

**WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION**

Form #8

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OFFICE WEST VIRGINIA
SECRETARY OF STATE

Effective Date

NOTICE OF AN EMERGENCY AMENDMENT TO AN EMERGENCY RULE

AGENCY: West Virginia Board of Dental Examiners TITLE NUMBER: 5

DATE EMERGENCY RULE WAS ORIGINALLY FILED: July 26, 2012

FIRST EMERGENCY AMENDMENT TO AN EXISTING RULE: YES x NO

SECOND EMERGENCY AMENDMENT TO AN EXISTING RULE: YES NO

DATE OF FIRST EMERGENCY AMENDMENT:

SERIES NUMBER OF RULE: 5 CSR 10

TITLE OF RULE: Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database

THE ATTACHED IS AN EMERGENCY AMENDMENT TO AN EXISTING EMERGENCY RULE. THIS EMERGENCY AMENDMENT BECOMES EFFECTIVE AFTER APPROVAL BY SECRETARY OF STATE OR 42ND DAY AFTER FILING, WHICHEVER OCCURS FIRST.

THE FACTS AND CIRCUMSTANCES CONSTITUTING THE EMERGENCY AMENDMENT ARE AS FOLLOWS:

As a result of comments received in regards to this rule, the Board has voted to make the following amendments:

Definitions were added for "authorized agent" and "chronic nonmalignant pain";

Language was added to clarify access by an "authorized agent"; and

Language was added for instances of unavailability of accessing the CSMP due to power outages, internet services being down or affordable broadband availability.

Use additional sheets if necessary



Authorized Signature

EMERGENCY RULE QUESTIONNAIRE

DATE: 7/20/2012

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency Name, Address & Phone No.) West Virginia Board of Dental Examiners

PO Box 1447

Crab Orchard, WV 25827-1447

EMERGENCY RULE TITLE: Practitioner Requirements for Accessing the West Virginia Cont

1. Date of filing 7-26-2012

2. Statutory authority for promulgating emergency rule:

SB 437 of the 2012 Regular Legislative Session requires this emergency rule.

3. Date of filing of proposed legislative rule: _____

4. Does the emergency rule adopt new language or does it amend or appeal a current legislative rule? New language.

5. Has the same or similar emergency rule previously been filed and expired?

no

6. State, with particularity, those facts and circumstances which make the emergency rule necessary for the **immediate** preservation of public peace, health, safety or welfare.

~~SB 437 requires the board to promulgate, by emergency rules and the regular rules process, a rule to require practitioners access the controlled substance monitoring database concerning patients they prescribe controlled substances to and requires documentation of such activity in the patient's chart.~~

7. If the emergency rule was promulgated in order to comply with a time limit established by the Code or federal statute or regulation, cite the Code provision, federal statute or regulation and time limit established therein.

SB 437 of the 2012 Legislative Session which went into effect June 8, 2012.

8. State, with particularity, those facts and circumstances which make the emergency rule necessary to prevent substantial harm to the public interest.

SB 437 requires this emergency rule. This rule will require practitioners to access and review their patients controlled substance record before prescribing. It also requires documentation of such review in the patients records.

SUMMARY OF PROPOSED RULE

TITLE 5 LEGISLATIVE RULE WEST VIRGINIA BOARD OF DENTAL EXAMINERS

SERIES 10 RULE FOR THE WEST VIRGINIA BOARD OF DENTAL EXAMINERS

This rule is being proposed as a new series to require practitioners to access the WV Controlled Substances Monitoring Program Database and review their patients controlled substances records before initially prescribing.

STATEMENT OF CIRCUMSTANCES

CONCERNING A PROPOSED RULE

TITLE 5

LEGISLATIVE RULE

WEST VIRGINIA BOARD OF DENTAL EXAMINERS

SERIES 10

RULE FOR THE WEST VIRGINIA BOARD OF DENTAL EXAMINERS

This rule is filed as required by Senate Bill 437 of the 2012 Legislative Session. The passage of this bill requires rules to be filed as an emergency and through the regular rule making process.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database

Type of Rule: ☒ Legislative ☐ Interpretive ☐ Procedural

Agency: West Virginia Board of Dental Examiners

Address: PO Box 1447
Crab Orchard, WV 25827-1447

Phone Number: (304)252-8266 Email: wvbde@suddenlinkmail.com

Fiscal Note Summary

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

There is no additional cost nor revenue to state government related to this proposed rule.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

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

Rule Title:

Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database

Rule Title: _____

3. **Explanation of above estimates (including long-range effect):**
Please include any increase or decrease in fees in your estimated total revenues.

n/a

MEMORANDUM

Please identify any areas of vagueness, technical defects, reasons the proposed rule would not have a fiscal impact, and/or any special issues not captured elsewhere on this form.

none

Date: 7-24-2012

Signature of Agency Head or Authorized Representative



**TITLE 5
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF DENTAL EXAMINERS**

FILED

AUG 31 AM 9:16

SERIES 10

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

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

§5-10-1. 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 Dental Examiners 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.

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

1.3. Filing date. –

1.4. Effective date. –

§5-10-2. Definitions.

2.1. As used in this rule, the following words and terms have the following meaning:

(a) "Administering" means the direct application of a drug to the body of a patient by injection, inhalation, ingestion or any other means.

(b) "Authorized Agent" means an individual who is an employee of a dentist permitted to have access to the CSMP repository and database who is specifically designated by the Dentist to access the database on his/her behalf.

~~(b)~~(c) “Board” means the West Virginia Board of Dental Examiners.

(d) “Chronic nonmalignant pain” means pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause 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.

~~(c)~~(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.

~~(d)~~(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.

~~(c)~~(g) “CSMP” means the West Virginia Controlled Substances Monitoring Program repository and database.

~~(f)~~(h) “DEA registration identification number” means the federal Drug Enforcement Administration registration identification number issued to a practitioner.

~~(g)~~(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.

~~(h)~~(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.

~~(i)~~(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.

~~(j)~~(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.

~~(k)~~(m) “Patient” means a person presenting himself or herself for treatment who is

not considered by the practitioner as suffering from a terminal illness.

(~~h~~)(n) “Practitioner” means a dentist licensed pursuant to the provisions of the West Virginia Dental Practice Act, W. Va. Code § 30-4-1 et seq. who possesses a valid DEA registration identification number.

(~~m~~)(o) “Provision” means prescribing or dispensing and includes administering.

(n)(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.

§5-10-3. 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, 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 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 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, 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, 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 twelve (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 twelve (12) month 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, 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 copy of the CSMP accessed report signed and dated by the current practitioner.

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 prevent 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 report shall be accessed, documented as described in this rule and the practitioner shall adjust patient care as needed. *Provided further*, that if a practitioner is unable to access the CSMP due to the unavailability of commercially affordable broadband coverage in a practitioner's area and it is determined by the practitioner that providing a controlled substances is medically necessary, this determination shall be documented in the medical record and the controlled substance may be provided in a limited amount. The practitioner shall access the CSMP through alternate means and document the treatment rendered and the practitioner shall adjust patient care as needed.

§5-10-4. Other legal authority.

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

§5-10-5. Discipline.

5.1. Any practitioner who fails to comply with this rule 5 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 § 30-4-20.