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

Form #3

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2012 AUG 31 PM 1:46

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

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

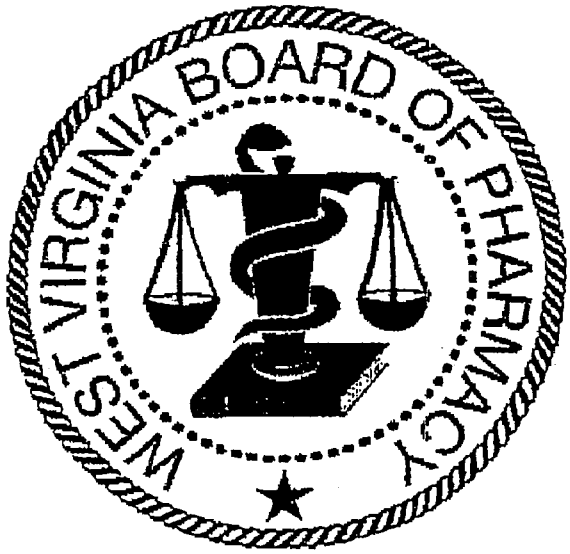
IF NO, SERIES NUMBER OF RULE BEING PROPOSED: ____

TITLE OF RULE BEING PROPOSED: ____

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

David E. Potters
Authorized Signature

Office
106 Capitol Street, Suite 100
Charleston, WV 25301



David E. Potters,
Executive Director &
General Counsel

Betty Jo Payne,
Asst. Exec. Director

(304) 558-0558
(304) 558-0572 (fax)
www.wvbop.com

APPROVAL OF FILING OF RULES

BE IT HEREBY KNOWN that the West Virginia Board of Pharmacy approves the filing of the following approved EMERGENCY RULES with the Secretary of State and the Legislative Rulemaking and Review Committee, which were considered and approved for filing by the Board following the period of public comment:

Title 15, Series 8, "CONTROLLED SUBSTANCES MONITORING"; and

Title 15, Series 11, "EPHEDRINE AND PSEUDOEPHEDRINE CONTROL".

Signed this **30th** day of **August, 2012,**

BY: Lydia Main
Lydia Main, President

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: August 31, 2012

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:(*Agency Name. Address & Phone No.*) West Virginia Board of Pharmacy
106 Capitol Street, Suite 100
Charleston, West Virginia 25301

304-558-0558

LEGISLATIVE RULE TITLE: Title 15, Series 11, "Ephedrine & Pseudoephedrine Control"

1. Authorizing statute(s) citation 60A-10-1, et seq.

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

Notice filed with Secretary of State on June 27, 2012

b. What other notice, including advertising, did you give of the hearing?

None, However, the emergency rules were discussed at several properly noticed board meetings prior to the filing. As a result, the Board received input from the industry during the meetings and in writing after the meetings, and made changes based upon that feedback, all prior to the public comment period.

c. Date of Public Hearing(s) ***or*** Public Comment Period ended:

July 28, 2012

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached _____ No comments received X

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

Filed with Secretary of State on August 31, 2012

f. **Name, title, address and <u>phone/fax/e-mail numbers</u>** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

David E. Potters
Executive Director & General Counsel
106 Capitol Street, Suite 100
Charleston, West Virginia 25301

304-558-0558
304-558-0572 (fax)
david.e.potters@wv.gov

g. **<u>IF DIFFERENT</u> FROM ITEM 'f'**, please give **Name, title, address and phone number(s)** of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

N/A

b. Date of hearing or comment period:

N/A

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

N/A

d. Attach findings and determinations and reasons:

Attached N/A

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

Form #2

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2012 JUN 27 AM 9:49

OFFICE OF WEST VIRGINIA SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

RULE TYPE: Emergency Rules Modifying Legislative Rules CITE AUTHORITY: _____

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: _____

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON July 28, 2012 AT 5:00 p.m. ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

West Virginia Board of Pharmacy
C/O Public Comments Series 11
106 Capitol Street, Suite 100
Charleston, West Virginia 25301

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.

David E. Potters
Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

Potters, David E

From: Judy Cooper <JCooper@wvsos.com>
Sent: Friday, July 06, 2012 9:28 AM
To: Potters, David E
Subject: emergency rules
Attachments: 15-8.pdf; 15-11 erd.pdf

Both of your emergency rules became effective yesterday afternoon.

