# 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 Full Board Meeting
## *June 6, 2022*
## 9AM

| TOPIC | PAGES |
|---|---|
| **Call to Order of Public Hearing:** Cheryl Nelson, PharmD, Chairman | |
| • Welcome & Introductions | |
| **Public Hearing:** | |
| • Placing Certain Chemicals into Schedule I | **31-41** |
| **Adjournment of Public Hearing** | |
| **Call to Order of Full Board Meeting:** Cheryl Nelson, Chairman | |
| • Approval of Agenda | |
| **Approval of Previous Board Meeting Minutes:** | |
| • March 15, 2022 Full Board Meeting | |
| • March 15, 2022, Formal Hearing | **1-27** |
| • March 29, 2022, Special Conference Committee | |
| • March 30, 2022, Telephone Conference Call | |
| • April 13, 2022, Formal Hearing | |
| • April 18, 2022, Innovative Pilot Program | |
| • May 3, 2022, Regulation Committee | |

**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

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| **Legislative/Regulatory/Guidance:** Erin Barrett, Esq./Caroline Juran, RPh | |
| • Chart of Regulatory Actions | **28-29** |
| • Regulatory/Policy Actions Resulting from 2022 General Assembly | **30** |
| • Adoption of Final Exempt Regulations to Place Certain Chemicals into Schedule I | **31-41** |
| • Report of the Regulation Committee - Erin Barrett/Caroline Juran/Dale St.Clair, PharmD | |
| ○ Adoption of Proposed Regulations for Centralized Warehouser or Wholesale Distributor to Verify Schedule VI drugs for Automated Dispensing Devices in Hospitals | **42-56** |
| ○ Adoption of Final Regulations for Implementation of Legislation for Registration of Pharmacy Technician Trainees | **57-75** |
| ○ Consideration of Petition for Rulemaking Concerning Automated Dispensing Devices in Nursing Homes Exclusively Stocked with Emergency or Stat Drugs | **76-91** |
| ○ Adoption of Final Regulations for Pharmacists Initiating Treatment | **92-98** |
| ○ Consideration of Legislative Proposals for Expanding Use of Technology for Storing and Dispensing Drugs in Certain Facilities; Authorizing Pharmacy Technicians to Administer Vaccines, and Authorizing Pharmacy Technicians to Clarify Refills and Quantity of Certain Schedule VI Prescriptions | **Handout** **99-101** |

- Consideration of Legislative Proposal to Add Pharmacy Technician Member to Board of Pharmacy **102**
- Adoption of Guidance Document regarding Cannabis Drug-Drug Interactions **103-105**

**New Business:** **106**

- Amend 2022 Pharmacist Workforce Survey
- Elections of Chairman and Vice-Chairman, July 1, 2022 through June 30, 2023

**Reports:**

- Chairman's Report – Cheryl Nelson, PharmD
- Report on Board of Health Professions – Sarah Melton, PharmD
- Report on Licensure of Individuals and In-State Facilities – Ryan Logan, RPh **107**
- Report on Nonresident Facilities – Beth O'Halloran, RPh **108**
- Report on Inspection Program – Melody Morton, Inspections Manager, Enforcement Division **109-116**
- Report on Pharmaceutical Processors – Annette Kelley, M.S., C.S.A.C. **117**
- Report on Disciplinary Program – Ellen B. Shinaberry, PharmD **118**
- Executive Director's Report – Caroline D. Juran, RPh **119**

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

**Adjourn**

****The Board will have a working lunch at approximately 11:30pm.****

*****A panel of the Board will tentatively convene at 12:00pm or immediately following adjournment of the board meeting, whichever is later.*****

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY**
**MINUTES OF FULL BOARD MEETING**

March 15, 2022

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

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| CALL TO ORDER: | A full board meeting was called to order at 9:07am. |
| PRESIDING: | Cheryl H. Nelson, PharmD, Chairman |
| MEMBERS PRESENT: | R. Dale St. Clair Jr, PharmD, Vice Chairman<br>William Lee, DPh<br>Sarah Melton, PharmD<br>Glenn Bolyard, RPh<br>Cheryl Garvin, RPh<br>Kristopher Ratliff, DPh<br>James L. Jenkins, Jr., RN |
| MEMBERS ABSENT: | Bernard Henderson, Jr.<br>Patricia Richards-Spruill, RPh |
| STAFF PRESENT: | Caroline D. Juran, RPh, Executive Director<br>Annette Kelley, MS, CSAC, Deputy Executive Director<br>Ryan Logan, RPh, Deputy Executive Director<br>Beth O'Halloran, RPh, Deputy Executive Director<br>Ellen B. Shinaberry, PharmD, Deputy Executive Director<br>Elaine Yeatts, Senior Policy Analyst, DHP<br>Erin Barrett, JD, Senior Policy Analyst, DHP<br>David Brown, DC, DHP Agency Director (left at 9:58am)<br>James Rutkowski, JD, Assistant Attorney General<br>Sorayah Haden, Executive Assistant |
| PHARMACISTS AWARDED 1-HOUR OF LIVE OR REAL-TIME INTERACTIVE CONTINUING EDUCATION FOR ATTENDING MEETING: | John Lubkowski<br>Derek Parvizi |
| QUORUM: | With 8 members present, a quorum was established. |

APPROVAL OF AGENDA: The following amendments to the agenda were presented as follows:

- The presentation of the 2021 Pharmacist and Pharmacy Technician Workforce Survey Reports by Dr. Yetty Shobo was moved up on the agenda to be presented after the Director's Report
- A discussion of pharmacy technician training programs was added to the New Business section.

**MOTION** **The agenda was adopted as presented and amended. (motion by Ratliff, seconded by Garvin)**

APPROVAL OF PREVIOUS BOARD MEETING MINUTES One amendment was offered to the draft minutes included in the agenda packet.

**MOTION:** **The Board voted unanimously to adopt the minutes for the meetings held between December 7, 2021 and March 2, 2022 as presented and amended as follows:**

- **On page 4 of January 18, 2022 Workgroup Regarding Unprofessional Working Conditions – Pharmacy Work Conditions minutes, amend "St. Clair recommended limiting staffing collaboration to the Pharmacist-in-Charge (PIC)." to read "St. Clair discussed limiting staffing collaboration to the Pharmacist-in-Charge (PIC)." (motion by Jenkins, seconded by Melton)**

PUBLIC COMMENT: Lauren Paul, Executive Director of Pharmacy Regulatory Affairs Team at CVS expressed support of the workgroup's efforts to improve the working conditions. She raised concerns regarding the draft guidance document stating pharmacists can assess staffing needs very differently, practice settings can vary, and the measures appear subjective. CVS supports objective measures and recommends further discussion with stakeholders, including citizen members, prior to adopting the guidance document.

Christina Barrille, Executive Director of VPhA, provided a handout of written comment in addition to her verbal comment. She stated the workgroup's discussions regarding pharmacy working conditions were very productive and VPhA supports the recommendations. She stated that she has heard that pharmacy technician hours are being cut again. She expressed appreciation to Del. Hodges for introducing HB 1324 and recognized Elaine Yeatts for her retirement.

Laura Churns, Senior Manager, Pharmacy Regulatory Affairs at Publix

Pharmacy, encouraged additional dialogue regarding the draft guidance document on pharmacy working conditions to ensure it is applied correctly by everyone. She stated the guidance as written could be applied inconsistently.

Jodi Roth, Director of Government Affairs at Virginia Retail Merchants Association representing the Virginia Association of Chain Drug Stores (VACDS) stated they associate their comments with CVS and Publix.

DHP DIRECTOR'S REPORT:

David Brown, D.C., Director, DHP presented the Director's Report. He informed the Board of the departure of Barbara Allison-Bryan, MD and expressed that she will be missed by the agency. He explained the "new normal" of the agency which will go into effect in April consisting of a hybrid work schedule with staff being on-site at least two days a week. He referenced a new CDC COVID-19 tool which indicates Henrico and Chesterfield Counties have a low-level of community spread. The new security team received praises as they continue to improve the security of the building including scanners and metal detectors which will be installed in the future. Upgrades to the conference center audio-visual equipment is taking slightly longer than expected due to supply chain challenges.

ADOPTION OF 2021 PHARMACISTS AND PHARMACY TECHNICIAN WORKFORCE SURVEY REPORTS:

Yetty Shobo, PhD, Deputy Director, DHP Healthcare Workforce Data Center and Data Analytics Division presented an overview via PowerPoint of the 2021 Pharmacists and Pharmacy Technician Workforce Survey Reports. She explained the statistics of the 2021 Pharmacist and Pharmacy Technicians report to reports of the previous years. Highlights included: pharmacist diversity slightly less than national healthcare average; increase in female pharmacists; age of pharmacists less than 30 has declined by 1%; 70% of pharmacists hold a PharmD degree; overall increase of pharmacist educational debt with median debt almost the same as median income; previously income was higher than debt; higher retirement intention of pharmacists with more planning to retire by age 65. She commented that educational debt and retirement intentions are a bit concerning. Regarding use of the pharmacist statewide protocols to initiate treatment effective in January 2021, 27% of survey respondents indicated they utilize the protocols. Breakdown: naloxone (17%); hormonal contraception and prenatal vitamins (1% each); emergency contraception (2%); epinephrine and lowering out-of-pocket expenses (3% each). Highlights of pharmacy technician survey report included: decline in number of pharmacy technicians over last 4 years; 85% female has stayed about the same; diversity index increased slightly and is about the same as state diversity index; shrinkage in nearly every age group; educational debt has not changed much and income remains higher than debt; retirement intention is about 50%.

**ACTION ITEM:**

**Dr. Shobo will work with Mike Gallini in IT to amend the statewide protocol question in the Pharmacist Survey to include the additional medical conditions which became effective in December 2021 and the**

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| | **Board can consider the amended question at the June board meeting.** |
| **MOTION** | **The Board voted unanimously to adopt the Pharmacist and Pharmacy Technicians Workgroup Survey Reports as presented and amended by inserting data regarding the use of statewide protocols into the Pharmacist report. (motion by Jenkins, seconded by Bolyard)** |
| LEGISLATIVE/ REGULATORY/GUIDANCE | |
| CHART OF REGULATORY ACTIONS | Ms. Yeatts briefly reviewed the chart in the agenda packet and provided updated information. |
| REPORT OF THE 2022 GENERAL ASSEMBLY | Ms. Yeatts referenced the legislative report included in the agenda packet regarding relevant bills considered or passed by the 2022 General Assembly. |
| **ACTION ITEM:** | **Staff will research SB591 and if appropriate, send an communication in June to pharmacies to cease selling products containing delta-8 THC as of July 1, 2022.** |
| ADOPTION OF NOIRA FROM PERIODIC REVIEW | The Board considered the adoption of a Notice of Intended Regulatory Review (NOIRA) regarding Chapters 20, 21, and 30 and the one comment received during the comment period that ended 2/25/22. It was stated that the Board must adopt emergency regulations on pharmacy working conditions in September as mandated by HB 1324. The Board decided to leave reference to pharmacy working conditions in the NOIRA for now and remove later, if necessary, based on development of emergency regulations. |
| **MOTION:** | **The Board voted unanimously to adopt the Notice of Intended Regulatory Action as presented for chapters 20, 21, and 30 and amended by striking "retail" from Chapter 20 regarding a change in the definition of "personal supervision" allowing audio-visual technology by pharmacists on premises for supervision of compounding in pharmacies. (motion by St. Clair, seconded by Bolyard)** |
| PROPOSED REGULATIONS FOR REMOTE PROCESSING OF DRUGS IN AUTOMATED DISPENSING DEVICES FOR HOSPITALS | No public comments were received during the comment period ending 2/16/22. Staff reminded the Board that this action results from a petition for rulemaking related to an ongoing innovative pilot program. |
| **MOTION:** | **The Board voted unanimously to refer to the Regulation Committee the development of proposed regulations to allow a pharmacist at a central distribution company to verify Schedule VI drugs to be placed in an automated dispensing device (ADD) prior to delivery to the receiving hospital and pharmacy technicians to load the drugs directly into the ADD without further verification by a pharmacist at the hospital.** |

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| | **(motion by Jenkins, seconded by Bolyard)** |
| ADOPTION OF FINAL REGULATIONS FOR USE OF MEDICATION CAROUSELS AND RFID TECHNOLOGY: | The Board fully considered the public comments received during the comment period that ended on 3/4/22. Ms. Yeatts indicated that the typo in 18VAC110-20-425 (C)(2)(c) had been corrected to read "A nurse "or" other person…". |
| **MOTION** | **The Board voted unanimously to adopt the final regulations for the use of medication carousels and RFID technology as presented. (motion by St. Clair, seconded by Ratliff)** |
| ADOPTION OF PROPOSED REGULATIONS FOR PHARMACISTS INITIATING TREATMENT: | The Board considered proposed regulations for pharmacists initiating treatment to replace the emergency regulations currently in effect. |
| **MOTION** | **The Board voted unanimously to adopt the proposed regulations for pharmacists initiating treatment as presented. (motion by Ratliff, seconded by Melton)** |
| ADOPTION OF EXEMPT REGULATIONS FOR PHARMACEUTICAL PROCESSORS: | No comments were received during the public comment period that ended on 3/4/22. The Board considered adoption of exempt regulations for pharmaceutical processors. |
| **MOTION** | **The Board voted unanimously to adopt the exempt regulations for pharmaceutical processors as presented. (motion by Jenkins, seconded by Garvin)** |
| ADOPTION OF GUIDANCE DOCUMENT REGARDING PHARMACY WORKING CONDITIONS: | The Board considered a draft guidance document as recommended by the workgroup regarding unprofessional conduct - pharmacy working conditions. |
| **MOTION** | **The Board voted unanimously to adopt the guidance document regarding pharmacy working conditions as presented and amended by inserting "; and all other duties required by Virginia Code §§ 54.1-3300 *et seq.*, 54.1-3400 *et seq.*, and 18VAC110-20-10 *et seq.*" after "patient testing" on page 2 of the document. (motion by Bolyard, seconded by Ratliff)** |
| CONSIDERATION OF REQUIRNG CONTINUING EDUCATION ON BUPRENORPHINE IN 2023 | Juran provided background regarding a recent SAMHSA Region 3 Buprenorphine Summit held to address the significant increase in overdose deaths and patient inability to access buprenorphine from pharmacies. Challenges discussed during the summit included stigma and reluctance to |

dispense drugs for opioid use disorder (OUD) for various reasons. She stated it was recommended during the summit that the Board consider mandating up to 2 hours of CE for pharmacists on buprenorphine to further educate pharmacists on the use of buprenorphine for OUD which may potentially increase access. Past required CE topics include: 1 hour in opioid use or abuse (2015); and, 1 hour in proper opioid use, opioid overdose prevention, or naloxone administration (2017).

**MOTION**

**Pursuant to 54.1-3314.1 of the Code of Virginia and of the 15 hours of CE that pharmacists must obtain in 2023, the Board voted unanimously that 2 of the hours must address the following subject: medication for OUD, including methadone, buprenorphine, naltrexone, naloxone, or any other drug indicated for OUD. (motion by Ratliff, seconded by Melton)**

NEW BUSINESS:

DISCUSSION OF PHARMACY TECHNICIAN TRAINING PROGRAMS:

Ratliff expressed concern that the new statutory requirement, effective July 1, 2022, for pharmacy technician training programs to be accredited may negatively impact the work pool of pharmacy technicians, particularly for independent pharmacies. He stated many chain pharmacies have accredited training programs, but worried there may be insufficient programs for independent pharmacies to use. Juran commented that staff has had ongoing conversations with ASHP regarding questions received. She stated there appears to be a lot of confusion on the subject and that staff will send a subsequent communication to licensees to clarify the issue. ASHP has been clarifying to independent pharmacies that they can take advantage of distance learning programs and do not necessarily need to implement an accredited training program. They can also serve as a practical experience site for any existing school-based programs. Garvin and Ratliff expressed concern for the cost of a student completing an accredited program. Juran reminded the Board that this was a subject the Board previously supported due to ongoing discussions to expand pharmacy technician scope of practice and address hospitals' inability to hire sufficiently trained pharmacy technicians. She referenced Louisiana having mandated accredited training programs and was not aware of a decrease in its work pool. She also reminded the Board that there is an allowance for obtaining a pharmacy technician registration during this transitional time. Specifically, 18VAC110-21-141, effective July 1, 2022 states "D. A person who successfully completed or was enrolled in a Board-approved pharmacy technician training program but did not successfully pass a national examination prior to July 1, 2022 may be eligible to obtain registration as a pharmacy technician after successfully passing a national certification examination administered by PTCB or NHA and submitting to the board documentation of such completion or enrollment in a Board-approved pharmacy technician training program and passing examination score. E. A person who passed a national certification examination administered by PTCB or NHA but did not complete a Board-approved

pharmacy technician training program prior to July 1, 2022 may be eligible to obtain registration as a pharmacy technician upon documentation of having passed such examination." The Board will further discuss the subject in June when adopting regulations on the subject to replace the emergency regulations currently in effect.

RECOGNITION OF FORMER BOARD MEMBER RYAN LOGAN AND RETIRING SENIOR POLICY ANALYST ELAINE YEATTS

The Board presented a plaque and expressed appreciation to former board member, Ryan Logan, for his almost 8 years of service on the Virginia Board of Pharmacy. The Board also recognized the upcoming retirement of Senior Policy Analyst, Elaine Yeatts, who has worked for the Department of Health Professions for 33 years.

REPORTS:

CHAIRMAN'S REPORT

Chairman Nelson offered brief comments and expressed her appreciation for everyone's participation. She thanked the pharmacists and pharmacy technicians for stepping up to provide extraordinary health care and ensure public safety to the world during the pandemic. She thanked the workgroup members for continuing to work hard to improve pharmacy working conditions. She informed the Board of her participation in a NABP virtual interactive member forum held in January 2022, along with Ms. Juran. Chairman Nelson, St. Clair, and Juran will be attending the NABP Annual Meeting in Phoenix, AZ in May 2022.

