WEST VIRGINIA SECRETARY OF STATE NATALIE E. TENNANT ADMINISTRATIVE LAW DIVISION

Form #3

Do Not Mark In This Box

FILEL

2012 JUL 31 PM 3: 59

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 Examiners for Registered Professional Nurses	TITLE NUMBER:
CITE AUTHORITY: § 60A-9-5a(a)(b)	
AMENDMENT TO AN EXISTING RULE: YES NO_x_	
IF YES, SERIES NUMBER OF RULE BEING AMENDED:	
TITLE OF RULE BEING AMENDED:	_
IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 14 TITLE OF RULE BEING PROPOSED: Practitioner Requirements for Access: Substances Monitoring Program Data	ing the West Virginia Controlled
Substances Monitoring Program Data	Dase

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.

Authorized Signature

email:rnboard@state.wv.us web address:www.wvrnboard.com



TELEPHONE: (304) 558-3596 FAX (304) 558-3666

STATE OF WEST VIRGINIA

BOARD OF EXAMINERS FOR REGISTERED PROFESSIONAL NURSES 101 Dee Drive, Suite 102

Charleston, WV 25311-1620

July 30, 2012

The Honorable Natalie Tennant Secretary of State Building 1, Suite 157-K 1900 Kanawha Blvd Charleston, WV 25305-0770

RE: Board Approved Legislative Proposed Rule WV 19 CSR 14

Dear Secretary Tennant:

The West Virginia Board of Examiners for Registered Professional Nurses (Board) in session July 27, 2012 approved the proposed rule WV 19 CSR 14 Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database following the comment period. This letter serves to notify your office of the agency approval and to provide the required brief summary for the proposed changes.

The proposed rule is required by SB 437, of the 2012 Regular Legislative Session. This law requires the Board to incorporate language into rule which would require practitioners to take necessary steps when prescribing controlled substances to patients by accessing the database to determine whether a patient previously received a controlled substance and to document the information in the patient's file.

Pursuant to the comments received, the Board approved amendments to the proposed rule which further clarify requirements for practitioners accessing the database and define terminology used in the rule.

Should you have any questions or desire more information please contact me.

For the Board.

Laura Skidmore Rhodes, MSN, RN

Executive Director

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:	. Ju	y 30, 2012
TO:	LEC	GISLATIVE RULE-MAKING REVIEW COMMITTEE
FROM	I:(Age	ncy Name, Address & Phone No.) West Virginia Board of Examiners for Registered Professional Nurses 101 Dee Drive, Suite 102
		Charleston, WV 25311 (304) 558-3596
LEGIS	SLAT	IVE RULE TITLE: Practitioner Requirements for Accessing the West Virginia Controlled Substance Monitoring Program Database
1.	Autl	norizing statute(s) citation §60A-9-5a(a)(b)
2.	a.	Date filed in State Register with Notice of Hearing or Public Comment Period:
		June 29, 2012
	b.	What other notice, including advertising, did you give of the hearing? Notice of rule changes was placed in RN News Magazine in March and June 2012.
	c.	Date of Public Hearing(s) or Public Comment Period ended:
		June 22, 2012 - July 22, 2012
	d.	Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.
		AttachedX No comments received

	e.	Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)
		July 31, 2012
	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)
		Laura S. Rhodes, RN, MSN
		Executive Director WV Board of Examiners for Registered Professional Nurses
		101 Dee Drive, Suite 102 Charleston, WV 25311
		(304) 558-3596 (Telephone) (304) 558-3666 (Facsimile) rnboard@wv.gov
	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.		ne statute under which you promulgated the submitted rules requires certain findings and erminations 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.

b.	Date of hearing or comment period:
c.	On what date did you file in the State Register the findings and determinations required together with the reasons therefor?
d.	Attached

Rhodes, Laura S

From:

Angelita Nixon <anmidwife@netzero.net>

Sent:

Monday, July 23, 2012 10:31 PM

To:

Rhodes, Laura S .

