WEST VIRGINIA
SECRETARY OF STATE
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OFFICE WEST VIRGINIA
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Effective Date

NOTICE OF AN EMERGENCY AMENDMENT TO AN EMERGENCY RULE

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

DATE EMERGENCY RULE WAS ORIGINALLY FILED: May 20, 2005

FIRST EMERGENCY AMENDMENT TO AN EXISTING RULE: YES x NO _____

SECOND EMERGENCY AMENDMENT TO AN EXISTING RULE: YES _____ NO _____

DATE OF FIRST EMERGENCY AMENDMENT: _____

SERIES NUMBER OF RULE: 11

TITLE OF RULE: ~~Ephedrine and Pseudoephedrine Control~~

THE ATTACHED IS AN EMERGENCY AMENDMENT TO AN EXISTING EMERGENCY RULE. THIS EMERGENCY AMENDMENT BECOMES EFFECTIVE AFTER APPROVAL BY SECRETARY OF STATE OR 42ND DAY AFTER FILING, WHICHEVER OCCURS FIRST.

THE FACTS AND CIRCUMSTANCES CONSTITUTING THE EMERGENCY AMENDMENT ARE AS FOLLOWS:

Amendments are being made after receiving written public comments. The key change is that the date that electronic reporting will be required has been changed to January 1, 2006. Other major changes include the number of years records must be kept and that electronic reporting will be at least monthly instead of weekly.

Use additonal sheets if necessary

William T. Douglass Jr.

Authorized Signature

304-558-0558

William T. Douglass Jr.

WEST VIRGINIA
SECRETARY OF STATE
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ADMINISTRATIVE LAW DIVISION

Form #7

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2005 MAY 20 P 2:06

Effective Date

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF AN EMERGENCY RULE

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

CITE AUTHORITY: §60A-10-7

EMERGENCY AMENDMENT TO AN EXISTING RULE: YES ____ NO X

IF YES, SERIES NUMBER OF RULE BEING AMENDED: ____

TITLE OF RULE BEING AMENDED: ____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 11

TITLE OF RULE BEING PROPOSED: Ephedrine and Pseudoephedrine Control

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:

SB 147 passed during the 2005 Legislative session requires the Board of Pharmacy to promulgate emergency and legislative rules before July 1, 2005 to implement a program to identify and limit access to drug products commonly used in the manufacture of methamphetamine.

Use additonal sheets if necessary

Legislative Rule Making

MAY 20 2005

Review Committee

William T. Douglass Jr.

Authorized Signature

William T. Douglass Jr.
304-558-0558

State of West Virginia
Board of Pharmacy

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

Office
232 Capitol Street
Charleston, West Virginia 25301

May 20, 2005

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

Dear Secretary Ireland:

I am writing to approve a proposed rule by the Board of Pharmacy being filed as an emergency rule, 15 CSR 11, Ephedrine and Pseudoephedrine Control. Thank you for your cooperation in this important matter.

Sincerely,

William T. Douglass, Jr.
Executive Director and
General Counsel

State of West Virginia
Board of Pharmacy

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

Office
232 Capitol Street
Charleston, West Virginia 25301

Summary of proposed rule- 15 CSR 11

The proposed rule is required to be promulgated by July 1, 2005 according to SB 147 passed during the 2005 legislative session. The rule establishes the requirements for the sale of Schedule V pseudoephedrine products from behind the pharmacy counter and the electronic reporting of required information. The rule lists certain persons who may lawfully possess Schedule V pseudoephedrine products and exempts from the classification products dispensed pursuant to a prescription. The rule requires records and invoices to kept for two years. The rule establishes a registration to sell, distribute, or transfer Schedule V pseudoephedrine products and the procedure to consult with the State Police to add products to a supplemental list.

EMERGENCY RULE QUESTIONNAIRE

DATE: May 20, 2005

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:(*Agency Name, Address & Phone No.*) West Virginia Board of Pharmacy
232 Capitol Street
Charleston, WV 25301 304-558-0558

EMERGENCY RULE TITLE: 15 CSR 11 Ephedrine and Pseudoephedrine Control

1. Date of filing May 20, 2005

2. Statutory authority for promulgating emergency rule:

~~§60A-10-7~~

3. Date of filing of proposed legislative rule: May 20, 2005

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

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.

~~SB 147 passed during 2005 Legislative session to restrict access to certain drug products containing pseudoephedrine that are being used in the illegal production of methamphetamine; i.e. "meth labs." The bill required rules be promulgated prior to~~ July 1, 2005.

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.

SB 147- WV Code §60A-10-7

Rules to be promulgated prior to July 1, 2005.

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

The illegal production of methamphetamine and abuse of this drug is creating ~~substantial harm to the public interest due to the crime and addiction arising from the~~ epidemic of meth use. The production of meth is an extremely volatile and dangerous ~~process that endangers entire neighborhoods and this rule will help in restricting access~~ to those products that are stolen or diverted to be used in these labs.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: 15 CSR 11 Ephedrine and Pseudoephedrine Control

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

Agency: West Virginia Board of Pharmacy

Address: 232 Capitol Street
Charleston, WV 25301

Phone Number: 304-558-0558 Email: wdouglass@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.