BOARD OF HEALTH PROFESSIONS

Melton informed the Board that the Board of Health Professions has not met since the last Board of Pharmacy meeting and therefore, there is no update to provide. The next meeting will be held on March 29, 2022. Additional information will be provided to the Board at the June meeting.

LICENSURE OF INDIVIDUALS AND IN-STATE FACILITIES

Logan presented the Licensing Report of Individuals and In-State Facilities which included data from August 2020 through February 2022. He stated there is a typo in the report and that the last column regarding license count should read "2/17/22", not "2/17/21". As of February 17, 2022, the Virginia Board of Pharmacy holds a current licensure count of 39,764 licenses representing individuals and various in-state permit categories.

LICENSURE OF NONRESIDENT FACILITIES

O'Halloran presented the Licensing Report of Nonresident Facilities which included data from August 2020 through February 2022. She stated there is a typo in the report and that the last column regarding license count should read "2/17/22", not "2/17/21". As of February 17, 2022, the Virginia Board of Pharmacy holds a current licensure count of 2,460 Nonresident facilities licensees. The 2,460 licensees consists of 7 license types.

INSPECTION PROGRAM

Melody Morton, Inspections Manager with the Enforcement Division

presented the Inspections Report including data from October 1, 2021 through December 21, 2021. The report included the number of inspections completed per licensing type, deficiencies noted during routine inspections per licensing type, and the categories for deficiencies for reoccurrences recorded more than 20 times with examples. She stated they have resumed more "normal practice" and are performing fewer virtual inspections.

PHARMACEUTICAL PROCESSORS

Kelley presented the Pharmaceutical Processors Report informing the Board of the continuation of adding licensed facilities. The Board currently has 6 licensed cannabis dispensing facilities. Assistant Attorney General, Jim Rutkowski, informed the Board that the Henrico County Circuit Court Judge ruled in favor of Board regarding PharmaCann's appeal. Kelley expressed her appreciation of the staff's hard work as the Pharmaceutical Processor Program will soon have registered 50,000 patients. The program continues to receive approximately 1,000 applications weekly.

DISCIPLINARY PROGRAM

Shinaberry presented the Disciplinary Program Report reporting as of February 22, 2022 the Board currently has 381 open cases consisting of 207 patient care cases and 174 non-patient care cases. Thirty-five of the non-patient care cases are compliance cases. There are currently two cases being appealed to Circuit Court. Shinaberry provided the dates for upcoming disciplinary proceedings.

EXECUTIVE DIRECTOR'S REPORT

Juran stated the agency will be transitioning to a hybrid schedule in April consisting of a schedule allowing up to 3 days of teleworking. The license count for the board has more than doubled consisting of approximately 41,000 traditional Board of Pharmacy licenses and approximately 46,000 cannabis licensees.

The Board recently filled one full-time licensing administrative position and one records management position. Licensing Administrative Assistant Sheila Sheranek will be retiring April 1, 2022. There is ongoing recruitment to fill her position. Recruitment for an additional full-time licensing administrative assistant and licensing supervisor for the pharmaceutical processor program continues. The Pharmaceutical Processor Program has recently filled 3 temporary positions and 2 P-14 positions.

The agency is preparing for the transition to utilizing digital disciplinary evidence packets. Also, Juran has attended multiple NABP meetings. She stated that Shinaberry and Logan recently offered a board presentation at the VCU School of Pharmacy.

CONSIDERATION OF CONSENT ORDERS, SUMARY SUSPENSIONS, OR SUMMARY RESTRICTIONS

Shinaberry presented a consent order for Board consideration regarding Denise A. Foley (License #0202215458).

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| CLOSED MEETING | Upon a motion by St. Clair, and duly seconded by Jenkins, the Board voted unanimously to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code") to reach a decision regarding the matter of Denise A. Foley (License #0202215458). Additionally, he moved that Caroline Juran, James Rutkowski, Ellen Shinaberry, and Sorayah Haden attend the closed meeting because their presence is deemed necessary and will aid the Board in its deliberations. |
| RECONVENE | Upon the motion by St. Clair, and duly seconded by Garvin, having certified that the matters discussed in the closed meeting met the requirements of §2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision. |
| DECISION | Upon a motion by St. Clair, and duly seconded by Lee, the Board unanimously voted to accept the consent order for Denise A. Foley (License #0202215458). |
| | Shinaberry presented a consent order for Board consideration regarding Williamsburg Drug #1963 (License #0201000676). Ratliff and St. Clair recused themselves from the presentation and attending the closed meeting. |
| CLOSED MEETING | Upon a motion by Bolyard, and duly seconded by Garvin, the Board voted unanimously to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code") to reach a decision regarding the matter of Williamsburg Drug #1963 (License #0201000676). Additionally, he moved that Caroline Juran, James Rutkowski, Ellen Shinaberry, and Sorayah Haden attend the closed meeting because their presence is deemed necessary and will aid the Board in its deliberations. |
| RECONVENE | Upon the motion by Bolyard, and duly seconded by Lee, having certified that the matters discussed in the closed meeting met the requirements of §2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision. |
| DECISION | Upon a motion by Jenkins, and duly seconded by Melton, the Board unanimously voted to accept the consent order for Williamsburg Drug #1963 (License #0201000676); Ratliff and St. Clair recused. |
| | Shinaberry presented a possible settlement for Board's consideration regarding Green Health Integrative and Wellness Pharmacy (License #0201004861). Bolyard recused himself from the presentation and closed session. |
| CLOSED MEETING | Upon a motion by St. Clair, and duly seconded by Ratliff, the Board voted |

unanimously to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code") to reach a decision regarding the matters of Green Health Integrative and Wellness Pharmacy (License #0201004861). Additionally, he moved that Caroline Juran, James Rutkowski, Ellen Shinaberry, and Sorayah Haden attend the closed meeting because their presence is deemed necessary and will aid the Board in its deliberations.

RECONVENE

Upon a motion by St. Clair, and duly seconded by Ratliff, having certified that the matters discussed in the closed meeting met the requirements of §2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision.

DECISION

Upon a motion by Melton, and duly seconded by Garvin, the Board unanimously voted to not accept the settlement for Green Health Integrative and Wellness Pharmacy (License #0201004861); Bolyard recused.

MEETING ADJOURNED: 1:40 PM

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

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DATE: DATE:

**VIRGINIA BOARD OF PHARMACY**
**MINUTES OF A PANEL OF THE BOARD**

Tuesday, March 15, 2022
Commonwealth Conference Center
Second Floor
Board Room 2

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

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

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| CALL TO ORDER: | A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 2:02 PM. |
| PRESIDING: | Cheryl Nelson, Chair |
| MEMBERS PRESENT: | Glenn Bolyard<br>Jim Jenkins<br>Kris Ratliff<br>Cheri Garvin<br>Bill Lee<br>Dale St.Clair<br>Sarah Melton |
| STAFF PRESENT: | Caroline D. Juran, Executive Director<br>Ellen B. Shinaberry, Deputy Executive Director<br>James Rutkowski, Assistant Attorney General<br>Sorayah Haden, Executive Assistant |
| QUORUM: | With eight (8) members of the Board present, a panel of the board was established. |
| Chukwuemeka S. Frank Obidike<br>License No. 0202-205025 | A formal hearing was held in the matter of Chukwuemeka S. Frank Obidike to discuss allegations that he have violated certain laws and regulations governing the practice of pharmacy in Virginia and to consider his application for reinstatement.<br><br>Erin Weaver, Assistant Attorney General for the Commonwealth, presented the case. Ms. Weaver was assisted by Jess Weber, DHP Adjudication Specialist.<br><br>Chukwuemeka S. Frank Obidike testified on his own behalf and was not represented by legal counsel.<br><br>Joyce Johnson, DHP Investigator, testified in person on behalf of the Commonwealth. |

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| CLOSED MEETING: | Upon a motion by Dr. St.Clair, and duly seconded by Ms. Garvin, the panel voted 8-0, 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 Chukwuemeka S. Frank Obidike. Additionally, he moved that Ellen Shinaberry, Caroline Juran, 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 Mr. Jenkins, and duly seconded by Mr. Ratliff, the panel voted 8-0 to deny reinstatement of the pharmacist license of Chukwuemeka S. Frank Obidike. |
| ADJOURN: | With all business concluded, the meeting adjourned at 4:05 PM. |

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

**VIRGINIA BOARD OF PHARMACY**
**SPECIAL CONFERENCE COMMITTEE MINUTES**

Tuesday, March 29, 2022
Commonwealth Conference Center
Second Floor
Board Room 3

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

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| CALL TO ORDER: | A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:17 am. |
| PRESIDING: | Kristopher Ratliff, Committee Chair |
| MEMBERS PRESENT: | Bernard Henderson, Committee Member |
| STAFF PRESENT: | Mykl Egan, Discipline Case Manager<br>Ileita Redd, Discipline Program Specialist<br>David Robinson, DHP Adjudication Specialist<br>Anne Joseph, DHP Adjudication Consultant<br>Jessica Weber, DHP Adjudication Specialist |
| KRS GLOBAL BIOTECHNOLOGY, INC., APPLICANT<br>Registration No. :0236-000015 | Elsa Kerpi, President, and Anxhela Gurra, Pharmacist-in-Charge appeared as representatives of KRS Global Biotechnology, Inc., ("KRS") to discuss KRS's application for registration as a non-resident outsourcing facility and that allegations exist to deny that application as stated in the December 21, 2021 Notice. The pharmacy 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 KRS Global Biotechnology, Inc. 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. |

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| 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 the application of KRS Global Biotechnology, Inc. for registration as a non-resident outsourcing facility. |
| ADRIENNE GAUTIER LOPEZ<br>License No. 0202-217377 | Adrienne Gautier Lopez appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the November 22, 2021 Notice. Ms. Lopez was represented by Nora Ciancio, Esq. |
| 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 Adrienne Gautier Lopez. 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 Reprimand Ms. Lopez, Order her to take continuing education and to be placed on probation under certain terms and conditions. |
| WALGREENS #11986<br>Permit No. 0201-001245 | No one appeared as representatives of Walgreens #11986 to discuss allegations that it may have violated certain laws and regulations governing the |

conduct of a pharmacy as stated in the March 2, 2022 Notice. They were not represented by counsel

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 Walgreens #11986. 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 Walgreens #11986.

ADJOURNED: 2:17 p.m.

_____ _____

Kristopher Ratliff, Chair

Mykl Egan
Discipline Case Manager

_____ _____

Date

Date

**VIRGINIA BOARD OF PHARMACY**
**MINUTES OF TELEPHONE CONFERENCE CALL**

Wednesday, March 30, 2022

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

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

TIME & PURPOSE: Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on March 30, 2022, at 9:04 AM, to consider settlement proposals for Case no. 200972 and Case no. 201687.

PRESIDING: Cheryl Nelson, Chair

MEMBERS PRESENT:
Cheri Garvin
Bernie Henderson
William Lee
Kristopher Ratliff
Dale St. Clair
Patricia Richards-Spruill
Glenn Bolyard
Sarah Melton

STAFF PRESENT:
Caroline Juran, Executive Director
Ellen Shinaberry, Deputy Executive Director
James Rutkowski, Senior Assistant Attorney General
Sean J. Murphy, Assistant Attorney General
Jess Weber, Adjudication Specialist

POLL OF MEMBERS: The Board members were polled as to whether they could have attended a regular meeting at the office in a timely manner for the purpose of hearing evidence in a possible summary restriction case. The Board members stated that they would not have been able to attend.

QUORUM: With nine (9) members participating a quorum was established.

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| CASE NO. 200972 | Board members Ms. Patricia Richards-Spruill and Dr. Bill Lee were recused from the conference call for discussion of this case. Sean J. Murphy, Assistant Attorney General, presented a possible settlement proposal for case no. 200972. |
| CLOSED MEETING: | Upon a motion by Dr. Ratliff, and duly seconded by Mr. Bolyard, the Board voted 7-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation regarding a possible settlement in the matter of Case No 200972. Additionally, he moved that Caroline Juran, Ellen Shinaberry, 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 Board re-convened an open meeting and announced the decision (Motion by Ratliff/Second by Bolyard).<br><br>Board members Richards-Spruill and Lee rejoined the teleconference at approximately 9:54 AM. |
| DECISION: | Upon a motion by Mr. Henderson and duly seconded by Mr. Bolyard, the Board unanimously voted (7-0) to reject the proposed settlement agreement. |
| CASE NO. 201687 | Board members Bolyard and St. Clair were recused from the conference call for discussion of this case. Ellen Shinaberry, Deputy Executive Director, and Jess Weber, Adjudication Specialist, presented a possible settlement proposal for case no. 201687. |
| CLOSED MEETING: | Upon a motion by Dr. Ratliff, and duly seconded by Mr. Henderson, the Board voted 7-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation regarding a possible settlement in the matter of Case No 201687. Additionally, he moved that Caroline Juran, Ellen Shinaberry, and Jim Rutkowski attend the closed meeting. |

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| RECONVENE: | Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board re-convened an open meeting and announced the decision (Motion by Ratliff/Second by Richards-Spruill). |
| DECISION: | Upon a motion by Mr. Henderson and duly seconded by Ms. Richards-Spruill, the Board unanimously voted (7-0) to reject the proposed settlement agreement. |
| ADJOURN: | The conference call adjourned at 10:46 AM. |

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| ADJOURN: | With all business concluded, the meeting adjourned at 10:02 AM. |

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| Cheryl Nelson, Chair | Ellen B. Shinaberry, PharmD<br>Deputy Executive Director |
| Date | |

**VIRGINIA BOARD OF PHARMACY**
**MINUTES OF A PANEL OF THE BOARD**

Wednesday, April 13, 2022
Commonwealth Conference Center
Second Floor
Board Room 2

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 9:05 AM.

PRESIDING: Cheryl Nelson, Chair

MEMBERS PRESENT: Sarah Melton
Bernie Henderson
Kris Ratliff
Cheri Garvin

STAFF PRESENT: Ellen B. Shinaberry, Deputy Executive Director
James Rutkowski, Assistant Attorney General
Sorayah Haden, Executive Assistant

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

GREEN HEALTH INTEGRATIVE & WELLNESS PHARMACY
Permit No. 0201-004861

A formal hearing was held in the matter of Green Health Integrative & Wellness Pharmacy to discuss allegations the pharmacy may have violated certain laws and regulations governing the practice of pharmacy in Virginia.

Sean Murphy, Assistant Attorney General for the Commonwealth, presented the case. Mr. Murphy was assisted by David Robinson, DHP Adjudication Specialist.

Kwame Ennin was represented by J. Burkhardt Beale, Esq. Mr. Ennin testified on his own behalf.

CLOSED MEETING: Upon a motion by Dr. Melton, and duly seconded by Mr. Henderson, 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 Green Health Integrative & Wellness Pharmacy. Additionally, she moved that Ellen Shinaberry, Sorayah Haden, 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.

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| DECISION: | Upon a motion by Dr. Melton, and duly seconded by Mr. Henderson, the panel voted 5-0 to issue a reprimand, a monetary penalty, and place the pharmacy on probation for not less than three years with certain terms and conditions. |
| | Board member Glenn Bolyard arrived at 10:50 AM. |
| LISA K. COTTER<br>License No. 0202-208184 | A formal hearing was held in the matter of Lisa K. Cotter to discuss allegations she may have violated certain laws and regulations governing the practice of pharmacy in Virginia. |
| | Sean Murphy, Assistant Attorney General for the Commonwealth, presented the case. Mr. Murphy was assisted by David Robinson, DHP Adjudication Specialist. |
| | Ms. Cotter was represented by Hunter Jamerson, Esq. and Lindsay Sessa, Esq. Ms. Cotter testified on her own behalf. |
| | Witnesses testifying in person for the Commonwealth included Emily Buss, DHP Pharmacy Inspector; Jessiann Tumbleston Allen, former pharmacy technician; Makenna Plum, former pharmacy technician; Kaitlyn Meadows, former pharmacy technician; and Whitney Price, former pharmacy technician. |
| CLOSED MEETING: | Upon a motion by Mr. Bolyard, and duly seconded by Mr. Henderson, the panel voted 6-0, 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 Lisa K. Cotters. Additionally, he moved that Ellen Shinaberry, Sorayah Haden, 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 Dr. Melton, and duly seconded by Mr. Henderson, the panel voted 6-0 to revoke the pharmacist license of Lisa K. Cotter. |
| ADJOURN: | 5:55 PM |

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

**VIRGINIA BOARD OF PHARMACY**
**MINUTES OF INNOVATIVE PILOT PROGRAM COMMITTEE**

Monday April 18, 2022
Commonwealth Conference Center
Second Floor
Board Room 2

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

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| CALL TO ORDER: | A meeting of a Special Conference Committee (Innovative Pilot) of the Board of Pharmacy was called to order at 10:03 AM. |
| PRESIDING: | Cheryl Nelson, Committee Chairman |
| MEMBER PRESENT: | Dale St. Clair, Committee Member |
| STAFF PRESENT: | Caroline D. Juran, Executive Director<br>Mykl Egan, Discipline Case Manager<br>David Robinson, DHP Adjudication Specialist<br>Sorayah Haden, Executive Assistant |
| PARTNERS PHARMACY OF VIRGINIA, LLC<br>Improving Safe Access to Medications in Virginia's Crisis Services System | Christopher Bowling, Pharmacist in Charge, Frank Wang, VP of Operations, and Jody Fenelon, Executive VP of Compliance of Partners Pharmacy appeared in person on behalf of Partners Pharmacy of Virginia, LLC. Additionally, Kevin Ann Huckshorn, PhD, RN, MSN, CADC, Executive Vice President, NE Region, Recovery Innovations International and Tammala Watkins, LCSW, Virginia State Director, Recovery Innovations International, appeared in person to discuss the proposed innovative pilot program "Establishing a Reliable and New Pharmacy Services Model: Improving Safe Access to Medications in Virginia's Crisis Services System" as stated in the April 14, 2022 Notice. |
| DISCUSSION: | Representatives of Partners Pharmacy presented information about the use of AP Passport in a recently approved pilot program and its proposed use in a new crisis stabilization unit in Chantilly, Virginia. Representatives from the Recovery Innovations International presented information about the nature of crisis stabilization units and the value of having an |

