

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

Form #3 ■

Do Not Mark In This Box

FILED

2002 JUL 17 A 11:29

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 30-5-7c(d) - HB 4277

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 RULE BEING PROPOSED: 10

TITLE OF RULE BEING PROPOSED: Board of Pharmacy Rules for Pharmacist Recovery
Networks

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.

Walter S. Doyle

Authorized Signature

Executive Director

558-0558

SCANNED



Board of Pharmacy

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

Office
232 Capital 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 10, Board of Pharmacy Rules for Pharmacist Recovery Networks. 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: Board of Pharmacy Rules for Pharmacist Recovery Networks

1. Authorizing statute(s) citation WV Code 30-5-7c (d)- HB 4277

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.

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 phone/fax/e-mail numbers** 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. **IF DIFFERENT 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 10

BOARD OF PHARMACY RULES FOR PHARMACIST RECOVERY NETWORKS

HB 4277 passed the Legislature on February 22, 2002 and authorized the Board of Pharmacy to enter into agreements with organizations to form pharmacist recovery networks for impaired pharmacists, interns, and technicians. Prior to entering into any agreement with any organization to form the network, the Board has to propose rules regarding the operation of the network. Impairment in the profession of pharmacy has become a serious problem and the sooner the network is formed, the sooner the public will be protected and the impaired professional can seek help.

The Rule establishes definitions of impairment; guidelines for program elements; procedures for receipt and use of information of suspected impairment; procedures for intervention and referral; arrangements for mandatory monitoring, treatment, rehabilitation, post-treatment support and performance; reports of individual cases to the Board; periodic reporting of statistical information; assurance of confidentiality of nonpublic information and of the peer review process; and assessment of a fee to be added to each licensure renewal for operation of pharmacist recovery networks.

STATEMENT OF CIRCUMSTANCES

Title 15

Legislative Rules

Series 10

Board of Pharmacy Rules for Pharmacist Recovery Networks

This rule is necessary in order to effectuate HB 4277 which the Legislature passed on February 22, 2002. HB 4277 authorized the Board to enter into agreements with organizations to form pharmacist recovery networks for impaired pharmacists, interns, and technicians. Prior to entering into these agreements, these rules regarding the operation of the network had to be proposed.

□
APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: 15 CSR 10 Board of Pharmacy Rules for Pharmacist Recovery Networks

Type of Rule: Legislative Interpretive Procedural

Agency: West Virginia Board of Pharmacy

Address: 232 Capitol Street Charleston, WV 25301

304-558-0558

1. Effect of Proposed rule:

	ANNUAL FISCAL YEAR				
	INCREASE	DECREASE	CURRENT	NEXT	THEREAFTER
ESTIMATED TOTAL COST	50,000		0	50,000	50,000
PERSONAL SERVICES	40,000			40,000	40,000
CURRENT EXPENSE					
REPAIRS & ALTERATIONS					
EQUIPMENT	2,000			2,000	0
OTHER	8,000			8,000	8,000

2. Explanation of Above Estimates:

The cost of the services for the pharmacist recovery network are not known but the above is an estimate for the payment of a part-time staff, a small amount of computer and office equipment, and office space. The Board will contract out the services so exact number won't be known until the contract is bid out.

3. Objectives of These Rules:

To allow the Board to enter into agreements to establish a pharmacist recovery network for impaired pharmacists, interns, and technicians. The rule establishes procedures of the network and sets an additional fee to be charged to licensees to fund the network

Rule Title: Board of Pharmacy Rules for Pharmacist Recovery Networks

4. Explanation of Overall Economic Impact of Proposed Rule:

A. Economic Impact on State Government:

Will cost the Board of Pharmacy up to \$50,000 per year for contracted services.

B. Economic Impact on Political Subdivisions; Specific Industries; Specific Groups of Citizens: Pharmacists will pay an additional \$20 every two years with their license renewal, interns will pay an additional \$5 per year, and technicians will pay an additional \$10 every two years with their registration renewal. These increased fees will bring in an estimated \$35,000-40,000 per year to pay for the network.

C. Economic Impact on Citizens/Public at Large.
None

Date: 06-11-02

Signature of Agency Head or Authorized Representative:

William T. Douglas Jr.

William T. Douglas Jr.
304-558-0558

TITLE 15
LEGISLATIVE RULES
BOARD OF PHARMACY

FILED

2002 JUL 17 A 11:29

SERIES 10

BOARD OF PHARMACY RULES FOR PHARMACIST RECOVERY NETWORKS

WEST VIRGINIA
SECRETARY OF STATE

§15-10-1. General.

- 1.1. Scope. – This rule establishes definitions of impairment; guidelines for program elements; procedures for receipt and use of information of suspected impairment; procedures for intervention and referral; arrangements for mandatory monitoring, treatment, rehabilitation, post-treatment support and performance; reports of individual cases to the Board; periodic reporting of statistical information; assurance of confidentiality of nonpublic information and of the peer review process; and assessment of a fee to be added to each licensure renewal for operation of pharmacist recovery networks.
- 1.2. Authority. – W.Va. Code §30-5-7c(d).
- 1.3. Filing Date. –
- 1.4. Effective Date. –

§15-10-2. Definitions.

