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

Form #3

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FILED

2012 AUG 28 AM 10: 02

OFFICE WEST VIRGINIA
SECRETARY OF STATE

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

AGENCY: WEST VIRGINIA BOARD OF MEDICINE TITLE NUMBER: 11

CITE AUTHORITY: WEST VIRGINIA CODE § 60A-9-5a(b)

AMENDMENT TO AN EXISTING RULE: YES ____ NO X

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 10

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 10

TITLE OF RULE BEING PROPOSED: PRACTITIONER REQUIREMENTS FOR ACCESSING THE WEST VIRGINIA CONTROLLED SUBSTANCES MONITORING PROGRAM DATABASE

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

Brent C Kaetzle

Authorized Signature

State of West Virginia
Board of Medicine

101 Dee Drive, Suite 103
Charleston, WV 25311
Telephone 304.558.2921
Fax 304.558.2084
www.wvbom.wv.gov

REV. O. RICHARD BOWYER
PRESIDENT

MARIAN SWINKER, MD, MPH
SECRETARY

MICHAEL L. FERREBEE, MD
VICE PRESIDENT

ROBERT C. KNITTLE
EXECUTIVE DIRECTOR

SUMMARY OF CONTENT AND STATEMENT OF CIRCUMSTANCES REQUIRING THE RULE

In accordance with the provisions of West Virginia Code § 60A-9-5a, the Rule provides that upon initially prescribing or dispensing any pain-relieving substance for a patient and at least annually thereafter if the prescriber or dispenser continues to treat the patient with controlled substances, all persons with prescribing or dispensing authority and in possession of a valid Drug Enforcement Administration registration identification number and licensed by the Board of Medicine must 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. The information obtained must be documented in the patient's medical record.

The Rule contains multiple definitions and explains that failure to comply with provisions of the Rule subjects the practitioner to Board of Medicine discipline for unprofessional, unethical and dishonorable conduct.

Effective June 8, 2012, a new comprehensive law is effective in West Virginia relating to drug diversion and abuse, which new law requires the Board of Medicine to promulgate a rule relating to the subject of Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database. In accordance with provisions of this new comprehensive law, the West Virginia Board of Medicine is acting in filing this Legislative Rule 11 CSR 10 as it has been instructed (West Virginia Code § 60A-9-5a).

West Virginia leads the nation in drug overdose death. Drug abuse and diversion is an epidemic in West Virginia.* If practitioners who prescribe/dispense pain-relieving controlled substances are required to check, have the ability to check, and do check, the controlled substance history of a patient, the practitioner will be better informed of the facts than at present, and the knowledge obtained may cause fewer controlled substances which are diverted to be prescribed/dispensed. Lowering the death rate in West Virginia from overdoses as a result of diverted drugs would be a welcome improvement and in everyone's interests.

*See attachment, Charleston Gazette May 24, 2012, article

Manchin amendment to reclassify painkillers

U.S. senators on Wednesday evening unanimously passed an amendment to a Food and Drug Administration reauthorization bill that would reclassify all hydrocodone substances and make punishment for their trafficking more severe.

The amendment, introduced by Sen. Joe Manchin, D-W.Va., would reclassify painkillers like Vicodin and Lortab as Schedule II drugs, which also affects how they are to be stored and prescribed.

For instance, patients would need an original prescription for refills, hydrocodone pills would need to be transported and stored more securely and traffickers would be subject to increased criminal penalties, according to a news release from Manchin's office.

Sen. Jay Rockefeller, D-W.Va., and three other senators — including two other Democrats and a Republican — co-sponsored the amendment.

The amendment would reclassify painkillers like Vicodin and Lortab as Schedule II drugs, which also affects how they are to be stored and prescribed.

"I'm truly pleased that this amendment has passed and will make it much harder for anyone to abuse these prescription drugs," Manchin said in a statement. "I offered this legislation on behalf of the countless West Virginians whose lives have been cut short by drug abuse and the families who are picking up the pieces.

