FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
REGULATION COMMITTEE MEETING

November 4, 2021

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER:	A meeting of the Regulation Committee was called to order at 9:05am.
PRESIDING:	Dale St. Clair, PharmD, Committee Chairman
MEMBERS PRESENT:	Kristopher Ratliff, DPh William Lee, DPh Glenn Bolyard, RPh Patricia Richards-Spruill, RPh
STAFF PRESENT:	Caroline D. Juran, RPh, Executive Director Ryan Logan, RPh, Deputy Executive Director Beth O'Halloran, RPh, Deputy Executive Director (arrived approx. 9:30am) Ellen B. Shinaberry, PharmD, Deputy Executive Director Barbara Allison-Bryan, M.D., Chief Deputy Director, DHP (departed 1pm) James Rutkowski, Assistant Attorney General Sorayah Haden, Executive Assistant
LINK TO AGENDA	https://www.townhall.virginia.gov/L/GetFile.cfm?File=Meeting\30\31603\Agenda_DHP_31603_v1.pdf
QUORUM	With five members present, a quorum was established.
APPROVAL OF AGENDA:	The agenda was accepted as presented.
PHARMACISTS AWARDED 1-HOUR OF LIVE OR REAL-TIME INTERACTIVE CONTINUING EDUCATION FOR ATTENDING MEETING:	Jamin Engel Leah Boardwine Christopher Bannon Larry Glenn Bolyard

PUBLIC COMMENTS:

Joseph Lavino, Senior Legal Counsel, CVS Health, provided public comment pertaining to the draft language regarding unprofessional conduct for consideration during the periodic regulatory review. Lavino acknowledged that times are tough, but questioned whether regulation that further scrutinize industry standards is appropriate. He encouraged the board to collaborate with pharmacies instead of imposing disciplinary action, and recommended letting the free market dictate. One size fits all regulations may prevent progress and innovation. He stated that CVS is looking at mandatory meal breaks and shared services; is mass hiring and increasing pharmacy technician wages. He commented that the draft language comes from Oregon about 9 years ago, results from a flawed survey, is unenforceable, denies due process, and are too vague. "Sufficient staffing" and "distraction" aren't clear, "fatigue" may be due to poor sleep, "production quotas" are used by all businesses to measure performance, and the draft language could prohibit metrics that focus on patients.

John Beckner, Senior Director, Strategic Initiatives at National Community Pharmacists Association (NCPA) referenced written comment submitted to the board and provided as a handout. NCPA commends the board for addressing issues of patient care, stated the proposed language is in response of pharmacists and pharmacy technicians experiencing greater workload and burnout which has resulted in serious errors. He offered comment supportive of the draft language regarding unprofessional conduct. NCPA welcomes the board's approach to encourage working conditions that prevent fatigue and give sufficient time to complete their professional duties and responsibilities.

Alicia Palombo, Senior Advisor Pharmacy Regulatory Affairs at CVS Health requested further guidance from the Board as to how a pharmacy manager could implement the draft regulations regarding unprofessional practice within his or her pharmacy. She stated the language is too vague. She commended the board for its consideration of "professional judgement" in 18VAC110-20-270. Regarding 18VAC110-20-110, she expressed concern for sourcing, hiring, and training a new employee within the 14-day change of PIC requirement and requested an extension of this timeframe. She commended the board for its consideration of amending the language in 18VAC110-20-550 regarding stat drug boxes.

Jodi Roth, representing Virginia Association of Chain Drugs provided a public comment regarding the proposed amendments for Chapters 20, 21, 30, 40, and 50. Roth expressed concerns for the draft language of unprofessional conduct presented in Chapter 20, Section 25 stating it was subjective and each pharmacy and pharmacist is different. Roth advised during the current pandemic, it would be better to expand the current regulations and seek input for how the board can assist pharmacies, instead of creating new regulations.

Roth expressed support for extending the 14-day PIC notification requirement and expanding pharmacy technician duties.

Tony Droppleman, Healthcare Specialty Supervisor at Walgreens expressed concern for the draft language in section 25 regarding assuming duties without training. He stated the language is too broad. He commented that "sufficient personnel" is too subjective. He questioned if the current ratio restriction is creating problems with having sufficient personnel. He questioned how a pharmacy is to distinguish quotas from goals, and stated feedback is not a bad thing. He asked for clarity regarding change of ownership draft language in section 690 and if it would require submission of a new FEIN.

