WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION

Form #3

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OFFICE WEST VIRGINIA
SECRETARY OF STATE

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

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

CITE AUTHORITY: West Virginia Code Section 30-5-19

AMENDMENT TO AN EXISTING RULE: YES X NO ____

IF YES, SERIES NUMBER OF RULE BEING AMENDED: Series 1

TITLE OF RULE BEING AMENDED: Board of Pharmacy Rules Regarding Licensure and the Practice of Pharmacy

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: ____

TITLE OF RULE BEING PROPOSED: ____

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

David E. Potters
Authorized Signature

Phone (304) 558-0558
Fax (304) 558-0572

State of West Virginia
Board of Pharmacy

David E. Potters,
Executive Director &
General Counsel

Betty Jo Payne,
Asst. Exec. Director

Office
232 Capitol Street
Charleston, West Virginia 25301

APPROVAL OF FILING OF REGULATIONS

BE IT HEREBY KNOWN that the West Virginia Board of Pharmacy approves the filing of the following modified rules and responses to public comment with the Secretary of State and the Legislative Rulemaking and Review Committee:

(1) Series 1, "Board of Pharmacy Rule Regarding Licensure and the Practice of Pharmacy"; and

(2) Series 8, "Controlled Substances Monitoring", proposing changes to effectuate SB 365, 2010 Regular Session.

Signed this 26th day of July, 2010,

BY: _____
George Karos, President

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: 7/29/2010

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:(*Agency Name. Address & Phone No.*) West Virginia Board of Pharmacy
232 Capitol Street
Charleston, West Virginia 25301

(304) 558-0558

LEGISLATIVE RULE TITLE: Board of Pharmacy Rules Regarding Licensure and the Practice of Pharmacy

1. Authorizing statute(s) citation West Virginia Code Sections 30-5-19

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

Filed with Secretary of State on June 17, 2010, at 1:38 p.m.

b. What other notice, including advertising, did you give of the hearing?

N/A

c. Date of Public Hearing(s) ***or*** Public Comment Period ended:

Public Comment Period ended July 18, 2010, at 4:30 p.m.

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached X No comments received _____

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

Filed with Secretary of State on July 29, 2010.

f. **Name, title, address and <u>phone/fax/e-mail numbers</u>** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

David E. Potters
Executive Director & General Counsel
West Virginia Board of Pharmacy
232 Capitol Street
Charleston, West Virginia 25301
(304) 558-0558
(304) 558-0572 (fax)
david.e.potters@wv.gov

g. **<u>IF DIFFERENT</u> FROM ITEM 'f'**, please give **Name, title, address and phone number(s)** of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

N/A

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

b. Date of hearing or comment period:

_____

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

_____

d. Attach findings and determinations and reasons:

Attached _____

BRIEF SUMMARY OF AND STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE PROPOSED LEGISLATIVE RULE

Board of Pharmacy Rules Regarding Licensure and the Practice of Pharmacy

15 CSR 1

Summary and Statement of Circumstances: SB 81 passed during the Regular Session, 2010, and duly enacted into law, requires the creation of the West Virginia Official Prescription Program Act for use in writing prescriptions by practitioners. SB 81, as set forth in West Virginia Code Section §16-5W-4, directs the West Virginia Board of Pharmacy to promulgate rules to implement the provisions of Article 5W. The proposed rules originally set forth the requirements for the official prescription paper program, selection of a vendor, and requirements for tracking and use of the paper. However, while the Board accepted certain comments and would agree to make modifications to the proposed rules, and rejected certain other comments, based upon the further concerns raised by the West Virginia State Medical Association and National Association of Chain Drug Stores in their public comments, and based upon other issues apparent to the Board, it voted to withdraw the rules as they pertain to SB 81 at this time. The other changes to 15-1-21 are pertinent changes as a result of changes to Series 8 which are currently pending to implement SB 365, however, and the Board wishes to go forward with those changes. Therefore, it deleted the proposed changes to Sections 15-1-21.1.2, and 21.1.3, and deleted all of newly proposed Section 15-1-27, leaving only the changes in Sections 15-1-21.1 and 15-1-21.4 (now renumbered as 21.3), to which no public comments were received. Thus, the Board has stripped any changes related to SB 81, and desires to go forward with the minor modifications to the rules which remain.

For Further Information: Copies of the proposed rule may be obtained from the website of the West Virginia Secretary of State at www.wvsos.com, or interested parties may call the Administrative Law Division of the Office of the Secretary of State at (304) 558-6000.

Further information may be obtained by contacting the West Virginia Board of Pharmacy, David E. Potters, Executive Director and General Counsel, 232 Capitol Street, Charleston, West Virginia, 25301, telephone (304) 558-0558.

Note: This is a proposed change to an existing series, such that there are strike-throughs and underlining of the language changes in the proposed rule.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Board of Pharmacy Rules Regarding Licensure and the Practice of Pharmacy

Type of Rule: [X] Legislative [ ] Interpretive [ ] Procedural

Agency: West Virginia Board of Pharmacy

Address: 232 Capitol Street
Charleston, West Virginia 25301

Phone Number: (304) 558-0558 Email: david.e.potters@wv.gov

Fiscal Note Summary

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

The modifications made based upon public comments pared this down to minor modifications of existing rules which will have no fiscal impact. While the original filing of proposed rules contemplated promulgation of rules to implement a Statewide Official Prescription Paper program created by West Virginia Code Section16-5W-4, the Board has deleted any of those provisions to further study the issue, leaving only minor changes to existing provisions which have been in place for some time.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

FISCAL YEAR			
Effect of Proposal	Current Increase/Decrease (use "-")	Next Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0.00	0.00	0.00
Personal Services	0.00	0.00	0.00
Current Expenses	0.00	0.00	0.00
Repairs & Alterations	0.00	0.00	0.00
Assets	0.00	0.00	0.00
Other	0.00	0.00	0.00
2. Estimated Total Revenues	0.00	0.00	0.00

Rule Title: Board of Pharmacy Rules Regarding Licensure and the Practice of Pharmacy

Rule Title: Board of Pharmacy Rules Regarding Licensure and the Practice of Pharmacy

3. Explanation of above estimates (including long-range effect):
Please include any increase or decrease in fees in your estimated total revenues.

The modifications made based upon public comments pared this down to minor modifications of existing rules which will have no fiscal impact. While the original filing of proposed rules contemplated promulgation of rules to implement a Statewide Official Prescription Paper program created by West Virginia Code Section16-5W-4, the Board has deleted any of those provisions to further study the issue, leaving only minor changes to existing provisions which have been in place for some time.

MEMORANDUM

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

The modifications made based upon public comments pared this down to minor modifications of existing rules which will have no fiscal impact. While the original filing of proposed rules contemplated promulgation of rules to implement a Statewide Official Prescription Paper program created by West Virginia Code Section16-5W-4, the Board has deleted any of those provisions to further study the issue, leaving only minor changes to existing provisions which have been in place for some time.

Date: 7/29/10

Signature of Agency Head or Authorized Representative

David E. Potters

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 1
LICENSURE AND PRACTICE OF PHARMACY

§15-1-1. General.

1.1. Scope. -- This rule provides definitions of many terms and establishes general provisions for Board operation; establishes internship requirements; provides the requirements for application as a pharmacist, including examination requirements, renewals, and reinstatement of lapsed licenses; establishes the qualifications for obtaining a license by reciprocity, including requirements for a foreign pharmacy graduates; establishes proceedings for disciplinary action; establishes how drugs may be transferred and the restrictions on refilling and transferring of prescription orders, including establishing communications requirements for the manual and electronic prescribing and dispensing of prescription drugs, specifically providing for E-prescribing and Electronic Data Intermediaries; establishes how drugs and devices may be returned; states the requirements for drug product selection and substitution; establishes the requirements for pharmacy permits, including the minimum requirements, security, and professional work environment; states the required equipment, facilities, and record systems required by a pharmacy; establishes the requirements for a permit to conduct sterile pharmaceutical compounding; establishes licensure and control of nuclear pharmacies; establishes the sanitary requirements in a pharmacy; establishes rules of professional conduct for pharmacists; establishes the duties and responsibilities of a pharmacist-in-charge; establishes the manner of issuance of a prescription; states different labeling requirements; establishes the requirements and responsibilities of a consultant pharmacist; establishes different types of specialized dispensing systems, including the use of emergency kits; states the requirement for places that need to obtain a controlled substance permit, including the fees for such permit.

1.2 Authority -- W. Va. Code §§30-5-12C(d), 30-5-14, and 30-5-19.

1.3 Filing date -- ~~June 9, 2009~~_____.

1.4 Effective date -- ~~July 1, 2009~~_____.

§15-1-2. Definitions.

2.1. The following words and phrases as used in this Rule have the following meanings:

2.1.1. "Act" or "Uniform Controlled Substance Act" means to West Virginia Code § 60A-1-1, et seq.

2.1.2. "Administer" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion or any other means.

2.1.3 "Automated pharmacy system" means mechanical systems which perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of medications, and which collect, control, and maintain all transaction information.

2.1.4. "Board of Pharmacy" or "Board" means the West Virginia State Board of Pharmacy.

2.1.5. "Compounding" means:

2.1.5.a. The preparation, mixing, assembling, packaging, or labeling of a drug or device:

2.1.5.a.1. As the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/ pharmacist relationship in the course of professional practice for sale or dispensing, or

2.1.5.a.2. For the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing, or

2.1.5.a.3. The preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

2.1.6. "Confidential information" means patient-identifiable information maintained by the pharmacist in the patient record or which is communicated to the patient as part of patient counseling, or which is communicated by the patient to the pharmacist.

This information is privileged and may be released only to the patient or to other members of the health care team and other pharmacists where, in the pharmacist's professional judgment, such release is necessary to the patient's health and well-being; to health plans, as that term is defined in 45 CFR § 160.103, for payment; to such other persons or governmental agencies authorized by law to receive such privileged information; as necessary for the limited purpose of peer review and utilization review; and as authorized by the patient or required by court order. Appropriate disclosure, as permitted by this rule, may occur by the pharmacist either directly or through an electronic data intermediary.

2.1.7. "Controlled Substance" means a drug, substance, or immediate precursor in Schedule I through Schedule V of either the Federal Controlled Substances Act, 21 USC Section 801, et seq., or the West Virginia Uniform Controlled Substances Act, W. Va. Code § 60A-1-1, et seq.

2.1.8. The term "Cosmetic" means:

2.1.8.a. Articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body, or any part of the human body for cleansing, beautifying, promoting attractiveness or temporarily altering the appearance;

2.1.8.b. Articles intended for use as a component of those articles, except that the term shall not include soap; and

2.1.8.c. shall be held to include "dentifrice" and “toilet articles”

2.1.9. "Deliver" or "delivery" means the actual, constructive or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

2.1.10. "Device" means an instrument, apparatus, implement or machine, contrivance, implant or other similar or related article, including any component part or accessory, which is required under federal law to bear the label, "Caution: Federal or state law requires dispensing by or on the order of a physician" or the language or symbol as determined by the U. S. Food and Drug Administration.

2.1.11. “Direct supervision” means that a licensed pharmacist is physically present in the pharmacy and is available to verify the accuracy of a prescription before it is dispensed.

2.1.12. "Dispense" or "dispensing" is that aspect of the practice of pharmacy concerned with the

preparation, verification of contents, and delivery of a drug or device in an appropriately labeled and suitable container to a patient or a patient's representative or surrogate pursuant to a lawful order of a practitioner for subsequent administration to, or use by, a patient. Dispensing has not occurred until the drug is actually delivered to the patient or patient's representative.

2.1.13. "Distribute" means the delivery of a drug or device other than by administering or dispensing.

2.1.14. "Distributor" means a person licensed as a wholesaler.

2.1.15. "Drug" means:

2.1.15.a. Articles recognized as drugs by the U. S. Food and Drug Administration (FDA) or published in such references as the USP-NF, Facts and Comparisons, Physicians Desk Reference or supplements thereto, for use in the diagnosis, cure, mitigation, treatment or prevention of disease in human or other animals;

2.1.15.b. Articles, other than food, intended to affect the structure or any function of the body of human or other animals; and

2.1.15.c. Articles intended for use as a component of any articles specified in subsection (b) or (c) of this section.

2.1.16. "Drug regimen review" includes, but is not limited to, the following activities:

2.1.16.a. Evaluation of prescription orders and patient records readily available to the pharmacist for:

2.1.16.a.1. Known significant allergies;

2.1.16.a.2. Rational drug therapy and contraindications;

2.1.16.a.3. Reasonable dose and route of administration; and

2.1.16.a.4. Reasonable directions for use.

2.1.16.b. Evaluation of readily available prescription drug orders and patient records for duplication of therapy;

2.1.16.c. Evaluation of the prescription drug for interactions and/or adverse effects which may include, but are not limited to, any of the following:

2.1.16.c.1. Drug-drug;

2.1.16.c.2. Drug-food;

2.1.16.c.3. Drug-disease; and

2.1.16.c.4. Adverse drug reactions.

2.1.16.d. Evaluation of the prescription drug orders and patient records for proper utilization, including over utilization, under utilization and optimum therapeutic outcomes.

2.1.17. "Electronic data intermediary" means an entity that provides the infrastructure to connect a computer system, hand-held electronic device or other electronic device used by a prescribing practitioner with a computer system or other electronic device used by a pharmacist to facilitate the secure transmission of:

2.1.17.a. An electronic prescription order;

2.1.17.b. A refill authorization request;

2.1.17.c. A communication; or

2.1.17.d. Other patient care information.

2.1.18. "E-prescribing" means the transmission, using electronic media, of prescription or prescription-related information between a practitioner, pharmacist, pharmacy benefit manager or health plan as defined in 45 CFR §160.103, either directly or through an electronic data intermediary. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the pharmacist. E-prescribing may also be referenced by the terms "electronic prescription" or "electronic order".

2.1.19. "Inpatient pharmacy" means the area within a licensed institution; i.e., a hospital, or other place where patients stay at least one night, where drugs are stored and dispensed to other areas of the institution for administration to the patients by other licensed health care providers.

2.1.20. "Inspector" means an agent of the Board, who is a licensed pharmacist, appointed by the Board to conduct periodic inspections of permittees and perform other duties as designated by the Board.

2.1.21. "Institutional facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, including but not limited to a hospital, convalescent home, nursing home, extended care facility, mental health facility, rehabilitation center, psychiatric center, developmental disability center, drug abuse treatment center, family planning clinic, correctional facility, hospice, public health facility, or athletic facility.

2.1.22. "Institutional pharmacy" means that physical portion of an institutional facility that is engaged in the compounding, dispensing, and distribution of drugs, devices, and other materials used in the diagnosis and treatment of injury, illness, and disease and which holds a pharmacy license from the Board.

2.1.23. "Intern" means an individual who is:

2.1.23.a. Currently licensed by the Board to engage in the practice of pharmacy while under the supervision of a licensed pharmacist and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist;

2.1.23.b. A graduate of an approved college of pharmacy or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee certificate, who is currently licensed by the Board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;

2.1.23.c. A qualified applicant who is licensed by the Board and is awaiting examination for licensure; or

2.1.23.d. An individual participating in a residency or fellowship program.

2.1.24. "Labeling" means the process of preparing and affixing a label and the affixing of auxiliary labels to a drug container exclusive, however, of a labeling by a manufacturer, packer or distributor of a nonprescription drug or commercially packaged legend drug or device. The label shall include all information required by federal law or regulation or state law or rule.

2.1.25. "Mail order pharmacy" means a pharmacy, regardless of its location, which dispenses greater than ten percent (10%) prescription drugs in the United States Mail or other mail or package delivery service.

2.1.26. "Manufacturer" means a person engaged in the manufacturing of drugs or devices.

