

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

Form #2

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2010 JUN 17 PM 1:37

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: Legislative CITE AUTHORITY: West Virginia Code Section 60A-9-6,

AMENDMENT TO AN EXISTING RULE: YES NO and West Virginia Code Section 30-5-19.

IF YES, SERIES NUMBER OF RULE BEING AMENDED: Series 8

TITLE OF RULE BEING AMENDED: Controlled Substances Monitoring

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 18, 2010 AT 4:30 p.m. ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

West Virginia Board of Pharmacy

C/O Series 8 Public Comments

232 Capitol Street

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



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

Board of Pharmacy

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

David E. Potters,
Executive Director &
General Counsel

Betty Jo Payne,
Asst. Exec. Director

Office
232 Capital Street
Charleston, West Virginia 25301

APPROVAL OF FILING OF REGULATIONS

BE IT HEREBY KNOWN that the West Virginia Board of Pharmacy approves the filing of the following legislative rules with the Secretary of State and the Legislative Rulemaking and Review Committee:

- (1) Series 1, "Board of Pharmacy Rule Regarding Licensure and the Practice of Pharmacy", proposing changes to effectuate SB 81, 2010 Regular Session; and
- (2) Series 8, "Controlled Substances Monitoring", proposing changes to effectuate SB 365, 2010 Regular Session.

Signed this 17th day of June, 2010,

BY: *George Karos*
George Karos, President

**BRIEF SUMMARY OF AND STATEMENT OF CIRCUMSTANCES WHICH REQUIRE
THE PROPOSED LEGISLATIVE RULE**

Controlled Substances Monitoring

15 CSR 8

Summary and Statement of Circumstances: SB 365 passed during the Regular Session, 2010, and duly enacted into law, among other things, permits the Office of the Chief Medical Examiner to have access to the Controlled Substances Monitoring Program database (the “CSMP”) maintained by the Board of Pharmacy, permits certain individuals or entities having access to the CSMP to designate duly authorized agents to access it on their behalf, and requires all practitioners who prescribe or dispense Schedule II, III, or IV controlled substances to have online access to the CSMP in their places of practice. West Virginia Code Section §60A-9-4 directs the West Virginia Board of Pharmacy to promulgate rules to implement the provisions of this Article 9. These proposed rules allow the Chief Medical Examiner’s Office’s access to the CSMP, set forth the requirements for designation of duly authorized agents for access, and require electronic access by practitioners.

For Further Information: Copies of the proposed rule may be obtained from the website of the West Virginia Secretary of State at www.wvsos.com, 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, 232 Capitol Street, Charleston, West Virginia, 25301, telephone (304) 558-0558.

Note: This is a proposed change to an existing series, such that there are strike-throughs and underlining of the language changes in the proposed rule.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Controlled Substances Monitoring

Rule Title: _____

Type of Rule: Legislative Interpretive Procedural

Agency: West Virginia Board of Pharmacy

Address: 232 Capitol Street
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 program has been in existence in its current form since 2002. The changes required by this modification of the rules should not have any additional impact over what has been in place to date.

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

Board of Pharmacy Rules Regarding Licensure and the Practice of Pharmacy

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.

This program has been in existence in its current form since 2002. The changes required by this modification of the rules should not have any additional impact over what has been in place to date.

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.

This program has been in existence in its current form since 2002. The changes required by this modification of the rules should not have any additional impact over what has been in place to date.

Date: June 17, 2010

Signature of Agency Head or Authorized Representative

FILED

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

2010 JUN 17 PM 1:37

SERIES 8
CONTROLLED SUBSTANCES MONITORING

WEST VIRGINIA
SECRETARY OF STATE

§15-8-1. General.

1.1. Scope. -- This rule establishes requirements for the recordation and retention in a single repository of information regarding the prescribing, dispensing and consumption of certain controlled substances.

1.2. Authority. -- W. Va. Code §60A-9-6.

1.3. Filing Date. -- ~~June 23, 2003~~_____.

1.4. Effective Date. -- ~~June 23, 2003~~_____.

§15-8-2. Definitions.

