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

Form #7

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OFFICE WEST VIRGINIA
SECRETARY OF STATE

Effective Date

NOTICE OF AN EMERGENCY RULE

AGENCY: WEST VIRGINIA BOARD OF MEDICINE TITLE NUMBER: 11

CITE AUTHORITY: West Virginia Code § 60A-9-5a in Com. Sub. for S.B. 437, effective June 8, 2012

EMERGENCY 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: 10

TITLE OF RULE BEING PROPOSED: Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database

THE ABOVE RULE IS BEING FILED AS AN EMERGENCY RULE TO BECOME EFFECTIVE AFTER APPROVAL BY SECRETARY OF STATE OR 42ND DAY AFTER FILING, WHICHEVER OCCURS FIRST.

THE FACTS AND CIRCUMSTANCES CONSTITUTING THE EMERGENCY ARE AS FOLLOWS:

West Virginia leads the nation in drug overdose death. Drug abuse and diversion is an epidemic in West Virginia. If practitioners who prescribe/dispense pain-relieving controlled substances have the ability to check, and do check, the controlled substance history of a patient, the practitioners will be better informed of the facts and the knowledge obtained may cause fewer controlled substances which are diverted to be prescribed/dispensed. Lowering the death rate in West Virginia from overdoses as a result of diverted drugs is a priority and in everyone's interests. Further delay benefits no one.

Authorized Signature

Use additional sheets if necessary

EMERGENCY RULE QUESTIONNAIRE

DATE: June 8, 2012

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:(*Agency Name, Address & Phone No.*) West Virginia Board of Medicine
101 Dee Drive, Suite 103
Charleston, WV 25311

EMERGENCY RULE TITLE: Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database

1. Date of filing June 8, 2012

2. Statutory authority for promulgating emergency rule:

West Virginia Code § 60A-9-5a(b)

3. Date of filing of proposed legislative rule: June 8, 2012

4. Does the emergency rule adopt new language or does it amend or appeal a current legislative rule?

The emergency rule adopts new language in a new rule.

5. Has the same or similar emergency rule previously been filed and expired?

No

6. State, with particularity, those facts and circumstances which make the emergency rule necessary for the **immediate** preservation of public peace, health, safety or welfare.

See attached printout

7. If the emergency rule was promulgated in order to comply with a time limit established by the Code or federal statute or regulation, cite the Code provision, federal statute or regulation and time limit established therein.

West Virginia Code § 60A-9-5a(b) requires the Board of Medicine to adopt an emergency rule requiring practitioners to access the West Virginia Controlled Substances Monitoring Program Database in certain circumstances.

8. State, with particularity, those facts and circumstances which make the emergency rule necessary to prevent substantial harm to the public interest.

See attached printout

6. and 8.

It has been documented and it is well known that there is a high level of pharmaceutical abuse and diversion in West Virginia, often leading to overdoses resulting in death. West Virginia leads the United States in the rate of overdose deaths (Charleston Gazette newspaper, four (4) part series beginning January 15, 2011: January 17, 2011, article "Doctors grapple with treating real pain vs. supplying pill seekers"). Drug abuse and diversion is an epidemic in West Virginia and immediate action is necessary to preserve the public health, safety, and welfare. If even one more overdose death may be avoided by authorization of this Emergency Rule, that is sufficient to justify this Emergency Rule.

Enrolled Com. Sub. for S.B. 437 is a comprehensive bill enacted during the 2012 Legislative Session in an effort to address and diminish the epidemic. A section of the bill at West Virginia Code § 60A-9-5a requires practitioners, when initially prescribing /dispensing a pain relieving controlled substance to a patient as part of a course of treatment for chronic, nonmalignant pain, and at least annually thereafter if the practitioner continues to prescribe/dispense controlled substances, to access the Controlled Substance Monitoring Program database and document information obtained in the patient's medical record. The section also requires an Emergency Rule to implement the requirement. The idea behind the new law is that if practitioners know the facts about the pain relieving controlled substance history of the patient, this may cause the amount of pain relieving controlled substances prescribed by practitioners to diminish and fewer drugs to be diverted and abused.

It is in the interests of all West Virginians to have a healthy and thriving citizenry in all our communities, and there will be substantial harm to the development of such a healthy and thriving citizenry and to the public interest if the Board of Medicine waits almost a year longer until a Legislative Rule is finally enacted through the regular lengthy legislative process requiring practitioners to access, and be informed by, Controlled Substance Monitoring Program data. Also, the West Virginia Legislature has expressed its view that an Emergency Rule is necessary by requiring an Emergency Rule.

State of West Virginia
Board of Medicine

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REV. O. RICHARD BOWYER
PRESIDENT

MARIAN SWINKER, MD, MPH
SECRETARY

MICHAEL L. FERREBEE, MD
VICE PRESIDENT

ROBERT C. KNITTLE
EXECUTIVE DIRECTOR

BRIEF SUMMARY OF THE PROPOSED EMERGENCY RULE, WITH STATEMENT OF CIRCUMSTANCES CONSTITUTING THE EMERGENCY

In accordance with the provisions of West Virginia Code § 60A-9-5a, the Rule provides that upon initially prescribing or dispensing any pain-relieving substance for a patient and at least annually thereafter if the prescriber or dispenser continues to treat the patient with controlled substances, all persons with prescribing or dispensing authority and in possession of a valid Drug Enforcement Administration registration identification number and licensed by the Board of Medicine, must 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. The information obtained must be documented in the patient's medical record.

