FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING

Tuesday, November 12, 2024
Commonwealth Conference Center
Second Floor
Board Room 2

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 9:15AM.

PRESIDING: **Ling Yuan**, PharmD, Committee Chairperson, Board Vice Chairperson

MEMBERS PRESENT:
Kristopher Ratliff, DPh
Kelly Hasty Kale, RPh
Larry Kocot, JD
Shannon Dowdy, PharmD

STAFF PRESENT:
Caroline Juran, RPh, Executive Director, Virginia Board of Pharmacy
Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP (left at 11:25AM)
Beth O'Halloran, RPh, Deputy Executive Director, Virginia Board of Pharmacy
Ryan Logan, RPh, Deputy Executive Director, Virginia Board of Pharmacy
Ellen Shinaberry, PharmD, Deputy Executive Director, Virginia Board of Pharmacy
Sorayah Haden, Executive Assistant, Virginia Board of Pharmacy

QUORUM: With all members of the Committee present, a quorum was established.

APPROVAL OF AGENDA: An amended agenda cover page, and an amended page 77 of the original agenda packet mailed to the board was provided by staff at the meeting. A link to the Board's routine inspection report was listed on the amended page 77, instead of including all pages of the inspection report.

MOTION: The Committee voted unanimously to accept the amended agenda as presented. (motioned by Ratliff, seconded by Kale)

PUBLIC COMMENT:

No public comment was offered during the public comment period of the meeting.

CHART OF CURRENT REGULATORY ACTIONS:

Erin Barret briefly reviewed the chart of regulatory actions provided in the agenda packet and provided the following updates on the Administrative Review process since the chart was posted:

- Proposed regulatory amendments of 18VAC110-20, 18VAC110-21, 18VAC110-30, and 18VAC110-50 for an *Increase in Fees* have moved from the Secretary's office to the Governor's Office for review and consideration.
- Notice of Intended Regulatory Action to amend 18VAC110-20 for the *Exclusion of private dwellings or residences from operating locations of CSRs* has moved from the Department of Planning and Budget to the Secretary's office for review and consideration.
- Proposed regulatory amendments of 18VAC110-21 for *2023 Pharmacists Initiating Treatment* have moved from the Office of the Attorney General to the Department of Planning and Budget for review and consideration.

The Committee questioned why several actions do not appear to be moving through the Administrative Review process timely such as the *Prohibition against incentives to transfer prescriptions* and the NOIRA for the *2021 Periodic Review*. Ms. Juran commented that the Board may have success in addressing critical subjects included in the NOIRA in separate regulatory actions such was recently done to address the prohibition of a private dwelling or residence to obtain a CSR. Additionally, she is aware that a petition for rulemaking may soon be received to address another subject included in the 2021 periodic review NOIRA.

ACTION ITEM:

There was general consensus that the Committee should review the *Prohibition against incentives to transfer prescriptions* regulatory action during the May 2025 Regulation Committee meeting to determine if a patient safety risk still exists or if the action should be withdrawn.

ADOPT RECOMMENDATIONS FOR GUIDANCE DOCUMENT FOR ACCESSIBLE PRESCRIPTION LABELS

The Committee reviewed enactment clause 3 of HB 516 requiring the Board to adopt guidance identifying appropriate technologies, packaging, labeling, and counseling for dispensing medications to blind or low-vision patients. The Committee also considered the public comment provided in the agenda packet from the National Federation of the Blind, Virginia chapter. Ms. Barrett commented that reiterating information captured in the U.S. Access Board's Best Practices document within a Board guidance document is generally

frowned upon and that it's more appropriate to simply provide a link to the Best Practices document. Additionally, it was acknowledged that listing specific technologies in the guidance document may give the appearance of a bias for one over another. Ms. Juran commented that the Virginia Pharmacy Association (VPhA) and/or the Virginia Society of Health-System Pharmacists (VSHP) may be willing to assist in educating pharmacists on technologies offered to aid patients, particularly if the National Association of the Blind was willing to develop and revise the document as needed over time. During the discussion, some members expressed concern for the financial survivability of pharmacies and the increased access challenges that will result from additional pharmacies closing.

MOTION:

MOTION:

The Committee voted unanimously to recommend that the Board adopt the guidance document, *Dispensing Medications to Blind or Low-Vision Patients,* as presented and for staff to contact VPhA and VSHP to request assistance in further educating pharmacists on best practices and technology options available for accommodating these patients. (motion by Kocot, seconded by Ratliff).

CONSIDERATION OF POTENTIAL CHANGES TO CRISIS STABILIZATION UNIT EMERGENCY REGULATIONS PRIOR TO BOARD ADOPTION OF PROPOSED STAGE

The Committee reviewed and discussed the draft proposed regulations for crisis stabilization units (CSU) and use of automated drug dispensing systems (ADS) and remote dispensing systems (RDS). It was noted that no comments were received during the public comment period which closed 9/25/24. Staff commented that they recently identified that 18VAC110-20-700(C) should probably be amended as well to conform with the allowance for pharmacy technicians to have access to the dispensing systems in a CSU. Additionally, staff stated that the Department of Planning and Budget questioned during the administrative review process if the language in 18VAC110-20-490(B)(3) regarding maintenance of a key to access an ADD or RDS should be added to 18VAC110-20-555 for consistency. The Committee had a lengthy discussion regarding whether any facility should have access to the key for an ADS or RDS since it can be used to bypass normal operations and may impose a safety risk with no record of identifying who used the key to access the device. Ms. Juran stated that certain innovative pilot program board orders for use of these devices had allowed a key to be maintained in the possession of the director of nursing (DON) or designee licensed to administer drugs when the provider pharmacy was not located within the facility. It was noted that should the board remove the allowance when adopting the proposed regulations, information may be gleaned during the next public comment period to help inform the adoption of the final regulations.

