

WEST VIRGINIA  
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OFFICE WEST VIRGINIA  
SECRETARY OF STATE

ADMINISTRATIVE LAW DIVISION

Form #3

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 30-5-1 (SB 1001, 2007 1ST Special Session) Electronic Prescribing

AMENDMENT TO AN EXISTING RULE: YES  NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 1

TITLE OF RULE BEING AMENDED: General: Definitions: and Manner of Issuance of a Prescription

Licensure & 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



## Board of Pharmacy

Phone (304) 558-0558

Fax (304) 558-0572

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 proposed regulations with the Secretary of State and the Legislative Rulemaking and Review Committee:

- (1) Electronic Prescribing (per SB 1001, 2007 1<sup>st</sup> Special Session);
- (2) Pharmacist Administration of Immunizations (per HB 3056, 2008 Regular Session); and
- (3) Regulation of Charitable Clinic Pharmacies (per SB 722, 2008 Regular Session).

This approval was granted by the Board at its regular meeting on July 14, 2008, wherein the Board reviewed drafts of the proposed regulations, and authorized our Executive Director and General Counsel, David E. Potters, to respond to any public comments properly received. In authorizing Mr. Potters to respond to the public comments, the Board further authorized him to make modifications or amendments to the proposed regulations as were appropriate in accordance with the goals and direction given by the Board in drafting these rules.

Signed this 29th day of August, 2008,

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: August 29, 2008

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: REGULATION OF ELECTRONIC PRESCRIBING  
(E-PRESCRIBING)  
(PART OF TITLE 15)

1. Authorizing statute(s) citation WV CODE SECTION 30-5-1 (SB 1001, 2007 1ST  
SPECIAL SESSION)

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:  
July 30, 2008--Public Comment Period

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:  
August 29, 2008

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)

August 29, 2008

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

David E. Potters  
Executive Director and General Counsel  
232 Capitol Street

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Charleston, West Virginia 25301

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304-558-0558  
304-558-0572 (fax)

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- g. **IF DIFFERENT 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

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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.

N/A

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b. Date of hearing or comment period:

N/A

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

N/A

d. Attach findings and determinations and reasons:

Attached N/A

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

Regulation of Electronic Prescribing (E-prescribing)

15 CSR 1

**Summary and Statement of Circumstances:** SB 1001, passed during the First Special Session, 2007, and duly enacted into law, permits electronic prescribing (e-prescribing) of legend drugs in this State, including through the use of electronic data intermediaries as defined therein. SB 1001 contains the following directive to the West Virginia Board of Pharmacy as set forth in West Virginia Code Section 30-5-12C(d): "The board shall promulgate emergency rules pursuant to the provisions of article three, chapter twenty-nine-a of this code to implement and enforce the provisions of this section." The Board did file emergency rules, which were in place, but since lapsed. This is a final version to put through the full Legislative Rule process. While the current rules allowed for electronic transmission of prescriptions, SB 1001 sets additional parameters defining this growing area. In addition, prescription drug diversion is an ongoing problem in this State and nation; e-prescribing done correctly is one method to combat the problem often perpetrated through passing fraudulent written prescriptions. Finally, e-prescribing aids in the accuracy of prescriptions by more timely presenting them electronically from the prescriber's office to the pharmacy in a clearly legible format, thus reducing fill-errors and facilitating patient compliance with the prescribed treatment.

Therefore, in accordance with the directive set forth by the Legislature, the purpose of this rule is to revise existing rules governing issuance of prescription orders to set specific standards to govern e-prescribing in West Virginia, thereby protecting the public health, safety, and welfare with regard to restricted drugs which may only be obtained by patients with a proper prescription.

**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](http://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:** Strike-throughs in the proposed rule indicate language that would be stricken from the present law, and underscoring indicates new language that would be added.

