COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Third Floor **(804) 367-4456 (Tel)**
Henrico, Virginia 23233 **(804) 527-4472(Fax)**

Tentative Agenda of Public Hearing and Full Board Meeting
December 7, 2021 Meeting
9AM

TOPIC	**PAGES**
Call to Order of Public Hearings: Cheryl Nelson, PharmD, Chairman	
• Welcome & Introductions	
Public Hearings:	
• Placing Certain Chemicals into Schedule I	**64-65**
Adjournment of Public Hearings	
Call to Order of Full Board Meeting: Cheryl Nelson, Chairman	
• Approval of Agenda	
Approval of Previous Board Meeting Minutes:	
• September 17, 2021, Special Conference Committee	**3-6**
• September 23, 2021, Workgroup Additional Duties Pharmacy Technicians	**7-11**
• September 24, 2021, Full Board Meeting	**12-19**
• September 24, 2021, Public Hearings Medication Carousels, RFID, Limited License Selling	**20-21**
• October 5, 2021, Special Conference Committee	**22-24**
• October 13, 2021, Formal Hearing	**25-26**
• October 18, 2021, Special Conference Committee	**27-30**
• November 4, 2021, Regulation Committee	**31-37**
• November 9, 2021, Special Conference Committee	**38-39**
• November 15, 2021, Special Conference Committee	**40-42**
Call for Public Comment: The Board will receive public comment at this time. The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters.	
DHP Director's Report: David Brown, DC	
Legislative/Regulatory/Guidance: Elaine Yeatts/Caroline Juran	
• Chart of Regulatory Actions	**43**
• Regulatory/Policy Actions resulting from 2021 General Assembly	**44-45**
• Legislative Report	**46**
○ Report of workgroup on expanded duties for pharmacy technicians	**47-52**
○ Report of workgroup on protocols for initiating treatment	**53-58**
• Petition for Rulemaking- pharmacy technician administration of vaccines	**59-62**
• Adoption of Exempt Regulations for Schedule I	**63-77**
• Report from Regulation Committee:	
○ Adoption of Recommendations on Periodic Review of Regulations	**78-81**
○ Adoption of Final Regulations for Medication Carousels	**82-106**
○ Adoption of Limited Licenses for Non-profit Clinics	**107-113**
○ Amendments to Guidance Documents	
▪ 110-42 CE Audits	**114-115**
▪ 110-19 Use of Automated Dispensing Devices in Certain Facilities	**116-117**
• Adoption of Exempt Regulations for Pharmaceutical Processors	**118-122**

- Adoption of Proposed Amendments to Pharmaceutical Processor Regulations (followed by 60-day comment period and adoption at March meeting) **123-128**
- Withdrawal of NOIRA for Chapter 60: Regulations Governing Pharmaceutical Processors **129-135**

Reports:

- Report on Prescription Monitoring Program – Ralph Orr, Director, PMP
- Chairman's Report – Cheryl Nelson, PharmD
- Report on Board of Health Professions – Caroline Juran, RPh
- Report on Licensure Program – Ryan Logan, RPh and Beth O'Halloran, RPh **136**
- Report on Inspection Program – Melody Morton, Inspections Manager, Enforcement Division **137-145**
- Report on Pharmaceutical Processors – Annette Kelley, M.S., C.S.A.C. **146**
- Report on Disciplinary Program – Ellen B. Shinaberry, PharmD **147**
- Executive Director's Report – Caroline D. Juran, RPh **148**

Consideration of consent orders, summary suspensions, or summary restrictions, if any.

Adjourn

****The Board will have a working lunch at approximately 12pm.****

*****A panel of the Board will tentatively convene at 1:00pm or immediately following adjournment of the board meeting, whichever is later.*****

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Friday, September 17, 2021
Commonwealth Conference Center
Second Floor
Board Room 2

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:11 am.
PRESIDING:	Patricia Richards-Spruill, Committee Chair
MEMBERS PRESENT:	William Lee, Committee Member
STAFF PRESENT:	Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Program Specialist Jessica Kelley, DHP Adjudication Specialist
GIHAN W. SERAKA License No. 0202-204419	Gihan W. Seraka, pharmacist reinstatement applicant, appeared to discuss her application for reinstatement of her license to practice pharmacy and that grounds may exist to deny her application as stated in the Notice dated August 5, 2021.
Closed Meeting:	Upon a motion by Mr. Lee, and duly seconded by Mrs. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Gihan W. Seraka. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Lee, and duly seconded by Mrs. Richards-Spruill, the Committee unanimously

voted to approve the reinstatement of Ms. Seraka's license subject to certain terms and conditions.

COAST QUALITY PHARMACY D/B/A/ ANAZAOHEALTH CORPORATION
Permit No. 0214-000324

Hal Weaver, President of Coast Quality Pharmacy d/b/a/ AnazaoHealth ("AnazaoHealth") appeared to discuss allegations that the pharmacy may have violated certain laws and regulations governing its conduct as a non-resident pharmacy delivering in the Commonwealth of Virginia as stated in the August 5, 2021 Notice. The pharmacy was represented by Lee H. Rosebush, Esq., Brian V. Johnson, Esq. and Marc Wagner, Esq.

Closed Meeting:

Upon a motion by Mr. Lee, and duly seconded by Mrs. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of AnazaoHealth. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:

Upon a motion by Mr. Lee and duly seconded by Mrs. Richards-Spruill, the Committee voted unanimously to assess a monetary penalty against AnazaoHealth.

KARE PHARMACY
Permit No. 0201-002103

Lisa Cotter, staff pharmacist for KARE Pharmacy, appeared to discuss allegations that KARE Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the July 20, 2021 Notice. The pharmacy was represented by Hunter Jamerson, Esq.

Closed Meeting:	Upon a motion by Mr. Lee, and duly seconded by Mrs. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of KARE Pharmacy. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Lee and duly seconded by Mrs. Richards-Spruill, the Committee voted unanimously to refer the matter to a formal administrative hearing.
LISA KAY COTTER License No. 0202-208184	Lisa K. Cotter, pharmacist appeared to discuss allegations that she may have violated certain laws and regulations governing her practice as a pharmacist as stated in the July 20, 2021, Notice. She was represented by Hunter Jamerson, Esq.
Closed Meeting:	Upon a motion by Mr. Lee, and duly seconded by Mrs. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Lisa K. Cotter. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:	Upon a motion by Mr. Lee, and duly seconded by Mrs. Richards-Spruill, the Committee unanimously voted to refer the matter to a formal administrative hearing.
ADJOURNED:	4:20 pm

_____	_____
Patricia Richards-Spruill, Chair	Mykl D. Egan Discipline Case Manager
_____	_____
Date	Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF PHARMACY TECHNICIAN DUTIES WORK GROUP MEETING

September 23, 2021

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

CALL TO ORDER: A meeting of a Pharmacy Technician Duties Work Group was called to order at approximately 1:04PM.

PRESIDING: William Lee, DPh, Board of Pharmacy Member

MEMBERS PRESENT:
Cheryl Nelson, PharmD, Chairman, Board of Pharmacy
Glenn Bolyard, RPh, Board of Pharmacy Member
Patricia Richards-Spruill, RPh, Board of Pharmacy Member
Jermaine Smith, PharmD, President, Virginia Association of Chain Drug Stores (VACDS)
Tana Kaefer, PharmD, Virginia Pharmacists Association (VPhA)
Jessica Langley, MS, Executive Director of Education and Advocacy, National Healthcareer Association
Jamin Engle, PharmD, Virginia Society of Health-System Pharmacists

STAFF PRESENT:
Caroline D. Juran, RPh, Executive Director, Board of Pharmacy
Ryan Logan, RPh, Deputy Executive Director, Board of Pharmacy
Beth O'Halloran, RPh, Deputy Executive Director, Board of Pharmacy
Ellen B. Shinaberry, PharmD, Deputy Executive Director, Board of Pharmacy
Elaine Yeatts, Senior Policy Analyst, DHP
Barbara Allison-Bryan, M.D., Chief Deputy Director, DHP
James Rutkowski, Assistant Attorney General
Sorayah Haden, Executive Assistant, Board of Pharmacy

QUORUM: A quorum was established.

APPROVAL OF AGENDA: An amended list of work group members correctly identifying Tana Kaefer, PharmD as representing the Virginia Pharmacists Association was provided to the members and public. A motion was unanimously passed to approve the agenda as presented.

PUBLIC COMMENTS: Jodi Roth, representing VACDS, read a portion of the written comments jointly prepared by VACDS and the National Association of Chain Drug

Stores (NACDS) which was provided to the members and the public as a handout. Within the handout entitled *Enhance Access to Patient Care in Virginia by Modernizing Laws and Regulations to Optimize the Use of Pharmacy Technicians for Technical and Administrative Tasks,* the organizations offered the following recommendations: eliminate pharmacy technician to pharmacist ratio and expand duties that pharmacy technicians can perform. Specifically, the recommended expanded duties included: permanent authority to administer vaccines consistent with PREP Act authorities; permanent authority to administer both COVID-19 and other point of care CLIA-waived tests; technician product verification; accept new telephone prescriptions; transfer prescriptions; clarify prescriptions; and other nondiscretionary functions as delegated by the supervising pharmacist.

Christina Barrille, Executive Director, VPhA commented that they have a few concerns regarding the recommendations offered by VACDS/NACDS. Specifically, VPhA opposes the elimination of the pharmacist to pharmacy technician ratio and that physical on-site supervision is important. She stated that any expansion of pharmacy technician duties should be done methodically. She referenced difficulty in getting pediatric appointments currently and that access to vaccines is important. She stated that it would be difficult to take away vaccine allowances after the pandemic since the current model under PREP Act allowances is working.

The work group reviewed two other handouts of public comment from the Virginia Chapter of the American Academy of Pediatrics (AAP) and the Medical Society of Virginia (MSV) that board staff received via email prior to the meeting. The Virginia Chapter of the AAP strongly opposes allowing pharmacy technicians to provide vaccinations to those under the age of 18 as they believe children should receive vaccines in their medical home. MSV believes expanding pharmacy technician duties may be premature and requests the work group to defer additional recommendations until after the work pertaining to statewide protocols for pharmacists.

CHARGE OF WORK GROUP

Lee provided an overview of the work group's charge pursuant to the third enactment of HB 1304 and SB 830 (2020 General Assembly session).

ELIMINATION OF PHARMACIST TO PHARMACY TECHNICIAN RATIO

The work group discussed VACDS/NACDS' request to eliminate the pharmacist to pharmacy technician ratio. Langley commented that Virginia has very high educational standards since now requiring completion of an accredited training program. Bolyard opposed elimination of ratio. Engle commented that VSHP agrees with VPhA that the ratio should not be eliminated.

MOTION:

Motion to eliminate the pharmacist to pharmacy technician ratio failed due to a lack of a second. (motion by Smith)

MOTION: **The work group voted 6:2 to decline VACDS/NACDS' recommendation to eliminate the pharmacist to pharmacy technician ratio. (motion by Nelson, seconded by Bolyard; opposed by Smith and Langley)**

VACCINE ADMINISTRATION

Kaefer recommended restricting vaccine administration to 18 years and older since pharmacists are limited to this age group. Bolyard supported administration to 3 years of age and older. Engle supported 3 years and older due to concerns with access and current model working, but believes training must continue to be required. Langley recommended keeping training requirements under PREP Act or adopt other requirements. Smith didn't want to close door to access given healthcare deserts. Kaefer stated training should focus on administration, not selection of vaccine as is required of a pharmacist. Engle stated pharmacy technician should obtain national certification. Langley commented that they should be required to maintain certification.

MOTION **The work group voted 7:1 to include a recommendation in the legislative report to permanently authorize a pharmacy technician, who has obtained and maintains national certification, to administer vaccines consistent with the authority and training required under the Health and Human Services PREP Act. (motion by Smith, seconded by Nelson; opposed by Richards-Spruill)**

ADMINISTRATION OF COVID-19 AND OTHER POINT OF CARE CLIA-WAIVED TESTS

Ms. Juran read from the COVID-19 Testing Resource Document on the board's website that states the following: *The Virginia Board of Pharmacy has a longstanding position that the performing of CLIA-waived tests is within the scope of practice of pharmacy. Tests must be administered in accordance with FDA's CLIA requirements. Pharmacists, along with pharmacy technicians and pharmacy interns under the supervision of a pharmacist may perform CLIA-waived tests. Per CLIA requirements, training for how to collect the sample and perform the test must be documented.* Because pharmacy technicians may already administer CLIA-waived tests, the work group took no action.

PRODUCT VERIFICATION

It was commented that responsibility for any verification errors should shift to the pharmacy technician and not fall back to the supervising pharmacist. Engle recommended for institutional settings. He referenced Schedule VI drugs, unit dose, if administered by a licensed health professional, and language similar to proposed regulations for medication carousel and RFID technology. Smith and Lee commented that additional input is necessary. Shinaberry briefly summarized the six innovative pilots authorizing pharmacy technician product verification. Five are in hospitals, one in long term care. One use medication carousels, one uses automated dispensing devices, one uses bar-code technology, and all settings use a licensed person at the point of

administration.

MOTION:

The work group voted unanimously to recommend that the Board of Pharmacy further explore the subject of pharmacy technician product verification. (motion by Nelson, seconded by Engle)

ACCEPTING NEW TELEPHONE PRESCRIPTIONS AND CLARIFYING PRESCRIPTIONS

Concerns were expressed by Bolyard and Richards-Spruill. Smith commented that Virginia's educational standards have increased and since most prescriptions are e-prescribed, there are very few verbal orders. He suggested restricting to Schedule VI drugs only and clarifying only refills or quantities.

MOTION:

The work group voted unanimously to include a recommendation in the legislative report to allow a pharmacy technician to clarify the number of refills and drug quantity for Schedule VI new prescriptions or refill prescriptions. (motion by Nelson, seconded by Bolyard)

MOTION:

The work group voted 6:2 to not allow pharmacy technicians to accept new prescriptions. (Nelson, Bolyard; opposed by Smith and Langley)

Members mentioned the inconvenience of requiring a physical authorization of the pharmacist for each new or transferred prescription received.

TRANSFER PRESCRIPTIONS

Discussion focused on Schedule VI drugs only and not an on-hold prescription, electronic transfer or faxed transfer. Discussion also focused on the importance of a pharmacist authorizing the transfer. There appeared to be consensus that the pharmacist-in-charge could document which qualifying pharmacy technicians were authorized to transfer certain Schedule VI prescriptions and that the document should be readily available for inspector review.

MOTION:

The work group voted unanimously to include a recommendation in the legislative report to allow a nationally certified pharmacy technician to electronically transfer a Schedule VI refill prescription that is not an on-hold prescription when authorized by the pharmacist-in-charge.

OTHER NONDISCRETIONARY

Engle recommended the work group consider an ability for pharmacy

FUNCTIONS

technicians to take accurate medication histories for patients. There was discussion regarding how this would differ from medication reconciliations. Staff commented that the Board has a long-standing position that pharmacy technicians may perform medication reconciliations. Engle commented that there is confusion among licensees and that perhaps clarification is simply needed. Board counsel agreed that 54.1-3321 of the Code of Virginia appears to already authorize pharmacy technicians to perform this task if the Board views this duty as "the entry of prescription information and drug history into a data system or other record keeping system".

MOTION

The work group voted unanimously to recommend to the Board of Pharmacy to clarify regulations, if necessary, to clearly authorize pharmacy technicians to take medication histories independently to include drug name, dose, and frequency. (motion by Engle, seconded by Nelson)

MEETING ADJOURNED: Having completed all business on the agenda, the meeting was adjourned at 4:15pm.

William Lee, Chairman

Caroline D. Juran, Executive Director

DATE:

DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING

September 24, 2021

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

CALL TO ORDER: A full board meeting was called to order at 9:18 AM.

PRESIDING: Cheryl H. Nelson, Chairman

MEMBERS PRESENT:
R. Dale St. Clair Jr, Vice Chairman
Bernard Henderson, Jr.
James L. Jenkins, Jr.
William Lee
Sarah Melton
Patricia Richards-Spruill
Glenn Bolyard
Cheryl Garvin
Kristopher Ratliff

STAFF PRESENT:
Caroline D. Juran, Executive Director
Annette Kelley, Deputy Executive Director
Ryan Logan, Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Ellen B. Shinaberry, Deputy Executive Director
Elaine Yeatts, Senior Policy Analyst, DHP
Barbara Allison-Bryan, M.D., Chief Deputy, DHP
James Rutkowski, Assistant Attorney General
Sorayah Haden, Executive Assistant, DHP

PHARMACISTS AWARDED 1-HOUR OF LIVE OR REAL-TIME INTERACTIVE CONTINUING EDUCATION FOR ATTENDING MEETING: Ademola Are

QUORUM: With ten members participating, a quorum was established.

APPROVAL OF AGENDA: An amended agenda, along with several documents, were provided as handouts. Changes included on the amended agenda were: reference to

handouts for amended minutes from June 28, 2021 and July 13, 2021; two handouts regarding Guidance Documents 110-9 and 110-34; a handout regarding the Adoption of Policy Regarding Meetings with Electronic Participation; and a handout regarding a Request from the Virginia Hospital and Healthcare Association (VHHA) for stakeholder meetings on white bagging. The amended agenda was accepted as presented.

APPROVAL OF PREVIOUS BOARD MEETING MINUTES

Several amendments were offered to the draft minutes included in the agenda packet.

MOTION:

The Board voted unanimously to adopt the minutes for June 3, 2021 through August 24, 2021 as presented and amended as follows:

- **On page 2 of June 4, 2021 full board minutes, under "Approval of Previous Board Meeting Minutes", correct to read "insert legislation to authorize adult use marijuana…" after "discussions regarding concerns for l";**
- **On page 3 of the July 26, 2021 Special Conference Committee, change "he" to "she" regarding Tina Dodson. (motion by Jenkins, seconded by Richards-Spruill)**

PUBLIC COMMENTS:

Christina Barrille, Executive Director, Virginia Pharmacists Association, welcomed newly-appointed board member, Cheri Garvin, and thanked staff, all pharmacists and pharmacy technicians for their hard work. She referenced National Pharmacists Month during the month of October. She provided a one-page handout of technical comments on agenda pages 160-214 regarding statewide protocols. She expressed concern for employee burnout and reported that October 5, 2021 is VPhA's Buddy Check Day.

The chairman highlighted to the Board that a handout of written public comment was provided at their seat. Staff received the written comment via email prior to the meeting from Ryan M. Martin, Esq. regarding "Board of Pharmacy Policy Regarding Department of Behavioral Health Licensed Facilities".

DHP DIRECTOR'S REPORT:

Barbara Allison-Bryan, M.D., Chief Deputy Director, Department of Health Professions presented the Director's Report on behalf of Dr. Brown. Dr. Allison-Bryan commented that 70% of the agency is currently teleworking and expected to return to the office in January 2022. She presented the vaccination status of the state. Virginia is ranked as the 12th state within the U.S. of vaccinated people. 71% of the people 18 years and older have received both doses of the vaccine. 80% of people 18 years and older have received at least one of the doses. DHP has implemented the mandate to be vaccinated or participate in weekly testing. 80% of DHP is currently fully vaccinated. IT has created a tracking portal for COVID testing and vaccination status on the Intranet for agency staff. She stated that a substance

abuse-related workgroup will meet next week regarding HB 2300.

CHART OF REGULATORY ACTIONS

Mrs. Yeatts briefly reviewed the information on pages 148-151 of the agenda.

REGULATORY/POLICY ACTIONS RESULTING FROM 2021 GENERAL ASSEMBLY SESSION

Required legislative reports are currently being prepared.

AMEND EMERGENCY REGULATIONS REGARDING PHARMACISTS INITIATING TREATMENT

Ms. Yeatts commented that the red language reflects draft proposed language based on 2021 legislative changes.

MOTION:

The Board voted unanimously to adopt the emergency regulations as presented. (motion by St. Clair Jr, seconded by Melton)

ADOPTION OF STATEWIDE PROTOCOLS FOR INITITATING TREATMENT

PHARMACIST VACCINE PROTOCOL

MOTION:

The Board unanimously adopted the vaccine statewide protocol for pharmacists to initiate treatment as presented. (motion by St. Clair, seconded by Melton)

PHARMACIST PROTOCOL TO LOWER OUT-OF-POCKET EXPENSES

MOTION:

The Board voted unanimously to amend the current protocol to lower out-of-pocket expenses as presented. (motion by Jenkins, seconded by Henderson)

HIV PrEP PROTOCOL

There was discussion regarding whether a pharmacist may order the labs referenced in the protocol. Ms. Juran commented that the law regarding collaborative practice agreements authorizes pharmacists to order laws. Counsel confirmed that the law regarding a pharmacist's ability to initiate

treatment appears to authorize pharmacists to order labs that would be necessary to determine if a particular drug should be initiated and at what dose.

MOTION: **The Board voted unanimously to adopt the PrEP protocol as presented and amended by: including a footnote that a pharmacy may convert the protocol documents to an electronic format if the questions and process are identical to the adopted protocol; changing drug brand names to generic names; and inserting a statement on page 171 of the agenda packet that the pharmacist may order necessary labs if not complete. (motion by Lee, seconded by Richards-Spruill)**

HIV PEP

MOTION: **The Board voted unanimously to adopt the PEP protocol as presented and amended by: including a footnote that a pharmacy may convert the protocol documents to an electronic format if the questions and process are identical to the adopted protocol. (motion by St.Clair, seconded by Melton)**

TUBERCULIN SKIN TEST ONE-STEP PROTOCOL

MOTION **The Board voted unanimously to adopt the Tuberculin Skin Test One-Step protocol as presented and amended by: including a footnote that a pharmacy may convert the protocol documents to an electronic format if the questions and process are identical to the adopted protocol. (motion by Richards-Spruill, seconded by Jenkins)**

TUBERCULIN SKIN TESTING TWO-STEP PROTOCOL

There was discussion that Appendix C is simply to show how to place the TST.

MOTION:

The Board voted unanimously to adopt the Tuberculin Skin Test Two-Step protocol as presented and amended by: including a footnote that a pharmacy may convert the protocol documents to an electronic format if the questions and process are identical to the adopted protocol. (motion by Richards-Spruill, seconded by Bolyard)

REGULATIONS GOVERNING PHARMACEUTICAL PROCESSORS

The Board previously adopted a NOIRA based on a petition for rulemaking. Actions identified on page 219. St.Clair acknowledged that educational presentations may be offered at offsite locations.

