

**WEST VIRGINIA
SECRETARY OF STATE
BETTY IRELAND
ADMINISTRATIVE LAW DIVISION**

Form #7

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SECRETARY OF STATE

Effective Date

NOTICE OF AN EMERGENCY RULE

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

CITE AUTHORITY: Emergency Rule-Legislative

EMERGENCY AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 1

TITLE OF RULE BEING AMENDED: ~~Legislative Rule West Virginia Board of Pharmacy~~

Licensure and the Practice of Pharmacy

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _____

TITLE OF RULE BEING PROPOSED: _____

THE ABOVE RULE IS BEING FILED AS AN EMERGENCY RULE TO BECOME EFFECTIVE AFTER APPROVAL BY SECRETARY OF STATE OR 42ND DAY AFTER FILING, WHICHEVER OCCURS FIRST.

THE FACTS AND CIRCUMSTANCES CONSTITUTING THE EMERGENCY ARE AS FOLLOWS:

David E. Potters

Authorized Signature

Use additional sheets if necessary

#6,40

EMERGENCY RULE QUESTIONNAIRE

DATE: 1/4/2008

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

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

EMERGENCY RULE TITLE: Title 15

1. Date of filing January 4, 2008

2. Statutory authority for promulgating emergency rule:
West Virginia Code §§ 30-5-12C (d) and 30-5-19

3. Date of filing of proposed legislative rule: January 4, 2008.

4. Does the emergency rule adopt new language or does it amend or appeal a current legislative rule? _____
Amends a current legislative rule.

5. Has the same or similar emergency rule previously been filed and expired?
No

6. State, with particularity, those facts and circumstances which make the emergency rule necessary for the **immediate** preservation of public peace, health, safety or welfare.

The West Virginia Legislature has found e-prescribing to be in the best interests of the public peace, health, safety or welfare and has directed the West Virginia Board of Pharmacy to file emergency rules to permit e-prescribing. E-Prescribing is currently being done around the State without appropriate rules in place to protect the integrity, privacy, security, or confidentiality of the prescriptions. Further, e-prescribing aids in accuracy of prescriptions and reduces fill errors.

7. If the emergency rule was promulgated in order to comply with a time limit established by the Code or federal statute or regulation, cite the Code provision, federal statute or regulation and time limit established therein.

WV Code § 30--5-12 C (d) calls for emergency rules.

8. State, with particularity, those facts and circumstances which make the emergency rule necessary to prevent substantial harm to the public interest.

The West Virginia Legislature has found e-prescribing to be in the best interests of the public peace, health, safety or welfare and has directed the West Virginia Board of Pharmacy to file emergency rules to permit e-prescribing. E-Prescribing is currently being done around the State without appropriate rules in place to protect the integrity, privacy, security, or confidentiality of the prescriptions. Further, e-prescribing aids in accuracy or prescriptions and reduces fill errors.

**BRIEF SUMMARY OF AND STATEMENT OF CIRCUMSTANCES WHICH REQUIRE
THE PROPOSED EMERGENCY 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." E-prescribing is already being done by prescribers around the state, with the amount and frequency of electronic prescriptions being received by pharmacies increasing each day as the technology becomes more accepted and available in the industry. While the current rules allowed for electronic transmission of prescriptions, SB 1001 states that e-prescribing may not be done in this State until emergency rules are promulgated, and further sets additional parameters defining this growing area. As such, the e-prescribing currently being done in this State is being done without appropriate legislative rules in place to protect the integrity, privacy, security and confidentiality of the prescription orders. 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.

Given these factors, the Legislature, through its deliberative process, has determined that an emergency exists requiring the need for emergency rules to govern the use of e-prescribing and electronic data intermediaries in this State for patients to access prescription medications in a safe and efficient manner. Therefore, in accordance with that directive, the purpose of this emergency 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, 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.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Title 15

Type of Rule: Legislative Interpretive Procedural

Agency: West Virginia Board of Pharmacy

Address: 232 Capitol Street
Charleston, WV 25301

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

Fiscal Note Summary

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

None.

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: _____

Rule Title:

Title 15

3. Explanation of above estimates (including long-range effect):

Please include any increase or decrease in fees in your estimated total revenues.

Costs will be borne by private market. This simply allows prescribers and pharmacists/pharmacies to do e-prescribing as a method to write and deliver prescription orders.

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.

None

Date: January 4, 2008

Signature of Agency Head or Authorized Representative

David E. Potters

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

FILED
2008 JAN -4 PM 4:12
CLERK OF COURTS
STATE

SERIES 1
BOARD OF PHARMACY RULES REGARDING LICENSURE AND THE 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 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~~ 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. 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.

21.1.2. If communicated orally or by way of electronic transmission, 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 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.

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.



Board of Pharmacy

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

Office
232 Capitol Street
Charleston, West Virginia 25301

January 4, 2008

Honorable Betty Ireland
Secretary of State
Building 1, Suite 157-K/ 1900 Kanawha Blvd. East
Charleston, WV 25305-0770

Dear Honorable Betty Ireland:

Please find enclosed Fourteen (14) copies of Notice of an Emergency rule regarding e-prescribing.

Should you have any questions or concerns please feel free to contact me.

Sincerely,

David E. Potters
Executive Director and General Counsel

cc: LRMRC (w/enclosure)