FISCAL NOTE FOR PROPOSED RULE

Rule Title: SB 1001 et seq: E-Prescribing

Type of Rule:  Legislative  Interpretive  Procedural

Agency: West Virginia Board of Pharmacy

Address: 232 Capitol Street, Charleston, West Virginia 25301

Phone Number: (304) 558-0558 Email: dpotters@wvbop.com

**Fiscal Note Summary**

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

While the current rules allowed for electronic transmission of prescriptions, SB 1001 sets additional parameters defining this growing area. Therefore, in accordance with the directive set forth by the Legislature, the purpose of this rule is to revise existing rules governing issuance of prescription orders to set specific standards to govern e-prescribing in West Virginia, thereby protecting the public health, safety, and welfare with regard to restricted drugs which may only be obtained by patients with a proper prescription. This rule will not have any impact on the day-to-day operations of the Board, and should have no financial impact to the State.

**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			
Current Expenses			
Repairs & Alterations			
Assets			
Other			
2. Estimated Total Revenues	0.00	0.00	0.00

Rule Title: \_\_\_\_\_

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

This rule will not have any impact on the day-to-day operations of the Board, and should have no financial impact to the State.

### 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.

Date: July 31, 2008

Signature of Agency Head or Authorized Representative

David E. Patters

TITLE 15  
LEGISLATIVE RULE  
WEST VIRGINIA BOARD OF PHARMACY

FILED

2007 FEB -4 AM 11:07

SERIES 1  
BOARD OF PHARMACY RULES REGARDING LICENSURE AND THE PRACTICE  
OF PHARMACY

OFFICE WEST VIRGINIA  
SECRETARY OF STATE

**§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 in accordance with SB 1001 passed during the 2007 1st Special Legislative Session; 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) and 30-5-19

1.3 Filing date -- June 25, 2002\_\_\_\_\_.

1.4 Effective date -- June 30, 2002\_\_\_\_\_.

**§15-1-2. Definitions.**

2.1. The following words and phrases as used in this Rule have the following meanings, unless the context otherwise requires:

2.1.1. "Act" or "Uniform Controlled Substance Act" means ~~and refers to~~ W. Va. Code §60a-1-1-60A-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:

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

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

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 judgement, 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 section, 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 or the West Virginia Uniform Controlled Substances Act.

2.1.8. The term "Cosmetic" which shall be held to include "Dentifrice" and "Toilet articles" means:

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; and

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

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:

a. Articles recognized as drugs by the U. S. Food and Drug Administration (FDA) and/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;

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

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:

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

1. Known significant allergies;
2. Rational drug therapy and contraindications;
3. Reasonable dose and route of administration; and
4. Reasonable directions for use.

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

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

1. Drug-drug;
2. Drug-food;
3. Drug-disease; and
4. Adverse drug reactions.

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:

- a. An electronic prescription order;
- b. A refill authorization request;
- c. A communication; or
- 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".

2.1.17-2.1.19. "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.

- ~~2.1.18~~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.
- ~~2.1.19~~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, penal institution, hospice, public health facility, or athletic facility.
- ~~2.1.20~~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.
- ~~2.1.21~~2.1.23. "Intern" means an individual who is:
- 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;
  - 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;
  - c. A qualified applicant who is licensed by the Board and is awaiting examination for licensure; or
  - d. An individual participating in a residency or fellowship program.
- ~~2.1.22~~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.
- ~~2.1.23~~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 otherwise.
- ~~2.1.24~~2.1.26. "Manufacturer" means a person engaged in the manufacturing of drugs or devices.
- ~~2.1.25~~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 the substance(s) or labeling or relabeling of its contents and the promotion and marketing of the drugs or devices. Manufacturing also includes the preparation or repackaging, and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners or other persons.
- ~~2.1.26~~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.
- ~~2.1.27~~2.1.29. "Nuclear pharmacist" means a pharmacist who has been certified in the specialty of nuclear pharmacy.
- ~~2.1.28~~2.1.30. "Nuclear pharmacy" means a place where radioactive drugs are prepared and dispensed and which operates under specialized rules.
- ~~2.1.29~~2.1.31. "Original License" means a license issued by the Board to an applicant when:

- a. the applicant is a new business;
- b. the applicant is an established business that is transferred to a successor;
- c. the applicant is an established business in which fifty percent (50%) ownership or more is transferred to a new owner;
- d. the applicant is an established business in which control of pharmaceutical services is transferred; not including a change in pharmacist-in-charge; or
- e. the applicant is an established business which moves to a new location.

