



State of West Virginia *Board of Medicine*

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ASHISH P. SHETH, MD
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MARK A. SPANGLER, MA
EXECUTIVE DIRECTOR

SUMMARY OF COMMENTS RECEIVED REGARDING PROPOSED AMENDMENTS TO 11 CSR 10 AND RESPONSES OF THE WEST VIRGINIA BOARD OF MEDICINE

On June 29, 2021, the West Virginia Board of Medicine filed a Notice of Comment Period on a Proposed Rule, 11 CSR 10. Series 10 is the Board's rule with regard to practitioner requirements for accessing the Controlled Substance Monitoring Program Database. The Notice established a thirty day comment period on the proposed rule, which concluded at 4:30 pm on July 29, 2021. During the comment period, the Board received two comments.¹ The Board has reviewed the comments received, and on July 29, 2021, the following responses were authorized by the Board. A copy of this summary is being provided to the commenters.

Commenter	Date Received
1. David M. Glener, MD,	June 29, 2021

Dr. Glener's communication to the Board asks for clarification of the proposed amendment and requests that the Board consider a carve-out exception in certain circumstances. Specifically, Dr. Glener commented:

I am a West Virginia licensee but have never practiced in WV. I am in the process of obtaining hospital privileges in WV. I am board-certified in anesthesiology and will limit my practice to the hospital, administering anesthesia in the operating room. I will not be issuing prescriptions of any kind for preoperative or postoperative usage.

My question: Do I still need to register for the WVCSP database? If so, am I obligated by law to check the database prior to administering any anesthetic, since the vast majority entail the administration of a controlled substance?

If I am required to do so, please advise and I will comply. However, might I suggest an exception to the above rule for the administration of anesthesia?

¹ A copy of the comments received by the Board and the Board's responses thereto are attached to this summary.

Imagine this scenario: I am called to labor and delivery for a stat Cesarean section. This is a lifesaving action for the child and sometimes the mother. Seconds count. Do I say to the patient and the obstetrician, "Sorry, I must first log onto the WVCSF database to check the patient's history of controlled substance prescriptions since I will be administering controlled substances during the anesthetic?" This scenario is not limited to parturients. Suppose there is a ruptured aortic aneurysm or a trauma patient? A patient having a seizure that requires securing their airway? The time needed to find a computer to check a database could cost a patient their life.

I respectfully request language be added to the amendment to specifically address this situation. I always want to do what is best for the patient; it seems unfair to ask a well-meaning physician to violate the rules and place themselves at risk for discipline to provide optimal patient care.

Response: This rule conforms to the statutory requirements set forth in W. Va. Code § 60A-9-5a, which provides:

(a) All practitioners, as that term is defined in §60A-2-201 of this code who prescribe or dispense Schedule II, III, IV or V controlled substances shall register with the West Virginia 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.

(b) 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 Medicine as set forth in §30-3-1 *et seq.* of this code, the Board of Registered Professional Nurses as set forth in §30-7-1 *et seq.* of this code, the Board of Dental Examiners as set forth in §30-4-1 *et seq.* of this code, the Board of Osteopathic Medicine as set forth in §30-14-1 *et seq.* of this code, the West Virginia Board of Optometrists as set forth in §30-8-1 *et seq.* of this code, and a pharmacist licensed by the West Virginia Board of Pharmacy as set forth in §30-5-1 *et seq.* upon initially prescribing or dispensing 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.

(c) The various boards mentioned in §60A-9-5(b) of this code shall amend its legislative rules pursuant to the provisions of §29A-3-1 *et seq.* of this code to effectuate the provisions of this article.

W. Va. Code § 60A-9-5a (emphasis added). The Uniform Controlled Substance Act defines the term “dispense” to include the administering of a controlled substance.

“Dispense” means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, **administering**, packaging, labeling or compounding necessary to prepare the substance for that delivery.

W. Va. Code § 60A-101-1(i) (emphasis added). The Board’s definition of “dispense” in 11 CSR 10 is consistent with the statutory definition.

In conformity with statute, 11 CSR 10 requires Board of Medicine licensees and registrants who prescribe or dispense (which includes administering) controlled substances to register with the Controlled Substance Monitoring Program and to obtain and maintain online or other access to the CSMP. See the amendments to section 3 of 11 CSR 10. Likewise, section 4 of the rule requires providers to access the CSMP before initially providing a patient any Schedule II controlled substance, any opioid, or any benzodiazepine.