Christina Barrille, Executive Director, VPhA expressed appreciation for the Governor's video highlighting pharmacists' month. She shared information verbally from the Academy of Workplace Well-Being 2019 meeting. She stated insufficient staffing of pharmacists and support staff are at the heart of this concern. Performance algorithms don't take distractions and interruptions into account. VPhA applauds the draft language under consideration in section 25 regarding unprofessional conduct. She questioned how many more duties can be added without providing additional staffing. Pharmacists should have time to research and make best clinical decisions. She commented that many pharmacists believe their concerns expressed to supervisors or corporate owners are falling on deaf ears. Not all metrics focus on the patient. She stated that the draft language will not stifle innovation, and the board can develop guidance to clarify the interpretation of regulations, if necessary.

CHART OF REGULATORY ACTIONS:

St. Clair briefly referenced the chart of regulatory actions included in the agenda packet.

CONSIDERATION OF FINAL REGULATIONS – MEDICATION CAROUSELS AND RFID TECHNOLOGY

The work group discussed the adoption of the final regulations regarding medication carousels and RFID technology. Juran provided the following background information: public comment period on proposed regulations ended 10/15/21 and 3 comments were received; comments from Sentara Virginia Beach General and Sentara Norfolk General were generally supportive; comment from VSHP (pages 5-13 of agenda) offered several recommended edits as it believes the proposed language may not be appropriate for all health systems.

There was much discussion regarding the recommendations offered by VSHP. Most committee members expressed concern with visual verification at the bedside and preferred bar code scanning, except in emergencies.

MOTION:

The Committee voted unanimously to recommend to the full board that

it adopt 18VAC110-20-425 and 18VAC110-20-500 as re-proposed regulations or as final regulations, if allowed, as presented and amended as follows:

- **Amend 18VAC110-20-425(C)(2)(b) and 18VAC110-20-425(C)(3)(b) by inserting an exception to the requirement for a nurse or other person authorized to administer drugs to scan each drug unit using barcode technology prior to administration of the drug if the drug is being administered to treat an emergent event where a delay would cause imminent harm to the patient;**
- **Amend 18VAC110-20-425(C)(2) by inserting a new paragraph c that reads akin to, "If a hospital does not have the capability for the patient-specific drug removed from the medication carousel by a pharmacy technician to be verified for accuracy by scanning each drug unit, then the hospital will utilize a secondary pharmacy technician check: the first pharmacy technician removing the patient-specific drug from the medication carousel performs a visual inspection for accuracy and then double checks the accuracy by scanning an individual unit dose of the order; a second, different pharmacy technician then performs a visual inspection double check and then shall scan an individual unit dose of the order for final verification. A nurse of other person authorized to administer the drug must scan each drug unit prior to administration unless the drug is being administered to treat an emergent event where a delay would cause imminent harm to the patient.";**
- **Amend 18VAC110-20-425(C)(3) by inserting a new paragraph c that reads akin to, "If a hospital does not have the capability for the drug intended for restocking an automated dispensing device removed from the medication carousel by a pharmacy technician to be verified for accuracy by scanning each drug unit, then the hospital will utilize a secondary pharmacy technician check: the first pharmacy technician removing the drug for restocking from the medication carousel performs a visual inspection for accuracy and then double checks the accuracy by scanning an individual unit dose for each drug of the automated dispensing device restock order prior to leaving the pharmacy; a second, different pharmacy technician then performs a visual inspection double check and then shall scan an individual unit dose for each drug of the restock order for final verification at the time of placing the drug into the automated dispensing device. A nurse or other person authorized to administer the drug must scan each drug unit prior to administration unless the drug is being administered to treat an emergent event where a delay would cause imminent harm to the patient." (motion by Ratliff, seconded by Bolyard)**

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

A colored handout identical to the black and white pages of 26-32 of the agenda packet was provided to the Committee. Items in black were previously recommended by the Board to be included in the periodic regulatory review. Items in red were staff suggestions for Board consideration. The Committee discussed each item in red.

Regarding Chapter 20, Section 25, there was consensus that the Board should consider amending this section to include language akin to "engaging in a manner such that the individual feels threatened or intimidated which discourages an individual to report a public safety concern in good faith or discourages an employee from cooperating with an employee of the Department of Health Professions in the conduct of an investigation or inspection."

It was noted that the last bullet in red on page 27 regarding incenting or inducing the transfer of a prescription absent professional rationale was almost identical to the regulatory action currently in the Governor's office. Other portions of the draft language in red for section 25 on page 27 referenced assuming duties without adequate training, failure to provide a work environment that protects health safety, and welfare of the patient including sufficient personnel to prevent fatigue, adequate time to complete professional duties, and introducing productivity quotas that interfere with ability to provide appropriate professional services. Ratliff and Richards-Spruill supported recommending that the Board include these subjects in the periodic review. The majority of the committee members did not support this recommendation commenting that the language may be too vague and that these subjects can be addressed as a violation of §54.1-3316(13) which states "Has conducted his practice, or activity requiring a license, permit, certificate, or registration from the Board in such a manner as to be a danger to the health and welfare of the public."