"I'm committed to working extremely hard across the aisle to see this most important legislation passed," he said.

Prescription drugs are responsible for about 90 percent of all drug-related deaths in West Virginia, and about 75 percent in the U.S, according to Manchin's release.

Schedule I drugs contain the most dangerous substances. Currently, hydrocodone is considered a Schedule II drug, but when combined with substances like Tylenol, they are listed in a less stringent category, Schedule III.

The amendment would make all substances containing hydrocodone Schedule II drugs.

Findings show that more than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone, methadone, oxycodone and oxymorphone.

"Prescription drug abuse is a very real epidemic that we must stop," Rockefeller said in a statement. "Too many West Virginia families and communities have been hurt terribly, and I've been fighting to turn the tide on abuse."

In addition to co-sponsoring Manchin's amendment, Rockefeller introduced a provision to the FDA reauthorization bill that helps to ensure that doctors, nurses and health-care professionals who prescribe painkillers "get the training they need so they don't overprescribe drugs and can reduce the potential for patient abuse," according to a news release from Rockefeller's office.

Rockefeller's provision would require the Institute of Medicine to study the scope and scale of education requirements for physicians and other people who prescribe medicine. The Institute of Medicine is an independent agency of medical and public health experts who advise Congress on medical and health issues.

Rockefeller also offered an amendment to help support state prescription drug monitoring programs.

11 CSR

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 any 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.

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

1.3. Filing date. –

1.4. Effective date. –

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

2.1.c. "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.

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 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.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.

2.1.n. "Provision" means prescribing or dispensing and includes administering.

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. 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 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 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.

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 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 substance 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, 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.

11-10-4. Other legal authority.

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

11-10-5. Discipline.

5.1. 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 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.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: PRACTITIONER REQUIREMENTS FOR ACCESSING THE WEST VIRGINIA CONTROLLED SUBSTANCES MONITORING PROGRAM DATABASE

Type of Rule: [X] Legislative [ ] Interpretive [ ] Procedural

Agency: WEST VIRGINIA BOARD OF MEDICINE

Address: 101 DEE DRIVE, SUITE 103

CHARLESTON, WV 25311

Phone Number: 304.558.2921 x70005 Email: robert.c.knittle@wv.gov

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	0.00	0.00	0.00
Personal Services			
Current Expenses			
Repairs & Alterations			
Assets			
Other			
2. Estimated Total Revenues	0.00	0.00	0.00

Rule Title: _____

Rule Title: PRACTITIONER REQUIREMENTS FOR ACCESSING THE WEST VIRGINIA CONTROLLED SUBSTANCES MONITORING PROGRAM DATABASE

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: August 28 2012

Signature of Agency Head or Authorized Representative

Robert C Knittle

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: August 28, 2012

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:(*Agency Name, Address & Phone No.*) WEST VIRGINIA BOARD OF MEDICINE
101 DEE DRIVE, SUITE 103
CHARLESTON, WV 25311

LEGISLATIVE RULE TITLE: PRACTITIONER REQUIREMENTS FOR ACCESSING THE WEST VIRGINIA CONTROLLED SUBSTANCES MONITORING PROGRAM DATABASE

1. Authorizing statute(s) citation WEST VIRGINIA CODE § 60A-9-5-a(b)

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

   JUNE 8, 2012

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

   NOTICE OF COMMENT PERIOD AND PROPOSED RULE WERE POSTED ON BOARD'S WEBSITE ON JUNE 8, 2012. EIGHT LETTERS WITH PROPOSED RULE SENT ON JUNE 8, 2012 (ATTACHED), TO INTERESTED PARTIES.

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

   JULY 20, 2012, COMMENT PERIOD ENDED

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

   Attached X (2) No comments received _____

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

August 28, 2012

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

ROBERT C. KNITTLE, EXECUTIVE DIRECTOR

WEST VIRGINIA BOARD OF MEDICINE

101 DEE DRIVE, SUITE 103

CHARLESTON, WV 25311
304.558.2921 x70005 robert.c.knittle@wv.gov

g. **<u>IF DIFFERENT</u> 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.

b. Date of hearing or comment period:

_____

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

_____

d. Attach findings and determinations and reasons:

Attached _____

State of West Virginia
Board of Medicine

101 Dee Drive, Suite 103
Charleston, WV 25311
Telephone 304.558.2921
Fax 304.558.2084
www.wvbom.wv.gov

June 8, 2012

Jeffrey Jay Findling, Jr., D.P.M.
President, West Virginia Association for Podiatric Medicine
102 Park Place Drive
Morgantown, West Virginia 26508

Re: 11 CSR 10, Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database

Dear Dr. Findling:

For your information, enclosed is the rule filed today by the Board of Medicine, both as a legislative and an emergency rule, pursuant to West Virginia Code § 60A-9-5a, part of Enrolled Committee Substitute for S.B. 437, relating to substance abuse. Note the scope of the rule, and please make this information available to your membership. The rule is available on the Board's website as well at www.wvbom.wv.gov. There is a comment period on the legislative rule ending July 20, 2012, at 4:30 p.m.

Sincerely,

Robert C. Knittle

RCK:eb

Enclosure

State of West Virginia
Board of Medicine

101 Dee Drive, Suite 103
Charleston, WV 25311
Telephone 304.558.2921
Fax 304.558.2084
www.wvbom.wv.gov

June 8, 2012

The Honorable Evan H. Jenkins, Executive Director
West Virginia State Medical Association
4307 MacCorkle Avenue, SE
P. O. Box 4106
Charleston, West Virginia 25364

Re: 11 CSR 10, Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database

Dear Senator Jenkins:

For your information, enclosed is the rule filed today by the Board of Medicine, both as a legislative and an emergency rule, pursuant to West Virginia Code § 60A-9-5a, part of Enrolled Committee Substitute for S.B. 437, relating to substance abuse. Note the scope of the rule, and please make this information available to your membership. The rule is available on the Board's website as well at www.wvbom.wv.gov. There is a comment period on the legislative rule ending July 20, 2012, at 4:30 p.m.

Sincerely,

Robert C. Knittle

RCK:eb

Enclosure

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Board of Medicine

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www.wvbom.wv.gov

June 8, 2012

David E. Potters, Executive Director and General Counsel
West Virginia Board of Pharmacy
106 Capitol Street, Suite 100
Charleston, West Virginia 25301

Re: 11 CSR 10, Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database

Dear Mr. Potters:

For your information, enclosed is the rule filed today by the Board of Medicine, both as a legislative and an emergency rule, pursuant to West Virginia Code § 60A-9-5a, part of Enrolled Committee Substitute for S.B. 437, relating to substance abuse. I am sending this to you inasmuch as the rule will require practitioners prior to the 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 to apply for and receive capability for accessing the Controlled Substances Monitoring Program repository and database. (11 CSR 10 3.1) The rule is available on the Board's website as well at www.wvbom.wv.gov. There is a comment period on the legislative rule ending July 20, 2012, at 4:30 p.m.

Sincerely,

Robert C. Knittle

RCK:eb

Enclosure

State of West Virginia
Board of Medicine

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Telephone 304.558.2921
Fax 304.558.2084
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June 8, 2012

HAND DELIVERY

Laura Skidmore Rhodes, M.S.N., R.N., Executive Director
West Virginia Board of Examiners for Registered Professional Nurses
101 Dee Drive, Suite 102
Charleston, West Virginia 25311

Re: 11 CSR 10, Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database

Dear Ms. Rhodes:

For your information, enclosed is the rule filed today by the Board of Medicine, both as a legislative and an emergency rule, pursuant to West Virginia Code § 60A-9-5a, part of Enrolled Committee Substitute for S.B. 437, relating to substance abuse. I am sending this to you inasmuch as the Board of Registered Professional Nurses is also required to promulgate a legislative and emergency rule on this subject. The rule is available on the Board's website as well at www.wvbom.wv.gov. There is a comment period on the legislative rule ending July 20, 2012, at 4:30 p.m.

Sincerely,

Robert C. Knittle

RCK:eb

Enclosure

State of West Virginia
Board of Medicine

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June 8, 2012

Greg Selasky, P.A.-C., President
West Virginia Association of Physician Assistants
491 Michigan Avenue
Morgantown, West Virginia 26501

Re: 11 CSR 10, Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database

Dear Mr. Selasky:

For your information, enclosed is the rule filed today by the Board of Medicine, both as a legislative and an emergency rule, pursuant to West Virginia Code § 60A-9-5a, part of Enrolled Committee Substitute for S.B. 437, relating to substance abuse. Note the scope of the rule, and please make this information available to your membership. The rule is available on the Board's website as well at www.wvbom.wv.gov. There is a comment period on the legislative rule ending July 20, 2012, at 4:30 p.m.

Sincerely,

Robert C. Knittle

RCK:eb

Enclosure

State of West Virginia
Board of Medicine

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June 8, 2012

Ms. Diana Shepard, Executive Director
West Virginia Board of Osteopathy
405 Capitol Street, Suite 402
Charleston, West Virginia 25301

Re: 11 CSR 10, Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database

Dear Ms. Shepard:

For your information, enclosed is the rule filed today by the Board of Medicine, both as a legislative and an emergency rule, pursuant to West Virginia Code § 60A-9-5a, part of Enrolled Committee Substitute for S.B. 437, relating to substance abuse. I am sending this to you inasmuch as the Board of Osteopathy is also required to promulgate a legislative and emergency rule on this subject. The rule is available on the Board's website as well at www.wvbom.wv.gov. There is a comment period on the legislative rule ending July 20, 2012, at 4:30 p.m.

Sincerely,

Robert C. Knittle

RCK:eb

Enclosure

State of West Virginia
Board of Medicine

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June 8, 2012

Richard Duff Smith, DDS, Executive Secretary
West Virginia Board of Dental Examiners
1319 Robert C. Byrd Drive
P.O. Box 1447
Crab Orchard, West Virginia 25827

Re: 11 CSR 10, Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database

Dear Dr. Smith:

For your information, enclosed is the rule filed today by the Board of Medicine, both as a legislative and an emergency rule, pursuant to West Virginia Code § 60A-9-5a, part of Enrolled Committee Substitute for S.B. 437, relating to substance abuse. I am sending this to you inasmuch as the Board of Dental Examiners is also required to promulgate a legislative and emergency rule on this subject. The rule is available on the Board's website as well at www.wvbom.wv.gov. There is a comment period on the legislative rule ending July 20, 2012, at 4:30 p.m.

Sincerely,

Robert C. Knittle

RCK:eb

Enclosure

June 17, 2012

Mr. Robert C. Knittle, MS
Executive Director
WV Board of Medicine
101 Dee Drive
Suite 103
Charleston, WV 25311

Dear Mr. Knittle,

Thank you for the advanced notice that the Board of Medicine has filed emergency rule 11CSR 10 titled *"Practitioner Requirements for Accessing the WV Controlled Substances Monitoring Program Database"*. We have reviewed this emergency rule and appreciate the opportunity to provide you with our comments. **We have identified one oversight that we believe is critical to the proper implementation of the rule by licensed physicians.**

The emergency rule is drafted upon the statutory direction under 60A-9-5a(b) which requires physicians licensed by the WV Board of Medicine, among other licensed practitioners, who prescribe controlled substances to check the Board of Pharmacy's controlled substances monitoring program database when they initially prescribe a schedule II –V drug to a non-terminal patient for treatment of "chronic nonmalignant pain", and annually thereafter. The Board's emergency rule is consistent with this language; however, neither the statute nor the rule define "chronic nonmalignant pain". We have concern that this omission will cause physicians to be unclear as to the requirements therein and there will be variations among physicians regarding what is considered "chronic nonmalignant pain".

The bill which established this new requirement, SB 437, included a definition for "chronic pain" under Chapter 16 with the creation of the Chronic Pain Clinic Licensing Act. That definition is the following:

§16-5H-2. Definitions.

(a) "Chronic 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 continuous months. For purposes of this article, "chronic pain" does not include pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.

West Virginia State Medical Association
[illegible]
Phone 304-925-0342 • Toll Free 800-257-4747 • Fax 304-925-0345
www.wvsma.com

We recommend that a definition for "chronic nonmalignant pain" be added to the emergency rule and this definition for "chronic pain" be used for consistency. **We believe that the definition of chronic pain is fundamental to the proper interpretation of this rule and that it should be added prior to the emergency rule's approval and implementation.**

We thank you for the opportunity to provide comment regarding this emergency rule. If you have any questions regarding our comments and suggestions please do not hesitate to contact Amy N. Tolliver, MS Government Relations Specialist at 304-925-0342 x 25 or Amy@wvsma.org.

Sincerely,

MaryAnn Cater, DO
President
West Virginia State Medical Association

CC: Ms. Natalie Tennant
Secretary of State

West Virginia State Medical Association
[illegible]
P.O. Box [illegible] • Charleston, West Virginia [illegible]
Phone 304-925-0342 • Toll Free 800-257-4747 • Fax 304-925-0345
www.wvsma.com

July 20, 2012

Mr. Robert Knittle, MS
Executive Director
WV Board of Medicine
101 Dee Drive
Suite 103
Charleston, WV 25311

Dear Mr. Knittle,

Thank you for the opportunity to provide comment once again on your proposed rule 11 CSR 10 *Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database.* We are appreciative of your positive response to our previous suggestion to add a definition for "chronic nonmalignant pain". We do believe that the addition of that definition added necessary clarity to the rule. In this vein we have a few additional suggestions to the rule.

The language in the rule is prescriptive of the "practitioner" to perform certain functions in relation to accessing the Controlled Substances Monitoring Program database (CSMP). As the term "practitioner" is defined in the rule, it is clear that the language throughout is referencing the functions that a licensee of the Board of Medicine must perform. Sections 3.2., 3.3 and 3.4 establish the requirement for a practitioner to "access" the database and document such access. Under the WV Board of Pharmacy rule 15 CSR 8 prescribing practitioners may designate authorized agents to access the CSMP on their behalf. We understand that it may be assumed in the language of this rule that this is allowed, but as drafted it appears to be a violation of this rule if the practitioner utilizes their otherwise duly authorized agent to access the database on their behalf. We recommend that it be clarified that the practitioner may utilize their duly authorized agents to assist them in compliance with this rule by performing the functions currently allowed under the WV Board of Pharmacy rule. In most practice settings it would be inefficient and contrary to practice protocols to require the prescribing practitioner to be the only one to perform the query.

Sections 3.3, 3.4 and 3.5 of the rule contain documentation requirements that direct the practitioner to document in the patient's medical record that he/she has checked the CSMP on the particular patient, document any controlled substances listed on the report the patient has been dispensed that were prescribed by another practitioner within the previous 12 months as well as retain a signed copy of the CSMP in the patient's chart. It is unnecessary to have such redundancy within the medical record and seems contrary to the whole movement to more efficient medical practices. The WV Board of Pharmacy retains and can produce a query history on any person with access to the database, therefore the creation of the additional burden to transcribe the information from the report, sign the report and retain a copy does not add value to the process. In any investigation of a practitioner, if there is question on whether they accessed the database as required, the Board of Medicine can request such a query history from the Board of Pharmacy for confirmation. To require the practitioner to access and review the database and document such action should be sufficient to demonstrate compliance with the statute.