ACTION ITEM: **Staff will research more information regarding request #4 on page 226 to**

amend 18VAC110-60-290 to remove duplicative information between the product label and patient label.

ACTION ITEM: **Regarding request #7 on page 226, staff will research if there is a better regulation to amend since really verifying patient registration prior to accessing facility and not prior to dispensing product.**

MOTION: **The Board voted unanimously to adopt the proposed regulations as presented. (motion by Jenkins, seconded by St.Clair)**

The Board voted unanimously to withdraw the three following pharmaceutical processor regulatory actions previously adopted by the Board since they have now been incorporated into the regulations that become effective September 1, 2021: 1)Action relating to changes in to law in 2020 General Assembly Session; 2) Action related to wholesale distribution and registered agents; and 3) Action related to vaping. (motion by Bolyard, seconded by Richards-Spruill)

HEALTHCARE WORKFORCE DATA CENTER DIRECTOR'S REPORT

Elizabeth Carter, PhD reported that pharmacist job satisfaction is up, even during a pandemic. 68% of the pharmacists responding to the survey obtained a PharmD degree. The workforce data center is starting to look at unemployment. Pharmacy technicians are making more money, but there are fewer in the workforce.

MOTION: **The Board voted unanimously to change any reference to "license" or "licensee" to "registration" or "registrant" in the Pharmacy Technician Workforce Survey Report. (motion by Richards-Spruill, seconded by Henderson)**

MOTION: **The Board voted unanimously to adopt the 2020 Pharmacist and Pharmacy Technician Healthcare Workforce Survey Reports as presented and amended. (motion by Henderson, seconded by Richards-Spruill)**

PETITION FOR RULEMAKING REGARDING AUTOMATED DISPENSING DEVICES

MOTION: **The Board voted unanimously to accept the petition and initiate rulemaking regarding 18VAC110-20-460 and 18VAC110-20-490.**

REPEALING PARTS OF 18VAC110-20-322 SCHEDULE I CHEMICALS

All of the board actions in 18VAC110-20-322 A through C have now been scheduled in the Drug Control Act so they need to be removed from the regulations.

MOTION: **The Board voted unanimously to adopt the final regulation of 18VAC110-20-322 as presented. (motion by Ratliff, seconded by Richards-Spruill)**

GUIDANCE DOCUMENTS

MOTION: **The Board voted unanimously to amend the draft language in Guidance Document 110-34 regarding background checks for certain facilities by changing six months to 90 days. (motion by Henderson, seconded by Jenkins)**

MOTION: **The Board voted unanimously to amend the following guidance documents as presented and amended:**

- **110-1 (Facility Categories)**
- **110-5 (Theft/Loss Reports)**
- **110-9 (Monetary Penalties)**
- **110-30 (Animal Shelters), amend further by removing reference to "Pound" as this term has been removed from the Code;**
- **110-31 (Approved Capture Drugs), amend further by changing Code section to 3.2-6500**
- **110-44 (Naloxone)**
- **110-34 (Certain Facility Background Checks) as previously amended. (motion by Richards-Spruill, seconded by Henderson)**

MOTION: **The Board voted unanimously to repeal Guidance Document 110-50 (Telemedicine by Registered Practitioners of Cannabis Oil) as this is outdated based on recent legislative changes. (motion by St.Clair, seconded by Bolyard)**

MOTION: **The Board voted unanimously to adopt as presented a new Guidance Document 110-20 regarding background checks for cannabis dispensing facilities. (motion by Henderson, seconded by Jenkins)**

MOTION: **The Board voted unanimously to adopt as presented a new Guidance Document 110-19 regarding use of automated dispensing devices in certain DBHDS-licensed facilities. (motion by Ratliff, seconded by Lee)**

MOTION/ACTION ITEM: **The Board voted unanimously to adopt as presented a new Guidance Document regarding emergency medical services (EMS) drug kits and to invite a representative from the Office of Emergency Medical Services to the next Regulation Committee meeting to further discuss any issues of concern regarding EMS drug kits. (motion by Ratliff, seconded by Lee)**

The Board voted unanimously to adopt as presented the policy regarding meetings with electronic participation. (motion by St. Clair, seconded by Melton)

OLD BUSINESS:

FDA MOU ON COMPOUNDING INORDINATE AMOUNTS

The Board requested that it be noted in the minutes that no action will be taken on the FDA MOU since the MOU has been withdrawn based on a recent federal court ruling.

NEW BUSINESS:

REQUEST FROM VHHA FOR STAKEHOLDER MEETINGS ON WHTE BAGGING

ACTION ITEM:

The Board requested that Ms. Juran respond to VHHA that the matter was discussed, no action will be taken at this time, and that they are welcome to share with the Board any specific requests it may have for rulemaking in the future.

REPORT FROM HEALTH PRACTITIONER'S PRESCRIPTION MONITORING PROGRAM

Dr. Allison-Bryan, Amy Ressler, and Chris Buisset presented a PowerPoint presentation to explain the functions and goals of the Health Practitioner's Monitoring Program. The program was created to assist in recovery, not treatment. It is considered an alternative to disciplinary action. The program has a contract with VCU which monitors the compliance of client's recovery plan. The program included a dedicated case manager and ongoing monitoring. Scholarships have been created to assist with the cost of the program. Contracts last 3-5 years, most commonly 5 years. Screening tests can cost approximately $35-50 per screen. VCU will assist with negotiating treatment options and will help client get on Medicaid, if necessary, to lower costs. Client must call test line daily. Most are diagnosed with substance use disorder (alcohol 40%; opioid 30%); mental health diagnosis about 10%. Cannot look for work without case manager cooperation. Pharmacist typically allowed to work at one location, no more than 40 hours per week, cannot serve as pharmacist-in-charge upon initial return, required to work with another pharmacist initially for most of the shift, worksite monitor and employer reports to HPMP monthly, peer monitor may be engaged.

REPORTS

CHAIRMAN'S REPORT:

The chairman recalled her experience during her recent trip to Annapolis, MD for the NABP/AACP Districts 1 & 2 Meeting.

REPORT ON BOARD OF HEALTH PROFESSIONS

Ms. Juran commented that there are a number of vacant member positions on the Board of Health Professions and that it has not met recently. This includes a vacancy from the Board of Pharmacy since Ryan Logan accepted the position of Deputy Executive Director with the Virginia Board of Pharmacy.

REPORT ON LICENSURE PROGRAM	Ms. O'Halloran provided a licensing report including data for various licenses issued by the Board. Page 309 of the agenda packet provides the number of newly issued licenses, registrations and permits for each category as well as a total number of licensees.
REPORT ON INSPECTION PROGRAM	Tim Reilly, DHP Pharmacist Inspector, presented the inspection report. He introduced to the Board Srini Peddi who is a new pharmacist inspector with the Department of Health Professions' Enforcement Division. Mr. Reilly reported that 431 inspections were conducted last quarter. Due to COVID-19, the inspectors are conducting 14-18 inspections per month per inspector. Page 310 of the agenda displayed a chart reporting the various types of inspections conducted from April 1, 2021 through June 30, 2021.
REPORT ON PHARMACEUTICAL PROCESSORS	Ms. Kelley provided a Pharmaceutical Processors Report. All four currently permitted pharmaceutical processors are now submitting medical cannabis product applications for approval. The Board is receiving, on average, 1,000 to 1,200 patient applications per week. The Board is currently recruiting three additional temporary staff members. The agency is working on acquiring a new patient registration platform for future Pharmaceutical Processors applicants.
REPORT ON DISCIPLINARY PROGRAM	Dr. Shinaberry presented the Disciplinary Report. The Board currently has 351 total cases, with majority regarding patient care. She reported the overall case load increased by 51 cases since last reported.
EXECUTIVE DIRECTOR'S REPORT	Ms. Juran provided the Executive Director's Report. She informed the Board of the vacant staffing positions available. The staff is continuing to telework with limited hours on-site. She provided an update on current projects of the Board including EMS guidance, E-newsletters, and the new licensing software for the cannabis program.
RATIFICATION OF CONSENT ORDERS	Dr. Shinaberry presented three signed consent orders for ratification.
MOTION:	**The Board voted unanimously to accept and ratify the three signed consent orders as presented by Dr. Shinaberry. (motion by Melton, seconded by Richards-Spruill)**
MEETING ADJOURNED:	3:14 PM

_____ _____

Cheryl H. Nelson, Chairman Caroline D. Juran, Executive Director

_____ _____

DATE: DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF PUBLIC HEARINGS REGARDING MEDICATION CAROUSELS AND RFID TECHNOLOGY; LIMITED LICENSE FOR SELLING SCHEDULE VI DRUGS IN NON-PROFIT CLINICS

September 24, 2021

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

CALL TO ORDER: Public hearings of the Board of Pharmacy were called to order at 9:11AM.

PRESIDING: Cheryl H. Nelson, Chairman

MEMBERS PRESENT:
R. Dale St. Clair Jr, Vice Chairman
Bernard Henderson, Jr.
James L. Jenkins, Jr.
William Lee
Patricia Richards-Spruill
Glenn Bolyard
Cheryl Garvin
Kristopher Ratliff

MEMBERS ABSENT: Sarah Melton

STAFF PRESENT:
Caroline D. Juran, Executive Director
Annette Kelley, Deputy Executive Director
Ryan Logan, Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Ellen B. Shinaberry, Deputy Executive Director
Elaine Yeatts, Senior Policy Analyst, DHP
Barbara Allison-Bryan, M.D., Chief Deputy, DHP
James Rutkowski, Assistant Attorney General
Sorayah Haden, Executive Assistant, DHP

PUBLIC HEARING: Public hearings were held to receive public comment on proposed regulations regarding: medication carousels and RFID technology; and, limited licenses to sell Schedule VI drugs in non-profit clinics.

PUBLIC COMMENTS: Mark Hickman representing the Virginia Society of Health-Systems Pharmacists referenced written comment submitted by the organization regarding medication carousels and RFID technology. The written comment

was provided as a handout to the Board.

No other public comments were offered to the Board.

MEETING ADJOURNED: 9:17 AM

Cheryl H. Nelson, Chairman

Caroline D. Juran, Executive Director

DATE:

DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, October 5, 2021
Commonwealth Conference Center
Second Floor
Board Room 2

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:06 am.
PRESIDING:	Kristopher Ratliff, Committee Chair
MEMBERS PRESENT:	Dale St. Clair, Committee Member
STAFF PRESENT:	Ellen Shinaberry, Deputy Executive Director Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Program Specialist Claire Foley, DHP Adjudication Specialist Jessica Weber, DHP Adjudication Specialist David Robinson, DHP Adjudication Specialist
CVS/PHARMACY #8302 Permit No. 0201-004432	Olivia L. Darvish-Basseri, Pharmacist-in-Charge of CVS/Pharmacy #8302 and Paul McCormick, CVS District Leader, appeared as representatives of the pharmacy to discuss allegations that it may have violated certain laws and regulations governing the conduct of a pharmacy as stated in the July 1, 2021 Notice. They were represented by George H. Parcells, Esq. and T. Huntley Thorpe, III, Esq.
Closed Meeting:	Upon a motion by Mr. St. Clair, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of CVS/Pharmacy #8302. Additionally, he moved that Ellen Shinaberry, Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. St. Clair and duly seconded by Mr. Ratliff, the Committee voted unanimously to assess a monetary penalty against CVS/Pharmacy #8302 and to impose certain terms and conditions against the pharmacy.
ADKOA Pharmacy Permit No. 0201-004744	Adwoa Addai, Pharmacist-in-Charge of AdKOA Pharmacy appeared as a representative of the pharmacy to discuss allegations that it may have violated certain laws and regulations governing the conduct of a pharmacy as stated in the August 19, 2021 Notice.
Closed Meeting:	Upon a motion by Mr. St. Clair, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of AdKOA Pharmacy. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. St. Clair and duly seconded by Mr. Ratliff, the Committee voted unanimously to assess a monetary penalty against AdKOA Pharmacy and to impose certain terms and conditions against the pharmacy.
ADJOURNED:	4:50 p.m.

_____ _____

Kristopher Ratliff, Chair

Mykl Egan
Discipline Case Manager

_____ _____

Date

Date

(DRAFT/UNAPPROVED)
VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

Wednesday, October 13, 2021
Commonwealth Conference Center
Board Room 4

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

Orders/Consent Orders referred to in these minutes are available upon request

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 09:28 AM.

PRESIDING: Cheryl Nelson, Chairman

MEMBERS PRESENT: Dr. Dale St. Clair, Ms. Cheri Garvin, Mr. Glenn Bolyard, Dr. Cheryl Nelson, Mr. Jim Jenkins

STAFF PRESENT: Caroline D. Juran, Executive Director; Ellen B. Shinaberry, Deputy Executive Director; James Rutkowski, Assistant Attorney General; Sorayah Hayden, Administrative Assistant

QUORUM: With five (5) members of the Board present, a panel of the board was established.

PHARMACY SERVICES OF AMERICA, LLC
Permit No. 0201-004868

A formal hearing was held in the matter of Pharmacy Services of America, LLC to discuss allegations the pharmacy may have violated certain laws and regulations governing the practice of pharmacy in Virginia.

Sean Murphy, Assistan Attorney General and David Robinson, DHP Adjudication Specialist, presented the case.

Donna Stevens, Pharmacist in Charge, was present on behalf of Pharmacy Services of America, LLC. Pharmacy Services of America, LLC was not represented by counsel.

Katrina Trelease, DHP Pharmacy Inspector, Billie Jo Prillaman, Pharmacy Technician, and Christy Sloan, Pharmacist, testified on behalf of the Commonwealth.

Donne Stevens testified on behalf of Pharmacy Services of America, LLC.

CLOSED MEETING:	Upon a motion by Dr. St. Clair, and duly seconded by Mr. Bolyard, the panel voted 5-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Pharmacy Services of America, LLC. Additionally, he moved that Caroline Juran, Ellen Shinaberry, Sorayah Hayden and Jim Rutkowski attend the closed meeting.
RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened an open meeting and announced the decision.
DECISION:	Upon a motion by Mrs. Garvin, and duly seconded by Dr. St. Clair, the panel voted 5-0 to accept the Findings and Facts and Conclusion of Law as proposed by the Commonwealth and revised by the Board. Upon a motion by Mr. Jenkins, and duly seconded by Mr. Bolyard, the panel voted 5-0 to revoke the pharmacy permit of Pharmacy Services of America, LLC and impose a monetary penalty.
ADJOURN:	With all business concluded, the meeting adjourned at 1:10 PM.

Cheryl Nelson, Chair	Caroline D. Juran Executive Director
Date	Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Monday, October 18, 2021
Commonwealth Conference Center
Second Floor
Board Room 2

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:00 am.
PRESIDING:	Dale St. Clair, Committee Chair
MEMBERS PRESENT:	Glenn Bolyard, Committee Member
STAFF PRESENT:	Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Program Specialist David Robinson, DHP Adjudication Specialist
DENNIS L. MAKOVSKY License No. 0202-009878	Dennis Makovsky appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the September 2, 2021 Notice. Mr. Makovsky was not represented by counsel.
Closed Meeting:	Upon a motion by Mr. Bolyard, and duly seconded by Mr. St. Clair, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Dennis Makovsky. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Bolyard and duly seconded by Mr. St. Clair, the Committee voted unanimously

to order Mr. Makovsky to take additional continuing education.

BRITTANY GOODMAN
License No. 0202-217611

Brittany Goodman appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the September 2, 2021 Notice. Ms. Goodman was not represented by counsel.

Closed Meeting:

Upon a motion by Mr. Bolyard, and duly seconded by Mr. St. Clair, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(15) for the purpose of discussing the medical records of Brittany Goodman. Additionally, he moved that Mykl Egan, Ileita Redd, David Robinson and Brittany Goodman attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Closed Meeting:

Upon a motion by Mr. Bolyard, and duly seconded by Mr. St. Clair, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Brittany Goodman. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:	Upon a motion by Mr. Bolyard and duly seconded by Mr. St. Clair, the Committee voted unanimously to place Ms. Goodman under certain terms and conditions.
CARMEN WITSKEN License No. Applicant	Carmen Witsken appeared to discuss her application for licensure as a pharmacist and that allegations exist to deny that application as stated in the September 9, 2021 Notice. Ms. Witsken was not represented by counsel.
Closed Meeting:	Upon a motion by Mr. Bolyard, and duly seconded by Mr. St. Clair, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(15) for the purpose of discussing the medical records of Carmen Witsken. Additionally, he moved that Mykl Egan, Ileita Redd, David Robinson and Carmen Witsken attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Closed Meeting:	Upon a motion by Mr. Bolyard, and duly seconded by Mr. St. Clair, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Carmen Witsken. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:	Upon a motion by Mr. Bolyard and duly seconded by Mr. St. Clair, the Committee unanimously voted to grant Ms. Witsken's application for licensure by examination.
ADJOURNED:	11:50 a.m.

_____ _____

Dale St. Clair, Chair

Mykl Egan
Discipline Case Manager

_____ _____

Date

Date

(DRAFT/UNAPPROVED)

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
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 Caroline Juran

_____ _____

Date: Date:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, November 9, 2021
Commonwealth Conference Center
Second Floor
Board Room 3

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:03 am.
PRESIDING:	Patricia Richards-Spruill, Committee Chair
MEMBERS PRESENT:	William Lee, Committee Member
STAFF PRESENT:	Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Program Specialist Jessica Kelley, DHP Adjudication Specialist
KEBEBEW ABOYE License No. 0202-206529	Kebebew Aboye, pharmacist appeared to discuss allegations that he may have violated certain laws and regulations governing his practice as a pharmacist as stated in the September 16, 2021, Notice.
Closed Meeting:	Upon a motion by Mr. Lee, and duly seconded by Mrs. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Kebebew Aboye. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:	Upon a motion by Mr. Lee, and duly seconded by Mrs. Richards-Spruill, the Committee unanimously voted to dismiss the case against Mr. Aboye.
PASCALE EL HAYEK License No. 0202-207815	Pascale El Hayek, pharmacist appeared to discuss allegations that she may have violated certain laws and regulations governing her practice as a pharmacist as stated in the September 9, 2021, and continued in a September 23, 2021, Notice. She was represented by Anisa P. Kelley Esq.
Closed Meeting:	Upon a motion by Mr. Lee, and duly seconded by Mrs. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Pascale El Hayek. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Lee, and duly seconded by Mrs. Richards-Spruill, the Committee unanimously voted to refer the matter to a formal administrative hearing.
ADJOURNED:	12:30 pm

Patricia Richards-Spruill, Chair	Mykl D. Egan Discipline Case Manager
Date	Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Monday, November 15, 2021
Commonwealth Conference Center
Second Floor
Board Room 3

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:00 am.
PRESIDING:	Kristopher Ratliff, Committee Chair
MEMBERS PRESENT:	Bernard Henderson, Committee Member
STAFF PRESENT:	Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Program Specialist David Robinson, DHP Adjudication Specialist
IBRAHIM AHMED-ADAM MOHAMMED License No. 0202-204553	Ibrahim Ahmed-Adam Mohammed appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the October 14, 2021 Notice. Mr. Mohammed was not represented by counsel.
Closed Meeting:	Upon a motion by Mr. Henderson, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Ibrahim Ahmed-Adam Mohammed. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:	Upon a motion by Mr. Henderson and duly seconded by Mr. Ratliff, the Committee voted unanimously to refer the matter to a formal administrative hearing and to offer Mr. Mohammed a Consent Order in lieu of a formal administrative hearing.
CVS/PHARMACY #17459 Permit No. 0201-004212	Gina Ng-Winn, Pharmacist-in-Charge of CVS/Pharmacy #17459 and Danielle Conklin-Gregory, CVS District Leader, appeared as representatives of the pharmacy to discuss allegations that it may have violated certain laws and regulations governing the conduct of a pharmacy as stated in the October 14, 2021 Notice. They were represented by George H. Parcells, Esq. and T. Huntley Thorpe, III, Esq.
Closed Meeting:	Upon a motion by Mr. Ratliff, and duly seconded by Mr. Henderson, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of CVS/Pharmacy #17459. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Ratliff and duly seconded by Mr. Henderson, the Committee voted unanimously to assess a monetary penalty against CVS/Pharmacy #17459 and to impose certain terms and conditions against the pharmacy.
MICHAEL GLENN MARTIN Registration No. Applicant	Michael Glenn Martin did not appear to discuss his application for registration as a pharmacy technician and that allegations exist to deny that

application as stated in the September 30, 2021 Notice. Mr. Martin was not represented by counsel.

Closed Meeting: Upon a motion by Mr. Henderson, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Michael Glenn Martin. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene: Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision: Upon a motion by Mr. Henderson and duly seconded by Mr. Ratliff, the Committee unanimously voted to deny Mr. Martin's application for registration as a pharmacy technician.

ADJOURNED: 3:03 p.m.