2.1.27. "Manufacturing" means production, preparation, propagation or processing of any drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes any packaging or repackaging of a substance or labeling or relabeling of its contents and the promotion and marketing of a drug or device. Manufacturing also includes the preparation or repackaging, and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners or other persons.

2.1.28. "Nonprescription drug" means a drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the requirements of the laws and rules of this state and the federal government.

2.1.29. "Nuclear pharmacist" means a pharmacist who has been certified in the specialty of nuclear pharmacy.

2.1.30. "Nuclear pharmacy" means a place where radioactive drugs are prepared and dispensed and which operates under specialized rules.

2.1.31. "Original License" means a license issued by the Board to an applicant when:

2.1.31.a. the applicant is a new business;

2.1.31.b. the applicant is an established business that is transferred to a successor;

2.1.31.c. the applicant is an established business in which fifty percent (50%) ownership or more is transferred to a new owner;

2.1.31.d. the applicant is an established business in which control of pharmaceutical services is transferred; not including a change in pharmacist-in-charge; or

2.1.31.e. the applicant is an established business which moves to a new location.

2.1.32. "Outpatient pharmacy" means any pharmacy, apothecary, or place within this state where drugs are dispensed and sold at retail or displayed for sale at retail and where the practice of pharmacy is conducted and pharmaceutical care is provided; and anyplace outside of this state where drugs are dispensed and the practice of pharmacy and pharmaceutical care is provided to residents of this state.

2.1.33. "Over-the counter drug" or "OTC drug" means any drug that is not a prescription drug or legend drug.

2.1.34. "Patient counseling" means the oral communication by the pharmacist of information, which may include supplemental media according to the pharmacist's professional judgment, to the patient or care giver, to ensure the proper use of drugs and devices.

2.1.35. "Permit" means any license, registration, or other privilege granted or issued by the board to any person for the purpose of providing a business or service to individuals or the public and the holder of the permit is the "permittee". No permit will be issued unless a business is operated or a service is provided. Not more than one permit may be issued in any one name in more than one location.

2.1.36. "Person" means an individual, corporation, partnership, association or any other legal entity, including government.

2.1.37. "Person Addicted" means one who has acquired the habit of using alcoholic beverages or controlled substances or other agents to such an extent as to deprive him or her of reasonable self-control.

2.1.38. "Pharmaceutical care" is the provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes related to:

2.1.38.a. The cure or prevention of a disease;

2.1.38.b. the elimination or reduction of a patient's symptoms; or

2.1.38.c. the arresting or slowing of a disease process.

2.1.39. "Pharmacist" or "registered pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacy and pharmaceutical care.

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

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

2.1.40.b. has the responsibility for the practice of pharmacy, 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;

2.1.40.c. works at least 30 hours a week, with the pharmacist-in-charge working at least three days per week, in that pharmacy, including the use of any accrued annual or sick leave; Provided That, in any pharmacy which is open on average less than 40 hours per week in a calendar year, he or she must work in the pharmacy a majority of the hours that the pharmacy is open (e.g., if open 20 hours per week, the pharmacist-in-charge must work 11 hours per week within the pharmacy); and

2.1.40.d. With regard to a pharmacist-in-charge in a Charitable Clinic Pharmacy, this position may be filled by a committee of up to three (3) pharmacists who accept as a group the responsibilities of the required pharmacist-in-charge. Further notwithstanding the requirements of subsection c, above, with regard to a Charitable Clinic Pharmacy, if the pharmacy is open an average of more than 40 hours per week, the pharmacist-in-charge or pharmacist-in-charge committee must work at least 8 hours per calendar month; if the pharmacy is open on average at least 30 and up to 40 hours per week, the pharmacist-in-charge or pharmacist-in-charge committee must work in the charitable clinic

pharmacy at least 6 hours per calendar month; if the pharmacy is open on average at least 15 and up to 30 hours per week, the pharmacist-in-charge or pharmacist-in-charge committee must work in the charitable clinic pharmacy at least 4 hours per calendar month; if the charitable clinic pharmacy is open on average at least 5 and up to 15 hours per week, the pharmacist-in-charge or pharmacist-in-charge committee must work in the charitable clinic pharmacy at least 2 hours per calendar month; and, if the charitable clinic pharmacy is open less than 5 hours per week, the pharmacist-in-charge or pharmacist-in-charge committee must work in the charitable clinic pharmacy the lesser of 2 hours per month or 50% of the hours the charitable clinic pharmacy is open.

Charitable Clinic Pharmacy hours per week	Hours required by PIC per month
More than 40	8
30 to 40	6
15 to 30	4
5 to 15	2
Less than 5	The lesser of 2 or 50% of hours open

2.1.41. "Pharmacy technician" means registered supportive personnel who work under the direct supervision of a pharmacist, and who have passed an approved training program; Provided That, in a Charitable Clinic Pharmacy, when no pharmacist is on-site, a pharmacy technician may work under the direct supervision of a prescribing practitioner who is licensed as a prescribing practitioner who is licensed as such in the State of West Virginia.

2.1.42. "Pharmacy technician trainee" means an individual currently engaged in a pharmacy technician training program which has been approved by the Board and who is under the direct supervision of a pharmacist.

2.1.43. "The practice of pharmacy" is the personal health 3service concerned with the preparing, compounding and dispensing of drugs and medical devices used in the diagnosis, treatment or prevention of disease, dispensed on the prescription of a practitioner, or otherwise legally dispensed or sold and shall include the proper and safe storage of drugs, the maintenance of proper records and the dissemination of information to other health care professionals and proper counseling to the patient concerning the therapeutic value and proper use of drugs and devices.

2.1.44. "Practitioner" or "prescribing practitioner" means an individual currently licensed, registered or otherwise authorized by any state, territory or district of the United States to prescribe and administer drugs in the course of professional practices, including allopathic and osteopathic physicians, dentists, physician assistants, optometrists, veterinarians, podiatrists and nurse practitioners as allowed by law.

2.1.45. "Preceptor" means an individual who is currently licensed as a pharmacist by the board, meets the qualifications as a preceptor under the rules of the board, and participates in the instructional training of pharmacy interns.

2.1.46. "Prescription drug" or "legend drug" means a drug which, under federal law, is required, prior to being dispensed or delivered, to be labeled with any of the following statements or the language or symbol as determined by the U. S. Food and Drug Administration.

2.1.46.a. "Caution: Federal law prohibits dispensing without prescription".

2.1.46.b. "Caution: Federal law restricts this drug to use by, or on the order of, a licensed

veterinarian"; or a drug which is required by any applicable federal or state law or rule to be dispensed pursuant to a prescription drug order or is restricted to use by practitioners only.

2.1.47. "Prescription" or "Prescription order" means a lawful order from a properly licensed practitioner to a pharmacist for a drug or device for a specific patient and transmitted by:

2.1.47.a. Written order;

2.1.47.b. An oral order to a pharmacist who shall immediately:

2.1.47.b.1. Reduce it to writing which becomes the original order;

2.1.47.b.2. Hand initial it to identify the receiver; and

2.1.47.b.3. Show the date, time and name of person transmitting the order;

2.1.47.c. An electronic transmission which has the capability to produce a printed copy, and shows the date, time and name of person transmitting the order; or

2.1.47.d. other methods of transmission approved by the Board.

2.1.48. "President" means the President of the West Virginia Board of Pharmacy.

2.1.49. "Sample" means a package of a legend drug provided by a manufacturer on the request of a practitioner or charitable clinic to be given to a patient without charge in accordance with federal law.

2.1.50. An approved or recognized "School of Pharmacy" means a school of pharmacy accredited by the American Council on Pharmaceutical Education.

2.1.51. "Secretary" means the Secretary of the West Virginia Board of Pharmacy.

2.1.52. "Vice-President" means the Vice-President of the West Virginia Board of Pharmacy.

2.1.53. A "Wholesaler" is a person or entity licensed by the Board to distribute, by sales or otherwise, prescription legend drugs to persons other than a consumer or patient.

§ 15-1-3. General Provisions.

3.1. The Board in general. – The Board of Pharmacy shall consist of five (5) practicing pharmacists and two (2) public members who shall be appointed by the governor, by and with the advice and consent of the Senate. Each member of the Board, at the time of his appointment, shall be a citizen and a licensed pharmacist of the State of West Virginia and actively engaged in the practice of pharmacy. The public members shall be residents of this state who have attained the age of majority and may not be a past or present member of the profession of pharmacy, the spouse of a member of the profession of pharmacy, a person who has ever had any material financial interest in providing of pharmacy service or who is engaged in any activity directly related to the practice of pharmacy.

3.2. Officers of the Board. – The members of the board shall annually elect as officers of the Board one (1) member to serve as President of the Board, one (1) to serve as Vice-president and one (1) to serve as Secretary, all to serve a one (1) year term or until their successors are elected. The election is to be held in June each year.

3.3. Official Seal – The Board hereby reaffirms and readopts, as the official seal of the Board the following: The outer circle of the seal has inscribed in it 'West Virginia Board of Pharmacy'; and the inner circle of the seal consists of a base upon which rests a graduate entwined about which there is an Aesculapius serpent and holding in balance a set of scales, an impression of which is affixed to it.

3.4. Meetings of the Board – The Board shall hold at least two (2) meetings a year for the purpose of examining applicants for licensure to practice pharmacy in West Virginia and for the transaction of any other business that may legally come before it. It may hold additional meetings for any legitimate purpose it may consider appropriate, which shall be called by the Secretary at the direction of the President or upon the written request of any three (3) members. 'Roberts Rules of Order' shall control conduct of all meetings.

3.5. Quorums – Four (4) members must be present at the time and place set for the meeting before any action can be taken by the Board. A majority vote of the members in attendance is required before any motion may be passed.

3.6. Location of Office – The Board shall determine the location of its office.

3.7. Disposition of moneys; report to auditor. – The Secretary shall receive and account for, all moneys derived by virtue of the provisions of W.Va. Code §§ 30-1-1 et. seq. and 30-5-1 et. seq. and shall pay such moneys into the State Treasury monthly on or before the tenth day of each month in which the monies are received. He or she shall also, on the first day of January and first day of July of each year within five (5) days thereafter, certify to the State Auditor, a detailed statement of all moneys received by him or her during the preceding six (6) months.

3.8. Every member of the board shall be paid a per diem for each day actually spent in attending sessions of the Board or of its committees and the necessary travel, as set by W. Va. Code § 30-5-2(c), and shall be reimbursed for all actual and necessary expenses incurred in carrying out the provisions of chapter thirty of the West Virginia Code applicable to the Board.

3.9. Record of proceedings; registration of applicant; certified copies of records prima facie evidence, report to governor. – The Secretary of the Board shall keep a record of its proceedings and a register of all applicants for license or registration, showing for each, the date of his or her application, name, age, educational and other qualifications, place of residence, whether an examination was required, whether the applicant was rejected or a certificate of licensure or registration granted. the license or registration number, if required, and any suspension or revocation of any license or registration. The books and register of the Board shall be open to public inspection at all reasonable times, and the books and register, or a copy of any part of them, certified by the Secretary and attested by the seal of the Board, is prima facie evidence of all matters recorded by the Board.

3.10. Roster of licensed or registered persons. – The Secretary shall prepare and maintain a complete roster of all persons, licensed and registered by it, alphabetically and by class or type and by whether within or without the state.

3.11. Power of Inspection and Investigation – The duly authorized agents of the Board may inspect and investigate in a lawful manner and during regular business hours all places or persons with permits. The investigation may include, but not be limited to, all inventories, invoices for prescription drugs, selling prices, and other records required by law, acts of individuals and facilities, but shall not extend to financial data or sales data other than shipment data or pricing data; unless the owner, operator or agent in charge of the controlled premises consents in writing. The pharmacy permit holder shall allow access to selling prices only when needed for a specific investigation or inquiry by the Board regarding a particular drug.

3.12. During the course of any inspection or investigation by an agent of the Board the agent may temporarily close any permittee upon the discovery of any of the following:

3.12.1. the ability of the pharmacist to practice pharmacy with reasonable skill, competency, or safety to the public is impaired because the permittee's cognitive, interpersonal, or psychomotor skills are affected by psychiatric, psychological, or emotional problems, or excessive alcohol or drug use or addiction; or

3.12.2. the absence of valid permit issued by the Board or by the absence of an available pharmacist to be on duty.

3.13. When a permittee is closed under subsection 3.12.1 of this section they shall remain closed until an unimpaired pharmacist arrives on the premises or when a permittee is closed under subsection 3.12.2 of this section, the permittee shall remain closed until a valid permit is obtained and on display as required by law.

3.14. Agents of the Board when acting in good faith and without malice are immune from individual civil liability while acting within the scope of their duties as such agents of the Board.

§ 15-1-4. Internship Requirements.

4.1. The principal purpose of serving an internship is for the intern to acquire practical experience under the direct supervision and instruction of a licensed pharmacist preceptor in the providing of pharmaceutical care including the compounding and dispensing of prescriptions.

4.2. The Board shall certify internship for an individual:

4.2.1. When a preceptor holds a current, valid license as a pharmacist from the board and the intern has been issued an intern certificate. The intern certificate expires on the 30th day of June of each year and shall be renewed annually up to four (4) years from the date of issue. The internship certificate shall be displayed at the place of internship;

4.2.2. When the intern has notified the Board within ten (10) days of the employment as an intern;

4.2.3 When the intern notifies the Board within ten (10) days subsequent to termination of any internship under a specific preceptor; and

4.2.4 When the internship is certified by the submission of a "Certification by Preceptor as to Internship" form immediately after termination of the internship. Forms are available from the board office.

4.3. No intern shall be certified by the Board unless the intern is enrolled in or is a graduate of a recognized school of pharmacy.

4.4. An intern may receive experience credit for any period of time during which he or she is enrolled in a recognized school of pharmacy and the Board may accept up to eight hundred (800) hours credit for interns participating or enrolled in a supervised internship as part of the pharmacy curriculum.

4.5. An intern shall earn internship hours only for hours obtained in the practice of pharmacy and in a licensed pharmacy.

4.6. The Board may accept internship hours gained outside West Virginia on a letter of credit or certification from the Board of Pharmacy of the state in which the intern acquired internship experience. Up to one third of the internship hours may be fulfilled by an internship in a foreign country.

§ 15-1-5. Examination for Licensure and Registration and Annual Renewal Requirements.

5.1. Application – All applicants for examination shall apply in writing to the Board at least fifteen (15) days before the date of examination is to be conducted and shall transmit with the application the prescribed fee. The application shall be made on a form provided by the Board..

5.2. The requirements for application as a pharmacist are as follows:

5.2.1. The applicant shall be eighteen (18) years of age or older, proof of which shall be shown by birth certificate or other acceptable document.

5.2.2. Every applicant shall present to the Board satisfactory evidence that he or she is a person of good moral character and has not been convicted of a felony involving controlled substances or violent crime and has not been addicted to alcohol or controlled substances.

5.2.3. The applicant for licensure as a pharmacist shall present to the Board satisfactory evidence that he or she is a graduate of an approved school of pharmacy.

5.2.4. The applicant shall have acquired one thousand five hundred (1500) hours of internship in a licensed pharmacy.

5.2.5. The applicant shall provide a signed waiver allowing the Board to obtain a certified criminal records check on the applicant.

5.3. Examinations.

5.3.1. State examinations shall be held at a time and place designated by the Board. The Board shall give at least thirty (30) days notice prior to the holding of any examination.

5.3.2. A maximum of two (2) days shall be allowed for all portions of the state examination.

5.3.3. An applicant for licensure as a pharmacist shall pass the NAPLEX examination administered by NABP and one or more state examinations in subjects determined by the Board as being reasonable, in testing his or her knowledge.