Subject:

Letters of support for RULE re. CSMP and prescriptive authority

Attachments:

Rule comments - WV RN Board- CSMP - from AN.docx; Rule comments - WV RN Board

- rx authority - from AN.docx

Hi, Laura,

Correction – these are the two final rule comments from me, same caveat from the last email about after the deadline and sorry they are electronic versions. (I just sent the last one for the CSMP, but then I noticed a couple of typos.) Hope these are helpful. Thanks again for all the hard work on getting these finalized!

Angy

From: Rhodes, Laura S [mailto:Laura.S.Rhodes@wv.gov]

Sent: Wednesday, July 18, 2012 4:27 PM

To: Angelita Nixon

Subject: RE: Letter of support for RULE re. fee increase

Thank you Angy.

Loura Rhodes

Laura Skidmore Rhodes **Executive Director** WV RN Board 101 Dee Drive, Suite 102 Charleston, WV 25311 www.wvrnboard.com 304-558-3596

Fax: 304-558-3666





Please consider the environment before printing this email.

From: Angelita Nixon [mailto:anmidwife@netzero.net]

Sent: Wednesday, July 18, 2012 4:23 PM

To: Rhodes, Laura S

Subject: Letter of support for RULE re. fee increase

Hi, Laura,

I'm sorry to have to send this letter by email, as I know you have asked for a hardcopy by mail but are willing to accept electronic copies. I also did fax it because I couldn't get the letterhead to transfer over to the word document. I'm working on this for the other letters I am preparing for comments on Rules, too – a technological challenge for me.

On a personal note, I want to thank you for the opportunity to work with the Board on so many joint efforts over the past six months. I look forward to continued collaborative efforts. In terms of the fee increase, each of these experiences has really given me an opportunity to develop a greater appreciation for the work of the Board and staff.

Sincerely, Angy

Angelita Nixon, CNM, LLC

Angy Níxon
certified Nurse-Midwife
147 Scenic Drive
Scott Depot, WV 25560
304-757-9006

WV Board of Examiners for Registered Professional Nursing 101 Dee Drive, Suite 102 Charleston, WV 25311

July 22, 2012

Dear Board Members/Staff:

I am responding to the proposed legislative rule title number 19 series 14 cite authority 60A-9-5a(a) titled "Practitioner requirements for accessing the WV controlled Substances Monitoring Program database."

I would first like to commend the entire board and staff for the hard work put forth on the drafting of these rules well with those of the boards of other prescribers. As an officer of the West Virginia ACNM Affiliate I appreciate the difficult work being done for the safety of our clients, our profession and our community. I would like to personally thank you all for your remarkable efforts in drafting these rules. Again let me reiterate that the ACNM Affiliate agrees 100% with the intent of this rule as proposed.

We would like to comment on a few a few specific concerns within the rule:

First there does not seem to be a definition of "Chronic nonmalignant pain." We feel this is a concern since there could be some future confusion as to the difference between acute and chronic pain and treatment for acute pain may fall into a grey area of concern.

Second the definition for "Provision" states "means prescribing and administering" We are concerned that this should include only the word prescribing and NOT administering. Administration of medication adds a totally separate profession scope that is not include and does not seem to be intended under the new code that is being addressed by this law. Furthermore there are concerns that this could cross over to pain control within hospital institutions, unless this is alternatively defined as an outpatient pain clinic setting only.

Finally with the new and current use of electronic record it does NOT seem practical to copy the CSMP, date, and sign the report. I am wondering if the Board of Pharmacy could have a receipt number or code that could be pasted to the electronic medical record as done in online banking with bill receipts.

Thank you for your consideration.

Respectfully,

Angelita Nixon



101 Dee Drive, Suite 102

Charleston, WV 25311

WV Board of Nursing:

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I would first like to commend the entire board and staff for the hard work put forth on the drafting of multiple regulatory legislative rules. The West Virginia Nurses Association would like to congratulate the board for their dynamism to address these tough public safety issues. As current president of the West Virginia Nurses Association I admire the difficult work being done for the safety of our clients, profession and community. I would like to personally thank you all for your remarkable efforts in drafting these rules. Again let me reiterate that WVNA agrees 100% with the intent of this rule as proposed.

Although, West Virginia Nurses association would like comment on a few a few specific concerns within the rule:

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Thank you for your consideration.

