacy technicians, pharmacy technician trainee, or pharmacy interns may stock prepared drugs, devices, and medical equipment in, or remove drugs, devices, and medical equipment from the inventory of a DTP system. The home pharmacy shall maintain records of any access to the DTP system by pharmacy personnel stocking or otherwise accessing the DTP system.

12.1.10. Before a home pharmacy allows pick up of drugs, devices and medical equipment to a patient through a DTP system, the home pharmacy shall secure the written consent of the patient to use the DTP system.

12.1.11. The dispensing pharmacist on any drugs, devices, or medical equipment picked up from a DTP system in West Virginia shall be licensed with this Board.

12.1.12. The counseling pharmacist on any drugs, devices, or medical equipment picked up from a DTP system in West Virginia shall be licensed with this Board or be employed at a non-resident pharmacy licensed with this Board.

12.1.13. Before a prescription is picked up from the DTP system, the dispensing pharmacist shall verify each prescription and shall conduct a drug utilization review and otherwise assure that the drug, device, or medical equipment may safely be picked up by the patient.

12.1.14. The labels of any drugs, devices, and medical equipment picked up from a DTP system shall be labeled for the individual patient and contain all information required by law.

12.1.15. The home pharmacy shall create and maintain records for any drugs, devices, and medical equipment picked up from a DTP system in compliance with State and federal law.

12.1.16. The DTP system shall have a means to identify each patient (or that patient's authorized agent) and release only that patient's prescription drugs, devices, or medical equipment to the patient (or the patient's authorized agent).

12.1.17. The DTP system shall convey the home pharmacy's offer to counsel a patient as required by W.Va. 15 CSR 1.15.13.6 and shall provide the ability for the patient to have an immediate real-time consultation with a pharmacist licensed by this Board and employed by the home pharmacy

who has access to all of the home pharmacy's information related to the patient. The communication link shall protect the confidentiality of the patient's information. The home pharmacy shall check the communication link at least daily and the DTP system shall be closed if the link malfunctions or if a licensed pharmacist is not available for counseling, unless a licensed pharmacist is physically present at the DTP system. A pharmacist who is responsible for counseling may not provide that service for more than three sites simultaneously. If the dispensing pharmacist has determined that the patient should receive counseling before the prescription is dispensed, the DTP system shall provide the ability for the pharmacist to force counseling before the DTP system allows pick up of the drug, device, or medical equipment.

12.1.18. The home pharmacy shall record and review any incident involving a complaint, delivery error, or omission regarding a DTP as part of the home pharmacy's quality assurance program.

12.1.19. Drugs, devices, or medical equipment that are not picked up by a patient may be returned to stock under the same conditions as if the item had been maintained in the pharmacy, as long as the requirements of this Rule for operating the DTP system have been followed.

12.2. This Rule does not alter the method by which patients or providers shall transmit prescriptions to the home pharmacy. Prescriptions may not be collected by the home pharmacy through the DTP system.