5.3.4. For the purpose of grading or rating, answers to the questions shall be valued by scores based upon their importance as determined by the Board. An applicant shall attain an individual test grade of seventy percent (70%) on each state examination and an average of seventy five percent (75%) on all the state examinations created and administered by the Board in order to qualify for licensure.

5.3.5. An applicant failing to achieve the required grade may repeat the state examinations one time without further cost within six (6) months, but one re-examination exhausts the applicant's privilege to sit for the state examinations under the current application.

5.4. Certificate of licensure or registration – An applicant for licensure who has successfully passed all the required examinations may receive a letter signed by the Secretary prior to preparation of a permanent certificate, or a permanent certificate evidencing that he or she is a licensed pharmacist. The permanent certificate of licensure shall bear a serial number, the full name of the applicant, the date of its

issuance, the seal of the Board, and shall be signed by at least four (4) member of the Board and shall be attested by the President and Secretary. For any duplicate of this certificate the Board shall charge twenty five dollars ($25.00). A certificate is not assignable.

5.5. License and registration renewal.

5.5.1. The board of pharmacy shall charge and collect the following fees:

a. Biennial renewal of license of pharmacist . . $100.00
b. License of intern pharmacist $10.00 plus $5.00 for each of the remaining periods of his or her internship
c. Registration of a consultant pharmacist . . $20.00 for each application
d. Registration of a pharmacy technician . . $25.00 initially and $20.00 for each biennial renewal

5.5.2. All licenses of pharmacists and registrations of pharmacy technicians expire on the thirtieth day of June, 2002. After the thirtieth day of June, 2002, one half of all licenses for pharmacists and registrations for pharmacy technicians shall be renewed for a period of one year to expire on the thirtieth day of June, and shall be biennially thereafter. The Board shall renew one half of all licenses for pharmacists and registrations for pharmacy technicians for a period of two years, to expire on the thirtieth day of June, and shall renew those licenses and registrations biennially thereafter: Provided, That registrations of interns shall continue to be renewed annually. Every licensed pharmacist, intern or pharmacy technician who desires to renew his or her license or registration shall apply to the state board of pharmacy for renewal of his or her license or registration, and shall transmit with his or her application the fee prescribed. The renewal application shall be sent by the board at least thirty days prior to expiration of the license or permit. The notification shall be mailed to the last known address of each pharmacist, inter or pharmacy technician as shown on record with the Board.. The Board has until August 30 of each year to issue the license or registration and no license or registration shall be considered lapsed until September 1. It is the responsibility of the applicant and if he or she has not received an application by June 1, the applicant should request one from the Board. If the applicant submitted a renewal application by June 30 and has not received his or her license or registration by July 30, the applicant should contact the Board.

5.5.3. If any pharmacist or pharmacy technician fails for a period of sixty days after his or her license or registration expires to apply to the board for a renewal of his or her license or registration, the board shall send a second notification of the required renewal to the last known address of the pharmacist or pharmacy technician. If the pharmacist or pharmacy technician fails to apply to the board for a renewal of his or her license or registration within thirty days after receipt of the second notification, the Board shall remove his or her name from the register of pharmacists and pharmacy technicians and the license or registration shall be considered lapsed.

5.5.4. In order for any pharmacist or pharmacy technician whose name has been removed from the register of the board to again become licensed or registered, the pharmacist or pharmacy technician shall appear personally before the board, or an authorized committee of the board, to show cause for permitting the license or registration to lapse. If the person submits to the board satisfactory reasons for allowing the license or registration to lapse and satisfies the board as to his or her qualifications to practice the profession by successfully passing the examinations administered by the board, the Board shall reinstate that person upon payment of reinstatement fee of two hundred fifty dollars for a pharmacist plus the renewal fee of one hundred dollars or upon payment of a reinstatement fee of fifty dollars for a pharmacy technician plus the renewal fee of twenty dollars.

§ 15-1-6. Reciprocity; Licensure of Pharmacists From Other States or Countries.

6.1. Qualifications – The Board may license and admit to practice pharmacists in this state that have been legally licensed or registered as pharmacists in other states or countries if:

6.1.1. The applicant is at least eighteen (18) years of age;

6.1.2. The original state in which the applicant is licensed or registered accords similar recognition to licensed pharmacists of West Virginia;

6.1.3. The applicant is in good standing in the state or country or original licensure or registration;

6.1.4. The applicant is in fact, competent and physically and mentally qualified to function as a pharmacist;

6.1.5. The applicant is of good moral character and not addicted to alcohol or a controlled substances;

6.1.6. The applicant has not been convicted, or had his or her license suspended or revoked for violation of pharmacy, liquor, controlled substance, or food and drug laws;

6.1.7. The applicant originally passed a written examination in subjects determined by the Board as being reasonable. The applicant also originally passed a practical examination (Errors and Omissions exam) determined by the Board as being a reasonable test of the applicant's ability to translate his or her technical knowledge into terms of actual practice; and

6.1.8. The applicant is familiar with West Virginia Laws and Rules and Regulations governing the practice of pharmacy and passes the state law examination.

6.2. An applicant may serve all or part of his or her internship in another state and up to one-third (1/3) of his or her internship in another country. In order to receive credit for that service an affidavit shall be signed by the supervising pharmacist and attested by the secretary of the board of pharmacy of the state or country where the internship was served.

6.3. Applicants for licensure by reciprocity shall not work as pharmacists until they receive a certificate of licensure from the state of West Virginia.

6.4. Foreign pharmacy graduate – Foreign pharmacy graduate – A foreign pharmacy graduate whose undergraduate pharmacy degree was conferred by a recognized school of pharmacy outside of the fifty (50) United States, the District of Columbia, and Puerto Rico, may establish educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee Certificate (FPGEC) from the National Association of Boards of Pharmacy (NABP). An applicant for licensure who receives FPGEC certification meets the educational requirement for licensure and may sit for the NAPLEX and state examinations provided he or she has completed 1500 hours of internship; of which 500 hours may have been earned in a foreign country.

6.5. Application.

6.5.1. The applicant shall complete a preliminary application form obtained from the National Association of Boards of Pharmacy and return it to that organization. After the preliminary application data has been verified by the National Association of Boards of Pharmacy and the Board receives notification to that effect, the Board shall supply the applicant who possesses the necessary qualifications

with application forms. An applicant must complete the forms and submit a fee of two hundred and fifty dollars ($250.00). In the event the applicant desires to take the examination at a time other than at the next scheduled examination the applicant shall submit to the Board an additional fee of one hundred fifty dollars ($150.00).

6.5.2. The application shall include the following provided by the applicant:

a. A certified copy of proof of experience, or the original pharmacist preceptor's affidavit proving experience, that was filed by the applicant when he or she took the examination in the state or country in which he or she is licensed or registered;
b. A recent head shot photograph with a statement signed by the applicant that it is a photograph of the applicant and has been made within the previous twelve (12) months; and
c. A signed waiver from the applicant allowing the Board to obtain a certified criminal records check on the applicant.

6.6. Appearance before the Board – Applicants for licensure by reciprocity shall appear before the Board or its designated agent at the time specified, for checking of credentials, an interview and examination as may be necessary to determine the fitness of the applicant to practice in West Virginia. The Board may revoke any applicant who misrepresents himself or herself to the Board.

§ 15-1-7. Proceedings for Disciplinary Action.

7.1. Hearing Procedures.

7.1.1. Any person who has had a permit denied, suspended, or revoked by the Board, and believes the action was in violation of W. Va. Code § 30-1-1, et. seq. or 30-5-1, et. seq., is entitled to a hearing on the action denying, suspending, or revoking the permit.

7.1.2. Any person who desires a hearing under the provisions of this section shall for the present a written demand for the hearing to the Board.

7.1.3. When the president of the Board or his or her authorized designee is presented with a demand for a hearing, he or she shall schedule a hearing within thirty (30)days of receipt of the written demand, unless postponed to a later date by mutual agreement.

7.1.4. The Board may institute charges against any person who has a permit issued by the Board when reasonable cause exists for believing that the person may have engaged in conduct or be in such condition that the permit should be suspended, revoked, or otherwise disciplined for one or more of the grounds set forth in W. Va. Code § 30-5-1, et. seq. or the rules of the Board. Charges may be based upon information received by way of a verified written complaint filed with the Board and further information gathered by the Board in the process on investigating the complaint. Charges may also be based upon information received solely through inspection or investigative activities undertaken by the Board.

7.1.5. The Board shall institute charges against a person holding a permit by issuing a Complaint and Notice of Hearing in the name of the Board. Such Complaint and Notice of Hearing shall designate the Board as the 'Complainant' and shall designate the permittee involved in the proceedings as the "Respondent"; shall set out the substance of each offense charged with sufficient particularity to reasonably apprise the Respondent of the nature, time and place of conduct or condition complained of in the Complaint and Notice of Hearing; shall state the date, time and place for the hearing; and shall contain a statement of intention of the Board to appoint a hearing examiner.

7.1.6. The Board may amend the charges set forth in a Complaint and Notice of Hearing as it considers proper.

7.1.7. The Board shall serve a Complaint and Notice of Hearing upon the demanding or charging party at least thirty (30) days prior to the date of hearing.

7.1.8. Upon written motion received by the Board no later than twenty (20) days prior to the date of the hearing, the Board shall provide a more definite statement of the matters charged or the reasons stated for denial of licensure to the demanding or charged party or his or her counsel, at least fifteen (15) days prior to the hearing date.

7.2. Hearings shall be conducted as follows:

7.2.1. Any party to the hearing may be represented by an attorney-at-law, duly qualified to practice law in the State of West Virginia.

7.2.2. Upon request by the Board, it shall be represented by West Virginia Attorney General's Office.

7.2.3. Irrelevant, immaterial, or unduly repetitious evidence shall be excluded from the hearing. Furthermore, the rules of evidence as applied in civil cases in the circuit courts of this State shall be followed. However, when necessary to ascertain facts not reasonably susceptible of proof under those rules, evidence not admissible thereunder may be admitted, except where precluded by statute, if it is of a type commonly relied upon by reasonable prudent persons in the conduct of their affairs.

7.2.4. The rules of privilege recognized by the law of this State shall be followed.

7.2.5. Objections to evidentiary offers shall be noted on record. Any party to the hearing may vouch the record as to any excluded testimony or evidence.

7.2.6. Any party to a hearing may appear with witnesses to testify on his or her behalf; may be heard in person, by counsel or both; may present other evidence in support of his or her position as determined appropriate by the Board or its designated hearing examiner; and, when appropriate, may cross-examine witnesses called by the Board in support of the charges or in defense of its decision to deny licensure.

7.2.7. The hearing shall be held at such time and place as is designated by the Board but no hearing shall be conducted unless and until at least thirty (30) days written notice thereof has been served upon the charged or demanding party and/or his or her attorney. The notice shall be given either personal delivery thereof to the person to be notified, or by depositing the notice in the United States Mail, postage prepaid. in an envelope addressed to that person at his or her last known address.

7.2.8. The hearing shall be open to the general public.

7.2.9. Members of the Board and its officers, agents and employees may testify at the hearing as to material and relevant matters: Provided, that no member of the Board who testifies at a hearing shall thereafter participate in the deliberations or decisions of the Board with respect to the case in which he or she testified.

7.2.10. A record of the hearing, including the complaint, if applicable, the notice of the hearing, all pleadings, motions, rulings, stipulations, exhibits, documentary evidence, evidentiary depositions and the stenographic report of the hearing, shall be made and a transcript shall be furnished to any party at his

or her expense.

7.2.11. Documentary evidence may be received in the form of copies or excerpts or by incorporation by reference.

7.2.12. Where a hearing is held after charges have been brought against a license pursuant to this rule, the board has the burden of proof and shall present its evidence and/or testimony in support of the charges first.

7.2.13. Where a hearing is held upon demand under the provisions of this section, the demanding party has the burden of proof and shall present its evidence and/or testimony in support of the charges first.

7.2.14. Following the conclusion of the Board's presentation of evidence in accordance with subdivision 7.2.12 of this section, the Respondent or charged party has the right to submit his or her evidence.

7.2.15. Following the conclusion of the demanding party's presentation of evidence in accordance with subdivision 7.2.14 of this section, the Board has the right to submit its evidence in rebuttal.

7.2.16. The Board shall call witnesses to testify in support of its decision to deny, suspend, or revoke a permit or in support of the charges instituted against a permittee; may present other evidence to support its position; and, may cross-examine witnesses called by the demanding party or charged party in support of his or her position.

7.1.17. All parties have the right to opening and closing arguments, not to exceed ten (10) minutes for each presentation.

7.2.18. Hearings held by the Board as a result of charges instituted against a permittee may be continued or adjourned to a later date or to a different place by the Board or its designee by appropriate notice to all parties.

7.2.19. Motions for a continuance of a hearing may be granted upon a showing of good cause. Motions for continuance shall be in writing and received in the office of the Board no later than seven (7) days prior to the hearing date. In determining whether good cause exists, the Board shall give consideration to the ability of the party requesting the continuance to proceed effectively without a continuance. The Board shall deny a motion for continuance filed less than seven (7) days from the date of the hearing unless the reason for the motion could not have been ascertained earlier. Motions for continuance filed prior to the date of the hearing may be ruled on by the officer of the Board to preside or the designated hearing examiner. The Board member or the hearing examiner presiding over the hearing shall rule on all other motions for continuance.

7.2.20. All motions related to a case set for hearing before the Board, except motions for continuance shall be received in the office of the Board at least ten (10) days before the hearing. Prehearing motions shall be heard at the prehearing conference or at the hearing prior to the commencement of testimony. The Board Member or the hearing examiner presiding at the hearing shall hear the motions and the response from the non-moving party and shall rule on the motions accordingly.

7.3. Transcription of Testimony and Evidence.

7.3.1. All testimony, evidence, arguments and rulings on the admissibility of testimony and

evidence shall be recorded by stenographic notes and characters or by mechanical means.

7.3.2. All recorded materials shall be transcribed. The Board shall make arrangements for the transcription of the recorded testimony and evidence.

7.3.3. Upon the motion of the Board or any party assuming error or omission in any part of any transcript, the Board or its appointed hearing examiner shall settle all differences arising as to whether the transcript truly discloses what occurred at the hearing and shall direct that the transcript be corrected and/or revised as appropriate so as to make it confirm the truth.

7.3.4. A transcript of the hearing shall be provided to all members of the Board for review at least ten (10) days before the vote is taken on its decision.

7.4. Any party may submit proposed findings of fact and conclusions of law at the time and manner designated by the Board or its duly appointed hearing examiner.

7.5. Hearing Examiner

7.5.1. The Board may appoint a hearing examiner who may administer oaths and affirmations, examine witnesses under oath, rule on evidentiary matters, hold conferences for settlement or simplification of issues by consent of parties, cause to be prepared a record of the hearing so that the Board is able to discharge its functions and otherwise conduct hearings.

7.5.2. Hearing examiners appointed by the Board may not grant, suspend, revoke or otherwise take disciplinary action upon any license.

7.5.3. The hearing examiner shall prepare recommended findings of fact and conclusions of law for submission to the Board. The Board may adopt, modify or reject the findings of fact and conclusions of law.

7.6. Conferences; Informal Disposition of Cases.

7.6.1. At any time prior to the hearing or thereafter, the Board, its designee or its duly appointed hearing examiner may hold conferences for the following purposes:

a. To dispose of procedural requests, prehearing motions or similar matters;
b. To simplify or settle issues by consent of the parties; of
c. To provide for informal disposition of cases by stipulation or agreement.

7.6.2. The Board or its duly appointed hearing examiner may cause the conferences to be held on the Board's or the hearing examiner's own motion by the request of a party.

7.6.3. The Board may also initiate or consider stipulation or agreement proposals with regard to the informal disposition of cases and may enter into the stipulations or agreements without conference.

7.7. Evidentiary depositions may be taken and read or otherwise included into evidence as in civil actions in the circuit courts of this State.