The Rule contains multiple definitions and explains that failure to comply with provisions of the Rule subjects the practitioner to Board of Medicine discipline for unprofessional, unethical and dishonorable conduct.

West Virginia leads the nation in drug overdose death. Drug abuse and diversion is an epidemic in West Virginia.* If practitioners who prescribe/dispense pain-relieving controlled substances are required to check, have the ability to check, and do check, the controlled substance history of a patient, the practitioners will be better informed of the facts and the knowledge obtained may cause fewer controlled substances which are diverted to be prescribed/dispensed. Lowering the death rate in West Virginia from overdoses as a result of diverted drugs is a priority and in everyone's interests. Further delay benefits no one.

*See attachment, Charleston Gazette May 24, 2012, article

Manchin amendment to reclassify painkillers

U.S. senators on Wednesday evening unanimously passed an amendment to a Food and Drug Administration reauthorization bill that would reclassify all hydrocodone substances and make punishment for their trafficking more severe.

The amendment, introduced by Sen. Joe Manchin, D-W.Va., would reclassify painkillers like Vicodin and Lortab as Schedule II drugs, which also affects how they are to be stored and prescribed.

For instance, patients would need an original prescription for refills, hydrocodone pills would need to be transported and stored more securely and traffickers would be subject to increased criminal penalties, according to a news release from Manchin's office.

Sen. Jay Rockefeller, D-W.Va., and three other senators — including two other Democrats and a Republican — co-sponsored the amendment.

The amendment would reclassify painkillers like Vicodin and Lortab as Schedule II drugs, which also affects how they are to be stored and prescribed.

"I'm truly pleased that this amendment has passed and will make it much harder for anyone to abuse these prescription drugs," Manchin said in a statement. "I offered this legislation on behalf of the countless West Virginians whose lives have been cut short by drug abuse and the families who are picking up the pieces.

"I'm committed to working extremely hard across the aisle to see this most important legislation passed," he said.

Prescription drugs are responsible for about 90 percent of all drug-related deaths in West Virginia, and about 75 percent in the U.S, according to Manchin's release.

Schedule I drugs contain the most dangerous substances. Currently, hydrocodone is considered a Schedule II drug, but when combined with substances like Tylenol, they are listed in a less stringent category, Schedule III.

The amendment would make all substances containing hydrocodone Schedule II drugs.

Findings show that more than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone, methadone, oxycodone and oxymorphone.

"Prescription drug abuse is a very real epidemic that we must stop," Rockefeller said in a statement. "Too many West Virginia families and communities have been hurt terribly, and I've been fighting to turn the tide on abuse."

In addition to co-sponsoring Manchin's amendment, Rockefeller introduced a provision to the FDA reauthorization bill that helps to ensure that doctors, nurses and health-care professionals who prescribe painkillers "get the training they need so they don't overprescribe drugs and can reduce the potential for patient abuse," according to a news release from Rockefeller's office.

Rockefeller's provision would require the Institute of Medicine to study the scope and scale of education requirements for physicians and other people who prescribe medicine. The Institute of Medicine is an independent agency of medical and public health experts who advise Congress on medical and health issues.

Rockefeller also offered an amendment to help support state prescription drug monitoring programs.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database

Type of Rule: [X] Legislative [ ] Interpretive [ ] Procedural

Agency: West Virginia Board of Medicine

Address: 101 Dee Drive, Suite 103

Charleston, WV 25311

Phone Number: 304.558.2921 Email: deborah.lewis.rodecker@wv.gov

Fiscal Note Summary

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

There is no additional cost nor revenue to state government related to this proposed rule.

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			
Current Expenses			
Repairs & Alterations			
Assets			
Other			
2. Estimated Total Revenues	0.00	0.00	0.00

Rule Title: _____

Rule Title: Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database

3. **Explanation of above estimates (including long-range effect):**
Please include any increase or decrease in fees in your estimated total revenues.

n/a

MEMORANDUM

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

none

Date: May 24, 2012

Signature of Agency Head or Authorized Representative

Scott C. Smith

11 CSR

TITLE 11

LEGISLATIVE RULE

WEST VIRGINIA BOARD OF MEDICINE

SERIES 10

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

11-10-1. 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 by the Board of Medicine 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. –

11-10-2. 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.

2.1.b. "Board" means the West Virginia Board of Medicine as described at W. Va. Code § 30-3-5.

2.1.c. "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.d. "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.e. "CSMP" means the West Virginia Controlled Substances Monitoring Program repository and database.

2.1.f. "DEA registration identification number" means the federal Drug Enforcement Administration registration identification number issued to a practitioner.

2.1.g. "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.h. "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.i. "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.j. "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 I controlled substance.

2.1.k. "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.l. "Practitioner" means a physician, podiatrist or physician assistant licensed pursuant to the provisions of the West Virginia Medical Practice Act, W. Va. Code § 30-3-1 *et seq.* who possesses a valid DEA registration identification number.

2.1.m. "Provision" means prescribing or dispensing and includes administering.

2.1.n. "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.

11-10-3. 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 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 copy of the CSMP accessed report 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 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 copy of the CSMP accessed report 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, 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 copy of the CSMP accessed report signed and dated by the current practitioner.

11-10-4. Other legal authority.

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

11-10-5. Discipline.

5.1. Any practitioner who fails to comply with this rule 11 CSR 10 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 § 30-3-14 and 11 CSR 1A 12.1 and 12.2.