WEST VIRGINIA
SECRETARY OF STATE
BETTY IRELAND
ADMINISTRATIVE LAW DIVISION

Do Not Mark In This Box

FILED

2006 APR 21 A 11:49

WEST VIRGINIA
SECRETARY OF STATE

Form #6

NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

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 HAS BEEN AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE.

AUTHORIZATION IS CITED IN (house or senate bill number) SB 299

SECTION §64-9-10 PASSED ON March 11, 2006

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON THE FOLLOWING DATE: May 1, 2006

Authorized Signature

#3.20

State of West Virginia
Board of Pharmacy

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

Office
232 Capitol Street
Charleston, West Virginia 25301

April 19, 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 the final filing of a legislative rule by the Board of Pharmacy, 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

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 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 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.