There was consensus that the draft language for appropriate opportunities for uninterrupted rest periods and meal breaks should be recommended to the Board to include in the periodic review under 18VAC110-20-110(B), not section 25. Ratliff commented that uninterrupted may not mean closed.

Regarding the draft suggestion for including a record requirement in 18VAC110-20-275 for an alternate delivery site further delivering the drug to a patient's home, the Committee recommended in concept that the Board should include this subject in the periodic review. **Staff was asked to research where, if at all, the language needs to be added.**

ACTION ITEM:

Committee recommended including the sections in red on page 28 and 29 regarding additional information to be required on a pharmacy permit or nonresident pharmacy registration application, except for the social security number or control number of the PIC and list of states into which it ships

prescription drugs. It was also noted that reference to "within 30 days" in bullet point B on page 29 may need to be amended for consistency with in-state pharmacy requirements.

ACTION ITEM: **Juran to work with Logan and Ratliff to explore drafting of an article on concerns with processing coupons printed on e-prescriptions.**

Regarding Chapter 21, the Committee recommended including in section 80 a prohibition of taking the board-approved integrated pharmacy examination when the candidate fails to pass on five occasions.

ACTION ITEM: **Staff to research with counsel if prohibiting the taking of the board-approved integrated pharmacy examination when the candidate fails to pass on five occasions is problematic.**

No additional subjects were identified in chapters 30, 40, and 50. St. Clair stated that the draft suggestion for requiring the NABP Drug Distributor Accreditation (formerly VAWD) in chapter 50 found on page 32 requires a statutory change and cannot be acted on through regulatory action.

MOTION: **The Committee voted unanimously to recommend to the full board no additional subjects in chapters 30, 40, and 50 for the periodic regulatory review and to include the following additional subjects in the periodic regulatory review for chapters 20 and 21:**

- **Chapter 20, Section 25, consider amending this section to include language akin to "engaging in a manner such that the individual feels threatened or intimidated and which discourages an individual to report a public safety concern in good faith or discourages an employee from cooperating with an employee of the Department of Health Professions in the conduct of an investigation or inspection."**
- **Chapter 20, Section 110, consider amending to address appropriate opportunities for uninterrupted rest periods and meal breaks which may or may not require the pharmacy to close.**
- **Chapter 20, Section 110, consider amending to include additional information to be required on a pharmacy permit or nonresident pharmacy registration application as outlined on pages 28 and 29 of agenda packet, except for the social security number or control number of the PIC, list of states into which it ships prescription drugs, and include a requirement to notify board of any changes within timeframe consistent with current laws.**
- **Chapter 20, Section 275, consider amending to include record requirement for an alternate delivery site further delivering the drug to a patient's home.**
- **Chapter 21, Section 80, consider amending to include prohibition**

of taking the board-approved integrated pharmacy examination when the candidate fails to pass on five occasions.

- **Chapter 21, Section 80, consider amending to authorize the Board to delegate to NABP the review and granting of testing accommodations for either examination based on a physical or mental impairment that substantially limits one or more major life activities, subject to the Americans with Disabilities Act. (motion by Bolyard, seconded by Richards-Spruill)**

DISCUSS RECOMMENDED SANCTION FOR CE NONCOMPLIANCE:

There was discussion regarding disciplinary action that should be taken against a pharmacist or pharmacy technician for noncompliance with obtaining the required continuing education annually. The offering of a pre-hearing consent order with monetary penalty and requirement to provide missing hours as indicated in Guidance Document 110-42 was referenced. There was additional discussion regarding appropriate disciplinary action that should be taken on this matter at an informal conference and the possibility that such a case may result in a formal hearing.

There was consensus to recommend to the Board that at an informal conference, the committee offer a reprimand and mandatory CE audit of the licensee for noncompliance with CE requirements. If the licensee has subsequent noncompliance with CE, staff should not offer a pre-hearing consent order as authorized in Guidance Document 110-42 but notice the licensee for an informal conference. It should be noted that this is a repeat violation and the informal conference committee should determine the appropriate sanction.

ACTION ITEM:

Staff to draft an article in the Board e-newsletter to remind licensees to check NABP CPE Monitor routinely to ensure CE has uploaded properly and to remind pharmacy technicians to include their registration number in the CPE Monitor.

MEETING ADJOURNED:

Having completed all business on the agenda, the meeting was adjourned at 2:20pm.

Dale St. Clair

12/7/21
Date:

Caroline Juran

12/7/2021
Date: