WEST VIRGINIA
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ADMINISTRATIVE LAW DIVISION

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OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

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

CITE AUTHORITY: West Virginia Code sections 60A-9-5a and 60A-3-301

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 Monitoring Program Database

THE ABOVE PROPOSED LEGISLATIVE RULES, FOLLOWING REVIEW BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE, IS HEREBY MODIFIED AS A RESULT OF REVIEW AND COMMENT BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE. THE ATTACHED MODIFICATIONS ARE FILED WITH THE SECRETARY OF STATE.

Authorized Signature

24CSR

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. Chronic Nonmalignant Pain – 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.d. 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.e. 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.f. 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.g. CSMP – The West Virginia Controlled Substances Monitoring Program repository and database.

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

2.1.i. 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.j. 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.k. 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.l. 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.m. Patient – A person presenting himself or herself for treatment who is not considered by the practitioner as suffering from a terminal illness.

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

2.1.p. 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~~ § 30-14-11 and rules of the Board.