WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #3

FILED

AUG 8 9 59 AM '96

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: W.Va. Board of Pharmacy TITLE NUMBER: 15

CITE AUTHORITY W.Va. Code Sections 29A-3-9, 60A-9-6

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 NEW RULE BEING PROPOSED: 8

TITLE OF RULE BEING PROPOSED: Controlled Substances Monitoring

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.

William S. Douglass Jr.
Authorized Signature Executive Director

4.40

DATE:

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:

LEGISLATIVE RULE TITLE: Controlled Substances Monitoring

1. Authorizing statute(s) citation W.Va. Code Section 60A-9-6

2. a. Date filed in State Register with Notice of Hearing

Notice of comment period filed July 1, 1996

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

N/A

c. Date of Hearing(s) N/A July 31, 1996

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)

N/A

f. Name and phone number(s) of agency person(s) to contact for additional information:

Samuel Kapourales 235-3535

William T. Douglass, Jr. 558-0558

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: 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

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 centeral 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.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Controlled Substances Monitoring

Type of Rule: x Legislative ____Interpretive ____Procedural

Agency W.Va. Board of Pharmacy

Address 236 Capitol Street

Charleston, WV 25301

1. Effect of Proposed Rule

	ANNUAL		FISCAL YEAR		
	INCREASE	DECREASE	CURRENT	NEXT	THEREAFTER
ESTIMATED TOTAL COST	$ 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 proceduresa and requirements of the Prescription Monitoring Program mandated by W.Va. Code S60A-9-4.

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 Reprensentative

Walter S. Dyer - 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 of a drug or device 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" refers to the central repository 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 that is required to submit the information outlined in W. Va. § 60A-9-4.

§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. The reporter shall use the National Association of Boards of Pharmacy (NABP) number assigned to the pharmacy to identify the reporter. If the reporter is a medical services provider without an assigned NABP number, then the medical services provider shall apply to the central repository for an assigned number to identify that reporter.

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 recipient or recipient representative's identification number

c. The name and address of the person for whom the prescription is written.

d. The name, address and drug enforcement administration controlled substances registration number of the practitioner writing the prescription.

e. The name and national drug code number of the Schedule II controlled substance dispensed.

f. The quantity and dosage of the Schedule II controlled substance dispensed.

g. The date the prescription was filled.

h. The number of refills, if any, authorized by the prescription.

4.2. The information required to be submitted by the provisions of this rule may be transmitted at any time but must be transmitted at least once in every 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.

6.5. All access to the data collected by the central respository shall be limited to regular business hours of the Board office unless an individual authorized to receive such information proves that an immediate danger to the public exists and immediate access is necessary to prevent further harm.