WEST VIRGINIA

SECRETARY OF STATE

KEN HECHLER

ADMINISTRATIVE LAW DIVISION

Form #4

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OFFICE OF
SECRETARY OF STATE

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

CITE AUTHORITY West Virginia Code § 60A-9-6

AMENDMENT TO AN EXISTING RULE: YES___ NO XX

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, FOLLOWING REVIEW BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE IS HEREBY MODIFIED AS A RESULT OF REVIEW AND COMMENT BY THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE. THE ATTACHED MODIFICATIONS ARE FILED WITH THE SECRETARY OF STATE.

William T. Douglass, Jr.

Authorized Signature
William T. Douglass, Jr.
Executive Director

$3.20

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-9-6

1.3. Filing Date. -- _____ __, 19__

1.4. Effective Date. -- _____ __, 19__

§15-8-2. Definitions.

2.1. "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.

2.2. "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.

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

(a) A driver's license number of a recipient or a recipient's representative issued by West Virginia or any other state;

(b) A valid social security number of the recipient or a recipient representative; or

(c) If the recipient is an animal, the valid driver's license number or social security number of the animal's owner.

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

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

2.6. "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.

2.7. "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.

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

2.9. "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 Controlled Substance is dispensed or filled for out-patient use, the medical services provider, health care facility, pharmacist or pharmacy shall transmit to the central repository information outlined in section 4 of this rule. A Pharmacy 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 the information outlined in section 4 of this rule utilizing one of the following methods:

(a) An electronic device compatible with the receiving device of the central repository;

(b) A computer diskette;

(c) A magnetic tape; or

(d) if the methods listed above are not feasible, the information may be submitted on reporting forms promulgated by the Board of Pharmacy.

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 methods outlined in subsection 3.2 of this section.

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; the 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. The central repository shall create a database for the information required to be transmitted by this rule.

5.2. The 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. 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.

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 carry out 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 duly authorized agent of a licensing board of practitioners authorized to prescribe schedule II controlled substances 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) A law enforcement officer who is authorized by the Division of Public Safety 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.

(c) A person with an enforceable court order or regulatory agency administrative subpoena.

6.4. Before the Board releases the confidential information to the above-stated persons, the person must demonstrate to the Board that he or she 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.

PHA03J

ANALYSIS OF PROPOSED LEGISLATIVE RULES

Agency: Board of Pharmacy

Subject: Controlled Substances Monitoring

PERTINENT DATES

Filed for public comment: July 1, 1996
Public comment period ended: July 31, 1996
Filed following public comment period: August 8, 1996
Filed LRMRC: August 8, 1996
Filed as emergency: August 8, 1996

Fiscal Impact: $65,000 increase

ABSTRACT

The proposed rule is new. The following is a section by section synopsis of the proposed rule.

Section 1 is the standard general section, setting forth the scope, authority, filing date and effective date of the proposed rule.

Section 2 defines terms

Section 3 relates to the Prescription Monitoring Program. It specifies the identification number to be used by providers reporting data and the methods which may be used to transmit the data. It states that the Board and the central repository are to pay for telephone access charges, line charges and switch charges for the transmission of data.

Section 4 sets forth the information which must be reported to the central repository and states that the information may be transmitted at any time, but must be transmitted at least once every two months.

Section 5 requires the central repository to create a data base from the information submitted, to provide the Board with continuing 24 hour per day on-line access to the data base and to provide that the data base is secure.

Section 6 requires the Board to maintain the confidentiality of the information received and specifies to whom the information may be released.

AUTHORITY

Statutory authority: W.Va. Code, §60A-9-6, which provides as follows:

> The board of pharmacy shall promulgate legislative rules to effectuate the purposes of this article in accordance with the provisions of chapter twenty-nine-a of this code.

ANALYSIS

I. HAS THE AGENCY EXCEEDED THE SCOPE OF ITS STATUTORY AUTHORITY IN APPROVING THE PROPOSED LEGISLATIVE RULE?

No.

II. IS THE PROPOSED LEGISLATIVE RULE IN CONFORMITY WITH THE INTENT OF THE STATUTE WHICH THE RULE IS INTENDED TO IMPLEMENT, EXTEND, APPLY, INTERPRET OR MAKE SPECIFIC?

Yes.

III. DOES THE PROPOSED LEGISLATIVE RULE CONFLICT WITH OTHER CODE PROVISIONS OR WITH ANY OTHER RULE ADOPTED BY THE SAME OR A DIFFERENT AGENCY?

