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SECRETARY OF STATE
JOE MANCHIN, III
ADMINISTRATIVE LAW DIVISION

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OFFICE WEST VIRGINIA
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Form #6

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 x NO ___

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 8

TITLE OF RULE BEING AMENDED: Controlled Substances Monitoring

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: ___

TITLE OF RULE BEING PROPOSED: ___

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

AUTHORIZATION IS CITED IN (house or senate bill number) SB 2014

SECTION §64-9-12(a), PASSED ON June 13, 2003

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON THE FOLLOWING DATE: June 23, 2003

Walter J. Dorsch

Authorized Signature

$3.00

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OFFICE WEST VIRGINIA
SECRETARY OF STATE

TITLE 15
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF PHARMACY

SERIES 8
CONTROLLED SUBSTANCES MONITORING

§15-8-1. General.

1.1. Scope. --- This rule establishes requirements for the 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. -- March 18, 2003

1.4. Effective Date. -- March 18, 2003

§15-8-2. Definitions.

2.1. "Central repository" refers to the central repository designated by the Board for the collection of the transmitted information 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 to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.

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

(a) The birth date of the recipient,

2.4. "Logo" means a symbol used by an individual, a pharmacy, professional practice, professional association or hospital.

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

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 "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.

2.9. "Schedule II, III, or IV Controlled Substance" means a controlled substance classified in those categories under W. Va. Code §60A-2-206, 208 and 210.

2.10. "Security prescription blank" means a prescription blank that complies with the requirements of Section 5 of this rule.

211.. "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, III, or IV Controlled Substance is dispensed or filled for outpatient use, the medical services provider, health care facility, pharmacist or pharmacy shall transmit to the central repository the information outlined in section 4 of this rule.

3.2. Any person reporting more than 20 controlled substance prescriptions in any given month shall transmit to the central repository the information outlined in section 4 of this rule using one of the following methods:

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

(b) A computer diskette; or

(c) A magnetic tape.

3.3. Any person reporting less than 20 Schedule II, III, or IV prescriptions in any given month may submit data using a Universal Claim Form or transmit the information using the methods outlined in subsection 3.2 of this section.

3.4. The Board may grant a waiver to a person who does not have an automated recordkeeping system capable of producing an electronic report in the established format. A person requesting a waiver shall make the request to the Board in writing and the Board shall grant the request if the dispenser agrees to report the data by submitting a completed Universal Claim Form..

3.5. The Board and the central repository shall provide for the electronic transmission of the information required to be provided by and through the use of a toll-free telephone line.

§15-8-4. Information To Be Transmitted Weekly.

4.1. The information required to be submitted by the provisions of this rule may be transmitted at any time, but shall be transmitted at least every week.

4.3. The Board may not penalize a reporter 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 Prescription Forms

5.1. The purpose of this section is to establish minimum requirements that will decrease the potential for forgery or alteration of a prescription or a prescription blank for a controlled substance.

5.2. After June 1, 2003, the Board of Pharmacy recommends that a written prescription for a controlled substance in Schedules II, III or IV be on a security prescription blank.

5.3. Minimum Requirements of a Security Prescription Blank.

5.3.1. A prescription for a controlled substance should contain the following security features:

(a) A latent, repetitive "void" pattern screened and printed across the entire front of the prescription blank. If the prescription is photocopied, the word "void" shall appear in a pattern across the entire front of the prescription;

(b) A watermark printed on the backside of the prescription blank so that it is only seen at a forty-five (45) degree angle;

(c) An opaque "Rx" symbol or an "Rx" symbol printed in disappearing ink shall appear in the upper part of the blank. The symbol shall disappear if the prescription copy is lightened;

(d) Six (6) quantity check-off boxes printed on the form and the following quantities shall appear:

(1) ! 1-24;

(2) ! 25-49;

(3) ! 50-74;

(4) ! 75-100;

(5) ! 101-150; and

(6) ! 151 and over:

Provided, That if the blank has the quantity prescribed electronically printed in both numeric and word format, then the quantity check-off boxes would not be necessary;

(e) The following statement printed on the bottom of the prescription blank: "Prescription is void if more than one (1) controlled substance prescription is written per blank"; and

(f) Refill options in the following order: Refill NR 1 2 3 4 5: *Provided*, That if the blank has the refill amount electronically printed in both numeric and word format, then the quantity check-off boxes

would not be necessary.

5.3.2. A prescription shall bear the preprinted, stamped, typed, or manually printed name, address and telephone number of the prescribing practitioner.

5.3.3. A prescription blank for a controlled substance shall not contain:

(a) An advertisement on the front or the back of the prescription blank;

(b) The preprinted name of a controlled substance; or

(c) The written, typed or rubber-stamped name of a controlled substance until the prescription blank is signed, dated and issued to a patient.

5.3.4. A prescription blank for a controlled substance shall provide space for the patient's name and address, the practitioner's signature and the practitioner's DEA registration number.

5.3.5. Only one (1) controlled substance prescription blank shall be written per prescription blank.

5.3.6. A quantity check-off box that corresponds to the quantity prescribed shall be marked or the quantity electronically printed in both numeric and word format.

5.3.7. If a prescribed drug is a schedule II, III or IV controlled substance, a refill option shall be marked or the refill amount electronically printed in both numeric and word format.

5.3.8. If a prescription for a schedule II, III or IV controlled substance will be transmitted to a pharmacy by facsimile, the practitioner or the practitioner's agent shall, prior to transmission, write or stamp "FAXED" on the face of the original prescription along with the date and the person's initials.

5.3.9. If a prescription for a schedule II, III or IV controlled substance has been transmitted to a pharmacy by facsimile, the transmitting practitioner shall file the original prescription in the patient's record.

5.3.10. A pharmacist shall not be required to use a security prescription blank to record an oral prescription or a transferred prescription for a Schedule II, III or IV controlled substance.

5.3.11. The requirements of this section do not apply to prescriptions for controlled substances that are electronically transmitted from a prescriber to a pharmacy: *Provided*, That all electronically transmitted prescriptions for controlled substances shall comply with all federal requirements."

§15-8-5 6. Central Repository; Designation; Powers and Duties.

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

6.2. The central repository shall provide the Board with continuous 24-hour a day, on-line access to the database maintained by the central repository.

6.3. 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.

6.4 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.

6.5. 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 7. Confidentiality.

7.1. The Board shall carry out a program to protect the confidentiality of the information received by the central repository.

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

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

(a) A duly authorized agent of a board in this state or another state that licenses practitioners authorized to prescribe controlled substances 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) members of the West Virginia state police expressly authorized by the superintendent of the West Virginia state police to have access to the information;

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

(d) authorized agents of the federal drug enforcement agency;

(e) inspectors and agents of the board; and

(f) prescribing practitioners and pharmacists.

7.4 All information released by the board must be related to a specific patient or a specific individual or entity under investigation by any of the persons set forth in subsection 7.3 of this section except that practitioners who prescribe controlled substances may request specific data related to their drug enforcement administration controlled substance registration number or for the purpose of providing treatment to a patient.

7.5. 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 the information proves that an immediate danger to the public exists and immediate access is necessary to prevent further harm.