_____ _____

Kristopher Ratliff, Chair

Mykl Egan
Discipline Case Manager

_____ _____

Date

Date

Agenda Item: Regulatory Actions - Chart of Regulatory Actions
As of November 17, 2021

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Reporting of immunizations to VIIS [Action 5598] Emergency - *Register Date: 10/12/20*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Implementation of 2021 legislation for pharmacists initiating treatment [Action 5861] Emergency/NOIRA - *AT Attorney General's Office*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Remote processing of drugs in automated dispensing devices for hospitals [Action 5868] NOIRA - *At Governor's Office for 19 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Use of medication carousels and RFID technology [Action 5480] Proposed - *Register Date: 8/16/21* *Board to adopt final or re-proposed regs*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Implementation of legislation for pharmacists initiating treatment [Action 5604] Proposed - *At Governor's Office for 13 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Final - *At Governor's Office for 1274 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Deletion of scheduling of certain chemicals now scheduled in Schedule I in the Code [Action 5846] Final - *AT Attorney General's Office*
[18 VAC 110 - 21]	Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians	Implementation of legislation for registration of pharmacy technicians [Action 5603] Proposed - *At Governor's Office for 13 days*
[18 VAC 110 - 30]	Regulations for Practitioners of the Healing Arts to Sell Controlled Substances	Limited license for prescribing Schedule VI drugs in non-profit clinics [Action 5605] Proposed - *Register Date: 8/16/21* *Board to adopt final: 12/7/21*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Response to petition for rulemaking [Action 5611] NOIRA - *Register Date: 3/1/21*

Department of Health Professions
Regulatory/Policy Actions – 2021 General Assembly

EMERGENCY REGULATIONS:

Legislative source	Mandate	Promulgating agency	Board adoption date	Effective date Within 280 days of enactment
HB2079	Authorization for a pharmacist to initiate treatment certain drugs, devices, controlled paraphernalia, and supplies and equipment described in § **54.1-3303.1**	Pharmacy	9/24/21	

EXEMPT REGULATORY ACTIONS

Legislative source	Mandate	Promulgating agency	Adoption date	Effective date
HB1988	Changes to pharmaceutical processors	Pharmacy	7/6/21	By Sept. 1st
HB2218/SB1333	Sale of cannabis botanical products	Pharmacy	7/6/21	By Sept. 1st
HB2218/SB1333	Revision of fee schedule for pharmaceutical processors and dispensaries to cover cost of new data system	Pharmacy	No planned adoption date	
SB1464	Deletion of sections of 322 with chemicals now scheduled in Code	Pharmacy	9/24/21	

NON-REGULATORY ACTIONS

Legislative source	Affected agency	Action needed	Due date
HB1304/SB830 (2020)	Pharmacy	To convene a workgroup composed of stakeholders including representatives of the Virginia Association of Chain Drug Stores, Virginia Pharmacists Association, Virginia Healthcareer Association, Virginia Society of Health-System Pharmacies, and any other stakeholders that the Board of Pharmacy may deem appropriate to develop recommendations related to the addition of duties and tasks that a pharmacy technician registered by the Board may perform.	November 1, 2021
HB2079	Pharmacy (with Medicine & VDH)	To establish protocols for the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment available over-the-counter by pharmacists in accordance with § **54.1-3303.1**. Such protocols shall address training and continuing education for pharmacists	Concurrent with emergency regulations

		regarding the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment.	
HB2079	Pharmacy (with Medicine)	To convene a work group to provide recommendations regarding the development of protocols for the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment by pharmacists to persons 18 years of age or older, including (i) controlled substances, devices, controlled paraphernalia, and supplies and equipment for the treatment of diseases or conditions for which clinical decision-making can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988, including influenza virus, urinary tract infection, and group A Streptococcus bacteria, and (ii) drugs approved by the U.S. Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy. The work group shall focus its work on developing protocols that can improve access to these treatments while maintaining patient safety.	November 1, 2021
HB2218/SB1333	Pharmacy	To work on acquisition of a new data system/analysis of costs	

Future Policy Actions:

HB2559 (2019) - requires the Secretary of Health and Human Resources to convene a work group to identify successes and challenges of the electronic prescription requirement and offer possible recommendations for increasing the electronic prescribing of controlled substances that contain an opioid and to report to the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by **November 1, 2022**.

Agenda Item: Legislative Report

Included in package:

Copies of reports required by 2021 General Assembly:

- Additional duties and tasks that a pharmacy technician may perform (HB1304 and SB830)

- Possible statewide protocols for pharmacists to initiate treatment (HB2079)

Staff note:

- No board action is required on reports.

- A verbal report on possible 2022 legislation will be provided.

Virginia Department of
Health Professions

REPORT ON DEVELOPMENT OF RECOMMENDATIONS FOR ADDITIONAL DUTIES AND TASKS THAT PHARMACY TECHNICIANS MAY PERFORM: HB1304 AND SB830

OCTOBER 19, 2021

VIRGINIA BOARD OF PHARMACY

VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS

9960 MAYLAND DRIVE, SUITE 300
HENRICO, VIRGINIA 23233-1463
(804) 367-4400
WWW.DHP.VIRGINIA.GOV

TABLE OF CONTENTS

I. EXECUTIVE SUMMARY

Pursuant to the third enactment clause of House Bill 1304 and Senate Bill 830 passed during the 2020 General Assembly Session, the Board of Pharmacy convened a work group on September 23, 2021 to develop recommendations related to the addition of duties and tasks that a pharmacy technician registered by the Board may perform.

Regarding the current pharmacist to pharmacy technician ratio, the work group voted 6:2 to decline a recommendation to eliminate the pharmacist to pharmacy technician ratio.

Regarding vaccine administration, the work group voted 7:1 to include a recommendation in this report to permanently authorize a pharmacy technician, who has obtained and maintains national certification, to administer vaccines consistent with the authority and training required under the Health and Human Services PREP Act; this would require legislative action.

Regarding product verification, the work group voted unanimously to recommend that the Board of Pharmacy further explore the subject of pharmacy technician product verification.

Regarding the ability to clarify prescriptions, the work group voted unanimously to include a recommendation in this report to allow a pharmacy technician to clarify the number of refills and drug quantity for Schedule VI new prescriptions or refill prescriptions; this would require legislative action.

Regarding the acceptance of new oral prescriptions, the work group voted 6:2 to not allow pharmacy technicians to accept new prescriptions.

Regarding the transfer of prescriptions, the work group voted unanimously to recommend that a nationally certified pharmacy technician be allowed to electronically transfer a Schedule VI refill prescription that is not an on-hold prescription when authorized by the pharmacist-in-charge; this would require either legislative or regulatory action.

Regarding the ability to take medication histories from patients, the work group voted unanimously to recommend the Board of Pharmacy clarify regulations, if necessary, to clearly authorize pharmacy technicians to independently take medication histories to include drug name, dose, and frequency.

Work Group Members

Bill Lee, DPh
Workgroup Chairman, Board of Pharmacy Member

Cheryl Nelson, PharmD
Chairman, Board of Pharmacy

Glenn Bolyard, RPh
Board of Pharmacy Member

Patricia Richards-Spruill, RPh
Board of Pharmacy Member

Jermaine Smith, PharmD
President, Virginia Association of Chain Drug Stores (VACDS)

Tana Kaefer, PharmD
Virginia Pharmacists Association

Jessica Langley, MS
Executive Director of Education and Advocacy, National Healthcareer Association

Jamin Engle, PharmD
Virginia Society of Health-System Pharmacists (VSHP)

II. PHARMACIST TO PHARMACY TECHNICIAN RATIO

The Virginia Association of Chain Drug Stores (VACDS) and the National Association of Chain Drug Stores (NACDS) requested that the current 4:1 pharmacist to pharmacy technician ratio be eliminated. There was disagreement regarding this request from several members, including the representative from the Virginia Society of Hospital Pharmacists (VSHP) and the Virginia Pharmacy Association (VPhA). The work group voted 6:2 to decline the VACDS/NACDS recommendation to eliminate the pharmacist to pharmacy technician ratio. Motion was opposed by Smith and Langley.

III. VACCINE ADMINISTRATION

There was discussion regarding the minimum age requirement of the patient receiving a vaccine, benefits of the current allowances under the Health and Human Services PREP Act for pharmacy technicians to administer vaccines to persons 3 years of age and older, and minimum training requirements. The work group voted 7:1 to include a recommendation in the legislative report to permanently authorize a pharmacy

technician, who has obtained and maintains national certification, to administer vaccines consistent with the authority and training required under the Health and Human Services PREP Act. Motion was opposed by Richards-Spruill due to concern for requiring pharmacy technician to maintain national certification.

IV. COVID-19 TESTING

There was discussion regarding the ability for a pharmacy technician to perform COVID-19 tests. Because the Virginia Board of Pharmacy has a longstanding position that the performing of CLIA-waived tests is within the scope of practice of pharmacy and that pharmacy technicians under the supervision of a pharmacist may perform CLIA-waived tests, no action was taken by the work group on this issue.

V. PRODUCT VERIFICATION

Some members of the work group commented that responsibility for any verification errors should shift to the pharmacy technician and not fall back to the supervising pharmacist. There was discussion regarding successful use of board-approved innovative pilot programs in institutional settings for product verification by pharmacy technicians with assistance of technology, e.g., medication carousels, radio-frequency identification (RFID), and bar-coding, and bedside scanning by a licensed healthcare professional. No consensus was reached. The work group voted unanimously to recommend that the Board of Pharmacy further explore the subject of pharmacy technician product verification.

VI. CLARIFYING PRESCRIPTIONS

There was consensus that an ability for a pharmacy technician to clarify prescriptions with a prescriber's office should be limited to certain required elements of a prescription and restricted to prescriptions for Schedule VI drugs only. The work group voted unanimously to include a recommendation in this report to allow a pharmacy technician to clarify the number of refills and drug quantity for Schedule VI new prescriptions or refill prescriptions.

VII. ACCEPTING NEW PRESCRIPTIONS

Many members expressed concern for pharmacy technicians accepting new oral prescriptions based on minimal educational requirements for obtaining registration. Members commented that a pharmacist assesses the clinical appropriateness of the drug as it is being communicated by the prescriber or his agent and will ask clinically probing

questions as necessary. The work group voted 6:2 to not allow pharmacy technicians to accept new oral prescriptions. Motion was opposed by Smith and Langley.

VIII. TRANSFERRING PRESCRIPTIONS

Members debated the benefits and concerns of allowing pharmacy technicians to transfer prescriptions. There is a level of oversight that a pharmacist should have when authorizing a pharmacy technician to transfer a particular prescription to ensure that the correct prescription, including current dose and dosing schedule is transferred. Discussion focused on Schedule VI drugs only (not including on-hold prescriptions), and transferring electronically or by facsimile. There appeared to be consensus that the pharmacist-in-charge could document which pharmacy technicians were authorized (qualified) to transfer certain Schedule VI prescriptions and that the list should be readily available for inspector review. The work group voted unanimously to include a recommendation in this report to allow a nationally certified pharmacy technician to electronically transfer a Schedule VI refill prescription that is not an on-hold prescription when authorized by the pharmacist-in-charge.

IX. TAKING PATIENT MEDICATION HISTORIES

It was recommended that the work group consider an ability for pharmacy technicians to take medication histories from patients. There was discussion regarding how this would differ from medication reconciliations. Staff commented that the Board has a long-standing position that pharmacy technicians may perform medication reconciliations. Engle commented that there is confusion among licensees and that perhaps clarification is all that is needed. Board counsel agreed that § 54.1-3321 of the Code of Virginia appears to already authorize pharmacy technicians to perform this task if the Board views this duty as "the entry of prescription information and drug history into a data system or other record keeping system." The work group voted unanimously to recommend the Board of Pharmacy clarify regulations, if necessary, to clearly authorize pharmacy technicians to independently take medication histories to include drug name, dose, and frequency.

Virginia Department of
Health Professions

Report on the Development of Recommendations for Possible Statewide Protocols for Pharmacists to Initiate Treatment for Tobacco Cessation and other Specific Conditions: HB2079

OCTOBER 15, 2021

VIRGINIA BOARD OF PHARMACY

VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS

9960 MAYLAND DRIVE, SUITE 300
HENRICO, VIRGINIA 23233-1463
(804) 367-4400
WWW.DHP.VIRGINIA.GOV

TABLE OF CONTENTS

I. EXECUTIVE SUMMARY

Pursuant to the fourth enactment clause of House Bill 2079 passed during the 2021 General Assembly Session, the Board of Pharmacy convened a work group on August 16, 2021 to develop recommendations for possible statewide protocols for pharmacists to initiate treatment for tobacco cessation and conditions for which CLIA-waived tests may be used to guide clinical diagnosis and treatment, including influenza, Group A Streptococcus, and urinary tract infections. Motions regarding recommendations for statewide protocols for tobacco cessation, Group A Streptococcus, and urinary tract infections failed and therefore, no recommendations resulted. A motion to not recommend a statewide protocol for treating influenza passed 3:1.

Work Group Members

Kris Ratliff, DPh
Work Group Chairman
Board of Pharmacy member*

Sarah Melton, PharmD
Board of Pharmacy member*

Jacob Miller, D.O.
Board of Medicine member*

Brenda Stokes, M.D.
Board of Medicine member*

Laurie Forlano, D.O., MPH
Deputy Director, Office of Epidemiology
Virginia Department of Health

Will Hockaday, Tobacco Control
Program/Outreach Coordinator
Virginia Department of Health

Kristin Collins, MPH
Policy Analyst Office of Epidemiology
Virginia Department of Health

Kelly Goode, PharmD, BCPS, FAPhA, FCCP
Virginia Commonwealth University School of Pharmacy

Iain Pritchard, PharmD, BCACP
Shenandoah University, Bernard J. Dunn School of Pharmacy

Zahra Raza, M.D.
Virginia Commonwealth University School of Pharmacy

John R. Lucas, D.O.
Edward Via College of Osteopathic Medicine

Michelle Thomas, PharmD, CDE, BCACP
Virginia Pharmacists Association

Wendy Klein, M.D.
Medical Society of Virginia

*Voting members

II. PHARMACIST EDUCATION AND TRAINING STANDARDS

A brief overview of pharmacist educational and training standards was provided by Dr. Goode. She indicated that 80-90% of students at VCU School of Pharmacy already have a Bachelor of Science degree upon entry into the Doctor of Pharmacy (PharmD) program. Students are taught how to perform a patient assessment, develop a plan, initiate follow-up care, and conduct motivational interviews. She outlined specific course in the curriculum relevant to the work group's discussion. She commented that students complete 2-4 + credit hour courses of didactic and clinical laboratory skills training on CLIA-waived laboratory testing regarding infectious diseases such as urinary tract infections, Strep, Influenza, and Tobacco Cessation. Dr. Goode indicated that older pharmacists who graduated with a Bachelor's of Science degree in pharmacy are well-prepared to participate in protocols, but may need some additional training in motivational interviewing techniques relative to those pharmacists who graduated with a PharmD degree.

III. PHARMACIST HEALTHCARE WORKFORCE SURVEY RESULTS

Dr. Ratliff provided a summary of the 2020 draft Pharmacist Healthcare Workforce Suvey results. He reported that 11% of pharmacists work in a non-metro area, 68% have earned a doctorate or ther professional degree, 19% have completed a PGY1 residency, 7% have completed a PGY2 residency, and 10% hold a board certification. Among those participating in collaborative practice agreements, common disease management included: anticoagulation, hypterention, hypercholesterolemia, asthma, tobacco cessation, travel medications, and diabetes.

IV. TOBACCO CESSATION

Fourteen states have laws addressing pharmacist prescribing of tobacco cessation aids without a collaborative practice agreement. The work group discussed the merits and challenges to allowing a statewide protocol for pharmacists to initiate drug therapy for tobacco cessation. Pharmacist members, along with the VDH Tobacco Control Program/Outreach Coordinator appeared to believe that additional access points could assist with the increased number of patients that are returning to smoking during the pandemic, that the state quit help line could be included in a protocol to provide support via qualified representatives with therapy skills to improve the success of quitting, and that patient harm with continued smoking would continue if access to these medications is not expanded. Physician members generally expressed the following considerations: the protocol included in the agenda packet used by another state seemed complicated; importance of follow-up within 7-21 days; a protocol should be limited to over-the-counter nicotine replacement therapy due to negative effects of the prescription-only drugs used for this purpose; desire to retain treatment option of prescribing prescription-

only drugs when patient who has failed on over-the-counter nicotine replacement therapy presents to physician; difficulty for some patients to complete a self-screening tool based on language barriers; and access to care will open up following the pandemic and telemedicine is currently increasing access.

Recommendation - No recommendation was offered by the work group.

A motion to recommend that pharmacists be authorized to initiate treatment with only over-the-counter nicotine replacement therapy failed 2:2 (motion by Dr. Stokes, seconded by Dr. Miller; opposed by Dr. Ratliff and Dr. Melton). A second motion to recommend that pharmacists be authorized to initiate treatment with both over-the-counter nicotine replacement therapy and the prescription-only drugs varenicline and bupoprion also failed 2:2 (motion by Dr. Melton, seconded by Dr. Ratliff; opposed by Dr. Stokes and Dr. Miller.

V. CONDITIONS WITH CLIA-WAIVED TESTS

A. Influenza

During discussion physician work group members generally offered the following considerations: concern for lack of training regarding physical exams and risk of misdiagnosing pneumonia; concern that protocols from other states don't include a requirement for a physical exam; risk that a protocol may encourage some patients to be seen at a pharmacy when they should be seen at an urgent care center; delays in receiving lab results may exceed window of opportunity for initiating treatment; difficulty in developing a protocol that could address all patients; and, the possibility of inappropriate prescribing of antibiotics increasing antibiotic resistance. The following considerations were generally offered by pharmacist work group members: pharmacy students minimally complete a 2-credit hour course on physical assessment training with 4 practical sessions; FDA is currently evaluating if Tamiflu should be made available over-the-counter based on its safety profile; and, a statewide protocol for pharmacists would allow patients to receive care at night and on the weekends when physician offices are often closed. Dr. Lucas offered that schools of medicine and pharmacy could collaborate regarding training for conducting physical exams, focusing on the diseases mentioned in the agenda. Dr. Forlano commented that a protocol should include antibiotic stewardship and that the pharmacist at VDH that oversees this program could serve as a resource.

Recommendation: The work group voted 3:1 to not include a recommendation for a statewide protocol for treating influenza in the work group's report (motion by Dr. Stokes, seconded by Dr. Miller; opposed by Dr. Melton).

B. Group A Streptococcus

Dr. Goode stated that pharmacists in other states are referring patients to primary care providers as appropriate and not inappropriately prescribing antibiotics. Dr. Klein expressed concern that something could be missed and that it can be difficult to identify salivary glands compared to lymph nodes. Dr. Raza stated that Group A Streptococcus is less prevalent in patients 18 years of age and older and can be more complicated.

Recommendation: No recommendation was offered by the work group. A motion to not include a recommendation for a statewide protocol for treating Group A Streptococcus in the work group's report failed 2:2 (motion by Dr. Miller, seconded by Dr. Stokes; opposed by Dr. Melton and Dr. Ratliff).

C. Urinary Tract Infections

The following comments were generally offered by physician work group members: the co-infection rate of sexually transmitted diseases for patients aged 18-45 with urinary tract infections is 20%; concern that patients may not provide a good history; symptoms for a younger patient may vary from an older patient with diabetes, prostate issues, or co-infection; concern if a protocol could appropriately address all of the variabilities; concern that pharmacists may not be able to rule out other infections; and question if urine samples would also be sent to laboratories for further analysis. The pharmacist work group members generally expressed the following: pharmacists in Canada have been doing this since 2014 and that there is good data on their program; concern for patients unnecessarily driving up healthcare costs by presenting at emergency departments or urgent care centers at night or on weekends with urinary tract symptoms that could be addressed or triaged at a pharmacy.

Recommendation: No recommendation was offered by the work group. A motion to not include in the work group's report a recommendation for a statewide protocol for treating urinary tract infections failed 2:2 (motion by Dr. Stokes, seconded by Dr. Miller; opposed by Dr. Ratliff and Dr. Melton).

Agenda Item: Petition for rulemaking:

Included in your package are:

Copy of petition from Cody Bishop

Copy of Notice on Townhall (there were no comments)

Staff note:

Refer to recommendations in the Report on Additional Duties and Tasks that can be delegated to pharmacy technicians

Board action:

To take no action (based on the need for a statutory change), or

To initiate rulemaking with publication of a NOIRA

COMMONWEALTH OF VIRGINIA
Board of Pharmacy

9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

(804) 367-4456 (Tel)
(804) 527-4472 (Fax)

Petition for Rule-making

The Code of Virginia (§ 2.2-4007) and the Public Participation Guidelines of this board require a person who wishes to petition the board to develop a new regulation or amend an existing regulation to provide certain information. Within 14 days of receiving a valid petition, the board will notify the petitioner and send a notice to the Register of Regulations identifying the petitioner, the nature of the request and the plan for responding to the petition. Following publication of the petition in the Register, a 21-day comment period will begin to allow written comment on the petition. Within 90 days after the comment period, the board will issue a written decision on the petition. If the board has not met within that 90-day period, the decision will be issued no later than 14 days after it next meets.

Please provide the information requested below. (Print or Type)

Petitioner's full name (Last, First, Middle initial, Suffix,)		
Cody M Bishop		
Street Address	**Area Code and Telephone Number**	
PO Box 690	(540)-493-1712	
City	**State**	**Zip Code**
Harrisonburg	VA	22803
Email Address (optional)	**Fax (optional)**	
Codybishop171@gmail.com		

Respond to the following questions:

1. What regulation are you petitioning the board to amend? Please state the title of the regulation and the section/sections you want the board to consider amending.

   I would like to petition for a new rule involving the Practice of Pharmacy. Under the direction and supervision of Pharmacists, Pharmacy Technicians across the state are providing Covid-19 Vaccinations, Thus showing the ability of Technicians to preform this duty.

2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule.

   The Board should authorize Pharmacy Technicians to administer all vaccinations under the supervision of a Pharmacist. The Idaho Board of Pharmacy has allowed Technicians to administer Vaccines since 2017.

   Idaho Law (According to the state's administrative rule 1.11.1B8b, "A technician II who has completed a recognized certificate training course on appropriate immunization administration technique and holds a current basic cardiopulmonary resuscitation training certificate, shall be permitted to administer vaccinations under the direct supervision and with the authorization of an immunizing pharmacist when; (1) The immunizing pharmacist has completed all of the requirements pursuant to §1.11 of this Part prior to administration of the vaccination.(2) The immunizing pharmacist is on the premises for postimmunization monitoring of the patient.")

3. State the legal authority of the board to take the action requested. In general, the legal authority for the adoption of regulations by the board is found in § 54.1-2400 of the Code of Virginia. If there is <u>other</u> legal authority for promulgation of a regulation, please provide that Code reference.