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| | AP Passport system in them. The Chantilly location currently is only providing services to short-term stay patients averaging a stay of 3-5 days. They do not currently accept patients intended to stay less than 24 hours. |
| DECISION: | Upon a motion by Dr. St. Clair, and duly seconded by Dr. Nelson, the Committee voted unanimously to approve the innovative pilot program for three years with certain terms and conditions. |
| ADJOURN: | With all business concluded, the meeting adjourned at 1:14 PM. |

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| Cheryl Nelson<br>Committee Chairman | Caroline D. Juran<br>Executive Director |
| Date | Date |

DRAFT/UNAPPROVED

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

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

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

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

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| CONSIDERATION OF PETITION FOR RULEMAKING – USE OF AUTOMATED DISPENSING SYSTEMS EXCLUSIVELY STOCKED WITH DRUGS FOR EMERGENCY OR STAT ADMINISTRATION | The committee discussed the details of the petition for rulemaking regarding automated dispensing systems exclusively stocked with drugs for emergency or stat administration to determine if the Board would like to initiate rulemaking or take no action regarding the automated dispensing systems. |
| **MOTION:** | **The committee voted unanimously to recommend to the full board that it adopt a Notice of Intended Regulatory Action (NOIRA) resulting from the petition for rulemaking that would amend 18VAC110-20-555 by removing the requirement for a pharmacist to review the order and electronically authorize access to the drug stored in an automated dispensing device when the device exclusively stocks drugs for emergency or stat use. (Motion by Ratliff, seconded by Bolyard)** |
| CONSIDERATION OF PROPOSED REGULATIONS FOR CENTRALIZED WAREHOUSER OR WHOLESALE DISTRIBUTOR TO VERIFY SCHEDULE VI DRUGS FOR AUTOMATED DISPENSING DEVICES IN HOSPITALS | The committee discussed draft proposed regulatory amendments of 18VAC110-20-490 to authorize a pharmacist at a centralized warehouser or wholesale distributor to verify schedule VI drugs for specific automated dispensing devices in hospitals and remove the requirement for a pharmacist at the hospital to verify the drugs prior to loading the drugs into the devices. This results from a petition for rulemaking received in May 2021. The requirements of an innovative pilot consent order on this subject issued to Central Shared Services, LLC and other hospital pharmacies in 2015 was reviewed as well. |
| **MOTION:** | **The committee voted unanimously to recommend that the full Board adopt the proposed regulatory amendments of 18VAC110-20-490 to authorize a pharmacist at a centralized warehouser or wholesale distributor to verify schedule VI drugs for specific automated dispensing devices in hospitals and remove the requirement for a pharmacist at the hospital to verify the drugs prior to loading the drugs into the devices as presented. (Motion by Bolyard, seconded by Ratliff)** |
| CONSIDERATION OF EMERGENCY REGULATIONS RESULTING FROM HB1324 | The committee generally discussed the concepts recommended for inclusion in the emergency regulations to implement HB1324 which will be presented to the Board at the September 2022 meeting. The committee discussed adding language for whistle-blower protections. Regarding the |

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

**MOTION:**

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

CONSIDERATION OF FINAL REGULATIONS – PHARMACY TECHNICIAN TRAINING PROGRAMS

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

**MOTION:**

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

CONSIDERATION OF FINAL REGULATIONS – PHARMACISTS INITIATING TREATMENT

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

**MOTION:**

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

CONSIDERATION OF RECOMMENDATIONS FOR ADDITIONAL DUTIES FOR PHARMACY TECHNICIANS

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

**MOTION:**

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

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

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

**MOTION:**

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

**ADJOURN:**

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

_____ _____

Dale St. Clair, Chairman

_____
DATE

Caroline Juran, Executive Director

_____
DATE

**Board of Pharmacy**
**Current Regulatory Actions**
**June 2022**

| VAC | Stage | Subject Matter | Date submitted* | Office; time in office** | Notes |
|---|---|---|---|---|---|
| 18VAC110-20 | Final | Prohibition against incentives to transfer prescriptions | 5/23/2018 | Governor 1463 days (4 years) | Addresses a patient safety concern. |
| 18VAC110-30 | NOIRA | Implementation of 2021 Periodic Review | 3/30/2022 | Governor 57 days | Implementation of changes identified during 2021 periodic review of regulations governing practitioners selling controlled substances |
| 18VAC110-20 | Proposed | Implementation of 2021 legislation for pharmacists initiating treatment | 5/12/2022 | Governor 13 days | Amendments to include additional drugs, devices, and treatment that can be initiated by pharmacists pursuant to 2021 legislation. |
| 18VAC110-21 | NOIRA | Implementation of 2021 Periodic Review | 4/3/2022 | Secretary 52 days | Implementation of changes identified during 2021 periodic review of regulations governing the licensure of pharmacists and registration of pharmacy technicians |
| 18VAC110-20 | Final | Use of medication carousels and RFID technology | 4/25/2022 | Secretary 30 days | Incorporation into regulation certain allowances that have been approved by the Board for pilot programs in several hospital systems. |

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| 18VAC110-60 | Exempt Final | Changes to access and labeling requirements (Processors) | Register date: 4/25/2022 Effective date: 5/25/2022 | | Amendments to clarify the process by which certain individuals at processors or dispensing facilities may determine eligibility for access to processor or facility, and changes to eliminate certain information on labels if that information is included on a batch label |
| 18VAC110-21 | Proposed | Implementation of legislation for registration of pharmacy technicians | Register date: 1/3/2022 | | Establishes requirements for registration of a pharmacy technician trainee and sets out the requirement for accreditation of training programs in accordance with law. |

* Date submitted to current location
** As of May 25, 2022

# Department of Health Professions
# Regulatory/Policy Actions – 2022 General Assembly

**EMERGENCY REGULATIONS**:

| Legislative source | Mandate | Promulgating agency | Board adoption date | Effective date Within 280 days of enactment |
|---|---|---|---|---|
| HB1324 | Working conditions regulations | Pharmacy | 9/6/22 | |
| HB1323/SB672 | Pharmacists treating | Pharmacy | 9/6/22 | |

**EXEMPT REGULATORY ACTIONS**

| Legislative source | Mandate | Promulgating agency | Adoption date | Effective date |
|---|---|---|---|---|
| HB193/SB759 | Repeal of drugs/chemicals scheduled in Drug Control Act | Pharmacy | 9/6/22 | 11/9/22 |
| HB933/SB671 | Numerous amendments to pharmaceutical processor regs | Pharmacy | 6/6/22 - propose 9/6/22 – final | 9/15/22 |

**NON-REGULATORY ACTIONS**

| Legislative source | Affected agency | Action needed | Due date |
|---|---|---|---|
| SB14 | Pharmacy | Workgroup on prescription drug donation program | 12/1/22 |
| HB1187/SB317 | All boards | System for record of temporary authorization | |
| HB1323/SB672 | Protocols for pharmacists treating | Medicine (in collaboration with Pharmacy and VDH) | Expanded protocol recommended by Governor rejected. Governor has until May 27 to approve original bill or veto. |

## Policy Actions at SHHR:

**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: Adoption of final regulations – placement of chemicals in Schedule I**

**Included in your agenda package are:**

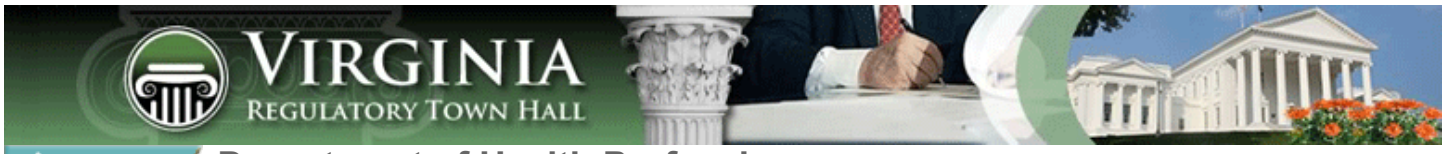
- Copy of notice of public hearing listing chemicals to be placed in Schedule I.
- Amendments to 18VAC110-20-322.

**Staff Note:** Public hearing held before the meeting.

**Action needed:**

- Motion to adopt exempt final changes to 18VAC110-20-322.

Virginia.gov Agencies | Governor




Agency Department of Health Professions

Board Board of Pharmacy

Edit Notice

## General Notice

**Notice for scheduling chemicals in Schedule I pursuant to 54.1-3443**

Date Posted: 4/21/2022

Expiration Date: 6/7/2022

Submitted to Registrar for publication: YES

No comment forum defined for this notice.

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**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 virtual public hearing will be conducted at **9:05 a.m. on June 6, 2022.** Instructions will be included in the agenda for the board meeting, also on June 6th. Public comment may also be submitted electronically or in writing prior to June 6thto Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

Pursuant to article § 54.1-3443(D), The Virginia Department of Forensic Science (DFS) has identified ten (10) compounds for recommended inclusion into Schedule I of the Drug Control Act.

**The following compound is classified as a synthetic opioid. Compounds of this type have been placed in Schedule I (§ 54.1-3446(1)) in previous legislative sessions.**

1. **2-(4-ethoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzimidazole (other names: N-pyrrolidino etonitazene, etonitazepyne),** 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 their chemical structures, the following compounds are expected to have hallucinogenic properties. Compounds of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.**

2. **1-(1,3-benzodioxol-5-yl)-2-(propylamino)-1-butanone (other names: 3,4-Methylenedioxy-alpha-propylaminobutiophenone; N-propyl butylone),** 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. **2-(ethylamino)-1-phenylpentan-1-one (other names: N-ethylpentedrone, alpha-ethylaminopentiophenone),** 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.

4. **3,4-methylenedioxy-alpha-cyclohexylaminopropiophenone (other name: Cyputylone),** 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.

5. **3,4-methylenedioxy-alpha-cyclohexylmethylaminopropiophenone (other name: 3,4-Methylenedioxy-N,N-cyclohexylmethcathinone**), 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.

6. **3,4-methylenedioxy-alpha-isopropylaminobutiophenone (other name: N-isopropyl butylone),** 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.

7. **4-chloro-N-butylcathinone (other names: 4-chlorobutylcathinone, para-chloro-N-butylcathinone),** 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.

8. **4-hydroxy-N-methyl-N-ethyltryptamine (other names: 4-hydroxy MET, Metocin),** 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 compound is classified as a central nervous system stimulant. Compounds of this type have been placed in Schedule I (§ 54.1-3446(5)) in previous legislative sessions.**

9. **4-methylmethamphetamine (other names: N-alpha,4-trimethyl-benzeneethanamine, 4-MMA)**, including its salts, isomers and salts of isomers.

**The following compound is classified as a cannabimimetic agent. Compounds of this type have been placed in Schedule I (§ 54.1-3446(6)) in previous legislative sessions.**

10. **N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indole-3-acetamide (other names: ADB-FUBIATA, AD-18, FUB-ACADB)**, 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.

**Contact Information**

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

*This general notice was created by Erin Barrett on 04/21/2022 at 2:21pm*

**Project 7200 - Exempt Final**

**Board Of Pharmacy**

**June 2022 Scheduling of Chemicals in Schedule 1**

**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 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, 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.

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.

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 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.

The placement of drugs listed in this subsection shall remain in effect until August 16, 2023, unless enacted into law in the Drug Control Act.

E. 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.

2-(4-ethoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzimidazole (other names: N-pyrrolidino etonitazene, etonitazepyne), 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. 1-(1,3-benzodioxol-5-yl)-2-(propylamino)-1-butanone (other names: 3,4-Methylenedioxy-alpha-propylaminobutiophenone; N-propyl butylone), 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. 2-(ethylamino)-1-phenylpentan-1-one (other names: N-ethylpentedrone, alpha-ethylaminopentiophenone), 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.

c. 3,4-methylenedioxy-alpha-cyclohexylaminopropiophenone (other name: Cyputylone), 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.

d. 3,4-methylenedioxy-alpha-cyclohexylmethylaminopropiophenone (other name: 3,4-Methylenedioxy-N,N-cyclohexylmethcathinone), 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.

e. 3,4-methylenedioxy-alpha-isopropylaminobutiophenone (other name: N-isopropyl butylone), 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.

f. 4-chloro-N-butylcathinone (other names: 4-chlorobutylcathinone, para-chloro-N-butylcathinone), 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.

g. 4-hydroxy-N-methyl-N-ethyltryptamine (other names: 4-hydroxy MET, Metocin), 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. Central nervous system stimulants.

4-methylmethamphetamine (other names: N-alpha,4-trimethyl-benzeneethanamine, 4-MMA), including its salts, isomers and salts of isomers.

4. Cannabbimimetic agent.

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indole-3-acetamide (other names: ADB-FUBIATA, AD-18, FUB-ACADB), 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 January 4, 2024, unless enacted into law in the Drug Control Act.

**Agenda Item: Consideration of proposed regulations for centralized warehouser or wholesale distributor to verify Schedule VI drugs for Automated Dispensing Devices in hospitals.**

**Included in your agenda package are:**

- 2015 Consent Order for pilot program.
- Proposed regulations as approved by Regulatory Committee

**Staff note:** Regulatory Committee recommended that the Board adopt proposed regulations.

**Action needed:**

- Motion to adopt proposed regulations as presented or amended.

VIRGINIA:

BEFORE THE BOARD OF PHARMACY

IN RE: **Central Shared Services, LLC; Chippenham Medical Center Pharmacy; Dominion Hospital; Hanover Emergency Center Pharmacy; Henrico Doctors' Hospital; John Randolph Medical Center Pharmacy; Johnston-Willis Hospital Pharmacy; LewisGale Hospital Alleghany, LewisGale Hospital Montgomery; Pulaski Community Hospital d/b/a Lewis Gale Hospital-Pulaski; LewisGale Medical Center; Parham Doctors' Hospital-A Campus of Henrico Doctors' Hospital; Reston Center Hospital Pharmacy; Retreat Doctors' Hospital-A Campus of Henrico Doctors' Hospital; Spotsylvania Regional Medical Center; Stone Spring Emergency Center; Westcreek Medical Center Pharmacy Pharmacy Central Distribution**
**Innovative Program Applicant**

**Permit No: 0216-000033, 0201001086, 0201003779, 0201004579, 0201001260, 0201001203, 0201001107, 0201001632, 0201002591, 0201001187, 0201001043, 0201003014, 0201002401; 0201001231, 0201004327, 0201004533, 0201004644**

## CONSENT ORDER

Now comes the Virginia Board of Pharmacy ("Board") and Central Shared Services, LLC, as evidenced by the signatures affixed below, and enter into this Consent Order affecting the application of Central Shared Services, LLC for approval of an innovative (pilot) program, Pharmacist Central Distribution, and waiver of compliance with certain provisions of Board of Pharmacy Regulations ("Regulations") 18 VAC 110-20-490 (C) and 18 VAC 110-20-460 (A).

## FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Central Shared Services, LLC holds wholesale distributor license number 0216-000033 issued by the Board on April 14, 2000.

2. On December 29, 2014, the Board received an application from Central Shared Services, LLC, requesting approval of an innovative program.

3. Central Shared Services, LLC is requesting a waiver of 18 VAC 110-20-490 (C) of the Regulations that requires the delivery record of drugs placed into an automated dispensing device (ADD) in a hospital to

DCH

include the initials of the pharmacist at the hospital that checked the drugs to be removed from the pharmacy and the delivery record for accuracy and 18 VAC 110-20-460 (A) that requires a pharmacist to check all Schedule II - VI drugs prior to delivery as nursing unit floor stock, plus the requirement of initialing or signing manually, or electronically, the record of distribution verifying the accuracy of distribution of Schedule II - IV drugs.

4. Central Shared Services, LLC intends to distribute Schedule VI drugs to hospitals to be placed in specific automated dispensing devices. A Virginia licensed pharmacist at Central Shared Services, LLC will verify all Schedule VI drugs to be placed in an ADD prior to delivery to the pharmacy department at each hospital. Pharmacy technicians at each hospital will load the drugs into the specific ADD.

5. The Application is properly before this Committee, and it is within its sound discretion to approve or deny said Application.

## CONSENT

Daniel Honerbrink, as the Chief Executive Officer, Central Shared Services, LLC, and on behalf of Central Shared Services, LLC, by affixing his signature hereon, agrees to the following:

1. Central Shared Services, LLC has been advised specifically to seek the advice of counsel prior to signing this document;

2. Central Shared Services, LLC admits the truth of the above Findings of Fact; and

3. Central Shared Services, LLC consents to the following Order.

## ORDER

WHEREFORE, on the basis of the foregoing Findings of Fact and Conclusions of Law, it is hereby ORDERED that the Board APPROVES the Application for a period of three (3) years from the date this Order is entered by the Board with the following terms and conditions:

1. The approval of this innovative (pilot) program is limited to Schedule VI drugs

2. The Central Shared Services warehouse shall deliver the drugs directly to the pharmacy at each facility.

3. A pharmacist at the Central Shared Services, LLC warehouse shall verify 100% of all drugs distributed to the pharmacy at a facility to be placed into an ADD.

4. The requirement in 18 VAC 110-20-490 C of the Regulations that requires the delivery record for the drugs to be removed from a pharmacy to be placed in an ADD to include the initials of the pharmacist checking shall be waived for those drugs received from the Central Shared Services, LLC warehouse.

5. The requirement in 18 VAC 110-20-460 (A) of the Regulations for a pharmacist to check all drugs delivered to a hospital unit as floor-stock before the drugs leave the pharmacy and shall initial or sign manually or electronically the record of distribution verifying the accuracy of the distribution shall be waived for the drugs received from the Central Shared Services, LLC warehouse to be placed in an ADD.

