



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-
MAKING REVIEW COMMITTEE**

AGENCY: Medicine TITLE-SERIES: 11-10
RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No
RULE NAME: 11-10 Practitioner Requirements for Accesing the West Virginia Controlled Substances
Monitoring Program Database

PRIMARY CONTACT

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CITE STATUTORY AUTHORITY: W.Va. Code § 60A-9-5a(c)

EXPLANATION OF THE STATUTORY AUTHORITY FOR THE LEGISLATIVE RULE, INCLUDING A DETAILED SUMMARY OF THE EFFECT OF EACH PROVISION OF THE LEGISLATIVE RULE WITH CITATION TO THE SPECIFIC STATUTORY PROVISION WHICH EMPOWERS THE AGENCY TO ENACT SUCH RULE PROVISION:

W.Va. Code § 60A-9-5a(c)

IS THIS FILING SOLELY FOR THE SUNSET PROVISION REQUIREMENTS IN W. VA. CODE §29A-3-19(e)? No

IF YES, DO YOU CERTIFY THAT THE ONLY CHANGES TO THE RULE ARE THE FILING DATE, EFFECTIVE DATE AND AN EXTENSION OF THE SUNSET DATE? No

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 6/29/2021

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 7/29/2021

COMMENTS RECEIVED: Yes

(IF YES, PLEASE UPLOAD IN THE COMMENTS RECEIVED FIELD COMMENTS RECEIVED AND RESPONSES TO COMMENTS)

PUBLIC HEARING: No

(IF YES, PLEASE UPLOAD IN THE PUBLIC HEARING FIELD PERSONS WHO APPEARED AT THE HEARING(S) AND TRANSCRIPTS)

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?

The Board publicized notice of the proposed rule change by: including a notice of the proposed amendments and comment period on the Board of Medicine website with a link to the proposed rule; sending email notification to licensees and registrants of the Board regarding notice of the proposed amendments and comment period with a link to the proposed rule; and notifying other interested professional associations and governmental entities including: West Virginia State Medical Association; West Virginia Podiatric Medical Association; West Virginia Primary Care Association and West Virginia Hospital Association.

SUMMARY OF THE CONTENT OF THE LEGISLATIVE RULE, AND A DETAILED DESCRIPTION OF THE RULE'S PURPOSE AND ALL PROPOSED CHANGES TO THE RULE:

This rule sets forth the requirements for licensees and registrants of the West Virginia Board of Medicine regarding obtaining and maintaining access to the West Virginia Controlled Substance Monitoring Program database.

Section 2 eliminates obsolete definitions, updates and modifies existing definitions and adds a definition for benzodiazepine.

A new section three is incorporated to identify practitioner requirements for obtaining and maintaining access to the CSMP, and for certifying compliance to the Board by licensees at renewal.

Section four is revised for clarity and to align with the current requirements of W. Va. Code § 60A-9-5a.

Section 6 is amended to incorporate current administrative penalties as set forth in W. Va. Code § 60A-9-7(f) and (g).

Clarification and general clean-up occur throughout the rule.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

This rule has not been amended since 2013. Amendments are offered to conform the rule to the current requirements of W. Va. Code § 60A-9-5a, and to clarify that the rule applies to licensees and interstate telehealth registrants of the Board.

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED LEGISLATIVE RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

None.

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

None.

C. ECONOMIC IMPACT OF THE LEGISLATIVE RULE ON THE STATE OR ITS RESIDENTS:

None.

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2021 Increase/Decrease (use "-")	2022 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost			
Personal Services			
Current Expenses			
Repairs and Alterations			
Assets			
Other			
2. Estimated Total Revenues			

E. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

N/A.

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Mark A Spangler -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

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.~~ This rule sets forth the requirements for licensees and registrants of the West Virginia Board of Medicine regarding accessing the West Virginia Controlled Substance Monitoring Program database.