Judy Cooper, Manager
Administrative Law Division
Secretary of State
1900 Kanawha Boulevard E
Charleston, WV 25305
304-558-6000
www.wvsos.com

Board Members
George Karos, Pres
Lydia Main, Vice Pres.
Charles Woolcock, Sec.
Martin Castleberry
Rebekah E. Hott
Carl K. Hedrick, Jr.
Sam Kapourales

Office
232 Capitol Street
Charleston, WV 25301

David E. Potters,
Executive Director &
General Counsel

Betty Jo Payne,
Asst. Exec. Director

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BRIEF SUMMARY OF AND STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE PROPOSED EMERGENCY RULE

TITLE 15, SERIES 11 (WV CSR 15-11-1, et seq.)
EPHEDRINE AND PSEUDOEPHEDRINE CONTROL

Summary and Statement of Circumstances: SB 437 (2012), effective June 8, 2012, makes changes to the Methamphetamine Laboratory Eradication Act. Among other things, it requires presentation and electronic reporting of government-issued photo identification to purchase the restricted products, and transitions reporting from sending the required information to the electronic PSE Database maintained by the Board, to reporting to a multi-state electronic logbook. As such, these modifications add a definition of "Government-issued photo identification card" and make changes to the definition of "Schedule V pseudoephedrine products", clarify reporting requirement, and clarify reporting to the current electronic database prior to transition to a new database on January 1, 2013. These rules are necessary to clarify the new requirements for restricted products, and information that must be reported. The ongoing substance abuse issues in this State and our surrounding states require every effort we can reasonably and appropriately make to give dispensers and law enforcement the appropriate tools they need to fight illegal methamphetamine laboratories supplied by the diversion of pseudoephedrine-containing products. Without these clarifications, wholesalers have questions about the products restricted (due to changes in definitions), and the reporting dispensers have questions about exactly they must report.

For Further Information: Copies of the proposed rule may be obtained from the website of the West Virginia Secretary of State at www.wvsos.wv.gov, 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, 106 Capitol Street, Suite 100, Charleston, West Virginia, 25301; telephone: (304) 558-0558.

Note: This is a proposed modification to existing rules, such that the changes are identified by strike-throughs and underlining in the proposed rule.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Title 15, Series 11: "Ephedrine and Pseudoephedrine Control

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

Agency: West Virginia Board of Pharmacy

Address: 106 Capitol Street, Suite 100
Charleston, West Virginia 25301

Phone Number: 304-558-0558 Email: david.e.potters@wv.gov

Fiscal Note Summary

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

This rule will have no detrimental impact on the Board of Pharmacy. In the long run, it will save the board the funds which it expends each year to maintain the PSE Database, sister to the Controlled Substances Monitoring Program.

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	- 24,800.00	- 24,800.00
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	- 24,800.00	- 24,800.00
2. Estimated Total Revenues	0.00	0.00	0.00

Title 15, Series 11: "Ephedrine and Pseudoephedrine Control

Rule Title:

Rule Title: _____

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

The system in place will continue to operate until January 1, 2013, at which time, pharmacies will cease reporting to the Board's PSE database, and will report to a free multi-state electronic logbook, NPLEX.

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.

Date: June 8, 2012

Signature of Agency Head or Authorized Representative

David E. Peters

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 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. "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. Examples of acceptable forms of ID include, but are not limited to: driver's licenses, non-driver identification cards, passports, and military IDs.

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 is intended to apply 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.~~3.2. 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~~3.3. Any 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; and

(b) 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 pharmacy, pharmacist, registered pharmacy intern, 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 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 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 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. 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;

(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 or pharmacy intern 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~~ 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 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~~7. 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 years from the date of sale or distribution.

§15-11-~~9~~8. 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.

~~9.2~~8.2. 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~~8.3. 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;

(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 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 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, 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 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~~9.5. 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.

Office
106 Capitol Street
Charleston, WV 25301

David E. Potters,
Executive Director &
General Counsel

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RESPONSES TO PUBLIC COMMENTS RECEIVED TO PROPOSED RULES

(Including explanation of any amendments made to the proposed rule as a result of comments)

TITLE 15, SERIES 11 (WV CSR 15-11-1, et seq.)
EPHEDRINE AND PSEUDOEPHEDRINE CONTROL

The Board of Pharmacy met on July 30, 2012, to receive written public comments to the proposed rules filed with the Secretary of State as emergency rules revisions to Title 15, Series 11, regarding SB 437 (Regular Legislative Session 2012) requirements for reporting to the Controlled Substances Monitoring Program and the Pseudoephedrine Database. No public comments were received by the Board, such that no responses were necessary. Therefore, the Board approved the rules for filing as previously proposed, without modification. The Board noted, however, that prior to drafting the rules changes, it received input from interested parties during board meetings at which the proposed changes were discussed and reviewed, and by receiving written comments from interested parties as a result of those board discussions at its open meetings, all prior to the rules being initially filed. Such input during drafting came either orally or in writing from the West Virginia Retailers Association, West Virginia Pharmacists Association, National Association of Chain Drug Stores, Walgreen Co., CVS Caremark, Rite Aid, and others, likely explaining the lack of any public comment.

Prepared by:

David E. Potters
Executive Director and General Counsel