Elizabeth Baldwin, PNP, BC

President West Virginia Nurses Association

Elegebeth Baldwan, PNP, BC

101 Dee Drive, Suite 102

Charleston, WV 25311

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Jain Kom com

WV RN BOARD RECEIVED 2012-07-20 01:44 PM



101 Dee Drive, Suite 102

Charleston, WV 25311

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Thank you for your consideration.

Elizabeth Baldwin, PNP, BC.

President West Virginia Nurses Association

101 Dee Drive, Suite 102

Charleston, WV 25311

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Jain Rom com

WV RN BOARD RECEIVED 2012-07-20 01:44 PM

email:rnboard@state.wv.us web address:www.wvrnboard.com



TELEPHONE: (304) 558-3596 FAX (304) 558-3666

STATE OF WEST VIRGINIA BOARD OF EXAMINERS FOR REGISTERED PROFESSIONAL NURSES 101 Dee Drive, Suite 102 Charleston, WV 25311-1620

July 30, 2012

To Interested Party/Stakeholder:

Thank you for your comments regarding the West Virginia Board of Examiners for Registered Professional Nurses' (Board) Legislative Rule 19 CSR 14, Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database:

As a result of comments the Board made the following amendments:

- 1. Definitions were added for "Authorized agent", "Chronic nonmalignant pain".
- 2. Language was added to further clarify that this rule pertains to licensees with prescriptive authority privileges.
- 3. Language was added addressing the correct procedures in the instance of an emergency relating to power and equipment failures.

Should you have any questions or desire more information please contact me.

For the Board,

Laura Skidmore Rhodes, MSN, RN

Executive Director

xc: File

email:rnboard@state.wv.us web_address:www.wvrnboard.com



TELEPHONE: (304) 558-3596 FAX (304) 558-3666

STATE OF WEST VIRGINIA BOARD OF EXAMINERS FOR REGISTERED PROFESSIONAL NURSES 101 Dee Drive, Suite 102 Charleston, WV 25311-1620

July 30, 2012

The Honorable Natalie Tennant Secretary of State Building 1, Suite 157-K 1900 Kanawha Blvd Charleston, WV 25305-0770

RE: Board Approved Legislative Proposed Rule WV 19 CSR 14

Dear Secretary Tennant:

As a result of the comments received on the above referenced rule the following amendments were approved by the Board:

- 1. Definitions were added for "Authorized agent", "Chronic nonmalignant pain".
- 2. Language was added to further clarify that this rule pertains to licensees with prescriptive authority privileges.
- 3. Language was added addressing the correct procedures in the instance of an emergency relating to power and equipment failures.

Should you have any questions or desire more information please contact me.

For the Board,

Laura Skidmore Rhodes, MSN, RN

Executive Director

xc: File

APPENDIX B FISCAL NOTE FOR PROPOSED RULES

Rule Title:	Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Progra Database.	am
Type of Rule:	Legislative Interpretive Procedural	
Agency:	WV Board of Examiners for Registered Professional Nurses	
Address:	101 Dee Drive, Suite 102	
	Charleston, WV 25311	
Phone Number:	(304) 558-3596 Email: <u>rnboard@wv.gov</u>	
	T' IN A Comment	_

Fiscal Note Summary

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

This measure will have no impact on the costs and revenues of state government as it relates to the WV
RN Board. There will be a cost incurred by the Board in providing adequate notification to practitioners.
This cost will be managed within the current budget.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

	FISCAL	YEAR	
Effect of Proposal	Current Increase/Decrease (use "-")	Next Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0.00	0.00	0.00
Personal Services	0.00	0.00	0.00
Current Expenses	0.00	0.00	0.00
Repairs & Alterations	0.00	0.00	0.00
Assets	0.00	0.00	0.00
Other	0.00	0.00	0.00
2. Estimated Total Revenues	0.00	0.00	0.00

Rule Title: Practitioner Recourements for Accessing the WV Controlled Substance Monitoring Data base

ANDUM	
•	
	RANDUM echnical defects, reasons the proposed es not captured elsewhere on this form

Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program

Database.