7.8. Subpoenas

7.8.1. Subpoenas to compel the attendance of witnesses and subpoenas duces tecum to compel the production of documents may be issued by any member of the Board or its executive director.

7.8.2. Written requests by a party for the issuance of subpoenas of subpoenas or subpoenas duces tecum must be received by the Board no later than ten (10) days before a scheduled hearing. Any party requesting the issuance of subpoenas or subpoenas duces tecum shall see that they are properly served in accordance with W. Va. Code § 29-5-1(b).

7.9. Orders

7.9.1. Any final order entered by the Board following a hearing conducted pursuant to this rule shall be made pursuant to the provisions of W. Va. Code § 29A-5-3 and § 30-1-8 (d). The orders shall be entered within forty-five (45) days following the submission of all documents and materials necessary for the proper disposition of the case, including transcripts, and shall contain findings of fact and conclusions of law.

7.9.2. The findings of fact and conclusions of law shall be approved by a majority of the Board either by a poll or vote at a regular meeting, before the final order is entered. A copy of the final order approved by a majority of the Board shall be served by personal service or by registered or certified mail upon the demanding record, if any within five (5) days after entry by the Board.

7.10. Appeal – An appeal from any final order entered in accordance with this rule shall comply with the provisions of W. Va. Code § 30-1-9.

§ 15-1-8. Review By Circuit Court and Supreme Court of Board's Refusal to Issue, or Suspend or Revoke Permit.

8.1. Any person who has been refused a permit for any cause other than failure to pass any examination given by the Board or whose license has been suspended or revoked, may, within thirty (30) days after the decision of the Board, present his or her petition in writing to the Circuit Court of the county in which he or she resides or to the judge of the court in vacation, praying for the review and reversal of the decision.

8.2. Before presenting his or her petition to the court or judge, the petitioner shall mail copies of the petition to the Board.

8.3. Upon receipt of the petition copy, the Secretary shall transmit to the clerk of the court, the record of the hearing.

§ 15-1-9. Transfer of Legend Drugs.

9.1. No legend drug may be transferred except by the following methods:

9.1.1. Transfer of drugs without prescription.

a. Legend drugs without a prescription may be transferred only to a permittee or practitioner and the transaction shall be recorded and the gross dollar value of the transfers shall not exceed five percent (5%) of the total prescription drug sales revenue of either the transferor or the transferee pharmacy during any twelve (12) consecutive month period.

b. The record showing transfers of legend drugs without a prescription shall contain:

1. the name of the drug and its quantity;
2. the date of transaction;

3. the permittee or practitioner to whom the legend drug was transferred; and
4. the selling price.

c. The record of the transfer shall be kept in the pharmacy and be immediately accessible within one year from the date of transfer, and available within forty-eight (48) hours if between one year and five years from the date of transfer.

d. Any pharmacy with transfers of prescription drugs that exceed the five percent restriction set forth in paragraph 9.1.1a of this section shall obtain a permit to be a wholesaler. Intracompany sales and transfers of drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage shall not be included in calculation of the drug sales revenue.

9.1.2. Transfer of drugs with a Prescription.

a. Legend drugs transferred by a practitioner's prescription order are dispensed. A prescription shall contain at least the following elements:

1. The patient's name and address and the date the prescription is written;
2. The drug's name and quantity; and
3. Directions for use.

A. If the prescription is written on a practitioner's date prescription blank, the order shall contain the following:

1. The practitioner's printed name, address, professional designation and practitioner identifier number; and
2. The practitioner's signature.

B. If the prescription is written on an institutional prescription blank, the order shall contain the following:

1. The printed name of the practitioner and DEA number with suffix; and
2. The practitioner's signature.

C. No sticker or other substance shall be allowed to obliterate or cover any of the information required by this subdivision.

9.2. Samples

9.2.1. Samples are the property of a practitioner and may only be received upon a signed request from the practitioner to the drug manufacturer.

9.2.2. Samples are not allowed in a pharmacy except that institutional pharmacies may receive, store, and dispense prescription drug samples without charge to patients of a practitioner that is affiliated with the institution, provided that the following requirements met:

a. All prescription drug samples received by the pharmacy are obtained pursuant to a written, signed and request of a licensed practitioner affiliated with that institution. For the purposes of this subsection "Affiliated" is interpreted to mean that the requesting practitioner treats patients at the facility;
b. the pharmacy retains a copy of all written, signed prescription drug sample requests;

c. prescription drug samples are stored separately from the prescription drug products held for sale (retail stock);
d. records of prescription drug sample receipt are dispensing are maintained separately from records of prescription drug products held for sale and sold (retail stock);
e. a relationship exists between the health care entity and the pharmacy which is evidenced by a written documentation;
f. prescription drug samples are dispensed by the pharmacy to patients in the manufacturer's or distributor's original packaging; and
g. the pharmacy and its employees do not sell, purchase, or trade or offer to sell, purchase, or trade any prescription drug sample.

§ 15-1-10. Refilling Prescription Orders.

10.0. A pharmacist may not refill any prescription order containing a drug if the label of the original container bears the statement, "CAUTION: Federal Law Prohibits Dispensing Without Prescription", or "RX Only", unless the practitioner has authorized the refill by written notation on the original prescription order. Subsequent refill authorization shall be treated as a new prescription order.

10.2. If a prescription order is refillable, the date of the refill and the hand written initials of the pharmacist shall be recorded upon the original written prescription order if electronic recording is used a daily printout of all prescription orders filled shall be made and verified and signed by each pharmacist responsible for that days work or a log may be kept of each refill number and this log shall be signed by each pharmacist.

10.3. No prescription order may be refilled after twelve (12) months from the original dispensing.

10.4. The refilling of prescription orders for controlled substances is limited by provisions of the Uniform Controlled Substances Act, W. Va. Code § 60A-3-308.

§ 15-1-11. Transferring Prescription Orders Between Pharmacies.

11.1. The pharmacist shall, upon the request of the patient, transfer the prescription information to the pharmacy designated by the patient.

11.2. The transfer of original prescription order information for the purpose of refilling the prescription order is permissible between pharmacies if the transfer is communicated directly between two pharmacists, and the following occurs:

11.2.1. The transferring pharmacist:

a. Writes the word "VOID" on the face of the original prescription order;
b. Records on the reverse of the original prescription the name, address, and Drug Enforcement Administration (DEA) registry number of the pharmacy to which the prescription was transferred and the name of the pharmacist receiving the prescription information; and
c. Records the date and time of the transfer and his or her first and last name;

11.2.2. The pharmacist receiving the transferred prescription order information:

a. Writes the word "TRANSFER" on the face of the transferred prescription; and
b. Provides all the information required to be on a prescription and includes:

1. Date of issuance of the original prescription;

2. Number of refills on the original prescription;
3. The date the original prescription was dispensed;
4. The number of valid refills remaining and date of last refill;
5. The pharmacy's name, address, DEA registry number and the original prescription number from which the prescription was transferred; and
6. The first and last name of the transferring pharmacist;

11.2.3. A pharmacist may give a copy of a prescription clearly marked "For Information Only" to a patient; and

11.2.4. A computer record may be used if it reflects the fact that the original prescription order has been voided and shall contain all the other information required in this subsection.

11.3. No pharmacy shall refuse to transfer information about a previously dispensed prescription to another pharmacy when requested by a patient. A pharmacy shall transfer prescription information in accordance with this rule as soon as possible in order to assure that the patient's drug therapy is not interrupted.

11.4. Information on a prescription is the property of the patient and is intended to authorize the dispensing of a specific amount of medication for the use by the patient. Pharmacies shall maintain original and transferred prescription drug orders for a period of five (5) years from the date of the last refill; maintained on-site for a period of twelve (12) months from last of last refill, and available within 48 hours of request if date of last refill is between one (1) and five (5) years.

11.5. Pharmacies accessing a common electronic file of database used to maintain required dispensing information are not required to transfer prescription drug orders or information for dispensing purposes between or among pharmacies participating in the same common prescription file. Provided, the common electronic file or database shall contain complete records of each prescription drug order and refill dispensed, and the system shall have the capability at the pharmacy refilling the prescription drug order or at the pharmacy where the prescription is transferred to generate a hard copy record of each prescription drug order transferred or accessed for purposes of refilling.

§ 15-1-12. Returning Drugs and Devices.

12.1. No pharmacist or pharmacy shall accept from a patient or other person, except for the purpose of destruction, any part of any unused prescription drug unless:

12.1.1. The returned drugs are in a manufacturer's original, sealed and visibly tamperproof container;

12.1.2. The returned drugs are in extemporaneously prepared unit dose packaging, as defined in this rule, and are returned within an institution or by an institution; and

12.1.3. All drugs are identified as to lot and control number and expiration date.

12.2. No controlled substance that has been dispensed may be returned and placed in stock for reuse or resale under any circumstances.

12.3. Any drugs returned within or by an institution shall be recorded in a log which lists the name of the patient, the name and strength of the drug with the name of its manufacturer, the prescription number (if applicable), the amount of the drug returned and the date of the return. The log shall contain the signatures of the receiving pharmacist and a registered nurse employed by the facility and the log shall be

retained for at least two (2) years.

§ 15-1-13. Drug Product Selection and Substitution.

13.1. The Board adopts the drug products in the Approved Drug Products with Therapeutic Equivalence Evaluations published by the Food and Drug Administration, Center for Drug Evaluation and Research, (commonly called the "Orange Book") with "AA", "AB", "AN", "AO", "AP", or "AT" ratings as acceptable products for generic substitution as required by W. Va. Code § 30-5-12b.The Board may approve drug products not listed in the Orange Book as acceptable products for generic substitution upon submission of a written request to the Board.

§ 15-1-14. Regulations Governing Pharmacy Permits.

14.1. Pharmacy permits and annual registration - A pharmacy shall first secure a permit from the Board and comply fully with W. Va. Code § 30-5-14 before it may lawfully conduct a pharmacy.

14.2. Application for permits – 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 permit to do so. 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.

14.2.1. The application for a new permit 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:

a. identification of the owner that is applying for the permit;
b. the name under which the business will be operated and which will be used in advertising;
c. the physical location of the pharmacy including;

    1. Its street number; and
    2. The city and county;

d. The mailing address of the pharmacy if different from its physical location;
e. The name and license number of the pharmacist-in-charge;
f. The name and license numbers of other pharmacists regularly employed at the pharmacy;
g. The name and registration numbers of pharmacy technicians and regularly employed at the pharmacy;
h. The pharmacy's hours of operation; and
i. detailed floor plans for the pharmacy made to scale.

14.2.2. Each individual pharmacy shall make separate applications and separate permit shall be issued for each individual pharmacy.

14.2.3. Pharmacies renewing permits shall have the current edition of the three volume set of the USP-DI and its supplements or appropriate texts or electronic media 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.

14.2.4. Each initial application for a pharmacy permit shall be accompanied by a fee of one hundred fifty dollars ($150.00), or an amount as set by statute.

14.2.5. Any pharmacy compounding parenteral/enteral compounding permit.

14.3. Issuance of permit.

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

14.3.2. The permit 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.

14.3.3. Permits shall be posted in a visibly conspicuous place. The permits may not be in a location that is out of sight of the dispensing area.

14.4. Renewal of permit.

14.4.1. The annual renewal of permits takes place on the first day of July of each year. The fee for the annual renewal is seventy five dollars ($75.00) or an amount as set by statute. Permits issued under this section are not transferable and expire on the thirtieth day of June of each calendar year. Renewal applications shall be delivered to the Board office by the fifteenth day of June to allow time for processing.

14.4.2. If a pharmacy does not make application renewal by the first day of August each year, the permit becomes null and void. To renew a lapsed permit the Board shall re-inspect the pharmacy and the permittee shall pay a fee of one hundred fifty dollars ($150.00) or an amount as set by statute for the permit and one hundred fifty dollars ($150.00) for the re-inspection or an amount set by statute.

14.5. Surrender of permit.

14.5.1. When a pharmacist-in-charge in whose name a pharmacy permit has been issued leave 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 permit to the Board office with the date of the change noted on the permit. For the purposes of this subsection 'full time employment' means working at least 30 hours per week, 3 days per week at one pharmacy. A copy of the permit shall be made and posted in the pharmacy with the newly designated pharmacist-in-charge written on the permit in indelible ink. If the pharmacist-in-charge fails to notify the Board and return the pharmacy permit the Board may take disciplinary action against the offending pharmacist.

14.5.2. 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 permit, or any other action which causes the pharmacist-in- charge to cease being in complete and actual charge of the pharmacy. The pharmacy permit holder shall immediately designate a new pharmacist-in-charge and write the name on a copy of the pharmacy permit in indelible ink and post it in the pharmacy. Until a pharmacist-in-charge is designated and written in indelible ink on the pharmacy permit, 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 permit holder shall notify the Board of the replacement in writing within thirty (30) days upon a form provided by the Board with the appropriate fee. Upon receipt of this notification, the Board shall provide a newly printed permit to the pharmacy If an interim pharmacist-in-charge is designated who is not the permanent pharmacist-in-charge listed upon the written form the name of the interim pharmacist-in-charge and the period of time that pharmacist served as pharmacist-in-charge. An

interim pharmacist-in-charge is not required to be employed the minimum number of hours as is the permanent pharmacist-in-charge.

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

14.5.4. When a pharmacy changes ownership the permit becomes null and void and a new permit must be obtained from the Board.

14.6. Violations.

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

14.6.2. All pharmacists 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.

14.6.3. Any person who employs any licensed pharmacist shall notify the Board within seven (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 permit holder who fails to notify the Board is subject to disciplinary action.

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

14.7. Security.

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

a. 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;
b. Physical barriers may be either of solid material or movable curtain type:

    1. 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
    2. 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;

14.7.2. 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 or approved by the Board, and are subject to the following conditions:

1. The device shall be sound, microwave, photoelectric, ultrasonic, or other accepted and suitable device;
2. The device shall be maintained in operating order and shall have an auxiliary source of power;
3. The device shall fully protect the prescription department and shall be capable of detecting breaking and/or entering by any means when activated;
4. 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 permit 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.
5. This subdivision shall not apply to pharmacies which are granted a permit prior to the effective date of this rule provided that a previously installed security system is in place, that no structural changes are made in the prescription department, that no changes are made in the security device, that the prescription department is not closed while the rest of the business remains open, and that a breaking and loss of drugs does not occur; and
6. This subsection does not apple to pharmacies which are open and staffed by pharmacists twenty four (24) hours a day;

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

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;
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;
3. During times that an institutional pharmacy may be unattended by a pharmacist, 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:
    (A) drugs are properly labels;
    (B) only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements;
    (C) whenever access to the cabinet occurs, written practitioner's orders and proof-of-use are provided;
    (D) all drugs in the cabinet are inventoried no less than once per week;
    (E) a complete audit of all activity concerning the cabinet is conducted no less than once per month; and

(F) written policies and procedures are established to implement the provisions of this subdivision; and

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";

14.7.4. 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;

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

14.7.6. Mobile pharmacy units are prohibited. Completed prescriptions must be picked up at or delivered from the same pharmacy at which they were prepared, except that this subdivision does not apply to a mail order pharmacy licensed by the Board, or to transfers of prescription drugs by a retail pharmacy to alleviate a temporary shortage; and

14.7.7. 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.

14.8. Professional Work Environment

14.8.1. No pharmacist may work more than twelve (12) hours within a twenty-four (24) hour period without at least eight (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 twelve (12) hours in order to keep the pharmacy open. The pharmacists would have to document and date and amount of time worked beyond the twelve (12) hour limit along with the reason for the extended hours of work and make it available to the Board.

14.8.2. Any pharmacy dispensing more than fifteen (15) prescriptions per hour on average during a day shall have a registered pharmacy technician or a pharmacy technician trainee assisting the pharmacist. The pharmacist-in-charge shall determine the work schedule for pharmacy technicians and pharmacy technician trainees based upon prior dispensing records.

