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

Form #7

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2012 JUN 29 PM 1:26

OFFICE WEST VIRGINIA
SECRETARY OF STATE

Effective Date

NOTICE OF AN EMERGENCY RULE

AGENCY: West Virginia Board of Osteopathic Medicine TITLE NUMBER: 24

CITE AUTHORITY: West Virginia Code section 60A-9-5a

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: 7

TITLE OF RULE BEING PROPOSED: Practitioner Requirements for Controlled Substances Licensure and Accessing the West Virginia Controlled Substances 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:

Senate Bill 437 added specific requirements for practitioners to the Uniform Controlled Substances Act and became effective June 8, 2012. This rule has been promulgated to conform to this Legislation and give effect to the policy underlying the bill. The bill authorized the West Virginia Board of Osteopathic Medicine to promulgate emergency rules to carry out this Legislation.

NOTE: Only sections 24-7-1, 24-7-2, 24-7-3 and 24-7-6 are submitted as emergency provisions. All other sections appearing in the attached rule are proposed for consideration by the Legislature pursuant to the regular schedule for Legislative rules.

Authorized Signature

Use additional sheets if necessary

EMERGENCY RULE QUESTIONNAIRE

DATE: June 29, 2012

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:(*Agency Name, Address & Phone No.*) West Virginia Board of Osteopathic Medicine
405 Capitol Street, Suite 402 (304) 558-6095
Charleston, WV 25301

EMERGENCY RULE TITLE: Practitioner Requirements for Controlled Substance Licensure an

1. Date of filing June 29, 2012

2. Statutory authority for promulgating emergency rule:

West Virginia Code section 60A-9-5a

3. Date of filing of proposed legislative rule: June 29, 2012

4. Does the emergency rule adopt new language or does it amend or appeal a current legislative rule? Adopts new language. However, only sections 24-7-1, 24-7-2, 24-7-3 and 24-7-6 are proposed for emergency provisions. The other sections of the rule will be offered for authorization through the normal legislative rule process.

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.

Senate Bill 437 which added provisions to the Uniform Controlled Substances Act now requires practitioners to access the Controlled Substances Monitoring Program for certain patients. This became effective June 8, 2012. This proposed rule has been promulgated to conform to this legislation and to give effect to the policy underlying the bill. The bill specifically authorized the West Virginia Board of Osteopathic Medicine to promulgate emergency rules to carry out the legislation.

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.

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

WEST VIRGINIA BOARD OF OSTEOPATHIC MEDICINE

PRACTITIONER REQUIREMENTS FOR CONTROLLED SUBSTANCES LICENSURE AND ACCESSING THE WEST VIRGINIA CONTROLLED SUBSTANCES MONITORING PROGRAM DATABASE
Title 24, Series 7

SUMMARY AND CIRCUMSTANCES FOR FILING AS AN EMERGENCY RULE

Senate Bill 437, passed during the 2012 Regular Session of the Legislature, places requirements on practitioners that prescribe controlled substances. This legislation, in West Virginia Code §60A-9-5(b) specifically authorizes the West Virginia Board of Osteopathic Medicine to propose emergency rules to implement this change. In the attached rule, the Board of Osteopathic Medicine requests that the following sections of the rule be considered for emergency application: § 24-7-1, § 24-7-2, § 27-7-3 and § 24-7-6 . Other sections that appear in the attached rule are not requested for emergency consideration and will be proposed for consideration by the Legislature pursuant to the regular schedule for Legislative rules.

Under the new law, prior to prescribing any pain-relieving controlled substances to patients not suffering from a terminal illness in the course of treatment for chronic nonmalignant pain practitioners must access the Controlled Substances Monitoring Program to determine whether the patient has obtained any controlled substance from another source within the twelve-month period immediately preceding the patient's visit. Any controlled substances reported within that period must be documented in the patient's medical record, along with the rationale for prescribing of controlled substances by the current practitioner. A copy of the report from the database signed and dated by the practitioner must also be placed in the medical record. If the practitioner continues to treat the patient with pain-relieving controlled substances, he or she must access the Controlled Substances Monitoring Program Database at least annually thereafter, and repeat the same documenting process. The proposed rule allows the West Virginia Board of Osteopathic Medicine to effectuate the provisions of the code.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

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

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

Agency: West Virginia Board of Osteopathic Medicine

Address: 405 Capitol Street, Suite 402
Charleston, WV 25301

Phone Number: (304) 558-6095 Email: wvbdosteo@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.

