I. 15CSR 1: Licensure and Practice of Pharmacy

This rule governs the following:

- Requirements for becoming licensed as a pharmacist by the West Virginia Board of Pharmacy ("Board");
- Reciprocity requirements;
- Proceedings for disciplinary action;
- The handling of confidential information;
- Transfer of prescription drugs;
- Refilling prescription orders;
- Transferring prescription orders;
- Returning drugs and devices;
- Drug product selection and substitution;
- Pharmacy permits;
- Equipment, facilities and record systems;
- Licensure and control of nuclear pharmacies;
- Sanitary regulation of pharmacies;
- Rules of professional conduct duties and responsibilities of the pharmacist-in-charge;
- Manner of issuance of a prescription;
- Labeling;
- Pharmacist consultants;
- Specialized dispensing systems;
- Institutions and other places needing a controlled substance permit;
- Emergency dispensing by pharmacists; West Virginia Official Prescription Paper Program rules;
- Practice of telepharmacy; and
- Criminal history record check.

This rule was first promulgated in 1982. Over the years, the following amendments occurred.

1990: Amendments were made to the following: application; drug product selection regulations; and automated data processing system. This allowed the Board to set application fees and adopted "The Orange Book" published by the FDA.

1993: The rule was amended regarding patient counseling.

1998: The definition of "pharmacy" or "drug store" or "apothecary" was clarifi1ed.

1999: The Board adopted changes to better keep up with the evolving practice of pharmacy

2002: The rule was amended to provide for biennial licensing with a staggered implementation schedule and a fee structure as authorized by HB 3051 passed during the 2001 Legislative Session.

2009: The rule was amended to allow for electronic prescribing of legend drugs.

2011: The rule was amended to clarify prescribing procedures and implement West Virginia Official Prescription Paper Program.

2015: The rule was amended to eliminate old state errors and omissions examination for pharmacists and continue to use the NAPLEX examination and the WV version of the MPJE examinations administered by NABP. The amendment also allowed pharmacist interns to be able to show credit for all 1,500 required internship hours through their ACPE accredited school of pharmacy experiential education curriculum. The amendment further made the rules of professional responsibility applicable to all pharmacy personnel and the pharmacy itself where appropriate.

2016: The rule was amended to move the definitions of "refill" and "renewal" from Series 4 to Series 1 and moved some record keeping requirement details from Series 1 to Series 4. The amendment also adopts NABP model law allowing for waiver requests.

2017: The rule was amended to require national background checks. Also, the rule was amended to permit prescriptions to be delivered to the patient at the location designated by the patient.

2018: A new series was added to allow for central filling of prescriptions.

2019: Certain sections have been cut and moved from 15 CSR 1 to newly created 15 CSR 15 and 15 CSR 16.

Our intention is to eliminate business standards where appropriate and defer to national standards. The Board has recently hired a staff pharmacist to review all Board rules for opportunities to cut unnecessary rules and regulations. We intend to work with industry partners and stakeholders over the next two years. However, at this time, the Board feels this rule is adequate as written.

II. 15 CSR 2: Uniform Controlled Substances Act

This rule governs the following:

- Adoption of federal law;
- Controlled substance permits;
- Security requirements;
- Definitions;
- Labeling and packaging;
- Requirements for controlled substances;
- Records and reports of registrants;
- Prescriptions; and
- Miscellaneous.

This rule was first promulgated in 1982. Over the years, the following amendments occurred.

2001: The amendment repealed and replaced the series to remove antiquated language and bring the rule into compliance with federal regulations.

2011: The amendment modified electronic prescribing, limited early refills, and clarified other provisions.

2015: The amendment allowed registrants to operate as collection sites for controlled substance take-back.

2018: This amendment modified suspicious order reports.

Our intention is to eliminate business standards where appropriate and defer to national standards. The Board has recently hired a staff pharmacist to review all Board rules for opportunities to cut unnecessary rules and regulations. We intend to work with industry partners and stakeholders over the next two years. However, at this time, the Board feels this rule is adequate as written.

III. 15 CSR 3: Continuing Education for Licensure of Pharmacists

This rule governs the following:

- Continuing pharmacy education requirements;
- Methods of acquiring continuing pharmacy education;
- Program administration;
- Continuing pharmacy education committee;
- Responsibilities of providers;
- Responsibilities of pharmacists;
- Approval of providers;
- Approval of continuing pharmacy programs;
- Program evaluation; and
- Credits and records.