6. The Central Shared Services, LLC warehouse shall maintain a record of all drugs distributed to facilities to be placed in a specific ADD. The record shall include the date; drug name, dosage form, and strength; quantity; facility name, hospital unit, a unique identifier for the specific device receiving the drug; and initials of the pharmacist checking the drugs for accuracy.

7. The pharmacy at each facility shall maintain a record of the initials of the person loading the automated dispensing device.

8. All records required by this section shall be maintained at the address of the applicable warehouse or facility 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. Central Shared Services, LLC shall provide each hospital with an invoice for drugs delivered to the hospital to be placed in a specific ADD.

9. Each facility receiving drugs from the Central Shared Services, LLC warehouse to be placed in an ADD shall maintain at least a 90% bar code scanning rate for restocking automated dispensing devices. If the scanning rate for restocking automated dispensing devices at a facility is less than 90% for any quarter, the pharmacy at that facility shall immediately reinstitute a 100% pharmacist verification process at the receiving pharmacy until the Board approves Central Shared Services, LLC resuming the allowances within the innovative (pilot) program.

10. The assignment of the Meditech and Pyxis ID code shall be performed by a Virginia-licensed pharmacist employed by Parallon.

11. Central Shared Services, LLC shall submit to the Board a quarterly report which indicates for each facility the restocking bar code scanning rate, bedside bar code scanning rate, and any errors in drug product received from Central Shared Services, LLC. These reports shall be submitted in March, June, September, and December.

12. The innovative (pilot) program shall be subject to two random, unannounced inspections by the Board or its designated representative within three (3) years following implementation of the program, one inspection to take place within the first twelve (12) months of implementation. Central Shared Services, LLC shall be solely responsible for the payment of an inspection fee of $150.00 each to be paid to the Board within thirty days from the date of the statement of monies owed which will be mailed following the inspection.

13. Reports of significant errors or other problems, or failure to comply with the terms and conditions described above shall constitute grounds for the rescission of the approval, and an administrative proceeding shall be convened to determine whether the approval should be rescinded or modified.

14. Except as specifically waived in the Consent Order, Central Shared Services, LLC and the facilities shall maintain compliance with all applicable federal and State laws and regulations.

15. Any operational changes or modifications to the innovative (pilot) program shall be approved by the Board prior to initiation of the modification.

Pursuant to § 2.2-4023 of the Code of Virginia (1950), as amended, the signed original of this Consent Order shall remain in the custody of the Department of Health Professions as a public record and shall be made available for public release, inspection and copying upon request.

FOR THE BOARD:

Caroline D. Juran
Executive Director

ENTERED: 6/17/15

SEEN AND AGREED TO:

Daniel Honerbrink, as the Chief Executive Officer, Central Shared Services, LLC, and on behalf of Central Shared Services, LLC

COMMONWEALTH OF VIRIGINA
CITY/COUNTY OF Chesterfield

Subscribed and sworn to before me, a Notary Public in and for the city/county of Chesterfield, this 17 day of June, 2015, by Daniel Honerbrink, Chief Executive Officer, Central Shared Services, LLC. My commission expires the 31 day of July, 2017.

7563376
Registration Number

Notary Public

**Project 7192 - Proposed**

**Board Of Pharmacy**

**Allowance for centralized warehouser or wholesale distributor to verify Schedule VI drugs for automated dispensing devices in hospitals**

**18VAC110-20-460. Floor stock drugs; proof of delivery; distribution records.**

A. ~~A~~ Except as provided in 18VAC110-20-490(D), a pharmacist shall check all Schedule II-VI drugs delivered to a hospital unit as floor-stock before the drugs leave the pharmacy and shall initial or sign manually or electronically the record of distribution verifying the accuracy of the distribution.

B. A delivery receipt shall be obtained for Schedule II through V drugs supplied as floor stock. This record shall include the date, drug name and strength, quantity, hospital unit receiving drug and the manual or electronic signatures of the dispensing pharmacist and the receiving nurse.

C. A record of disposition/administration shall be used to document administration of Schedule II through V drugs when a floor stock system is used for such drugs. The record shall be returned to the pharmacy within three months of its issue. The PIC or his designee shall:

1. Match returned records with delivery receipts to verify that all records are returned;

2. Periodically audit returned administration records for completeness as to patient's names, dose, date and time of administration, signature or initials of person administering the drug, and date the record is returned;

3. Verify that all additions to inventory are recorded, that all additions to and deductions from inventory are correctly calculated, that sums carried from one record to the next are correctly recorded, and periodically verify that doses documented on administration records are reflected in the medical record; and

4. Initial the returned record.

D. All records required by this section shall be filed chronologically by date of issue, and retained for two years from the date of return at the address of the pharmacy. Schedule VI 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. Schedule II-V records may only be stored offsite or electronically as described in this subsection if authorized by DEA or in federal law or regulation. The filing requirements of 18VAC110-20-240 A 1 for separation of Schedule II records shall be met for administration records if the Schedule II drugs are listed in a separate section on a page that contains other schedules of drugs.

**18VAC110-20-490. Automated devices for dispensing and administration of drugs.**

A. A hospital may use automated devices for the dispensing and administration of drugs pursuant to § 54.1-3301 of the Code of Virginia and §§ 54.1-3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420, or 18VAC110-20-460 as applicable.

B. Policy and procedure manual; access codes.

1. Proper use of the automated dispensing devices and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual, which shall include provisions for granting and terminating user access.

2. Personnel allowed access to an automated dispensing device shall have a specific access code that records the identity of the person accessing the device. The device may verify access codes using biometric identification or other coded identification after the initial log-on in order to eliminate sharing or theft of access codes.

C. Distribution of drugs from the pharmacy.

1. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device. The delivery record shall include the date; drug name, dosage form, and strength; quantity; hospital unit and a unique identifier for the specific device receiving the drug; initials of the person loading the automated dispensing device; and initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.

2. At the time of loading any Schedules II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the pharmacist in charge, who shall be responsible for ensuring reconciliation of the discrepancy or properly reporting of a loss.

D. Distribution of drugs from a central warehouser or wholesale distributor.

Notwithstanding subsection (C)(1), a central warehouser or wholesale distributor may distribute Schedule VI drugs to hospitals to be placed in specific automated dispensing devices under the following conditions:

1. A pharmacist licensed in Virginia, employed by or otherwise working at the central warehouser or wholesale distributor, shall verify the accuracy of all Schedule VI drugs to be placed in specific automated dispensing devices within the hospital prior to delivery of the drugs directly to the hospital pharmacy;

2. A pharmacist at the hospital pharmacy shall not be required to: (i) verify the accuracy of these drugs prior to leaving the hospital pharmacy for delivery to the hospital unit as floor stock as required in 18VAC110-20-460(A), or (ii) initial the delivery record as required in 18VAC110-20-490(C)(1).

3. The central warehouser or wholesale distributor shall maintain a record of all Schedule VI drugs distributed to a hospital for placement in a specific automated dispensing device. The record shall include the date; drug name, dosage form, and strength; quantity; hospital name; hospital unit and a unique identifier for the specific automated dispensing device receiving the drug; and initials of the pharmacist employed by or working at the central warehouser or wholesale distributor who is responsible for verifying the drugs for accuracy;

4. The central warehouser or wholesale distributor shall provide an invoice to each hospital pharmacy indicating the drugs delivered to the hospital to be placed in a specific automated dispensing device;

5. A pharmacist or pharmacy technician at each hospital shall load the drugs into the specific automated dispensing device and the hospital pharmacy shall maintain a record which consists of the initials of the person loading the automated dispensing device;

6. A pharmacist licensed in Virginia, employed by or otherwise working at the warehouser or wholesale distributor, shall perform barcode linking of any drug to the related drug files in the hospital information system and automated dispensing device;

7. Each hospital receiving drugs from the central warehouser or wholesale distributor shall maintain at least a 90% bar code scanning rate for restocking automated dispensing devices. If the scanning rate for restocking the automated dispensing device is less than 90% for any quarter, the pharmacy at the hospital shall immediately reinstitute a 100% pharmacist verification process at the receiving pharmacy until a 90% scanning rate for a subsequent quarter is achieved and documented; and

8. The hospital pharmacy receiving such services from a central warehouser or wholesale distributor shall maintain quarterly reports containing the hospital's restocking bar code

scanning rate, bedside bar code scanning rate, and any errors in drug product received from the central warehouser or wholesale distributor.

~~D.~~E. Distribution of drugs from the device.

1. Automated dispensing devices in hospitals shall be capable of producing a hard-copy record of distribution that shall show patient name, drug name and strength, dose withdrawn, date and time of withdrawal from the device, and identity of person withdrawing the drug. The record shall be filed in chronological order from date of issue or maintained electronically.

2. If an automated dispensing device is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.

~~E.~~F. Discrepancy reports. A discrepancy report for all Schedules II through V drugs and any drugs of concern, as defined in § 54.1-3456.1 of the Code of Virginia, shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be initiated or resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

~~F.~~G. Reviews and audits.

1. The PIC or his designee shall conduct at least a monthly review for compliance with written policy and procedures that are consistent with § 54.1-3434.02 A of the Drug Control Act for security and use of the automated dispensing devices, to include procedures for timely termination of access codes when applicable, accuracy of distribution from the device, and proper recordkeeping.

2. The PIC or his designee shall conduct at least a monthly audit to review distribution of Schedules II through V drugs from each automated dispensing device as follows:

a. The audit shall reconcile records of all quantities of Schedules II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drug recorded as removed from the pharmacy was diverted rather than placed in the proper device.

b. If a pharmacy has an ongoing method for perpetually monitoring drugs in Schedules II through V to ensure drugs dispensed from the pharmacy have been loaded into the device and not diverted, such as with the use of perpetual inventory management software, then the audit required in this subsection may be limited to the discrepancies or exceptions as identified by the method for perpetually monitoring the drugs.

3. The PIC or his designee shall conduct at least a monthly audit to review the dispensing and administration records of Schedules II through V drugs from each automated dispensing device as follows:

a. The audit shall include a review of administration records for each device per month for possible diversion by fraudulent charting. The review shall include all Schedules II through V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

b. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

c. The PIC or his designee shall be exempt from requirements of this audit if reconciliation software that provides a statistical analysis is used to generate reports at least monthly. The statistical analysis shall be based on:

(1) Peer-to-peer comparisons of use for that unit or department; and

(2) Monitoring of overrides and unresolved discrepancies.

d. The report shall be used to identify suspicious activity, which includes usage beyond three standard deviations in peer-to-peer comparisons. A focused audit of the suspicious activity and individuals associated with the activity shall be performed whenever suspicious activity is identified from the reports.

4. The PIC or his designee shall maintain a record of compliance with the reviews and audits in accordance with subsection H of this section.

~~G.~~H. Inspections. Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs, and validity of access codes. The PIC or his designee shall maintain documentation of the inspection in accordance with subsection H of this section. With the exception of a monthly physical review of look-alike and sound-alike drugs stored within matrix drawers or open access areas within the device, such monthly inspection shall not require physical inspection of the device if the device is capable of and performs the following:

1. At least daily monitoring of refrigerator or freezer storage with documented temperature ranges, variances, and resolutions;

2. Automatic identification and isolation of the location of each drug within the device using a machine readable product identifier, such as barcode technology, and generation of a report verifying the applicable settings;

3. Electronic tracking of drug expiration dates and generation of proactive reports allowing for the replacement of drugs prior to their expiration date; and

4. Electronic detection of the opening of the device, identification of the person accessing the device, automatic denial of access to the device during malfunctions and mechanical errors, and generation of reports of any malfunction and mechanical error.

~~H.~~I. Records.

1. All records required by this section shall be maintained for a period of not less than two years. Records required to be maintained by the pharmacy shall be maintained at the address of the pharmacy providing services to the hospital ~~except manual~~ . Records required to be maintained by the warehouser or wholesale distributor shall be maintained at the address of the applicable facility. Manual Schedule VI distribution records, reports auditing for indications of suspicious activity, ~~and~~ focused audits, ~~all of which~~ and records required to be maintained by the warehouser or wholesale distributor distributing Schedule VI drugs to specific automated dispensing devices may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic records are retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

2. Distribution and delivery records and required initials may be generated or maintained electronically provided:

a. The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

b. The records are maintained in a read-only format that cannot be altered after the information is recorded.

c. The system used is capable of producing a hard-copy printout of the records upon request.

3. Schedules II through V distribution and delivery records may also be stored off site or electronically in compliance with requirements of subdivision 1 of this subsection and if authorized by DEA or in federal law or regulation.

4. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained at an off-site location or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

**Agenda Item: Consideration of final regulations for implementation of legislation for registration of pharmacy technician trainees.**

**Included in your agenda package are:**

- Regulatory Town Hall summary page.
- Town Hall public comment.
- Public comment received by the agency.
- FAQs sent to board-approved training programs and licensees.
- Final regulations as approved by Regulatory Committee implementing legislation for the registration of pharmacy technician trainees as required by Chapter 237 of the 2020 Acts of Assembly.

**Staff note:** Regulatory Committee recommended that the Board adopt proposed regulations.

**Action needed:**

- Motion to adopt final regulations.

Virginia.gov Agencies | Governor


Agency **Department of Health Professions**

Board **Board of Pharmacy**

Chapter **Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians [18 VAC 110 - 21]**

**Action**: Implementation of legislation for registration of pharmacy technicians

## Proposed Stage

Action 5603 / Stage 9243

Edit Stage | Withdraw Stage | Go to RIS Project

| Documents | | |
|---|---|---|
| Proposed Text | 4/12/2021 10:14 am | Sync Text with RIS |
| Agency Background Document | 4/12/2021 | Upload / Replace |
| Attorney General Certification | 5/4/2021 | |
| DPB Economic Impact Analysis | 6/17/2021 | |
| Agency Response to EIA | 7/13/2021 | Upload / Replace |
| Governor's Review Memo | 12/2/2021 | |
| Registrar Transmittal | 12/6/2021 | |

| Status | |
|---|---|
| **Changes to Text** | The proposed text has changed from that of the emergency stage. |
| **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<br>Review Completed: 5/4/2021<br>Result: Certified |
| **DPB Review** | Submitted on 5/4/2021<br>Economist: Jini Rao Policy Analyst: Jeannine Rose<br>Review Completed: 6/17/2021 |
| **Secretary Review** | Secretary of Health and Human Resources Review Completed: 11/4/2021 |
| **Governor's Review** | Review Completed: 12/2/2021<br>Result: Approved |
| **Virginia Registrar** | Submitted on 12/6/2021<br>The Virginia Register of Regulations<br>Publication Date: 1/3/2022 Volume: 38 Issue: 10 |
| **Public Hearings** | 02/07/2022 8:45 AM |

| | |
|---|---|
| **Comment Period** | **Ended 3/4/2022**<br>**1 comments** |

| Contact Information | |
|---|---|
| **Name / Title:** | Caroline Juran, RPh / *Executive Director* |
| **Address:** | 9960 Mayland Drive<br>Suite 300<br>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 04/12/2021 at 10:14am*
*This stage was last edited by Elaine J. Yeatts on 04/12/2021 at 10:14am*

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Agency **Department of Health Professions**

Board **Board of Pharmacy**

Chapter

**Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians [18 VAC 110 - 21]**

| | |
|---|---|
| **Action** | **Implementation of legislation for registration of pharmacy technicians** |
| **Stage** | **Proposed** |
| **Comment Period** | Ends 3/4/2022 |

1 comments

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

**Back to List of Comments**

**Commenter:** douglas schiffman, Rappahannock Center for Education
www.rappce.org

2/23/22 8:48 pm

**Are you aware of the impact on Pharmacy Tech Training Programs?**

The regulations, which follow up on legislation enacted in 2020, will drastically reduce the number of pharmacy tech training programs, thereby drastically reducing the pool of trained pharmacy technicians. Responsibility for regulating training programs moves from the Board of Pharmacy to the ASHP beginning in July 2022. After July, pharmacy tech training programs not accredited by ASHP will not be able to train students to become Virginia certified Pharmacy Technicians. Many if not most of the current Board of Nursing approved programs will not be able to attain ASHP certification, due to the costs ($720 plus $2900 PER YEAR annual assessment fee), the length of the program (400 hours!) and the time and expense needed to assemble the required information. The current fee to apply to the Board of Pharmacy is $200.

As of today (Feb 23, 2022), there are just 2 programs accredited by ASHP. There are over one hundred programs approved by the Board of Pharmacy, and a number of applications pending. After July, pharmacy tech students will still need to take and pass either the ExCPT or the PTCB exam, but unless their training program is ASHP accredited, they will not be eligible to become state certified.

If Virginia wonders why there are so few new pharmacy tech students, look no further than the impact of the law and the new regulations. Is anyone on the Board of Pharmacy thinking about this?

CommentID: **120133**

March 1, 2022

Dear Ms. Yeatts:

I'd like to make a few comments regarding the Proposed Regulations for Pharmacy Technician Training Programs. By way of background, I own The Compounding Center in Leesburg, Virginia and have practiced pharmacy since 1990. We employ 16 registered technicians and have had at least 12 technicians take and pass our Board approved technician training program.

I have some concerns regarding the requirement that training programs be ASHP/ACPE accredited. The shortage of technicians is the worst I've seen in my entire career. This change may throw up additional barriers to this career path which will make the staffing situation worse.

I do not agree with the following statement in the summary:

> *Small Businesses[5] Affected. The proposed amendments are unlikely to adversely affect any small businesses. Pharmacies in Virginia that are independently operated small businesses would benefit from standardized education requirements for pharmacy technicians to the extent that it results in a better-trained pool of potential employees.*

It is not financially realistic for a small business (independent pharmacies) to obtain ASHP/ACPE accreditation for their technician training program. We currently have a Board approved training course and this was one advantage we had in recruiting. We could put a prospective technician through our course at no cost to the employee and minimal cost to the business.

