

Form #3

OFFICE WEST VIRGINIA
SECRETARY OF STATE

TITLE OF RULE BEING PROPOSED: Practitioner Requirement for Accessing the West Virginia Controlled Substance Monitoring Program Database


Authorized Signature

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: 8/29/2012

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency Name, Address & Phone No) WV Board of Dental Examiners
PO Box 1447
Crab Orchard, WV 25827
304-252-8266

LEGISLATIVE RULE TITLE: Practitioner Requirement for Accessing the West Virginia
Controlled Substance Monitoring Program Database

1. Authorizing statute(s) citation §60A-9-5a in Com. Sub. for S. B. 437

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

July 26, 2012

b. What other notice, including advertising, did you give of the hearing?

Written notice was sent to the WV Dental Association, WV Dental Hygienist's Association and
WV Dental Assistants Association.

Proposed rules were posted on the Board's website.

c. Date of Public Hearing(s) *or* Public Comment Period ended:

Comment period ended August 25, 2012 @ 12:00 pm

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached _____

No comments received 5

- e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

8-31-2012

- f. **Name, title, address and phone/fax/e-mail numbers** of agency person(s) to receive all written correspondence regarding this rule: (Please type)

Richard D. Smith, DDS
Executive Secretary
WV Board of Dental Examiners
PO Box 1447
Crab Orchard, WV 25827
(304)252-8266
(304)253-9454 - fax

- g. **IF DIFFERENT FROM ITEM 'f', please give Name, title, address and phone number(s)** of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

- a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

n/a

b. Date of hearing or comment period:

n/a

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

n/a

d. Attach findings and determinations and reasons:

Attached n/a

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

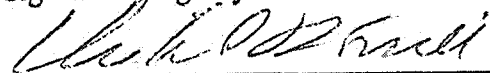
MEMORANDUM

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

2012 AUG 31 AM 9:15

SERIES 10

OFFICE 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)~~ (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.

~~(e)~~(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.

~~(f)~~(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.

~~(e)~~(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.

WEST VIRGINIA DENTAL ASSOCIATION

2016 1/2 Kanawha Boulevard, East • Charleston, WV 25311

TEL: (304) 344-5246

FAX: (304) 344-5316

West Virginia Board of Dental Examiners
1319 Robert C. Byrd Drive
PO Box 1447
Crab Orchard, WV 25827-1447

August 22, 2012

Re: Emergency Rule Series 10
Legislative Rule Series 10

Dear Board Members;

Thank you for your July 27 letter and opportunity to comment on the two above proposed rules, each of which are titled: "Practitioner Requirements for Accessing the West Virginia Controlled Substance Monitoring Program Database."

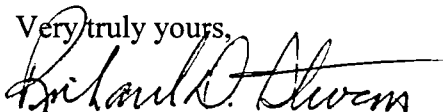
Sections 3.2, 3.3 and 3.4 call for dentists to "access" the database and document such access. Under the Board of Pharmacy rule 15 CSR 8 practitioners may designate authorized agents to access the database on their behalf. It may be assumed your emergency and legislative rules allow an authorized agent of the dentist to access the database, this Association respectfully recommends it be clarified that the dentist may utilize their authorized agent to assist them in compliance with your rule by performing the functions that have been allowed under the Board of Pharmacy's rule for several years.

Sections 3.2, 3.3, and 3.4 of your rule require dentists to document in the patient's record that he or she has accessed the patient's drug history on the database and document any controlled substances listed on the report that has been prescribed and dispensed the patient within the previous 12 months as well as retain a signed copy of the database report in the patients's chart. This Association suggests it is unnecessary to have such redundancy within the medical record. The Board of Pharmacy has a history on dentists and patients prescriptions. In any investigation of a dentist, if there is question on whether they accessed the database as required, your Board can request such a history from the Board of Pharmacy for confirmation.

Problems may arise with accessing the database that are beyond the control of the dentist. For example, a power outage can cause the Internet to be down. In such instances, dentists are unable to access the database when writing a prescription.. Therefore, language should be added requiring a dentist to document in a patient's record the reason the database was not accessed..

Thank you for your consideration of this Association's comments and recommendations.

Very truly yours,



Richard D. Stevens
Executive Director

AUG 23 2012

cc: WVDA Officers and Executive Council Delegates

WEST VIRGINIA DENTAL ASSOCIATION

2016 1/2 Kanawha Boulevard, East • Charleston, WV 25311

TEL: (304) 344-5246

FAX: (304) 344-5316

WV Board of Dental Examiners
1319 Robert C. Byrd Drive
PO Box 1447
Crab Orchard, WV 25827-1447

August 22, 2012

Re: Emergency Rule Series 10
Legislative Rule Series 10

Dear Board Members:

Thank you for your July 27 letter and opportunity to comment on the two (2) above proposed rules, each of which are titled: "Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database."

The rule is drafted under direction of 60A-9--5a which requires dentists, as well as other practitioners, who prescribe controlled substances to access the Board of Pharmacy's Controlled Substance Monitoring Program database when they initially prescribe a schedule II - V drug to a non-terminal patient for treatment of "chronic nonmalignant pain." Your rule is consistent with this language, however, neither the statute nor the rule define "chronic nonmalignant pain." This omission will cause dentists to be unclear as to the requirements of accessing the database.

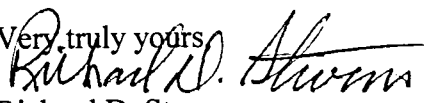
A review of this same rule proposed by the WV Board of Medicine, WV Board of Osteopathic Medicine and WV Board of Examiners of Registered Professional Nurses reveal the language of their respective rules is identical to the language in your Board's rule except each of their rules contain the definition of "chronic nonmalignant pain."