The Board does not have the discretion to implement the proposed exception identified by Dr. Glener, as the statute is clear on who must obtain access to the CSMP and when it must be accessed by providers. However, the Board appreciates Dr. Glener’s concerns, and Board staff conducted outreach to the West Virginia Board of Pharmacy regarding CSMP use and access in hospital settings. Board staff were able to confirm that some hospitals in West Virginia have real-time access to the CSMP data for hospitalized patients as a functionality built into the electronic health record system. If this is the case, the practitioners who provide patients with Schedule II controlled substances, opioids and/or benzodiazepines “access” the CSMP data directly in the patient electronic medical record. Additionally, providers routinely utilize delegates to conduct the actual CSMP data search. This can also occur in hospital settings, where the results can then be made available to all prescribing/dispensing/administering providers. There are important public safety objectives underpinning the requirements of W. Va. Code § 60A-9-5a. A review of a patient’s controlled substance prescription history may be highly relevant to whether a patient should be provided certain controlled substances in a hospital setting. While there may be emergency situations where a lack of patient identity information may impede compliance W. Va. Code § 60A-9-5a, the advancement of hospital electronic health records to include real-time access to the CSMP data and the use of delegates

weigh against the need for a specific carve-out for providers of anesthesiology. Regardless, any such exception would be the province of the Legislature as it would require a statutory change.

Commenter	Date Received
1. Richard Topping, MD Legislative Chairman West Virginia Orthopaedic Society	July 28, 2021

The West Virginia Orthopaedic Society (“WVOS”) submitted a comment addressing two of the Board’s proposed rules. With regard to 11 CSR 10, WVOS wrote:

First, in the prescribing of narcotic rules for utilization of the data bank, I see no clarification if this includes the emergency room and operating room setting. It would be very difficult to add this to the must do list during on call visits to reduce fractures and providing other emergent call without the support of office staff. The same applies to the operating room setting. Frequently, there is minimal time to complete orders and other already required paper work before starting another surgery. This is especially so for private practice based surgeons without residents to assist in such requirements. The office setting has multiple tiers of staff to assist for patients in that setting.

Response: For all of the reasons set forth in response to the first comment, this rule conforms to the statutory requirements set forth in W. Va. Code § 60A-9-5a, which does not incorporate an exception for providing Schedule II controlled substances, opioids or benzodiazepines to patients in the emergency room or operating room. In conformity with statute, section 4 of 11 CSR 10 requires providers to access the CSMP before initially providing a patient any Schedule II controlled substance, any opioid, or any benzodiazepine.

The Board does not have the discretion to implement the proposed exception identified by WVOS, as the statute is clear on who must obtain access to the CSMP and when it must be accessed by providers.

Conclusion

In conclusion, the Board has not made any changes to 11 CSR 10 in response to the comments received. The Board again expresses its appreciation to all who submitted comments, which the Board carefully considered.

From: Spangler, Mark A
To: Eramo, Jamie C
Subject: FW: [External] Comment on proposed amendment to 11 CSR 10
Date: Wednesday, June 30, 2021 9:06:58 AM

Mark A. Spangler

Executive Director

West Virginia Board of Medicine
101 Dee Drive, Suite 103
Charleston, West Virginia 25311
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From: David Glener <davidglener@yahoo.com>
Sent: Tuesday, June 29, 2021 4:39 PM
To: Spangler, Mark A <Mark.A.Spangler@wv.gov>
Subject: [External] Comment on proposed amendment to 11 CSR 10

CAUTION: External email. Do not click links or open attachments unless you verify sender.

Hello, Mr. Spangler.

I read the proposed amendment and would like to ask for clarification to the language in the proposed amendment, as is, and to make a suggestion to carve out an exception, if need be.

I am a West Virginia licensee but have never practiced in WV. I am in the process of obtaining hospital privileges in WV. I am board-certified in anesthesiology and will limit my practice to the hospital, administering anesthesia in the operating room. I will not be issuing prescriptions of any kind for preoperative or postoperative usage.

My question: Do I still need to register for the WVCSP database? If so, am I obligated by law to check the database prior to administering any anesthetic, since the vast majority entail the administration of a controlled substance?

If I am required to do so, please advise and I will comply. However, might I suggest an exception to the above rule for the administration of anesthesia?