I inquired at our local community college to ask about their technician program and was told they will be discontinuing it due to the accreditation requirements. "The change to the requirements will make the cost of the program triple (or more). We will be shutting it down as I'm not sure too many students want to borrow $8-$10k for a job that pays what Target pays."

www.compoundingcenter.com

36-C Catoctin Circle, SE
Leesburg, VA 20175
(703) 779-3301

It seems that passing the PTCB or NHA exam is the ultimate measure of successful training. I feel certain that our FREE on the job training, supplemented with course material is equal to or better than an online course for which they will have to pay. I'm certain the chains have programs in place because they can afford the fees of accreditation spread over many stores, but there are many other pharmacies across the Commonwealth that are not affiliated with a chain.

I also wanted to ask about the two year time limit to finish the course and pass the exam. Is the Technician Trainee registration specific to the training program? What would happen if the Technician changed jobs during their Trainee period? Would they re-register with the Board or notify the Board of a change in their program enrollment/employment, and would their two year time frame start over?

Thank you for your time in reviewing my concerns. I look forward to seeing you at our next Board of Pharmacy meeting.

Sincerely,

Cheri Garvin, RPh

**Project 6513 - Proposed**

**Board Of Pharmacy**

**Implementation of legislation for registration of pharmacy technicians**

**18VAC110-20-111. Pharmacy technicians.**

A. Every pharmacy that employs or uses pharmacy technicians shall maintain a site-specific training program and manual for training pharmacy technicians to work at that pharmacy. The program shall include training consistent with that specific pharmacy 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 at the pharmacy in performing technician duties, and pharmacy calculations consistent with the duties at that pharmacy.

B. Every pharmacy shall maintain documentation of successful completion of the site specific training program for each pharmacy technician for the duration of the employment and for a period of two years from date of termination of employment. Documentation for currently employed pharmacy technicians 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.

C. Every pharmacy that employs or uses a person enrolled in ~~an approved~~ a pharmacy technician training program pursuant to § 54.1-3321 ~~D~~ of the Code of Virginia shall allow such person to conduct tasks restricted to pharmacy technicians ~~for no more than nine months without that person becoming registered as a pharmacy technician with the board as set forth in 18VAC110-20-101. Every pharmacy using such a person shall have documentation on site and available for inspection showing that the person is currently enrolled in an approved training program and the start date for each pharmacy technician in training~~ only if the person is currently registered as a pharmacy technician trainee.

**18VAC110-21-10. Definitions.**

In addition to words and terms defined in §§ 54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"ACPE" means the Accreditation Council for Pharmacy Education.

"ASHP" means the American Society of Health-System Pharmacists.

"Board" means the Virginia Board of Pharmacy.

"CE" means continuing education as required for renewal of licensure by the board.

"CEU" means a continuing education unit awarded for credit as the equivalent of 10 contact hours.

"Contact hour" means the amount of credit awarded for 60 minutes of participation in and successful completion of a continuing education program.

"Foreign school of pharmacy" means a school outside the United States and its territories offering a course of study in basic sciences, pharmacology, and pharmacy of at least four years in duration resulting in a degree that qualifies a person to practice pharmacy in that country.

"FPGEC certificate" means 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.

"Inactive license" means a license that is registered with the Commonwealth but does not entitle the licensee to practice, and the holder of which is not required to submit documentation of CE necessary to hold an active license.

"NABP" means the National Association of Boards of Pharmacy.

"NHA" means National Healthcareer Association.

"Pharmacy technician trainee" means a person who is registered with the board and is currently enrolled in an approved pharmacy technician training program ~~and is performing~~ to perform duties restricted to pharmacy technicians for the purpose of obtaining practical experience in accordance with provisions of subsection G of § 54.1-3321 ~~D~~ of the Code of Virginia.

"PTCB" means the Pharmacy Technician Certification Board, co-founded by the American Pharmaceutical Association and the American Society of Health System Pharmacists, as the national organization for the voluntary examination and certification of pharmacy technicians.

**18VAC110-21-20. Fees.**

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Unless otherwise provided, any fees for taking required examinations shall be paid directly to the examination service as specified by the board.

C. Initial application fees.

| | |
|---|---|
| 1. Pharmacist license | $235 |
| 2. Pharmacy intern registration | $20 |
| 3. Pharmacy technician trainee registration | $20 |
| 4. Pharmacy technician registration | $35 |
| ~~4.~~ 5. Approval of a pharmacy technician training program | $200 |
| ~~5.~~ 6. Approval of a continuing education program | $130 |

D. Annual renewal fees.

| | |
|---|---|
| 1. Pharmacist active license – due no later than December 31 | $120 |
| 2. Pharmacist inactive license – due no later than December 31 | $60 |

| | |
|---|---|
| 3. Pharmacy technician registration – due no later than December 31 | $35 |
| 4. Pharmacy technician training program | $100 every two years |

E. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license or registration within one year of the expiration date or within two years in the case of a pharmacy technician training program. In addition, engaging in activities requiring a license or registration after the expiration date of such license or registration shall be grounds for disciplinary action by the board.

| | |
|---|---|
| 1. Pharmacist license | $40 |
| 2. Pharmacist inactive license | $20 |
| 3. Pharmacy technician registration | $15 |
| 4. Pharmacy technician training program | $20 |

F. Reinstatement fees. Any person or entity attempting to renew a license or registration more than one year after the expiration date, or more than two years after the expiration date in the case of a pharmacy technician training program, shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

| | |
|---|---|
| 1. Pharmacist license | $275 |
| 2. Pharmacist license after revocation or suspension | $650 |
| 3. Pharmacy technician registration | $45 |
| 4. Pharmacy technician <u>or pharmacy technician trainee</u> registration after revocation or suspension | $165 |
| 5. A pharmacy technician training program that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus a reinstatement fee of $75. A pharmacy technician training program that ceases operation and wishes to resume shall not be | |

| | |
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| eligible for reinstatement but shall apply for a new registration. | |

G. Miscellaneous fees.

| | |
|---|---|
| 1. Duplicate wall certificate | $50 |
| 2. Returned check | $35 |
| 3. Duplicate license or registration | $15 |
| 4. Verification of licensure or registration | $35 |

**18VAC110-21-40. Unprofessional conduct.**

The following practices shall constitute unprofessional conduct within the meaning of § 54.1-3316 of the Code of Virginia:

1. Failing to comply with provisions of § 32.1-127.1:03 of the Code of Virginia related to the confidentiality and disclosure of patient records or related to providing patient records to another practitioner or to the patient or the patient's personal representative;

2. Willfully or negligently breaching the confidentiality of a patient unless otherwise required or permitted by applicable law;

3. Failing to maintain the confidentiality of information received from the Prescription Monitoring Program, obtaining such information for reasons other than to assist in determining the validity of a prescription to be filled, or misusing information received from the program;

4. Engaging in disruptive or abusive behavior in a pharmacy or other health care setting that interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient;

5. Engaging or attempting to engage in a relationship with a patient that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a patient or the patient's family, including sexual

misconduct with a patient or a member of the patient's family or other conduct that results or could result in personal gain at the expense of the patient;

6. Failing to maintain adequate safeguards against the diversion of controlled substances;

7. Failing to appropriately respond to a known dispensing error in a manner that protects the health and safety of the patient;

8. Delegating a task within the practice of pharmacy to a person who is not adequately trained to perform such a task;

9. Failing by the pharmacist in charge to ensure that pharmacy interns ~~and~~, pharmacy technicians, and pharmacy technician trainees working in the pharmacy are registered and that such registration is current;

10. Failing to exercise professional judgment in determining whether a prescription meets the requirements of law before dispensing;

11. Obtaining money or property of a patient or client by fraud or misrepresentation;

12. Providing false information or failing to cooperate with an employee of the Department of Health Professions in the conduct on an investigation or inspection;

13. Violating any provision of this chapter, 18VAC110-20, or Chapter 33 (§ 54.1-3300 et seq.) or 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia;

14. Performing any act likely to deceive, defraud, or harm the public; or

15. Having a restriction of a license to practice pharmacy or a registration as a pharmacy technician in another jurisdiction in the United States.

**18VAC110-21-135. Registration as a pharmacy technician trainee.**

A. A person desiring to gain practical pharmacy experience toward completion of a pharmacy technician training program in Virginia shall first register with the board as a pharmacy technician

trainee on a form provided by the board prior to engaging in the duties of a pharmacy technician pursuant to § 54.1-3321 of the Code of Virginia.

B. In order to be eligible to register as a pharmacy technician trainee, an applicant shall be enrolled in a pharmacy technician training program. An expiration date, not to exceed two years, shall be assigned to the registration to cover the estimated time period for the trainee to complete the practical pharmacy experience required for completion of the training program and pass the required examination. If the trainee is no longer enrolled in the training program, takes a voluntary break from the program, or is otherwise not actively progressing toward completion of such program, the registration is no longer valid and shall be returned to the board immediately.

C. A pharmacy technician trainee shall be directly monitored by a supervising pharmacist who holds a current active license and assumes full responsibility for the training and supervision of the trainee.

D. A pharmacy technician trainee shall notify the board in writing of any change in address of record within 14 days of such change.

**18VAC110-21-140. Application for registration as a pharmacy technician (Effective until July 1, 2022).**

A. Any person wishing to apply for registration as a pharmacy technician shall submit the application fee and an application on a form approved by the board.

B. To be registered as a pharmacy technician, an applicant shall provide evidence of the following:

1. Satisfactory completion of a board-approved training program; and

2. A passing score on a board-approved examination.

C. In lieu of the requirements of subsection B of this section, an applicant may provide evidence of current PTCB certification or NHA certification.

~~D. A pharmacy technician trainee enrolled in an approved pharmacy technician training program pursuant to § 54.1-3321 D of the Code of Virginia may perform tasks restricted to pharmacy technicians for no more than nine consecutive months from the date the trainee begins performing duties restricted to a pharmacy technician without becoming registered as a pharmacy technician.~~

**18VAC110-21-141. Requirements for pharmacy technician training (Effective July 1, 2022).**

A. Any person wishing to apply for registration as a pharmacy technician shall submit the application fee and an application on a form approved by the board.

B. To be registered as a pharmacy technician, an applicant shall provide evidence of the following:

1. Completion of a pharmacy technician training program that is:

a. Jointly accredited by the ASHP and ACPE;

b. An accredited training program operated through the Department of Education's Career and Technical Education Program;

c. Operated through a federal agency or branch of the military; or

d. Accredited by an accreditation body approved by the board.

2. Successfully having passed a national certification examination administered by PTCB or NHA.

C. A pharmacy technician who has previously practiced in another United States jurisdiction may be eligible to obtain registration as a pharmacy technician upon documentation of previous practice and having passed a national certification examination administered by PTCB or NHA.

D. A person who successfully completed or was enrolled in a board-approved pharmacy technician training program but did not successfully pass a national examination prior to July 1, 2022, may be eligible to obtain registration as a pharmacy technician after successfully passing a national certification examination administered by PTCB or NHA and submitting to the board documentation of such completion or enrollment in a board-approved pharmacy technician training program and passing examination score.

E. A person who passed a national certification examination administered by PTCB or NHA but did not complete a board-approved pharmacy technician training program prior to July 1, 2022, may be eligible to obtain registration as a pharmacy technician upon documentation of having passed such examination.

**18VAC110-21-150. Criteria for approval for training programs (Effective until July 1, 2022).**

A. Any person wishing to apply for approval of a pharmacy technician training program shall submit the application fee, a sample certificate, and an application on a form approved by the board and meet the criteria established in this section.

B. The curriculum of a training program for pharmacy technicians shall include instruction in applicable current laws and regulations and in the tasks that may be performed by a pharmacy technician to include the following or any other task restricted to pharmacy technicians in regulation:

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

2. The preparation of prescription labels or patient information;

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

4. The counting, measuring, or compounding of the drug to be dispensed;

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

6. The stocking or loading of automated dispensing devices or other devices used in the dispensing process; and

7. The acceptance of refill authorization from a prescriber or the prescriber's authorized agent provided there is no change to the original prescription.

C. Each program shall have a program director who shall be either (i) a pharmacist with a current license in any jurisdiction and who is not currently suspended or revoked in any jurisdiction in the United States; (ii) a pharmacy technician with at least one year of experience performing technician tasks who holds a current registration in Virginia or current PTCB certification and who is not currently suspended or revoked as a pharmacy technician in any jurisdiction; or (iii) other person approved and deemed qualified by the board to be a program director.

D. Instructors for the core components listed in subsection B of this section shall meet the requirements for the program director listed in subsection C of this section. The program director may serve as an instructor.

E. The length of the program shall be sufficient to prepare a program participant to sit for the board-approved examination and demonstrate entry-level competency.

F. The program shall maintain records of program participants either on site or at another location where the records are readily retrievable upon request for inspection. A program shall provide a certificate of completion, including the program approval number, to participants who successfully complete the program and provide verification of completion of the program for a participant upon request by the board. Records shall be maintained for two years from date of completion or termination of program.

G. The program shall report within 14 days any substantive change in the program to include a change in program name, program certificate, program director, instructors, name of institution or business if applicable, address, program content, length of program, or location of records.

H. A pharmacy technician training program approval expires after two years, after which the program may apply for renewal. For continued approval, the program shall submit the renewal application, renewal fee, and a self-evaluation report on a form provided by the board at the time of renewal notification. Renewal of a program's approval is at the discretion of the board, and the decision to renew shall be based on documentation of continued compliance with the criteria set forth in this section.

**18VAC110-21-160. ~~Examination.~~ (Repealed.)**

~~A. The board shall approve one or more examinations to test entry-level competency for pharmacy technicians. In order to be approved, a competency examination shall be developed in accordance with and meet the recognized acceptable test measurement standards of the Joint Technical Standards for Education and Psychological Testing (American Psychological Association, current edition), and shall be administered by an independent third party.~~

~~B. The board may contract with an examination service for the development and administration of a competency examination.~~

~~C. The board shall determine the minimum passing standard on the competency examination.~~

~~D. Any requests for testing accommodations under the Americans with Disabilities Act shall be in accordance with the provisions of 18VAC110-21-80 F.~~

**18VAC110-21-170. Renewal and reinstatement of registration.**

A. Pharmacy technician registrations expire on December 31 and shall be renewed annually prior to that date by the submission of a renewal fee, renewal form, and an e-profile number issued by NABP. A pharmacy technician newly registered on or after July 1 shall not be required to renew

that registration until December 31 of the following year. Failure to receive the application for renewal shall not relieve the pharmacy technician of the responsibility for renewing the registration by the expiration date.

B. A pharmacy technician who fails to renew his registration by the expiration date may renew his registration at any time within one year of its expiration by submission of the renewal fee and late fee, renewal form, and attestation of having met the continuing education requirements.

C. A pharmacy technician who fails to renew his registration for more than one year following expiration and who wishes to reinstate such registration shall submit an application for reinstatement, pay the current renewal fee and a reinstatement fee, and submit documentation showing compliance with continuing education requirements. Reinstatement is at the discretion of the board and may be granted by the executive director of the board provided no grounds exist to deny said reinstatement. Practicing as a pharmacy technician with a lapsed registration shall be illegal and may subject the registrant to disciplinary action by the board.

D. A person who fails to reinstate a pharmacy technician registration within five years of expiration shall ~~not be eligible for reinstatement and shall repeat an approved training program and repeat and pass the examination or hold current PTCB certification before applying to be reregistered~~:

1. Take and pass a national certification examination administered by PTCB or NHA unless national certification is currently maintained;

2. Document completion of 20 hours of continuing education; and

3. Pay the current renewal fee and a reinstatement fee.

**18VAC110-21-180. Requirements for continued competency.**

A. A pharmacy technician shall be required to have completed a minimum of 0.5 CEUs or five contact hours of approved continuing education for each annual renewal of registration. Hours in excess of the number required for renewal may not be transferred or credited to another year.

B. An approved continuing education program shall meet the requirements as set forth in 18VAC110-21-120 B or 18VAC110-21-130 B.

C. Upon written request of a pharmacy technician, the board may grant an extension of up to one year in order for the pharmacy technician to fulfill the continuing education requirements for the period of time in question. The granting of an extension shall not relieve the pharmacy technician from complying with current year requirements. Any subsequent extension shall be granted for good cause shown.

D. Up to one hour of the five hours required for annual renewal may be satisfied through delivery of pharmacy services as a pharmacy technician, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those services. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic.

E. ~~Original documentation~~ Documentation showing successful completion of continuing education programs shall be maintained by the pharmacy technician for a period of two years following the renewal of his registration. The pharmacy technician shall provide such documentation to the board upon request in a manner to be determined by the board.

**Agenda Item: Consideration of petition for rulemaking concerning automated dispensing systems.**

**Included in your agenda package are:**

- Petition for rulemaking from Renae M. Cregger.
- Initial letter of response from Ms. Juran.
- Regulatory Town Hall summary page showing no comments on petition.
- Regulations referenced in the petition (18VAC110-20-540; 18VAC110-20-550; 18VAC110-20-555).

**Staff note:** Regulatory Committee recommended that the Board initiate rulemaking.

**Action needed:**

- Consider whether to (1) accept the Regulatory Committee's recommendation that the Board initiate a rulemaking, or (2) take no action on the petition.

## 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


Chapter Affected:

**18 vac 110 - 20: Regulations Governing the Practice of Pharmacy**

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

Date Petition Received 02/22/2022

Petitioner Renae M. Cregger

**Petitioner's Request**

To exempt automated dispensing systems exclusively stocked with drugs that would be kept in a stat-drug box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency use from the requirements of 18VAC110-20-555(1), (4)(a), and (4)(b).

**Agency Plan**

The petition will be published on March 14, 2022 in the Register of Regulations and also posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov to receive public comment ending April 13, 2022. The request to amend the regulations and any comments for or against the petition will be considered by the Board at its meeting scheduled for June 6, 2022. The petitioner will receive information on the Board's decision after that date.

