FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF VIRTUAL REGULATION COMMITTEE MEETING

May 3, 2021
Virtual Meeting

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER:	A virtual WebEx meeting of the Regulation Committee was called to order at 9:07AM. Due to the COVID-19 declared state of emergency and consistent with Amendment 28 to HB29 (Budget Bill for 2018-2020) and the applicable provisions of § 2.2-3708.2 in the Freedom of Information Act, the committee convened a virtual meeting to consider such business matters as was presented on the agenda necessary for the board to discharge its lawful purposes, duties, and responsibilities.
PRESIDING:	Cheryl Nelson, Committee Chairman
MEMBERS PRESENT:	Glen Bolyard, Jr. Dale St.Clair William Lee Patricia Richards-Spruill (Joined at 12:40 PM)
STAFF PRESENT:	Caroline D. Juran, Executive Director Ellen B. Shinaberry, Deputy Executive Director Beth O'Halloran, Deputy Executive Director Elaine J. Yeatts, Senior Policy Analyst, DHP James Rutkowski, Assistant Attorney General Kiara Christian, Executive Assistant
QUORUM:	With four members of the Committee present, a quorum was established.
APPROVAL OF AGENDA:	Agenda was approved as provided.
PUBLIC COMMENT:	No public comment was received.
UPDATE ON REGULATORY ACTIONS	Ms. Yeatts reviewed the chart of regulatory action found on pages 1-2 of the agenda packet.
CHART OF REGULATORY /WORKGROUPS FROM 2021 GENERAL ASSEMBLY ACTIONS	Ms. Yeatts reviewed the chart found on page 3 of the agenda packet. She informed the board that staff will publish a draft of proposed pharmaceutical processor regulations resulting from legislative changes by May 6th which will open a 60-day public comment period until July 5th as required by the legislation. The board will convene a special virtual

meeting on July 6th to consider the draft language and any comment received, and adopt the regulations which must be effective by September 1, 2021. Early submission of comment is strongly encouraged. Ms. Juran shared that staff is working with the chairman to identify dates for the statewide protocols and pharmacy technician workgroups and will contact invited stakeholders in the near future. The virtual pharmacy technician workgroup meeting resulting from HB1304/SB830 will be tentatively held on a date between September 13-17 or 20-23. One to two virtual meetings to establish statewide protocols resulting from H2079 will be tentatively held on August 2, or 8-11. A virtual meeting to provide recommendations for future protocols resulting from HB2079 will be tentatively convened on August 16 or 17th. Dr. St.Clair reminded everyone that the topic of remote order processing by pharmacy technicians was referred to the pharmacy technician workgroup for consideration.

PETITION FOR RULEMAKING 18VAC110-20-290; REQUEST TO SHORTEN EXPIRATION DATE OF SCHEDULE II PRESCRIPTIONS

Ms. Yeatts reviewed the petition starting on page 5 of the agenda packet. The committee reviewed the public comments received and discussed concerns related to shortening the expiration date to 7 days as it may impact the ability to partial dispense Schedule II prescriptions. This may impact individuals who obtain 90-day prescriptions and negatively impact patient access.

MOTION:

The committee voted unanimously to recommend to the full board in June to deny the petition for rulemaking to shorten the expiration date of Schedule II prescriptions. (Motion by St.Clair, seconded by Bolyard)

PERIODIC REVIEW OF CHAPTERS 20, 21, 30, 40, AND 50

Ms. Yeatts provided background of the boards' previous periodic review starting on page 16 of the agenda packet which was a comprehensive review of chapters 15, 20, 21, and 50 with amendments becoming effective December 11, 2019. She reminded the board that it must periodically review its regulations every 4 years. The board directed staff in December 2020 to publish a Notice of Periodic Review and to request comment on changes the public would like considered. No comments were received between January 4, 2021 and January 25, 2021. The committee reviewed comments received from the last periodic review on pages 36-37 that were either not included in the proposed regulations or not on sections being amended. The committee discussed each comment to determine if the subject should be included in the current periodic review.

Section 10, amend the definition of personal supervision to allow a pharmacist to not be physically present in the pharmacy but to supervise through the use of "real-time, two-way technology communication" between the pharmacist and the technician

The committee had some discussion about subsection 10 regarding personal supervision. The board expressed interest, but had some discussion about concerns regarding supervision of activities in the pharmacy. Mr. Rutkowski confirmed that it appears this subject could not be addressed through regulatory action since 54.1-3432 of the Code of Virginia references personal supervision of a pharmacist on the premises of the pharmacy.

Section 10, delete definition of "personal supervision" to allow audio-visual technology to supervision of compounding in retail pharmacies

Ms. Juran commented that use of audio-visual technology by a pharmacist on the premises of the pharmacy is currently being used to verify accuracy of compounded preparations. The committee agreed that this subject may need to be clarified in the regulation to ensure licensees are aware that this activity may occur.