14.8.3. The pharmacist on duty or the pharmacy permit holder 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.

§ 15-1-15. Equipment, Facilities and Record Systems.

15.1. The Board shall not issue a permit to operate a pharmacy unless the necessary professional, physical, and technical equipment requirements have been fulfilled.

15.1.1. The pharmacy shall have a separate area available for patient counseling which will ensure the privacy and confidentiality of the discussions; and which has adequate space to use any equipment , visual aids, and publications, if necessary, to provide proper counseling. This subdivision does not apply to pharmacies which have been granted a permit prior to the effective date of this rule

15.1.2. All standards set by the United States Pharmacopeial Convention shall be the minimum standards followed by all licensed pharmacists and pharmacies during the course of the professional practice of pharmacy.

15.2. Every pharmacy shall continually possess the following:

15.2.1. A sanitary method of measuring and dispensing between five (5) and 250 milliliters of liquids;

15.2.2. Mortars and pestles, spatulas, ointment pads, counting trays, balance and weights, and any other equipment or supplies necessary to satisfy the requirements of this rule;

15.2.3. For pharmacies compounding ophthalmic preparations, IV additives, enteral nutritional products or other pharmaceuticals requiring more sophisticated techniques, the proper equipment and facilities to prepare sterile products and meet the requirements of good compounding practice;

15.2.4. Adequate facilities for the proper storage of pharmaceuticals. All areas where drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the drugs prior to their dispensing as stipulated by the USP and/r the manufacturer's or distributor's labeling unless otherwise indicated by the Board;

15.2.5. Facilities for the safe storage of controlled substances if the dispersion method is not used;

15.2.6. An acceptable system of keeping records of prescriptions dispensed as required by the Uniform Controlled Substance Act and any Rules and Regulations pertaining to the Act;

15.2.6. A system of keeping patient profiles which allows immediate review of at least the following data about the patient which may be reasonably obtained by the pharmacist:

a. The patient's biographical data;
b. The patient's medications;
c. The patient's disease states and drug allergies;
d. The pharmacist's notes; and
e. Any other data necessary to make rational judgments about pharmaceutical care; and

15.2.8. The most currently available Pharmacy Law Book and book of Rules and Regulations published by the Board.

§ 15-1-16. Sterile Pharmaceutical Compounding.

16.1. Permitting and Control.

16.1.1. A pharmacy compounding or mixing prescription orders for sterile solutions or suspensions to be administered parenterally, enterally, by irrigation or ophthalmic drops shall obtain a Sterile Pharmaceutical Compounding Permit from the Board in addition to a pharmacy license. The Board shall issue a permit after a satisfactory inspection of the completed facilities.

16.1.2. The compounding and preparation of sterile prescription orders shall be accomplished in a pharmacy environment subject to the West Virginia Code and the Rules of this Board and all Federal laws and regulations.

16.1.3. Sterile compounding or mixing shall be under the supervision and control of a pharmacist who shall be present on duty during all hours of prescription preparation.

16.1.4. This section shall not apply to pharmacies which were granted a parenteral-enteral compounding permit prior to the effective date of this rule; if the current compounding environment meets the requirements of the rule in effect prior to this rule and the public health, safety, and welfare is not jeopardized.

16.2. An applicant for a Sterile Pharmaceutical Compounding Permit shall provide the Board with the following:

16.2.1. A completed Board application form;

16.2.2. A copy of the Policy and Procedure Manual required under subsection 16.5 of this section;

16.2.3. Statement and plans showing how the applicant meets the minimum requirements regarding space, equipment, supplies and publications.

16.3. The compounding environment for this practice shall be separate rooms set apart from all other activities. The environment shall facilitate controlled aseptic conditions and meet all standards of the United States Pharmacopeial Convention (USP) including:

16.3.1. Separation from other areas by a 'clean' entry room or vestibule;

16.3.2. Adequate space for at least one certified air flow hood in each sterile admixture compounding room along with other necessary equipment and supplies; and

16.3.3. Sufficient space to allow pharmacists and other employees room to work safely and accurately fulfill their duties.

16.4. General Requirements.

16.4.1. Special handling and packaging shall be available to maintain stability of the prepared prescription orders during delivery to the patient.

16.4.2. All prescriptions shall include labeling, in addition to that required by other state or federal law or rule, showing:

a. The drug's expiration date;

b. The date of preparation; and
c. The drug's control number.

16.4.3. A pharmacy with a Sterile Pharmaceutical Compounding Permit shall provide a twenty four (24) hour telephone number to allow its patients or other health care providers who may be administering its prescriptions to contact its pharmacists.

16.5. A pharmacy with a Sterile Pharmaceutical Compounding Permit shall comply with the following requirements:

16.5.1. A Policy and Procedure Manual shall be maintained either separately or as a section of the Pharmacy Policy and Procedure Manual, and shall contain at least the following:

a. A statement in detail of the objectives and operational guidelines of the permittee;
b. A Description of a Quality Assurance Program which monitors:

1. personnel qualifications,
2. Continuing training and performance of staff;
3. Equipment and facilities requirements;
4. Standards for compounding and dispensing; and
5. Any other requirements of this Board; and

16.5.2. The pharmacy shall provide protection for its personnel involved in the handling of cytotoxic agents by:

a. Utilizing the proper equipment and supplies; and
b. Having a special section of the Policy and Procedure Manual devoted to handling procedures, including:

1. A statement that compounding shall be conducted within a properly certified vertical airflow hood;
2. A discussion of the proper use of protective garb;
3. A description of the proper techniques to prevent all contamination of the prescription and chemical contamination of the person preparing the prescription; and
4. Disposal procedures of cytotoxicagents in accordance with accepted professional standards and applicable law.

16.6. Space, Equipment, Supplies, and Reference Works.

16.6.1. A pharmacy operating under a Sterile Pharmaceutical Permit shall meet the minimum requirements for space, equipment, supplies and reference materials, which are in addition to those required for a regular pharmacy permit, and include the following:

a. Space.

1. The area for preparing sterile preparations, as provided for in this rule and referred to as the sterile admixture room, shall be set apart from general work and storage areas.
2. Adequate sit conditioning or positive air pressure must be maintained to prevent easy entry of outside air.
3. An operating sink with hot and cold running water shall be located in the "clean"

anteroom adjoining the buffer room according to United States Pharmacopeia standards.

4. The compounding area shall be large enough to allow working room for all personnel to be in the room at one time without interference with each other.
5. The buffer room must contain at least one certified airflow hood, vented if necessary;

b. At least the following equipment shall be available and shall be maintained in working order:

1. Properly certified airflow hood;
2. Adequate refrigerator and freezer space;
3. A sink and wash area in the anteroom as provided for in this section; and
4. Appropriate waste containers for:

A. Used needles and syringes;
B. All cytotic waste including disposable apparel used in its preparation;

c. Minimum supplies on hand shall include, but not be limited to:

1. Cloves, masks, and disposable gowns;
2. Disposable syringes and needles in necessary sizes;
3. Disinfectant cleaning material for equipment surfaces;
4. Disposable towels;
5. Liquid bactericidal cleanser for hand washing; and
6. Spill kits for cytotoxic agent spills;

d. Minimum reference works required in a pharmacy with a Sterile Pharmaceutical Compounding permit are:

1. A current edition of the three volume set of the USP-DI with supplements, or referenced texts designated by the Board;
2. Handbook of Injectable Drugs published by the American Society of Hospital Pharmacists, or its equivalent.

§ 15-1-17. Licensure and Control of Nuclear Pharmacies.

17.1. General Requirements.

17.1.1. A pharmacy providing radiopharmaceutical services, and compounding or mixing prescription orders for radiopharmaceuticals shall obtain a Nuclear Pharmacy license from the Board. The license will be issued after satisfactory inspection of the completed facilities. The license will be issued only when the pharmacist-in-charge is a qualified nuclear pharmacist and the pharmacy has been approved by the appropriate federal agency.

17.1.2. Pharmacies providing regular pharmaceutical care in addition to radiopharmaceutical services shall comply with all sections of this rule applicable to pharmacies in general.

17.2. Space.

17.2.1. The nuclear pharmacy area shall be separate from all other pharmacy areas for non-radioactive drugs and shall be secured from unauthorized personnel.

17.2.2. A pharmacy handling radiopharmaceuticals shall provide a radioactive storage and product decay area which meets the requirements of the appropriate federal agency.

17.3. Dispensing and labeling.

17.3.1. A prescription order for a radiopharmaceutical shall be dispensed in a package that is properly labeled.. A pharmacy may furnish radiopharmaceuticals only to practitioners for administration to patients and for the occasional transfer to another pharmacist.

17.3.2. In addition to any label requirements of the Board for nonradioactive drugs, the immediate outside container of a radiopharmaceutical to be dispensed shall also be labeled with:

a. the standard radiation symbol;
b. The words "CAUTION-Radioactive Material";
c. the name of the radio nucleotide;
d. the chemical form;
e. The amount of radioactive material contained in millicuries or microcuries;
f. The volume in milliliters, if the material is a liquid;
g. The requested calibration time for the amount of radioactivity contained; and
h. The practitioner's name and the assigned lot number.

17.3.3. The immediate inner container shall be labeled with:

a. The standard radiation symbol;
b. The words "CAUTION-Radioactive Material"; and
c. The prescription number

17.3.4. The amount of radioactivity shall be determined by radiometric methods for each dose immediately prior to dispensing.

17.4. Distribution – Nuclear pharmacies may distribute approved radioactive drugs to any receiving pharmacy if the receiving pharmacy does not process the radioactive drugs in any manner nor violate or change the product packaging except that a licensed pharmacist may divide the product into individual doses.

§ 15-1-18. Sanitary Regulation of Pharmacies.

18.1. The pharmacist-in-charge of a pharmacy shall maintain the prescription room and equipment in the prescription room in a clean and orderly condition and in good operating order at all times.

18.2. The prescription counter shall be used for no other purpose than for the compounding and dispensing of prescriptions and shall be maintained free from dust and in orderly condition.

18.3. The sink, with hot and cold running water, in the pharmacy shall be used for no other purpose than the cleaning of equipment and articles used in the preparation of prescriptions and the cleaning of hands of those preparing and dispensing prescriptions.

18.4. All pharmacist and interns when providing pharmaceutical care, shall wear a clean white coat or jacket with a name tag identifying the individual and showing their job designation, and are required to keep themselves and their apparel in clean condition. All pharmacy technicians and pharmacy technician trainees shall wear a name tag identifying the individual and showing their job designation and shall wear

clean attire and a coat, jacket, or apron of a color other than white.

18.5. Any area used for providing pharmaceutical care shall be maintained in an orderly and clean condition. All instruments, articles, stock bottles, containers, shelving, cabinets and other equipment and fixtures shall be free from dust, insects, rodents or any other foreign material.

18.6. The prescription room and anywhere drugs are stores shall be well ventilated, temperature controlled, free from obnoxious odors and equipped with adequate lighting.

18.7. Only permittees or pharmacy technician trainees, except agents of the Board, may be present in the prescription area when dispensing and pharmaceutical care is being provided, unless the pharmacist on duty considers the presence of another individual appropriate. The pharmacy permit holder may enter the pharmacy without a pharmacist present for immediate security or surveillance purposes as long as the reason for entry, the name of the person entering, and the time and date of entry are documented and immediately available to the Board.

§ 15-1-19. Rules of Professional Conduct.

19.1. Statement of purpose

19.1.1. The practice of pharmacy is a profession dedicated to the service of public health which requires knowledge, skill and integrity. The practice of pharmacy is restricted to persons who possess special education and qualifications and licenses to practice pharmacy. The pharmacist recognizes his or her responsibility to the public in providing pharmaceutical care, providing safe storage and handling of drugs, in dispensing drugs and devices and the dissemination of information on drugs and devices to other health care specialists. For these reasons he or she is obligated to the highest standards of professional conduct.

19.1.2. In order that the citizens of West Virginia shall receive the best possible pharmaceutical care, and that the public health, welfare and safety be fully protected, the following rules of professional conduct shall be followed at all times.

19.2. Freedom of practice.

19.2.1. No pharmacist shall engage in conduct, in the practice of pharmacy or the operation of a pharmacy, which tends to reduce the public confidence in the ability and integrity of the profession of pharmacy, or endangers the public health, safety and welfare; nor shall he or she interfere in the provision of pharmaceutical care or offer pharmaceutical services under any terms or conditions which tend to impair the free and complete exercise of the professional skill and judgment of another pharmacist. A pharmacist shall at all times practice his or her profession in conformity with federal and state laws and regulations and the rules of this Board.

19.2.2. Every pharmacist, when practicing the profession of pharmacy, shall provide pharmaceutical care as defined in this rule.

19.3. Uncertain Prescription orders.

19.3.1. No pharmacist shall compound or dispense any prescription order which, in his or her judgment and/r professional opinion, contains any error, irregularity or ambiguity. The pharmacist shall hold a conference with the prescriber before dispensing, if there is any doubt that the prescription order is not legal or correct or issued for a legitimate medical purpose.

19.4. Professional services – It is the duty of a practicing pharmacist to make his or her professional services available to the public. Every licensed pharmacy, except for a nuclear pharmacy, shall provide pharmaceutical care, including the compounding and dispensing of all prescription orders which may reasonable be expected to be compounded or dispensed by pharmacists.

19.5. Confidential information.

19.5.1. No pharmacist shall exhibit, discuss or reveal any patient-specific confidential information as defined in this rule with any person other than:

a. Agents of the Board engaged in the performance of their official duties;
b. Another pharmacist or pharmacy technician when necessary;
c. The patient or his or her authorized representative;
d. The prescriber or other members of the health care team treating the patient; or
e. Any person authorized by law to receive the information.

19.6. Diagnosis or treatment – No pharmacist shall attempt to diagnose any disease, illness or organic disorder. This does not preclude evaluation of a patient after a diagnosis is made by a practitioner. A pharmacist may advise individuals on the merits and quality of over-the-counter (OTC) products.

19.7. Coded prescription orders – No pharmacist shall dispense any prescription order which is coded. A "coded" prescription order is one which bears letters, numbers, words, or symbols, or any other device used in lieu of the name, quantity, strength and directions for use, other than those normal letters, numbers, words or symbols recognized by the profession of pharmacy as a means of conveying information by prescription order.

19.8. False or misleading advertising – No pharmacist or pharmacy shall make, permit to be made, conduct or otherwise participate in any false, misleading or fraudulent advertising.

19.9. Promotion of and reliability of drugs.

19.9.1. No pharmacist shall promote to the public by any means a controlled substance or any other drug which may only be dispensed pursuant to a prescription order, which tends to cause the drugs to be used in excess of the requirements established in a legitimate physician-patient-pharmacist relationship.

19.9.2. No pharmacist shall purchase, accept, compound or dispense any medicinal preparation, whether by prescription order or otherwise which in his or her professional judgment is not therapeutically reliable.

19.10. Prescription order forms – No pharmacist shall provide any practitioner with prescription orders forms imprinted with any reference to a pharmacy or pharmacist.

19.11 Place of practice – No place of practice or location shall be maintained to dispense prescription orders other than a pharmacy for which a permit has been issued by the Board.

19.12. Physician agreements – No pharmacist shall enter into or engage in any agreement or arrangement with any practitioner which may tend to exploit the patient, nor shall he or she enter into an agreement of any kind where in any way a patient's free choice of pharmacist or pharmacy is limited in any manner.

19.13. Duties and responsibilities – It is the duty and responsibility of the pharmacist in every pharmacy to perform, at the minimum, the following duties:

19.13.1. To accept all new prescription orders from authorized prescribers transmitted by oral communication, immediately reduce them to writing and document the prescription by entering on the prescription order form:

a. the name of the caller;
b. the time and date of transmission; and
c. the hand-written initials of the receiver.