~~2.1.30-2.1.32.~~ "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. ~~The terms pharmacy, drug store, or apothecary do not include a free clinic or physician's office that dispenses drugs for free.~~

~~2.1.31-2.1.33.~~ "Over-the counter drug" or "OTC drug" means any drug that is not a prescription drug or legend drug.

~~2.1.32-2.1.34.~~ "Patient counseling" means the oral communication by the pharmacist of information, which may include supplemental media according to the pharmacist's professional judgement, to the patient or care giver, to ensure the proper use of drugs and devices.

~~2.1.33-2.1.35.~~ "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.

~~2.1.34-2.1.36.~~ "Person" means an individual, corporation, partnership, association or any other legal entity, including government.

~~2.1.35-2.1.37.~~ "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.

~~2.1.36-2.1.38.~~ "Pharmaceutical care" is the provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes related to:

- a. The cure or prevention of a disease;
- b. the elimination or reduction of a patient's symptoms; or
- c. the arresting or slowing of a disease process.

~~2.1.37-2.1.39.~~ "Pharmacist" or "registered pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacy and pharmaceutical care.

~~2.1.38-2.1.40.~~ "Pharmacist-in-charge" means a pharmacist currently licensed in this state who:

- 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;

- 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 on administrative and operational matters but following such advice shall not be legally ~~required~~ responsible; and

- 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

d. Notwithstanding the requirements of subsection c. above, with regard to a pharmacist-in-charge in a Charitable Clinic Pharmacy, if the pharmacy is open an average of more than 40 hours per week, the pharmacist-in-charge must work at least 8 hours per calendar month; if the charitable clinic pharmacy is open on average at least 30 and up to 40 hours per week, the pharmacist-in-charge must work in the charitable clinic pharmacy at least 6 hours per calendar month; if the charitable clinic pharmacy is open on average at least 15 and up to 30 hours per week, the pharmacist-in-charge 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 must work 2 hours per calendar month; and, if the charitable clinic pharmacy is open less than 5 hours per week, the pharmacist-in-charge 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.

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

~~2.1.39~~-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 dispensing physician or other such dispenser by his or her own State licensing board.

~~2.1.40~~-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.

~~2.1.41~~-2.1.43. "The practice of pharmacy" is the personal health service 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.

~~2.1.42~~-2.1.44. "Practitioner" means an individual currently licensed, registered or otherwise authorized by the jurisdiction in which he or she practices to prescribe and administer drugs in the course of professional practices, as allowed by law.

~~2.1.43~~-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.

~~2.1.44~~-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.

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

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.

~~2.1.45-2.1.47.~~ "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:

a. Written order;

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

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

2. Hand initial it to identify the receiver; and

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

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

d. other methods of transmission approved by the Board.

~~2.1.46-2.1.48.~~ "President" means the President of the West Virginia Board of Pharmacy.

~~2.1.47-2.1.49.~~ "Sample" means a package of a legend drug provided by a manufacturer on the request of a practitioner to be given to a patient without charge.

~~2.1.48-2.1.50.~~ An approved or recognized "School of Pharmacy" means a school of pharmacy accredited by the American Council on Pharmaceutical Education.

~~2.1.49-2.1.51.~~ "Secretary" means the Secretary of the West Virginia Board of Pharmacy.

~~2.1.50-2.1.52.~~ "Vice-President" means the Vice-President of the West Virginia Board of Pharmacy.

~~2.1.51-2.1.53.~~ 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.

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

20.1. 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.

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

20.2.1. 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 on administrative and operational matters but following such advice shall not be legally required.

20.2.2. 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.

20.2.3. 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;

20.2.4. 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;

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

20.2.6. 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;

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

- a. Change of employment or responsibility as the PIC;
- b. Change of ownership of the pharmacy;
- c. Change of address of the pharmacy; or
- d. Permanent closing of the pharmacy;

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

20.2.9. 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;

20.2.10. 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

20.2.11. 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:

- a. The name and address of the pharmacy;
- b. The location of the automated equipment; and
- c. The identification of the responsible pharmacist.

