WEST VIRGINIA
SECRETARY OF STATE
BETTY IRELAND
ADMINISTRATIVE LAW DIVISION

Form #7

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2003 MAY -2 P 3:3

OFFICE OF WEST VIRGINIA SECRETARY OF STATE

Effective Date

NOTICE OF AN EMERGENCY RULE

AGENCY: ~~å~~ West Virginia Board of Pharmacy TITLE NUMBER: 15

CITE AUTHORITY: West Virginia Code §60A-10-7(b)

EMERGENCY AMENDMENT TO AN EXISTING RULE: YES X NO ___

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 11

TITLE OF RULE BEING AMENDED:
Ephedrine and Pseudoephedrine Control

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:

Use additional sheets if necessary

William J. Douglas
Authorized Signature

$4.20

State of West Virginia
Board of Pharmacy

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

Office
232 Capitol Street
Charleston, West Virginia 25301

May 2, 2006

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 amendment to 15 CSR 11, Ephedrine and Pseudoephedrine Control, an existing rule by the Board of Pharmacy. The amendment is being filed as an emergency rule,. Thank you for your cooperation in this important matter.

Sincerely,

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

EMERGENCY RULE QUESTIONNAIRE

DATE: May 2, 2006

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 2, 2006

2. Statutory authority for promulgating emergency rule:

West Virginia Code §60A-10-7 (b)

3. Date of filing of proposed legislative rule: May 2, 2006

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.

Superintendent of West Virginia State Police via April 6, 2006 letter has recommended that the Board add two drug products to the supplemental list: Products containing pseudoephedrine and tripolidine and products containing pseudoephedrine and loratidine. The products have been found in numerous clandestine laboratories in the manufacture of methampetamine.

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.

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

These items are desirable for use in the clandestine manufacturing of methamphetamine ~~and have been found in labs throughout the state. The items must be restricted in access~~ to the public to prevent those manufacturing meth from easily obtaining these ~~ingredients.~~

SUMMARY OF PROPOSED RULE

Title 15

Legislative Rules

Series 11

Ephedrine and Pseudoephedrine Control

This rule amends the current Series 11, entitled "Ephedrine and Pseudoephedrine Control" This rule adds two drug products to the supplemental list referred to in West Virginia Code §60A-10-7 (b). The Superintendent of the West Virginia State Police sent a letter to the Board on April 6, 2006 asking the Board to add the following products to the list:

1. Products that contain pseudoephedrine and triolidine; and
2. Products that contain pseudoephedrine and loratidine.

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.

No impact on costs and revenues of state government expected except for possible reduction in law enforcement costs of responding to methamphetamine related crimes.

Fiscal Note Detail

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

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

Rule Title: _____

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.

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.

Rule is only adding two drug product classifications to supplemental list of products containing pseudoephedrine that are restricted to sale from behind the pharmacy counter. No known impact on state revenue or expenditures as result of adding products to list.

Date: 05/02/2006

Signature of Agency Head or Authorized Representative

[signature]

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. It 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.

2.3 The following products have been added to the supplemental list pursuant to West Virginia Code §60A-10-7:

(a) products that contain pseudoephedrine and tripolidine; and

(b) products that contain pseudoephedrine and loratadine.

§15-11-3. Pharmacy Requirements

3.1. Schedule V pseudoephedrine products 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 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 subsection 4.1 of this rule and attest-

ing 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 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 West Virginia Board of Pharmacy Rule, Rules of the Board of Pharmacy for the Uniform Controlled Substances Act, 15 CSR 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 purchaser; 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 until transmission to the central repository has been confirmed.

§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;

©) 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 the 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) The applicant is actively engaged in the interstate sale of grocery or pharmaceutical items;

(b) The 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;

©) The applicant does not have a history of association with the diversion of pseudoephedrine; or of having failed to guard against the diversion of pseudoephedrine or other products used in manufacturing illegal drugs

(d) The 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) The applicant submits a fully completed application to the Board with a fee of $200 for annual registration.

9.3. All licenses allowing the sale, distribution, or transfer of Schedule V pseudoephedrine products 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 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.