WVUMedicine

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July 26th, 2022

Mark A. Spangler, MA
West Virginia Board of Medicine
101 Dee Drive, Suite 103
Charleston, WV, 25311

Re: Proposed amendment to the existing legislative rules for Collaborative Pharmacy Practice, title-series 11-08, statutory authority W. Va. Code §30-5-7(c).

Dear Mr. Spangler,

The Pharmacy Enterprise of WVU Medicine is pleased to submit comments regarding the proposed amendment to the existing legislative rules for Collaborative Pharmacy Practice. The Pharmacy Enterprise comprises pharmacy departments from 14 West Virginia-based member hospitals of the WVU Health System and is led by Chief Pharmacy Officer Todd Karpinski, PharmD. With a rapidly expanding clinical pharmacist presence in ambulatory clinics, we are excited to see the updates to the Collaborative Pharmacy Practice rules and look forward to partnering with physicians across the state to enhance patient care. The WVU Medicine Pharmacy Enterprise thanks the West Virginia Board of Medicine for the opportunity to comment on the proposed rule. We hope that our feedback will assist you in refining these rules to meet our shared patient care and quality goals.

- **Section 2.8.4:** Recommend using the terminology "drug specific monitoring tests" instead of *laboratory tests*. Certain medications require close cardiac monitoring such as EKGs which are not considered laboratory tests, and it would improve patient safety if pharmacists could order them since they are routinely missed.
- **Section 3.7/Section 4.7.7:** Recommend clarifying if the practice notification/fee is a one-time requirement upon the commencement of a collaborative pharmacy practice agreement (CPPA), or if it is required every two years when the "collaborative drug therapy management protocol" is reviewed/updated/re-executed.
- **Section 3.8.4e:** Clarify what qualifies as "informed consent." Recommend that informed consent may be verbally obtained, and then verbal consent may be documented in the medical record by the pharmacist. If not, state that a signed consent form required.
- **Section 4.7.1:** Recommend using terminology "drug classes" rather than "drug or drugs". Since new medications are approved by the FDA continuously (particularly oncology agents), it would create a significant burden to keep the CPPA updated as written with the current language. Anecdotally, physicians at WVU Medicine clinics have wanted to use full drug classes versus listing individual drugs when drafting CPAs with pharmacists.
- **Section 4.7.1a:** Clarify that protocols may authorize initiation of drug therapy. Section 4.7.1 permits therapy initiation, so assuming initiation is permitted per protocol.

We appreciate the opportunity to offer our input and suggestions on the proposed rule. If we can provide further information or assist the agency in any way, please do not hesitate to contact me at 304-548-4148 extension 73352 or ashley.street@wvumedicine.org.

Sincerely,

Ashley Street, PharmD, MSHA
Assistant Director of Pharmacy, Adult Clinical Services & Education
WVU Medicine – WVU Hospitals

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July 29, 2022

VIA ELECTRONIC MAIL ONLY
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Re: Proposed Amendments to W. Va. Code R. § 11.8.1 *et seq.*

Dear Dr. Street:

On behalf of the West Virginia Board of Medicine, the West Virginia Board of Osteopathic Medicine and the West Virginia Board of Pharmacy ("the Boards"), thank you for taking the time to review and comment on the proposed amendments to Joint Rule 11 CSR 8, *Collaborative Pharmacy Practice*.

During the 2022 legislative session, the West Virginia Legislature passed House Bill 4323, which modified W. Va. Code §§ 30-5-4 and 30-5-19 to modernize collaborative pharmacy practice and to streamline procedures relating to the registration of collaboration with the Boards. To implement these changes, on June 29, 2022, the Boards filed a Notice of Comment Period for proposed amendments to 11 CSR 8, *Collaborative Pharmacy Practice*. The Notice established a thirty-day comment period on the proposed amended rule, which concluded at 9:00 am today, July 29, 2022. The comments you submitted on behalf of the Pharmacy Enterprise of WVU Medicine were the only comments received on this rule. As this is a joint rule, all proposed modifications must be jointly agreed upon by the Board of Medicine, the Board of Osteopathic Medicine and the Board of Pharmacy. Each of the boards have reviewed the comments that you submitted. Your comments and the Boards' responses are provided below.