Rule Title:

TITLE 19

LEGISLATIVE RULE

FILEL

2012 JUL 31 PM 3: 59

WEST VIRGINIA BOARD OF

EXAMINERS FOR REGISTERED

OFFICE WEST VIRGINIA SECRETARY OF STATE

PROFFESIONAL NURSES

SERIES 14

PRACTITIONER REQUIREMENTS FOR ACCESSING THE WEST VIRGINIA CONTROLLED SUBSTANCES MONITORING PROGRAM DATABASE

§19-14-1. General.

- 1.1. Scope. W. Va. Code § 60A-9-5a(a) provides that upon initially prescribing or dispensing any pain-relieving substance for a patient and at least annually thereafter should the prescriber or dispenser continue to treat the patient with controlled substances, all persons with prescriptive or dispensing authority and in possession of a valid Drug Enforcement Administration registration identification number and licensed shall access the West Virginia Controlled Substances Monitoring Program database for information regarding specific patients for whom they are providing pain-relieving controlled substances as part of a course of treatment for chronic, nonmalignant pain but who are not suffering from a terminal illness, and that the information obtained shall be documented in the patient's medical record. W. Va. Code§ 60A-9-5a(b) provides that emergency and legislative rules are to be promulgated to effectuate the provisions of W.Va. Code § 60A-9-5a.
- 1.2. Authority. W. Va. Code § 60A-9-5a(b)
- 1.3. Filing date. -
- 1.4. Effective date. -

§19-14-2. Definitions.

- 2.1. As used in this rule, the following words and terms have the following meaning:
 - 2.1.a. "Administering" means the direct application of a drug to the body of a patient by injection, inhalation, ingestion or any other means by a registered professional nurse with valid prescribing privileges.
 - 2.1.b. <u>"Authorized agent" means an individual, who is an employee of any of the covered persons or entities permitted to have access to the central repository who is specifically designated by the by the Advanced Practice Registered Nurse with prescriptive privileges to access the central repository on behalf of the covered person or entity.</u>
 - 2.1.bc. "Board" means the West Virginia Board of Examiners for Registered Professional Nurses as described at W. Va. Code § 30-7-1 et. seq.
 - 2.1.bd. "Chronic nonmalignant pain" means pain that has persisted after reasonable medical

efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three (3) continuous months. For purposes of this rule, "chronic nonmalignant pain" does not include pain associated with a terminal condition or illness or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition or illness.

- 2.1.ee. "Controlled substance" means a drug that is classified by federal or state law in Schedules I, II, III, IV or V, as defined in W.Va. Code§ 60A-2-204 through 212.
- 2.1.df. "Course of treatment" means the period of time necessary to effect a cure for an acute disease, or the period of time from one office visit until the next scheduled or anticipated office visit for a chronic disease.
- 2.1.eg. "CSMP" means the West Virginia Controlled Substances Monitoring Program repository and database.
- 2.1.fh. "DEA registration identification number" means the federal Drug Enforcement Administration registration identification number issued to a practitioner.
- 2.1 gi. "Dispensing" means the preparation and delivery of a drug to an ultimate user by or pursuant to a lawful order of a practitioner, including the prescribing, packaging, labeling, administering or compounding necessary to prepare the drug for that delivery.
- 2.1.hj. "Medical records" means records including the medical history and physical examination; diagnostic, therapeutic and laboratory results; evaluations and consultations; treatment objectives; discussion of risks and benefits; informed consent; treatments; medications (including date, type, dosage and quantity provided); instructions and agreements; and periodic reviews.
- 2.1.<u>k</u>. "Opioid" means natural and semi-synthetic derivatives of the opium poppy, as well as similar synthetic compounds that have analgesic or pain relieving properties because of their effects in the central nervous system. These include, but are not limited to, codeine, morphine, hydromorphone, hydrocodone, oxycodone, methadone, and fentanyl.
- 2.1.jl. "Pain-relieving controlled substance" means, but is not limited to, an opioid or other drug classified as a Schedule II through V controlled substance and recognized as effective for pain relief, and excludes any drug that has no accepted medical use in the United States or lacks accepted safety for use in treatment under medical supervision including, but not limited to, any drug classified as a Schedule controlled substance.
- 2.1.km. "Patient" means a person presenting himself or herself for treatment who is not considered by the practitioner as suffering from a terminal illness.
- 2.1.<u>In.</u> "Practitioner" means a registered professional nurse licensed pursuant to the provisions of The Nurse Practice Act W. Va. Code § 30-7-1 *et seq.* who possesses a valid DEA registration identification.
- 2.1.mo.. "Provision" means prescribing and administering.
- 2.1.<u>ap.</u> "Terminal illness" means an incurable or irreversible condition as diagnosed by the attending physician or a qualified physician for which the administration of life-prolonging intervention will serve only to prolong the dying process.