This rule was first promulgated in 1991. Since then, the following amendments have occurred.

2002: The amendment reflected the change to a biennial renewal of a license.

2012: The amendment modernized certain language and updated requirements to match national standards.

2014: The amendment required certain continuing pharmacy education credits for the dispensing of controlled substances designed to reduce and prevent drug diversion.

The Board feels that 15 CSR 3 should be continued without change because it meets the requirements of the law without being unduly burdensome.

IV. 15 CSR 4: Record Keeping and Automated Data Processing Systems

This rule governs the following:

- Use of automated data processing systems;
- Record of dispensing prescription drugs;
- Record of retrieval;
- Auxiliary recordkeeping system;

- Operating the ADP system; and
- Records of provision of pharmacist care outside of a licensed pharmacy.

This rule was first promulgated in 1992. The rule has been amended as follows.

2016: The amendment eliminated outdated provisions, moved one recordkeeping provision from Series 1 to Series 4, and provided for recordkeeping with regard to the practice of telepharmacy.

Our intention is to eliminate business standards where appropriate and defer to national standards. The Board has recently hired a staff pharmacist to review all Board rules for opportunities to cut unnecessary rules and regulations. We intend to work with industry partners and stakeholders over the next two years. However, at this time, the Board feels this rule is adequate as written.

V. 15 CSR 5: Licensure of Wholesale Drug Distributors, Third Party Logistics Providers, and Manufacturers.

The rule governs the following:

- Wholesale drug distributor and third-party logistics provider licensing and manufacturer permit requirements;
- Minimum required information for wholesale drug distributor or third-party logistics provider licensure, and manufacturer permits; applications and renewals;
- Minimum qualifications;
- Personnel;
- Violations and penalties;
- Minimum requirements for wholesale drug distributors for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug records;
- Minimum requirements for third party logistics providers and manufacturers for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug records; and
- The West Virginia Board of Pharmacy inspection powers and access to licensee and permittee records.

This rule was first promulgated in 1992. Since then, the following amendments have occurred.

2012: The amendment updated language as required by federal law and clarified requirements for licensing of distributors who maintain title, ownership, or control over their product which is brought into the State by another entity on their behalf.

2016: This amendment creates a new category for third-party logistics providers licensing pending the federal guidance to close the gap now created by the Drug Quality and Security Act ("DQSA").

Our intention is to eliminate business standards where appropriate and defer to national standards. The Board has recently hired a staff pharmacist to review all Board rules for opportunities to cut unnecessary rules and regulations. We intend to work with industry partners and stakeholders over the next two years. However, at this time, the Board feels this rule is adequate as written.

VI. 15 CSR 6: Mail-Order and Non-Resident Pharmacies

This rule governs the following:

- Registrations for mail-order pharmacies;
- Prescription record and reporting;
- Doing business in West Virginia;
- Resident agent; and
- Pharmacist-in-charge licensure requirement.

This rule was first promulgated in 1992. In 2017, the rule was amended to make some minor changes in terminology to reflect current language used in the industry, and clarify that the PIC of the non-resident registration may be the PIC of the non-resident pharmacy or any other pharmacist at that pharmacy who is willing to get licensed to practice pharmacist care in the State of West Virginia and be the PIC of the West Virginia mail-order registration.

Our intention is to eliminate business standards where appropriate and defer to national standards. The Board has recently hired a staff pharmacist to review all Board rules for opportunities to cut unnecessary rules and regulations. We intend to work with industry partners and stakeholders over the next two years. However, at this time, the Board feels this rule is adequate as written.

VII. 15 CSR 7: Registration of Pharmacy Technicians

This rule governs the following:

- Qualifications for registration as a pharmacy technician; 20 hour training program;
- Learning institution or training center provided and on-the-job pharmacy-provided competency-based training program;
- Duties and restrictions of a pharmacy technician;
- Identification of technicians and technician trainees;
- Certificate of registration; and
- Transfer of registration.

This rule was first promulgated in 1997. Since then, the following amendments have occurred.

2015: The rule was amended to modify the requirements and qualifications for becoming a pharmacy technician.

2017: The rule was amended to allow high school students enrolled in a high school pharmacy technician training program to be eligible for registration as a pharmacy technician trainee.

2018: The rule was amended to add the term “pharmacy technician trainee” wherever pertinent.

2019: The rule was amended to exempt cashiers from the licensure requirements and to allow for reciprocity of pharmacy technicians.

Our intention is to eliminate business standards where appropriate and defer to national standards. The Board has recently hired a staff pharmacist to review all Board rules for opportunities to cut unnecessary rules and regulations. We intend to work with industry partners and stakeholders over the next two years. However, at this time, the Board feels this rule is adequate as written.

VIII. 15 CSR 8: Controlled Substances Monitoring Program

This rule governs the following:

- Prescription monitoring program;
- Information to be transmitted within 24 hours;
- Accuracy of information transmitted;
- Central repository;
- Designation;
- Powers and duties; and
- Confidentiality.

This rule was first promulgated in 1982. Since then, the following amendments have occurred.

1997: The rule was amended to establish the procedures and requirements of the Prescription Monitoring Program.

2003: The rule was amended to provide definitions of may terms used in the collection of data for the controlled substances monitoring program; established the reporting mechanism for the data and provides the procedure to seek waivers from reporting; delineates the information that is to be transmitted for each prescription and requires security prescription blanks to be used for all written controlled substance prescriptions; and provides for protection of confidential patient information and authorizes disclosure to specified representatives.

2011: The rule was amended to permit the Office of the Chief Medical Examiner to have access to the CSMP; permit certain individuals or entities having access to the CSMP to designate duly authorized agents to access it on their behalf; and requires all practitioners who prescribe or dispense Schedule II, III, or IV controlled substances to have online access to the CSMP in their places of practice.

2013: The rule was amended to make changes to the CSMP including new fields of information to be reported, requiring presentation of government-issued identification, and giving the Board authority to require reporting of the required information within 24-hours of dispensing of a controlled substance, rather than 7 days.

2014: The rule was amended to require dispensers to report dispensing information to the CSMP, including the full legal name, address, and birth date of anyone picking up a prescription on behalf of the actual patient.

2015: The rule was amended to make changes to the CSMP regarding when users can run certain patient profiles on intake of a potential new patient or a newborn, and on storage and access to reports in the practitioner's patient medical chart or file.

2017: The rule was amended to account for new requirements that opioid antagonist dispensing be reported to the CSMP.

2018: The rule was amended to include Gabapentin as a drug of concern to be reported to the CSMP.

Our intention is to eliminate business standards where appropriate and defer to national standards. The Board has recently hired a staff pharmacist to review all Board rules for opportunities to cut unnecessary rules and regulations. We intend to work with industry partners and stakeholders over the next two years. However, at this time, the Board feels this rule is adequate as written.

IX. 15 CSR 9: Complaint Procedures.

This rule governs complaint procedures.

This rule was first promulgated in 2001. In 2018, the rule was amended to pull disciplinary procedures from 15 CSR 1 to this series.

Our intention is to eliminate business standards where appropriate and defer to national standards. The Board has recently hired a staff pharmacist to review all Board rules for opportunities to cut unnecessary rules and regulations. We intend to work with industry partners and stakeholders over the next two years. However, at this time, the Board feels this rule is adequate as written.

X. 15 CSR 10: Pharmacist Recovery Networks

This rule governs the following:

- Pharmacist recovery network agreements;
- Due process;
- Receipt and use of information of suspected impairment;
- Intervention and referral;
- Monitoring treatment;
- Monitoring rehabilitation and performance;
- Monitoring post-treatment support;
- Reports of case of impairment to the Board;
- Periodic reporting of statistical information;
- Confidentiality; and
- Fees.

This rule was first promulgated in 2013. In 2018, the rule was amended to modernize the rule.

This rule was recently amended. The rule is up to date and should be continued as written.

XI. 15 CSR 11: Ephedrine and Pseudoephedrine Control

This rule governs the following:

- Pharmacy requirements;
- Pseudoephedrine monitoring program;
- Lawful possession of Schedule V pseudoephedrine products;
- Records and invoices;
- Registration to sell, distribute, or transfer Schedule V pseudoephedrine products; and
- Supplement list.

The rule was first promulgated in 2006. Since then, the rule has been amended as follows.

2007: The rule was amended to add two drugs to the supplemental list.

2013: The rule was amended to change the restrictions and requirements for sale and reporting to central database maintained by the Board.

Our intention is to eliminate business standards where appropriate and defer to national standards. The Board has recently hired a staff pharmacist to review all Board rules for opportunities to cut unnecessary rules and regulations. We intend to work with industry partners and stakeholders over the next two years. However, at this time, the Board feels this rule is adequate as written.

XII. 15 CSR 12: Immunizations Administered by Pharmacists

This rule governs the following:

- Qualifications;
- Registration;
- Immunizations;
- Record-keeping and reporting;
- Emergencies; and
- Immunization training programs.

This rule was first promulgated in 2009. Since then, the rule has been amended as follows.

2012: The rule was amended to expand the vaccines permitted to be administered by pharmacists.

2015: The rule was amended to allow pharmacist interns to administer immunizations under appropriate pharmacist supervision.

2018: The rule was amended to permit HPV vaccines to be given to someone over the age of 18 and allows for influenza and HPV vaccines to be administered to any person age eleven through eighteen with written informed parental consent and a prescription from a provider.

Our intention is to eliminate business standards where appropriate and defer to national standards. The Board has recently hired a staff pharmacist to review all Board rules for opportunities to cut unnecessary rules and regulations. We intend to work with industry partners and stakeholders over the next two years. However, at this time, the Board feels this rule is adequate as written.

XIII. 15 CSR 13: Charitable Clinic Pharmacies

This rule governs the following:

- Charitable clinic pharmacy permit required;
- Controlled substances restricted;
- Prescriptions to qualified patients;
- Prescription drug samples;
- Pharmacist-in-charge responsibilities;
- Limitations of charitable clinic pharmacies;

- Continuing education credits for volunteering in charitable clinic pharmacy; and
- Inspection and investigation of charitable clinic pharmacies.

This rule was fist promulgated in 2009 and has not been amended since then.

Our intention is to eliminate business standards where appropriate and defer to national standards. The Board has recently hired a staff pharmacist to review all Board rules for opportunities to cut unnecessary rules and regulations. We intend to work with industry partners and stakeholders over the next two years. However, at this time, the Board feels this rule is adequate as written.

XIV. 15 CSR 14: Centralized Prescription Processing

This rule governs the following:

- General requirements; and
- Remote order entry and remote order review.

This rule was promulgated in 2018 and has not been amended since then.

This rule was recently promulgated, and the Board feels the rule should be continued as written at this time.

XV. 15 CSR 15: Regulations Governing Pharmacy Permits

This rule governs the following:

- Registration;
- Issuance of Permit;
- Renewal of registration;
- Surrender of registration;
- Violations;
- Security; and
- Professional work environment.

This rule was pulled from 15 CSR 1 and is currently in progress.

Our intention is to eliminate business standards where appropriate and defer to national standards. The Board has recently hired a staff pharmacist to review all Board rules for opportunities to cut unnecessary rules and regulations. We intend to work with industry partners and stakeholders over the next two years. However, at this time, the Board feels this rule is adequate as written.

XVI. 15 CSR 16: Regulations Governing Pharmacists

This rule governs the following:

- Examination for licensure and registration and annual renewal requirements;
- Examinations;
- Certificate of licensure;
- License and registration renewal

- Reciprocity;
- Licensure of pharmacists from other states or countries; and
- Application.

This rule was pulled from 15 CSR 1 and is currently in progress.

Our intention is to eliminate business standards where appropriate and defer to national standards. The Board has recently hired a staff pharmacist to review all Board rules for opportunities to cut unnecessary rules and regulations. We intend to work with industry partners and stakeholders over the next two years. However, at this time, the Board feels this rule is adequate as written.

XVII. 15 CSR 17: Substitution of Biological Pharmaceuticals

This rule governs the following:

- Substitution requirements;
- Patient notification;
- Communication with prescriber;
- Records; and
- Dispensing responsibilities.

This rule was promulgated pursuant to the creation of WVC 30-5-12c and is currently in progress.

Our intention is to eliminate business standards where appropriate and defer to national standards. The Board has recently hired a staff pharmacist to review all Board rules for opportunities to cut unnecessary rules and regulations. We intend to work with industry partners and stakeholders over the next two years. However, at this time, the Board feels this rule is adequate as written.