Publication Date 03/14/2022 *(comment period will also begin on this date)*

Comment End Date 04/13/2022

# 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,) | | |
|---|---|---|
| Cregger, Renae M. | | |
| **Street Address**<br>860 Stafford Umberger Dr | **Area Code and Telephone Number**<br>866-768-8479 ext 6001 | |
| **City**<br>Wytheville | **State**<br>VA | **Zip Code**<br>24382 |
| **Email Address (optional)**<br>renae.cregger@southrx.com | **Fax (optional)**<br>866-928-3983 | |

**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.

   18VAC110-20-555 Use of automated dispensing devices
   Sections 1, 4a, 4b

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

   See attached.

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 other legal authority for promulgation of a regulation, please provide that Code reference.

   54.1-2400 of the Code of Virginia authorizes the board to take action on this regulation

**Signature:** Renae M Cregger **Date:** 1-17-22

Since the introduction of automated dispensing systems in hospitals which provide ready access to medications and improved patient care, the long-term care industry embraced the use of these systems as a way to provide emergency and stat medications through a more secure and trackable platform. I propose the following changes to 18VAC110-20-555 when automated dispensing systems are exclusively stocked with medications that would be kept in an emergency or stat-drug kit and are used for emergency or stat administration.

18VAC110-20-555 Sections 1, 4a, and 4b currently read as follows:

Section 1 – *"Drugs placed in an automated drug dispensing system in a nursing home shall be under the control of the pharmacy providing services to the nursing home, the pharmacy shall have online communication with and control of the automated drug dispensing system, and access to any drug for a patient shall be controlled by the pharmacy."*

Sections 4a and 4b – *"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 under the following conditions:*

> *a. A drug, including a drug that would be stocked in a stat-drug box pursuant to subsection B of 18VAC110-20-550, may not be administered to a patient from an automated dispensing device until a pharmacist has reviewed the prescription order and electronically authorized the access of that drug for that particular patient in accordance with the order.*
>
> *b. The PIC of the provider pharmacy shall ensure that a pharmacist who has online access to the system is available at all times to review a prescription order as needed and authorize administering pursuant to the order reviewed."*

The same requirements as in Sections 1, 4a, and 4b do not exist in the regulation for a "tackle-box" style stat-drug box (18VAC110-20-550); therefore, these requirements encourage facilities to opt for the tackle-box which is less secure in terms of access and record keeping. Advantages of automated dispensing systems over tackle boxes include increased security in terms of access and increased trackability of medications removed from the system. The regulations as currently written can also lead to a delay in patient care. If the nurse has a valid order from a prescriber for a medication in the automated dispensing system, the nurse should be able to access the system to obtain the medication for the resident as quickly as possible when the medications in the system are drugs that would be kept in a stat-drug box. The contents of the automated dispensing system being medications that would be kept in an emergency or stat-drug box and the administration of such medications in an emergency or stat/first dose manner should dictate

which regulations apply to such systems rather than whether the stat-drug "box" is an electronic system or a tackle box.

I would propose an exception be added to 18VAC110-20-555 Sections 1, 4a, and 4b as currently written in 18VAC110-20-555 Section 2:

*"unless the system is exclusively stocked with drugs that would be kept in a stat-drug box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency administration."*

COMMONWEALTH of VIRGINIA

David E. Brown, D.C.
Director

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

www.dhp.virginia.gov
TEL (804) 367-4400
FAX (804) 527-4475

February 23, 2022

Renae M. Cregger
860 Stafford Umberger Dr.
Wytheville, Virginia 24382

Dear Ms. Cregger,

The Virginia Board of Pharmacy would like to thank you for submission of a petition for rule-making relating to automated dispensing systems exclusively stocked with drugs that would be kept in a stat-box or an emergency drug kit and are solely administered for stat or emergency use.

In accordance with Virginia law, the petition will be filed with the Register of Regulations and published on March 14, 2022 and posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov. Comment on the petition will be requested until April 13, 2022 and may be posted on the Townhall or sent to the Board.

Following receipt of all comments on the petition to amend regulations, the matter will be considered by the Board at its meeting scheduled for June 6, 2022.

The Board appreciates your interest in amending the regulations governing the practice of pharmacy and will notify you of its decision on the petition after the June meeting.

Very truly yours,

Caroline Juran
Executive Director
Virginia Board of Pharmacy

cc: Elaine J. Yeatts
Agency Regulatory Coordinator

Virginia.gov Agencies | Governor


Secretariat **Health and Human Resources**

Agency **Department of Health Professions**

Board **Board of Pharmacy**

Edit Petition

Petition 361

| Petition Information | |
|---|---|
| **Petition Title** | Use of automated dispensing systems exclusively stocked with emergency or stat-drug kits |
| **Date Filed** | 2/22/2022 [Transmittal Sheet] |
| **Petitioner** | Renae M. Cregger |
| **Petitioner's Request** | To exempt automated dispensing systems exclusively stocked with drugs that would be kept in a stat-drug box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency use from the requirements of 18VAC110-20-555(1), (4)(a), and (4)(b). |
| **Agency's Plan** | The petition will be published on March 14, 2022 in the Register of Regulations and also posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov to receive public comment ending April 13, 2022. The request to amend the regulations and any comments for or against the petition will be considered by the Board at its meeting scheduled for June 6, 2022. The petitioner will receive information on the Board's decision after that date. |
| **Comment Period** | Ended 4/13/2022<br>0 comments |
| **Agency Decision** | Pending |

| Contact Information | |
|---|---|
| **Name / Title:** | Caroline Juran, RPh / *Executive Director* |
| **Address:** | 9960 Mayland Drive<br>Suite 300<br>Richmond, 23233 |
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*This petition was created by Erin Barrett on 02/22/2022 at 8:13am*

## Part X. Pharmacy Services to Long-Term Care Facilities

## 18VAC110-20-540. Emergency drug kit.

A. The pharmacist providing services may prepare an emergency kit for a long-term care facility in which access to the kit is restricted to a licensed nurse, pharmacist, or prescriber and only these licensed individuals may administer a drug taken from the kit and only under the following conditions:

1. The contents of the emergency kit shall be of such a nature that the absence of the drugs would threaten the survival of the patients.

2. The contents of the kit or an automated drug dispensing system, as provided in subsection B of this section, shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the institutions and shall be limited to drugs for administration by injection or inhalation only, except that Nitroglycerin SL, diazepam rectal gel, and the intranasal spray formulation of naloxone may be included.

3. The kit is sealed in such a manner that it will preclude any possible loss of the drug.

a. The dispensing pharmacy must have a method of sealing such kits so 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, resealing, or both. The pharmacy shall maintain a record of the seal identifiers when placed on a box or kit and maintain the record until such time as the seal is replaced.

c. In lieu of seals, a kit with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy is also acceptable.

4. The kit shall have a form to be filled out upon opening the kit and removing contents to write the name of the person opening the kit, the date, time, and name and quantity of items removed. The opened kit is maintained under secure conditions and returned to the pharmacy within 72 hours for replenishing.

5. Any drug used from the kit shall be covered by a prescription, signed by the prescriber, when legally required, within 72 hours.

B. Drugs that would be stocked in an emergency kit, pursuant to this section, may be stocked in an automated drug dispensing system in a nursing home in accordance with 18VAC110-20-555.

**Statutory Authority**

§§ 54.1-2400 and 54.1-3307 of the Code of Virginia.of the Code of Virginia.

**Historical Notes**

Derived from VR530-01-1 § 11.3, eff. October 25, 1989; amended, Virginia Register Volume 9, Issue 4, eff. December 16, 1992; Volume 10, Issue 1, eff. November 4, 1993; Volume 11, Issue 21, eff. August 9, 1995; Volume 15, Issue 8, eff. February 3, 1999; Volume 20, Issue 23, eff. August 25, 2004; Volume 25, Issue 24, eff. September 2, 2009; amended, Virginia Register Volume 32, Issue 22, eff. August 11, 2016; Volume 35, Issue 3, eff. October 31, 2018.

## Part X. Pharmacy Services to Long-Term Care Facilities

### 18VAC110-20-550. Stat-drug box.

A. An additional drug box called a stat-drug box may be prepared by a pharmacy to provide for initiating therapy prior to the receipt of ordered drugs from the pharmacy. Access to the stat-drug box is restricted to a licensed nurse, pharmacist, or prescriber and only these licensed individuals may administer a drug taken from the stat-drug box. Additionally, a valid prescription or lawful order of a prescriber must exist prior to the removal of any drug from the stat-drug box. A stat-drug box shall be subject to the following conditions:

1. The box is sealed in such a manner that will preclude the loss of drugs.

    a. The dispensing pharmacy must have a method of sealing such boxes so 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, or both. The pharmacy shall maintain a record of the seal identifiers when placed on a box and maintain the record until such time as the seal is replaced.

    c. In lieu of seals, a box with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy is also acceptable.

2. The box shall have a form to be filled out upon opening the box and removing contents to write the name of the person opening the box, the date, the time, and the name and quantity of items removed. When the stat-drug box has been opened, it is returned to the pharmacy.

3. There shall be a listing of the contents of the box maintained in the pharmacy and also attached to the box in the facility. This same listing shall become a part of the policy and procedure manual of the facility served by the pharmacy.

4. The drug listing on the box shall bear an expiration date for the box. The expiration date shall be the day on which the first drug in the box will expire.

5. The contents of the box shall be limited to those drugs in which a delay in initiating therapy may result in harm to the patient.

    a. The listing of drugs contained in the stat-drug box shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the long-term care facility.

    b. The stat-drug box shall contain no more than 20 solid dosage units per schedule of Schedules II through V drugs except that one unit of liquid, not to exceed 30 ml, may be substituted for a solid dosage unit in each drug schedule. If the unit of a liquid that may

contain more than one dose is removed from the stat-drug box pursuant to a patient order, the remainder shall be stored with that patient's other drugs, may be used for subsequent doses administered to that patient, and shall not be administered to any other patient.

B. Drugs that would be stocked in a stat-drug box, pursuant to this section, may be stocked in an automated drug dispensing system in a nursing home in accordance with 18VAC110-20-555, except that the quantity of drugs in Schedules II through V stocked in the system shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the nursing home.

C. The pharmacy may provide more than one stat-drug box to a long-term care facility. Contents of the multiple boxes are not required to be uniform.

**Statutory Authority**

§§ 54.1-2400 and 54.1-3307 of the Code of Virginia.

**Historical Notes**

Derived from VR530011 § 11.4, eff. October 25, 1989; amended, Virginia Register Volume 9, Issue 4, eff. December 16, 1992; Volume 10, Issue 1, eff. November 4, 1993; Volume 11, Issue 21, eff. August 9, 1995; Volume 15, Issue 8, eff. February 3, 1999; Volume 20, Issue 23, eff. August 25, 2004; Volume 25, Issue 24, eff. September 2, 2009; Volume 26, Issue 6, eff. January 7, 2010; Volume 35, Issue 3 eff. October 31, 2018; Volume 36, Issue 6, eff. December 11, 2019.

## Part X. Pharmacy Services to Long-Term Care Facilities

### 18VAC110-20-555. Use of automated dispensing devices.

Nursing homes licensed pursuant to Chapter 5 (§ 32.1-123 et seq.) of Title 32.1 of the Code of Virginia may use automated drug dispensing systems, as defined in § 54.1-3401 of the Code of Virginia, upon meeting the following conditions:

1. Drugs placed in an automated drug dispensing system in a nursing home shall be under the control of the pharmacy providing services to the nursing home, the pharmacy shall have online communication with and control of the automated drug dispensing system, and access to any drug for a patient shall be controlled by the pharmacy.

2. A nursing home without an in-house pharmacy shall obtain a controlled substances registration prior to using an automated dispensing system, unless the system is exclusively stocked with drugs that would be kept in a stat-drug box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency administration.

3. For facilities not required to obtain a controlled substance registration, access to the automated dispensing device shall be restricted to a licensed nurse, pharmacist, or prescriber, or a registered pharmacy technician for the purpose of stocking or reloading.

4. 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 under the following conditions:

a. A drug, including a drug that would be stocked in a stat-drug box pursuant to subsection B of 18VAC110-20-550, may not be administered to a patient from an automated dispensing device until a pharmacist has reviewed the prescription order and electronically authorized the access of that drug for that particular patient in accordance with the order.

b. The PIC of the provider pharmacy shall ensure that a pharmacist who has online access to the system is available at all times to review a prescription order as needed and authorize administering pursuant to the order reviewed.

c. Drugs that would be stocked in an emergency drug kit pursuant to 18VAC110-20-540 may be accessed prior to receiving electronic authorization from the pharmacist provided that the absence of the drugs would threaten the survival of the patients.

d. Automated dispensing devices shall be capable of producing a hard-copy record of distribution that shall show patient name, drug name and strength, dose withdrawn, dose to be administered, date and time of withdrawal from the device, and identity of person

withdrawing the drug.

5. Drugs placed in automated dispensing devices shall be in the manufacturer's sealed original unit dose or unit-of-use packaging or in repackaged unit-dose containers in compliance with the requirements of 18VAC110-20-355 relating to repackaging, labeling, and records.

6. Prior to the removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device, which shall include the date; drug name, dosage form, and strength; quantity; nursing home; a unique identifier for the specific device receiving drugs; and initials of the pharmacist checking the order of drugs to be removed from the pharmacy and the records of distribution for accuracy.

7. At the direction of the PIC, drugs may be loaded in the device by a pharmacist or a pharmacy technician adequately trained in the proper loading of the system.

8. At the time of loading, the delivery record for all Schedules II through VI drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy.

9. At the time of loading any Schedules II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the PIC, who shall be responsible for reconciliation of the discrepancy or the proper reporting of a loss.

10. The PIC of the provider pharmacy or his designee shall conduct at least a monthly audit to review distribution and administration of Schedules II through V drugs from each automated dispensing device as follows:

a. The audit shall reconcile records of all quantities of Schedules II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.

b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

c. The audit shall include a review of a sample of administration records from each device per month for possible diversion by fraudulent charting. A sample shall include all Schedules II through V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered.

e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper

recordkeeping.

f. The hard copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

11. Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes.

12. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device.

13. The PIC of the pharmacy providing services to the nursing home shall establish, maintain, and assure compliance with written policy and procedure for the accurate stocking and proper storage of drugs in the automated drug dispensing system, accountability for and security of all drugs maintained in the automated drug dispensing system, preventing unauthorized access to the system, tracking access to the system, complying with federal and state regulations related to the storage and dispensing of controlled substances, maintaining patient confidentiality, maintaining required records, and assuring compliance with the requirements of this chapter. The manual shall be capable of being accessed at both the pharmacy and the nursing home.

14. All records required by this section shall be filed in chronological order from date of issue and maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the nursing home except:

a. Manual Schedule VI distribution records may be maintained in offsite storage or electronically 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. Distribution and delivery records and required signatures may be generated or maintained electronically provided:

(1) The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

(2) The records are maintained in a read-only format that cannot be altered after the information is recorded.

(3) The system used is capable of producing a hard-copy printout of the records upon request.

c. Schedules II through V distribution and delivery records may only be stored offsite or electronically as described in subdivisions 14 a and 14 b of this section if authorized by DEA or in federal law or regulation.

d. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained offsite or electronically provided they can be

readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

**Statutory Authority**

§§ 54.1-2400 and 54.1-3307 of the Code of Virginia.

**Historical Notes**

Derived from Virginia Register Volume 15, Issue 8, eff. February 3, 1999; amended, Virginia Register Volume 20, Issue 23, eff. August 25, 2004; Volume 25, Issue 24, eff. September 2, 2009; Volume 35, Issue 3, eff. October 31, 2018.

**Agenda Item: Adoption of final regulations for implementation of 2020 legislation regarding pharmacists initiating treatment**

**Included in your agenda package are:**

- Regulatory Town Hall summary page showing no comments.
- Final regulations regarding pharmacists initiating treatment as required by Chapter 731 of the 2020 Acts of Assembly. Final regulations will replace emergency regulations.

**Staff Note:** Regulatory Committee recommended adoption of final regulations with minor changes from proposed stage.

**Action needed:**

- Motion to adopt final regulations.

Virginia.gov Agencies | Governor


Agency **Department of Health Professions**

Board **Board of Pharmacy**

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

**Action**: Implementation of legislation for pharmacists initiating treatment

## Proposed Stage

Action 5604 / Stage 9242

Edit Stage | Withdraw Stage | Go to RIS Project

| Documents | | |
|---|---|---|
| Proposed Text | 6/17/2021 2:49 pm | Sync Text with RIS |
| Agency Background Document | 4/12/2021 (modified 6/17/2021) | Upload / Replace |
| Attorney General Certification | 5/4/2021 | |
| DPB Economic Impact Analysis | 6/9/2021 | |
| Agency Response to EIA | 7/13/2021 | Upload / Replace |
| Governor's Review Memo | 12/2/2021 | |
| Registrar Transmittal | 12/6/2021 | |

| 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<br>Review Completed: 5/4/2021<br>Result: Certified |
| **DPB Review** | Submitted on 5/4/2021<br>Economist: Larry Getzler Policy Analyst: Melanie West<br>Review Completed: 6/17/2021 |
| **Secretary Review** | Secretary of Health and Human Resources Review Completed: 11/4/2021 |
| **Governor's Review** | Review Completed: 12/2/2021<br>Result: Approved |
| **Virginia Registrar** | Submitted on 12/6/2021<br>The Virginia Register of Regulations<br>Publication Date: 1/3/2022 Volume: 38 Issue: 10 |
| **Public Hearings** | 02/07/2022 8:45 AM |

| | |
|---|---|
| **Comment Period** | Ended 3/4/2022<br>0 comments |

| Contact Information | |
|---|---|
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*This person is the primary contact for this chapter.*

*This stage was created by Elaine J. Yeatts on 04/12/2021 at 10:10am*
*This stage was last edited by Elaine J. Yeatts on 07/13/2021 at 2:20pm*

**Project 6488 - Proposed**

**Board Of Pharmacy**

**Implementation of legislation for pharmacists initiating treatment**

**18VAC110-20-150. Physical standards for all pharmacies.**

A. The prescription department shall not be less than 240 square feet. The patient waiting area or the area used for counseling, devices, cosmetics, and proprietary medicines shall not be considered a part of the minimum 240 square feet. The total area shall be consistent with the size and scope of the services provided.

