



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

eFILED

7/26/2022 12:04:49 PM

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: Registered Nurses WV Board of TITLE-SERIES: 19-14

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

RULE NAME: 19-14 Practitioner Requirements for Accessing the West Virginia Controlled Substances
Monitoring Program Database

PRIMARY CONTACT

NAME: Sue Painter

ADDRESS: 5001 Maccorkle Ave Sw
South Charleston, WV 25309

EMAIL: sue.a.painter@wv.gov

PHONE NUMBER: 304-744-1110

CITE STATUTORY AUTHORITY: 60A-9-5A

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:

The requirements Practitioner requirements for accessing the W.V. Controlled Substances Monitoring Program Database.

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: 5/16/2022

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 6/15/2022

COMMENTS RECEIVED: No

(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?

Emailed organizations interested in the rule

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

Provides that all practitioners who prescribe or dispense Schedule II, III, IV or V controlled substances shall register with the Controlled Substances Monitoring Program and obtain and maintain online or other electronic access to the program database

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

Updates the language to be consistent with W.V. Code 60A-9-5A(a)

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		
	2022 Increase/Decrease (use "-")	2023 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services	0	0	0
Current Expenses	0	0	0
Repairs and Alterations	0	0	0
Assets	0	0	0
Other	0	0	0
2. Estimated Total Revenues	0	0	0

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

None

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

Yes

Sue Ann Painter -- 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 19
LEGISLATIVE RULE
WEST VIRGINIA BOARD FOR REGISTERED NURSES

SERIES 14
PRACTITIONER REQUIREMENTS FOR ACCESSING THE
WEST VIRGINIA CONTROLLED SUBSTANCES MONITORING PROGRAM DATABASE

§19-14-1. General.

1.1. Scope. -- W. Va. Code §60A-9-5aA(a) provides that all practitioners who prescribe or dispense Schedule II, III, IV or V controlled substances shall register with the Controlled Substances Monitoring Program and obtain and maintain online or other electronic access to the program database: *Provided*, That compliance with the provisions of this subsection must be accomplished within 30 days of the practitioner obtaining a new license: *Provided*, however, That the Board of Pharmacy may renew a practitioner's license without proof that the practitioner meet the requirements of this subsection. W. Va. Code §60A-9-5A(b) provides that all persons with prescriptive or dispensing authority and in possession of a valid Drug Enforcement Administration registration identification number and who are licensed by the Board of Registered Nurses upon initially prescribing or dispensing any pain-relieving substance for a patient, any Schedule II controlled substance, any opioid or any benzodiazepine to a patient who is not suffering from a terminal illness, and at least annually thereafter should the practitioner or dispenser continue to treat the patient with a controlled substance, shall access the West Virginia Controlled Substances Monitoring Program Database for information regarding specific patients. The information obtained from accessing the West Virginia Controlled Substances Monitoring Program Database for the patient shall be documented in the patient's medical record maintained by a private prescriber or any inpatient facility licensed pursuant to the provisions of Chapter 16 of this code. A pain-relieving controlled substance shall be defined as set forth in §30-3A-1 of this code. ~~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 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-9-5aA(b) provides that emergency and legislative rules are to be promulgated to effectuate the provisions of W. Va. Code §60A-9-5aA.

1.2. Authority. -- W. Va. Code §60A-9-5aA(bc)

1.3. Filing Date. -- ~~May 13, 2013.~~

1.4. Effective Date. -- ~~July 1, 2013.~~

1.5 Sunset Provision. -- This rule shall terminate and have no further force or effect upon August 1, 2033.

§19-14-2. 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 by a registered professional nurse with valid prescribing privileges.

19CSR14

2.1.b. "Authorized agent" means an individual, who is an employee of any of the covered persons or entities permitted to have access to the central repository who is specifically designated by the Advanced Practice Registered Nurse with prescriptive privileges to access the central repository on behalf of the covered person or entity.

2.1.c. "Board" means the West Virginia Board for Registered Nurses as described at W. Va. Code §30-7-1 et seq.

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

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

2.1.i. "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.j. "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.k. "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.l. "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.m. "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.n. "Practitioner" means a registered professional nurse licensed pursuant to the provisions of The Nurse Practice Act W. Va. Code §30-7-1 et seq. who possesses a valid DEA registration identification.

2.1.o. "Provision" means prescribing or administering.

2.1.p. "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.

§19-14-3. 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, or the practitioner's authorized agent, 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 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 access and any controlled substances reported to the CSMP within the 12 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 paper or electronic copy of the CSMP accessed report maintained in the patient medical record.

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, or the practitioner's authorized agent, 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 12 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 12 months 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 paper or electronic copy of the CSMP accessed report maintained in the patient medical record.

3.5. Nothing herein prohibits the CSMP from being accessed for a specific patient more frequently than annually by the current practitioner, or the practitioner's authorized agent; 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 paper or electronic copy of the CSMP accessed report maintained in the patient medical record.

3.6. Accessing the CSMP must occur prior to the provision of the controlled substance Provided, that if there is an equipment failure, electricity outage or other disaster or event that renders review of the CSMP impossible prior to provision of the required controlled substances and it is determined by the practitioner that providing a controlled substance is medically necessary, this determination of medical necessity shall be documented in the medical record and the controlled substance may be provided in a limited amount. The circumstances preventing the access to the CSMP prior to provision of the controlled substance shall be documented in the patient's medical record, and immediately upon having access restored the CSMP

19CSR14

report shall be accessed, documented as described in this rule and the practitioner shall adjust patient care as needed.

§19-14-4. Other Legal Authority.

4.1. Practitioners shall comply with all other applicable federal and state laws, rules, and regulations.

§19-14-5. Discipline.

5.1. Any practitioner who fails to comply with this rule 19CSR14 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 §30-7-11 and 19CSR3.