

**WEST VIRGINIA
SECRETARY OF STATE
BETTY IRELAND
ADMINISTRATIVE LAW DIVISION**

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Form #3

OFFICE 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-10-7

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 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.

W. T. Douglas

Authorized Signature

304-558-0558

William T. Douglas Jr.



Board of Pharmacy

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

Office
232 Capitol Street
Charleston, West Virginia 25301

July 7, 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 a legislative rule and 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

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: July 7, 2005

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: *(Agency Name, Address & Phone No.)* West Virginia Board of Pharmacy

232 Capitol Street

Charleston, WV 25301 Phone: 304-558-0558

LEGISLATIVE RULE TITLE: 15-CSR 11

Ephedrine and Pseudoephedrine Control

1. Authorizing statute(s) citation §60A-010-7

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

May 20, 2005

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

Posted on website, notice to pharmacists-in-charge of each pharmacy in WV, conference call with National Association of Chain Drug Stores.

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

Comment period ended June 20, 2005.

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

Attached X No comments received

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

July 7, 2005

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

William T. Douglass, Jr.

Executive Director and General Counsel

Phone: 304-558-0558 Fax: 304-558-0572

Email: wdouglass@wvbop.com

- g. **IF DIFFERENT 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.

b. Date of hearing or comment period:

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

d. Attach findings and determinations and reasons:

Attached



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 be 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.



Board of Pharmacy

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232 Capitol Street
Charleston, West Virginia 25301

STATEMENT OF CIRCUMSTANCES
15 CSR 11
EPHEDRINE AND PSEUDOEPHEDRINE CONTROL

SB 147 passed during the 2005 Legislative Session which restricts access to certain drug products containing pseudoephedrine that are being used in the illegal production of methamphetamine, i.e. "Meth labs." The bill requires rules to be promulgated by the Board by July 1, 2005.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: 15 CSR 11 Ephedrine and Pseudoephedrine Control

Type of Rule: 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 initial 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			

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 initial 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

W. T. Douglas Jr.

William T. Douglas Jr.

304-558-0558

FILED

2005 JUL -7 P 2:40

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

OFFICE WEST VIRGINIA
SECRETARY OF STATE

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 upload 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 its 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 ~~of guard~~ 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.



Board of Pharmacy

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

Office
232 Capital Street
Charleston, West Virginia 25301

July 6, 2005

Diane L. Darvey, Director, Pharmacy Regulatory Affairs
NACDS
413 North Lee Street
P.O. Box 1417-D49
Alexandria, VA 22313-1480

Dear Ms. Darvey:

The West Virginia Board of Pharmacy met on June 27, 2005, in Charleston, WV, and discussed your comments on the emergency rules filed in order to comply with SB 147. After discussion, the Board addressed your concerns as follows:

1. The Board could not change the rule to allow other pharmacy employees to sell the products because §60A-3-308(d)(2)(A) states that the substance shall be dispensed, sold, or distributed only by a pharmacist or a pharmacy technician. We have however amended rule 3.1 to state that the products may be sold, delivered, or provided as you had requested.
2. The information can be sent in a batch transmission but we cannot accept it by mail or fax. §60A-10-8 requires reporting the information to the central repository established in article nine. §60A-9-04 is the statutory section which originally established the prescription monitoring program and §60A-9-4 (c) includes the pseudoephedrine products among those to be submitted to the central repository. Since this electronic reporting system is already in place, it would not be practical to avoid this technology and backtrack into a cumbersome paper reporting mechanism. The Board did change the effective date of the electronic reporting to January 1, 2006 to allow time for software vendors to make the necessary changes and will allow other means than internet transmission if approved by the Board. The provision requiring the NDC number will remain since this is the most effective way to pull out the name and dosage of the product

from a data table for reporting purposes. The rule was changed to require retention of this information for 60 days after transmission.

3. The rule was changed to allow possession by other pharmacy employees although only a pharmacist or registered pharmacy technician may make the sale.
4. Rule 8.1 was changed to require that the pharmacy log records be kept for a period of five years which matches the amount of time other controlled substance records must be kept by pharmacy law. This would apply only to the signature log information while the information submitted to the central repository must be kept only 60 days as mentioned above.
5. The rule was changed to include the West Virginia Community Pharmacy Council in the notification process.

Although the Board does not dispute that some of these provisions will place quite a burden upon the pharmacies when selling these products, the rule may not conflict with the statute and does not exceed the scope of the act. Thank you for your comments on this proposed rule.

Sincerely,



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

June 22, 2005

William T. Douglass, Jr.
Executive Director & General Counsel
West Virginia Board of Pharmacy
232 Capitol Street
Charleston, WV 25301

RE: Proposed Rules on Ephedrine and Pseudoephedrine Control

Dear Mr. Douglas:

The National Association of Chain Drug Stores is a national trade association that represents more than 210 chain pharmacy companies that operate nearly 35,000 community retail pharmacies and employ nearly 100,000 pharmacists. Our members dispense more than 70 percent of all outpatient retail prescription drugs in the United States. We have fourteen members operating approximately 279 pharmacies in the State of West Virginia.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

On behalf of our members operating in West Virginia, NACDS has reviewed the proposed rules on ephedrine and pseudoephedrine. Based on our review, we have identified several concerns and are requesting that certain provisions of the proposed rule be amended. We believe that these amendments adhere to the requirements of the new law and will aid in implementation. We thank the board for consideration of our comments and proposed amendments.