Section 112, eliminate the current ratio of four pharmacy technicians to one pharmacist. Possibly allow the "prescription department manager" or "consultant pharmacist" to determine the number of technicians

The committee reviewed section 112. Staff shared on the screen a summary of the 2020 NABP Annual Survey that summarizes the Pharmacist to Pharmacy Technician ratio requirement in various states. There was some concern expressed for pharmacists supervising more than four pharmacy technicians at one time. Dr. St.Clair referenced information from George Mason, actions taken recently by Washington and Ohio, and expressed support for at least evaluating the subject. Dr. Lee commented that the board would need to decide if this was safe for the public. It was stated that discussions during the upcoming pharmacy technician workforce meeting may be helpful. The committee determined it would not recommend including this subject in the periodic review at this time.

Section 150, delete the square footage requirement and allow pharmacies to decide the amount of space "adequate to perform the practice of pharmacy." Allow for trailers or other moveable facilities in a declared emergency

Dr. Lee commented that the current square footage requirement does not appear to be burdensome. Staff shared that the board routinely exercises its existing ability to waive square footage requirements as needed and other requirements during a declared emergency. The committee did not believe this subject needed to be included in the periodic review.

Section 270, except for electronic prescriptions, only require written prescriptions for "controlled substances" to have a signature.

The committee had some discussion about section 270 and the requirement for signatures on written prescriptions. The committee expressed that more information on this subject may be needed to fully understand the request as a prescriber signature on a prescription appears to be a crucial element.

Section 270, allow a pharmacist to use his professional judgment to alter or adapt a prescription, to change dosage, dosage form or directions, to complete missing information, or to extend a maintenance drug.

The committee briefly discussed the ability for a pharmacist to alter prescriptions, change dosage form, complete missing information, and/or extend a maintenance drug. Dr. St.Clair stated that Ohio has some language on pharmacists addressing omissions, but that the language would need to be reviewed. Members stated this may be helpful in authorizing a pharmacist to change a prescription from tablets to liquid without needing to bother the prescriber. The committee recommended that it be included in the periodic review.

ACTION ITEM:

Ms. Juran will gather language from other states on this subject for the Board's consideration.

Section 270, amend the rule to not require data entry verification and prospective drug utilization review by a pharmacist who is dispensing an on-hold prescription at a future date

Staff commented that the current regulation requires the pharmacist to verify data entry verification at the time the prescription is placed on-hold. The committee expressed concern about not requiring a prospective drug utilization review by the dispensing pharmacist as the drug history may have changed since the time the prescription was first placed on-hold.

Section 355, amend to allow for using returns of dispensed drugs to be restocked for reuse in an automated counting device

Staff provided an overview of the current language related to the current process utilized when a dispensed drug is returned. Committee members expressed concern for recalls when placing returned drugs into an automated counting device as the lot numbers of these drugs would not be known.

Section 360, amend the regulation to allow pharmacy technicians to be involved in prescription transfers; pharmacist on duty should be able to delegate that task

ACTION ITEM:

The committee recommended that the subject of allowing pharmacy technicians to transfer prescriptions be forwarded to the Pharmacy Technician Workgroup for review so that more information may be obtained.

Section 420, change the provision of a seven-day supply of a drug in a unit dose systems in hospitals or long-term care facilities to allow for dispensing of a 14-day supply

The committee expressed concerns of risk associated with having a 14-day supply of multiple drugs being dispensed recognizing that drug changes and errors may occur during this time period.

In new chapter 21, section 10, strike the definition of PTCB and insert new definition for certification meaning any individual who has passed a certification exam administered by an organization accredited by the National Commission for Certifying Agencies.

The committee determined that this issue was addressed in recent regulatory amendments for pharmacy technicians.

Consideration of including a requirement for an e-profile identification number for facilities

Ms. Juran reminded the committee that if it is decided that the board will sign the NABP FDA MOU, facilities impacted would be required to have a NABP E-Profile ID. Ms. Juran confirmed that there is no cost for facilities to obtain an NABP E-profile ID and that staff would be able to communicate easier with NABP if this requirement was in place. The committee supported this concept.

Requirement for applicants to graduate from pharmacy school prior to taking examinations

Staff explained that NABP will not allow a candidate to schedule for taking the NAPLEX or MPJE until the board approves the applicant and the school has provided NABP with a transcript conferring the degree, therefore, this amendment is not necessary.

Change of timeframe for notification of a change in the PIC from 14 to 30 days

The committee had some discussion about the process of assigning a new PIC and the current 14-day allowance.

ACTION ITEM:

Ms. Juran will survey other states to assess their change of PIC notification requirements and report back to the board.

ADDITIONAL ITEMS CONSIDERED BY THE COMMITTEE:

Dr. St.Clair recommended that the board consider amending 18VAC110-20-550 to remove the restriction that a stat-drug box contain no more than 20 solid dosage units per schedule of Schedules II through V drugs. Allowing more flexibility with the contents of the boxes may be beneficial. The committee was supportive.

