

WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #2

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OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: WV Board of Pharmacy TITLE NUMBER: 15

RULE TYPE: Legislative; CITE AUTHORITY WV Code §60A-9-1

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED: 8

TITLE OF RULE BEING PROPOSED: Controlled Substances Monitoring

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 31, 1996 AT 5:00 p.m.

ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS.

WV Board of Pharmacy

236 Capitol St.

Charleston, WV 25301

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

William J. Dylka
Executive Director

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

4.00

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Controlled Substances Monitoring

Type of Rule: Legislative Interpretive Procedural

Agency W.Va. Board of Pharmacy

Address 236 Capitol Street
Charleston, WV 25301
Doug Douglass

1. Effect of Proposed Rule

	ANNUAL FISCAL YEAR				
	INCREASE	DECREASE	CURRENT	NEXT	THEREAFTER
<u>ESTIMATED TOTAL COST</u>	\$ 65,000	\$	\$ 65,000	\$	\$
PERSONAL SERVICES					
CURRENT EXPENSE					
REPAIRS & ALTERNATIONS					
EQUIPMENT					
OTHER					

2. Explanation of above estimates:

\$65,000 is cost of contract with vendor to create central repository to electronically monitor Schedule II Controlled Substance Prescriptions in the State.

3. Objectives of these rules:

Establishes the procedures and requirements of the Prescription Monitoring Program mandated by W.Va. Code S60A-9-4.

SUMMARY OF PROPOSED LEGISLATIVE RULE

15 C.S.R. 8.

Controlled Substance Monitoring.

West Virginia Code § 60A-9-3 passed by the West Virginia Legislature in 1995 states that, the Board of Pharmacy shall implement a program wherein a central repository is established and maintained which shall contain information regarding Schedule II controlled substances prescriptions written or filled in this state. The following rule establishes the procedures for the prescription monitoring program including what information is required to be reported and in what manner it is reported to the central repository. The rule also elaborates on the confidentiality of the information received and states certain individuals to whom the Board may release confidential information.

STATEMENT OF CIRCUMSTANCES

15 C.S.R. 8.

Controlled Substances Monitoring.

West Virginia Code § 60A-9-3 passed by the West Virginia Legislature in 1995 states that, the Board of Pharmacy shall implement a program wherein a central repository is established and maintained which shall contain information regarding Schedule II controlled substances prescriptions written or filled in this state. The statute requires that the Board implement this program on or before the 1st day of May 1996, but the Board was unable to finalize a contract with an appropriate vendor until recently. The next step in implementing this program is the promulgation of this legislative rule, which in order to avoid further delaying such implementation must be promulgated prior to the 1997 legislative session as an emergency rule.

Rule Title: Controlled Substances Monitoring

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

\$65,000 annual cost to W.Va. Board of Pharmacy

B. Economic Impact on Political Subdivisions; Specific Industries; Specific groups of Citizens.

Not Applicable

C. Economic Impact on Citizens/Public at Large.

Not Applicable

Date: 7/1/96

Signature of Agency Head or Authorized Representative

Walter S. Dyck - Executive Director

15 C.S.R. 8
TITLE 15
WEST VIRGINIA BOARD OF PHARMACY

SERIES 8
CONTROLLED SUBSTANCES MONITORING

§15-8-1. General.

1.1. Scope. -- To establish rules for 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-9-1, et seq.

1.3. Filing Date. -- _____, 19__

1.4. Effective Date. -- _____, 19__

§15-8-2. Definitions.

2.1. "Dispense" means the actual or constructive transfer from one person to another whether or not there is an agency relationship.

2.2. "Medical Services Provider" means a licensed practitioner with the legal authority to dispense Schedule II Controlled Substances.

2.3. "Schedule II Controlled Substance" means a controlled substance classified in Schedule II under W. Va. Code § 60A-2-206.

2.4. "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.

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

2.6. "Recipient" means an individual for whom a controlled substance is dispensed or filled.

2.7. "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.

2.8. "Identification number" means any of the following:

1. Driver's license number of a recipient or a recipient's representative issued under West Virginia Law or the Law of any other state.
2. A valid social security number of the recipient or a recipient representative.
3. If the recipient is an animal, the valid driver's license number or social security number of the animal's owner.

2.9. "Reporter" means any medical services provider, health care facility, pharmacist or pharmacy required to transmit information to the central repository.

§15-8-3. Prescription Monitoring Program.

3.1. Each time a Schedule II Controlled Substance is dispensed or filled, the medical services provider, health care facility, pharmacist or pharmacy shall transmit to the central repository information outlined in W. Va. Code § 60A-9-4 as applicable.

3.2. Any person reporting more than 20 Schedule II prescriptions in any given month must transmit to the central repository information outlined in W. Va. Code § 60A-9-4 utilizing one of the following:

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

3.3. Any person reporting less than 20 Schedule II prescriptions in any given month may submit data utilizing a Universal Claim Form or transmit the information utilizing the ways outlined in § 3.2.

3.4. The Board may grant a waiver to a person who is unable to transmit the required data in accordance with this rule for a period of 180 days from the effective

date of this rule which 180 day period may be extended by the Board at its discretion. During the effective period of the waiver and any extension granted by the Board, the person shall submit the required data in a format acceptable to the Board.

3.5. The Board and the central repository shall pay for telephone access charges, line charges, and switch charges for transmission of data by reporters to the central repositories.

§15-8-4. Information and Prescription Forms.

4.1. Each time a controlled substance is dispensed or filled, the reporter shall transmit to the central repository the following information, as applicable:

- a. The name, address, pharmacy, prescription number and DEA controlled substance registration number of the dispensing pharmacy.
- b. The name and address 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 controlled substance dispensed.
- e. The quantity and dosage of the Schedule II controlled substance dispensed.
- f. The date the prescription was filled.
- g. The number of refills, if any, authorized by the prescription.

4.2. The information required to be submitted by the provisions of this rule must be transmitted no more frequently than once in a 2 month period.

4.3. A reporter may not be penalized 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. Central Repository; Designation; Powers and Duties.

5.1. Central repository shall create a database for the information required to be transmitted by this rule.

5.2. Central repository shall provide the Board with continuing 24-hour a day, on-line access to the database maintained by the central repository.

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

5.4. 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.

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

§15-8-6. Confidentiality.

6.1. The Board shall carryout a program to protect the confidentiality of the information received by the central repository.

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

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

- a. A member of the Board, or another governing body that licenses practitioners and 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. An investigator for the Consumer Protection Division of the Office of the Attorney General, a prosecuting attorney, the Attorney General, a Deputy Attorney General, or an investigator from the Office of the Attorney General, 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.
- c. A law enforcement officer who is authorized by the State Police Department to receive information of the type requested, approved by

the Board to receive information of the type requested, and engaged in an investigation or prosecution of a violation under any state or federal law that involves a controlled substance.

6.4. Before the Board releases the confidential information to the above-stated persons, the applicant must demonstrate to the Board that he has reason to believe that a violation under any state or federal law that involves a controlled substance has occurred and the requested information is reasonably related to the investigation, adjudication, or prosecution of that violation.

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