WEST VIRGINIA SECRETARY OF STATE
KRIS 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: Osteopathic Medicine TITLE-SERIES: 24-07

RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No

RULE NAME: 24-07 Practitioner Requirements for Controlled Substances Licensure and Accessing the West Virginia Controlled Substances Monitoring Program Database

PRIMARY CONTACT

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CITE STATUTORY AUTHORITY: W. Va. Code§ 60A-9-5a(c) and§ 60A-3-301

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) and§ 60A-3-301

IS THIS FILING SOLELY FOR THE SUNSET PROVISION REQUIREMENTS IN W. VA. CODE §29A-3-19(e)? Yes

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? Yes

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD:

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED:

COMMENTS RECEIVED:

(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?

N/A

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 Osteopathic Medicine regarding controlled substances licensure and accessing the West Virginia Controlled Substances Monitoring Program database. This rule is based upon the West Virginia Controlled Substances Monitoring Act, W. Va. Code Chapter 60A, Article 9. The only changes to the rule are an extension of the sunset date.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

Extension of sunset date.

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

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

N/A

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

N/A

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

N/A

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2026 Increase/Decrease (use "-")	2027 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):

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

Yes

Jonathan Osborne -- 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 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. -- This rule sets forth the requirements for licensees and registrants of the West Virginia Board of Osteopathic Medicine regarding controlled substances licensure and accessing the West Virginia Controlled Substances Monitoring Program database.

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

1.3. Filing Date. -- ~~April 20, 2022~~.

1.4. Effective Date. -- ~~May 1, 2022~~.

1.5. Sunset Provision. -- This rule shall terminate and have no further force or effect upon August 1, ~~2027~~2032.

§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. Benzodiazepine – A class of medicines approved to treat generalized anxiety disorder, insomnia, seizures, social phobia, and panic disorder.

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

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. 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. Patient – 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 – An osteopathic physician or physician assistant who possesses a valid DEA registration identification number and who is licensed by the Board pursuant to W. Va. Code § 30-14-1 *et seq.* or W. Va. Code § 30-3E-1 *et seq.*, or who holds an interstate telehealth registration issued by the Board pursuant to W. Va. Code § 30-1-26.

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

2.1.n. 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.

2.1.o. "Website" or "Board's website" means the set of related web pages operated by or on behalf of the West Virginia Board of Osteopathic Medicine located at the domain name www.wvbdosteo.org, or at any successor domain name published by the Board.

§24-7-3. Practitioner Requirements for Obtaining and Maintaining Access to the CSMP.

3.1. A practitioner who prescribes or dispenses 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.

§24-7-4. General Rules for Practitioners for Patients Not Suffering from a Terminal Illness.

4.1. Prior to the initial provision of any Schedule II controlled substance, any opioid, or any benzodiazepine 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.

4.2. Prior to the initial provision of 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 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.

4.3. Upon accessing the CSMP prior to the initial provision of any Schedule II controlled substance, any opioid, or any benzodiazepine, 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 Schedule II controlled substance, opioid, and/or benzodiazepine by the current practitioner, with a copy of the CSMP accessed report signed and dated by the current practitioner.

4.4. After the initial provision of any Schedule II controlled substance, any opioid, or any benzodiazepine, should the patient continue as a patient with the current practitioner, and the current practitioner continues to treat the patient with a controlled substance, 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 controlled substance by the current practitioner, with a copy of the CSMP accessed report signed and dated by the current practitioner.

4.5. 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 controlled substance by the current practitioner, with a copy of the CSMP accessed report signed and dated by the current practitioner.

§24-7-5. Application for Registration to Dispense Controlled Substances in West Virginia.

5.1. An applicant for a controlled substances license shall complete an application provided by the Board, which is available on the Board's website.

5.2. An application for a controlled substances license shall include the following:

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

5.2.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.

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

5.4. A 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, which is available on the Board's website.

24-7-6. Discipline and Administrative Penalties.

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 W. Va. Code § 30-14-11, W. Va. Code § 30-3E-17, and/or rules of the Board.

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.