- 2.1. Board means the West Virginia Board of Pharmacy.
- 2.2. Committee means the Board of Directors established to function as a supervisory and advisory body to the Program.
- 2.3. Executive Director means the administrator or clinical director selected by the Board of Directors to administer the program.
- 2.4. Impairment means mental illness, chemical dependency, physical illness, or any abnormal physical or mental condition of a pharmacist, intern or technician which threatens himself or herself or the safety of persons to whom such person might sell or dispense prescription drugs or devices.
- 2.5. Licensee means a licensed pharmacist, licensed intern, or registered pharmacy technician.
- 2.6. Program or West Virginia Pharmacist Recovery Network (WVPRN) means the program established by agreements between special impaired pharmacist peer review organizations and the Board.

§15-10-3. Pharmacist Recovery Network Agreements.

- 3.1. Pharmacist Recovery Network activities shall include:
 - 3.1.1. investigation;
 - 3.1.2 review and evaluation of records, reports, complaints, litigation, and other information about

the practices and practice patterns of licensees of the Board;

3.1.3. programs for impaired licensees of the Board; and

3.1.4. other activities as deemed appropriate by the Board.

3.2 Pharmacist Recovery Network Agreements with the Board shall require the following:

3.2.1 Upon receiving a report or request, the Executive Director will make contact with the licensee to verify concerns.

3.2.2. If it is determined there is sufficient reason for concern and action, such as behavioral signs, documented evidence of impairment, and/or drug diversion, the Executive Director shall encourage the licensee to present themselves to the WVPRN office within 48 hours of initial contact for a complete substance abuse assessment.

a. If the individual resists coming in for an assessment, one repeat contact shall be pursued.

b. After two unsuccessful interventions within a period not to exceed 14 days, the individual will be informed of WVPRN's intent to close the file and disclose all evidence of impairment allowed by law to the Board of Pharmacy.

3.2.3. Upon arriving at the WVPRN office, the Executive Director and/or Clinical Director will conduct a substance abuse evaluation to include among other things, a psychoactive substance use history, administration of a Substance Abuse Subtle Screening Inventory (SASSI), urinalysis, and Breathalyzer.

3.2.4. If a diagnosis of substance abuse or dependence as per DSM-IV (or current edition) is made, the Executive Director and/or Clinical Director will arrange for further evaluation and treatment to be conducted at a facility or individual approved by the WVPRN program. If there is insufficient evidence to warrant a diagnosis of substance abuse or dependence, the file shall be placed in an inactive status, and destroyed after 5 years.

3.2.5. The Executive Director and/or Clinical Director will draw up a final agreement between the individual and WVPRN for the individual to enter into a treatment or other appropriate program. The Executive director and /or Clinical Director will work with the treatment provider to determine the guidelines of treatment and aftercare, and will consult with the primary care giver on a regular basis.

3.2.6. The Executive Director will collect appropriate paper work, as specified in the contract, regarding treatment progress, group therapy participation, urine and/or blood analysis, discharge summaries, etc.

3.2.7. Monitors will assist the licensee in transition into the workplace by providing

information if requested to the supervisors and co-workers regarding chemical dependency, relapse, and diversion.

3.2.8. Upon the completion of treatment and rehabilitation, and the expiration of the 5 year recovery contract, WVPRN involvement may conclude.

§15-10-4. Due Process.

4.1. Any action taken pursuant to a pharmacist recovery network must afford the licensee all due process rights enumerated in West Virginia Code §29A-1-1 et. seq.

§15-10-5. Receipt and Use of Information of Suspected Impairment

5.1. Information concerning suspected impairment may be received by the program through reports by licensees, family members, and others, and through self-referral.

5.2. Upon receipt of information of a suspected impairment, the program shall initiate an investigation.

5.3. The program may conduct routine inquiries regarding suspected impairments.

5.4. Licensees suspected of impairment may be required to submit to personal interviews before any person authorized by the program.

§15-10-6. Intervention and Referral.

6.1. When, following an investigation, impairment is confirmed, an intervention shall be conducted using specialized techniques designed to assist the licensee in acknowledging responsibility for dealing with the impairment. The licensee shall be referred to an appropriate treatment source acceptable to the program.

6.2. The program shall decide the methods and objectives of interventions on a case-by-case basis.

6.3. The program shall arrange and conduct interventions as soon as possible.

6.4. The program shall evaluate treatment sources before making case referrals for treatment.

6.5. The program shall record intervention outcomes including treatment contracts that are elements of an intervention.

§15-10-7. Monitoring Treatment.