   The legal authority of the Board of Pharmacy to adopt this regulation appears in § 54.1-2400 of the Code of Virginia

Signature: Cody Bishop **Date:** 08/26/2021

Virginia.gov Agencies | Governor

Secretariat **Health and Human Resources**

Agency **Department of Health Professions**

Board **Board of Pharmacy**

Edit Petition

Petition 351

Petition Information	
Petition Title	Administration of vaccines by pharmacy technicians
Date Filed	8/30/2021 [Transmittal Sheet]
Petitioner	Cody Bishop
Petitioner's Request	To amend regulations to authorize pharmacy technicians to administer all vaccinations under the supervision of a pharmacist
Agency's Plan	Pharmacy technicians are allowed to administer COVID-19 vaccinations because of legislation passed by the General Assembly authorizing administration by certain "non-traditional" vaccinators. It is likely the amendment requested will necessitate a permanent change in the Code in Virginia, specifically in § 54.1-3408, which allows prescribers to authorize pharmacists and nurses to administer adult vaccines under a protocol. There is no mention of authorization for pharmacy technicians. Pursuant to legislation passed in the 2021 Special Session of the General Assembly, a workgroup is meeting on September 24th to discuss possible of expansion of duties for pharmacy technicians. The petition will be included in the agenda for the workgroup. In accordance with Virginia law, the petition has been filed with the Register of Regulations and will be published on September 27, 2021. Comment on the petition may be sent by email, regular mail or posted on the Virginia Regulatory Townhall at **www.townhall.virginia.gov**; comment will be requested until October 27, 2021. If the Board does not have statutory authority to amend its regulations in accordance with your petition, it will decide whether it would support a change in the Code of Virginia. This matter will be on the Board's agenda for its next meeting following the close of comment, scheduled for December 7, 2021.
Comment Period	Ended 10/27/2021 0 comments
Agency Decision	Pending

Contact Information	
Name / Title:	Caroline Juran, RPh / *Executive Director*
Address:	9960 Mayland Drive Suite 300 Richmond, 23233
Email Address:	caroline.juran@dhp.virginia.gov

Request for Comment on Petition for Rulemaking

Promulgating Board: **Board of Pharmacy**

Regulatory Coordinator:	Elaine J. Yeatts (804)367-4688 elaine.yeatts@dhp.virginia.gov
Agency Contact:	Caroline Juran, RPh Executive Director (804)367-4456 caroline.juran@dhp.virginia.gov
Contact Address:	Department of Health Professions 9960 Mayland Drive; Suite 300 Richmond, VA 23233

Regulations Governing the Practice of Pharmacy

Statutory Authority: State: Chapters 33 and 34 of Title 54.1

Date Petition Received 08/30/2021

Petitioner Cody Bishop

Petitioner's Request

To amend regulations to authorize pharmacy technicians to administer all vaccinations under the supervision of a pharmacist

Agency Plan

Pharmacy technicians are allowed to administer COVID-19 vaccinations because of legislation passed by the General Assembly authorizing administration by certain "non-traditional" vaccinators. It is likely the amendment requested will necessitate a permanent change in the Code in Virginia, specifically in § 54.1-3408, which allows prescribers to authorize pharmacists and nurses to administer adult vaccines under a protocol. There is no mention of authorization for pharmacy technicians. Pursuant to legislation passed in the 2021 Special Session of the General Assembly, a workgroup is meeting on September 24th to discuss possible of expansion of duties for pharmacy technicians. The petition will be included in the agenda for the workgroup. In accordance with Virginia law, the petition has been filed with the Register of Regulations and will be published on September 27, 2021. Comment on the petition may be sent by email, regular mail or posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov; comment will be requested until October 27, 2021. If the Board does not have statutory authority to amend its regulations in accordance with the petition, it will decide whether it would support a change in the Code of Virginia. This matter will be on the Board's agenda for its next meeting following the close of comment, scheduled for December 7, 2021.

Publication Date 09/27/2021 *(comment period will also begin on this date)*

Comment End Date 10/27/2021

Agenda Item: **Regulatory Action – Adoption of Final Regulations**

Scheduling Chemicals in Schedule I - Exempt action

Included in agenda package:

Copy of Notice of Public Hearing listing chemicals to be scheduled in Schedule I

Amendments to regulation: 18VAC110-20-322

Staff Note:

A public hearing was conducted before the meeting this morning.

Action is exempt from the provisions of the Administrative Process Act in accordance with § 2.2-4006.

Board action:

Adoption of final regulation in sections 322

Notice of Public Hearing

Pursuant to subsection D of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act. The public hearing will be conducted at **9:05 a.m. on December 7, 2021.**

Pursuant to article § 54.1-3443(D), The Virginia Department of Forensic Science (DFS) has identified five (5) compounds for recommended inclusion into the Code of Virginia.

The following compounds are classified as synthetic opioids. Compounds of this type have been placed in Schedule I (§ 54.1-3446(1)) in previous legislative sessions.

1. **1-(4-cinnamyl-2,6-dimethylpiperazin-1-yl)propan-1-one (other name: AP-238),** its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

Based on its chemical structure, the following compound is expected to have hallucinogenic properties. Compounds of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

2. **4-methallyloxy-3,5-dimethoxyphenethylamine (other name: Methallylescaline),** its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. **alpha-pyrrolidino-2-phenylacetophenone (other name: alpha-D2PV),** its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The following compounds are classified as cannabimimetic agents. Compounds of this type have been placed in Schedule I (§ 54.1-3446(6)) in previous legislative sessions.

4. **ethyl 2-[1-pentyl-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: EDMB-PINACA)**, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

5. **N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-phenethyl-1H-indazole-3-carboxamide (other name: ADB-PHETINACA)**, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

Project 6922 - Final

Board Of Pharmacy

Deletion of scheduling of certain chemicals now scheduled in Schedule I in the Code

18VAC110-20-322. Placement of chemicals in Schedule I.

A. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

~~1. Synthetic opioids.~~

~~a. N-[2-(dimethylamino)cyclohexyl]-N-phenylfuran-2-carboxamide (other name: Furanyl UF-17), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.~~

~~b. N-[2-(dimethylamino)cyclohexyl]-N-phenylpropionamide (other name: UF-17), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.~~

~~2. Research chemicals.~~

~~a. 5-methoxy-N,N-dibutyltryptamine (other name: 5-methoxy-DBT), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~b. 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-butanone (other name: Eutylone, bk-EBDB), its optical, position, and geometric isomers, salts, and salts of isomers~~

~~whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~c. 1-(1,3-benzodioxol-5-yl)-2-(butylamino)-1-pentanone (other name: N-butylpentylone), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~d. N-benzyl-3,4-dimethoxyamphetamine (other name: N-benzyl-3,4-DMA), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~e. 3,4-methylenedioxy-N-benzylcathinone (other name: BMDP), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~3. Cannabimimetic agents.~~

~~a. Ethyl 2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoate (other name: EMB-FUBINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~b. Methyl 2-[1-4-fluorobutyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: 4-fluoro-MDMB-BUTINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~The placement of drugs listed in this subsection shall remain in effect until June 10, 2021, unless enacted into law in the Drug Control Act.~~

~~B. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:~~

~~1. Synthetic opioids.~~

~~a. N-phenyl-N-[1-(2-phenylmethyl)-4-piperidinyl]-2-furancarboxamide (other name: N-benzyl Furanyl norfentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.~~

~~b. 1-[2-methyl-4-(3-phenyl-2-propen-1-yl)-1-piperazinyl]-1-butanone (other name: 2-methyl AP-237), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.~~

~~2. Research chemicals.~~

~~a. N-hexyl-3,4-dimethoxyamphetamine (other names: N-hexyl-3.4-DMA), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~b. N-heptyl-3,4-dimethoxyamphetamine (other names: N-heptyl-3.4-DMA), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~c. 2-(isobutylamino)-1-phenylhexan-1-one (other names: N-Isobutyl Hexedrone, α-isobutylaminohexanphenone), its optical, position, and geometric isomers, salts, and~~

~~salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~d. 1-(benzo[d][1,3]dioxol-5-yl)-2-(sec-butylamino)pentan-1-one (other name: N-sec-butyl Pentylone), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~e. 2-fluoro-Deschloroketamine (other name: 2-(2-fluorophenyl)-2-(methylamino)-cyclohexanone), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~3. Cannabimimetic agents.~~

~~a. Methyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-methylbutanoate (other name: MMB-2201), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~b. Methyl 2-[1-(4-penten-1-yl)-1H-indole-3-carboxamido]-3-methylbutanoate (other names: MMB022, MMB-4en-PICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~c. Methyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-phenylpropanoate (other name: 5-fluoro-MPP-PICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

d. 1-(5-fluoropentyl)-N-(1-methyl-1-phenylethyl)-1H-indole-3-carboxamide (other name: 5-fluoro CUMYL-PICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until February 4, 2022, unless enacted into law in the Drug Control Act.

C. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. Synthetic opioids.

a. N-phenyl-N-(4-piperidinyl)-propanamide (other name: Norfentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

b. N,N-diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine (other name: Isotonitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Research chemicals.

a. (2-ethylaminopropyl)benzofuran (other name: EAPB), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 2-(ethylamino)-1-phenylheptan-1-one (other name: N-ethylheptedrone), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence

~~of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~c. 4-ethyl-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (other name: 25E-NBOH), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~d. 4-hydroxy-N-ethyl-N-propyltryptamine (other name: 4-hydroxy-EPT), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~e. N-ethyl-1-(3-hydroxyphenyl)cyclohexylamine (other name: 3-hydroxy-PCE), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~f. 1-cyclopropionyl lysergic acid diethylamide (other name: 1cP-LSD), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~g. 1-(4-methoxyphenyl)-N-methylpropan-2-amine (other names: para-Methoxymethamphetamine, PMMA), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~3. Cannabimimetic agents.~~

~~a. Methyl 2-[1-(pent-4-enyl)-1H-indazole-3-carboxamindo]-3,3-dimethylbutanoate (other name: MDMB-4en-PINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~b. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butylindazole-3-carboxamide (other name: ADB-BUTINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~c. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-chloropentyl)indazole-3-carboxamide (other name: 5-chloro-AB-PINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~d. Methyl 2-({1-[(4-fluorophenyl)methyl]-1H-indole-3-carbonyl}amino)-3-methylbutanoate (other names: MMB-FUBICA, AMB-FUBICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~The placement of drugs listed in this subsection shall remain in effect until May 24, 2022, unless enacted into law in the Drug Control Act.~~

~~D. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:~~

1. Synthetic opioid. N,N-diethyl-2-[(4-methoxyphenyl)methyl]-1H-benzimidazole-1-ethanamine (other name: Metodesnitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Compounds expected to have hallucinogenic properties.

a. 4-fluoro-3-methyl-alpha-pyrrolidinovalerophenone (other name: 4-fluoro-3-methyl-alpha-PVP), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 4-fluoro-alpha-methylamino-valerophenone (other name: 4-fluoropentedrone), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers (optical, position, and geometric), and salts of isomers is possible within the specific chemical designation.

c. N-(1,4-dimethylpentyl)-3,4-dimethoxyamphetamine (other name: N-(1,4-dimethylpentyl)-3,4-DMA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers (optical, position, and geometric), and salts of isomers is possible within the specific chemical designation.

d. 4,5-methylenedioxy-N,N-diisopropyltryptamine (other name: 4,5-MDO-DiPT), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers (optical, position, and geometric), and salts of isomers is possible within the specific chemical designation.

e. Alpha-pyrrolidinocyclohexanophenone (other name: alpha-PCYP), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers (optical, position, and geometric), and salts of isomers is possible within the specific chemical designation.

f. 3,4-methylenedioxy-alpha-pyrrolidinoheptiophenone (other name: MDPV8), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers (optical,

~~E.~~ B. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. Synthetic opioids.

a. 1-{1-[1-(4-bromophenyl)ethyl]-4-piperidinyl}-1,3-dihydro-2H-benzimidazol-2-one (other name: Brorphine), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

b. N-(4-chlorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other names: para-chlorofentanyl, 4-chlorofentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

c. 2-[(4-methoxyphenyl)methyl]-N,N-diethyl-5-nitro-1H-benzimidazole-1-ethanamine (other name: Metonitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

d. N,N-diethyl-2-{[(4-ethoxyphenyl) methyl]-1H-benzimidazol-1-yl}-ethan-1-amine (other name: Etazene, Desnitroetonitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Depressant.

5-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one (other name: Meclonazepam), its salts, isomers, and salts of isomers whenever the existence

of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Cannabimimetic agent.

Ethyl-2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 5-fluoro EDMB-PICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until December 23, 2022, unless enacted into law in the Drug Control Act.

~~F.~~ C. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. Compound expected to have hallucinogenic properties.

4-chloro-alpha-methylaminobutiophenone (other name: 4-chloro Buphedrone), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

2. Cannabimimetic agents.

a. Ethyl-2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3-methylbutanoate (other names: 5-fluoro-EMB-PINACA, 5F-AEB), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-enyl)indazole-3-carboxamide (other name: ADB-4en-PINACA), its salts, isomers, and salts of isomers whenever the

existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until March 14, 2023, unless enacted into law in the Drug Control Act.

D. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. Synthetic opioid.

1-(4-cinnamyl-2,6-dimethylpiperazin-1-yl)propan-1-one (other name: AP-238), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

2. Compounds expected to have hallucinogenic properties.

a. 4-methallyloxy-3,5-dimethoxyphenethylamine (other name: Methallylescaline), its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. alpha-pyrrolidino-2-phenylacetophenone (other name: alpha-D2PV), its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Cannabimimetic agents.

a. ethyl 2-[1-pentyl-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: EDMB-PINACA), its salts, isomers, and salts of isomers whenever the existence of

position, and geometric), and salts of isomers is possible within the specific chemical designation.

3. Compounds expected to have depressant properties.

a. Bromazolam, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. Deschloroetizolam, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

c. 7-chloro-5-(2-fluorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one (other name: Norfludiazepam), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

4. Cannabimimetic agents.

a. Methyl 2-[1-(4-fluorobutyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 4-fluoro-MDMB-BUTICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. Ethyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-methylbutanoate (other name: 5-fluoro-EMB-PICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until October 27, 2022, unless enacted into law in the Drug Control Act.

such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-phenethyl-1H-indazole-3-carboxamide (other name: ADB-PHETINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

Agenda Item: Periodic Review of Chapters 20, 21, 30, 40, and 50

Included in Agenda Package:

- Draft decisions for Chapters 20, 21, 30, regarding regulatory sections that the Board will consider amending during the current periodic review
- No regulatory sections have been identified in Chapters 40 and 50

Staff note:

The amendments recommended by the Committee with be included in the Report of Findings for each chapter. Those reports will then be distributed to interested parties on the Board's Public Participation Guidelines list for an opportunity to offer additional amendments or comment on the recommendations. At its March meeting, the Board will need to promulgate amendments by either a fast-track action or publication of a Notice of Intended Regulatory Action.

Board Action:

Motion to report the result of its periodic review of Chapters 20, 21, and 30 with a decision to continue the chapters with amendments and the result of its periodic review of Chapters 40 and 50 with a decision to continue without amendment.

Periodic Review

Chapter 20: Regulations Governing the Practice of Pharmacy

Decision

Explain the basis for the promulgating agency's decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).

The Board will amend the regulation. While there was no public comment on this chapter resulting from the Notice of Periodic Review, the Board has identified several sections that it will consider for amendments:

- Section 10, amend definition of "personal supervision" to allow audio-visual technology to supervision of compounding in retail pharmacies
- Section 25, amend the unprofessional conduct section to add language about acting in a manner that causes an individual to feel threatened or intimidated so that such individual is discouraged from reporting a public safety concern in good faith or is discouraged from cooperating with an employee of the Department of Health Professions in the conduct of an investigation or inspection.
- Section 110, amend to address appropriate opportunities for uninterrupted rest periods and meal breaks which may or may not require the pharmacy to close.
- Section 110, amend to include additional information to be required on a pharmacy permit or nonresident pharmacy registration application and include a requirement to notify board of any changes within timeframe consistent with current laws.
- 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.
- Including a requirement for an e-profile identification number for facilities
- Extending timeframe beyond 14 days for notification of a change in the PIC
- Section 275, subsections B, C, and F, consider including exemption to requirement for returning to initiating pharmacy any prescriptions not delivered to the patient if prohibited under federal law.
- Section 275, amend to include record requirement for an alternate delivery site further delivering the drug to a patient's home.
- Section 290, consider amendment to provision that allows dispensing of a Schedule II drug for up to six months after the date on which the prescription was issued
- Section 550, amend 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
- Subsection J of Section 110 to require an applicant for a pharmacy permit to report to the Board any prior disciplinary action by a regulatory authority, prior criminal convictions, or ongoing investigations related to the practice of pharmacy
- Section 690 to prohibit controlled substance registration from being issued to private dwelling or residence just as there is a current prohibition on such issuance of a pharmacy permit.
- Clarifying expectation regarding administration records, particularly if drug administered by someone other than the pharmacist whose initials are captured on the dispensing record.

•

After further opportunity for comment and recommendations for amendments, the Board will publish a Notice of Intended Regulatory Action.

Chapter 21: Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians

Decision

Explain the basis for the promulgating agency's decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).

The Board will amend the regulation. While there was no public comment on this chapter resulting from the Notice of Periodic Review, the Board has identified at least two sections that it will consider for amendments:

- Section 80, to include a prohibition on taking the board-approved integrated pharmacy examination when the candidate fails to pass on five occasions.
- Section 80, to authorize the Board to delegate to the National Association of Boards of Pharmacy 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.
- Section 90 to clarify the requirement for FPGEC. A FPGEC is the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign Pharmacy Equivalency Examination and a credential review of foreign training to establish educational equivalency to board approved schools of pharmacy and has passed approved examinations establishing proficiency in English.

After further opportunity for comment and recommendations for amendments, the Board will publish a Notice of Intended Regulatory Action.

Chapter 30: Regulations Governing Physicians Selling Drugs

Decision

Explain the basis for the promulgating agency's decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).

The Board will amend the regulation. While there was no public comment on this chapter resulting from the Notice of Periodic Review, the Board has identified at least one section that it will consider for amendments:

- Insertion of requirements, similar to other facilities permitted by the Board of Pharmacy, to declare hours of operation the location will be open to service the public

and report changes in the hours of operation expected to last for more than one week to the board and the public at least 14 days prior to the anticipated change. Include exemptions for emergency circumstances beyond control of the owner or responsible party or expansion of hours.

After further opportunity for comment and recommendations for amendments, the Board will publish a Notice of Intended Regulatory Action.

Agenda Item: Consideration of Final Regulations – Medication carousels

Included in your agenda package are:

Notice from the Va. Regulatory Townhall

Copy of comments on proposed regulations

A copy of the proposed regulations with amendments recommended by the Regulation Committee in [brackets]

Board action:

To adopt recommended amendments and re-propose the regulation

Virginia.gov Agencies | Governor

VIRGINIA REGULATORY TOWN HALL

Agency **Department of Health Professions**

Board **Board of Pharmacy**

Chapter **Regulations Governing the Practice of Pharmacy [18 VAC 110 - 20]**

Action: Use of medication carousels and RFID technology

Proposed Stage

Action 5480 / Stage 9236

Edit Stage | Withdraw Stage | Go to RIS Project

Documents		
Proposed Text	8/10/2021 9:52 am	Sync Text with RIS
Agency Background Document	3/24/2021	Upload / Replace
Attorney General Certification	4/19/2021	
DPB Economic Impact Analysis	6/2/2021	
Agency Response to EIA	7/22/2021	Upload / Replace
Governor's Review Memo	7/22/2021	
Registrar Transmittal	7/22/2021	

Status	
Incorporation by Reference	No
Exempt from APA	No, this stage/action is subject to Article 2 of the *Administrative Process Act*
Attorney General Review	Submitted to OAG: 3/24/2021 Review Completed: 4/19/2021 Result: Certified
DPB Review	Submitted on 4/19/2021 Economist: Jini Rao Policy Analyst: Jerry Gentile Review Completed: 6/2/2021
Secretary Review	Secretary of Health and Human Resources Review Completed: 7/5/2021
Governor's Review	Review Completed: 7/22/2021 Result: Approved
Virginia Registrar	Submitted on 7/22/2021 The Virginia Register of Regulations Publication Date: 8/16/2021 Volume: 37 Issue: 26
Public Hearings	**09/24/2021 9:10 AM**
Comment Period	**Ended 10/15/2021** **2 comments**

Virginia.gov Agencies | Governor

Export to PDF Export to Excel

Agency **Department of Health Professions**

Board **Board of Pharmacy**

Chapter **Regulations Governing the Practice of Pharmacy [18 VAC 110 - 20]**

Action	**Use of medication carousels and RFID technology**
Stage	**Proposed**
Comment Period	Ends 10/15/2021

2 comments

All good comments for this forum **Show Only Flagged**

Back to List of Comments

Commenter: Tyler Martinson Sentara Virginia Beach General Hospital 8/17/21 11:59 am

Fully Support amendments

After reviewing the amendments, I fully support this regulation change to bring Virginia into line with many other states that already allow the use of both technologies. This regulation will allow us to apply the skills of our technicians to make sure we provide the correct drugs and free up pharmacists to assist with more clinical based needs of our patients. We have been using RFID tagging for our OR/Code carts/RSI boxes as a pilot program for over 5 years and never had any safety issues. The scanning technology within carousels, and ADDs, has grown significantly, and barcode scanning by nursing prior to administration is a Leap Frog measure that will make sure our nursing partners are validating for patient safety. Thank you for the work you do and moving Virginia pharmacy in the correct direction!

CommentID: **99769**

Commenter: Catherine Floroff - Sentara Norfolk General Hospital 8/22/21 2:59 pm

Support this regulation

I fully support this regulation change. It is in line with the skills of our technician staff. This would allow the pharmacist to assist with more complex, clinical needs. We have been using RFID tagging for our OR/Code carts/RSI boxes as a pilot program for over 5 years and never had any errors or safety issues.

CommentID: **99858**

Virginia.gov Agencies | Governor

VIRGINIA REGULATORY TOWN HALL

Agency **Department of Health Professions**

Board **Board of Pharmacy**

Chapter **Regulations Governing the Practice of Pharmacy [18 VAC 110 - 20]**

Action: Use of medication carousels and RFID technology

Proposed Stage

Action 5480 / Stage 9236

Edit Stage | Withdraw Stage | Go to RIS Project

Documents		
Proposed Text	8/10/2021 9:52 am	Sync Text with RIS
Agency Background Document	3/24/2021	Upload / Replace
Attorney General Certification	4/19/2021	
DPB Economic Impact Analysis	6/2/2021	
Agency Response to EIA	7/22/2021	Upload / Replace
Governor's Review Memo	7/22/2021	
Registrar Transmittal	7/22/2021	

Status	
Incorporation by Reference	No
Exempt from APA	No, this stage/action is subject to Article 2 of the *Administrative Process Act*
Attorney General Review	Submitted to OAG: 3/24/2021 Review Completed: 4/19/2021 Result: Certified
DPB Review	Submitted on 4/19/2021 Economist: Jini Rao Policy Analyst: Jerry Gentile Review Completed: 6/2/2021
Secretary Review	Secretary of Health and Human Resources Review Completed: 7/5/2021
Governor's Review	Review Completed: 7/22/2021 Result: Approved
Virginia Registrar	Submitted on 7/22/2021 The Virginia Register of Regulations Publication Date: 8/16/2021 Volume: 37 Issue: 26
Public Hearings	09/24/2021 9:10 AM
Comment Period	Ended 10/15/2021 2 comments

Contact Information	
Name / Title:	Caroline Juran, RPh / *Executive Director*
Address:	9960 Mayland Drive Suite 300 Richmond, VA 23233-1463
Email Address:	**caroline.juran@dhp.virginia.gov**
Telephone:	(804)367-4456 FAX: (804)527-4472 TDD: ()-

This person is the primary contact for this chapter.

