

WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #6

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OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

**NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED
BY THE WEST VIRGINIA LEGISLATURE.**

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

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: 08

TITLE OF RULE BEING PROPOSED: Controlled Substances Monitoring

THE ABOVE RULE HAS BEEN AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE.

AUTHORIZATION IS CITED IN (house or senate bill number) SB 209

SECTION 64-9-11 (b), PASSED ON 4-12-97

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON
THE FOLLOWING DATE: 6-1-97

William T. Douglass, Jr.
William T. Douglass, Jr.
Executive Director



Board of Pharmacy

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

Office
232 Capital Street
Charleston, West Virginia 25301

Title 15, Series 8, Controlled Substances Monitoring Promulgation History

Comment Period: Notice of Comment Period filed July 1, 1996,
Comment Period ending July 31, 1996.

The filing of Proposed Rule: August 8, 1996.

The filing of Modified Rule: November 22, 1996.

Effective Date: June 1, 1997.

FILED

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

MAY 5 3 48 PM '97

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-9-6

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

1.4. Effective Date. --- June 1, 1997

§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.

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KEN HECHLER
Secretary of State

MARY P. RATLIFF
Deputy Secretary of State

JAN CASTO
Deputy Secretary of State

CATHERINE FREROTTE
Executive Assistant

Telephone: (304) 558-6000
Corporations: (304) 558-8000
FAX: (304) 558-0900



WILLIAM H. HARRINGTON
Chief of Staff

JUDY COOPER
Director, Administrative Law

PENNEY BARKER
Supervisor, Corporations

**STATE OF WEST VIRGINIA
SECRETARY OF STATE**

Building 1, Suite 157-K
1900 Kanawha Blvd., East
Charleston, WV 25305-0770

(Plus all the volunteer
help we can get)

TO: WILLIAM T DOUGLASS JR

AGENCY: BOARD OF PHARMACY

FROM: JUDY COOPER, DIRECTOR, ADMINISTRATIVE LAW DIVISION

DATE: May 7, 1997

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE
MAY 9 9 07 AM '97
FILED

THE ATTACHED RULE FILED BY YOUR AGENCY HAS BEEN ENTERED INTO OUR COMPUTER SYSTEM. PLEASE REVIEW, PROOF AND RETURN IT WITH ANY CORRECTIONS. IF THERE ARE NO CORRECTIONS, PLEASE SIGN THIS MEMO AND RETURN IT TO THIS OFFICE. YOU WILL BE SENT A FINAL VERSION OF THE RULE FOR YOUR RECORDS.

PLEASE RETURN EITHER THE CORRECTED RULE OR THIS FORM WITHIN TEN (10) WORKING DAYS OF THE DATE YOU RECEIVED THIS REQUEST. CALL IF YOU HAVE ANY QUESTIONS.

SERIES: 8 TITLE: 15 BOARD OF PHARMACY

* THE ATTACHED RULE HAS BEEN REVIEWED AND IS CORRECT.

SIGNED: William S. Douglas Jr.

TITLE OF PERSON SIGNING: Executive Director

DATE: 5-8-97

* THE ATTACHED RULE HAS BEEN REVIEWED AND NEEDS CORRECTING. THE CORRECTIONS HAVE BEEN MARKED.

SIGNED: _____

TITLE OF PERSON SIGNING: _____

DATE: _____

NOTE: IF YOU ARE NOT THE PERSON WHO HANDLES THIS RULE, PLEASE FORWARD TO THE CORRECT PERSON.