7.1. The program shall monitor a treatment source receiving referrals from them as to its ability to provide:

7.1.1. adequate medical and non-medical staffing;

7.1.2. appropriate treatment;

7.1.3. affordable treatment;

7.1.4. adequate facilities; and

7.1.5 appropriate post-treatment support.

§15-10-8. Monitoring Rehabilitation and Performance.

8.1. The program shall designate monitoring requirements for each licensee participating in the program. Licensees may be required to be tested regularly or randomly on demand of the program.

8.2. The program may require treatment sources to submit reports regarding a licensee's rehabilitation and performance to the program.

8.3. The program may require impaired licensees to submit to periodic personal interviews before any person authorized by the program.

8.4. The program shall maintain appropriate case records regarding participants.

§15-10-9. Monitoring Post-Treatment Support.

9.1. Post-treatment support may include family counseling, advocacy and other services and programs deemed appropriate to improve recoveries.

9.2. The program shall monitor the post-treatment support of treatment sources on an ongoing basis.

9.3. The program's own post-treatment support shall be monitored by the program on an ongoing basis.

§15-10-10. Reports of Cases of Impairment to the Board.

10.1. Upon investigation and review of a licensee, the program shall report immediately to the Board detailed information about any licensee as required by West Virginia Code §30-5-7c(e).

10.2. The program shall submit quarterly a report to the Board on the status of all licensees then involved in the program who have been previously reported to the Board. The program shall submit monthly to the Board a report on the status of any licensee previously reported to the Board then in active treatment until such time as mutually agreed to by the Board and the program.

10.3. In the event the program becomes aware that the licensee has diverted controlled substances to a person other than themselves, the program shall report this infraction to the Board. In this case, the individual is not protected by the program's confidentiality provisions or from disciplinary action by the Board.

§15-10-11. Periodic Reporting of Statistical Information.

11.1. The program shall compile and annually report to the Board comprehensive statistical reports concerning suspected impairments, impairments, self-referrals, post-treatment support and other significant demographic and substantive information collected through program operations.

§15-10-12. Confidentiality.

12.1. All information, interviews, reports, statements, memoranda, or other documents furnished to or produced by the program, all communications to or from the program, and all proceedings, findings, and conclusions of the program, including those relating to intervention, treatment, or rehabilitation, that in any way pertain to or refer to a person participating in a pharmacist recovery network shall be privileged and confidential.

12.2. All records and proceedings of the program that pertain or refer to a person participating in a pharmacist recovery network shall be privileged and confidential, used by the program and its members only in the exercise of the proper function of the program, not be considered public records, and not be subject to court subpoena, discovery, or introduction as evidence in any civil, criminal, or administrative proceedings, except as provided in Section 10.1 of this rule.

12.3. The program may only disclose the information relative to an impaired licensee if:

12.3.1. it is essential to disclose the information to persons or organizations needing the information in order to address the intervention, treatment, or rehabilitation needs of the impaired licensee;

12.3.2. the release is authorized in writing by the impaired licensee; or

12.3.3 the program is required to make a report to the board pursuant to Section 10.1 of this rule.

§15-10-13. Fees.

13.1. The Board shall assess the following fees to be added to each licensure renewal application fee payable to the Board with any revenue generated by the assessment dedicated to the operation of the pharmacist recovery network:

13.1.1. Pharmacist- \$20 with each biennial renewal;

13.1.2. Intern- \$5 with each annual renewal; and

13.1.3. Pharmacy Technician- \$10 with each biennial renewal.



Board of Pharmacy

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

Office
232 Capital Street
Charleston, West Virginia 25301

WRITTEN COMMENTS RECEIVED AND RESPONSE

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.

- 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.

National Association of Chain Drug Stores

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

Page 3

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,

A handwritten signature in black ink, appearing to read "Kevin N. Nicholson". The signature is fluid and cursive, with the first name "Kevin" being more prominent than the last name "Nicholson".

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

cc: Mary Ann Wagner
Vice President, Pharmacy Regulatory Affairs

Attachment: 1



Board of Pharmacy

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

Office
232 Capital 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.

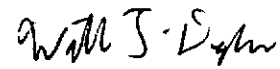
1. All information that is required to be submitted is mandated by the statute and cannot be changed by legislative rule. I have enclosed a copy of the bill, HB 4419, which lists the required information under §60A-9-4 (a).
2. As you state the bill states that information shall be submitted no more frequently 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



Board of Pharmacy

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

Office
232 Capital Street
Charleston, West Virginia 25301

Amendments made to proposed rule, 15 CSR 10, after public comment

The following section was amended after comments from the National Association of Chain Drug Stores pointed out that the exception at the end of the rule incorrectly referenced section 9.1 instead of 10.1.

12.2. All records and proceedings of the program that pertain or refer to a person participating in a pharmacist recovery network shall be privileged and confidential, used by the program and its members only in the exercise of the proper function of the program, not be considered public records, and not be subject to court subpoena, discovery, or introduction as evidence in any civil, criminal, or administrative proceedings, except as provided in Section 10.1 of this rule.