This stage was created by Elaine J. Yeatts on 03/24/2021 at 9:00am
This stage was last edited by Elaine J. Yeatts on 03/24/2021 at 9:00am

Comment - Public hearing
Medication carousels

Virginia Society of Health-System Pharmacists
3015 N Shannon Lakes Dr, #303
Tallahassee, FL 32309
Phone (850) 906-0779
Fax (678) 401-0259

September 23, 2021

Ms. Caroline Juran
Executive Director, Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233

Dear Ms. Juran:

On behalf of the Virginia Society of Health-System Pharmacists (VSHP), this written comment is to provide a high level overview of medication carousel technology and its role within the health-system pharmacy environment, as well as to clarify our requests for considerations for the Board to review.

We hope to provide more insight to the efficiencies and patient safety strategies that are availability from this technology to mitigate potential errors stemming from inventory, filling and dispensing process.

We also include requests of the Board of Pharmacy to consider proposed revised language with regards to the proposed regulatory language for **18VAC110-20-425**. Robotic pharmacy systems concerning medication carousel technology.

Medication Carousel Technology

This type of automated technology utilizes barcode scanning technology and electronic interfaces for safe and accurate storage, filling, and final verification of medications for dispensing. A summary comparison of specific actions and technology functions are described below. For more detailed steps, please refer to Appendix A, which includes language included in an approved pilot by the Board.

Using Carousel Technology	Without Using Carousel Technology
Inventory Management	
□ Maintains electronic inventory with associated min/max inventory levels	□ On-hand inventory is manual and often on paper.
□ Since inventory is electronic, items are separated throughout the carousel in individually located bins, and not side-by-side.	□ Items are located on shelves, often in alphabetical order.
□ Inventory may also include electronic tracking of expiration dating.	□ Expiration dating is manually tracked.
Medication Procurement	
□ Reordering occurs through electronic interface with wholesaler for products below suggested MIN levels	□ Reordering occurs through assessing inventory manually, and then entering each item into ordering system.

Using Carousel Technology	Without Using Carousel Technology
□ Once ordered, there is an electronic purchase order receiving process for what was ordered, and what is fulfilled by the wholesaler.	□ Purchase order, invoices, and receiving is manually verified.
□ When receiving the order, staff scan the individual product, and the carousel spins to the appropriate shelf and indicates location of bin to restock/receive the medication.	□ Items are placed back into appropriate bins without any barcode validation.
□ Staff electronically receive the medication to adjust inventory levels, and load the medication into the indicated location.	
Medication Dispensing for Restock or Patient-Specific	
□ Automated Dispensing Cabinets and Electronic Health Systems interface with carousels to indicate needed medication.	□ Items needed for dispensing are indicated by physical labels or paper reports.
□ The carousel spins to the appropriate shelf and indicates location of bin for staff to pick medications.	□ Staff go to the location of the medication, and manually match the label to the medication.
□ Staff remove the medication quantity and visually inspects the medication for integrity and expiration date.	□ Staff remove the medication quantity and visually inspects the medication for integrity and expiration date.
□ Staff scan the barcode of the product, which validates the accuracy of the medication and adjusts the electronic inventory.	□ There is no barcode validation that the correct product was obtained.
□ The technician then places the medication in the plastic bag with the label and provides it to the pharmacist for verification.	□ The technician then places the medication in the plastic bag with the label and provides it to the pharmacist for verification.
If dispensed to the **patient**, the medication is then administered by a nurse or other licensed health professional as defined by their scope of practice. This may or may not include a barcode scanning requirement. Note that per administration requirements, any health care professional that administers a drug should be performing the appropriate review regarding the rights of administration (i.e., right patient, right drug, right dose, right time, right route, right indication, and right documentation). Many health-systems have adopted barcode scanning technology for administration as another layer of safety.	
If dispensed to the **automated dispensing cabinet**, the pharmacy technician refilling the automated dispensing cabinet scans the drug prior to filling each pocket/ drawer. Upon refiling they perform a visual inspection of inventory being added to the pocket/drawer and existing inventory to ensure medication accuracy and that there are no expired medications. Only designated healthcare professionals may access these medications.	

NOTE: When a community pharmacy utilizes barcode technology for filing medications, each tablet or capsule is not "scanned," as the bottle is usually scanned. Visual inspection is still expected by the pharmacy technician and pharmacist at each of these steps to ensure the accuracy of medication prepared and dispensed. In addition, upon returning unused stock to the original bottle, there is no scanning involved; visual inspection is how the correct tablet or capsule is returned to the original bottle. We believe that the multiple layers of checks from the point of ordering, restocking, filling, dispensing, and ultimate verification by a licensed healthcare professional authorized to administer medications complement safety checks within the medication use system.

Advantages Of Utilizing Carousel Technology

1. Patient Safety
    - Utilization of barcode technology at receiving, restocking, and patient order fulfillment ensures accurate medication distribution processes
        - This technology allows utilization of barcodes from receiving through administration.
    - Electronic inventory and dispensing allow for:
        - Separating different concentrations of the same medication
        - Separating sound-alike or look-alike medications (thus you are not defined by having to store medications in alphabetical order)
        - Limited access to entire inventory compared to inventory located on shelves
    - Password-protected access allows for security and traceability: pharmacists and pharmacy technicians must log onto the medication carousel technology to log their actions
    - Controlled database management allows for safe ordering and dispensing through accurate medication and barcode inputs

2. Inventory Management
    - Integration with wholesaler to improve accurate order of medications (for example, the system can order up to the designated MAX/PAR and submit through the medication carousel technology, eliminating the need for a pharmacy technician to manually enter in the order, thus make errors. This function has been critical to staying abreast with drug shortage management)
    - Real-time inventory management
    - Simplified barcode restocking
    - Reduction of inventory waste by allowing for analytical review of inventory turns and expiration dating
    - Cycle Counting: During downtimes, pharmacy technicians will review assigned medication bins and assess accuracy of the quantity in the system as well as review for expired medications for removal. This ensures the medication stored in the bin matches what is designated by the medication carousel technology.

3. Efficient Use of Limited Space
    - Vertical carousel spinning allows for more medications in a confined space as well as improved design to access of fast-mover vs. slow-mover medications

VSHP respectfully asks the following:

ASK#1: Amend and approve the proposed language, per the recommendation below. VSHP supports the Board's intent to bring the practices and experiences through the pilots on medication carousel technology into regulation as the technology is widely utilized across many health-systems. Based on the discussions so far, we believe that the language as written supports *specific* health-systems who are able to scan every single unit bar code per medication order for patient-specific orders or refilling automated dispensing cabinets.

There is one clarification to the medication administration language that VSHP would like the Board to consider:

- Section C, Subsection 2, Statement b and Section C, Subsection 3, Statement b: replace "a nurse or other person authorized to administer drug scans each drug unit using barcode technology to verify the accuracy of the drug prior to administration of the drug to the patient" with **"a nurse or other person authorized to administer medications, will verify the accuracy of the drug prior to administration of the drug to the patient according to their scope of practice."**

Reasoning:

- Many institutions have adopted bedside barcode scanning medication administration technology as an added error mitigation strategy in addition to the current requirements of medication verification prior to administration. In addition, there may be scenarios where the nurse may be withdrawing a medication in the event of an emergent event such as a Code Blue, and there is no time for medication scanning. They are still required to review the 7 rights of administration prior to administration.
- This recommended language reflects the current state where the barcode is the validation of accuracy by a pharmacist within medication carousel technology. Pilots have been able to demonstrate the safety utilizing the barcode scanning elements performed by a pharmacy technician to validate the accuracy of the medication product for the order in lieu of the visual inspection by a pharmacist.

ASK#2: Although we support the Board of Pharmacy's efforts, we believe that there is still opportunity to amend the language to support feasibility for all health-system pharmacy practice.

To make this applicable for all hospitals, we recommend adding the following language to the following sections:

- Section C, Subsection 2, Statement c: 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 or other person authorized to administer the drug then provides the medication administration. Bar code scan verification at the point of administration is encouraged, but not required.

- Section C, Subsection 3, Statement c: The drug removed from the medication carousel is verified for accuracy first through visual inspection followed by the pharmacy technician by scanning an individual unit dose of the automated drug dispensing system restock order prior to leaving the pharmacy and delivering the drug to the automated drug dispensing system or distributed to another entity, and a nurse or other person authorized to administer the drug then provides the medication administration. Bar code scan verification at the point of administration is encouraged, but not required. In this case, an individual unit dose of the restock order must be scanned prior to restocking to the automated drug dispensing system pocket or drawer prior to withdrawal by a nurse or other person authorized to administer the drug for medication administration.

Reasoning: Our concerns stem from the undue burden of the requirement to scan every single unit dose.

- The requirement to scan every single barcode is not realistic for health-systems with larger order volumes. For instance, if a health-system dispenses an average of 14,000 doses per day for inpatient and ambulatory units, and each patient-specific or restock order has 2 to 20 unit doses, the range in volume for scanning can increase to the range of 28,000 to 280,000 scans per day, requiring additional hours from a pharmacy technician to support this model.
- Bar code scanners are not ergonomically designed for high volume, consecutive scanning such as scanning 20 unit doses of a medication order. This may lead to higher incidences of hand injuries within the workplace and may cause long-term damage such as carpel tunnel syndrome.
- This requirement may also lead to alert fatigue. This may redirect the pharmacy technician's attention from the visual inspection elements to ensuring that the correct number is scanned; or encourage workarounds due to human factors engineering elements for higher volume processes.

- Medications dispensed from medication carousel technology are ultimately administered by a licensed healthcare professional who must perform the 7 rights of administration as part of their scope of practice for medication administration. The use of barcode scanning technology is another added "forcing function" strategy that most health-systems have adopted for added patient safety strategies. Note that additional administration strategies at the point of administration include independent double checks (by another licensed healthcare professional) or requirements for provider-level administration for certain high alert medications.

We would like to further emphasize the current strategies <u>already employed</u> to ensure patient safety:

- Pharmacist validates barcode of a medication prior to its addition into inventory
    - Note: Verification by scanning the bar code has been demonstrated to be more accurate than visual inspection by the human eye.
- Medication restocking – information for restocking is already automated, allowing for technician scanning and visual inspection of accuracy, quantity, and expiration dating
- Medication storage – medications that can be potentially confused (such as different concentrations of the same medications, sound alike or look alike medications) can be physically separated and do not need to be stored next to each other
- Intentional medication filling processes: Medication orders are filled each drug at a time
- Medication inventory management: cycle counting practices
- Analytical reporting – cycle count, expired medications and near misses reporting are possible reporting functions for quality improvement opportunities
- Medications dispensed from medication carousels are administered by licensed healthcare professionals when intended for patient-specific orders and automated dispensing system fills

<u>ASK#3:</u> We understand the Board's role in protecting the public within the medication use process.

We also recommend the additional language to support the quality assurance strategies to ensure patient safety. In addition to the pharmacist 5% check, we recommend the following additions if the previous addition is supported:

- <u>Section C, Subsection 6:</u> The hospital will also perform quality assurance surveillance to ensure the integrity of the medication carousel process by performing at a minimum monthly cycle counts (which include confirmation of the correct drug in the storage bin, correct quantity and appropriate expiration dating). A manual or electronic record from which information can be readily retrieved, shall be maintained that includes:
    - a. The date of verification
    - b. A description of all discrepancies identified, if any; and
    - c. The initials of pharmacist or pharmacy technician verifying the accuracy of the process.

- <u>Section C, Subsection 7:</u> If the hospital is utilizing this process to restock automated drug dispensing systems, a pharmacist or pharmacy technician shall perform a monthly random check for verification of the accuracy of 5% of drugs dispensed to an automated drug dispensing system. A manual or electronic record from which information can be readily retrieved, shall be maintained that includes:
    - a. The date of verification
    - b. A description of all discrepancies identified, if any; and
    - c. The initials of pharmacist or pharmacy technician verifying the accuracy of the process.

As described previously, medication carousel technology adds additional layers of safety, allowing for accurate dispensing when the barcode scanning is utilized during the medication restocking process, filling process, and verification process.

Thus, we strongly encourage the Board to consider the implications of the current language of the proposed regulations on medication carousel technology and its impact to all health-system pharmacies across the Commonwealth of Virginia.

We appreciate the Board's consideration of amendments to incorporate changes currently in approved as pilots for medication carousel technology and its application to all hospitals within the Commonwealth of Virginia.

Sincerely,

Craig Kirkwood, PharmD, MS

Virginia Society of Health-System Pharmacists (VSHP) President

Appendix A

1. Method of ensuring accurate packaging and loading of the carousel

1. Upon receiving the daily medication purchase order, the Purchaser signs for the product and sequesters it from the current pharmacy inventory. Purchases are already segregated by tote as to which inventory location it will eventually go to.
2. The purchaser or a pharmacy technician scans each medication to ensure that it is scanable and recognized in the pharmacy's medication database.
    a. If the drug is recognized by the scanner and is found in the pharmacy medication database, this medication is then ready to move to step 3.
    b. If the drug is not recognized by the scanner or is not found in the pharmacy medication database, a pharmacist is contacted.
        i. If it is a completely new product, the IS Pharmacist must be contacted to build the new drug entry into the medication database.
        ii. If it is a new barcode of an existing product (example: new generic manufacturer), a pharmacist can link the new barcode to an existing medication in the database.
3. After the product has been identified by the scanner, it is placed in the pharmacy inventory:
    a. If the product is packaged and can be scanned at the product's lowest unit of measure (LUM), then it is ready to move to step 4.
    b. For bulk packages, they can go through one of two pathways:
        i. Slow moving bulk items have their own carousel inventory location and can be placed in inventory similar to a LUM product.
        ii. Fast moving bulk items will be set aside to be prepacked. Once they are prepacked, they will then go through the process beginning at step 2.
4. Below is a description for loading packaged medications in to the Carousel.
    a. After logging into the system and selecting the restock function, the User will be prompted to scan the medication to be restocked.
    b. After scanning the bar code on the medication The Carousel will rotate to the appropriate location and the position and depth indicators illuminate.
        i. If the item is stocked outside of the Carousel device in another location (static shelving or the refrigerator), the User will obtain location information from the Restock Location field. The other locations do not have lights that display the position of the medication; the Restock Location field will tell the User exactly where the medication is located.
    c. The User will:
        i. Enter the quantity to be restocked in Restock Qty field.
        ii. Enter the earliest expiration date found on items to be restocked and already in the bin into the Expires field.
        iii. Count the medications in the bin to verify that the quantity equals the display in the Inventory field.
    d. The End Inventory field automatically updates based on the Restock Qty entered. However, if necessary, the User will enter a different number in the End Inventory field to correct the total quantity in the bin.
    e. The User will then scan the label on the side of the bin. The application automatically saves the restocking information.
        i. The label on the side of each medication bin is specifically associated with the bar code on each product's lowest unit of measure.

2. Procedures for conducting quality control checks of final dispensing for accuracy

1. When dispensing drugs from the Carousel, there are 4 methods in place: First dose dispensing, Cartfill dispensing, and Automated Dispensing Cabinet (ADC) batch/stock-out dispensing, and Manual dispensing.

a. **First Doses** are dispensed as follows:
   i. After an order has been entered by the pharmacist for a First Dose, the dispense request appears on the Carousel Order queue
   ii. When the technician processes the dispense request, a drug-patient specific label (adjacent to the Carousel) prints. The Carousel will rotate to the appropriate location and the position and depth indicators illuminate.
   iii. If the item is stocked in another location (static shelving or the refrigerator), the technician will obtain location information from the Location field.
   iv. The technician will scan the individual medication to be dispensed and then scan the patient-specific label.
   v. The drug will then be placed by the technician in a clear bag with the order-specific label affixed to it.
   vi. Simultaneously following the scan of the drug-patient specific label, the next dispense request (if one exists) in the queue will appear to be processed.
   vii. The medication is then ready to be transported by the pneumatic tube system or delivery to the specific unit.

b. **Cartfill doses** are dispensed as follows:
   i. The technician processes the Cartfill Batch in the RxIS.
   ii. Patient specific dispense requests appear on the Carousel Order queue
   iii. When the technician processes the dispense request, a drug-patient specific label (adjacent to the Carousel) prints. The Carousel will rotate to the appropriate location and the position and depth indicators illuminate.
   iv. If the item is stocked in another location (static shelving or the refrigerator), the technician will obtain location information from the Location field.
   v. The technician will scan the individual medication to be dispensed and then scan the patient-specific label.
   vi. The technician will then look for a confirmation message to ensure that scanned medication is correct. If incorrect medication is scanned, a warning message appears and flashes.
   vii. The drug will then be placed by the technician in a clear bag with the order-specific label affixed to it.
   viii. Simultaneously following the scan of the drug-patient specific label, the next dispense request (if one exists) in the queue will appear to be processed.
   ix. The medication is then ready to be transported by the pneumatic tube system or delivery to the specific unit.

c. **ADC Batch and Stockouts** are dispensed as follows:
   i. The ADC sends batch refill information or stockout information directly to the Carousel Dispense queue via an electronic interface.
   ii. The technician processes the batch and stockout dispense in the Carousel Order queue.
   iii. When the technician processes the dispense request, an ADC restock label (adjacent to the Carousel) prints. The Carousel will rotate to the appropriate location and the position and depth indicators illuminate.
   iv. If the item is stocked in another location (static shelving or the refrigerator), the technician will obtain location information from the Location field.
   v. The technician will scan the individual medication to be dispensed and then scan the ADC restock label.
   vi. The technician will then look for a confirmation message to ensure that scanned medication is correct. If incorrect medication is scanned, a warning message appears and flashes.
   vii. The drug will then be placed by the technician in a clear bag with the label affixed to it.
   viii. Simultaneously following the scan of the drug-patient specific label, the next dispense request (if one exists) in the queue will appear to be processed.

ix. The medication is then ready to be delivered to the specific ADC.

d. **A Manual dispense** may be needed for a variety of reasons: Emergent need for a dose which has not been entered via the electronic medical record, filling of the trauma boxes for the local EMS teams, pulling stock that has been recalled or expired, or replenishing floor stock requisitions. Manual dispense doses are dispensed as follows:

i. In order to fulfill the requested order the User will log into the Carousel software and select Manual Pick.

1. In the **Search** field, type in the first few letters of the generic name of the medication and Enter. This will give the User a list of medications that fit the generic description.
2. The User will then **carefully** select the medication that they wish to obtain from the list by highlighting that drug.
3. In the **Pick Quantity** field, type the quantity to be dispensed and press Enter.
4. The Carousel will spin to the correct shelf. The position and depth lights will illuminate on the posting board indicating the medication's location. The system will automatically subtract the quantity picked from the **Current inventory** count, and display the new inventory value in the **New Inventory Count** field.
5. The Technician will then **scan the barcode on the medication being dispensed.**
6. The technician will then look for a confirmation message to ensure that scanned medication is correct. If incorrect medication is scanned, a warning message appears and flashes.

2. Prior to dispensing a medication to the patient on the patient care unit, the nurse, using the scanner, will scan the patient's wrist band to verify the patient, and then scan the bar code on the medication to verify that the drug is indeed on the patient's profile to be administered and that it is the right dose, route and time.

a. This process will chart the medication on the patient's electronic medical record as given.

Project 6271 - Proposed

Board Of Pharmacy

Use of medication carousels and RFID technology

18VAC110-20-425. Robotic pharmacy systems.

A. Consistent with 18VAC110-20-420, a pharmacy providing services to a hospital or a long-term care facility and operating a robotic pharmacy system that dispenses drugs in barcoded unit dose or compliance packaging is exempted from 18VAC110-20-270 C, provided the accuracy of the final dispensed prescription product complies with a written quality assurance plan and requirements of this chapter. The following requirements for operation of a robotic pharmacy system shall apply:

1. Pharmacists shall review for accuracy and appropriateness of therapy all data entry of prescription orders into the computer operating the system.

2. The packaging, repackaging, stocking, and restocking of the robotic pharmacy system shall be performed by pharmacy technicians or pharmacists.

3. Pharmacists shall verify and check for the accuracy of all drugs packaged or repackaged for use by the robot by a visual check of both labeling and contents prior to stocking the drugs in the robotic pharmacy system. A repackaging record shall be maintained in accordance with 18VAC110-20-355 A, and the verifying pharmacist shall initial the record. Packaging and labeling, including the appropriate beyond-use date, shall conform to requirements of this chapter and current USP-NF standards.

4. A written policy and procedure must be maintained and complied with and shall include at a minimum procedures for ensuring:

a. Accurate packaging and repackaging of all drugs for use in the robotic pharmacy system, to include properly labeled barcodes, and method for ensuring pharmacist verification of all packaged and repacked drugs compliant with this chapter and assigned barcodes;

b. Accurate stocking and restocking of the robotic pharmacy system;

c. Removing expired drugs;

d. Proper handling of drugs that may be dropped by the robotic pharmacy system;

e. Performing routine maintenance of robotic pharmacy system as indicated by manufacturer's schedules and recommendations;

f. Accurate dispensing of drugs via robotic pharmacy system for cart fills, first doses, and cart fill updates during normal operation and during any scheduled or unscheduled downtime;

g. Accurate recording of any scheduled or unanticipated downtime with an explanation of the problem to include the time span of the downtime and the resolution;

h. Appropriately performing an analysis to investigate, identify, and correct sources of discrepancies or errors associated with the robotic pharmacy system; and

i. Maintaining quality assurance reports.

5. All manual picks shall be checked by pharmacists.

6. If it is identified that the robot selected an incorrect medication, the pharmacy shall identify and correct the source of discrepancy or error in compliance with the pharmacy's policies and procedures prior to resuming full operations of the robot. An investigation of

the cause of the event shall be completed, and the outcome of the corrective action plan shall be summarized and documented in a readily retrievable format.

