WEST VIRGINIA
SECRETARY OF STATE
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ADMINISTRATIVE LAW DIVISION

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SECRETARY OF STATE

Form #6

NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE

AGENCY: WEST VIRGINIA BOARD OF MEDICINE TITLE NUMBER: 11

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

THE ABOVE RULE HAS BEEN AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE.

AUTHORIZATION IS CITED IN (house or senate bill number) HOUSE BILL 2689

SECTION §64-9-1(a), PASSED ON April 13, 2013

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON THE FOLLOWING DATE: May 6, 2013

Barbara Knitter

Authorized Signature

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 inquiry and information obtained from such accessing 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. – May 6, 2013.

1.4. Effective date. – May 6, 2013.

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

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

2.1.h. "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.i. "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.j. "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.k. "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.l. "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.m. "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.n. "Provision" means prescribing or dispensing and includes administering.

2.1.o. "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 date of 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 by the current practitioner, with rationale for provision of the pain-relieving controlled substance 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 date of access. The date of access and any controlled substances from any other source other than the current practitioner reported to the CSMP within such twelve (12) month period immediately preceding the date of access shall be then promptly documented in the patient's medical record by the current practitioner, with rationale for continuing provision of the pain-relieving substance 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 by the current practitioner, with the date of access and rationale for provision of the pain-relieving controlled substance 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., except where the current practitioner documents in the patient's medical record that the failure to timely comply is a result of failure in internet connectivity and/or power outages.