B. Access to stock rooms, rest rooms, and other areas other than an office that is exclusively used by the pharmacist shall not be through the prescription department. A rest room in the prescription department, used exclusively by pharmacists and personnel assisting with dispensing functions, may be allowed provided there is another rest room outside the prescription department available to other employees and the public. This subsection shall not apply to prescription departments in existence prior to November 4, 1993.

C. The pharmacy shall be constructed of permanent and secure materials. Trailers or other moveable facilities or temporary construction shall not be permitted.

D. The entire area of the location of the pharmacy practice, including all areas where drugs are stored, shall be well lighted and well ventilated; the proper storage temperature shall be maintained to meet USP-NF specifications for drug storage.

E. The prescription department counter work space shall be used only for the compounding and dispensing of drugs and necessary recordkeeping.

F. A sink with hot and cold running water shall be within the prescription department. A pharmacy issued a limited-use permit that does not stock prescription drugs as part of its operation is exempt from this requirement.

G. Adequate refrigeration facilities equipped with a monitoring thermometer for the storage of drugs requiring cold storage temperature shall be maintained within the prescription department if the pharmacy stocks such drugs.

H. A pharmacy stocking drugs requiring cold storage temperature shall record the temperature daily and adjust the thermostat as necessary to ensure an appropriate temperature range. The record shall be maintained manually or electronically for a period of two years.

I. The physical settings of a pharmacy in which a pharmacist initiates treatment with, dispenses, or administers drugs [ ~~and~~ , ] devices [ , controlled paraphernalia, or other supplies or equipment ] pursuant to § 54.1-3303.1 of the Code of Virginia and 18VAC110-21-46 shall protect patient confidentiality and comply with the Health Insurance Portability and Accountability Act, 42 USC § 1320d et seq.

**18VAC110-21-46. Initiation of treatment by a pharmacist.**

A. Pursuant to § 54.1-3303.1 of the Code of Virginia, a pharmacist may initiate treatment with, dispense, or administer the following drugs [ ~~and~~ , ] devices [ , controlled paraphernalia, or other supplies or equipment ] to persons 18 years of age or older:

1. Naloxone or other opioid antagonist, including such controlled paraphernalia as defined in § 54.1-3466 of the Code of Virginia as may be necessary to administer such naloxone or other opioid antagonist;

2. Epinephrine;

3. Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;

4. Prenatal vitamins for which a prescription is required;

5. Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services; and

6. Medications covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug.

B. Pharmacists who initiate treatment with, dispense, or administer a drug [ ~~or~~ , ] device [ , controlled paraphernalia, or other supplies or equipment ] pursuant to subsection A of this section shall:

1. Follow the statewide protocol adopted by the board for each drug or device.

2. Notify the patient's primary health care provider that treatment has been initiated with such drug [ ~~or~~ , ] device [ , controlled paraphernalia, or other supplies or equipment ] or that such drug [ ~~or~~ , ] device [ ~~has~~ , controlled paraphernalia, or other supplies or equipment have ] been dispensed or administered to the patient, provided that the patient consents to such notification. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist

is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

3. Maintain a patient record for a minimum of six years following the last patient encounter with the following exceptions:

a. Records that have previously been transferred to another practitioner or health care provider or provided to the patient or the patient's personal representative; or

b. Records that are required by contractual obligation or federal law to be maintained for a longer period of time.

4. Perform the activities in a manner that protects patient confidentiality and complies with the Health Insurance Portability and Accountability Act, 42 USC § 1320d et seq.

**2023 Legislative Proposal**

**§ 54.1-3320. Acts restricted to pharmacists.**

A. Within the practice of pharmacy as defined in § 54.1-3300, the following acts shall be performed by pharmacists, except as provided in subsection B:

1. The review of a prescription, in conformance with this chapter and Chapter 34 (§ 54.1-3400 et seq.) of this title and with current practices in pharmacy, for its completeness, validity, safety, and drug-therapy appropriateness, including, but not limited to, interactions, contraindications, adverse effects, incorrect dosage or duration of treatment, clinical misuse or abuse, and noncompliance and duplication of therapy;

2. The receipt of an oral prescription from a practitioner or his authorized agent;

3. The conduct of a prospective drug review and counseling as required by § 54.1-3319 prior to the dispensing or refilling of any prescription;

4. The provision of information to the public or to a practitioner concerning the therapeutic value and use of drugs in the treatment and prevention of disease;

5. The communication with the prescriber, or the prescriber's agent, involving any modification other than refill authorization of a prescription or of any drug therapy <u>in Schedules III-VI or clarification of quantity or refill of a prescription issued for a Schedule VI drug</u>, resolution of any drug therapy problem, or the substitution of any drug prescribed;

6. The verification of the accuracy of a completed prescription prior to dispensing the prescription;

7. The supervision of pharmacy interns and pharmacy technicians; and

8. Any other activity required by regulation to be performed by a pharmacist.

B. A pharmacy intern may engage in the acts to be performed by a pharmacist as set forth in subsection A or the Drug Control Act (§ 54.1-3400 et seq.) for the purpose of obtaining practical experience required for licensure as a pharmacist, if the supervising pharmacist is directly monitoring these activities.

C. A registered pharmacy technician, working under the direct supervision of a qualified nuclear pharmacist, as defined by regulations of the Board, may accept oral prescriptions for diagnostic, nonpatient specific radiopharmaceuticals in accordance with subsection C of § 54.1-3410.1.

D. Consistent with patient safety, a pharmacist shall exercise sole authority in determining the maximum number of pharmacy technicians that he shall supervise; however, no pharmacist shall supervise more pharmacy technicians than allowed by Board regulations.

**§ 54.1-3321. Registration of pharmacy technicians.**

A. No person shall perform the duties of a pharmacy technician without first being registered as a pharmacy technician with the Board. Upon being registered with the Board as a pharmacy technician, the following tasks may be performed:

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

2. The preparation of prescription labels or patient information;

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

4. The counting, measuring, or compounding of the drug to be dispensed;

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

6. The stocking or loading of automated dispensing devices or other devices used in the dispensing process;

7. The acceptance of refill authorization of a prescription for a Schedule III-VI drug, or clarification of quantity and refills for a prescription issued for a Schedule VI drug from a prescriber or his authorized ~~agency~~ agent, so long as there is no other change to the original prescription; ~~and~~

8. Under the supervision of a pharmacist, meaning the supervising pharmacist is at the same physical location of the technician or pharmacy intern, and consistent with the requirements of § 54.1-3303.1, administration of the following drugs and devices to persons three years of age or older as set forth in regulations of the Board: vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19; and

8. The performance of any other task restricted to pharmacy technicians by the Board's regulations.

B. To be registered as a pharmacy technician, a person shall submit :

1. An application and fee specified in regulations of the Board;

2. (Effective July 1, 2022) Evidence that he has successfully completed a training program that is (i) an accredited training program, including an accredited training program operated through the Department of Education's Career and Technical Education program or approved by the Board, or (ii) operated through a federal agency or branch of the military; and

3. Evidence that he has successfully passed a national certification examination administered by the Pharmacy Technician Certification Board or the National Healthcareer Association.

C. The Board shall promulgate regulations establishing requirements for :

1. Issuance of a registration as a pharmacy technician to a person who, prior to the effective date of such regulations, (i) successfully completed or was enrolled in a Board-approved pharmacy technician training program or (ii) passed a national certification examination required by the Board but did not complete a Board-approved pharmacy technician training program;

2. Issuance of a registration as a pharmacy technician to a person who (i) has previously practiced as a pharmacy technician in another U.S. jurisdiction and (ii) has passed a national certification examination required by the Board; and

3. Evidence of continued competency as a condition of renewal of a registration as a pharmacy technician.

D. The Board shall waive the initial registration fee for a pharmacy technician applicant who works as a pharmacy technician exclusively in a free clinic pharmacy. A person registered pursuant to this subsection shall be issued a limited-use registration. A pharmacy technician with a limited-use registration shall not perform pharmacy technician tasks in any setting other than a free clinic pharmacy. The Board shall also waive renewal fees for such limited-use registrations. A pharmacy technician with a limited-use registration may convert to an unlimited registration by paying the current renewal fee.

E. Any person registered as a pharmacy technician prior to the effective date of regulations implementing the provisions of this section shall not be required to comply with the requirements of subsection B in order to maintain or renew registration as a pharmacy technician.

F. A pharmacy technician trainee enrolled in a training program for pharmacy technicians described in subdivision B 2 may engage in the acts set forth in subsection A for the purpose of obtaining practical experience required for completion of the training program, so long as such activities are directly monitored by a supervising pharmacist.

G. To be registered as a pharmacy technician trainee, a person shall submit an application and a fee specified in regulations of the Board. Such registration shall only be valid while the person is enrolled in a pharmacy technician training program described in subsection B and actively progressing toward completion of such program. A registration card issued pursuant to this section shall be invalid and shall be returned to the Board if such person fails to enroll in a pharmacy technician training program described in subsection B.

H. A pharmacy intern may perform the duties set forth for pharmacy technicians in subsection A when registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

**2023 Legislative Proposal**

**§ 54.1-3305. Board; membership; terms; meetings; quorum; officers.**

The Board of Pharmacy shall consist of ~~ten~~ eleven members, as follows: eight licensed pharmacists who are graduates of an approved school or college of pharmacy, ~~and~~ two citizen members, and one pharmacy technician. The terms of office of the members shall be four years.

The Board shall meet at least annually at such times and places, and upon such notice as the Board may determine and as its business may require. A majority of the members of the Board shall constitute a quorum for the transaction of business.

The Board shall annually elect from its members a chairman.

There shall be an executive director for the Board of Pharmacy who shall be licensed or eligible for licensure in the Commonwealth as a pharmacist.

# Cannabis: Potential Drug Interactions

Virginia Code § 54.1-3319(A) requires a pharmacist to conduct a prospective drug review before each new prescription is dispensed or delivered to a patient or a person acting on behalf of the patient. That review must include screening for potential drug therapy problems due to drug-drug interactions. As legal allowances for the use of cannabis increase, the Board of Pharmacy offers the following guidance to assist pharmacists performing prospective drug reviews, including the screening for drug-drug interactions.

**What is cannabis and how is it used?**

Cannabis is a psychoactive drug. The primary psychoactive component of cannabis is delta-9-tetrahydrocannabinol (THC).[1-2] Along with THC, cannabis contains over 500 chemicals with over 100 of those being cannabinoids.[1] Cannabis can be consumed several different ways by joints, pipes, bongs, blunts, oils, edibles, or vaporizer pens.[2] There are three cannabis plants with psychoactive properties, *Cannabis sativa, Cannabis indica,* and *Cannabis ruderalis*.[3] Cannabis is often used as a recreational drug or can be used for medical purposes in disease states including pain, glaucoma, Parkinson's Disease, fibromyalgia, PTSD, and many others.[4]

**How can cannabis affect other medications?**

Cannabis contains over 100 cannabinoids, such as delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD), that bind to cannabinoid receptors throughout the body.[5-7] These cannabinoids also interfere with the metabolism of many prescription medications through the cytochrome P450 enzyme system.[5-7] When a metabolic enzyme is inhibited, it results in increased concentrations of enzyme substrate in the body. In contrast, when a metabolic enzyme is induced, it results in decreased concentrations of enzyme substrate in the body. Both THC and CBD are present in high concentrations within the cannabis plant and are inhibitors and substrates of multiple CYP450 enzymes.[5-7]

THC, the primary psychoactive component of cannabis, is metabolized by CYP2C9 and CYP3A4 enzymes.[5-7] CBD is metabolized by CYP3A4 and CYP2C19. Thus, drug interactions may occur when cannabis is used in combination with inducers and inhibitors of the respective enzymes. THC also acts as an inhibitor of CYP1A2, CYP2B6, CYP2C9, and CYP2D6. CBD inhibits CYP3A4, CYP2B6, CY92C9, CYP2D6, and CYP2E1.[5-7] Currently, cannabis-drug interactions are mostly theoretical or come from case reports due to the lack of clinical trial results that evidences the effects of the interactions and the probability of their occurrence.[5] Additive effects can occur with other drugs such as tachycardia and hypertension with sympathomimetics, drowsiness and ataxia with central nervous system depressants, and confusion with anticholinergics.[7]

## What are the potential drug interactions of cannabis?

| Potential Drug Interactions with Cannabis[8] | | | | |
|---|---|---|---|---|
| **CYP3A4 Substrate + Inhibitor** | | **CYP2C19 Substrate + Inhibitor** | | **CYP2C9 Inhibitor** |
| **CBD + Drug Levels** | **Drug +/- CBD Levels** | **CBD + Drug Levels** | **Drug +/- CBD Levels** | **CBD + Drug Levels** |
| Benzodiazepines* | Protease Inhibitors* | Benzodiazepines* | PPIs* | Sulfonylureas* |
| Corticosteroids* | Ketoconazole | PPIs* | Azole Antifungals* | NSAIDs* |
| Statins* | Loperamide | Azole Antifungals* | Cimetidine | Buprenorphine |
| Alfuzosin | Amiodarone | Clopidogrel | Clopidogrel | Montelukast |
| Budesonide | Verapamil | Cyclophosphamide | Efavirenz | Rosiglitazone |
| Cyclosporine | Cimetidine | Warfarin | Rifampin | Phenobarbital |
| Disopyramide | Aprepitant | Escitalopram | Carbamazepine | Phenytoin |
| Ergotamine | Imatinib | Meclobemide | Phenobarbital | Rosuvastatin |
| Fluticasone | Nefazodone | Pentamidine | Phenytoin | Warfarin |
| Quinidine | Enzalutamide | Proguanil | St. John's Wort | Diclofenac |
| Sildenafil | Phenytoin | Sertraline | Fluvoxamine | Dronabinol |
| Tadalafil | Carbamazepine | Thalidomide | Fluoxetine | Tolbutamide |
| Vardenafil | Topiramate | Propranolol | | Valsartan |
| | Phenobarbital | Carisoprodol | | Losartan |
| | Rifampicin | | | |
| | Efavirenz | | | |
| | Pioglitazone | | | |
| *Most, if not all drugs in the class are affected | | | | |

## What interactions have demonstrated clinical relevance?

| Clinical Relevance of Drug interactions with Cannabis[5] | | |
|---|---|---|
| **Drug** | **Mechanism** | **Effects** |
| **Level 1 Interaction: Very High Risk** | | |
| Warfarin | CYP2C9 Inhibition | Increased INR with concomitant use of CBD resulting in GI bleeding. Monitor INR closely for warfarin adjustments. Avoid combination if possible. |
| **Level 2 Interaction: High Risk** | | |
| Buprenorphine | CYP3A4 Inhibition | Increased concentrations of buprenorphine. Avoid combination if possible or adjust buprenorphine doses.[1] |
| Tacrolimus | CYP3A4 Inhibition | Increased tacrolimus concentrations. Avoid combination if possible or adjust tacrolimus doses.[1] |
| **Level 3 Interaction: Medium Risk** | | |
| Clozapine | CYP3A4 and 2C19 Induction | Decreased clozapine concentrations. Consider dose adjustment.[1] |
| Methadone | CYP3A4 and 2C19 Inhibition | Increased methadone levels resulting in increased somnolence. Consider dose adjustment.[1] |
| Clobazam | CYP2C19 Inhibition | Increased clobazam concentrations. Consider dose adjustment.[1] |
| Chlorpromazine | Possible CYP1A2 Induction | Decreased chlorpromazine concentrations. Consider dose adjustment.[1] |
| Hexobarbital | Possible CYP3A4 Inhibition | Increased hexobarbital concentrations. Consider dose adjustment.[1] |
| Ketoconazole | CYP3A4 Inhibition | Increased concentrations of THC/CBD |
| Rifampicin | CYP3A4 Induction | Decreased concentrations of THC/CBD |
| Stiripentol | CYP2C19 Induction | Increased concentrations of stiripentol. Consider dose adjustment.[1] |
| Theophylline | CYP1A2 Induction | Decreased theophylline concentration. Consider dose adjustment.[1] |
| Valproate | Possible UGT1A9 and UGTB7 Inhibition | Increased LFTs. Assess liver function before taking in combination. |
| **Level 5 Interaction: Co-administration with CBD does not lead to significant changes in drug levels (rufinamide, topiramate, zonisamide, nelfinavir)** | | |

Levels of clinical relevance of drug interactions were determined according to the combination of severity and probability of occurrence.
[1]Monitor plasma levels if possible.

Resources:


1. NIDA. What is marijuana? National Institute on Drug Abuse website. https://nida.nih.gov/publications/research-reports/marijuana/what-marijuana. April 13, 2021 Accessed March 22, 2022.
2. "Cannabis." *Cannabis - Alcohol and Drug Foundation*, Alcohol and Drug Foundation, 10 Nov. 2021, https://adf.org.au/drug-facts/cannabis/.
3. Meds Safety. "List of Drugs That Interact with Marijuana (Cannabis)." *Meds Safety*, Meds Safety, 10 Jan. 2022, https://medssafety.com/list-of-drugs-that-interact-with-marijuana-cannabis/.
4. Peter Grinspoon, MD. "Medical Marijuana." *Harvard Health*, Harvard Health Publishing, 10 Apr. 2020, https://www.health.harvard.edu/blog/medical-marijuana-2018011513085.
5. Lopera V, Rodríguez A, Amariles P. Clinical Relevance of Drug Interactions with Cannabis: A Systematic Review. *Journal of Clinical Medicine*. 2022; 11(5):1154. https://doi.org/10.3390/jcm11051154
6. John R. Horn, PharmD, and PharmD Philip D. Hansten. "Drug Interactions with Marijuana." *Pharmacy Times*, Pharmacy Times, 8 Mar. 2021, https://www.pharmacytimes.com/view/drug-interactions-with-marijuana.
7. Antoniou T, Bodkin J, Ho JM. Drug interactions with cannabinoids. *CMAJ*. 2020;192(9):E206. doi:10.1503/cmaj.191097
8. CBD drug interactions. NCPA CBD Source Powered by PRS. https://ncpacbdsource.com/pharmacist-education/cbd-drug-interactions/. Published July 16, 2020. Accessed August 12, 2021.