20.3. 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.

20.3.1. 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.

20.3.2. 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.

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 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.

- 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, signed prescription ~~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:

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;

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

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. 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:

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);

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;

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.

21.1.5. 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:

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

- b. the prescription is transmitted ~~directly~~ either directly or through an electronic data intermediary to a pharmacist in a licensed pharmacy of the patient's choice with no unauthorized intervening person having access to the prescription;
- 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;
- d. the pharmacist exercises professional judgment regarding the accuracy, validity, and authenticity of the prescription communicated by way of electronic transmission; and
- e. all electronic equipment for receipt of prescriptions communicated by way of electronic transmission is maintained so as to ensure against unauthorized access.

#### 21.1.6 Electronic Data Intermediaries

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.

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

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

(2) Transmit prescriptions to the pharmacy of the patient's choice.

(3) Maintain the integrity, confidentiality, 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.

FILED

TITLE 15  
LEGISLATIVE RULE  
WEST VIRGINIA BOARD OF PHARMACY

2008 AUG 29 PM 5: 33

SERIES 1  
BOARD OF PHARMACY RULES REGARDING LICENSURE AND THE PRACTICE  
OF PHARMACY

OFFICE WEST VIRGINIA  
SECRETARY OF STATE

§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 in accordance with SB 1001 passed during the 2007 1st Special Legislative Session; 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) and 30-5-19

1.3 Filing date – June 25, 2002\_\_\_\_\_.

1.4 Effective date ---June 30, 2002\_\_\_\_\_.

§15-1-2. Definitions.

2.1. The following words and phrases as used in this Rule have the following meanings, unless the context otherwise requires:

2.1.1. "Act" or "Uniform Controlled Substance Act" means ~~and refers to~~ W. Va. Code §~~60a-1-1~~ 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:

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

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

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 judgement, 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 section, 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 or the West Virginia Uniform Controlled Substances Act.

2.1.8. The term "Cosmetic" which shall be held to include "Dentifrice" and "Toilet articles" means:

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; and

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

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:

a. Articles recognized as drugs by the U. S. Food and Drug Administration (FDA) and/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;

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

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:

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

1. Known significant allergies;

2. Rational drug therapy and contraindications;

3. Reasonable dose and route of administration; and

4. Reasonable directions for use.

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

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

1. Drug-drug;

2. Drug-food;

3. Drug-disease; and

4. Adverse drug reactions.

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:

(A) An electronic prescription order;

(B) A refill authorization request;

(C) A communication; or

(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".

~~2.1.17~~ 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.

~~2.1.18~~ 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.

~~2.1.19~~ 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, penal institution, hospice, public health facility, or athletic facility.

~~2.1.20~~ 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.

~~2.1.21~~ 2.1.23. "Intern" means an individual who is:

- 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;
- 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;
- c. A qualified applicant who is licensed by the Board and is awaiting examination for licensure; or
- d. An individual participating in a residency or fellowship program.

~~2.1.22~~ 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.

~~2.1.23~~ 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 otherwise.

~~2.1.24~~ 2.1.26. "Manufacturer" means a person engaged in the manufacturing of drugs or devices.

~~2.1.25~~ 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 the substance(s) or labeling or relabeling of its contents and the promotion and marketing of the drugs or devices. Manufacturing also includes the preparation or repackaging, and promotion of commercially available products from bulk compounds for resale by pharmacies,

practitioners or other persons.

~~2.1.26~~ 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.

~~2.1.27~~ 2.1.29. "Nuclear pharmacist" means a pharmacist who has been certified in the specialty of nuclear pharmacy.

~~2.1.28~~ 2.1.30. "Nuclear pharmacy" means a place where radioactive drugs are prepared and dispensed and which operates under specialized rules.

~~2.1.29~~ 2.1.31. "Original License" means a license issued by the Board to an applicant when:

- a. the applicant is a new business;
- b. the applicant is an established business that is transferred to a successor;
- c. the applicant is an established business in which fifty percent (50%) ownership or more is transferred to a new owner;
- d. the applicant is an established business in which control of pharmaceutical services is transferred; not including a change in pharmacist-in-charge; or
- e. the applicant is an established business which moves to a new location.

