WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION

Form #4

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SECRETARY OF STATE

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

CITE AUTHORITY: 60A-10-1, et seq.

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 PROPOSED LEGISLATIVE RULES, FOLLOWING REVIEW BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE, IS HEREBY MODIFIED AS A RESULT OF REVIEW AND COMMENT BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE. THE ATTACHED MODIFICATIONS ARE FILED WITH THE SECRETARY OF STATE.

David E. Potters

Authorized 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. -- ~~April 30, 2007~~ June 8, 2012.

1.4. Effective Date. -- ~~May 1, 2007~~ July 5, 2012.

§15-11-2. Definitions.

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

2.2. "Government-issued photo identification card" means an identification card of an individual that provides a photograph of him or her and is issued by a State or the Federal Government of the Unites States of America, or a document that, with respect to identification, is considered acceptable for purposes of sections 274a.2(b)(1)(v)(A) and 274a.2(b)(1)(v)(B) of title 8, Code of Federal Regulations.

2.~~2~~3. "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 W. Va. 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 W. Va. 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, behind the pharmacy counter, by a pharmacist, registered pharmacy intern, or registered pharmacy technician. This limitation applies to consumer transactions or dispensings, and does not apply to wholesale or distribution transactions between licensed manufactures, wholesale drug distributors, pharmacies or other healthcare practitioners holding the products as stock. ~~and~~Schedule V pseudoephedrine products 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.~~f

~~3.3~~3.2. The ~~pharmacist and all registrants~~ pharmacy, pharmacist, registered pharmacy intern, and registered pharmacy technician with access to the Schedule V pseudoephedrine products have an affirmative duty to guard against the theft and diversion of the products.

~~3.4~~3.3. ~~Any~~ A pharmacy that sells Schedule V pseudoephedrine products shall offer patient counseling for each transaction, and require the person purchasing, receiving or otherwise acquiring the drug product to:

(a) Produce a valid ~~drivers license or~~ government-issued photo identification showing his or her date of birth. Examples of acceptable forms of ID include, but are not limited to: driver's licenses, non-driver identification cards, passports, and military IDs; and

(b) ~~s~~Sign a ~~form~~ logbook containing the information required by subsection 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~~3.4. ~~Each~~ The pharmacy, pharmacist, registered pharmacy intern, and/or 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 as indicated on the required government-issued photo identification.

~~3.6~~3.5. 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~~ Pseudoephedrine Monitoring Program.

4.1. After January 1, 2006, and continuing thereafter until January 1, 2013, each time any Schedule V pseudoephedrine product is transferred, sold, or delivered, the ~~pharmacist or pharmacy technician~~pharmacy shall electronically transmit not less than monthly to the central repository the ~~following~~ information required by West Virginia Code § 60A-10-8~~:~~.

~~(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~~ Until January 1, 2013, the ~~Board~~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 upload from the pharmacy via the internet or other means approved by the ~~Board~~board. Beginning on January 1, 2013,

the information shall be transmitted to the Multi-State Real-Time Tracking System as required by West Virginia Code § 60A-10-8. 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~~board;

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

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

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

(e) ~~h~~Health care professionals appropriately licensed and engaged in legitimate patient care: and

(f) ~~p~~Persons possessing the products pursuant to a valid prescription.

§15-11-6. Prescriptions for Schedule V Pseudoephedrine Products.

6.1. ~~Products containing pseudoephedrine~~ Schedule V pseudoephedrine products that are dispensed pursuant to a valid prescription are exempt from ~~classification as Schedule V~~ the reporting required by this Rule, and by West Virginia Code Chapter 60A, Article 10, and are subject to the requirements of non-scheduled prescription drugs. Any product that is dispensed by prescription ~~must~~shall be provided in a container that is supplied by the pharmacy and ~~must~~shall 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.~~

§15-11-87. Records and Invoices.

~~8.1~~7.1. 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~~ 5 years from the date of sale or distribution.

§15-11-98. Registration to Sell, Distribute, or Transfer Schedule V Pseudoephedrine Products.

~~9.1~~8.1. Every wholesaler, manufacturer, or distributor of Schedule V pseudoephedrine products shall obtain a registration annually from the ~~Board~~board.

~~9.2~~8.2. ~~Any~~A facility that holds a license as a pharmacy, manufacturer, or wholesaler from the ~~Board~~board ~~shall~~ does 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~~8.3. ~~Any~~ A facility that does not hold a license as a pharmacy, manufacturer, or wholesaler from the ~~Board~~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;

(c) 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~~board with a fee of $200 for annual registration.

~~9.3~~8.4. ~~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~~9. Supplemental List.

~~10.1~~9.1. The Superintendent of the State Police and the Executive Director of the ~~Board~~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~~9.2. 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~~9.3. The ~~Board~~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~~9.4. The ~~Board~~board shall provide written notification to the pharmacist-in-charge of each pharmacy physically located in West Virginia and to the West Virginia Community Pharmacy Council that Schedule V pseudoephedrine products ~~must~~shall be sold, transferred or dispensed only from behind a pharmacy counter and a list of brand name Schedule V pseudoephedrine products that are subject to this rule.

~~10.5~~9.5. The ~~Board~~board shall provide written notification to the pharmacist-in-charge of each pharmacy physically located 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~~9.3 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.