2.1. "Central repository" refers to the central repository designated by the Board for the collection of the transmitted information, which may be a vendor designated by the Board and under contract with the Board to act as the central repository.

2.2. "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.

2.3. "Duly authorized agent" means an individual, who is an employee of any of the covered persons or entities permitted to have access to the central repository pursuant to Rule 15-8-7.3 of this rule, who is specifically designated by the duly authorized representative of the covered person or entity to access the central repository on behalf of the covered person or entity.

2.4. "Electronic access" means the ability to connect with and view the information in the central repository maintained by the Board using the Internet or some other electronic means, such as an Intranet or satellite connection which permits real-time connectivity to the central repository the same as if connected through the Internet.

~~2.3~~2.5. "Identification number" means any of the following:

- (a) The birth date of the recipient;

2.6. "Internet" means an interconnected system of networks that connects computers around the world via the Transmission Control Protocol (TCP) and the Internet Protocol (IP) established by the Internet Society (ISOC).

2.7. "Intranet" means a privately maintained computer network that can be accessed only by authorized persons, especially members or employees of the organization that owns it.

~~2-42.8.~~ "Logo" means a symbol used by an individual, a pharmacy, professional practice, professional association or hospital.

~~2-52.9.~~ "Medical Services Provider" means a licensed practitioner with the legal authority to dispense Controlled Substances.

~~2.10.~~ "Practitioner" means:

~~(a) A physician, dentist, veterinarian, scientific investigator or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state; and~~

~~(b) A pharmacy, hospital or other institution licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state.~~

~~2-62.11.~~ "Recipient" means an individual for whom a controlled substance is dispensed or filled.

~~2-72.12.~~ "Recipient representative" means an individual to whom a controlled substance is dispensed or filled if the recipient is either less than 18 years of age or unavailable to receive the controlled substance.

~~2-82.13.~~ "Reporter" means any medical services provider, health care facility, pharmacist, or pharmacy that is required to submit the information outlined in section 4 of this rule.

~~2-92.14.~~ "Schedule II, III, or IV Controlled Substance" means a controlled substance classified in those categories under W. Va. Code §§60A-2-206, 208 and 210.

~~2-102.15.~~ "Security prescription blank" means a prescription blank that complies with the requirements of Section ~~5 of this rule~~ 15-1-27 of the West Virginia Code of State Rules.

~~2-112.16.~~ "Universal Claim Form" means a nationally recognized standard form developed by the National Council for Prescription Drug Programs used for billing drug claims to insurance plans.

§15-8-3. Prescription Monitoring Program.

3.1. Each time a Schedule II, III, or IV Controlled Substance is dispensed or filled for out-patient use, the medical services provider, health care facility, pharmacist or pharmacy who dispensed the controlled substance shall transmit to the central repository the information outlined in section 4 of this rule, following information:

(a) The name, address, pharmacy prescription number and Drug Enforcement Administration controlled substance registration number of the dispensing pharmacy;

(b) The name, including middle initial, address and birth date of the person for whom the prescription is written;

(c) The name, address and Drug Enforcement Administration controlled substances registration number of the practitioner writing the prescription;

(d) The name and national drug code number of the Schedule II, III and IV controlled substance dispensed;

(e) The quantity and dosage of the Schedule II, III and IV controlled substance dispensed;

(f) The date the prescription was filled; and

(g) The number of refills, if any, authorized by the prescription.

3.2. Any person reporting more than 20 controlled substance prescriptions in any given month shall transmit to the central repository the information outlined in section 4 of this rule using one of the following methods:

- (a) An electronic device compatible with the receiving device of the central repository;
- (b) A computer diskette; or
- (c) A magnetic tape.

3.3. Any person reporting less than 20 Schedule II, III, or IV prescriptions in any given month may submit data using a Universal Claim Form or transmit the information using the methods outlined in subsection 3.2 of this section.

3.4. The Board may grant a waiver to a person who does not have an automated recordkeeping system capable of producing an electronic report in the established format. A person requesting a waiver shall make the request to the Board in writing and the Board shall grant the request if the dispenser agrees to report the data by submitting a completed Universal Claim Form.-

3.5. The Board and the central repository shall provide for the electronic transmission of the information required to be provided by and through the use of a toll-free telephone line or other Internet connection.

