WEST VIRGINIA
SECRETARY OF STATE
JOE MANCHIN, III
ADMINISTRATIVE LAW DIVISION

Form #4

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OFFICE OF WEST VIRGINIA SECRETARY OF STATE

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

CITE AUTHORITY: WV Code §60A-9-6

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 PROPOSED LEGISLATIVE RULES, 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.

Will J. Dan

Authorized Signature

304-558-0558

$3.60

State of West Virginia
Board of Pharmacy

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October 28, 2002

Joe Manchin, III, Secretary of State
State Capitol Complex, Building 1, Suite 157-K
1900 Kanawha Blvd, East
Charleston, WV 25305-0770

Dear Secretary Manchin:

I am writing to approve for filing a modified rule by the Board of Pharmacy, 15 CSR 8, Controlled Substances Monitoring. Thank you for your cooperation in this important matter.

Sincerely,

William T. Douglass, Jr.
Executive Director and
General Counsel

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. -- ~~May 5, 1997.~~

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 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 ~~the actual or constructive transfer of a drug or device from one person to another whether or not there is an agency relationship~~ 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 ~~A driver's license number of a recipient or a recipient's representative issued by West Virginia or any other state;~~ birth date of the recipient,

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

2.~~4~~5. "Medical Services Provider" means a licensed practitioner with the legal authority to dispense ~~Schedule II~~ Controlled Substances.

2.~~5~~6. "Recipient" means an individual for whom a controlled substance is dispensed or filled.

2.~~6~~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.~~7~~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.~~8~~9. "Schedule II, III, or IV Controlled Substance" means a controlled substance classified in ~~Schedule II~~ 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.

2.~~9~~10. "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. ~~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~~ controlled substance prescriptions in any given month ~~must~~ shall transmit to the central repository the information outlined in section 4 of this rule ~~utilizing~~ 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~~; 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, III, or IV prescriptions in any given month may submit data ~~utilizing~~ using a Universal Claim Form or transmit the information ~~utilizing~~ 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.. ~~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 provide for the electronic transmission of the information required to be provided by and through the use of a toll-free telephone line. ~~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~~ To Be Transmitted Weekly.

~~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.~~4.1. The information required to be submitted by the provisions of this rule may be transmitted at any time, but ~~must~~ shall be transmitted at least ~~once in~~ every week ~~2 month period~~.

4.3. The Board may not penalize 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 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 January 1, 2003, a written prescription for a controlled substance shall be on a security prescription blank unless, pursuant to subsection 5.4 of this rule, the Board has granted a waiver to the practitioner who wrote the prescription or to the pharmacy that dispenses it.

5.3. Requirements of a Security Prescrip tion Blank.

5.3.1. A prescription blank shall be four and one-quarter (41/4) inches high and five and one-half (51/2) inches wide.

5.3.2. A prescription for a controlled substance shall contain the following security features:

(a) A latent, repetitive"void"pattern screened at five (5) percent in pantone green printed across the entire front of the prescription blank. If a 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. The watermark shall consist of the words "West Virginia Security Prescription", and appear horizontally in a step-and-repeated format in five (5) lines on the back of the prescription using twelve (12) point Helvetica bold type style;

(c) An opaque symbol shall in the upper right-hand corner, one-eighth (1/8) of an inch from the top of the prescription blank and five-sixteenths (5/16) of an inch from the right side of the prescription blank. The symbol shall be three-fourths (3/4) of an inch in size and 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;

(e) A logo if desired. The upper left one (1) inch square of the prescription blank shall be reserved for a logo;

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

(g) Refill options below any logo on the left side of the prescription blank in the following order: Refill NR 1 2 3 4 5.

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

5.3.4. A prescription blank for a con-trolled 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.

5.3.5. A prescription blank for a con-trolled substance shall provide space for the patient's name and address, the practitioner's signature and the practitioner's DEA registration number.

5.3.6. Only one (1) prescription shall be written per prescription blank.

5.3.7. A quantity check-off box that corresponds to the quantity prescribed shall be marked.

5.3.8. If a prescribed drug is a schedule III, IV or V controlled substance, a refill option shall be marked.

5.3.9. If a prescription for a schedule III, IV, or V 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.

5.3.10. If a pharmacist uses due diligence in ascertaining the validity of a prescription, a prescription for a schedule III, IV, or V controlled substance that is transmitted to a pharmacy by facsimile is exempt from the requirement of green ink in paragraph 5.3.1(a) of this rule and the requirement of a watermark in paragraph 5.3.1(b) of this rule.

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

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

5.3.13. If a pharmacist receives a prescription for a controlled substance that is not in compliance with this rule, then the pharmacist shall refuse to fill the prescription. Provided, that if the pharmacist in his or her professional judgement determines the immediate necessity for the patient to receive his or her medication, then the prescriptions may be dispensed and the pharmacist shall document in a log the prescription numbers and drugs dispensed. This log shall be kept in the pharmacy and be available for inspection. The pharmacist shall contact the prescriber as soon as possible to inform them that the prescription was not written according this rule. If the pharmacist continues to receive prescriptions from the same practitioner that do not comply with this rule, then the pharmacist shall inform the Board.

5.3.14. 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.

5.4. Waiver of Security Prescription Blanks.

5.4.1. A practitioner or a pharmacy may apply in writing to the Board for a

waiver from the requirement for security prescription blanks. A request for a waiver shall include:

(a) A detailed statement of the security features provided by the system proposed by the applicant for the prevention of forgery or alteration of an original prescription; or

(b) The format of the alternative prescription blank.

5.4.2. The system or prescription blank proposed by the applicant shall provide a level of security equivalent to a security prescription blank.

5.4.3. The board shall grant or deny the application in writing within sixty (60) days after the request is received.

5.4.4. When a waiver has been granted, the Board may suspend or revoke the waiver if the alternative system or alternative prescription blank does not provide security equivalent to a security prescription blank.

5.4.5. Upon notification of denial, suspension, or revocation of the waiver of the requirement for a security prescription blank, the practitioner or pharmacy may make a written request for a hearing before the Board.

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

~~5~~ 6.1. The central repository shall create a database for the information required to be transmitted by this rule.

~~5~~ 6.2. The central repository shall provide the Board with ~~continuing~~ continuous 24-hour a day, on-line access to the database maintained by the central repository.

~~5~~ 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.

~~5~~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.

~~5~~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.

~~6~~ 7.1. The Board shall carry out a program to protect the confidentiality of the information received by the central repository.

~~6~~ 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.

~~6~~ 7.3. The Board may release confidential information received by the central repository to the following persons:

(a) A duly authorized agent of a ~~licensing~~ board in this state or another state ~~of~~ that licenses 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.~~ 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.

~~6~~ 7.4. ~~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.~~ 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.

~~6~~ 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 ~~such~~ the information proves that an immediate danger to the public exists and immediate access is necessary to prevent further harm.