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

Form #3

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FILED

2002 JUL 17 A 11:26

OFFICE WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

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 RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

Will T. Digh
Authorized Signature
Executive Director
558-0558

SCANNED

$6.20

State of West Virginia
Board of Pharmacy

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

Office
232 Capitol Street
Charleston, West Virginia 25301

July 15, 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 the filing of a proposed 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

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: 07-15-02

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:(*Agency Name, Address & Phone No.*) West Virginia Board of Pharmacy
232 Capitol Street
Charleston, WV 25301 Phone: 558-0558

LEGISLATIVE RULE TITLE: Controlled Substances Monitoring

1. Authorizing statute(s) citation WV Code 60A-9-6

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

June 11, 2002

b. What other notice, including advertising, did you give of the hearing?

Put information on website, contacted several interested associations via email such as WV Pharmacists Association, WV Medical Association.

c. Date of Public Hearing(s) ***or*** Public Comment Period ended:

July 12, 2002

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached X No comments received _____

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

July 17, 2002

f. **Name, title, address and <u>phone/fax/e-mail numbers</u>** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

William T. Douglass, Jr.- Executive Director

232 Capitol Street

Charleston, WV 25301

Phone: 304-558-0558 Fax: 304-558-0572 Email: wdouglass@wvbop.com

g. **<u>IF DIFFERENT</u> FROM ITEM 'f'**, please give **Name, title, address and phone number(s)** of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

N/A

b. Date of hearing or comment period:

N/A

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

N/A

d. Attach findings and determinations and reasons:

Attached N/A

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:

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.

5.3.13. The above rules under section 5 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 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.

56.4 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.

56.5. 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.

State of West Virginia
Board of Pharmacy

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

Office
232 Capitol Street
Charleston, West Virginia 25301

WRITTEN COMMENTS RECEIVED AND RESPONSE

NACDS
NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

July 10, 2002

Mr. William T. Douglass, Jr.
Executive Director and General Counsel
West Virginia Board of Pharmacy
232 Capitol Street
Charleston, WV 25301

RE: Notice of emergency rules to reestablish a controlled substance monitoring program; and Notice of proposed rules to establish pharmacist recovery networks

Dear Mr. Douglass:

On behalf of the 316 chain drug stores operating in the State of West Virginia, and the National Association of Chain Drug Stores (NACDS), we thank you for the opportunity to submit comments on the proposed rules to establish a controlled substance monitoring program, and to establish pharmacist recovery networks.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

1. Under §15-8-4, The Board is Proposing to Require that Non-Standard Information be Transmitted

   Currently, all states that electronically monitor controlled substance prescriptions use the same standard format. That standard format is the "ASAP (American Society for Automation in Pharmacy) Telecommunications Format for Controlled Substances." Utilization of this standard format allows states to implement controlled substance monitoring programs as economically and efficiently as possible. It prevents multi-state pharmacy operators from having to comply with a patchwork of state requirements. Pharmacies and software vendors have come to rely upon the ASAP standard when designing their pharmacy practice management systems. Any deviation from the standard format will delay compliance with a controlled substance monitoring program as software and, in some cases, system hardware will need to be altered. For the Board's review, we have attached a document describing the ASAP standard. We urge the Board to propose regulations that follow this standard.

   Specifically, the deviations from the ASAP standard that the Board is proposing are as follows. All deviations are found under proposed rule §15-8-4:
   - 4.1(a): The name and address of the pharmacy is non-standard. The Board can achieve the same goal by requiring only the pharmacy NCPDP number or DEA number.
   - 4.1(c): The name and address of the prescribing practitioner is non-standard. The Board can achieve the same goal by requiring only the DEA number of the prescribing practitioner.

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

- 4.1(d): The name of the controlled substance dispensed is non-standard. The Board can achieve the same goal by requiring only the NDC number of the controlled substance dispensed.
- 4.1(e): The dosage of the controlled substance dispensed is non-standard. The Board can achieve the same goal by requiring the day's supply of the controlled substance dispensed.