Comment One

Section 2.8.4: Recommend using the terminology "drug specific monitoring tests" instead of laboratory tests. Certain medications require close cardiac monitoring such as EKGs which are not considered laboratory tests, and it would improve patient safety if pharmacists could order them since they are routinely missed.

Joint Response: The boards appreciate the intent of this comment but are unable to adopt this recommendation. The language of Section 2.8.4 mirrors the language of W. Va. Code § 30-5-

4(21)(D), which authorizes "laboratory tests." Substituting "drug specific monitoring tests" would require a statutory change.

Comment Two

Section 3.7/Section 4.7.7: Recommend clarifying if the practice notification/fee is a one-time requirement upon the commencement of a collaborative pharmacy practice agreement (CPPA), or if it is required every two years when the "collaborative drug therapy management protocol" is reviewed/updated/re-executed.

Joint Response: The practice notification fee is a one-time fee associated with the notice filed with the boards. The two-year requirement for review/update/re-execution of the collaborative pharmacy practice should occur at the practice level and requires no filing with the boards. To further clarify this point, the following modification to the rule is made:

> 3.9. A complete practice notification is effective upon filing, **remains valid until the collaborative pharmacy practice agreement terminates, and is not subject to renewal or renewal fees.**

Comment Three

Comment Three - Section 3.8.4e: Clarify what qualifies as "informed consent." Recommend that informed consent may be verbally obtained, and then verbal consent may be documented in the medical record by the pharmacist. If not, state that a signed consent form required.

Joint Response: As the boards understand it, the purpose of House Bill 4324 (2022) was to provide for more robust opportunities for collaborative pharmacy practice and to permit most decisions regarding the scope of the collaboration to be made at the practice level by the collaborating health care professionals. The proposed amendments to this rule require the parties to a collaborative pharmacy practice agreement to obtain informed consent from the patient prior to initiating collaborative practice. The informed consent must be documented in the patient record. The rule as proposed permits the collaborating physicians and pharmacists to determine acceptable methods for obtaining and recording informed consent. This approach provides maximum flexibility for the development of collaboration protocols which are appropriate for the practice setting. Pursuant to Subdivision 4.7.6, procedures for documenting the patient's informed consent must be included in the collaborative pharmacy practice agreement protocols. In an effort to maintain maximum flexibility, the boards have elected not to make any modification to the rule based upon this comment.

Comment Four

Section 4.7.1: Recommend using terminology "drug classes" rather than "drug or drugs". Since new medications are approved by the FDA continuously (particularly oncology agents), it would create a significant burden to keep the CPPA updated as written with the current language. Anecdotally, physicians at WVU Medicine clinics have wanted to use full drug classes versus listing individual drugs when drafting CPAs with pharmacists.

Joint Response: The boards appreciate the intent of this comment but are unable to adopt this recommendation. The language of Section 4.7.1 mirrors the language of W. Va. Code § 30-5-19(b)(1), which requires the protocol to include "[t]he specific drug or drugs to be managed by the pharmacist." Notwithstanding, the boards do not believe that the proposed modification is necessary to permit the identification of full drug classes. "Every drug which belongs to drug class X" adequately identifies the specific drug or drugs to be managed.

Comment Five

Section 4.7.1a: Clarify that protocols may authorize initiation of drug therapy. Section 4.7.1 permits therapy initiation, so assuming initiation is permitted per protocol.

Joint Response: The Boards believe this is clearly permitted in the rule, but in an effort to provide additional clarity have modified Subdivision 4.7.1.a as follows:

> 4.7.1.a. The protocols may authorize **implementation or** modification of drug dosages based on symptoms or laboratory or patient evaluations defined in the protocol

The agency-approved version of 11 CSR 8 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 comments that you provided, and this response 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, which assisted the boards review of its proposed amended rule and resulted in modification which the Boards believe improved the rule.

Sincerely,

Mark A. Spangler

MAS/jcf

cc: Jonathan Osborne, Esq., Executive Director
West Virginia Board of Osteopathic Medicine

Michael L. Goff, Executive Director & CSMP Administrator
West Virginia Board of Pharmacy