§19-14-3. General Rules for Practitioners for Patients Not Suffering from a Terminal Illness.

- 3.1. Prior to the initial provision of any pain-relieving controlled substance as part of a course of treatment for chronic nonmalignant pain to any patient not considered by a practitioner to be suffering from a terminal illness, a practitioner shall apply for and receive capability to access the CSMP for purposes of compliance with this rule.
- 3.2. Prior to the initial provision of a pain-relieving controlled substance as part of a course of treatment for chronic nonmalignant pain to a patient not considered by the current practitioner to be suffering from a terminal illness, a current practitioner, or the practitioner's authorized agent, is required to access the CSMP to determine whether the patient has obtained any controlled substance reported to the CSMP from any source other than the current practitioner within the twelve (12) month period immediately preceding the visit of the patient to the current practitioner.
- 3.3. Upon accessing the CSMP prior to the initial provision of a pain-relieving controlled substance as part of a course of treatment for chronic nonmalignant pain, the access and any controlled substances reported to the CSMP within the twelve (12) month period immediately preceding the visit of the patient shall be then promptly documented in the patient's medical record, with rationale for provision of the pain-relieving controlled substance by the current practitioner with a paper or electronic copy of the CSMP accessed report maintained in the patient medical record, signed and dated by the current practitioner.
- 3.4. After the initial provision of a pain-relieving controlled substance as part of a course of treatment for chronic nonmalignant pain, should the patient continue as a patient with the current practitioner, and the current practitioner continues to provide pain-relieving controlled substances as part of a course of treatment for chronic, nonmalignant pain, the CSMP shall be accessed by the current practitioner, or the practitioner's authorized agent, at least annually to determine whether the patient has obtained any controlled substances reported to the CSMP from any source other than the current practitioner within the twelve.(12) month period immediately preceding the access. The access and any controlled substances from any other source other than the current practitioner reported to the CSMP-within such twelve (12) month immediately preceding the access shall be then promptly documented in the patient's medical record, with rationale for continuing provision of the pain-relieving substance by the current practitioner, with a paper or electronic copy of the CSMP accessed report maintained in the patient medical record. signed and dated by the current practitioner.
- 3.5. Nothing herein prohibits the CSMP from being accessed for a specific patient more frequently than annually by the current practitioner, or the practitioner's authorized agent; however, upon any such additional access of the CSMP, controlled substances reported to the CSMP from any source other than the current practitioner shall be promptly documented in the patient's medical record, with rationale for provision of the pain-relieving controlled substance by the current practitioner, with a paper or electronic copy of the CSMP accessed report maintained in the patient medical record. signed and dated by the current practitioner. Provided, that an electronic date and signature of the current practitioner will meet this requirement.
- 3.6. Accessing the CSMP must occur prior to the provision of the controlled substance Provided, that if there is an equipment failure, electricity outage or other disaster or event that renders review of the CSMP impossible prior to provision of the required controlled substances and it is determined by the practitioner that providing a controlled substance is medically necessary, this determination of medical necessity shall be documented in the medical record and the controlled substance may be provided in a limited amount. The circumstances preventing the access to the CSMP prior to provision of the controlled substance shall be documented in the patient's medical record, and immediately upon having access restored the

CSMP report shall be accessed, documented as described in this rule and the practitioner shall adjust patient care as needed.

§19-14-4. Other legal authority

4.1. Practitioners must comply with all other applicable federal and state laws, rules, and regulations.

§19-14-5. Discipline.

5.1. Any practitioner who fails to comply with this rule 19 CSR 14 is subject to Board disciplinary proceedings for failing to perform any statutory or legal obligation placed upon the practitioner and unprofessional, unethical, and dishonorable conduct, pursuant to W. Va. Code § 30-7-11 and 19CSR 3.