19.13.2. To dispense, deliver, or distribute a prescription drug order accurately as prescribed. For the purposes of this paragraph "accurately as prescribed" means:

a. To the correct patient (or agent of the patient) for whom the drug or devise was prescribed;
b. with the correct drug in the correct strength, quantity, and dosage form ordered by the practitioner; a pharmacist may substitute a generic drug pursuant to W. Va. Code § 30-5-12b; and
c. With correct labeling (including directions for use) as ordered by the practitioner;

19.13.3. To ensure that his or her initials are on all prescription labels dispensed while he or she is on duty, whether prepared by him or her or prepared by a pharmacy technician under his or her supervision;

19.13.4. To ensure that his or her initials are on all prescription order forms dispensed while he or she is on duty, whether prepared by him or her or prepared by a pharmacy technician under his or her supervision;

19.13.5. To possess a list of the drugs which may be prescribed by a physician's assistant with prescriptive privileges and also to possess prescriptive authority of nurse practitioners prior to dispensing prescription orders from those prescribers;

19.13.6. To counsel or inform patients about their drugs. An offer to counsel shall be made by the pharmacist or designee in an oral communication with the patient, care giver or agent who presents a new prescription order, unless in the professional judgment of the pharmacist it is permissible for the offer to counsel to be made in a written communication, by telephone, in person, or in a manner determined by the pharmacist to be appropriate. The exercise of and reasons for this judgment shall be documented including the hand- written pharmacist's initials. An offer to counsel has not been made by a mere question of whether the patient has any questions.

a. In those cases, when the offer to counsel, as described in this subsection, has been accepted, a pharmacist who provides pharmaceutical care to patients shall discuss with the patient or care giver or agent who presents a new prescription order, any matter which in the exercise of the pharmacist's professional judgment he or she considers significant, which may or may not include the following:

1. The name of and a description of the medication;
2. the dosage form, route of administration, degree, and duration of drug therapy;
3. Special directions and precautions for preparation, administration, and use by the patient;

4. Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance and the actions required if they occur;
5. Techniques for ser-monitoring drug therapy;
6. Proper storage and handling;
7. Prescription refill information; and
8. Any action to take in the event of a missed dose.

b. Nothing in this sub-section requires a pharmacist to provide consultation if the patient, care giver, or agent does not accept the offer to counsel. If counseling is refused it shall be documented, followed by the initials of the recording pharmacist. Patient counseling is not required for inpatients of a hospital or institution where other licensed health care workers are authorized to administer the drugs;

19.13.7. To make a reasonable effort to obtain, record, and maintain at least the following information at the individual pharmacy:

a. The patients name, address, telephone number, date of birth or age, and gender;
b. The patient's individual history including disease states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and
c. The pharmacist's comments regarding the patient's therapy;

19.13.8. To perform all of the functions in this section;

19.13.9. To adequately supervise all interns, registered pharmacy technicians and pharmacy technician trainees; and

19.13.10. To perform any other functions of any nature or kind which:

a. Require the knowledge, ability or skill of a licensed pharmacist and
b. Attempt to improve the therapeutic outcome to the patient of the pharmaceutical care provided by the pharmacist.

19.4. Violation of the rules of professional conduct.

19.4.1. The rules of professional conduct in this section are intended to govern all pharmacists licensed by the Board and improve the pharmaceutical care provided to the citizens of West Virginia.

19.14.2. The violation of the provisions of this section by a licensed pharmacist or person with a permit to operate a pharmacy shall result in disciplinary action.

19.14.3. Any pharmacist who knowingly accepts and continues employment with any permittee who violates the rules of the Board is guilty of a violation of the rule the same as if he or she had personally engaged in the violation.

19.15. Publication and posting of rules – The Board shall make a copy of the Rules of Professional Conduct in this section available to every pharmacy and pharmacist licensed by the Board. Every pharmacy shall visibly post a copy of the rules in the prescription area.

§15-1-20. Duties and Responsibilities of the Pharmacist-in-Charge.

3.1. A pharmacy may not operate without a pharmacist-in-charge (hereinafter "PIC"), who shall be

designated on the application for a pharmacy license, and in each license renewal. A pharmacist may not serve as PIC unless he or she is physically present in the pharmacy a sufficient amount of time to provide supervision and control. A pharmacist may not serve as PIC for more than one pharmacy at any one time; Provided that, he or she may volunteer as the pharmacist-in-charge at a charitable clinic pharmacy while serving as a PIC in another pharmacy.

3.2. The pharmacist-in-charge has the following responsibilities:

3.2.1. The pharmacist-in-charge shall be responsible for the practice of pharmacy, as defined in this rule, at the pharmacy for which he or she is the pharmacist-in-charge. The pharmacy permit holder shall be responsible 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;

3.2.2. The pharmacist-in-charge shall notify the pharmacy permit holder of potential violations of any statute, rule or court order existing within the pharmacy. If appropriate action has not been taken within a reasonable amount of time the pharmacist-in-charge shall reduce to writing the above and submit to the pharmacy permit holder with a copy to the Board. No pharmacist-in-charge shall be sanctioned by the Board for any violation of any statute, rule or court order if they have previously given this written notice to the pharmacy permit holder. The pharmacy permit holder shall be responsible for such violations;

3.2.3. Implementing quality assurance programs for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems. Quality assurance programs shall be designed to prevent and detect drug diversion;

3.2.4. The PIC shall implement, and maintain a Pharmacy Technician Training Manual for the specific practice setting of which he or she is in charge. He or she shall supervise a training program conducted pursuant to the training manual for all individuals employed by the pharmacy who will assist in the practice of pharmacy. The PIC shall maintain a record of all technicians successfully completing the pharmacy's technician training program and shall attest to the Board, in a timely manner, those persons who, from time to time, have met the training requirements necessary for registration with the Board;

3.2.5. Implementing policies and procedures for the procurement, storage, security, and disposition of drugs and devices;

3.2.6. Assuring that all pharmacists and interns employed at the pharmacy are currently licensed and that all pharmacy technicians employed at the pharmacy are currently registered with the board;

3.2.7. Notifying the board immediately of any of the following changes:

3.2.7.a. Change of employment or responsibility as the PIC;

3.2.7.b. Change of ownership of the pharmacy;

3.2.7.c. Change of address of the pharmacy; or

3.2.7.d. Permanent closing of the pharmacy;

3.2.8. Making or filing any reports required by state or federal laws, rules, and regulations;

3.2.9. Responding to the board regarding any warning notice issued by the Board. The Board shall provide notification of the issuance of the warning notice to the pharmacy permit holder;

3.2.10. Implementing policies and procedures for maintaining the integrity and confidentiality of prescription information and patient health care information, or verifying their existence and ensuring that all employees of the pharmacy read, sign, and comply with the established policies and procedures; and

3.2.11. Providing the board with prior written notice of the installation or removal of an Automated Pharmacy System. The notice shall include, but is not limited to:

3.2.11.a. The name and address of the pharmacy;

3.2.11.b. The location of the automated equipment; and

3.2.11.c. The identification of the responsible pharmacist.

3.3. The PIC shall be assisted by a sufficient number of pharmacists and pharmacy technicians as may be required to competently and safely provide pharmacy services.

3.3.1. The PIC shall maintain and file with the Board, on a form provided by the Board, a current list of all pharmacy technicians assisting in the provision of pharmacy services.

3.3.2. The PIC shall implement written policies and procedures to specify the duties to be performed by pharmacy technicians. The duties and responsibilities of these personnel shall be consistent with their training and experience. These policies and procedures shall specify that pharmacy technicians are to be personally and directly supervised by a pharmacist stationed within the same work area who has the ability to control and who is responsible for the activities of pharmacy technicians, and that pharmacy technicians are not assigned duties that may be performed only by a pharmacist.

§15-1-21. Manner of Issuance of a Prescription.

21.1. A prescription, to be valid, shall be issued for a legitimate medical purpose by a practitioner acting within the course of legitimate professional practice~~.~~, and shall bear the preprinted, stamped, typed, or manually printed name, address and telephone number, and the National Provider Identification (NPI) number of the prescribing practitioner. If it is a prescription for a controlled substance listed in Schedules II through V, then it shall also contain the prescriber's DEA registration number, including any suffix.

21.1.1. A pharmacist shall receive the communication of a prescription. A pharmacist may accept a prescription, including that for a controlled substance listed in Schedules II through V, that is communicated in written form or by E-prescribing. A pharmacist may accept a prescription, including that for a controlled substance listed in Schedules III through V, and, in certain situations, that for a controlled substance listed in Schedule II, that is communicated orally (including telephone voice communication) or by way of electronic transmission other than E-prescribing.

21.1.2. If communicated orally or by way of electronic transmission other than E-prescribing, the pharmacist shall immediately reduce the prescription to a form that may be

maintained for the time period required by any applicable federal and State of West Virginia laws and rules.

21.1.3. A prescription blank for a controlled substance shall not contain the preprinted name of a controlled substance or the written, typed or rubber-stamped name of a controlled substance until the prescription blank is signed, dated and issued to a patient.

21.1.~~3~~4. A prescription for a Schedule II controlled substance may be communicated orally or by way of electronic transmission other than E-prescribing only in the following situations and with the following restrictions. Otherwise, a prescription for a Schedule II controlled substance shall be communicated in written form or by E-prescribing.

21.1.~~3~~5.a. A prescription for a Schedule II controlled substance may be communicated by the practitioner or the practitioner's agent by way of electronic transmission, provided the original written prescription, signed by the practitioner, is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except the hard copy of the electronic transmission may serve as the original, written prescription in the following instances:

21.1.~~3~~5.a.1. the prescription for a Schedule II narcotic substance is to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion;

21.1.~~3~~5.a.2. the prescription for a Schedule II controlled substance is for a resident of a Long Term Care Facility; or

21.1.~~3~~5.a.3. the prescription for a Schedule II controlled substance is for a patient under the care of a hospice certified by Medicare or licensed by the state. The practitioner or Practitioner's agent shall note on the prescription that the patient is a hospice patient.

21.1.4~~6~~. In the case of an emergency situation, a prescription for a Schedule II controlled substance may be communicated by the practitioner orally or by way of electronic transmission, provided that if the prescribing practitioner is not known to the pharmacist, he or she shall make a reasonable effort to determine that the oral authorization came from a registered practitioner, which may include a callback to the practitioner using the practitioner's phone number as listed in the telephone directory and other good faith efforts to insure his identity; and:

21.1.4~~6~~.a. the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing practitioner);

21.1.4~~6~~.b. the orally communicated prescription is immediately reduced to writing by the pharmacist, or, if necessary, the prescription communicated by way of electronic transmission is immediately reduced to a hard copy;

21.1.4~~6~~.c. within seven (7) days after authorizing an emergency oral prescription, the practitioner has a written prescription for the emergency quantity prescribed

delivered to the dispensing pharmacist. The prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the orally or electronically transmitted prescription. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the seven (7) day period. Upon receipt, the dispensing pharmacist shall attach this written prescription to the emergency oral prescription which had earlier been reduced to writing or to the hard copy of the electronically transmitted prescription. The pharmacist shall notify the nearest office of the U.S. Drug Enforcement Administration if the prescribing practitioner fails to deliver a written prescription.

21.1.57. A prescribing practitioner may authorize his or her agent to communicate a prescription orally or by way of electronic transmission either directly or through an electronic data intermediary to a pharmacist in a licensed pharmacy, provided:

21.1.57.a. the identity of the transmitting agent is included in the order;

21.1.57.b. the prescription is transmitted either directly or through an electronic data intermediary to a pharmacist in a licensed pharmacy of the patient's choice with no unauthorized person having access to the prescription;

21.1.57.c. the prescription identifies the transmitter's phone number for verbal confirmation, the time and date of transmission, and the identity of the pharmacy intended to receive the transmission, as well as any other information required by federal or state law;

21.1.57.d. the pharmacist exercises professional judgment regarding the accuracy, validity, and authenticity of the prescription communicated by way of electronic transmission; and

21.1.57.e. all electronic equipment for receipt of prescriptions communicated by way of electronic transmission is maintained so as to ensure against unauthorized access.

21.1.68 Electronic Data Intermediaries.

21.1.68.a. Electronic data intermediaries may transmit electronic prescriptions, prescription refill authorization requests, communications, and other patient care information using a secure infrastructure between an authorized prescribing practitioner and a pharmacy of the patient's choice.

21.1.68.b. Electronic data intermediaries shall meet the following requirements for electronically transmitted prescription orders, refill authorization requests, communications and other transmitted patient care information:

21.1.68.b.1. Maintain the confidentiality and security of transmitted information as required by applicable federal and state laws.

21.1.68.b.2. Transmit prescriptions to the pharmacy of the patient's choice.

21.1.68.b.3. Maintain the integrity, privacy, and security of archived copies of the electronic information related to the transmissions as required by applicable state and federal laws, including maintaining them as confidential information.

§ 15-1-22. Labeling.

22.1. All drugs dispensed by a licensed pharmacy shall be labeled according to the requirements of this section.

22.1.1. All drugs dispensed for use by inpatients of a hospital or other health care facility, where the drug is not in the possession of the ultimate user prior to administration, shall meet the following requirements:

a. the label of a single-unit package of an individual-dose or unit-dose system of packaging of drugs shall include:

    1. the name of the drug;
    2. the route of administration, if other than oral;
    3. the strength and volume, where appropriate, expressed in the metric system whenever possible;
    4. the control number and expiration date;
    5. special storage conditions, if required; and

b. Identification of the repackager by name or by license number shall be clearly distinguishable from the rest of the label.
c. When a multiple-dose drug distribution system is utilized, including dispensing of single unit packages, the drugs shall be dispensed in a container to which is affixed a label containing the following information:

    1. identification of the dispensing pharmacy;
    2. the patient's name;
    3. the date of dispensing;
    4. then name of the drug dispensed; and
    5. the strength, expressed in the metric system whenever possible.

22.1.2. All drugs dispensed to inpatients for self-administering shall be labeled in accordance with subdivision 22.1.4 of this section.

22.1.3. Whenever any drugs are added to parental solutions, the admixtures shall bear a distinctive label indicating:

a. the name of the solution, the lot number, and the volume of the solution;
b. the patient's name;
c. the infusion rate;
d. the bottle sequence number or other system control number;
e. the name and quantity of each additive;
f. the date of the preparation;

g. the beyond-use date and time of parental admixture; and
h. ancillary precaution labels.

22.1.4. All drugs dispensed to ambulatory or outpatients shall contain a label affixed to the container in which the drug is dispensed including:

a. the name and address of the pharmacy dispensing the drug;
b. the name of the patient for whom the drug is prescribed; or, if the patient is an animal, the name of the owner and species of the animal;
c. the name of the prescribing practitioner;
d. directions stated on the prescription;
e. the date of dispensing;
f. any cautions which may be required by federal or state law;
g. the serial number of the prescription drug order;
h. the name or initials of the dispensing pharmacist;
i. the proprietary or generic name of the drug dispensed and its strength, if more than one strength of the drug is marked;

    1. when dispensing an equivalent drug product, the word "substitution" or the letters "sub" shall appear on the label affixed to the container in which the drug is dispensed, followed by the generic name and manufacturer, or reasonable abbreviation, and/or distributor of the chosen product. This requirement only applies to single-entity, multiple-course drugs;
    2. when dispensing a single-entity, single-source drug, the trade name of the prescribed drug may also appear on the label, and the generic name of the prescribed drug may also appear on the label;
    3. when dispensing a fixed combination product, the United States Pharmacopeia's publication of Pharmacy Equivalent Names (PEN) for fixed combination products is the official list of abbreviations for labeling, and is the approved abbreviation for identifying the combination product dispensed;

j. the name of the manufacturer or distributor of the drug; and
k. they beyond- use date

22.1.5. No radiopharmaceutical may be dispensed unless a label is affixed to the immediate container bearing the following information:

a. the standard radiation symbol;
b. the words "Caution- Radioactive Material; and
c. the prescription number.