ACTION ITEM:

Board staff will research the need for a key to have been used by a DON or designee to access such devices under the previous innovative pilot programs or if routinely provided in other facilities, e.g., long term care, community service boards.

MOTION:

The Committee voted unanimously to recommend to the full Board that it strike the proposed amendment in 18VAC110-20-490 (B)(3) which reads "If a key may be used to access the automated drug dispensing system or remote dispensing system and the provider pharmacy is not located within the facility, a key may be maintained in the possession of the director of nursing or an individual designated by the director of nursing who is licensed to administer medications." when adopting the proposed regulations for CSUs and use of ADSs and RDSs. (motion by Kocot, seconded by Kale)

MOTION:

The Committee voted unanimously to recommend to the full Board that it amend 18VAC110-20-700 (C) as presented which:

- **inserts "drug" after "automated",**
- **strikes "devices",**
- **inserts "systems or remote dispensing systems" after "dispensing", and**
- **strikes "Access to stock drugs in a crisis stabilization unit shall be limited to prescribers, nurses, or pharmacists."**

and to include it in the proposed regulations for CSUs and use of ADSs and RDSs. (motion by Ratliff, seconded by Dowdy)

CONSIDERATION OF PUBLIC COMMENTS TO EMERGENCY MEDICAL SERVICES EMERGENCY REGULATIONS PRIOR TO BOARD ADOPTION OF PROPOSED STAGE

The Committee reviewed and discussed the draft proposed regulations for emergency medical services (EMS) and the public comment received following the publication of the emergency/NOIRA stage of the regulatory process. Several written comments described the need for emergency drug kits to be maintained on quick response vehicles (QRV) which may be parked at a location other than an EMS agency. Ms. Juran stated that the Office of Emergency Medical Services (OEMS) confirmed to her that a QRV is a permitted EMS vehicle regulated by OEMS that are often used by rural EMS agencies and are equipped and staffed by a certified EMS provider. The vehicles respond to the scene of an emergency to render care until an ambulance arrives that is transport capable. The QRV is locked at all times and equipped with auxiliary power connections (shore power) to maintain temperature of the drug boxes. OEMS agreed that it would be appropriate for a QRV to maintain an emergency drug kit. In response to a written comment to provide more clarity regarding drug storage requirements, the Committee believed the regulatory requirements were sufficient and feared being more specific may decrease an EMS agency's

flexibility in determining optimal storage mechanisms for that location. In response to a written comment to allow for use of automated dispensing machines, the Committee acknowledged that such allowance already exists in 18VAC110-20-710(E).

MOTION:

The Committee voted unanimously to recommend to the full Board that it adopt the proposed EMS regulations as presented and amended as follows:

- **18VAC110-20-710(G)(3), at the end, insert ", or location where an EMS agency or EMS council approves an EMS vehicle to be stored";**
- **18VAC110-20-710(G)(4), after "council", insert "or location where an EMS agency or EMS council approves an EMS vehicle to be stored". (motion by Ratliff, seconded by Dowdy)**

REQUEST FROM GATES HEALTHCARE ASSOCIATES, INC. TO RECOGNIZE ITS INSPECTION REPORT AS AN ACCEPTABLE ALTERNATIVE TO AN INSPECTION BY THE LICENSING OR REGULATORY AGENCY OF JURISDICTION OR AN INSECTION BY THE BOARD OF PHARMACY'S OWN AGENT

The Committee discussed and reviewed the inspection report provided by Gates Healthcare Associates, Inc. to the full board at the September full Board Meeting. The Virginia Board of Pharmacy's Inspection Report was provided as additional documentation to compare to Gates Healthcare Associates, Inc. inspection report.

MOTION/ACTION ITEM:

The Committee voted unanimously to recommend to the full Board to approve Gates Healthcare Associates, Inc.'s request to recognize its inspection report of an out of state pharmacy as an acceptable alternative to an inspection by the licensing or regulatory agency of jurisdiction or an inspection by the Board's own agent pending responses to the following questions:

- **Which states currently recognize a pharmacy inspection performed by Gates?**
- **Will the report include a list of deficiencies observed by the inspector at the time of the inspection, along with the pharmacy's corrective action to address the deficiencies? (motion by Kocot, seconded by Ratliff)**

The Committee Chairman asked if there was any other business to

discuss. Ms. Kale questioned if the Board had considered convening a retreat to discuss various pharmacy-related topics to assist the Board, particularly new board members. It was shared with Ms. Kale that Dr. Nash had raised such a request last year and that the members had responded to a survey of topics it may wish to discuss at a retreat. The Board ultimately decided at that time that it would not convene a retreat, but that the Chairman would work with Ms. Juran to address individual topics from the survey during already scheduled meetings. During the discussion the following topics were mentioned by some of the Committee members as subjects they may be interested in discussing: learning what's going on in the other board members' practice settings, workplace challenges, if lesser expensive alternatives for licensees exist compared to the HPMP, the future of pharmacy, length of the routine pharmacy inspection report, barriers to using statewide protocols, report on innovative pilot programs, and major challenges facing the profession or agency.

ACTION ITEM:

Ms. Juran will consult with the Chairman regarding a possible December full board meeting agenda item to re-discuss if the Board would like to convene a Retreat, and if so, the development of the agenda. Ms. Juran will gather information from previous Board retreats and the topics suggested by the Board members during last year's survey.

ADJOURN:

With all business concluded, the meeting adjourned at 12:25PM.

Caroline Juran, RPh
Executive Director

12/17/2024
DATE