Imagine this scenario: I am called to labor and delivery for a stat Cesarean section. This is a lifesaving action for the child and sometimes the mother. Seconds count. Do I say to the patient and the obstetrician, "Sorry, I must first log onto the WVCSP database to check the patient's history of controlled substance prescriptions since I will be administering controlled substances during the anesthetic?" This scenario is not limited to parturients. Suppose there is a ruptured aortic aneurysm or a trauma patient? A patient having a seizure that requires securing their airway? The time needed to find a computer to check a database could cost a patient their life.

I respectfully request language be added to the amendment to specifically address this situation. I always want to do what is best for the patient; it seems unfair to ask a well-meaning physician to violate the rules and place themselves at risk for discipline to provide optimal patient care.

Thank you, Mr. Spangler, for your time and attention.

Regards,

David M. Glener, M.D.



State of West Virginia *Board of Medicine*

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VICE PRESIDENT

MARK A. SPANGLER, MA
EXECUTIVE DIRECTOR

July 30, 2021

VIA ELECTRONIC MAIL ONLY

David M. Glener, MD
davidglener@yahoo.com

Re: Proposed Amendments to West Virginia Board of Medicine Rule 11 CSR 10

Dear Dr. Glener:

Thank you for taking the time to review and comment on the Board's proposed amendments to 11 CSR 10, *Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database*.

The Legislative Committee of the Board met yesterday, July 29, 2021, to review and consider all of the comments that were received. Discussion occurred, however, no modifications were made to the proposed rule in response to the comments it received. Enclosed please find the Board's *Summary of Comments Received Regarding 11 CSR 10 and Responses of the West Virginia Board of Medicine* (without attachments).

The agency-approved version of 11 CSR 10 will be filed with the West Virginia Secretary of State's Office today and will be available for review on their website at <https://apps.sos.wv.gov/adlaw/csr/>. The enclosed summary, along with all comments will also be available on the Secretary of State's website.

Thank you again for your participation in the rulemaking process and for your comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark A. Spangler", written in a cursive style.

Mark A. Spangler

MAS/jcf
Enclosure



Frame, Jamie C <jamie.c.frame@wv.gov>

Fwd: West Virginia Orthopaedic Society comments

1 message

Spangler, Mark A <mark.a.spangler@wv.gov>

Thu, Jul 29, 2021 at 9:48 AM

To: Jamie Alley <jamie.s.alley@wv.gov>, "Frame, Jamie C" <jamie.c.frame@wv.gov>

This came in after hours

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----- Forwarded message -----

From: r topping <retopping@yahoo.com>

Date: Wed, Jul 28, 2021 at 4:47 PM

Subject: West Virginia Orthopaedic Society comments

To: Mark.A.Spangler@wv.gov <Mark.A.Spangler@wv.gov>

Cc: wvos@frontier.com <wvos@frontier.com>

Dear Mr. Spangler,

Our society has 2 concerns with the BOM proposals. First, in the prescribing of narcotic rules for utilization of the data bank, I see no clarification if this includes the emergency room and operating room setting. It would be very difficult to add this to the must do list during on call visits to reduce fractures and providing other emergent call without the support of office staff. The same applies to the operating room setting. Frequently, there is minimal time to complete orders and

7/29/2021

State of West Virginia Mail - Fwd: West Virginia Orthopaedic Society comments

other already required paper work before starting another surgery. This is especially so for private practice based surgeons without residents to assist in such requirements. The office setting has multiple tiers of staff to assist for patients in that setting.

Also, the telehealth bill concerns us in specialty care. We practice on very tight margins in one of the poorest states in US. Telehealth would make it much easier for mega tertiary centers such as UPMC and Cleveland Clinic to cherry pick well insured patients for orthopedic surgery. This would leave us treating an even higher percentage of Medicare/Medicaid patients while we would still be stuck taking care of complications on those that left in our emergency rooms. Further cuts from any reason would most likely make it impossible to continue the private practice model of orthopedic care in our state.

Please feel free to contact me for further details.

Richard Topping, MD
WVOS legislative chairman



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July 30, 2021

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Richard Topping, MD
West Virginia Orthopaedic Society
rstopping@yahoo.com

Re: Proposed Amendments to West Virginia Board of Medicine Rule 11 CSR 10

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Sincerely,

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Mark A. Spangler

MAS/jcf
Enclosure