**Amendments (red) to 2023 Pharmacist Workforce Survey**

30b) If you participate in a collaborative practice agreement for disease state management at this or any other work locations, which disease states are being managed? Check all that apply.

Hypertension
Hypercholesterolemia
Asthma
Tobacco cessation
Travel medications
Anticoagulation
Diabetes

30c) If you initiate patient treatment in accordance with statewide protocols at this or any other work locations, which of the statewide protocols below do you utilize? Check all that apply

Hormonal contraception
Emergency contraception
Prenatal vitamins
Naloxone
Epinephrine
Lowering out-of-pocket expenses
**Vaccines**
**Tuberculosis**
**HIV Pre-exposure Prophylaxis (PrEP)**
**HIV Post-exposure Prophylaxis (PEP)**

Virginia Board of Pharmacy
June 06, 2022
Licenses Issued

| | 11/1/20-1/31/21 | 2/1/21-4/30/21 | 5/1/21 - 7/31/21 | 8/1/21 - 10/31/21 | 11/1/21 - 1/31/22 | 2/1/22 - 4/30/22 | License Count 5/09/2022 |
|---|---|---|---|---|---|---|---|
| Business CSR | 8 | 25 | 44 | 25 | 28 | 35 | 1,434 |
| Cannabis Dispensing Facility | | | | 1 | 2 | 2 | 5 |
| CE Courses | 0 | 1 | 1 | 1 | 0 | 1 | 9 |
| Limited Use Pharmacy Technician | 0 | 0 | 0 | 0 | 0 | 0 | 7 |
| Medical Equipment Supplier | 8 | 5 | 1 | 6 | 0 | 0 | 212 |
| Non-restricted Manufacturer | 0 | 1 | 0 | 1 | 2 | 0 | 31 |
| Outsourcing Facility | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Permitted Physician | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| Pharmaceutical Processor | 0 | 0 | 0 | 0 | 0 | 0 | 4 |
| Pharmacist | 178 | 175 | 275 | 279 | 157 | 187 | 15,941 |
| Pharmacist Volunteer Registration | 0 | 0 | 0 | 1 | 0 | 1 | 2 |
| Pharmacy | 8 | 11 | 10 | 9 | 16 | 9 | 1,767 |
| Pharmacy Intern | 99 | 107 | 59 | 179 | 87 | 88 | 1,284 |
| Pharmacy Technician | 482 | 424 | 460 | 353 | 360 | 360 | 12,612 |
| Pharmacy Technician Trainee | 149 | 1256 | 1414 | 1280 | 1385 | 1042 | 5,963 |
| Pharmacy Technician Training Program | 2 | 7 | 3 | 1 | 1 | 3 | 126 |
| Physician Selling Controlled Substances | 16 | 7 | 19 | 39 | 14 | 17 | 544 |
| Physician Selling Drugs Location | 2 | 4 | 4 | 1 | 4 | 2 | 159 |
| Pilot Programs | 1 | 0 | 0 | 0 | 0 | 2 | 25 |
| Registered Physician For Medical Cannabis | 140 | 122 | 162 | 66 | 81 | 106 | 817 |
| Repackaging Training Program | 0 | 0 | 0 | 0 | 0 | 0 | 2 |
| Restricted Manufacturer | 0 | 1 | 0 | 0 | 0 | 0 | 36 |
| Third Party Logistics Provider | 0 | 1 | 0 | 0 | 0 | 1 | 7 |
| Warehouser | 1 | 5 | 0 | 1 | 1 | 1 | 120 |
| Wholesale Distributor | 0 | 1 | 1 | 1 | 0 | 0 | 62 |
| **Total** | **1,094** | **2,153** | **2,453** | **2,244** | **2,138** | **1,858** | **41,170** |

| | 11/1/20-1/31/21 | 2/1/21-4/30/21 | 5/1/21 - 7/31/21 | 8/1/21 - 10/31/21 | 11/1/21 - 1/31/22 | 2/1/22 - 4/30/22 | License Count 5/3/2021 |
|---|---|---|---|---|---|---|---|
| Nonresident Manufacturer | 1 | 6 | 6 | 10 | 1 | 12 | 207 |
| Nonresident Medical Equipment Supplier | 9 | 8 | 6 | 10 | 5 | 5 | 338 |
| Non-resident Outsourcing Facility | 0 | 1 | 1 | 1 | 1 | 0 | 27 |
| Non-resident Pharmacy | 31 | 37 | 17 | 17 | 22 | 25 | 885 |
| Non-resident Third Party Logistics Provider | 15 | 10 | 9 | 4 | 7 | 1 | 182 |
| Non-resident Warehouser | 9 | 12 | 5 | 4 | 5 | 6 | 99 |
| Non-resident Wholesale Distributor | 10 | 20 | 18 | 14 | 14 | 6 | 628 |
| **Total** | **75** | **94** | **62** | **60** | **55** | **55** | **2,366** |

# Quarterly Review - Date Range: 01/01/2022 ending 03/31/2022

## Number of Inspections Completed by License Type

| Count of Insp ID | | Insp Typ | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Insp Status | License Type | Change of Location | Compliance | Focus | New | Pilot | Reinspection | Remodel | Routine | Grand Total |
| Completed | Business CSR | 7 | | | 23 | | | 2 | 80 | 112 |
| | Cannabis Dispensing Facility | | | | 2 | | | | | 2 |
| | Medical Equipment Supplier | 1 | | | | | | | 8 | 9 |
| | Non-restricted Manufacturer | | | | | | | | 1 | 1 |
| | Pharmaceutical Processor Permit | | | | | | | 2 | | 2 |
| | Pharmacy | | 1 | 1 | 13 | | 3 | 25 | 214 | 257 |
| | Physician Selling Drugs Location | | | | 2 | | | | 23 | 25 |
| | Pilot Programs | | | | | 3 | | | | 3 |
| | Third Party Logistics Provider | | | | 1 | | | | | 1 |
| | Warehouser | 1 | | | | | | | 14 | 15 |
| | Wholesale Distributor | 1 | | | | | | | 3 | 4 |
| Completed Total | | 10 | 1 | 1 | 41 | 3 | 3 | 29 | 343 | 431 |
| Completed Virtu | Business CSR | | | | 7 | 1 | | 1 | 28 | 37 |
| | Medical Equipment Supplier | | | | | | | | 2 | 2 |
| | Pharmacy | | | | 3 | | | 4 | | 7 |
| | Physician Selling Drugs Location | 1 | | | | | 1 | | 1 | 3 |
| | Pilot Programs | | | | | 1 | | | | 1 |
| | Warehouser | | | | | | | | 1 | 1 |
| | Wholesale Distributor | | | | | | | 1 | | 1 |
| Completed Virtual Total | | 1 | | | 10 | 2 | 1 | 6 | 32 | 52 |
| Grand Total | | 11 | 1 | 1 | 51 | 5 | 4 | 35 | 375 | 483 |

# Date Range: 01/01/2022 ending 03/31/2022

## Routine Inspections, Deficiencies by License Type

| Count of Insp ID | Result | | | |
|---|---|---|---|---|
| License Type | Deficiency | Deficiency & IPHCO | No Deficiency | Grand Total |
| Business CSR | 37 | | 71 | 108 |
| Medical Equipment Supplier | 2 | | 8 | 10 |
| Non-restricted Manufacturer | | | 1 | 1 |
| Pharmacy | 58 | 122 | 34 | 214 |
| Physician Selling Drugs Location | 19 | | 5 | 24 |
| Warehouser | 3 | | 12 | 15 |
| Wholesale Distributor | 1 | | 2 | 3 |
| Grand Total | 120 | 122 | 133 | 375 |

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

# Date Range: 01/01/2022 ending 03/31/2022

## Categories of Deficiencies for Occurrences, Routine Inspections Only Recorded >20 Times with Examples

| Description | Number of times for occurrence |
|---|---|
| 110-20-110 | 22 |

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 | 58 |

Deficiency 9a. The alarm system does not include a feature by which any breach shall be communicated to the PIC
Deficiency 9a: Alarm is operational but does not fully protect the prescription department
Deficiency 10: Unauthorized access to alarm and locking device to the prescription department

| | |
|---|---|
| 110-20-190 | 33 |

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 | 21 |

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

| | |
|---|---|
| 110-20-240 | 61 |

Deficiency 14: No incoming change of Pharmacist-in-Charge inventory
Deficiency 15: Perpetual inventory not being maintained as required
Deficiency 113: Drugs listed in Schedule II were not maintained separately from all other records
Deficiency 113: Inventories taken on time, but not in compliance

Deficiency 14: The Pharmacist-in-Charge inventory was taken 3 days prior to the effective date of change

| 110-20-270 | 28 |
|---|---|

Deficiency 19: Pharmacists not verifying accuracy of dispensed prescriptions in all respects

| 110-20-275 | 32 |
|---|---|

Deficiency 122: Engaging in alternate delivery not in compliance

| 110-20-276 | 47 |
|---|---|

Deficiency 123: Engaging in remote processing not in compliance

| 110-20-355 | 28 |
|---|---|

Deficiency 20: Pharmacists initals veriftying the accuracy of the process
Deficiency 109: Dispensed drugs being returned to stock not in compliance
Deficiency 127: Repackanging records and labeling not in compliance

| 110-20-418 | 40 |
|---|---|

Deficiency 142. No record maintained and available for 12 months from date of analysis of dispensing errors/ patient safety
Deficiency 142. No record maintained and available for 12 months from date of analysis of dispensing errors

| 54.1-3404 | 35 |
|---|---|

Deficiency 13: No biennial inventory. No biennial inventory has been completed
Deficiency 16: Theft/unusual loss of drugs not reported to the Board
Deficiency 112: Biennial taken late but within 30 days
Deficiency 113: Inventories taken on time, but not in compliance
Deficiency 148: Unusual loss of drugs reported to board but report not maintained by pharmacy

| 54.1-3410 | 43 |
|---|---|

Deficiency 116: Prescriptions not transmitted as required
Deficiency 116: Prescriptions do not include required information
Deficiency 124: Labels do not include all required information

| 54.1-3410.2 | 174 |
|---|---|

800: Assessment of Risk has not been performed
Deficiency 20a: Pharmacist not documenting verification of accuracy of non-sterile compounding
Deficiency 130a: Compounded products not properly labeled
Deficiency 130: Required compounding records not complete and properly maintained

| 54.1-3434 | 22 |
|---|---|

Deficiency 1: No Pharmacist-in-Charge
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

# Two Year Review - Date Range: 03/31/2020 ending 03/31/2022

## Number of Inspections Completed by License Type

| Count of Insp II | | Insp Type | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Insp Status | License Type | Change of Location | Compliance | Focus | New | Pilot | Reinspection | Remodel | Routine | Grand Total |
| ⊟Completed | Business CSR | 55 | | | 112 | | 8 | 18 | 427 | 620 |
| | Cannabis Dispensing Facility | | | | 6 | | 2 | | | 8 |
| | Medical Equipment Supplier | 15 | | | 17 | | | | 81 | 113 |
| | Non-restricted Manufacturer | 1 | | | 5 | | 3 | 2 | 3 | 14 |
| | Pharmaceutical Processor Permit | 1 | | | | | 7 | 8 | 18 | 34 |
| | Pharmacy | 30 | 8 | 10 | 70 | 1 | 29 | 207 | 1060 | 1415 |
| | Physician Selling Drugs Location | 3 | | 1 | 12 | | 5 | 2 | 78 | 101 |
| | Pilot Programs | | | | | 8 | | | | 8 |
| | Restricted Manufacturer | 1 | | | 2 | | | | 1 | 4 |
| | Third Party Logistics Provider | | | | 3 | | | | 3 | 6 |
| | Warehouser | 10 | | | 8 | | 2 | 2 | 62 | 84 |
| | Wholesale Distributor | 3 | | 1 | 4 | | | 3 | 33 | 44 |
| Completed Total | | 119 | 8 | 12 | 239 | 9 | 56 | 242 | 1766 | 2451 |
| ⊟Completed V | Business CSR | 22 | 1 | | 94 | 1 | 7 | 16 | 394 | 535 |
| | Medical Equipment Supplier | 5 | | | 6 | | | 2 | 45 | 58 |
| | Pharmacy | 11 | | 1 | 14 | | 17 | 73 | 1 | 117 |
| | Physician Selling Drugs Location | 2 | | | 13 | | 5 | 1 | 8 | 29 |
| | Pilot Programs | | | | | 13 | | | | 13 |
| | Third Party Logistics Provider | | | | 1 | | | | | 1 |
| | Warehouser | 1 | | | 3 | | 1 | 1 | 29 | 35 |
| | Wholesale Distributor | | | | 1 | | 2 | 2 | 12 | 17 |
| Completed Virtual Total | | 41 | 1 | 1 | 132 | 14 | 32 | 95 | 489 | 805 |
| Grand Total | | 160 | 9 | 13 | 371 | 23 | 88 | 337 | 2255 | 3256 |

# Date Range: 03/31/2020 ending 03/31/2022

## Routine Inspections, Deficiencies by License Type

| Count of Insp ID | Result | | | |
|---|---|---|---|---|
| License Type | Deficiency | Deficiency & IPHCO | No Deficiency | Grand Total |
| Business CSR | 395 | | 426 | 821 |
| Medical Equipment Supplier | 44 | | 82 | 126 |
| Non-restricted Manufacturer | | | 3 | 3 |
| Pharmaceutical Processor Permit | 13 | | 5 | 18 |
| Pharmacy | 364 | 439 | 258 | 1061 |
| Physician Selling Drugs Location | 70 | | 16 | 86 |
| Restricted Manufacturer | 1 | | | 1 |
| Third Party Logistics Provider | 3 | | | 3 |
| Warehouser | 18 | | 73 | 91 |
| Wholesale Distributor | 22 | | 23 | 45 |
| Grand Total | 930 | 439 | 886 | 2255 |

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

# Two Staffing Announcements -

- One of the Pharmacy Inspectors will attend the NABP Sterile Compounding training class in New Jersey in July.
- One of the Senior Inspectors has resigned and will be going into retirement. He spent 26 years with our agency and 30 years total with the Commonwealth. We are currently in recruitment for a replacement.

# Reports Extracted on 5/17/2022 –

- Data extrapolated from My License Office (MLO) / Inspection Completed Detail Report /Inspection Result Detail Report

***Report prepared by:  Melody J. Morton, Inspections Manager Enforcement Division***

**Pharmaceutical Processors Report-June 6, 2022**

- No additional cannabis dispensing facilities have been permitted during the last quarter.
- 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 continues to receive, on average, 1000 patient applications per week.
- The Board successfully recruited for an administrative specialist and Licensing Manager position for the pharmaceutical processor program. Both staff began employment on April 10, 2022.
- Board and agency staff continue work to develop specific components of a new patient registration platform.
- The Board has been developing regulations and procedures to address the 2022 legislative changes impacting the program.

Pharmaceutical Processors Program-By the Numbers
As of 5/23/2022

| | |
|---|---|
| Registered Practitioners | 827 |
| Registered Patients | 50,935 |
| Registered Parents/Guardians | 260 |
| Registered Agents | 172 |
| Registered Cannabis Oil Products (cumulative) | 1,375 |

# Discipline Program Report

Open Cases as of 5/5/22:

| | PC | APD | Investigation | FH | IFC | Other | Pending Closure | Entry | TOTALS |
|---|---|---|---|---|---|---|---|---|---|
| **Patient Care Cases** | 88 | 11 | 104 | 3 | 4 | 1 | 0 | 4 | 215 |
| **Non-Patient Care Cases** | 94 | 13 | 26 | 1 | 5 | 1 | 18 | 0 | 158 |
| | | | | | | **TOTAL:** | | | **373** |

- The Board has two cases currently being appealed in circuit court and notice of appeal has been received for a third case.
- APD has hired a third employee to assist with Board of Pharmacy cases.
- Electronic case management is coming soon!

Upcoming Disciplinary Proceedings:

| | | |
|---|---|---|
| June 13, 2022 | Full Board | Formal Hearings |
| June 14, 2022 | St. Clair/Bolyard | Informal Conference |
| July 13, 2022 | TBD | Informal Conference |
| July 27, 2022 | TBD | Informal Conference |
| July 28, 2022 | Full Board | Formal Hearing (Day 1 of 2) |
| July 29, 2022 | Full Board | Formal Hearing (Day 2 of 2) |
| August 4, 2022 | TBD | Pilot Committee |
| August 17, 2022 | TBD | Informal Conference |
| August 23, 2022 | Full Board | Formal Hearing (Day 1 of 2) |
| August 24, 2022 | Full Board | Formal Hearing (Day 2 of 2) |

**Executive Director's Report** – June 6, 2022

*Operations:*

- Telework will likely be restricted to one day/week effective July 5th.

*Staffing:*

- Recruiting for vacant licensing administrative assistant position.
- Recently hired licensing administrative assistant and licensing supervisor for medical cannabis program.

*Projects:*

- Ongoing efforts to acquire new licensing software for cannabis program
- Preparing for digital disciplinary evidence packets and meeting agendas; Use of Box, SharePoint, and DocuSign
- Development of BOTs to assist with licensing activities
- SAMHSA Buprenorphine Access
- Budget Development

*Recent Meetings Attended:*

- APhA and NASPA Annual Meetings
- FSMB Annual Meeting
- JCPP Meeting
- NABP Annual Meeting

*Presentations:*

- NASPA
- JCPP