22.1.6. No radiopharmaceutical may be dispensed unless a label is affixed to the outer or delivery container bearing the following information:

a. the standard radiation symbol;
b. the words "Caution- Radioactive Material";

c. the radionuclide and chemical form;
d. the activity and date and time of assay;
e. the volume, if in liquid form;
f. the requested activity and the calibrated activity;
g. the prescription number;
h. the patient's name or space for the patient's name. When the patient's name is not available at the time of dispensing, a 72 hour exemption is allowed to obtain the name of the patient. No later than 72 hours after dispensing the radiopharmaceutical, the pharmacist shall obtain the patient's name and it shall become a part of the prescription to be retained for a period of five years;
i. the name and address of the nuclear pharmacy;
j. the name of the practitioner; and
k. the lot number of the prescription.

§ 15-1-23. Pharmacist Consultants.

23.1. Places needing consultants.

23.1.1. The requirements of this section apply to pharmacists serving as pharmacy consultants to hospitals, skilled nursing facilities, intermediate nursing facilities, nursing homes, rest homes, personal care centers, governmental agencies, jails, correctional facilities, clinics and any other place where a pharmacy permit is not held, but a controlled substance permit is required; or any place here a pharmacist's expertise is needed to increase or improve patient care and safety in the use of drugs and devices or where the expertise is needed to ensure proper storage conditions and safeguards.

23.2. Requirements and registration.

23.2.1. A pharmacist providing consulting services shall be registered as a consultant pharmacist with the Board and shall be licensed to practice pharmacy in West Virginia.

23.2.2. Every pharmacist providing pharmacy consulting services shall apply annually on the on the prescribed form, to register with the Board as follows:

a. The consultant pharmacist shall file an application with the Board for each institution, place or person to whom consulting services are provided;
b. The application shall contain, but is not limited to:

1. The name, address and phone number of the applying consultant and his or her license number;
2. The name, address, phone number and type of institution, entity or person receiving the consulting services;
3. A description of the services to be provided by the consultant; and
4. The name and signature of the facility administrator.

23.2.3. The consultant pharmacist shall immediately report to the Board any change in the data previously placed on the application for registration as a consultant. If the consulting

arrangement is discontinued the consultant pharmacist shall immediately return the consulting permit to the Board.

23.2.4. The fee for registration as a consultant is twenty dollars ($20.00) for each registration.

23.3. Education – All pharmacist registered as consultants shall have three (3) hours of continuing education in the subjects of consulting practice each year. These three (3) hours may be included in the mandatory fifteen (15) hours of continuing education required for license renewal as a pharmacist.

23.4. Responsibilities.

23.4.1. A pharmacist consultant shall document by date and time, in a permanent log book, his or her activities for each place where he or she is registered. This log book shall be present in each facility for which the consultant pharmacist is registered and shall be available for inspection by the Board at any time.

23.4.2. The pharmacist consultant shall initiate and maintain, in each facility, appropriate records and procedures for the receipt, storage and disposition of all drugs including but not limited to:

a. Prescriptions;
b. Floor stock;
c. Emergency boxes or kits;
d. Investigational drugs;
e. Samples; and
f. Outdated or discontinued drugs.

23.4.3. The pharmacist consultant shall maintain a Policy and Procedures Manual for pharmaceutical services. The Manual shall be available to all inspectors and available to patient care providers for their guidance in drug handling. The manual shall include, but not be limited to, provisions for the following:

a. Transcribing drug orders and prescription ordering;
b. Prescription delivery system and in-house verification;
c. Drug recall;
d. Automatic stop orders;
e. Formulary or standards for drug quality;
f. Systematic review of drug orders;
g. Reconciliation of controlled substances;
h. Disposition by the following means of prescriptions not totally consumed by the patient:

    1. Return to pharmacy for credit; and
    2. Destruction by the pharmacist in the presence of a registered nurse; and

i. In-serving drug education for other personnel.

23.4.4. The pharmacist consultant shall maintain an appropriate drug reference library for use by other health care personnel.

23.4.5. The pharmacist consultant shall insure compliance with all applicable laws and regulations, both state and federal.

23.4.6. The pharmacist consultant shall make every effort to separate consulting duties from dispensing duties. Remuneration shall be comparable to that charged by a pharmacist consultant not associated with the supplier of drugs or devices.

a. The pharmacist or his or her employer shall receive remuneration directly from the facility to which he or she is proving the service.
b. If the pharmacist consultant has any financial interest in the pharmacy providing drugs or devices to the facility he or she may not provide consulting service in order to obtain an agreement to be the supplier.

23.4.7. Nothing in this rule precludes a patient in a skilled or intermediate nursing facility, or other voluntarily entered facility, from free choice of pharmacy services.

§ 15-1-24. Specialized Dispensing Systems.

24.1. Definition.

24.1.1. Specialized dispensing systems are those systems other than traditional bottle systems used to provide controlled administration of drugs, for oral administration, to patients and residents of health institutions.

24.2. Types.

24.2.1. A unit dose dispensing system is a system in which each individual unit of medication dosage form is in a separate container, which is intended to be placed in a larger prescription container which is complete with prescription labeling and contains several unit doses. Each individual unit-dose container shall be labeled with the following:

a. The name and strength of the drug;
b. The name of the manufacturer or the packager;
c. The lot number; and
d. The expiration date.

24.2.2. A unit of use system is a system in which all doses containing different medications to be administered at a given time are placed together in a single package, or packet, which is intended to be placed in a larger prescription container which is complete with prescription labeling and contains several unit of use packets. Each unit of use packet shall be labeled with the following:

a. The name and strength of each drug contained in the unit of use packet;

b. The name of the manufacturer or the packager of each drug in the unit of use packet;
c. The lot number of each drug in the unit use packet; and
d. The expiration date of each drug in the unit of use packet;

24.2.3. Punch card packaging is a system, which does not constitute unit does packaging, in which several doses of the same drug are packaged in a card, which is a prescription container, in which each dose has its own space and may be removed without disturbing the packaging for the remaining doses. A punch card shall be labeled with the following:

a. The name and strength of the drug contained in the punch card;
b. The name of the manufacturer or packager of the drug contained in the punch card;
c. The lot number of the drug contained in the punch card;
d. The expiration date of the drug contained in the punch card; and
e. All other information required to be on the label of a completed prescription order.

24.3.1. All extemporaneous unit dose, unit of use, punch card or any other specialized packaging shall be done by pharmacists, interns, or pharmacy technicians or pharmacy technician trainees under the direct supervision of a pharmacist.

24.3.2. Expiration dates may be no more than twenty five percent (25%) of the time between the day of packaging and the expiration date on the stock bottle, not to exceed twelve (12) months in any case.

24.3.3. These specialized packaging systems may not be used without the required prescription labeling being on the package that is intended to hold several doses for an individual patient.

24.4. Methods of supplying drugs and devices.

24.4.1. Institutions may not have drugs supplied in floor stock quantities unless a controlled substance permit is held by the institution.

24.4.2. Drugs may be supplied by prescription for individual patients.

24.4.3. Drugs, other than by prescription, may be stocked in emergency kits when the following conditions are met:

a. Drugs in emergency kits are to be administered only by those persons licensed to administered drugs;
b. The drugs in the emergency kit are of such nature that their absence would threaten the survival of the patients or intended recipients;
c. The contents of the emergency kit are determined by the pharmacist consultant and the medical director and the nursing director;
d. The emergency kit is sealed so that it is obvious if it has been opened and it is stored under secure conditions;

e. Administration of drugs from the kit is ordered by a practitioner and a record kept of administration;
f. Drugs stocked in the emergency kit are unit dose packaged;
g. Any drug used from the kit is replaced only upon a prescription or physician institution order form fir the patient to which the dose was administered; and
h. Any emergency kit containing controlled substances is kept only at a facility holding a controlled substance permit from the Board.

§ 15-1-25. Institutions and Other Places Needing a Controlled Substance Permit.

25.1. Any facility, including any hospital, skilled nursing facility, intermediate nursing facility, personal care home, jail, correctional institution, emergency organization, clinic or any other place which is responsible to administer drugs to in-patients or out-patients which, may or may not, hold a permit from this Board to operate a pharmacy, shall have a permit to handle controlled substances on hand at the facility. A practitioner whose office is his or her primary place of practice is not required to obtain a permit for the office but shall obtain a permit for any satellite offices or clinics with controlled substances on the premises.

25.2. The Board shall issue a controlled substance permit to those persons required by W. Va. Code §§60A-3-301, 302 to possess a permit.

25.3. Fees –The fees for a controlled substance permit are as follows unless changed by statute:

25.3.1. Manufacturer and wholesaler $50.00

25.3.2. Hospital or Clinic $50.00

25.3.3. Extended care facility or nursing home $25.00

25.3.4. Non-government training institution $25.00

25.3.5. Non-government researcher $25.00

25.3.6. Pharmacy $10.00

25.3.7. Jails and correctional facilities $25.00

25.3.8. Non-government rescue or emergency squads . . $25.00

25.3.9. Non-government humane societies $25.00

25.3.10 All government agencies or employees are exempt from paying the fee.

§15-1-26. Emergency Dispensing by Pharmacists.

26.1. A pharmacist may dispense an emergency supply refill of life-sustaining prescription drugs to a patient without a prescription when, in the professional judgment of the pharmacist, the emergency supply is appropriate and the prescribing practitioner is not available. The emergency supply may not be more than a ten (10) days supply and the pharmacist shall immediately document the dispensing indicating the patient name, drug and its strength and amount, date filled, the name of the dispensing pharmacist, and the reasons for emergency dispensing. The dispensing pharmacist shall contact the prescribing practitioner as soon as possible subsequent to the drugs being dispensed.

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Board of Pharmacy

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RESPONSES TO COMMENTS RECEIVED TO PROPOSED RULES

(Including explanation of amendments made to the proposed rule as a result of comments)

TITLE 15, SERIES 1 (WV CSR 15-1-1, et seq.)
LICENSURE AND PRACTICE OF PHARMACY
Pertaining to SB 81, West Virginia Official Prescription Paper Program

The Board of Pharmacy received written public comments to the proposed rules filed with the Secretary of State on June 17, 2010, making amendments to Title 15, Series 1. The Board reviewed those comments at a public meeting on July 21, 2010. Following are the Board's responses to those comments.

1. The Board received a written comment from Dr. R. Thomas Bowden of Charleston Internal Medicine Inc referencing Section 15-1-9.1.2, and specifically discussing the requirements for physician's signatures on prescriptions. He asks that the Board consider amending the rule to allow for electronic signatures on written prescriptions issued by practitioners that are taken to the pharmacy by patients. He references that the electronic prescribing software and electronic medical or health records used in many practices today are highly secure, and allow him to generate prescriptions with his electronic signature. He indicates his belief that a faxed prescription may have an electronic signature; however this is incorrect, as any written prescription, including a faxed prescription, must have a wet signature under current law (in the instances that a physician faxes a prescription and fails to sign it, the pharmacy may, if it chooses, decide to treat the prescription as an oral prescription, call the prescriber's office to verify it, and fill it). The Board voted to reject this recommendation at this time. First, federal law on controlled substances does not allow for any electronic signature on any written or faxed prescriptions. While Dr. Bowden in oral discussions focused his comments on non-controlled prescriptions, the federal law in instructive, as they view it as a security and potential identity theft/forgery issue. A pharmacy must be sure on any kind of prescription that it was actually issued by a properly authorized prescriber in the ordinary course of practice and for a legitimate medical purpose. A physician's actual signature on a written prescription is very important for that verification. The DEA's position on controlled substances does permit electronic signatures on electronic prescriptions, but,

even then, they have very stringent standards requiring both the sending electronic prescription software, any third party data intermediary, and the receiving pharmacy's software to be officially certified through a federally approved third-party audit or certification for verification of the identity of the sender of the prescription. In no instance is it authorized for prescriptions actually handed to the patient. The opportunity for abuse, including forgery, is too great given the nature of electronic documents and the ease of reproduction. As such, the Board will not make any modifications or amendments on this point at this time. The Board did vote to study this issue, however.

2. The Board received one comment from Mark Polen of The Arnold Agency. He, in essence, asks that Section 15-1-21.1 be amended to add language setting forth many requirements for electronic prescribing software and electronic health records, requiring that they provide prescribers with certain information or refrain from suggesting certain alternative therapies or drugs during the electronic prescribing process. This proposal is about electronic health records and e-prescribing, and is not relevant to the issue at hand, which is the creation of official prescription paper for written prescriptions in this State. Further, the Board has no jurisdiction to require that electronic prescribing systems or electronic health records provide or not provide certain information to the prescribers. As such, the Board will not make any modifications or amendments on this point at this time. However, this comment does touch on the project being conducted by the West Virginia Health Information Network which is funded by the West Virginia Department of Health and Human Resources. The Board notes this as it supports its position to potentially refer this Official Prescription Program to the WVDHHR which is set forth below.

3. The Board received a comment from the West Virginia State Medical Association ("WVSMA") supporting this effort to prevent drug diversion through fraudulently obtained and/or altered written prescriptions. However, WVSMA also raises several points of concern with the proposed rules implementing Senate Bill 81:

    a) WVSMA points out that SB 81 was modeled after the similar program and statute in place in the State of New York, and indicates that the New York program runs out of equivalent to this State's Department of Health and Human Resources. New York's Medicaid program, also under its DHHR, has used its significant savings from avoiding reimbursing for fraudulent prescriptions to pay for all of the costs associated with their program. However, the Board of Pharmacy here does not have any ability to provide such funding, so that it anticipates passing along all of the costs to the prescribers and vendor. Because the Board of Pharmacy does not have the funding or staff to create and operate a single database created to house the information for verification by providers and payers of the prescription paper presented for dispensing, WVSMA correctly anticipates the Board's likely approach of selecting a single vendor who would be required as part of the bid and contract process to both provide the paper and create and maintain the database that would be needed. In that case, WVSMA does not support a monopoly. Additionally, because of the added expense to the ultimate vendor for the database, WVSMA is concerned about the price that prescribers will have to pay for the prescription paper, which, to this point, is fully unknown. In evaluating these comments, the Board agrees that it cannot implement this

program in a comprehensive nature such as is in place in New York. Further, because of the unknown nature of the database which would be necessary, and the unknown cost of the prescription paper which must be borne by the prescribers, the Board concluded that it needs further study of this issue, and encourages the Legislature to consider placing the program under the WVDHHR which will directly recognize any cost savings to its budget from the program and will be best positioned to fund and staff it. As such, the Board voted to withdraw all rules changes it proposed pertaining to SB 81 at this time to allow for further investigation and study. Therefore, the Board deleted the proposed changes to Sections 15-1-21.1.2, and 21.1.3, and deleted all of newly proposed Section 15-1-27. Thus, the only changes remaining to the rule are in Sections 15-1-21.1 and 15-1-21.4 (now renumbered as 21.3), to which no public comments were received.

b) In its comment to Section 15-1-27.6.a, of the proposed rule, WVSMA points out that it requires prescribers to take certain safety measures to prevent loss, destruction, theft, or unauthorized use of the prescription paper that would be issued to them. While supportive of the concept, WVSMA points out that it requires the prescribers to maintain certain records, and believes this would place an undue burden on the prescribers' work flow and practices. Chief among that concern is the language that would require maintenance "of a record of the disposition of all forms, including but not limited to use as a prescription, cancellation, return, loss, destruction, unauthorized use, and non-receipt." Further, the Board has no jurisdiction for enforcement over any of the prescribers for this or any other issue which arises under this new program. Therefore, the Board recognizes that these concern as valid, and believes it needs further study. If it were going forward with the rules at this time, the Board would amend the language to strike the words "use as a prescription" and go forward with the remainder of this clause. However, as stated above, the Board voted to withdraw all rules changes it proposed pertaining to SB 81 at this time to allow for further investigation and study.

c) In its comment to Section 15-1-27.6.c. of the proposed rule, WVSMA requests the Board to amend the requirement that a prescriber who has retired, or the next of kin to a prescriber that has died, be required to return to the vendor any unused prescription paper. They suggest that the prescriber or the responsible party on behalf of the estate be allowed to simply destroy any unused prescription paper, and notify the Board of the destruction as allowed in subsection 27.6.b. The Board voted to accept this recommendation, and would modify the rule accordingly. However, as stated above, the Board voted to withdraw all rules changes it proposed pertaining to SB 81 at this time to allow for further investigation and study.

d) In its comment to Section 15-1-27.6.d, of the proposed rule, WVSMA points out that the language requires the selected vendor to provide audits of the prescription paper it issues and has on-hand. WVSMA is concerned that this would require intrusive audits into the prescribers' offices. Although that is not what was contemplated by the Board, the language, which it borrowed from New York's

program, is very broad, and would appear to allow for this. Obviously, for the program to be successful, the State would need to have some control over the paper supply, which necessitates the ability to have meaningful audits. However, as stated above, the Board voted to withdraw all rules changes it proposed pertaining to SB 81 at this time to allow for further investigation and study, including into how New York handles this issue.