§15-8-4. Information To Be Transmitted Weekly.

4.1. The information required to be submitted by the provisions of this rule may be transmitted at any time, but shall be transmitted at least every week.

4.2. The Board may not penalize a reporter for failure to comply with the program if the Board or the central repository can-not secure adequate funding to implement the program and recover the cost.

§15-8-5. ~~Prescription Forms.~~ Accuracy of Information Transmitted.

~~5.1. The purpose of this section is to establish minimum requirements that will decrease the potential for forgery or alteration of a prescription or a prescription blank for a controlled substance.~~

~~5.2. After June 1, 2003, the Board of Pharmacy recommends that a written prescription for a controlled substance in Schedules II, III or IV be on a security prescription blank.~~

~~5.3. Minimum Requirements of a Security Prescription Blank.~~

~~5.3.1. A prescription for a controlled substance should contain the following security features:~~

~~(a) A latent, repetitive "void" pattern screened and printed across the entire front of the prescription blank. If the prescription is photocopied, the word "void" shall appear in a pattern across the~~

entire front of the prescription:

~~_____ (b) A watermark printed on the backside of the prescription blank so that it is only seen at a forty-five (45) degree angle;~~

~~_____ (c) An opaque "Rx" symbol or an "Rx" symbol printed in disappearing ink shall appear in the upper part of the blank. The symbol shall disappear if the prescription copy is lightened;~~

~~_____ (d) Six (6) quantity check-off boxes printed on the form and the following quantities shall appear:~~

~~_____ (1) 1-24;~~

~~_____ (2) 25-49;~~

~~_____ (3) 50-74;~~

~~_____ (4) 75-100;~~

~~_____ (5) 101-150; and~~

~~_____ (6) 151 and over;~~

~~_____ Provided, That if the blank has the quantity prescribed electronically printed in both numeric and word format, then the quantity check-off boxes would not be necessary;~~

~~_____ (e) The following statement printed on the bottom of the prescription blank: "Prescription is void if more than one (1) controlled substance prescription is written per blank"; and~~

~~_____ (f) Refill options in the following order: Refill NR 1 2 3 4 5; Provided, That if the blank has the refill amount electronically printed in both numeric and word format, then the quantity check-off boxes would not be necessary.~~

~~_____ 5.3.2. A prescription shall bear the preprinted, stamped, typed, or manually printed name, address and telephone number of the prescribing practitioner.~~

~~_____ 5.3.3. A prescription blank for a controlled substance shall not contain:~~

~~_____ (a) An advertisement on the front or the back of the prescription blank;~~

~~_____ (b) The preprinted name of a controlled substance; or~~

~~_____ (c) The written, typed or rubber-stamped name of a controlled substance until the prescription blank is signed, dated and issued to a patient.~~

~~_____ 5.3.4. A prescription blank for a controlled substance shall provide space for the patient's name and address, the practitioner's signature and the practitioner's DEA registration number.~~

~~_____ 5.3.5. Only one (1) controlled substance prescription blank shall be written per prescription blank.~~

~~_____ 5.3.6. A quantity check-off box that corresponds to the quantity prescribed shall be marked or the quantity electronically printed in both numeric and word format.~~

~~5.3.7. If a prescribed drug is a schedule II, III or IV controlled substance, a refill option shall be marked or the refill amount electronically printed in both numeric and word format.~~

~~5.3.8. If a prescription for a schedule II, III or IV controlled substance will be transmitted to a pharmacy by facsimile, the practitioner or the practitioner's agent shall, prior to transmission, write or stamp "FAXED" on the face of the original prescription along with the date and the person's initials.~~

~~5.3.9. If a prescription for a schedule II, III or IV controlled substance has been transmitted to a pharmacy by facsimile, the transmitting practitioner shall file the original prescription in the patient's record.~~

~~5.3.10. A pharmacist shall not be required to use a security prescription blank to record an oral prescription or a transferred prescription for a Schedule II, III or IV controlled substance.~~

~~5.3.11. The requirements of this section do not apply to prescriptions for controlled substances that are electronically transmitted from a prescriber to a pharmacy: Provided, That all electronically transmitted prescriptions for controlled substances shall comply with all federal requirements."~~

The information required to be transmitted by this rule must be reported accurately. If the reporting individual or entity discovers that information contained in the central repository is not accurate, he or she must notify the Board of the inaccuracy and the necessary corrections in writing immediately so that the Board may take the necessary steps to correct the error within the database.