~~2.1.30~~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. The terms pharmacy, drug store, or apothecary do not include a free clinic or physician's office that dispenses drugs for free.

~~2.1.31~~2.1.33. "Over-the counter drug" or "OTC drug" means any drug that is not a prescription drug or legend drug.

~~2.1.32~~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 judgement, to the patient or care giver, to ensure the proper use of drugs and devices.

~~2.1.33~~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.

~~2.1.34~~2.1.36. "Person" means an individual, corporation, partnership, association or any other legal entity, including government.

~~2.1.35~~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.

~~2.1.36~~2.1.38. "Pharmaceutical care" is the provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes related to:

- a. The cure or prevention of a disease;
- b. the elimination or reduction of a patient's symptoms; or
- c. the arresting or slowing of a disease process.

~~2.1.37~~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.

~~2.1.38~~2.1.40. "Pharmacist-in-charge" means a pharmacist currently licensed in this state who:

- 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;
- 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 on administrative and operational matters but following such advice shall not be legally required; and
- 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.

~~2.1.39~~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.

~~2.1.40~~ ~~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.

~~2.1.41~~ ~~2.1.43~~. "The practice of pharmacy" is the personal health service 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.

~~2.1.42~~ ~~2.1.44~~. "Practitioner" means an individual currently licensed, registered or otherwise authorized by the jurisdiction in which he or she practices to prescribe and administer drugs in the course of professional practices, as allowed by law.

~~2.1.43~~ ~~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.

~~2.1.44~~ ~~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.

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

~~2.1.45~~ ~~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:

- a. Written order;
- b. An oral order to a pharmacist who shall immediately:
  1. Reduce it to writing which becomes the original order;
  2. Hand initial it to identify the receiver; and
  3. Show the date, time and name of person transmitting the order;
- 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
- d. other methods of transmission approved by the Board.

~~2.1.46~~ ~~2.1.48~~. "President" means the President of the West Virginia Board of Pharmacy.

~~2.1.47~~ ~~2.1.49~~. "Sample" means a package of a legend drug provided by a manufacturer on the request of a practitioner to be given to a patient without charge.

~~2.1.48~~ ~~2.1.50~~. An approved or recognized "School of Pharmacy" means a school of pharmacy accredited by the American Council on Pharmaceutical Education.

~~2.1.49~~ ~~2.1.51~~. "Secretary" means the Secretary of the West Virginia Board of Pharmacy.

~~2.1.50~~ ~~2.1.52~~. "Vice-President" means the Vice-President of the West Virginia Board of Pharmacy.

~~2.1.51~~ ~~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.

§15-1-21. 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.

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 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.

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, signed prescription~~ 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:

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;

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

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. 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:

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);

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;

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.

21.1.5. 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:

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

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;

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

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

#### 21.1.6 Electronic Data Intermediaries

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.

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

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

(2) Transmit prescriptions to the pharmacy of the patient's choice.

(8) Maintain the integrity, confidentiality, 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.



# Board of Pharmacy

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## RESPONSES TO COMMENTS RECEIVED

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

### PROPOSED REGULATIONS

Electronic Prescribing

WV CSR 15-1-1, et seq.

The Board of Pharmacy received written public comments to the proposed rules filed with the Secretary of State on July 30, 2008. Following are the Board's responses to those comments.

1. The Board received a comment from the National Association of Chain Drug Stores approving of the rules as proposed. The Board appreciates the support of NACDS.
2. The Board received an oral comment from counsel for the Board of Medicine inquiring as to what effects of the federal Drug Enforcement Administration's new proposed rules on e-prescribing of controlled substances may have on the Board's proposed rules. The DEA is proposing that Schedule II drugs be permitted to be prescribed by E-prescribing under federal law. The Board discussed this issue at its meeting on July 14, 2008, and stated that they wished to open up the regulations in West Virginia to allow for E-prescribing of controlled substances as may be allowed by the DEA regulations. Thus, the proposed regulations as filed by the Board on July 30, 2008, were amended to allow prescribing of Schedule II substances by E-prescribing. This was accomplished by adding the words "or by E-prescribing" and "other than E-prescribing" in Section 15-1-21 where indicated by underlining in the proposed rule, including in subsection 21.1.1, 21.1.2, and 21.1.3. Of course, if the DEA regulations are written with tighter controls, they will control through the doctrine of preemption. The Board thanks the Board of Medicine for their comment.

