

FINAL/APPROVED

**VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING**

Tuesday, May 3, 2022
Commonwealth Conference
Center
Second Floor, Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

- CALL TO ORDER:** A meeting of the Regulation Committee of the Board of Pharmacy (“Board”) was called to order at 9:08am.
- PRESIDING:** Dale St. Clair, PharmD, Committee Chairman
- MEMBERS PRESENT:** Patricia Richards-Spruill, RPh
Glenn Bolyard, RPh
Kristopher Ratliff, DPh
William Lee, DPh
- STAFF PRESENT:** Caroline Juran, RPh, Executive Director
James Rutkowski, Esq., Assistant Attorney General
Erin Barrett, Esq., DHP Senior Policy Analyst (left at 9:46am, returned at 9:57am)
Ellen B. Shinaberry, PharmD, Deputy Executive Director
Ryan Logan, RPh, Deputy Executive Director
Beth O’Halloran, RPh, Deputy Executive Director
Sorayah Haden, Executive Assistant
- QUORUM:** With five members of the Committee present, a quorum was established.
- APPROVAL OF AGENDA:** The Board voted unanimously to approve the agenda as presented. (motion by Ratliff, seconded by Richards-Spruill)
- PUBLIC COMMENT:** Comment on regulatory actions for which the official comment period was closed could not be accepted. No other public comment was offered.
- UPDATE ON REGULATORY ACTIONS** Ms. Barrett reviewed the chart of regulatory action found on pages 1-2 of the agenda packet.
- CHART OF REGULATORY /POLICY ACTIONS FROM 2022 GENERAL ASSEMBLY** Ms. Barrett provided updates of the regulatory/policy actions resulting from the 2022 General Assembly session and reviewed the information in the agenda packet. She reported that HB1323/SB672 are not finalized.

CONSIDERATION OF
PETITION FOR
RULEMAKING – USE OF
AUTOMATED
DISPENSING SYSTEMS
EXCLUSIVELY STOCKED
WITH DRUGS FOR
EMERGENCY OR STAT
ADMINISTRATION

The committee discussed the details of the petition for rulemaking regarding automated dispensing systems exclusively stocked with drugs for emergency or stat administration to determine if the Board would like to initiate rulemaking or take no action regarding the automated dispensing systems.

MOTION:

The committee voted unanimously to recommend to the full board that it adopt a Notice of Intended Regulatory Action (NOIRA) resulting from the petition for rulemaking that would amend 18VAC110-20-555 by removing the requirement for a pharmacist to review the order and electronically authorize access to the drug stored in an automated dispensing device when the device exclusively stocks drugs for emergency or stat use. (Motion by Ratliff, seconded by Bolyard)

CONSIDERATION OF
PROPOSED
REGULATIONS FOR
CENTRALIZED
WAREHOUSER OR
WHOLESALE
DISTRIBUTOR TO VERIFY
SCHEDULE VI DRUGS
FOR AUTOMATED
DISPENSING DEVICES IN
HOSPITALS

The committee discussed draft proposed regulatory amendments of 18VAC110-20-490 to authorize a pharmacist at a centralized warehouse or wholesale distributor to verify schedule VI drugs for specific automated dispensing devices in hospitals and remove the requirement for a pharmacist at the hospital to verify the drugs prior to loading the drugs into the devices. This results from a petition for rulemaking received in May 2021. The requirements of an innovative pilot consent order on this subject issued to Central Shared Services, LLC and other hospital pharmacies in 2015 was reviewed as well.

MOTION:

The committee voted unanimously to recommend that the full Board adopt the proposed regulatory amendments of 18VAC110-20-490 to authorize a pharmacist at a centralized warehouse or wholesale distributor to verify schedule VI drugs for specific automated dispensing devices in hospitals and remove the requirement for a pharmacist at the hospital to verify the drugs prior to loading the drugs into the devices as presented. (Motion by Bolyard, seconded by Ratliff)

CONSIDERATION OF
EMERGENCY
REGULATIONS
RESULTING FROM HB1324

The committee generally discussed the concepts recommended for inclusion in the emergency regulations to implement HB1324 which will be presented to the Board at the September 2022 meeting. The committee discussed adding language for whistle-blower protections. Regarding the

staffing report form referenced in Guidance Document 110-26, it was discussed that staff could develop the form once the emergency regulations are in effect or staff could collect information while the emergency regulations are in place and publish a form once the final regulations are adopted that will replace the emergency regulations. It was recommended that the form highlight any whistle blower protections at the bottom of the form.