7. Quarterly quality assurance reports demonstrating the accuracy of the robot shall be maintained. At a minimum, these reports shall include a summary indicating the date and description of all discrepancies that include discrepancies involving the packaging, repackaging, and dispensing of drugs via the robotic pharmacy system found during that quarter plus a cumulative summary since initiation of the robotic pharmacy system.

~~8. All records required by this section shall be maintained at the address of the pharmacy for a minimum of two years. Records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.~~

B. Intravenous admixture robotics may be utilized to compound drugs in compliance with § 54.1-3410.2 of the Code of Virginia and 18VAC110-20-321; however, a pharmacist shall verify the accuracy of all compounded drugs pursuant to ~~18VAVC110-20-270~~ 18VAC110-20-270 B.

C. Medication carousels functioning with or without a robotic pharmacy system in a hospital may be utilized to store and guide the selection of drugs to be dispensed or removed from the pharmacy under the following conditions:

1. The entry of drug information into the barcode database for assignment of a barcode to an individual drug shall be performed by a pharmacist who shall verify the accuracy of the barcode assignment.

2. A pharmacist is not required to verify the accuracy of a patient-specific drug removed from a medication carousel if:

a. The entry of the order for a patient-specific drug into the pharmacy's dispensing software is verified by a pharmacist for accuracy and is electronically transmitted to the medication carousel; and

b. The patient-specific drug removed from the medication carousel by a pharmacy technician is verified for accuracy by the pharmacy technician who shall scan each drug unit removed from the medication carousel prior to dispensing, and a nurse or other person authorized to administer the drug scans each drug unit using barcode technology to verify the accuracy of the drug prior to administration of the drug to the patient. [The requirement for scanning by a nurse or other person authorized to administer is waived in an emergent event when a delay would cause imminent harm to the patient; or

c. The patient-specific drug is checked by two pharmacy technicians if a hospital does not have the capability for the drug to be verified for accuracy by scanning each drug unit. The first pharmacy technician removing the patient-specific drug from the medication carousel shall perform a visual inspection of each drug unit for accuracy and then double check the accuracy by scanning an individual unit of each drug. A second, different pharmacy technician shall perform a separate visual inspection of each drug unit and scan an individual unit of each drug for final verification. A nurse of other person authorized to administer the drug shall scan each drug unit prior to administration, unless the drug is being administered to treat an emergent event when a delay would cause imminent harm to the patient] .

3. A pharmacist is not required to verify the accuracy of the drug removed from the medication carousel by a pharmacy technician if that drug is intended to be placed into an automated drug dispensing system as defined in § 54.1-3401 of the Code of Virginia or distributed to another entity legally authorized to possess the drug if:

a. The list of drugs to be removed from the medication carousel for loading or replenishing an individual automated dispensing system is electronically transmitted to the medication carousel; and

b. The drug removed from the medication carousel is verified for accuracy by the pharmacy technician by scanning each drug unit removed from the medication carousel prior to leaving the pharmacy and delivering the drug to the automated drug dispensing system or distributed to another entity, and a nurse or other person authorized to administer the drug scans each drug unit using barcode technology to verify the accuracy of the drug prior to administration of the drug to the patient. If the drug is placed into an automated drug dispensing system located within a hospital, or the entity receiving the distributed drug, wherein a nurse or other person authorized to administer the drug will not be able to scan each drug unit using barcode technology to verify the accuracy of the drug prior to patient administration, then a second verification for accuracy shall be performed by a pharmacy technician by scanning each drug unit at the time of placing the drugs into the automated dispensing system [; or

c. The drug intended for restocking an automated dispensing device is checked by two pharmacy technicians if the hospital does not have the capacity for scanning each drug unit. The first pharmacy technician removing the drug for restocking from the medication carousel shall perform a visual inspection of each drug unit for accuracy and then double check the accuracy by scanning an individual unit of each drug of the automated dispensing device restock order prior to leaving the pharmacy. A second, different pharmacy technician shall perform a separate visual inspection of each drug unit and scan an individual unit 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 shall 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].

4. A pharmacist shall verify the accuracy of all drugs that are manually removed from the medication carousel by a pharmacy technician without the use of barcode scanning technology to verify the accuracy of the selection of the drug product prior to dispensing those drugs or those drugs leaving the pharmacy.

5. A pharmacist shall perform a daily random check for verification of the accuracy of 5.0% of drugs prepared that day utilizing the medication carousel technology. A manual or electronic record, from which information can be readily retrieved, shall be maintained and shall include:

a. The date of verification;

b. A description of all discrepancies identified, if any; and

c. The initials of the pharmacist verifying the accuracy of the process.

D. All records required by this section shall be maintained at the address of the pharmacy for a minimum of two years. Records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible, provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent of the board.

18VAC110-20-500. Licensed emergency medical services (EMS) agencies ~~program~~.

A. The pharmacy may prepare a kit for a licensed EMS agency provided:

1. The PIC of the hospital pharmacy shall be responsible for all prescription drugs and Schedule VI controlled devices contained in this kit. ~~A~~ Except as authorized in

18VAC110-20-505, a pharmacist shall check each kit after filling and initial the filling record certifying the accuracy and integrity of the contents of the kit.

2. The kit is sealed, secured, and stored in such a manner that it will deter theft or loss of drugs and devices and aid in detection of theft or loss.

a. The hospital pharmacy shall have a method of sealing the kits such that once the seal is broken, it cannot be reasonably resealed without the breach being detected.

b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication or resealing. The pharmacy shall maintain a record of the seal identifiers when placed on a kit and maintain the record for a period of one year.

c. In lieu of a seal, a kit with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy may be used.

3. Drugs and devices may be administered by an EMS provider upon an oral or written order or standing protocol of an authorized medical practitioner in accordance with § 54.1-3408 of the Code of Virginia. Oral orders shall be reduced to writing by the EMS provider and shall be signed by a medical practitioner. Written standing protocols shall be signed by the operational medical director for the EMS agency. A current copy of the signed standing protocol shall be maintained by the pharmacy participating in the kit exchange. The EMS provider shall make a record of all drugs and devices administered to a patient.

4. When the drug kit has been opened, the kit shall be returned to the pharmacy and exchanged for an unopened kit. The record of the drugs administered shall accompany the opened kit when exchanged. An accurate record shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year. A pharmacist, pharmacy technician, or nurse shall reconcile the Schedule II, III, IV, or V drugs in the kit

at the time the opened kit is returned. A record of the reconciliation, to include any noted discrepancies, shall be maintained by the pharmacy for a period of two years from the time of exchange. The theft or any other unusual loss of any Schedule II, III, IV, or V controlled substance shall be reported in accordance with § 54.1-3404 of the Code of Virginia.

5. Accurate records of the following shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year:

a. The record of filling and verifying the kit to include the drug contents of the kit, the initials of the pharmacist verifying the contents, the date of verification, a record of an identifier if a seal is used, and the assigned expiration date for the kit, which shall be no later than the expiration date associated with the first drug or device scheduled to expire.

b. The record of the exchange of the kit to include the date of exchange and the name of EMS agency and EMS provider receiving the kit.

6. Destruction of partially used Schedules II, III, IV, and V drugs shall be accomplished by two persons, one of whom shall be the EMS provider and the other shall be a pharmacist, nurse, prescriber, pharmacy technician, or a second EMS provider. Documentation shall be maintained in the pharmacy for a period of two years from the date of destruction.

7. The record of the drugs and devices administered shall be maintained as a part of the pharmacy records pursuant to state and federal regulations for a period of not less than two years.

8. Intravenous and irrigation solutions provided by a hospital pharmacy to an emergency medical services agency may be stored separately outside the kit.

9. Any drug or device showing evidence of damage or tampering shall be immediately removed from the kit and replaced.

10. In lieu of exchange by the hospital pharmacy, the PIC of the hospital pharmacy may authorize the exchange of the kit by the emergency department. Exchange of the kit in the emergency department shall only be performed by a pharmacist, nurse, or prescriber if the kit contents include Schedule II, III, IV, or V drugs.

B. A licensed EMS agency may obtain a controlled substances registration pursuant to § 54.1-3423 D of the Code of Virginia for the purpose of performing a one-to-one exchange of Schedule VI drugs or devices.

1. The controlled substances registration may be issued to a single agency or to multiple agencies within a single jurisdiction.

2. The controlled substances registration issued solely for this intended purpose does not authorize the storage of drugs within the agency facility.

3. Pursuant to § 54.1-3434.02 of the Code of Virginia, the EMS provider may directly obtain Schedule VI drugs and devices from an automated drug dispensing device.

4. If such drugs or devices are obtained from a nurse, pharmacist, or prescriber, it shall be in accordance with the procedures established by the pharmacist-in-charge, which shall include a requirement to record the date of exchange, name of licensed person providing drug or device, name of the EMS agency and provider receiving the drug or device, and assigned expiration date. Such record shall be maintained by the pharmacy for one year from the date of exchange.

5. If an EMS agency is performing a one-to-one exchange of Schedule VI drugs or devices, Schedule II, III, IV, or V drugs shall remain in a separate, sealed container and shall only be exchanged in accordance with provisions of subsection A of this section.

18VAC110-20-505. Use of radio-frequency identification.

A hospital pharmacy may use radio-frequency identification (RFID) to verify the accuracy of drugs placed into a kit for licensed emergency medical services pursuant to 18VAC110-20-500 or other kits used as floor stock throughout the hospital under the following conditions:

1. A pharmacist shall be responsible for performing and verifying the accuracy of the following tasks:

a. The addition, modification, or deletion of drug information into the RFID database for assignment of a RFID tag to an individual drug; and

b. The development of the contents of the kit in the RFID database and the associated drug-specific RFID tags.

2. A pharmacy technician may place the RFID tag on the drugs, and a pharmacist shall verify that all drugs have been accurately tagged prior to storing the drugs in the pharmacy's inventory.

3. A pharmacy technician may remove RFID-tagged drugs from the pharmacy's inventory whose RFID tags have been previously verified for accuracy by a pharmacist and place the drugs into the kit's container. A pharmacy technician may then place the container into the pharmacy's device that reads the RFID tags to verify if the correct drugs have been placed into the container as compared to the list of the kit's contents in the RFID database.

4. A pharmacist shall perform a daily random check for verification of the accuracy of 5.0% of all kits prepared that day utilizing the RFID technology. A manual or electronic record from which information can be readily retrieved, shall be maintained that includes:

a. The date of verification;

b. A description of all discrepancies identified, if any; and

c. The initials of pharmacist verifying the accuracy of the process.

5. Pharmacies engaged in RFID tagging of drugs shall be exempt from the requirements in subsection C of 18VAC110-20-490, subsection A of 18VAC110-20-460, and subsection A of 18VAC110-20-355.

6. All records required by this subsection shall be maintained for a period of one year from the date of verification by the pharmacist.

Agenda Item: Adoption of Final Regulations – Limited use permit for non-profit facilities

Included in your agenda package are:

A copy of notification on Townhall for proposed regulations

A copy of the proposed regulations (identical to emergency)

Staff note:

There were no public comments on the proposed regulations

Recommended Board action:

Adoption of final regulations without changes from the proposed and emergency regulations

Virginia.gov Agencies | Governor

VIRGINIA REGULATORY TOWN HALL

Agency Department of Health Professions

Board Board of Pharmacy

Chapter **Regulations for Practitioners of the Healing Arts to Sell Controlled Substances [18 VAC 110 - 30]**

Action: LImited license for prescribing Schedule VI drugs in non-profit clinics

Proposed Stage

Action 5605 / Stage 9244

Edit Stage | Withdraw Stage | Go to RIS Project

Documents		
Proposed Text	8/10/2021 9:48 am	Sync Text with RIS
Agency Background Document	4/12/2021	Upload / Replace
Attorney General Certification	4/26/2021	
DPB Economic Impact Analysis	6/7/2021	
Agency Response to EIA	7/13/2021	Upload / Replace
Governor's Review Memo	7/22/2021	
Registrar Transmittal	7/22/2021	

Status	
Changes to Text	The proposed text for this stage is identical to the emergency regulation.
Incorporation by Reference	No
Exempt from APA	No, this stage/action is subject to Article 2 of the *Administrative Process Act*
Attorney General Review	Submitted to OAG: 4/12/2021 Review Completed: 4/26/2021 Result: Certified
DPB Review	Submitted on 4/26/2021 Economist: Larry Getzler Policy Analyst: Cari Corr Review Completed: 6/8/2021
Secretary Review	Secretary Review Completed: 7/5/2021
Governor's Review	Review Completed: 7/22/2021 Result: Approved
Virginia Registrar	Submitted on 7/22/2021 The Virginia Register of Regulations Publication Date: 8/16/2021 Volume: 37 Issue: 26
Public Hearings	09/24/2021 9:05 AM

Comment Period	Ended 10/15/2021 0 comments

Contact Information	
Name / Title:	Caroline Juran, RPh / *Executive Director*
Address:	9960 Mayland Drive Suite 300 Richmond, VA 23233-1463
Email Address:	**caroline.juran@dhp.virginia.gov**
Telephone:	(804)527-4456 FAX: (804)527-4472 TDD: ()-

This person is the primary contact for this chapter.

This stage was created by Elaine J. Yeatts on 04/12/2021 at 10:15am
This stage was last edited by Elaine J. Yeatts on 04/12/2021 at 10:15am

Proposed Text

highlight

Action: LImited license for prescribing Schedule VI drugs in non-profit ...

Stage: Proposed

8/10/21 9:48 AM [latest]

18VAC110-30-10 Definitions

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise.

"Board" means the Virginia Board of Pharmacy.

"Controlled substance" means a drug, substance or immediate precursor in Schedules I through VI of the Drug Control Act.

"Licensee" means a practitioner who is licensed by the Board of Pharmacy to sell controlled substances.

"Personal supervision" means the licensee must be physically present and render direct, personal control over the entire service being rendered or acts being performed. Neither prior nor future instructions shall be sufficient nor shall supervision be rendered by telephone, written instructions, or by any mechanical or electronic methods.

"Practitioner" or "practitioner of the healing arts" means a doctor of medicine, osteopathic medicine or podiatry who possesses a current active license issued by the Board of Medicine. For the purpose of a limited-use permit for a nonprofit facility, a "practitioner" or "practitioner of the healing arts" may also mean a physician assistant with a current active license issued by the Board of Medicine or a nurse practitioner with a current active license issued by the Joint Boards of Nursing and Medicine.

"Sale" means barter, exchange, or gift, or offer thereof, and each such transaction made by any person, whether as an individual, proprietor, agent, servant or employee. It does not include the gift of manufacturer's samples to a patient.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the controlled substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"U.S.P.-N.F." means the United States Pharmacopeia-National Formulary.

18VAC110-30-20 Application for licensure

A. Prior to engaging in the sale of controlled substances, a practitioner shall make application on a form provided by the board and be issued a license. After June 7, 2016, the practitioner shall engage in such sale from a location that has been issued a facility permit.

B. ~~In order to be eligible for a license to sell controlled substances, a practitioner shall possess a current, active license to practice medicine, osteopathic medicine, or podiatry issued by the Virginia Board of Medicine.~~ Prior to engaging in the sale

of Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances from a nonprofit facility, a doctor of medicine, osteopathic medicine, or podiatry, a nurse practitioner, or a physician assistant shall make application on a form provided by the board and be issued a limited-use license.

C. Any disciplinary action taken by the Board of Medicine, or in the case of a nurse practitioner, by the Joint Boards of Nursing and Medicine, against the practitioner's license to practice shall constitute grounds for the board to deny, restrict, or place terms on the license to sell.

18VAC110-30-21 Application for facility permit

A. After June 7, 2016, any location at which practitioners of the healing arts sell controlled substances shall have a permit issued by the board in accordance with § 54.1-3304.1 of the Code of Virginia. A licensed practitioner of the healing arts shall apply for the facility permit on a form provided by the board.

B. For good cause shown, the board may issue a limited-use facility permit when the scope, degree, or type of services provided to the patient is of a limited nature. The permit to be issued shall be based on conditions of use requested by the applicant or imposed by the board in cases where certain requirements of this chapter may be waived.

1. The limited-use facility permit application shall list the regulatory requirements for which a waiver is requested, if any, and a brief explanation as to why each requirement should not apply to that practice.

2. A policy and procedure manual detailing the type and volume of controlled substances to be sold and safeguards against diversion shall accompany the application.

3. The issuance and continuation of a limited-use facility permit shall be subject to continuing compliance with the conditions set forth by the board.

4. A limited-use facility permit may be issued to a nonprofit facility for the purpose of dispensing Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances.

C. The executive director may grant a waiver of the security system when storing and selling multiple strengths and formulations of no more than five different topical Schedule VI drugs intended for cosmetic use.

18VAC110-30-40 Acts to be performed by the licensee

A. The selection of the controlled substance from the stock, any preparation or packaging of a controlled substance or the preparation of a label for a controlled substance to be transferred to a patient shall be the personal responsibility of the licensee.

1. Any compounding of a controlled substance shall be personally performed by the licensee or a registered pharmacy technician under the supervision of the licensee.

2. A licensee may supervise one person who may be present in the storage and selling area to assist in performance of pharmacy technician tasks, as set forth in § 54.1-3321 of the Code of Virginia, provided such person is not licensed to sell controlled substances and is either:

a. A pharmacy technician registered with the board; or

b. A licensed nurse or physician assistant who has received training in technician tasks consistent with training required for pharmacy technicians.

3. Unless using one of the board-approved training courses for pharmacy technicians, a licensee who uses a nurse or physician assistant to perform pharmacy technician tasks shall develop and maintain a training manual and shall document that such licensee has successfully completed general training in the following areas:

a. The entry of prescription information and drug history into a data system or other recordkeeping system;

b. The preparation of prescription labels or patient information;

c. The removal of the drug to be dispensed from inventory;

d. The counting or measuring of the drug to be dispensed to include pharmacy calculations;

e. The packaging and labeling of the drug to be dispensed and the repackaging thereof;

f. The stocking or loading of automated dispensing devices or other devices used in the dispensing process, if applicable; and

g. Applicable laws and regulations related to dispensing.

4. A licensee who employs or uses pharmacy technicians, licensed nurses or physician assistants to assist in the storage and selling area shall develop and maintain a site-specific training program and manual for training to work in that practice. The program shall include training consistent with that specific practice to include~~, but not be limited to,~~ training in proper use of site-specific computer programs and equipment, proper use of other equipment used in the practice in performing technician duties, and pharmacy calculations consistent with the duties in that practice.

5. A licensee shall maintain documentation of successful completion of the site-specific training program for each pharmacy technician, nurse or physician assistant for the duration of the employment and for a period of two years from date of termination of employment. Documentation for currently employed persons shall be maintained on site or at another location where the records are readily retrievable upon request for inspection. After employment is terminated, such documentation may be maintained at an off-site location where it is retrievable upon request.

B. Prior to the dispensing, the licensee shall:

1. Conduct a prospective drug review and offer to counsel a patient in accordance with provisions of § 54.1-3319 of the Code of Virginia; and

2. Inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of sale as certification of the accuracy of, and the responsibility for, the entire transaction.

C. If the record of sale is maintained in an automated data processing system as provided in 18VAC110-30-200, the licensee shall personally place his initials with each entry of a sale as a certification of the accuracy of, and the responsibility for, the entire transaction.

18VAC110-30-270 Grounds for disciplinary action

In addition to those grounds listed in § 54.1-3316 of the Code of Virginia, the board may revoke, suspend, refuse to issue or renew a license to sell controlled substances or may deny any application if it finds that the licensee or applicant

has had his license to practice medicine, osteopathic medicine, or podiatry or license as a physician assistant or nurse practitioner suspended or revoked in Virginia or in any other state or no longer holds a current active license to practice in the Commonwealth of Virginia.

Agenda Item: Amendments to Guidance documents

Staff Note:

Guidance document on continuing education audits – 110-42
Changes recommended by Regulation Committee

Guidance document on use of automated dispensing devices - 110-19
Changes to document as adopted by Board in September as recommended by the Department of Behavioral Health and Developmental Services

Board action:

To revise the guidance documents as presented in the agenda package

Guidance Document: 110-42

Revised: December 7, 2021
Effective: February 3, 2022

Virginia Board of Pharmacy

Continuing Education Audit

Procedure for enforcement of CE requirements:

Following each renewal cycle, Board staff may audit the following persons for CE compliance:

- Persons checking "no" to the CE attestation on the annual license renewal form, either paper or online
- Persons who requested a continuance from the previous year
- Persons selected for random audit. The audit will be conducted pursuant to procedures established by the Department of Health Professions to ensure a statistically valid audit sample and randomness of those selected.

This procedure does not preclude the auditing and special handling of CE non-compliance as may be specified in a Board order.

If the response to the audit does not show compliance with CE requirements, Board staff will send a letter to the respondent offering resolution of the matter by consent, payment of an established monetary penalty, and proof of late compliance with CE requirements. The letter will also offer an additional opportunity for the respondent to furnish proof that CE requirements were actually met during the specified time period or the opportunity to request an informal conference. A signed letter will constitute an order of the Board and the licensee's consent to the imposition of a monetary penalty and an agreement to the submission of documentation of late CE compliance. If there is no response to the letter, within 30 days, an informal conference before an agency subordinate, or IFC if more expedient, will be scheduled.

The monetary penalty offered in the letter ~~shall~~ will be $250 for each year a pharmacist does not meet CE requirements. Because the maximum audit period is 2 years, the maximum penalty would be $500. The monetary penalty offered for each year that a pharmacy technician does not meet CE requirements will be $50, for a maximum penalty of $100. ~~Board-imposed penalties for CE non-compliance not resolved by consent may result in additional penalties following the informal conference proceedings.~~

Board-imposed penalties for CE non-compliance not resolved by consent may result in the issuance of a reprimand and mandatory CE audit in the subsequent year following the informal conference proceedings. If the licensee has subsequent noncompliance with CE, staff will not offer a pre-hearing consent order but will notice the licensee for an informal conference. It will be noted that this is a repeat violation, and the informal conference committee ~~shall~~ will determine the appropriate sanction.