Practitioners who utilize technology such as Electronic Medical Records may or may not have the ability save a copy of the CSMP report directly into their patient's EMR depending upon the product they use. We understand that the WV Board of Pharmacy and GOHELP are currently looking into developing the technology to allow the CSMP to interface with EMR's but this technology is not currently available. It would be inefficient to require such paperless providers to retain a signed paper copy of the report, or to go through the additional steps of printing, scanning and saving.

Additionally, it is our understanding that when the State of Ohio implemented similar rules for their practitioners to check their OARRS database, the Ohio Board of Medicine advised against practitioners retaining a copy of the report in the patient's medical record. In WV the CSMP has strict confidentiality protections. CSMP information retained in a patient's medical record is subject to the statutory confidentially protections. The CSMP data is not discoverable under the WV Freedom of Information Act or obtainable without a court order. We raise this point to suggest that you confer with the Ohio Board of Medicine on this topic. We are not suggesting that practitioners be disallowed from retaining a copy of the report in the medical record, simply that mandating they do in all cases may be ill advised in some situations due to the confidentiality of the information and the concerns with technological interfaces.

Lastly, periodically problems arise with accessing the database that are beyond the control of the practitioner. For example, there may be power outages that cause the internet to be down and telephone access is not possible because it is after business hours for the WV Board of Pharmacy. In these cases, it still may be medically necessary to provide the prescription to the patient without delay. We recommend that language be added to clarify the process that a practitioner must undertake if they are to prescribe under such circumstances. It would seem reasonable to require they document their failed attempt to access the database but still require the practitioner to check the database at the soonest available time thereafter.

Again, we thank you for the opportunity to provide comment to the Board regarding this very important matter. If you have any questions regarding our comments and suggestions, please do not hesitate to contact our office.

Sincerely,

MaryAnn Cater, DO
President

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August 28, 2012

Mary Ann Cater, DO, President
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Re: June 17, 2012, and July 20, 2012, Comments on Emergency Rule 11 CSR 10 and Proposed Legislative Rule 11 CSR 10

Dear Dr. Cater:

Thank you for the assistance of the West Virginia State Medical Association as the Board of Medicine has developed the above rule relating to Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database (CSMP). Because of your timely comment relating to a needed definition of "chronic nonmalignant pain," the Board inserted that definition in its emergency rule currently in effect and has added that definition to its proposed Legislative Rule.

In addition, almost all of your other suggestions for the proposed Legislative Rule have been adopted by the Board. After much thoughtful discussion by Board members, the only suggestion that the Board did not adopt was the one relating to providing in the proposed rule that an authorized agent of the practitioner may access the CSMP database. As you noted in your July 20, 2012, letter, it may be assumed in the language of 11 CSR 10 as now proposed that an authorized agent may access the database. The Board of Medicine does not agree that it appears to be a violation of the Agency Approved Rule 11 CSR 10 as filed if the practitioner should utilize an otherwise duly authorized agent to access the database on behalf of the practitioner in the absence of a specific rule provision allowing an authorized agent to access the database.

Moreover, it does not seem to be in the public interest, which the Board by law is required to protect, to make specific provision in the Agency Approved Rule for an authorized agent to access the database, given the precise requirements imposed by both the new law and this proposed rule on the practitioner to provide the pain-relieving controlled substances. In any event, the Board of Medicine does not seek to micromanage the internal procedures employed in the practitioner's office any more than is mandated.

The Board is grateful to you for your comments and hopes you will find the Agency Approved Rule satisfactory upon its filing.

Best wishes to you.

Sincerely,

Robert C. Knittle

RCK:eb

pc: Evan H. Jenkins, Executive Director

Reasons for Changes

The definition of "chronic nonmalignant pain," as noted in the Board's letter to the President of the West Virginia State Medical Association, was much needed, an integral component of the rule which had been omitted. Also, an exception for discipline was added in case of internet connectivity or power outages. This seemed reasonable in light of the recent derecho experienced in West Virginia.