MOTION:

The committee directed staff to draft emergency regulations for the full Board's consideration in September that include the workgroup's recommendations referenced on page 32 and 33 of this meeting's agenda packet, Guidance Document 110-26, and language for whistle blower protections for both internal pharmacy complaints and complaints submitted to DHP. (Motion by Richards-Spruill, seconded by Lee)

CONSIDERATION OF
FINAL REGULATIONS –
PHARMACY TECHNICIAN
TRAINING PROGRAMS

The committee discussed the details of the adoption of proposed final regulations for implementing legislation for registration of pharmacy technician trainees and accredited training programs. Mr. Ratliff expressed concern for the legislative requirement for most training programs to be accredited and the impact it may have on independent pharmacies. Ms. Juran and Mr. Logan highlighted portions of the Frequently Asked Questions document included in the agenda packet, sent to licensees recently, and posted on the board's website that address many of these concerns. Certain FAQs address opportunities for independent pharmacies to participate as a practical experience worksite for a distance learning training program or the ability to hire pharmacy technician trainees outside of the practical experience requirement, even if the pharmacy does not wish to obtain accreditation for its own pharmacy technician training program. Staff noted that one amendment regarding reinstatement requirements has been included in red in the agenda packet, specifically, 18VAC110-21-170 (D)(1). The amendment would not require the passing of the PTCB or NHA exam if the reinstatement applicant currently maintains one of these national certifications.

MOTION:

The committee voted unanimously to recommend to the full Board the adoption of the final regulations for pharmacy technician training programs as presented. (Motion by Lee, seconded by Bolyard)

CONSIDERATION OF
FINAL REGULATIONS –
PHARMACISTS
INITIATING TREATMENT

MOTION:

Ms. Barrett provided a handout with a technical amendment based on discussions with the Department of Planning and Budget. The committee reviewed the proposed final regulations regarding pharmacists initiating treatment.

The committee voted unanimously to recommend the full Board adopt the proposed final regulatory amendments of 18VAC110-20-150 and 18VAC110-21-46 as presented on the handout. (Motion by Bolyard, seconded by Ratliff)

CONSIDERATION OF
RECOMMENDATIONS
FOR ADDITIONAL DUTIES
FOR PHARMACY
TECHNICIANS

MOTION:

Ms. Juran informed the committee that the three bullet points under Staff Note listed on page 66 had actually already been included in the periodic review of chapter 20 and therefore, no action was necessary.

The committee voted unanimously to recommend that the full Board adopt a legislative proposal to permanently authorize pharmacy technicians to administer vaccines as recommended on page 69, if HB1323/SB672 are not passed, and a legislative proposal to authorize a pharmacy technician to clarify the number of refills and drug quantity for a Schedule VI new or refill prescription as recommended on page 69. (Motion by Ratliff, seconded by Richards-Spruill)

CONSIDERATION OF
LEGISLATIVE PROPOSAL
FOR EXPANDING USE OF
TECHNOLOGY FOR
STORING AND
DISPENSING DRUGS IN
CERTAIN FACILITIES


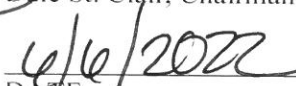
MOTION:


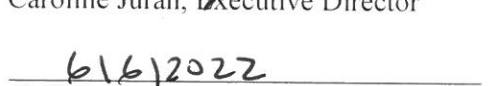
Ms. Juran provided an overview of the draft legislative proposal to expand allowances for certain facilities to use automated dispensing devices which would reduce the need for innovative pilots. The language has been sent to DBHDS for review as well regarding its affected facilities.

The committee voted unanimously to recommend the Board adopt the legislative proposal as presented. (Motion by Ratliff, seconded by Bolyard)

ADJOURN:

With all business concluded, the meeting adjourned at 11:13am.


Dale St. Clair, Chairman

DATE


Caroline Juran, Executive Director

DATE