VIRGINIA BOARD OF PHARMACY

Use of Automated Dispensing Devices in Certain Facilities

The Board interprets "Hospitals licensed pursuant to Title 32.1 or Title 37.2" as found in § 54.1-3434.02(A) to include state facilities licensed or operated by the Department of Behavioral Health and Developmental Services as "inpatient" ~~or "partial hospitalization"~~ and which only use licensed health care professionals authorized in law to administer medications. Such facilities may use automated dispensing devices in compliance with § 54.1-3434.02.

From the Code of Virginia, July 1, 2021:

§ 54.1-3434.02. Automated drug dispensing systems.

A. Hospitals licensed pursuant to Title 32.1 or Title 37.2 may use automated drug dispensing systems, as defined in § 54.1-3401, upon meeting the following conditions:

1. Drugs are placed in the automated drug dispensing system in a hospital and are under the control of a pharmacy providing services to the hospital;

2. The pharmacist-in-charge of the pharmacy providing services to the hospital has established procedures for assuring the accurate stocking and proper storage of drugs in the automated drug dispensing system and for ensuring accountability for and security of all drugs utilized in the automated drug dispensing system until the time such drugs are removed from the automated drug dispensing system for administration to the patients;

3. Removal of drugs from any automated drug dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber;

4. Adequate security for automated drug dispensing systems is provided, as evidenced by written policies and procedures, for (i) preventing unauthorized access, (ii) complying with federal and state regulations on prescribing and dispensing controlled substances, (iii) maintaining patient confidentiality, and (iv) assuring compliance with the requirements of this section;

5. Accountability for drugs dispensed from automated drug dispensing systems is vested in the pharmacist-in-charge of a pharmacy located within the hospital or the pharmacist-in-charge of any outside pharmacy providing pharmacy services to the hospital;

6. Filling and stocking of all drugs in automated drug dispensing systems shall be performed under the direction of the pharmacist-in-charge. The task of filling and stocking of drugs into an automated drug dispensing system shall be performed by a pharmacist or a registered pharmacy technician, who shall be an employee of the provider pharmacy and shall be properly trained in accordance with established standards set forth in a policy and procedure manual maintained by the provider pharmacy. The pharmacist stocking and filling the automated drug dispensing system

or the pharmacist-in-charge, if the automated drug dispensing system is stocked and filled by a registered pharmacy technician, shall be responsible for the proper and accurate stocking and filling of the automated drug dispensing system.

B. Drugs placed into and removed from automated drug dispensing systems for administration to patients shall be in the manufacturer's or distributor's sealed original packaging or in unit-dose containers packaged by the pharmacy. Drugs in multi-dose packaging, other than those administered orally, may be placed in such a device if approved by the pharmacist-in-charge in consultation with a standing hospital committee comprised of pharmacy, medical, and nursing staff.

C. The pharmacist-in-charge in a pharmacy located within a hospital or the pharmacist-in-charge of any outside pharmacy providing pharmacy services to a hospital shall be responsible for establishing procedures for (i) periodically inspecting and auditing automated drug dispensing systems to assure the proper storage, security, and accountability for all drugs placed in and removed from automated drug dispensing systems, and (ii) reviewing the operation and maintenance of automated drug dispensing systems. This monitoring shall be reviewed by a pharmacist while on the premises of the hospital and in accordance with the pharmacist-in-charge's procedures and the Board of Pharmacy's regulations.

D. The Board of Pharmacy shall promulgate regulations establishing minimum requirements for random periodic inspections and monthly audits of automated drug dispensing systems to assure the proper storage, security, and accountability of all drugs placed in and removed from automated drug dispensing systems and for reviewing the operation and maintenance of automated drug dispensing systems.

Agenda Item: Adoption of Exempt Regulations for Pharmaceutical Processors

Included in your agenda package are:

Copy of statutory authority for adoption of exempt regulations

Copy of the Notice of Public Comment

Copy of proposed regulations as adopted by the Board at its September meeting

Staff note:

A notice of a public comment period was published in the Register of Regulations, posted on the Virginia Regulatory Townhall and sent to interested parties

Comment was requested from 9/27/21 to 11/26/21.

Board action:

To adopt the amendments to Regulations Governing Pharmaceutical Processors by and exempt action

§ 54.1-3442.6. Permit to operate pharmaceutical processor or cannabis dispensing facility.

N. With the exception of § 2.2-4031, neither the provisions of the Administrative Process Act (§ 2.2-4000 et seq.) nor public participation guidelines adopted pursuant thereto shall apply to the adoption of any regulation pursuant to this section. Prior to adopting any regulation pursuant to this section, the Board of Pharmacy shall publish a notice of opportunity to comment in the Virginia Register of Regulations and post the action on the Virginia Regulatory Town Hall. Such notice of opportunity to comment shall contain (i) a summary of the proposed regulation; (ii) the text of the proposed regulation; and (iii) the name, address, and telephone number of the agency contact person responsible for receiving public comments. Such notice shall be made at least 60 days in advance of the last date prescribed in such notice for submittals of public comment. The legislative review provisions of subsections A and B of § 2.2-4014 shall apply to the promulgation or final adoption process for regulations pursuant to this section. The Board of Pharmacy shall consider and keep on file all public comments received for any regulation adopted pursuant to this section.

Notice of Public Comment Period

Board of Pharmacy
Regulations Governing Pharmaceutical Processors

In accordance with subsection N of § 54.1-3442.6 of the Code of Virginia, the Board of Pharmacy is providing an opportunity to comment on a draft of proposed regulations for pharmaceutical processors that will be considered for adoption as an exempt action.

The proposed regulations as drafted make technical corrections to regulations that became effective on September 1, 2021

The 2021 legislation requires posting of a notice 60 days in advance of submittals for public comment. The Board of Pharmacy is scheduled to meet on December 7, 2021 with the intent of adopting amendments to 18VAC110-60 (Regulations Governing Pharmaceutical Processors) by exempt action.

The Board will receive public comment from September 27, 2021 to November 26, 2021, commenters are **strongly encouraged** to submit comments by November 22, 2021 in order to have them included in the Board's agenda package and adequately considered for the December meeting.

Comments may be sent to: elaine.yeatts@dhp.virginia.gov

Elaine J. Yeatts
Agency Regulatory Coordinator
9960 Mayland Drive
Henrico, VA 23233
(804) 367-4688

Proposed amendments to 18VAC110-60: Regulations Governing Pharmaceutical Processors

18VAC110-60-10. Definitions.

"Electronic tracking system" means an electronic radio-frequency identification (RFID) seed-to-sale tracking system that tracks the Cannabis from either the seed or immature plant stage until the cannabis ~~oil~~ product is sold to a registered patient, parent, legal guardian, or registered agent or until the Cannabis, including the seeds, parts of plants, and extracts, are destroyed. The electronic tracking system shall include, at a minimum, a central inventory management system and standard and ad hoc reporting functions as required by the board and shall be capable of otherwise satisfying required recordkeeping.

"Perpetual inventory" means an ongoing system for recording quantities of cannabis ~~oil~~ product received, dispensed, or otherwise distributed by a cannabis dispensing facility.

18VAC110-60-160. Grounds for action against a pharmaceutical processor permit or a cannabis dispensing facility.

In addition to the bases enumerated in § 54.1-3316 of the Code of Virginia, the board may suspend, revoke, or refuse to grant or renew a permit issued; place such permit on probation; place conditions on such permit; or take other actions permitted by statute or regulation on the following grounds:

6. Failure to cooperate or give information to the board on any matter arising out of conduct at a pharmaceutical processor or cannabis dispensing facility; or

18VAC110-60-190. Pharmacy technicians; ratio; supervision and responsibility.

A. The ratio of pharmacy technicians to pharmacists on duty in the areas of a pharmaceutical processor ~~a cannabis dispensing facility~~ designated for production or dispensing or in a cannabis dispensing facility shall not exceed six pharmacy technicians to one pharmacist.

18VAC110-60-230. Inventory requirements.

D. The record of all cannabis products sold, dispensed, or otherwise disposed of shall show the date of sale or disposition; the name of the pharmaceutical processor or cannabis dispensing facility; the name and address of the registered patient, parent, legal guardian, or registered agent to whom the cannabis product was sold; the kind and quantity of cannabis product sold or disposed of; and the method of disposal.

18VAC110-60-300. Laboratory requirements; testing.

B. After processing and before dispensing the cannabis oil product, a pharmaceutical processor shall make a sample available from each homogenized batch of product for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue~~, and, for botanical cannabis, the water activity and moisture content~~; and (ii)

conduct an active ingredient analysis and terpenes profile. Each laboratory shall determine a valid sample size for testing, which may vary due to sample matrix, analytical method, and laboratory-specific procedures. A minimum sample size of 0.5% of individual units for dispensing or distribution from each homogenized batch of cannabis oil is required to achieve a representative sample for analysis.

G. If a sample of cannabis oil product does not pass the microbiological, mycotoxin, heavy metal, pesticide chemical residue, or residual solvent test based on the standards set forth in this subsection, the batch may be remediated with further processing. After further processing, the batch shall be retested for microbiological, mycotoxin, heavy metal, pesticide chemical residue, and residual solvent, and an active ingredient analysis and terpenes profile shall be conducted.

5. For purposes of the active ingredient analysis, a sample of the cannabis oil product shall be tested for:

a. Tetrahydrocannabinol (THC);

b. Tetrahydrocannabinol acid (THC-A);

c. Cannabidiols (CBD); and

d. Cannabidiolic acid (CBDA).

~~For botanical cannabis products, only the total cannabidiol (CBD) and total tetrahydrocannabinol (THC) are required.~~

Note: For 300 B: "and, for botanical cannabis, the water activity and moisture content," has been included in 300 C
For 300 G 5 "For botanical cannabis products, only the total cannabidiol (CBD) and total tetrahydrocannabinol (THC) are required and has been included in 300 H 5.

Agenda Item: Adoption of Proposed Regulations for Pharmaceutical Processors

Included in your agenda package are:

Copy of proposed regulations to be published for a 60-day comment period and then adopted by the Board as an exempt action in March of 2022

Board action:

To adopt the proposed amendments to Regulations Governing Pharmaceutical Processors

18VAC110-60-210. General provisions.

A. A pharmaceutical processor or cannabis dispensing facility shall only sell cannabis products in a child-resistant, secure, and light-resistant container. Upon a written request from the registered patient, parent, legal guardian, or registered agent, the product may be dispensed in a non-child-resistant container so long as all labeling is maintained with the product.

B. Only a pharmacist may dispense cannabis products to registered patients or parents or legal guardians of patients who are minors or incapacitated adults and who are registered with the board, or to a registered agent. A pharmacy technician who meets the requirements of 18VAC110-60-170 C may assist, under the direct supervision of a pharmacist, in the dispensing and selling of cannabis products.

C. The PIC, pharmacist, responsible party, or person who is qualified to provide supervision in accordance with 18VAC110-60-170 on duty shall restrict access to the pharmaceutical processor or cannabis dispensing facility to:

1. A person whose responsibilities necessitate access to the pharmaceutical processor or cannabis dispensing facility and then for only as long as necessary to perform the person's job duties; or

2. A person who is a registered patient, parent, legal guardian, registered agent, or a companion of the patient, in which case such person shall not be permitted behind the service counter or in other areas where Cannabis plants, extracts, or cannabis products are stored.

D. A pharmacist, pharmacy technician, or an employee of the pharmaceutical processor or cannabis dispensing facility who has routine access to confidential patient data and who has signed a patient data confidentiality agreement with the processor or dispensing facility, may determine eligibility for access to the processor or facility by verifying through a verification source recognized by the board, that the registration of the patient, parent, legal guardian, or registered agent is current.

~~D~~ E. All pharmacists and pharmacy technicians shall at all times while at the pharmaceutical processor or cannabis dispensing facility have their current license or registration available for inspection by the board or the board's agent.

~~E~~F. While inside the pharmaceutical processor or cannabis dispensing facility, all employees shall wear name tags or similar forms of identification that clearly identify them, including their position at the pharmaceutical processor or cannabis dispensing facility.

~~F~~G. A pharmaceutical processor or cannabis dispensing facility shall be open for registered patients, parents, legal guardians, or registered agents to purchase cannabis products for a minimum of 35 hours a week, except as otherwise authorized by the board.

~~G~~H. A pharmaceutical processor or cannabis dispensing facility that closes the dispensing area during its normal hours of operation shall implement procedures to notify registered patients, parents, legal

guardians, and registered agents of when the pharmaceutical processor or cannabis dispensing facility will resume normal hours of operation. Such procedures may include telephone system messages and conspicuously posted signs. If the cultivation, production, or dispensing area of the pharmaceutical processor or if a cannabis dispensing facility is or will be closed during its normal hours of operation for longer than two business days, the pharmaceutical processor or cannabis dispensing facility shall immediately notify the board.

~~H~~I. A pharmacist shall counsel registered patients, parents, legal guardians, and registered agents, if applicable, regarding the use of cannabis products. Such counseling shall include information related to safe techniques for proper use and storage of cannabis products and for disposal of the products in a manner that renders them nonrecoverable.

~~I~~J. The pharmaceutical processor or cannabis dispensing facility shall establish, implement, and adhere to a written alcohol-free, drug-free, and smoke-free work place policy that shall be available to the board or the board's agent upon request.

18VAC110-60-310. Dispensing of cannabis products.

A. A pharmacist in good faith may dispense cannabis products to any registered patient, parent, or legal guardian as indicated on the written certification or to a registered agent for a specific patient.

1. Prior to the initial dispensing of cannabis products pursuant to each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor or cannabis dispensing facility shall view in person or by audiovisual means a current photo identification of the patient, parent, legal guardian, or registered agent. The pharmacist or pharmacy technician shall verify in the Virginia Prescription Monitoring Program of the Department of Health Professions or other program recognized by the board that the registrations are current, the written certification has not expired, and the date and quantity of the last dispensing of cannabis products to the registered patient.

2. A pharmacist or pharmacy technician employed by the processor or cannabis dispensing facility shall make a paper or electronic copy of the current written certification that provides an exact image of the document that is clearly legible and shall maintain it on site or by electronic means for two years.

3. Prior to any subsequent dispensing, the pharmacist or pharmacy technician shall verify that the written certification on file has not expired. An employee or delivery agent shall view a current photo identification and current registration of the patient, parent, legal guardian, or registered agent and shall maintain record of such viewing in accordance with policies and procedures of the pharmaceutical processor or cannabis dispensing facility.

B. A pharmacist may dispense a portion of a registered patient's 90-day supply of cannabis product. The pharmacist may dispense the remaining portion of the 90-day supply of cannabis products at any time except that no registered patient, parent, legal guardian, or registered agent shall receive more than a 90-day supply of cannabis products for a patient in a 90-day period from any pharmaceutical processor or cannabis dispensing facility. A pharmaceutical processor or cannabis dispensing facility may dispense more than one cannabis product to a patient at one time. However, no more than four ounces of botanical cannabis shall be dispensed for each 30-day period for which botanical cannabis is dispensed. In determining the appropriate amount of cannabis product to be dispensed to a patient, a pharmacist shall consider all cannabis products dispensed and adjust the amount dispensed accordingly.

C. A dispensing record shall be maintained for three years from the date of dispensing, and the pharmacist or pharmacy technician under the direct supervision of the pharmacist shall affix a label to the container of cannabis product that contains:

1. A serial number assigned to the dispensing of the product;

2. The brand name of cannabis product that was registered with the board pursuant to 18VAC110-60-285 and its strength;

3. The serial number assigned to the product during production;

4. The date of dispensing the cannabis product;

5. The quantity of cannabis products dispensed;

6. A terpenes profile and a list of all active ingredients, including:

a. Tetrahydrocannabinol (THC);

b. Tetrahydrocannabinol acid (THC-A);

c. Cannabidiol (CBD); and

d. Cannabidiolic acid (CBDA);

For botanical cannabis products, only the total cannabidiol (CBD) and total tetrahydrocannabinol (THC) are required;

7. A pass rating based on the laboratory's microbiological, mycotoxins, heavy metals, residual solvents, pesticide chemical residue analysis, and for botanical cannabis, the water activity and moisture content analysis;

8. The name and registration number of the registered patient;

9. The name and registration number of the certifying practitioner;

10. Directions for use as may be included in the practitioner's written certification or otherwise provided by the practitioner;

11. For botanical cannabis, the amount recommended by the practitioner or dispensing pharmacist;

12. The name or initials of the dispensing pharmacist;

13. Name, address, and telephone number of the pharmaceutical processor or cannabis dispensing facility;

14. Any necessary cautionary statement; ~~and~~

15. A prominently printed expiration date based on stability testing; and ~~the pharmaceutical processor's or cannabis dispensing facility's recommended conditions of use and storage that can be read and understood by the ordinary individual~~;

16. The pharmaceutical processor's or cannabis dispensing facility's recommended conditions of use and storage that can be read and understood by the ordinary individual.

D. The label shall be exempt from containing the items listed in 6, 7 and 15 of subsection C if the items are included on the batch label as required in 18VAC110-60-290 and are clearly visible to the patient.

~~D~~E. A pharmaceutical processor shall not label cannabis products as "organic" unless the Cannabis plants have been organically grown and the cannabis oil products have been produced, processed, manufactured, and certified to be consistent with organic standards in compliance with 7 CFR Part 205.

~~E~~F. The cannabis products shall be dispensed in child-resistant packaging, except as provided in 18VAC110-60-210 A. A package shall be deemed child-resistant if it satisfies the standard for "special packaging" as set forth in the Poison Prevention Packaging Act of 1970 Regulations, 16 CFR 1700.1(b)(4).

~~F~~G. No person except a pharmacist or a pharmacy technician operating under the direct supervision of a pharmacist shall alter, deface, or remove any label so affixed.

~~G~~H. A pharmacist shall be responsible for verifying the accuracy of the dispensed product in all respects prior to dispensing and shall document that each verification has been performed.

~~H~~I. A pharmacist shall document a registered patient's self-assessment of the effects of cannabis products in treating the registered patient's diagnosed condition or disease or the symptoms thereof. If the authorization for botanical cannabis for a minor is communicated verbally or in writing to the pharmacist at the time of dispensing, the pharmacist shall also document such authorization. A pharmaceutical processor or cannabis dispensing facility shall maintain such documentation in writing or electronically for three years from the date of dispensing and such documentation shall be made available in accordance with regulation.

~~I~~J. A pharmacist shall exercise professional judgment to determine whether to dispense cannabis products to a registered patient, parent, legal guardian, or registered agent if the pharmacist suspects that dispensing cannabis products to the registered patient, parent, legal guardian, or registered agent may have negative health or safety consequences for the registered patient or the public.

Agenda Item: Withdrawal of NOIRA for Chapter 60: Regulations Governing Pharmaceutical Processors

Included in package:

Substance of the Notice of Intended Regulatory Action published 3/1/21 in response to a petition for rulemaking

Staff note:

The issues set out in the NOIRA have been addressed in other regulatory proposals now adopted by exempt actions (regulations effective 9/1/21; regulations adopted by the Board in Sept. and in Dec. 2021)

Board action:

Motion to withdraw the Response to Petition rulemaking action

Virginia.gov Agencies | Governor

VIRGINIA REGULATORY TOWN HALL

Agency **Department of Health Professions**

Board **Board of Pharmacy**

Chapter **Regulations Governing Pharmaceutical Processors [18 VAC 110 - 60]**

Action: Response to petition for rulemaking

Notice of Intended Regulatory Action (NOIRA)

Action 5611 / Stage 9081

Edit Stage | Withdraw Stage | Go to RIS Project

Documents		
Preliminary Draft Text	None submitted	Sync Text with RIS
Agency Background Document	9/21/2020	Upload / Replace
Governor's Review Memo	2/5/2021	
Registrar Transmittal	2/5/2021	

Status	
Public Hearing	Will be held at the **proposed** stage
Exempt from APA	No, this stage/action is subject to Article 2 of the *Administrative Process Act*
DPB Review	Submitted on 9/21/2020 Policy Analyst: Jerry Gentile Review Completed: 10/1/2020
Secretary Review	Secretary of Health and Human Resources Review Completed: 12/9/2020
Governor's Review	Review Completed: 2/5/2021 Result: Approved
Virginia Registrar	Submitted on 2/5/2021 The Virginia Register of Regulations Publication Date: 3/1/2021 **Volume: 37 Issue: 14**
Comment Period	Ended 3/31/2021 0 comments

Contact Information	
Name / Title:	Caroline Juran, RPh / *Executive Director*
Address:	9960 Mayland Drive Suite 300 Richmond, VA 23233
Email Address:	caroline.juran@dhp.virginia.gov

Telephone:	(804)367-4456 FAX: (804)527-4472 TDD: ()-

This person is the primary contact for this board.

This stage was created by Elaine J. Yeatts on 09/21/2020 at 2:33pm
This stage was last edited by Elaine J. Yeatts on 09/21/2020 at 2:33pm

Changes requested by the Va. Medical Cannabis Coalition in a petition for rulemaking and included in the Notice of Intended Regulatory Action

Note: Some amendments have already been made as a result of legislation passed in the 2021 Session of the General Assembly. Those amendments became effective Sept. 1.

1) 18VAC110-60-170: **Remove the two-year requirement for pharmacy technicians employed by a pharmaceutical processor – Already amended**

D. A person who holds a current, unrestricted registration as a pharmacy technician pursuant to § 54.1-3321 of the Code of Virginia ~~and who has had at least two years of experience practicing as a pharmacy technician~~ may perform the following duties under supervision of a pharmacist:

2) 18VAC110-60-220(F,G): **Visitors Policy: Remove the requirement that the Board must approve or waive all visitors. Also, allow younger minor children to accompany their parent into the dispensing area and allow visitors to assist someone into the facility that might have mobility issues. - This was partially addressed in amendment to subsection F and in the adoption of Guidance document 110-40 that allows access to processors or facilities by contractors without board approval.**

18VAC110-60-220. Pharmaceutical processor or cannabis dispensing facility prohibitions.

A. No pharmaceutical processor shall:

…F. No person except a pharmaceutical processor or cannabis dispensing facility employee or a registered patient, parent, legal guardian, registered agent, **or a companion of a patient** shall be allowed on the premises of a processor or facility with the following exceptions: laboratory staff may enter a processor for the sole purpose of identifying and collecting Cannabis or cannabis products samples for purposes of conducting laboratory tests; the board or the board's authorized representative may waive the prohibition upon prior written request.