4. The Board received a comment from the National Association of Chain Drug Stores ("NACDS") raising several points of concern with newly proposed Section 15-1-27. Part of the comment, regarding Subsection 15-1-27.5 is well-taken, and, if the Board were moving forward with the proposed rule, would be accepted. However, as stated above, the Board voted to withdraw all rules changes it proposed pertaining to SB 81 at this time to allow for further investigation and study. In so stating, it is important for the Board to note that NACDS' comments pertaining to Subsection 15-1-27.2 about how the paper would be required to be capable of supporting automated validation through the use of pharmacy claims processing systems and the official control numbers that would be required for each blank dovetail directly with WVSMSA's concerns about how the database required for such a process would work. As NACDS notes, the Board is not yet clear as to how that database will be constructed or how the information required will be reported into it. The Board needs further study into this issue, specifically into how New York operates its database and claims verification process to get appropriate information about the issued prescriptions, and to avoid reimbursing for fraudulent written prescriptions in its program.

In conclusion, while the Board accepted certain comments and agreed to make modifications to the proposed rules as outlined above, and rejected certain other comments, based upon the further concerns raised by the WVSMA and NACDS, and based upon other issues apparent to the Board, it voted to withdraw the rules as they pertain to SB 81 at this time. The other changes to 15-1-21 are pertinent changes as a result of changes to Series 8 which are currently pending, however, and the Board wishes to go forward with those changes. Therefore, it deleted the proposed changes to Sections 15-1-21.1.2, and 21.1.3, and deleted all of newly proposed Section 15-1-27, leaving only the changes in Sections 15-1-21.1 and 15-1-21.4 (now renumbered as 21.3), to which no public comments were received. Thus, the Board has stripped any changes related to SB 81, and desires to go forward with the minor modifications to the rules which remain.

Prepared by:

David E. Potters

David E. Potters
Executive Director and General Counsel

CIM
Charleston Internal Medicine, Inc.

July 9, 2010

West Virginia Secretary of State
Administrative Law Division
c/o Natalie E. Tennant
Building 1 Suite 157-K
1900 Kanawha Blvd, East
Charleston, WV 25305-0770

Dear Ms. Tennant:

I am writing this letter in response to a public comment we requested regarding 15 space CSR 1 Board of Pharmacy Rules regarding licensure and the practice of pharmacy. More specifically, section 9.1.2 of section A2 and B2.

As our State is advancing in the computer era, as recommended in all healthcare and Legislative circles, I find it interesting that we still do not allow for electronic signatures on written prescriptions that are taken to the pharmacy by our patients.

I am aware of certain Legislative changes that are proposed for the electronic transfer from physician offices to pharmacies and the like, but still, a lot of work is needed.

Under the sections referenced above, "the practitioner's signature" could be changed to "the practitioner's signature or electronic signature."

As you can see, we, as practicing physicians in the State of West Virginia, are slowly adopting electronic medical record, myself having this capability for the past four years and utilizing it to protect my patients' well-being.

As you probably know, the requirements for privacy are high, especially in this electronic age and with healthcare, and I can assure you most systems have repeated levels of security that allowed me to generate a prescription with my electronic signature just like in the case of a faxed prescription that was handwritten. Since the electronic signature of a fax prescription is allowed under West Virginia law, I do not see why a computer-generated reproduction of my personal signature could not be allowed also.

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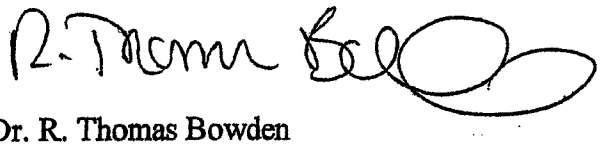
As we move forward in these changes, I think this is the time since proposed changes are already being made, to make these changes to allow this electronic signature to a hard copy prescription legal for pharmacies to fill in the State of West Virginia.

Thank you very much for your time and I do request a response to this inquiry, and I would like to be updated on any further changes in this matter.

Sincerely,



Dr. R. Thomas Bowden
Charleston Internal Medicine Inc.

RTB/dlh

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July 16, 2010

David E. Potters
Executive Director & General Counsel
West Virginia Board of Pharmacy
232 Capitol Street
Charleston, WV 25301

RE: Comments on Proposed Series 1 "Board of Pharmacy Rule Regarding Licensure and the Practice of Pharmacy"

Dear Mr. Potters:

I would like to submit the following formal written comments in connection with the Board's proposed modifications to its Series 1 rule pertaining to licensure and the practice of pharmacy that were filed with the Secretary of State on June 17, 2010.

As I understand the proposed rule, it is in response to legislative action taken during the 2010 session creating the West Virginia Official Prescription Program Act. I believe that this proposed rule can be improved and clarified through the inclusion of the following new subdivision as a part of the proposed new language of Section 21.1:

21.1.4. Electronic equipment for transmitting prescriptions (or electronic transmittal technology) must be designed to promote the highest quality of patient care by: (a) using an open platform without regard to commercial interests of any particular health insurance plan or payor; (b) transmitting only scientifically accurate, balanced and unbiased information to healthcare providers and their staff; (c) supporting access to data necessary for clinical decision-making, including for example, adverse events and up to date formulary information (e.g. tier and co-pay); (d) allowing a healthcare provider to electronically include instructions to the pharmacy not to substitute a prescribed medication; (e) facilitating navigation of health plan administrative requirements, including a means to seek exceptions for coverage of restricted medications using a uniform prior authorization form; and (f) including equivalent capability for healthcare providers to access information about, prescribe and transmit a prescription to a pharmacy for any medication available in the United States, without any barriers, including for example, those based on formulary status.

The modification to the proposed rule we propose will, in my view, be a complement to the Board's work in this area and a significant enhancement of the ability of prescribing providers and patients to ensure that treatment plans are followed for maximum patient benefit. I welcome your support of this modification and its inclusion in a revised rule prior to it being considered by the Legislative Rule-Making Review Committee.

Thank you very much for your consideration.

Sincerely,

Mark Polen
President

WEST VIRGINIA State Medical Association

RECEIVED ON

JUL 19 2010

WV BOARD OF PHARMACY

Mr. David E. Potters
Executive Director
WV Board of Pharmacy
C/O Series 1 Public Comments
232 Capitol Street
Charleston, WV 25301

Dear Mr. Potters,

Thank you for the opportunity to provide written comment to the West Virginia Board of Pharmacy regarding your rule **15 CSR 1 Board of Pharmacy Rules Regarding Licensure and the Practice of Pharmacy**. As you know, the West Virginia State Medical Association supported the passage of **SB 81 Creating the WV Official Prescription Program Act**. Fraudulently obtained and/or altered written prescriptions are a significant problem in the state of West Virginia as well as nationwide. Addressing this issue is a critically important component in reducing drug diversion overall. This is why the WVSMA was a supporter of the legislation.

In our review of this rule we have identified a few issues and questions that we would like to raise here and hope our comment is constructive as you finalize this document.

First we would like to comment on the issue of the choice of the vendor. The statute contemplates the approval by the Board of Pharmacy (Board) more than one vendor. As the bill was originally written, the responsibility of establishing this program lied within the Department of Health and Human Resources. This was modeled after the statute in the state of New York which was the first state to mandate such a statewide program. Their health department runs the program and also assumes all the costs of implementing the program including the cost of the prescription paper distributed to practitioners in the state. The argument for this is justified since their state Medicaid program has appreciated a savings in excess of $140 million from their program. As this bill was passed, this responsibility was moved to the Board of Pharmacy and the burden of the cost was placed upon the physicians and other practitioners who must use the paper.

Understanding this reality, it is not the interest of the WVSMA to support the creation of a monopoly. Given that the physicians will bear the burden of the cost of the paper (which historically has been provided free of charge in many instances from various pharmaceutical manufacturers) yet the gross benefit of the program will be assumed by Medicaid, PEIA and private insurers. Additionally, we have a strong concern regarding the unknown cost of the paper and ultimate impact on physicians since the price has not been contemplated in this rule.

It is our interest to ensure this program is kept competitive so that the price of the paper does not become prohibitive. If a concern of the Board's is that it would be difficult to implement a program with official prescription numbers if there were multiple vendors due to the requirement to maintain a database housing the information, then we recommend that at this time the Board not implement that component of the program. Understanding that per the statute under **§16-5W-4 (c)** it is permissible

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for the board to choose whether to implement that feature. It was foreseen by the WVSMA that this program would simply expand to all prescriptions similar provisions established by Medicaid for their tamper resistant prescription program.

Section 15-1-27.6.a requires physicians to undertake adequate safeguards and security measures to assure against the loss, destruction, theft or unauthorized use of the forms. This language seems reasonable and appropriate given the purpose of the rule. However, the section further requires physicians to "maintain a record of the disposition of all forms, including but not limited to use as a prescription, cancellation, return, loss, destruction, unauthorized use and non-receipt". It is unclear as to what type of record must be maintained and how the practices will implement this process. The WVSMA has serious concern with the hassle factor that will be placed upon physician offices to comply with this provision and the minutia of detail that has been contemplated. In light of the focus on administrative simplification in the reforming healthcare system, this type of requirement will place a new undue burden on practices and for what purpose?

In addition to this concern, and possibly the more important point, the WVSMA fears the Board has overstepped their authority and is contemplating the regulation of physicians and other practitioners under this rule. It is the opinion of the WVSMA that the statute is not so far reaching as to place such regulatory authority within the hands of the Board of Pharmacy.

Section 15-1-27.6.c contemplates the closure of a physician office due to retirement, death or other factors. The rule requires the physician or their "next of kin" to return to the vendor any unused prescription paper. Yet again, this requirement puts an undue burden on the practitioner, and in the incidence of a death, those responsible for handling their estate. Additionally, it would be reasonable to assume that the general population beyond the physician themselves would likely not be aware of this requirement and fail to comply. We question the impact on the liability to the physician and the person responsible for handling their estate. Understanding that the statute does contemplate the notification to the board of the loss, destruction etc., of the paper. The WVSMA recommends the physician simply be required to destroy the remaining prescriptions and notify the board of the destruction.

Section 15-1-27.6.d requires the program vendor to provide audits of the prescription paper blanks. It is unclear as to who the audits are of, but seems to reference the physicians and other practitioners. For what purpose would these audits be done and why would the state give such authority to a paper vendor? If this is an audit of the physician office, the WVSMA has serious concern and requests clarification on the purpose and breadth of such envisioned audits.

We thank you for your consideration of our comments and offer you an open door to discuss any of the issues we have raised with us.

Sincerely,

Carlos C. Jimenez, MD
President

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

July 16, 2010

Sent via Certified U.S. Mail and facsimile (304.558.0572) and

David E. Potters, Executive Director and General Counsel
West Virginia Board of Pharmacy
232 Capitol Street
Charleston, WV 25301

RE: Board of Pharmacy Rules regarding West Virginia Official Prescription Paper Program -- CO Series I Public Comments

Dear Executive Director and General Counsel Potters:

On behalf of our members operating pharmacies in the state of West Virginia, the National Association of Chain Drug Stores is submitting comments on the proposed rules regarding licensure and the practice of pharmacy. In particular, we are commenting on Section 15-1-27.

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We have fourteen members operating approximately 272 pharmacies in the State of West Virginia. NACDS members operating in West Virginia include RiteAid, CVS Caremark, Wal-mart, Fruth Pharmacies, Health Mart, Medicine Shoppe, Drug Emporium of West Virginia, Sears Holding, Target, Walgreen Company, Ahold, and Weis Markets.

NACDS members operating in West Virginia support the Board of Pharmacy's efforts to address requirements for the West Virginia Official Prescription Paper Program. However, as the Board of Pharmacy moves forward with these proposed rules, we have several comments and ask for the Board's assistance in clarifying certain provisions.

Intent of Section 15-1-27.2

We have questions about the intent of provision 4 in section 15-1-27.2 for the definition of "West Virginia Official Prescription Paper" which provides in pertinent part as follows:

> 'West Virginia Official Prescription Paper' means prescription paper, which has been authorized by the state for use, and meets the following criteria:
> . . .
> 4. Capable of supporting automated validation through pharmacy claims processing systems using the official state prescription control number.

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It is not clear to us what is meant by "supporting automated validation through pharmacy claims processing systems." While pharmacies can collect the official

prescription control number from the official prescription paper and report it to the prescription monitoring program, we do not believe that they are capable of automated validation in the claims processing system of the control number that is printed on the prescription paper. Does the Board mean by this that the official prescription forms would have use barcodes for the serial number?

Another issue is that the claims processing systems is different from the pharmacy computer systems. Claims processing systems are part of third party payor systems, not pharmacy computer systems. How does the Board intend this requirement to be placed on the program vendor? In any event, we ask for clarification from the Board on how this would operate for pharmacies and what it would mean for pharmacy computer systems and processing of prescriptions. For instance, does the Board intend that the program vendor would use a barcode on the official prescription paper that could be scanned?

For these reasons, we ask for the Board's consideration of the following clarifying changes.

27.2. Definitions. As used in this rule:

a. "Program Vendor" means the private contractor or contractors selected to manage the production and delivery of official state prescription paper.

b. "West Virginia Official Prescription Paper" means prescription paper, which has been authorized by the state for use, and meets the following criteria:

1. Prevention of unauthorized copying;

2. Prevention of erasure or modification:

3. An ability to prevent counterfeit prescription pads: and

4. Capable of supporting automated *recording of the control number* ~~validation~~ through *use of a barcode for* ~~pharmacy claims processing systems using~~ the official state prescription control number.

Section 15-1-27.5

We also ask that section 15-1-27.5 in the proposed regulation state affirmatively that pharmacists may fill prescriptions from out of state practitioners that are not written on the official prescription paper. While we understand that the proposed regulation provides that every prescription written in West Virginia must be written on West Virginia Official Prescription Paper and that pharmacists may not fill a written prescription from a West Virginia practitioner unless issued upon an official state issued prescription form, we believe that a statement in the proposed rule that pharmacies may dispense prescriptions from out of state practitioners that are not

written on the official prescription paper would provide needed clarification for pharmacists.

Thank you for your consideration of our comments. Should you have any questions or need any further information, please do not hesitate to contact us.

Sincerely,

Diane L. Darvey

Diane L. Darvey, Pharm.D., JD
Director, Public Policy, Government Affairs