Board of Pharmacy is a special revenue account so rule will not have an impact on general revenue of state. The rule will add some intial increased cost for computer programming services to the Board in implementing the changes to allow for the electronic reporting of the pseudoephedrine products to the controlled substances monitoring program. The Board will be issuing limited distributor license for a $200 annual fee but there is no estimate of the number of distributors that will apply for such a license since most distributors of such products to pharmacies currently hold a full wholesale distributor license and will not need to obtain the limited permit.

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	2005 Increase/Decrease (use "-")	2006 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	10,000.00		
Personal Services			
Current Expenses			
Repairs & Alterations			
Assets			
Equipment			
Other	10,000.00		
2. Estimated Total Revenues			

Rule Title: 15 CSR 11 Ephedrine and Pseudoephedrine Control

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

Will charge $200 annual fee for limited Schedule V pseudoephedrine product distributor license. Will be very few if any applicants because pharmaceutical wholesale distributors that already hold a license from the board to distribute prescription drugs will not need an additional license. Therefore, only a distributor that ships such products currently to retail locations without a pharmacy that intends to ship these products to pharmacies will apply and obtain the license.

MEMORANDUM

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

The only fiscal impact would be the intial computer programming costs of approximately $10,000 to upgrade the controlled substances monitoring program to be able to receive transmissions of sales of Schedule V pseudoephedrine products. A small undetermined amount of revenue from issuance of limited distributor licenses may occur.

Date: May 20, 2005

Signature of Agency Head or Authorized Representative

William T. Douglass Jr.
304-558-0558

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 11
EPHEDRINE AND PSEUDOEPHEDRINE CONTROL

§15-11-1. General.

1.1. Scope. --- To establish rules for ephedrine and pseudoephedrine control in West Virginia including pharmacy reporting requirements; notification processes; and special registration for distributors. .

1.2. Authority. --- W. Va. Code §60A-10-1 et.seq .

1.3. Filing Date. --

1.4. Effective Date. --

§15-11-2. Definitions.

2.1. "Central repository" refers to the central repository designated by the Board for the collection of controlled substance information transmitted which may be a vendor designated by the Board and under contract with the Board to act as the central repository.

2.2."Schedule V pseudoephedrine products" means any compound, mixture or preparation containing as its single active ingredient ephedrine, pseudoephedrine or phenylpropanolamine, their salts or optical isomers, or salts of optical isomers, including any drug products added to the supplemental list pursuant to West Virginia Code §60A-10-7, except products which are for pediatric use primarily intended for administration to children under the age of twelve.

§15-11-3. Pharmacy Requirements

3.1. Schedule V pseudoephedrine prod -ucts may be sold, delivered, or provided only in licensed pharmacies by a pharmacist or registered pharmacy technician and may not be sold, delivered, or provided to any person who is under the age of eighteen.

3.2. Schedule V pseudoephedrine products shall be kept behind the pharmacy counter and all storage of these products shall be in a controlled and locked access location that is not accessible by the general public.

3.3. The pharmacist and all registrants with access to the Schedule V pseudoephedrine products will have an affirmative duty to guard against the theft and diversion of the products.

3.4. Any pharmacy that sells Schedule V pseudoephedrine products shall require the person purchasing, receiving or otherwise acquiring the drug product to:

(a) Produce a drivers license or government-issued photo identification showing his or her date of birth; and

(b) sign a form containing the information required by paragraph 4.1 of this rule and attesting to the validity of the information. The signature may be captured electronically and the information maintained as an electronic record as long as a hard copy may be produced upon request.

3.5. Each pharmacy, pharmacist, and registered pharmacy technician involved in the sale of the product shall have the responsibility to

ensure that the information required in this rule provided by the customer is recorded accurately.

3.6. The bound record book kept for distribution of Schedule V exempt narcotics pursuant to §15-2-7.19.1(e) may be used for recording the information required by this rule.

§15-11-4. Prescription Monitoring Program.

4.1. After January 1, 2006, each time any Schedule V pseudoephedrine product is transferred, sold, or delivered, the pharmacist or pharmacy technician shall electronically transmit not less than monthly to the central repository the following information:

(a) The date of the transaction;

(b) The name, address and driver's license or state-issued identification number of the person; and

(c) The name, National Drug Code (NDC) number, quantity of packages and total gram weight of the product or products purchased, received or otherwise acquired.

4.2. The information may be transmitted at any time during the month as a batch transmission and may be sent with the Schedule II, III, and IV information.

4.3. The Board and the central repository shall receive the electronic transmission of the information required to be provided by and through the use of a secure upoload from the pharmacy via the internet or other means approved by the Board. The pharmacy shall retain the information for 60 days after transmission to the central repository.