2. Under §15-8-4, the Board's Proposal to Require Information to be Submitted to the Central Repository every Week is Wasteful and Burdensome

   Currently, no state that monitors controlled substance prescriptions requires information to be transmitted to a central repository as frequently as every week. Most states require information to be transmitted once a month, while a minority of states requires transmission twice a month. The Board's current proposal will require information to be transmitted as much as five times a month. This will increase administrative costs to the state, as the information collection entity (Atlantic Associates) will have to collect and process information much more frequently than it is currently accustomed to. Moreover, this will burden pharmacies that are not able to transmit the required information via a telephone line. Those pharmacies will have to run batch computer programs to download information to a tape or diskette medium, and mail the medium to the repository every single week.

   We question the necessity of weekly reporting when currently no other state requires this. The enabling legislation for this program (HB 4419) states that the required information shall be submitted no more frequently than once a week. We urge the Board to consider monthly or semi-monthly reporting.

3. We request clarification of proposed rule subsection 5.3.1(g) under §15-8-5. The proposed states, "Refill options shall appear below any." This is an incomplete sentence. Please clarify this.

4. We are concerned that the proposed rules that require a security prescription blank would hinder the electronic transmission of prescriptions for controlled substances. Currently, the DEA is proposing rules that will allow the electronic transmission of controlled substance prescriptions in Schedules II, III, IV and V. We recommend adding the following additional language under §15-8-5 to clarify that the security prescription blank requirements for written prescriptions do not apply to electronically transmitted prescriptions:

   5.3.13. The above rules under §15-8-5, rules 5.1 through 5.3.12, do not apply to prescriptions for controlled substances that are electronically transmitted from a prescriber to a pharmacy. Electronically transmitted prescriptions must comply with all federal requirements.

5. Under the Board proposal for pharmacist recovery networks, we believe the reference under subsection 12.2 (under §15-10-12) that refers to section 9.1 should instead refer to section 10.1.

Thank you very much for considering these comments. Please do not hesitate to contact us if we can be of further assistance.

Sincerely,

Kevin N. Nicholson, R.Ph., J.D.
Director, Pharmacy Regulatory Affairs

cc: Mary Ann Wagner
Vice President, Pharmacy Regulatory Affairs

Attachment: 1

State of West Virginia
Board of Pharmacy

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

Office
232 Capitol Street
Charleston, West Virginia 25301

July 12, 2002

Kevin N. Nicholson, R.Ph., J.D.
National Association of Chain Drug Stores
413 North Lee Street, P.O. Box 1417-D49
Alexandria, VA 22313-1480

Dear Mr. Nicholson:

I am writing in response to your comments on our proposed legislative rules, 15 CSR 8 and 15 CSR 10.

1. All information that is required to be submitted is mandated by the statute and cannot be changed by legislative rule. I have enclosed a copy of the bill, HB 4419, which lists the required information under §60A-9-4 (a).

2. As you state the bill states that information shall be submitted no more frequently than once a week. The Board chose to require weekly submission in order to make the data in the system as current as possible to assist the pharmacists, practitioners, and law enforcement or regulatory personnel when they are seeking timely information from the system. The costs for the database vendor are not affected dramatically due to this timeline. Most pharmacies will submit their information electronically and probably should modify their systems if they are not set up to do so. If a pharmacy chooses not to submit electronically, then they indeed will have the burden of making 52 mailings a year but the benefits obtained from timely data outweigh that burden.

3. Subsection 5.3.1 (g) continues onto page 4 of the enclosed rule and is a complete sentence.

4. The Board will modify the rule to include the language you proposed in 5.3.13 to exempt electronically transmitted prescriptions from the security prescription blank

requirements since those requirements were intended to apply only to written blanks that physically leave the practitioners's office.

5. I will make that correction to reference section 10.1 when I file the modified rule. Thank you for bringing that error to my attention.

Thank you for your relevant comments and taking the time to thoroughly review our proposed legislative rules.

Sincerely,

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

State of West Virginia
Board of Pharmacy

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

Office
232 Capitol Street
Charleston, West Virginia 25301

Amendments made to proposed rule, 15 CSR 8, after public comment

The following section was added after comments from the National Association of Chain Drug Stores. The purpose of the amendment is to clarify that the security blank provisions are meant to apply only to written prescriptions that physically leave the practitioner's office.

5.3.13. The above rules under section 5 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.