This Association understands licensing boards agreed to identical language in the interest of consistency of the rule among all licensed prescribers. Copies of the rules of these three licensing boards are enclosed so you may assess the uniformity of the rules.

Therefore, you are respectfully requested to amend the two (2) above referenced rules to include the definition of "chronic nonmalignant pain" to read as follows:

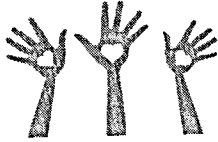
"Chronic nonmalignant pain" means pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause that has continued, either continuously or episodically, for longer than three (3) continuous months. For purposes of this rule, "chronic nonmalignant pain" 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.

Your consideration of this Association's requested is appreciated.

Very truly yours,

Richard D. Stevens
Executive Director

cc: WVDA Officers and Executive Council Delegates

West Virginia Dental Assistants Association



"The Third Hand of the Dentist"

Debra McCallister, C.D.A., E.F.D.A
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(304)757-7182
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Dr Diane Paletta, President and Board Members
West Virginia Board of Dental Examiners
1319 Robert C Byrd Drive
P O Box 1447
Crab Orchard, WV 25827-1447
Fax 304-253-9454

Dear Doctor Paletta and Board Members,

Thank you for informing the West Virginia Dental Assistants Association of your proposed changes in rules and the opportunity to comment on the changes.

The Association supports your emergency rule regarding accessing the Controlled Substance Monitoring Program Database, as required under Senate Bill 437 introduced at the request of Governor Earl Ray Tomblin and passed by the 2012 Legislature. We view this to improve methods of ceasing the diversion and illegal use of prescription drugs.

This Association understands your Board is not changing expanded duties allowed by dental assistants after completing Board approved courses, which include restorative expanded duties, coronal polishing, orthodontic expanded duties and monitoring nitrous oxide. The proposed changes are merely a reorganization of current rules, which this Association supports.

Thank you for your service to the dental profession and dental assistants.

Very truly yours

Kim Vickers, CDA
President
West Virginia Dental Assistants Association

AUG 24 2012

From: Diana Frum <dr.dfrum@gmail.com>
Sent: Friday, August 24, 2012 10:50 AM
To: wvbde@suddenlinkmail.com
Subject: Emergency Rule

Dr Smith

In response to the emergency rule letter received today... I have one thing that needs clarified.

Please define "chronic" in terms of time. I think I read that it is a patient needing pain meds for over a three month period. Is that correct?

Thanks

Dr Frum

--

Diana Oliver Frum, DDS
406 Holland Ave
Westover, WV 26501
304-296-3786

frumandciddental.com

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Shahan Comment

From: Michael Shahan, DDS <wvperio@gmail.com>
Sent: Wednesday, August 22, 2012 12:29 PM
To: wvbde@suddenlinkmail.com
Subject: Controlled Substance Monitoring Program

Dear Sir:

I just received the board publication dealing with the substance abuse monitoring program recently forced upon us by the federal government and rubber stamped by the WV Legislature. I read it and have determined that 99.9% of the dentist in this state do not treat chronic nonmalignant pain. In the section on definitions I suggest adding the definition of chronic nonmalignant pain. Also, in your letter signed by Dr. Smith, there should have been a note that the board recognizes that very few, if, any dentist treat chronic pain. I'm open for discussion.

Michael H. Shahan, DDS
2000 Dudley Ave, Ste 2
Parkersburg, WV 26101

COMMENTS & BOARD RESPONSE

During the comment period, the Board received five written comments concerning this rule. Comments were received from the West Virginia Dental Association, West Virginia Dental Assistants Association, Dr. Diana Frum and Dr. Michael Shahan.

The West Virginia Dental Assistants Association supports this rule and views the rule as a way to improve methods of ceasing the diversion and illegal use of prescription drugs.

The West Virginia Dental Association, Dr. Diana Frum and Dr. Michael Shahan all request the Board to include a definition for “chronic nonmalignant pain” with suggested language from the West Virginia Dental Association.

In addition to the definition requested, the West Virginia Dental Association also requested or suggested the following:

Clarification that dentists may utilize their authorized agent to assist them to comply with this rule.

That it is unnecessary to retain a signed copy of the database report in the patient’s chart when it is documented in the patient’s record that he or she has accessed the patient’s drug history on the database and documented any controlled substances listed on the report that has been prescribed and dispensed the patient within the previous 12 months.

Language should be added requiring a dentist to document in a patient’s record the reason the database was not accessed in cases where a power outage may cause internet services to be down.

During the Board’s meeting on August 28, 2012, the Board responded to these comments as follows:

Upon motion by Dr. George D. Conard, Jr., and properly seconded by Mr. William E. Ford, III, and unanimously passed the Board approved the request for addition of a definition of “chronic nonmalignant pain” with suggested definition from the Dental Association.

Upon motion by Dr. George D. Conard, Jr., and properly seconded by Mrs. Beverly L. Stevens, and unanimously passed, the Board approved a request to add a definition of authorized agent.

Upon motion by Dr. C. Richard Gerber, and properly seconded by Mrs. Beverly L. Stevens, and unanimously passed, the Board approved the suggestion to add language to the rule concerning

instances when a dentist may be unable to access the database due to power outages. The Board's Counsel will come up with proper language to cover such outages or unavailability of broadband services.

Mr. Richard Stevens, Executive Director of the West Virginia Dental Association requested that dentists only have to download, but not print out and sign the record, after discussion and comments by the Board's Counsel, Mr. Stevens withdrew this request.

The Board voted unanimously to accept the rule as amended. The motion was made by Dr. George D. Conard, Jr., and properly seconded by Mrs. Beverly L. Stevens.