§15-11-5 Lawful possession of Schedule V pseudoephedrine products

5.1 The following persons are allowed to lawfully possess Schedule V pseudoephedrine products while in the course of legitimate business:

(a) Any Schedule V pseudoephedrine-only limited pharmaceutical distributor, or it agents, licensed by the Board;

(b) Any wholesale distributor, or its agents, licensed by the Board;

(c) Any manufacturer of controlled substances, or its agents, licensed by the Board;

(d) a pharmacist licensed by the Board or a pharmacy technician registered with the Board or other pharmacy employee under the direct supervision of a pharmacist;

(e) health care professionals appropriately licensed and engaged in legitimate patient care: and

(f) persons possessing such products pursuant to a valid prescription.

§15-11-6 Prescriptions for Schedule V pseudoephedrine products

6.1 Products containing pseudoephedrine that are dispensed pursuant to a valid prescription are exempt from classification as Schedule V and are subject to the requirements of non-scheduled prescription drugs. Any product that is dispensed by prescription must be provided in a container that is supplied by the pharmacy and must be labeled with the information required on a prescription label.

§15-11-7. Thirty day requirement

7.1 Pharmacists and registered pharmacy

technicians that sell Schedule V pseudoephedrine products shall exercise reasonable care to ensure that the purchaser has not purchased more than three packages or more than nine grams of pseudoephedrine in a 30-day period. The nine-gram limit applies to the amount of pseudoephedrine contained in products purchased, not the overall weight of the product including all ingredients.

§15-11-8. Records and invoices.

8.1 Any pharmacy, wholesaler, manufacturer, or distributor of Schedule V pseudoephedrine products shall keep readily retrievable records and invoices documenting the sale and distribution of these products. All pharmacy log records of sales of Schedule V pseudoephedrine products shall be kept for a minimum of five years from the date of sale or distribution.

§15-11-9. Registration to sell, distribute, or transfer Schedule V pseudoephedrine products.

9.1 Every wholesaler, manufacturer, or distributor of Schedule V pseudoephedrine products shall obtain a registration annually from the Board.

9.2 Any facility that holds a license as a pharmacy, manufacturer, or wholesaler from the Board shall not need to obtain an additional permit to sell, distribute, or transfer Schedule V pseudoephedrine products or be required to meet any additional storage or security requirements.

9.2 Any facility that does not hold a license as a pharmacy, manufacturer, or wholesaler from the Board may apply for and be granted a limited Schedule V pseudoephedrine distributor license. An applicant for this registration shall meet the following conditions:

(a) Applicant is actively engaged in the interstate sale of grocery or pharmaceutical items;

(b) Applicant's sales are not limited to pseudoephedrine items alone, or to pseudoephedrine items in conjunction with other items associated with the illegal manufacture of methamphetamine or other controlled drugs;

(c) Applicant does not have a history of association with the diversion of pseudoephedrine; or of having failed against the diversion of pseudoephedrine or other products used in manufacturing illegal drugs;

(d) Applicant verifies that Schedule V pseudoephedrine products shall be stored in a locked area that is monitored and the applicant has established security measures to guard against diversion; and

(e) Applicant submits fully completed application to the Board with a fee of $200 for annual registration.

9.3. All licenses allowing the sell, distribution, or transfer of Schedule V pseudoephedrine products shall expire on June 30th of each year, and shall be renewed on an annual basis.

§15-11-10. Supplemental List

10.1 The Superintendent of the State Police and the Executive Director of the Board shall meet at least quarterly to identify drug products which are a designated precursor, in addition to those that contain as their single active ingredient ephedrine, pseudoephedrine, or phenylpropanolamine, that are commonly being used in the production and distribution of methamphetamine.

10.2. The Superintendent of the State Police shall demonstrate by empirical evidence those drug products being used in the manufacture of methamphetamine and recommend the addition of these products to the list of Schedule V pseudoephedrine products.

10.3. The Board, upon receiving such a recommendation from the Superintendent of the State Police, shall promulgate emergency and legislative rules to implement an updated supplemental list of Schedule V pseudoephedrine products.

10.4. The Board shall provide written notification to the pharmacist-in-charge of each pharmacy in West Virginia and to the West Virginia Community Pharmacy Council that Schedule V pseudoephedrine products must be sold, transferred or dispensed from behind a pharmacy counter and a list of brand name Schedule V pseudoephedrine products that are subject to this rule.

10.5. The Board shall provide written notification to the pharmacist-in-charge of each pharmacy in West Virginia and to the West Virginia Retailers Association, West Virginia Community Pharmacy Council, West Virginia Oil Marketers and Grocers Association, and West Virginia Wholesalers Association of each drug product added to the list of Schedule V pseudoephedrine products pursuant to the legislative rule referred to in subsection 10.3 of this rule. Any changes in pseudoephedrine products subject to this rule shall become effective 30 days after notice is provided pursuant to this section.