§15-8-6. Central Repository; Designation; Powers and Duties.

6.1. The central repository shall create a database for the information required to be transmitted by this rule. This database shall be referred to as the "Controlled Substances Monitoring Program", or the "CSMP".

6.2. The central repository shall provide the Board with continuous 24-hour a day, on-line access to the database maintained by the central repository.

6.3. The central repository shall secure the information collected by the central repository and the database maintained by the central repository against access by unauthorized persons.

6.4. If the relationship between the Board and the central repository is terminated by statute, the central repository shall provide to the Board within a reasonable time, all collected information and the database maintained by the central repository.

6.5. The Board may accept a designated grant, public and private financial assistance, and licensure fees to provide funding for the central repository.

§15-8-7. Confidentiality.

7.1. The Board shall carry out a program to protect the confidentiality of the information received by the central repository.

7.2. The Board may disclose confidential information received by the central repository to any person who is engaged in receiving, processing, or storing the information.

7.3. The Board may release confidential information received by the central repository to the following persons:

(a) ~~A~~ a duly authorized agent of a board in this state or another state that licenses practitioners authorized to prescribe Schedules II, III, and IV controlled substances ~~and who~~ is engaged in an investigation, an adjudication, or a prosecution of a violation under any state or federal law that involves a controlled substance;

(b) members of the West Virginia state police expressly authorized by the superintendent of the West Virginia state police to have access to the information;

~~(c) A person with an enforceable court order or regulatory agency administrative subpoena; a member of a local law-enforcement agency who is acting as a member of a State recognized drug task force;~~

(d) authorized agents of the federal ~~d~~Drug ~~e~~Enforcement ~~agency~~Administration;

~~(e) The Chief Medical Examiner for the State of West Virginia or his or her duly authorized agent for use in post-mortem examinations;~~

~~(f) A person with an enforceable court order or regulatory agency administrative subpoena;~~

~~(eg) inspectors and agents of the board; and~~

~~(fh) prescribing practitioners or their duly authorized agents and pharmacists;~~

~~(i) pharmacists or a registered pharmacy technician as the agent of the pharmacist; and~~

~~(j) a person using the data for compilation of educational, scholarly, or statistical purposes so long as the individually identifiable data of the persons or entities stored in the central repository remains confidential.~~

7.4. All information released by the board must be related to a specific patient or a specific individual or entity under investigation by any of the persons set forth in subsection 7.3 of this section except that practitioners who prescribe controlled substances may request specific data related to their drug enforcement administration controlled substance registration number or for the purpose of providing treatment to a patient.

7.5. All access to the data collected by the central repository shall be limited to regular business hours of the Board office unless an individual authorized to receive the information proves that an immediate danger to the public exists and immediate access is necessary to prevent further harm. Provided That the Board may permit access at any time to authorized users through the use of a secure connection and through the use of proper security features designed to protect the integrity and confidentiality of the information from unauthorized access or disclosure.

7.6. Any person or entity having access to the central repository and who is permitted to designate a duly authorized agent to have access to the central repository pursuant to this rule must make any such designation on a form to be supplied by the Board. It is the responsibility of the designating individual to insure that the designated agent maintains the confidentiality of the information in the central repository as required. Further, should the designating individual remove the authority of the designated agent to act as the duly authorized agent, or should the designated agent leave the employment of the covered person

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or entity such that he or she is no longer eligible to act as the duly authorized agent, then the designating individual must immediately notify the Board, at which time the designee's access to the central repository shall be removed.

15-8-8. Access Required. All practitioners must have electronic access to the central repository in each of their individual places of practice by July 1, 2011.