1. Amend § 15-11-3.1 to Allow Other Pharmacy Employees to sell Schedule V Pseudoephedrine product and to clarify that the products may be sold, delivered, or provided in a pharmacy *NO*

60A-3-308(d)(2)(A)

A. We request that the proposed rule be amended to allow other pharmacy employees, in addition to pharmacists and pharmacy technicians, to sell the Schedule V pseudoephedrine products because the proposed rule is more restrictive than the law. §60A-10-5 allows pharmacists, pharmacy technicians or other pharmacy employees to have access to the restricted pseudoephedrine products. Conversely, the proposed rule at § 15-11-3.1 is more restrictive by only allowing the products to be sold by a pharmacist or registered pharmacy technicians. This restriction is not in accord with the law and therefore we request the following amendment. In addition, these ancillary pharmacy employees, such as cashiers and clerks, are already involved in providing filled prescriptions for controlled substance prescriptions. As such, it is reasonable and appropriate for them to be allowed to handle the sales of these products also.

(703) 549-3001

Fax (703) 836-4869

www.nacds.org

OK
B. We also request that § 15-11-3.1 be amended to clarify that licensed pharmacies may sell, deliver or provided the Schedule V pseudoephedrine products. As drafted, the proposed rule would only allow licensed pharmacies to sell the products. We believe that this is an inadvertent drafting error as the other provisions of the new law refer to the products being sold, delivered or provided. We request the change indicated below to allow these products to be sold, delivered, or provided by licensed pharmacies in accord with the law.

§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 or other pharmacy employee and may not be sold, delivered, or provided to any person who is under the age of eighteen.

2. Amend § 15-11-4 to Allow Pharmacies to Submit Information on the Sales of Schedule V Pseudoephedrine products in Batch Transmission.

NO
We request that the proposed rule be amended to allow pharmacies to report the required information on their sales of Schedule V pseudoephedrine products by ~~mail, fax,~~ or electronic means to the board of pharmacy for the board to maintain in a central repository and to allow a pharmacy owner to transmit the information in batch from a number of their pharmacies under common ownership or control whether by fax, mail, or electronically in accord with their operational systems. We believe that a central location for the reported information would be most beneficial to the board of pharmacy and to law enforcement. In addition, this is the most cost effective and efficient means to provide the information. Moreover, as pharmacies are not connected to the Internet for a number of reasons, including operational capability, cost, and security concerns, we have removed that language. We request the following amendments.

We also ask that the requirement to send the NDC number be removed as that is not required to be collected under the reporting provisions of the law. OK?

§15-11-4. ~~Prescription Monitoring Program~~ Reporting of Sales of Schedule V Pseudoephedrine Products

4.1. Each time any Schedule V pseudoephedrine product is transferred, sold, or delivered, the pharmacist, ~~or~~ pharmacy technician or designated representative of the pharmacy owner or operator shall by facsimile, mail or electronic transmission transmit weekly to the board of pharmacy 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 week as a batch transmission **by facsimile, mail or electronic transmission**.

4.3. The Board and the central repository shall receive the electronic, **facsimile or mail** transmission of the information required to be provided ~~by and through the use of a secure upload from the pharmacy via the internet.~~ **The pharmacy shall retain the original records for 60 days after transmission to the board of pharmacy.** *OK*

3. Amend § 15-11-5 to Allow Other Pharmacy Employees to Lawfully Possess Schedule V Pseudoephedrine products. *of other means approved by the Board.*

We request that § 15-11-5 of the proposed rule be amended to allow other pharmacy employees to lawfully possess Schedule V pseudoephedrine products in the scope and course of their duties as pharmacy employees. This is in accord with § 60A-10-5 that allows pharmacists, pharmacy technicians or other pharmacy employees to have access to the restricted pseudoephedrine products. Conversely, the proposed rule at § 15-11-4 would contradict the law by not permitting other pharmacy employees to lawfully possess these products. Therefore, we request the following amendment. *OK*

§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 its 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;** *OK*

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

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

4. Amend § 15-11-8 to Set a 60-Day Record Requirement for Pharmacy Log Records for Schedule V Pseudoephedrine Product Sales Because They Have Been Transmitted to the Board of Pharmacy.

We request that the proposed rules be amended to set a 60-day record keeping requirement for pharmacy log records for sales of Schedule V pseudoephedrine products. We believe that this 60-day period is reasonable and appropriate in view of the pharmacy providing these records to the board of pharmacy for centralized record keeping. We request the following amendment.