WVC §60A-9-5, specifies those persons to whom the information in the data base may be released and under what conditions. The proposed rule allows access to more persons under less stringent standards.

IV. IS THE PROPOSED LEGISLATIVE RULE NECESSARY TO FULLY ACCOMPLISH THE OBJECTIVES OF THE STATUTE UNDER WHICH THE PROPOSED RULE WAS PROMULGATED?

Yes.

V. IS THE PROPOSED LEGISLATIVE RULE REASONABLE, ESPECIALLY AS IT AFFECTS THE CONVENIENCE OF THE GENERAL PUBLIC OR OF PERSONS AFFECTED BY IT?

Yes.

VI. CAN THE PROPOSED LEGISLATIVE RULE BE MADE LESS COMPLEX OR MORE READILY UNDERSTANDABLE BY THE GENERAL PUBLIC?

No.

VII. WAS THE PROPOSED LEGISLATIVE RULE PROMULGATED IN COMPLIANCE WITH THE REQUIREMENTS OF CHAPTER 29A, ARTICLE 3 AND WITH ANY REQUIREMENTS IMPOSED BY ANY OTHER PROVISION OF THE CODE?

Yes.

VIII. OTHER.

Counsel has technical modifications to suggest.

West Virginia Legislature

Legislative Rule-Making Review Committee

Room MB47-State Capitol
Charleston, West Virginia 25305
(304) 347-4840

Senator Mike Ross, Co-Chair
Delegate Vicki Douglas, Co-Chair

Debra A. Graham, Counsel
Joe Altizer, Associate Counsel
Marie Nickerson, Admr. Assistant

November 20, 1996

NOTICE OF ACTION TAKEN BY LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

TO: Ken Hechler, Secretary of State, State Register

TO: Mr. William Douglas
WV Board of Pharmacy
236 Capitol Street
Charleston, WV 25301

FROM: Legislative Rule-Making Review Committee

PROPOSED RULE: Controlled Substances Monitoring

The Legislative Rule-Making Review Committee recommends that the West Virginia Legislature:

1. Authorize the agency to promulgate the Legislative Rule
   (a) as originally filed ___
   (b) as modified by the agency X

2. Authorize the agency to promulgate part of the Legislative rule; a statement of reasons for such recommendation is attached. ___

3. Authorize the agency to promulgate the Legislative rule with certain amendments; amendments and a statement of reasons for such recommendation is attached. ___

4. Authorize the agency to promulgate the Legislative rule as modified with certain amendments; amendments and a statement of reasons for such recommendation is attached. ___

5. Recommends that the rule be withdrawn; a statement of reasons for such recommendation is attached. ___

Pursuant to Code 29A-3-11(c), this notice has been filed in the State Register and with the agency proposing the rule.

Senate Bill No. 202

(By Senator(s) Ross, Anderson, Macnaughtan, Boley and Buckalew)

[Introduced March 3, 1997; referred to the Committee on Health and Human Resources; and then to the Committee on the Judiciary.]

A BILL to amend article nine, chapter sixty-four of the code of West Virginia, one thousand nine hundred thirty-one, as amended, by adding thereto a new section, designated section eight, relating to authorizing the board of pharmacy to promulgate a legislative rule relating to controlled substances monitoring.

Be it enacted by the Legislature of West Virginia:

That article nine, chapter sixty-four of the code of West Virginia, one thousand nine hundred thirty-one, as amended, be amended by adding thereto a new section, designated section eight, to read as follows:

ARTICLE 9. AUTHORIZATION FOR MISCELLANEOUS AGENCIES AND BOARDS TO PROMULGATE LEGISLATIVE RULES.

15-8

§64-9-8. Board of pharmacy.

The legislative rule filed in the state register on the eighth day of August, one thousand nine hundred ninety-six, under the authority of section six, article nine, chapter sixty-a, of this code, modified by the board of pharmacy to meet the objections of the legislative rule-making review committee and refiled in the state register on the twenty-second day of November, one thousand nine hundred ninety-six, relating to the board of pharmacy (controlled substances monitoring, 15 CSR 8), is authorized.

NOTE: The purpose of this bill is to authorize the Board of Pharmacy to promulgate a legislative rule relating to the Controlled Substances Monitoring.

This section is new; therefore, strike-throughs and underscoring have been omitted.

S7EC

H. B. 2365

Bill-Pharmacy, Controlled

(By Delegate(s) Douglas, Hunt, Compton, Faircloth, Linch and Riggs)

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