The committee also discussed requirements to reactivate a pharmacist license after a period of inactivity. Ms. Juran said that there is currently regulation that requires the passing of the MPJE prior to reactivating an inactive license after 5 years of inactivity. Ms. O' Halloran added that these individuals must also provide proof of 160 hours of practical experience as a pharmacy intern. No additional action was taken.

The committee had some discussion about background requirements for pharmacy owners. Ms. Juran recommended an amendment to 18VAC-110-20-110 to require certain disclosures by a pharmacy owner. The committee recommended that the board may want to require disclosure of similar information on pharmacy permit renewals as well.

Dr. St.Clair questioned if pharmacists and pharmacy technicians should report their current places of employment to the board. Since the board cannot currently collect this information electronically, no action was taken on this subject.

Staff questioned if 18VAC110-20-276 should be amended to require a pharmacy technician's program director to be a pharmacist or pharmacy technician. The committee was comfortable with the program director not being a pharmacist or pharmacy technician as long as they were not an instructor.

Ms. Juran asked the board to consider amending 18VAC110-21-190 to align with current NABP policies that a foreign graduate of pharmacy school obtain the FPGEC even if they complete a post-baccalaureate degree from an ACPE-accredited school of pharmacy. This will help to create parity among the states during the licensure endorsement process.

Ms. Juran asked the board to consider amendments to 18-VAC110-20-190 and 18VAC110-30-80 to prohibit a controlled substances registration or a physician selling license to be issued to a location in a private residence or dwelling. Enforcement Division has concerns with placing inspectors in a potentially dangerous situation when inspecting a private residence. This will align these regulations with other regulations impacting pharmacies, medical equipment suppliers, wholesale distributors, and other types of facilities.

MOTION:

The committee voted unanimously to recommend to the full board that it include the following items in the periodic review and solicit the public for other items following the June board meeting:

- **Section 10, amend definition of "personal supervision" to allow audio-visual technology to supervision of compounding in retail pharmacies**
- **Section 270, allow a pharmacist to use his professional judgment to alter or adapt a prescription, to change dosage, dosage form or directions, to complete missing information, or to extend a maintenance drug.**
- **Consideration of including a requirement for an e-profile identification number for facilities**
- **Consideration of extending timeframe beyond 14 days for notification of a change in the PIC**
- **Consider amending 18VAC110-20-550 to remove the restriction that a stat-drug box contain no more than 20 solid dosage units per schedule of Schedules II through V drugs.**
- **Amend 18VAC110-20-110 (J) to include allowance to consider prior disciplinary action by a regulatory authority, prior criminal convictions, or ongoing investigations related to the practice of pharmacy by the pharmacist-in-charge or immediate family members of the pharmacist-in-charge, and owners, directors, or officers**
- **Amend 18VAC110-21-90(A) by requiring FPGEC prior to obtaining pharmacist license through endorsement or score transfer and delete exemption from FPGEC in subsection D.**
- **Amend 18VAC110-20-690 and 18VAC110-30-80 to prohibit registration and permit from being issued to private dwelling or residence. (Motion by St.Clair, seconded by Lee)**

REVISION/RE-ADOPTION OF GUIDANCE DOCUMENTS 110-17 AND

Ms. Juran reviewed page 53 of the agenda packet and provided background information related to Guidance Document 110-2 and the licensing process for pharmacist. She recommended that the board amend the document to

110-2

meet NABP's policies which now requires the receipt of a college transcript prior to allowing the candidate to schedule for the NAPLEX or MPJE.

Ms. O'Halloran reviewed Guidance Document 110-7 beginning on page 50 of the agenda packet related to NABP confirmation of the graduation conferral date.

MOTION:

The committee voted unanimously to recommend that the full board adopt the revision to Guidance 110-17 as presented and 110-2 as presented and amended by changing on page two "and NABP has received a college transcript conferring the date of graduation" to "and NABP has received a college transcript indicating the graduation conferral date". (Motion by St.Clair, seconded by Bolyard)

FEEDBACK ON ACPE STANDARDS 2025

Ms. Juran indicated ACPE is soliciting feedback on its revised standards.

MOTION:

The committee voted unanimously to recommend that the full board provide supportive feedback on the 2025 ACPE Standards as presented. (Motion by Bolyard, seconded by St.Clair)

IDENTIFY SUBJECTS FOR POSSIBLE LEGISLATIVE PROPOSALS FOR 2022 GENERAL ASSEMBLY SESSION

There was some discussion regarding whether legislation was needed to support the recent regulatory amendment requiring a federal criminal background check for the responsible party of a wholesale distributor. Ms. Juran commented that staff was researching the ability for a responsible party to request his/her own background check through the FBI since staff could not, and then the responsible party forwarding this information to the board office. The committee was comfortable with monitoring this issue for now. No other subject for possible legislative proposal was offered.

ADJOURN:

With all business concluded, the meeting adjourned at approximately 12:45 PM.

Caroline D. Juran
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Caroline D. Juran, Executive Director

6/4/2021
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DATE