The proposed rule will not have any fiscal impact on the general revenues of the State. Practitioners may apply for and receive capability to access the West Virginia Controlled Substances Monitoring Program repository and database at no cost.

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: Practitioner Requirements for Controlled Substances Licensure and Accessing the West Virginia Controlled Substances Monitoring Program Database

Rule Title: Practitioner Requirements for Controlled Substances Licensure and 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.

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.

Date: June 29, 2012

Signature of Agency Head or Authorized Representative

24CSR

FILED

2012 JUN 29 PM 1:26

OFFICE WEST VIRGINIA SECRETARY OF STATE

TITLE 24
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF OSTEOPATHIC MEDICINE

SERIES 7
PRACTITIONER REQUIREMENTS FOR CONTROLLED SUBSTANCES LICENSURE AND ACCESSING THE WEST VIRGINIA CONTROLLED SUBSTANCES MONITORING PROGRAM DATABASE

§24-7-1. General.

1.1. Scope. -- West Virginia 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 Osteopathic 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. West Virginia Code § 60A-3-301 requires each department, board or agency which licenses or registers practitioners authorized to dispense controlled substances to promulgate rules relating to the registration and control of the dispensing of controlled substances within the state.

1.2. Authority. -- W. Va. Code § 60A-9-5a(b) and W. Va. Code § 60A-3-301.

1.3. Filing Date. --

1.4. Effective Date. --

§24-7-2. Definitions.

2.1. As used in this rule, the following words and terms have the following meaning:

2.1.a. Administering – The direct application of a drug to the body of a patient by injection, inhalation, ingestion or any other means.

2.1.b. Board – The West Virginia Board of Osteopathic Medicine.

2.1.c. Controlled Substance – 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. Controlled Substances License – A registration to dispense controlled substances in the state of West Virginia issued by the West Virginia Board of Osteopathic Medicine.

2.1.e. Course of Treatment – 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.f. CSMP – The West Virginia Controlled Substances Monitoring Program repository and database.

2.1.g. DEA Registration Identification Number – The federal drug Enforcement Administration registration identification number issued to a practitioner.

2.1.h. Dispensing – 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.i. Medical Records – 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.j. Opioid – Natural and semi-synthetic derivatives of the opium poppy, as well as similarly 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.k. Pain-relieving Controlled Substance -- (is not limited to) An opioid or other drug classified as a Schedule II through V controlled substances 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.l. Patient – A person presenting himself or herself for treatment who is not considered by the practitioner as suffering from a terminal illness.

2.1.m. Practitioner – A physician or physician assistant licensed pursuant to the provisions of West Virginia Code § 30-14-1 *et. seq.* who possesses a valid DEA registration identification number.

2.1.n. Provision – Prescribing or dispensing, including administering.

2.1.o. Terminal Illness – 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.

§24-7-3. 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-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-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-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-month period 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.

§24-7-4. Application for Registration to Dispense Controlled Substances in West Virginia.

4.1. An applicant for a registration to dispense controlled substances in West Virginia, also known as a controlled substances license, shall complete an application provided by the Board.

4.2. An application for a registration to dispense controlled substances in West Virginia should include the following:

4.2.a. A current copy of the applicant's Federal Drug Enforcement Administration Certificate of Registration for West Virginia.

4.2.b. Complete payment to the Board of the amount established by the Board under the West Virginia Board of Osteopathic Medicine Rule, Fees for Services Rendered By the Board of Osteopathic Medicine, Title 24, CSR 5. If the licensure fee is paid by personal check, the licensing process is not considered complete until the check has cleared the bank.

4.2.c. Any other documents as may be required by the Board.

4.3. The application, together with all photocopied documents submitted with the application, become the property of the Board and shall not be returned.

4.4. A registration to dispense controlled substances in West Virginia or controlled substances license is valid for a term of one year and shall be renewed by June 30 of the following year. The license shall be renewed upon the receipt of a non-refundable fee, established by the Board, together with an application provided by the Board.

§24-7-5. Other Legal Authority.

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

§24-7-6. Discipline.

6.1. Any practitioner who fails to comply with this rule is subject to Board disciplinary action for failing to perform any statutory or legal obligation placed upon the practitioner and unprofessional, unethical and dishonorable conduct, pursuant to West Virginia Code §§ 30-14-3, 30-14A-1 and rules of the Board.