1.2. Authority. -- W.Va. Code § 60A-9-5a**(b)**(c)

1.3. Filing Date. -- May 6, 2013.

1.4. Effective Date. -- May 6, 2013.

1.5. Sunset Provision -- This rule shall terminate and have no further force or effect upon August 1, 2027.

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. "Benzodiazepine" means a class of controlled substance medications that produce sedation, induce sleep, relieve anxiety and prevent seizures and which are generally approved to treat anxiety disorder, insomnia, seizures, social phobia, and panic disorder.

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

2.1.e. ~~"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~~ Chapter 60A, Article 2.

~~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 controlled substance medications which are 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 Opioids~~ 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.~~ a physician, podiatric physician or physician assistant who possesses a valid DEA registration identification number and who is licensed by the Board pursuant to Articles 3 or 3E of Chapter 30, or holds an interstate telehealth registration issued by the Board pursuant to W. Va. Code § 30-1-26.

2.1.n. ~~“Provision Providing” means prescribing, or dispensing and includes or~~ “Provision Providing” means prescribing, or dispensing and includes or administering medication.

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. Practitioner Requirements for Obtaining and Maintaining Access to the CSMP.

3.1. Practitioners who prescribe or dispense Schedule II, III, IV, or V controlled substances shall register with the CSMP and obtain and maintain online or other electronic access to the program database. Compliance with the provisions of this section must be accomplished within 30 days of the practitioner obtaining a new license or registration or within 30 days of re-licensure or re-registration.

3.2. Licensees shall be required to certify compliance with the provisions of this section when renewing a license. The Board may conduct an audit to verify compliance therewith.

11-10-34. General Rules for Practitioners for Patients Not Suffering from a Terminal Illness.

4.1. The provisions of this section only apply to a practitioner's prescribing, administering or dispensing of Schedule II controlled substances, opioids, or benzodiazepines to a patient that the practitioner does not consider to be suffering from a terminal illness.

~~3.1.4.2. 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~~ A practitioner shall apply for and receive capability to access the CSMP for purposes of compliance with this rule, before providing a patient any Schedule II controlled substance, any opioid, or any benzodiazepine.

~~3.2.4.3. Prior to the initial provision of a pain-relieving controlled substance as part of a course of treatment for chronic nonmalignant pain~~ Before initially providing any Schedule II controlled substance, any opioid, or any benzodiazepine to a patient not considered by the current practitioner to be suffering from a terminal illness, a current practitioner is required to shall 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's encounter with the patient.

~~3.34.4. 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. The practitioner shall promptly document the initial CSMP data review in the patient's medical record. Documentation must include the date the practitioner accessed the patient's CSMP record, a dated copy of the CSMP report or a list of all controlled substances reported to the CSMP as dispensed to the patient within the preceding twelve months, and the practitioner's rationale for providing the patient Schedule II controlled substance(s), opioid(s), and/or benzodiazepine(s).~~

~~3.4. 4.5. If a practitioner-patient relationship continues and the course of treatment includes the continued prescribing, dispensing or administering of any controlled substance, the practitioner shall access the CSMP at least annually 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 controlled substance by the current practitioner.

~~3.5.4.6. 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. A practitioner may review a patient's CSMP data more frequently than annually. However, a practitioner must document each CSMP data review in the patient medical record. Documentation must include the date the practitioner accessed the patient's CSMP record, a dated copy of the CSMP report or a list of all controlled substances reported to the CSMP for the patient from any source other than the practitioner, and the practitioner's rationale for discontinuing or continuing to provide controlled substances to the patient.~~

4.7. A practitioner who is providing a patient controlled substance medication shall review a patient's CSMP data whenever the provider has a specific concern regarding controlled substance abuse, misuse, or diversion of controlled substances by the patient.

11-10-45. Other legal authority.

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

11-10-5.6 Discipline and Administrative Penalties.

~~5.6.1. 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, W. Va. Code § 30-3E-17, and/or the rules of the Board. 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.~~~~

6.2. Any practitioner who fails to comply with the requirements described in W. Va. Code § 60A-9-7(f) or (g) shall be subject to the respective administrative penalties set forth in those subsections. All fines collected pursuant to those subsections shall be transferred by the Board to the Fight Substance Abuse Fund created under W. Va. Code § 60A-9-8.