§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 records shall be kept for a minimum of two years from the date of sale or distribution except that pharmacy log records of sales of Schedule V pseudoephedrine products shall be kept for 60 days after being sent to the board of pharmacy pursuant to § 15-11-4. ~~ok~~

5. Amend § 15-11-10 to Have the Board of Pharmacy Notify the West Virginia Community Pharmacy Council of Changes Products Identified as Schedule V Pseudoephedrine Drug Products and Set Time-period for Implementation *ok*

We request that the board amend § 15-11-10 to provided that Board also notify the West Virginia Community Pharmacy Council of any changes in pseudoephedrine drug products subject to the restrictions. We believe that this would assist the board with notification to chain pharmacies of any changes in a drug product's status. We also request that the rule give pharmacies 30 days after notice to begin implementation of any new restrictions as this is a reasonable time-frame for pharmacies to implement the new restrictions. Accordingly, we request the following changes to the proposed rules.

§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

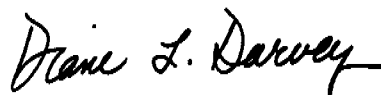
William T. Douglass, Jr.
Executive Director & General Counsel
West Virginia Board of Pharmacy
June 22, 2005
Page 5 of 5

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.

Thank you for your consideration of our comments. Should you have any questions or need any further information, please call me at (703) 837- 4182.
Thank you.

Sincerely,



Diane L. Darvey, Pharm.D., JD
Director, Pharmacy Regulatory Affairs

cc: Nicole Valentine, Regional Manager, NACDS



Board of Pharmacy

Phone (304) 558-0558

Fax (304) 558-0572

Office

232 Capital Street

Charleston, West Virginia 25301

July 6, 2005

G. Nicholas Casey Jr.
Lewis, Glasser, Casey & Rollins
300 Summers Street, BB&T Square, Suite 700
Post Office Box 1746
Charleston, WV 25326

Dear Mr. Casey:

The West Virginia Board of Pharmacy met on June 27, 2005, in Charleston, WV, and discussed your comments on the emergency rules filed in order to comply with SB 147. After discussion, the Board decided that Rule 4.1 must remain due to the fact that §60A-10-8 requires reporting the information to the central repository established in article nine. §60A-9-04 is the statutory section which originally established the prescription monitoring program and §60A-9-4 (c) includes the pseudoephedrine products among those to be submitted to the central repository. In addition, §60A-10-5(d) also requires the use of a log book or form to collect this information and signature of the person acquiring the drug product. The statute has established these recording and reporting requirements and the proposed rule merely provides the specific means by which pharmacies may accomplish this. Although the Board does not dispute that this will place quite a burden upon the pharmacies when selling these products, the rule may not conflict with the statute and does not exceed the scope of the act.

Sincerely,

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



Lewis Glasser
Casey & Rollins
PLLC
LAW OFFICES

RECEIVED
MAY 31 2005
WV BOARD OF PHARMACY

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gncasey@lgr.com

May 26, 2005

William T. Douglass, Esq.
Executive Director & General Counsel
West Virginia Board of Pharmacy
232 Capitol Street
Charleston, West Virginia 25301

Re: Comments on Rules to Implement the Provisions of SB 147

Dear Mr. Douglass:

I am writing to comment on the draft rules that the West Virginia Board of Pharmacy proposed pursuant to the relevant provisions of Senate Bill 147, W.Va. Code § 60A-10-1, et seq., the Methamphetamine Laboratory Eradication Act (the "Act").

As we have discussed previously, § 60A-9-4(c) of the Act provides that products regulated by Article Ten of the Act are subject to the reporting requirements of Article Nine. In the proposed rules, Rule 3.6 provides that the bound record book kept for distribution of Schedule V exempt narcotics may be used for recording the information required under the Act. This provision is consistent with the legislative intent and the requirements of § 60A-10-8. However, Rule 4.1 of the draft rules imposes a requirement that exceeds the Act's permissible scope by mandating weekly electronic transmission of sales information similar to the way pharmacies report information on prescription drug sales. In that respect, the proposed rules attempt to establish two conflicting systems for reporting the same information. If Rule 4.1 were implemented, the reporting requirements for the sale of single ingredient ephedrine or pseudoephedrine products would require data entry by pharmacist or pharmacy technician. Under Rule 4.1, pharmacies will be saddled with unnecessary administrative duties when selling single ingredient products will take valuable time away from patient counseling and patient safety issues when dispensing scheduled drugs.

Lewis Glasser
Casey & Rollins
PLLC

Based on my review of the Act and the proposed rules, I believe that the bound record book contemplated by Rule 3.6 for recording the single ingredient ephedrine or pseudoephedrine sales is the appropriate method for collecting customer information required by § 60A-10-8 of the Act. I further believe that Rule 4.1 exceeds the scope of the Act and will result in the unintended consequence of compromising patient safety. Accordingly, in order to promote patient counseling and patient safety and to ensure that the draft rules are consistent with the Act, I recommend that the Board of Pharmacy delete Rule 4.1 from the draft rules. Rule 3.6 promotes the Legislature's goals by restricting access to the ingredients used to manufacture methamphetamine without compromising patient counseling and patient safety.

If you have any questions, or would like to discuss this matter further, please do not hesitate to contact me.

Very truly yours,



G. Nicholas Casey, Jr.

cc: James Krahulec

GNC:jcp

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