G. All persons who have been authorized in writing to enter the facility by the board or the board's authorized representative shall obtain a visitor identification badge from a pharmaceutical processor or cannabis dispensing facility employee prior to entering the processor or facility.

1. An employee shall escort and monitor an authorized visitor at all times the visitor is in the pharmaceutical processor or cannabis dispensing facility.

2. A visitor shall visibly display the visitor identification badge at all times the visitor is in the pharmaceutical processor or cannabis dispensing facility and shall return the visitor identification badge to an employee upon exiting the processor or facility.

3. All visitors shall log in and out. The pharmaceutical processor or cannabis dispensing facility shall maintain the visitor log that shall include the date, time, and purpose of the visit and that shall be available to the board.

4. If an emergency requires the presence of a visitor and makes it impractical for the pharmaceutical processor or cannabis dispensing facility to obtain a waiver from the board, the processor or facility shall provide written notice to the board as soon as practicable after the onset of the emergency. Such notice shall include the name and company affiliation of the visitor, the purpose of the visit, and the date and time of the visit. A pharmaceutical processor or cannabis dispensing facility shall monitor the visitor and maintain a log of such visit as required by this subsection.

3) 18VAC110-60-230(A)(1), (B): Inventory: **Remove requirement that a pharmacist or pharmacy technician must conduct inventory. Change to require a pharmacist or pharmacy technician to verify the inventory, not conduct. – Already amended**

A. Each pharmaceutical processor or cannabis dispensing facility prior to commencing business shall:
1. Conduct an initial comprehensive inventory of all Cannabis plants, including the seeds, parts of plants, extracts, and cannabis ~~oil~~ products, at the facility. The responsible party shall ensure all required inventories are performed in the cultivation and production areas, and the PIC shall ensure all required inventories are performed in the dispensing area. The ~~inventory~~ inventories shall include, at a minimum, the date of the inventory, a summary of the inventory findings, and the name, signature, and title of the pharmacist, ~~or~~ pharmacy technician, responsible party, or person authorized by the responsible party who provides supervision of cultivation or production-related activities who conducted the inventory. If a facility commences business with no Cannabis or cannabis products on hand, the pharmacist or responsible party shall record this fact as the initial inventory; and

4) 18VAC110-60-290: **Product Label: Remove requirements for duplicative information between the product label and patient label.** – **Amendment proposed for adoption 12/7/21**

5) 18VAC110-60-290(B)(2)(e): **Expiration Dates: Set a specific expiration date range for products until stability testing is feasible. Specifically consider between 6 and 12 months –Already amended**

B. Cannabis ~~oil~~ products produced as a batch shall be:

1. Processed, packaged, and labeled according to the U.S. Food and Drug Administration's Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 21 CFR Part 111; and

2. Labeled with:

a. The name and address of the pharmaceutical processor;

b. The brand name of the cannabis ~~oil~~ product that was registered with the board pursuant to 18VAC110-20-285;

c. A unique serial number that matches the product with the pharmaceutical processor batch and lot number so as to facilitate any warnings or recalls the board or pharmaceutical processor deem appropriate;

d. The date of testing and packaging;

e. The expiration date ~~based on~~, which shall be six months or less from the date of packaging, unless supported by stability testing;

6) 18VAC110-60-300(F): **Remediation: Allow for remediation if a sample does not pass testing requirements. Already amended**

~~F.~~ G. If a sample of cannabis oil product does not pass the microbiological, mycotoxin, heavy metal, ~~or~~ pesticide chemical residue, or residual solvent test based on the standards set forth in this subsection, the ~~pharmaceutical processor shall dispose of the entire batch from which the sample was taken~~ batch may be remediated with further processing. After further processing, the batch shall be retested for microbiological, mycotoxin, heavy metal, pesticide chemical residue, and residual solvent, and an active ingredient analysis and terpenes profile shall be conducted.

7) 18VAC110-60-310(A)(1): VCPRL: **Allow non-licensed personnel to access the VCPRL to allow access to the processor. – Amendment proposed for adoption 12/7/21**

18VAC110-60-310 Dispensing of cannabis ~~oil~~ products

A. A pharmacist in good faith may dispense cannabis ~~oil~~ products to any registered patient, parent, or legal guardian as indicated on the written certification or to a registered agent for a specific patient.

1. Prior to the initial dispensing of cannabis ~~oil~~ products pursuant to each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor or cannabis dispensing facility shall view in person or by audiovisual means a current photo identification of the patient, parent, ~~or~~ legal guardian, or registered agent. The pharmacist or pharmacy technician shall verify in the Virginia Prescription Monitoring Program of the Department of Health Professions or other program recognized by the board that the registrations are current, the written certification has not expired, and the date and quantity of the last dispensing of cannabis ~~oil~~ products to the registered patient.

Statute for obtaining information prior to dispensing cannabis product

§ 54.1-3408.3. Certification for use of cannabis oil for treatment

J. Information obtained under the registration process shall be confidential and shall not be subject to the disclosure provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et seq.). However, reasonable access to registry information shall be provided to (i) the Chairmen of the House Committee for Courts of Justice and the Senate Committee on the Judiciary, (ii) state and federal agencies or local law enforcement for the purpose of investigating or prosecuting a specific individual for a specific violation of law, (iii) licensed practitioners or pharmacists, or their agents, for the purpose of providing patient care and drug therapy management and monitoring of drugs obtained by a registered patient, (iv) a pharmaceutical processor or cannabis dispensing facility involved in the treatment of a registered patient, or (v) a registered patient, his registered agent, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian, but only with respect to information related to such registered patient.

Statutory standard for delegation of confidential information in the Prescription Monitoring Program

§ 54.1-2523.2. (Effective until July 1, 2022) Authority to access database.

Any prescriber or dispenser authorized to access the information in the possession of the Prescription Monitoring Program pursuant to this chapter may, pursuant to regulations promulgated by the Director to implement the provisions of this section, delegate such authority to individuals who are employed or engaged at the same facility and under the direct supervision

of the prescriber or dispenser and (i) are licensed, registered, or certified by a health regulatory board under the Department of Health Professions or in another jurisdiction or (ii) have routine access to confidential patient data and have signed a patient data confidentiality agreement.

§ 54.1-2523.2. (Effective July 1, 2022) Authority to access database.

Any prescriber or dispenser authorized to access the information in the possession of the Prescription Monitoring Program pursuant to this chapter may, pursuant to regulations promulgated by the Director to implement the provisions of this section, delegate such authority to health care professionals who are (i) licensed, registered, or certified by a health regulatory board under the Department of Health Professions or in another jurisdiction and (ii) employed at the same facility and under the direct supervision of the prescriber or dispenser.

8) 18VAC110-60-310(C): **Patient Labels: Remove requirements for duplicative information between the product label and patient label (same request as product label).** – **Amendment proposed for adoption 12/7/21**

Virginia Board of Pharmacy
December 7, 2021
Licenses Issued

	5/1/20-7/30/20	8/1/20-10/31/20	11/1/20-1/31/21	2/1/21-4/30/21	5/1/21 - 7/31/21	8/1/21 - 10/31/21	License Count 11/10/2021
Business CSR	28	23	8	25	44	25	1,489
Cannabis Dispensing Facility						1	1
CE Courses	2	0	0	1	1	1	9
Limited Use Pharmacy Technician	0	0	0	0	0	0	8
Medical Equipment Supplier	5	4	8	5	1	6	230
Nonresident Manufacturer	6	3	1	6	6	10	214
Nonresident Medical Equipment Supplier	5	11	9	8	6	10	367
Non-resident Outsourcing Facility	3	2	0	1	1	1	33
Non-resident Pharmacy	22	29	31	37	17	17	876
Non-resident Third Party Logistics Provider	5	12	15	10	9	4	189
Non-resident Warehouser	5	11	9	12	5	4	96
Non-resident Wholesale Distributor	11	5	10	20	18	14	656
Non-restricted Manufacturer	1	0	0	1	0	1	29
Outsourcing Facility	0	0	0	0	0	0	0
Permitted Physician	0	0	0	0	0	0	0
Pharmaceutical Processor	1	1	0	0	0	0	4
Pharmacist	309	301	178	175	275	279	16,315
Pharmacist Volunteer Registration	0	0	0	0	0	1	0
Pharmacy	12	7	8	11	10	9	1,767
Pharmacy Intern	76	177	99	107	59	179	1,474
Pharmacy Technician	333	447	482	424	460	353	13,849
Pharmacy Technician Trainee			149	1256	1414	1280	4,034
Pharmacy Technician Training Program	2	7	2	7	3	1	133
Physician Selling Controlled Substances	22	24	16	7	19	39	624
Physician Selling Drugs Location	5	4	2	4	4	1	167
Pilot Programs	1	0	1	0	0	0	17
Registered Physician For Medical Cannabis	68	106	140	122	162	66	948
Repackaging Training Program	0	0	0	0	0	0	2
Restricted Manufacturer	1	0	0	1	0	0	41
Third Party Logistics Provider	0	0	0	1	0	0	7
Warehouser	1	4	1	5	0	1	121
Wholesale Distributor	2	1	0	1	1	1	67
Total	**926**	**1,179**	**1,169**	**2,245**	**2,515**	**2,304**	**43,767**

Inspection Update: Board of Pharmacy Meeting December 2021

Date Range: 07/01/2021 Ending 09/30/2021

Number of Inspections Completed by License Type:

Count of Result		Insp Type								
Insp Status	License Type	Change of Location	Change of Owner	Focus	New	Pilot	Reinspection	Remodel	Routine	Grand Total
Completed	Business CSR	9				14	1	2	84	110
	Cannabis Dispensing Facility					1				1
	Crematories					2			6	8
	Funeral Establishment			2		1	1		14	18
	Medical Equipment Supplier	4				6			9	19
	Non-restricted Manufacturer					1	1		1	3
	Pharmacy	4			1	5	6	28	233	277
	Physician Selling Drugs Location	1				1			17	19
	Pilot Programs						1			1
	Sedation Permit Holder Location								10	10
	Veterinary Establishment - Ambulatory					7			4	11
	Veterinary Establishment - Stationary	6	2			4			52	64
	Warehouser					1			5	6
	Wholesale Distributor					1			5	6
Completed Total		24	4	1		44	1	9	30	440	553
Completed Vi	Branch Establishment								1	1
	Business CSR	1				5	1		14	21
	Medical Equipment Supplier					1			1	2
	Pharmacy						2	1		3
	Sedation Permit Holder Location								2	2
	Veterinary Establishment - Ambulatory					2			1	3
	Veterinary Establishment - Stationary					1		1		2
Completed Virtual Total		1				9	3	2	19	34
Grand Total		25	4	1		53	1	12	32	459	587

Inspection Update: Board of Pharmacy Meeting 14 December 2021

Routine Inspections, Deficiencies by License Type:

Count of InspStatus	Result			
LicenseType	Deficiency	Deficiency & IPHCO	No Deficiency	Grand Total
Business CSR	89		46	135
Medical Equipment Supplier	5		6	11
Non-restricted Manufacturer			1	1
Pharmacy	216	434	57	707
Physician Selling Drugs Location	77		3	80
Warehouser	3		3	6
Wholesale Distributor	6		1	7
Grand Total	396	434	117	947

** New, Change of Location, Remodel, Reinspection, Pilot, and Compliance Inspections Removed*

*** Multiple deficiencies can occur at one site.*

Inspection Update: Board of Pharmacy Meeting 14 December 2021

Categories of Deficiencies for Occurrences Recorded >20 Times with Examples:

Description	Total
110-20-110	26

Deficiency 1: No Pharmacist in Charge
Deficiency 2: Pharmacists in Charge / Application not filed with Board
Deficiency 3: Unregistered persons performing duties restricted to pharmacy tech

110-20-180	31

Deficiency 9a: The alarm system shall include a feature by which any breach in the alarm shall be communicated
Deficiency 10: Unauthorized access to alarm and locking device to the prescription department

110-20-190	28

Deficiency 10: Emergency key not maintained in compliance
Deficiency 10: Unauthorized access to locking device to the prescription area
Deficiency 12: Storage of prescription drugs not in the prescription department
Deficiency 108: Emergency access alarm code/key not maintained in compliance

110-20-200	30

Deficiency 12a: Schedule II drugs are not dispersed with other schedules of drugs or maintained in a secure locked cabinet
Deficiency 109: Expired drugs in working stock

Inspection Update: Board of Pharmacy Meeting December 2021

110-20-240	73

Deficiency 14: The Pharmacist-in-Charge inventory was taken 3 days prior to the effective date of change
Deficiency 15: Schedule II perpetual inventory
Deficiency 113: Inventories taken on time, but not in compliance

110-20-275	39

Deficiency 122: Engaging in alternate delivery not in compliance
Deficiency Noted: Procedure for tracking and assuring security, accountability, integrity, and accuracy of delivery for the dispensed prescription from the time it leaves the pharmacy until it is handed to the patient or agent of the patient is not maintained per the policy and procedure guidelines

110-20-276	27

Deficiency 123: Engaging in remote processing not in compliance

110-20-355	29

Deficiency 20: Pharmacists initals verifying the accuracy of the process
Deficiency 109: Dispensed drugs being returned to stock not in compliance
Deficiency 127: Repackaging records not in compliance

110-20-418	36

Deficiency 142: No record maintained and available for 12 months / dispensing errors / patient safety

Deficiency 142: Incomplete records maintained of analysis of dispensing errors
Deficiency Noted: Pharmacy doesn't maintain a zero error report on the record if no dispensing erros have occurred within the last 30 days.

110-20-710	23

Deficiency Noted: Expired drugs within working stock
Deficiency Noted: Any drug which has exceeded the expiration date shall not be administered
Deficiency Noted: The controlled substances registrant previously disposed of unwanted or expired Schedule VI drugs by disposing of them into a drug buster container; however, the responsible party stated that all unwanted or expired drugs are now returned via a reverse distributor
Deficiency Noted: The controlled substance registrant does not utilize a reverse distributor for the disposal of unwanted or expired Schedule II through VI drugs.
Deficiency Noted: Surgical technicians that are not authorized to administer drugs have badge access to the medication room

54.1-3404	58

Deficiency 13: Biennial inventory substantially incomplete, i.e., did not include all drugs in Schedules II-V
Deficiency 16: Unusual loss of drugs not reported to the Board as required
Deficiency 112: Biennial taken late but within 30 days
Deficiency 116: Prescriptions do not include required information
Deficiency 124: Labels do not include all required information

Inspection Update: Board of Pharmacy Meeting December 2021

Deficiency 148: Theft/unusual loss of drugs reported to board but report not maintained by pharmacy
Deficiency 131: Viable air sampling was due every 6 months
Deficiency Noted: Drug invoices were not signed and dated
Deficiency Noted: Biennial inventory had not been done within the last two years
Deficiency Noted: There were no drug invoices available for review
Deficiency Noted: No biennial inventory available for review
Deficiency Noted: After the initial inventory is taken, every person described herein has not taken a new inventory

54.1-3410	24

Deficiency 116: Prescriptions do not include required information
Deficiency 118: Schedule II emergency oral prescriptions not dispensed in compliance

54.1-3410.2	218

Deficiency Noted: 800: Assessment of risk has been performed
Deficiency 20a: Pharmacist not documenting verification of accuracy of non-sterile compounding
Deficiency 22: Certification of the direct compounding area (DCA) for compounded sterile preparations
Deficiency 25a: No documentation of initial fingertip testing for persons performing high-risk level compounding of sterile preparations
Deficiency 26: No documentation of initial media-fill testing or gloved fingertip testing for persons performing low and medium-risk level compounding

Deficiency 32: Have clean room, but not all physical standards in compliance
Deficiency 33: Low or medium-risk compounded sterile preparations
Deficiency 123: Engaging in remote processing not in compliance
Deficiency 130: Records for products compounded when bulk drug substances are used did not include the manufacturer of each component
Deficiency 130a: Compounded products not properly labeled

54.1-3434	21

Deficiency 1: Pharmacist-In-Charge not fully engaged in practice at the pharmacy location
Deficiency 2: Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe
Deficiency 14: No incoming change of Pharmacist-in-Charge inventory

Inspection Update: Board of Pharmacy Meeting December 2021

Two Year Review: 09/30/2019 Ending 09/30/2021Number of Inspections Completed by License Type:

Count of Result		Insp Type									
Insp Status	License Type	Change of Location	Compliance	Fed Agency	Focus	New	Pilot	Reinspection	Remodel	Routine	Grand Total
Completed	Business CSR	50				111		7	24	482	674
	Cannabis Dispensing Facility					1					1
	Medical Equipment Supplier	21				24				99	144
	Non-restricted Manufacturer	1				4		1	1	2	9
	Pharmaceutical Processor P	1				10		8	4	18	41
	Pharmacy	32	7		12	65	1	44	251	1069	1481
	Physician Selling Drugs Loc	6			2	17		8	3	92	128
	Pilot Programs		1				8				9
	Restricted Manufacturer	2				3				1	6
	Third Party Logistics Provider					1		2		6	9
	Warehouser	10				12		2	3	56	83
	Wholesale Distributor	2		1	1	4			2	32	42
Completed Total		125	8	1	15	252	9	72	288	1857	2627
Completed Virtual	Business CSR	22	1			82		5	12	358	480
	Medical Equipment Supplier	5				6			2	43	56
	Pharmacy	11			1	11		16	46	1	86
	Physician Selling Drugs Loc	1				15		3		7	26
	Pilot Programs						12				12
	Third Party Logistics Provider					1					1
	Warehouser	1				3		1	1	27	33
	Wholesale Distributor					1		2	1	12	16
Completed Virtual Total		40	1		1	119	12	27	62	448	710
Grand Total		165	9	1	16	371	21	99	350	2305	3337

Inspection Update: Board of Pharmacy Meeting December 2021

Routine Inspections, Deficiencies by License Type:

Count of InspType	Result				
LicenseType	Deficiency	Deficiency & IPHCO	Deficiency-Response Required	No Deficiency	Grand Total
Business CSR	845		1	407	1253
Medical Equipment Supplier	72			101	173
Non-restricted Manufacturer				3	3
Pharmaceutical Processor Permit	47			3	50
Pharmacy	985	1510		323	2818
Physician Selling Drugs Location	245			13	258
Restricted Manufacturer				1	1
Third Party Logistics Provider	10			3	13
Warehouser	23			67	90
Wholesale Distributor	44			22	66
Grand Total	2271	1510	1	943	4725

** Deficiency-Response required is no longer used result type in our database*

*** New, Change of Location, Remodel, Reinspection, Pilot, and Compliance Inspections Removed*

**** Multiple deficiencies can occur at one site.*

Pharmaceutical Processors Report-December 7, 2021

- Two additional cannabis dispensing facilities have been permitted-one in Health Service Area II (Sterling) and one in Health Service Area IV (Glen Allen).
- The RFA for a pharmaceutical processor permit in Health Service Area I that was posted from September 25, 2020 to December 4, 2020 resulted in 26 applications being received. Currently the application review process continues to be on hold due to a court order.
- The Board is receiving, on average, 1000-1200 patient applications per week.
- In addition to two full time administrative specialist and two temporary administrative staff, the Board is recruiting for three additional temporary staff to assist with processing the high volume of applications.
- Board and agency staff continue work to develop specific components of a new patient registration platform.

Pharmaceutical Processors Program-By the Numbers
As of 11/14/2021

Registered Practitioners	950
Registered Patients	35,832
Registered Parents/Guardians	220
Registered Agents	151
Registered Cannabis Oil Products (cumulative)	688

Discipline Program Report

Open Cases as of 11-12-2021:

	Entry	PC	APD	Investigation	FH	IFC	Pending Closure	Total #
Patient Care Cases	2	87	9	75	1	12	0	186
Non-Patient Care Cases	0	97	5	20	2	5	20	149
							Total:	**335**

- There are four fewer patient care cases at Probable Cause to September 2021. The number of cases remains fairly consistent in an upward trend overall.

- There are two cases currently being contested in Circuit Court.

Upcoming Meetings and Disciplinary Proceedings 2022:

January 6, 2022	IFC-C	Richards-Spruill/Lee
January 11, 2922	Formal Hearings	All Board Members
January 26, 2022	IFC-A	Ratliff/Henderson
February 7, 2022	Formal Hearings	All Board Members
February 16, 2022	IFC-B	StClair/Bolyard
March 2, 2022	IFC-C	Richards-Spruill/Lee
March 15, 2022	Full Board Meeting	All Board Members

Executive Director's Report – December 7, 2021

Staffing:

- Recruitment for two licensing administrative assistants near completion
- Filled one temporary licensing position for cannabis program; recruitment for two additional temps and three P-14s ongoing

Operations:

- Continuing to telework with limited hours on-site, preparing for new normal in 2022
- Preparing for Administration Transition and General Assembly Session
- Annual evaluations of staff completed
- License Count has almost doubled as of 11/18/21:
  - 44,001 traditional BOP licensees
  - 37,328 cannabis patient registrants
- Quarterly Applicant Satisfaction Survey Results FY21: 99.3% 96.4% 99.2% 95.8%
- Discipline statistics:
  - Clearance rate (goal 100%): Q2 2021 = 153%; Q3 2021 = 70%; Q4 2021 = 82%; July 2021 = 163%; August 2021= 59%
  - Pending caseload (goal less than 20%): Q2 2021 = 13%; Q3 2021 = 10%; Q4 2021 = 9%.
  - Time to disposition (goal 90%): Q2 2021 = 92%; Q3 2021 = 87%; Q4 2021 = 91%.

Projects:

- Ceased routine printing of registration cards for cannabis program
- Ongoing efforts to acquire new licensing software for cannabis program
- Initiating agency discussions to develop performance reports for licensing
- Legislative reports submitted

Recent Meetings Attended:

- NABP Task Force on State Oversight of Drug Importation
- NABP Interactive Executive Officer Forum
- NABP/AACP District Meetings
- FDA Virtual Intergovernmental Meeting on Compounding
- NABP Executive Committee
- NABP Interactive Compliance Officer and Legal Counsel Forum
- Daily BOP staff huddles, weekly review of cases and select applications
- Monthly staff meetings with deputies, BOP staff; DHP executive directors, and DHP executive leadership team

Presentations:

- Panelist - FDA Virtual Intergovernmental Meeting on Compounding
- Law Update – Virginia Society of Health-Systems Pharmacists
- Upcoming – Virginia Association of Chain Drug Stores
- Presidential message – NABP/AACP District Meetings