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

Form #2

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OFFICE WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: WV Board of Pharmacy TITLE NUMBER: 15

RULE TYPE: Legislative 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: ____

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON July 12, 2002 AT 4:00 p.m. ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

WV Board of Pharmacy
232 Capitol Street
Charleston, WV 25301
Fax: 304-558-0572

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.

Walt S. Dalton
Authorized Signature
Executive Director
558-0558

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

SCANNED

$4.40

State of West Virginia

Board of Pharmacy

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

Office
232 Capitol Street
Charleston, West Virginia 25301

June 11, 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 a proposed rule by the Board of Pharmacy to be filed, 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

SUMMARY OF PROPOSED RULE

Title 15

Legislative Rules

Series 8

Controlled Substances Monitoring

This rule amends current Series 8, entitled "Controlled Substances Monitoring." This rule provides definitions of many terms used in the collection of data for the controlled substances monitoring program. The rule establishes the reporting mechanism for the data and provides for procedure to seek waivers from reporting. The rule delineates the information that is to be transmitted for each prescription and requires security prescription blanks to be used for all written controlled substance prescriptions. The rule provides for protection of confidential patient information and authorizes disclosure to specified representatives.

STATEMENT OF CIRCUMSTANCES

Title 15

Legislative Rules

Series 8

Controlled Substances Monitoring

This rule amends the current Series 8, entitled "Controlled Substances Monitoring." HB 4419 requires the Board of Pharmacy to implement a controlled substances monitoring program by September 1, 2002 and the Board must promulgate rules to accomplish this. HB 4419 was the result of several meetings during the legislative session of a task force of stakeholders and interested parties concerned with diversion and inappropriate prescribing and abuse of controlled substances.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Controlled Substances Monitoring

Type of Rule: x Legislative ____ Interpretive ____ Procedural

Agency: WV Board of Pharmacy

Address: 232 Capitol Street

Charleston, WV 25301

Phone: 304-558-0558

1. Effect of Proposed rule:

	ANNUAL		FISCAL YEAR		
	INCREASE	DECREASE	CURRENT	NEXT	THEREAFTER
ESTIMATED TOTAL COST	$140,000		$140,000	$111,000	$111,000
PERSONAL SERVICES	$36,000		$36,000	$36,000	$36,000
CURRENT EXPENSE					
REPAIRS & ALTERATIONS					
EQUIPMENT	$4,000		$4,000	0	0
OTHER	$100,000		$100,000	$75,000	$75,000

2. Explanation of Above Estimates:
The increase under personal services is to hire an additional employee as controlled substances monitoring assistant. The $100,000 fee is the estimated startup amount to be paid to the vendor that collects the data that is electronically submitted from the reporters. The annual fee to be paid to that vendor is estimated to be $75,000 thereafter.

3. Objectives of These Rules:
To help prevent diversion of controlled subtances and allow health care practitioners to appropriately and legitmately treat patients with controlled substances and monitor their compliance.

Rule Title: Controlled Substances Monitoring

4. Explanation of Overall Economic Impact of Proposed Rule:

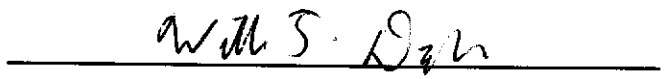
   A. Economic Impact on State Government:
   Vendor fee of $100,000 was appropriated to the Board this year from the Health Care Authority fund. A revenue source will need to be found for the $75,000 annual fee to the vendor.

   B. Economic Impact on Political Subdivisions; Specific Industries; Specific Groups of Citizens: There will be a slight economic impact on some pharmacies that have to update their computer software but the costs will be minimal or nonexistent.

   C. Economic Impact on Citizens/Public at Large.
   N/A

Date: 05/28/2002

Signature of Agency Head or Authorized Representative:



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2002 JUN 11 P 1:40

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. --- 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. -- ~~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 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;~~ birth date of the person for whom the prescription was written;

~~(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 utilized 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, 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 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; 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 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 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.

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)~~(b) The name, ~~and~~ address, and birth date of the person for whom the prescription is written.

~~(d)~~(c) The name, address and drug enforcement administration controlled substances registration number of the practitioner writing the prescription.

~~(e)~~(d) The name and national drug code number of the ~~Schedule II~~ controlled substance dispensed.

~~(f)~~ (e)The quantity and dosage of the ~~Schedule II~~ controlled substance dispensed.

~~(g)~~(f) The date the prescription was filled.

~~(h)~~ (g) 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 week ~~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 Prescription Forms

5.1 The purpose of this rule 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. Security Prescription Blanks Required.

5.2.1. 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.

5.2.2. A practitioner who is licensed in West Virginia and in another state shall utilize a security prescription blank for writing a prescription for a controlled substance while practicing his profession within West Virginia unless, pursuant to subsection 5.4 of this rule, the Board has granted a waiver to the practitioner or to the pharmacy that dispenses the controlled substance.

5.3. Requirements of a Security Prescrip tion Blank.

5.3.1. 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 shall be 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 shall be printed on the backside of the prescription blank so that it shall only be 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 appear 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 shall be 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 may appear on the prescription blank. The upper left one (1) inch square of the prescription blank shall be reserved for a logo;

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

(g) Refill options shall appear below any

logo on the left side of the prescription blank in the following order: Refill NR 1 2 3 4 5; and

(h) 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 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 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.

5.3.4 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.

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

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

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

5.3.8. 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.

5.3.9. 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 shall be 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.

5.3.10. 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.

5.3.11. 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.

5.3.12. 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 West Virginia Board of Pharmacy.

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 prescrip-

tion 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 cabinet 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 request 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 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 of practitioners in this state and other states 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 state board of pharmacy; 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 state board of pharmacy must be related to a specific patient or a specific individual or entity under investigation by any of the above parties 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 information proves that an immediate danger to the public exists and immediate access is necessary to prevent further harm.