Prepared by:

David E. Potters

David E. Potters

Executive Director and General Counsel

February 12, 2008

Via email to [dpotters@wvbop.com](mailto:dpotters@wvbop.com)  
David E. Potters, Esq.  
Executive Director & General Counsel  
West Virginia Board of Pharmacy  
232 Capitol Street  
Charleston, WV 25301

RE: Emergency Rules for Electronic Prescribing

Dear Mr. Potters:

The National Association of Chain Drug Stores is a national trade association that represents 13 chain pharmacy companies that operate approximately 300 pharmacies in the State of West Virginia.

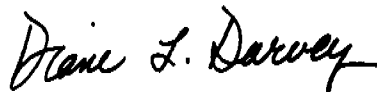
413 North Lee Street  
P.O. Box 1417-D49  
Alexandria, Virginia  
22313-1480

On behalf of our members operating in West Virginia, NACDS applauds the Board of Pharmacy for these rules that will foster the use of electronic prescriptions in the state. Electronic prescribing provides many benefits. E-prescribing enhances patient safety and enables a secure electronic prescribing environment for prescribing practitioners and pharmacies. In addition, the benefits of e-prescribing include preventing miscommunication due to illegible handwriting and unclear abbreviations, elimination of unclear telephone or verbal orders and instant connectivity between the prescriber and pharmacy.

In 2006, the Institute of Medicine (IOM) recommended that all prescriptions be received electronically by the year 2010. Recognizing the problems of today's paper system detailed in the IOM report, and recognizing the benefits of e-prescribing and the opportunities to reduce the costs of care, many are calling for the increased support for e-prescribing at the federal level and for controlled substances.

We thank the Board of Pharmacy for moving quickly with these emergency rules.

Sincerely,



Diane L. Darvey, Pharm.D., JD  
Director, Pharmacy Regulatory Affairs

(703) 549-3001

Fax (703) 836-4869

[www.nacds.org](http://www.nacds.org)

cc: Nicole Valentine, Regional Director, NACDS



**West Virginia Pharmacists Association**

2016 1/2 Kanawha Boulevard, East, Charleston, West Virginia 25311

Telephone (304) 344-5302 • FAX (304) 344-5316 • Email WVRDS@AOL.COM

August 29, 2008

West Virginia Board of Pharmacy  
232 Capitol Street  
Charleston, WV 25301

Hand Delivered

Dear Board Members:

Representing the profession of pharmacy in our State since the late 1890's, the West Virginia Pharmacists Association expresses its support of your proposed rule implementing electronic prescription procedures in our State.

Your Board is commended for its initiative in promulgating this rule. It will result in improved patient safety and help assure accurate prescribing and dispensing.

Your rule will assure standards for E-prescribing and establish a secure electronic prescribing environment for pharmacists and pharmacies.

Your rule is timely as electronic prescribing comprises three percent (3%) of the prescriptions in our State, and continues to grow. West Virginia pharmacists and pharmacies need your Board's rule as electronic prescribing is become a condition of some government prescription drug programs in the future.

Your Board is respectfully requested to approve your rule as you have proposed.

Very truly yours,

Richard D. Stevens  
Executive Director

August 28, 2008

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

**RECEIVED**  
AUG 29 2008  
WV BOARD OF PHARMACY

RE: Proposed Rules for Electronic Prescribing

Dear Mr. Potters:

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We thank the Board of Pharmacy for promulgating these proposed rules.

Sincerely,

*Diane L. Darvey*

Diane L. Darvey, Pharm.D., JD  
Director Legislative and Regulatory Affairs

cc: Nicole Valentine, Regional Director, NACDS