

WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

FILED

AUG 8 10 00 AM '96

Form #7

OFFICE OF WEST VIRGINIA
SECRETARY Effective Date

Sept 19, 1996

NOTICE OF AN EMERGENCY RULE

AGENCY: WV Board of Pharmacy TITLE NUMBER: 15

CITE AUTHORITY: W.Va. Code Sections 29-A-3-15, 60A-9-6

EMERGENCY 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 RULE BEING FILED AS AN EMERGENCY: 8

TITLE OF RULE BEING FILED AS AN EMERGENCY: Controlled Substances Monitoring

THE ABOVE RULE IS BEING FILED AS AN EMERGENCY RULE TO BECOME EFFECTIVE AFTER APPROVAL BY SECRETARY OF STATE OR 42ND DAY AFTER FILING, WHICHEVER OCCURS FIRST.

THE FACTS AND CIRCUMSTANCES CONSTITUTING THE EMERGENCY ARE AS FOLLOWS:

Use additional sheets if necessary

William S. Douglas Jr.
Signature Executive Director

DATE:

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:

EMERGENCY RULE TITLE: Controlled Substances Monitoring

1. Date of Filing August 7, 1996

2. Statutory authority for promulgating emergency rule:
W.Va. Code Sections 29A-3-15, 60A-9-6

3. Date of filing of proposed legislative rule: August 8, 1996

4. Does the emergency rule adopt new language or does it amend or appeal a current legislative rule?
Adopts new language

5. Has the same or similar emergency rule previously been filed and expired?
No

6. State, with particularity, those facts and circumstances which make the emergency rule necessary for the immediate preservation of public peace, health, safety or welfare.
The West Virginia Legislature in 1995 passed W.Va. Code Section 60A-9-3, which required the Board to implement a program to establish and maintain a central repository for information regarding Schedule II controlled substances prescriptions written or filled in this State.

7. If the emergency rule was promulgated in order to comply with a time limit established by the Code or federal statute or regulation, cite the Code provision, federal statute or regulation and time limit established therein.

~~W.Va. Code Section 60A-9-1, et. seq. requires that by May 1, 1996
establish a central repository for collecting Schedule II Prescription
information and promulgate rules to effectuate the purposes of the article.~~

8. State, with particularity, those facts and circumstances which make the emergency rule necessary to prevent substantial harm to the public interest.

~~The legislature found it in the best interests of the public health,
safety and welfare to establish a system to monitor the writing and
filling of Schedule II prescriptions in the State and to achieve this
aim. The Board must promulgate rules and implement the system.~~

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.

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

1. Effect of Proposed Rule

| | ANNUAL FISCAL YEAR | | | | |
|-----------------------------|--------------------|----------|-----------|------|-----------|
| | INCREASE | DECREASE | CURRENT | NEXT | HEREAFTER |
| <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.

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

FILED

AUG 8 10 00 AM '96

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

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

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 repository 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.



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(Plus all the volunteer
help we can get)

September 19, 1996

NOTICE OF EMERGENCY RULE DECISION BY THE SECRETARY OF STATE

AGENCY: West Virginia Board of Pharmacy

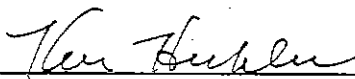
RULE: New Rule, Series 8, Controlled Substances Monitoring

DATE FILED AS AN EMERGENCY RULE: August 8, 1996

DECISION NO. 18-96

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE
SEP 19 2 40 PM 1996
FILED

Following review under WV Code 29A-3-15a, it is the decision of the Secretary of State that the above emergency rule is **approved**. A copy of the complete decision with required findings is available from this office.


KEN HECHLER
Secretary of State

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EMERGENCY RULE DECISION (ERD 18-96)

AGENCY: West Virginia Board of Pharmacy
RULE: New Rule, Series 8, Controlled Substances Monitoring
FILED AS AN EMERGENCY RULE: August 8, 1996

- par. 1 The West Virginia Board of Pharmacy (Board) has filed the above new rule as an emergency rule.
- par. 2 West Virginia Code 29A-3-15a requires the Secretary of State to review all emergency rules filed after March 8, 1986. This review requires the Secretary of State to determine if the agency filing such emergency rule: 1) has complied with the procedures for adopting an emergency rule; 2) exceeded the scope of its statutory authority in promulgating the emergency rule; or 3) can show that an emergency exists justifying the promulgation of an emergency rule.
- par. 3 Following review, the Secretary of State shall issue a decision as to whether or not such an emergency rule should be disapproved [29A-3-15a].
- par. 4 (A) Procedural Compliance: WV Code 29A-3-15 permits an agency to adopt, amend or repeal, without hearing, any legislative rule by filing such rule, along with a statement of the circumstances constituting the emergency, with the Secretary of State and forthwith with the Legislative Rule-Making Review Committee (LRMRC).
- par. 5 If an agency has accomplished the above two required filings with the appropriate supporting documents by the time the emergency rule decision is issued or the expiration of the forty-two day review period, whichever is sooner, the Secretary of State shall rule in favor of procedural compliance.
- par. 6 The Board filed this emergency rule with supporting documents with the Secretary of State August 8, 1996 and with the LRMRC August 8, 1996.
- par. 7 It is the determination of the Secretary of State that the Board has complied with the procedural requirements of WV Code §29A-3-15 for adoption of an emergency rule.

par. 8 (B) Statutory Authority -- WV Code 60A-9-6 reads:

The board of pharmacy shall promulgate legislative rules to effectuate the purposes of this article in accordance with the provisions of §29A-1-1 et seq. of this code.

par. 9 It is the determination of the Secretary of State that the Board has not exceeded its statutory authority in promulgating this emergency rule.

par. 10 (C) Emergency -- WV Code 29A-3-15(f) defines "emergency" as follows:

(f) For the purposes of this section, an emergency exists when the promulgation of a rule is necessary for the immediate preservation of the public peace, health, safety or welfare or is necessary to comply with a time limitation established by this code or by a federal statute or regulation or to prevent substantial harm to the public interest.

par. 11 There are essentially three classes of emergency broadly presented with the above provision: 1) immediate preservation; 2) time limitation; and 3) substantial harm. An agency need only document to the satisfaction of the Secretary of State that there exists a nexus between the proposal and the circumstances creating at least one of the above three emergency categories.

par. 12 The facts and circumstances as presented by the Board are as follows:

The West Virginia Legislature in 1995 passed W. Va. Code §60A-9-3, which required the Board to implement a program to establish and maintain a central repository for information regarding Schedule II controlled substances prescriptions written or filled in this State.

W. Va. Code §60A-9-1 et seq. requires that by May 1, 1996 establish a central repository for collecting Schedule II prescription information & promulgate rules.

The legislature found it in the best interests of the public health, safety & welfare to establish a system to monitor the writing and filling of Schedule II prescriptions in the State and to achieve this aim, the Board must promulgate rules and implement the system.

par. 13 It is the determination of the Secretary of State that this proposal qualifies under the definition of an emergency as defined in §29A-3-15(f). . . "time limitation" and "public health, safety and welfare".

par. 14

This decision shall be cited as Emergency Rule Decision 18-96 or ERD 18-96 and may be cited as precedent. This decision is available from the Secretary of State and has been filed with the West Virginia Board of Pharmacy, the Attorney General and the Legislative Rule Making Review Commission.



KEN HECHLER
Secretary of State

Entered _____

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

SEP 19 2 41 PM '96

FILED