

COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Third Floor Henrico, Virginia 23233

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

Tentative Agenda of Full Board Meeting March 30, 2023 9AM

TOPIC	DACEC
Call to Order of Public Hearing: Dale St. Clair, PharmD, Chairman	<u>PAGES</u>
Welcome & Introductions	
 Public Hearings: Placing Certain Chemicals into Schedule I Conforming Drug Schedules to Federal Scheduling Action 	56-64 65-73
Adjournment of Public Hearings	
Call to Order of Full Board Meeting: Dale St. Clair, PharmD, ChairmanApproval of Agenda	
Approval of Previous Board Meeting Minutes:	
• November 21, 2022, Telephone Conference Call	3-4
• December 6, 2022, Full Board Meeting	5-15
• December 6, 2022, Public Hearings	16-18
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• February 8, 2023, Innovative Pilot Program	27-28
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• February 16, 2023, Special Conference Committee	34-36
Call for Public Comment: The Board will receive public comment at this time. The Board will not receive	

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: Arne Owens

Legislative/Regulatory/Guidance: Erin Barrett, JD/Caroline Juran, RPh

• Report of 2023 Virginia General Assembly

• Chart of Regulatory Actions

 Adoption of Exempt Final Regulation to Place Certain Chemicals into Schedule I Adoption of Exempt Final Regulation to Conform Drug Schedules to Federal Scheduling Action Adoption of Final Regulations from 2021 Pharmacists Initiating Treatment Legislation Adoption of Proposed Regulations Following Periodic Review of Chapter 30 Adoption of Proposed Regulations for Exemption of ADDs Stocked Solely with Stat-use or Emergency Drugs 	57-65 66-74 75-82 83-88 89-100 101-106
 Adoption of Fast-Track Action to Repeal 18VAC110-21-140 and 18VAC110-21-150 Amend Guidance Document 110-9 Adoption of Guidance 110-37 for Unanticipated Shortened Hours of Pharmacy Operation Adoption of Guidance for Pharmacy Administration Records Amend Guidance Document 110-44, Protocol for the Prescribing and Dispensing of Naloxone Amend Statewide Protocols for Vaccines for Adults and Minors 	
New Business: • Adoption of 2022 Pharmacist and Pharmacy Technician Healthcare Workforce Survey Reports	150-208
 Reports: Chairman's Report –Dale St.Clair, PharmD Report on Board of Health Professions – Sarah Melton, PharmD Report on Licensure of Individuals and In-State Facilities – Ryan Logan, RPh 	209
 Report on Nonresident Facilities – Beth O'Halloran, RPh Report on Inspection Program – Melody Morton, Inspections Manager, Enforcement Division Report on Pharmaceutical Processors – Annette Kelley, M.S., C.S.A.C. Report on Disciplinary Program – Ellen B. Shinaberry, PharmD Executive Director's Report – Caroline D. Juran, RPh 	210 211-217 218 219 220

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

Adjourn

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

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

VIRGINIA BOARD OF PHARMACY MINUTES OF TELEPHONE CONFERENCE CALL

Monday, November 21, 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 § 54.1-2408.1(A) of the Code of Virginia, a

> telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on November 21, 2022, at 10:31 AM, to consider the summary suspensions in case

no. 220051.

PRESIDING: Dale St. Clair, Chair

BOARD MEMBERS PRESENT: Larry Kocot

> Cheri Garvin Sarah Melton William Lee Wendy Nash

Kristopher Ratliff

STAFF PRESENT: Mykl Egan, Discipline Case Manager

Caroline Juran, Executive Director

James Rutkowski, Senior Assistant Attorney General

Sean J. Murphy, Assistant Attorney General David Robinson, DHP 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 suspension case. The Board members stated that they would not have been able to attend.

With seven (7) members participating and three (3) members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

DEVON KEITH Registration No. 0230-037583	Sean Murphy, Assistant Attorney General, presented a summary of the evidence in case no. 220051 regarding the pharmacy technician registration of Devon Keith. Mr. Murphy was assisted by David Robinson, DHP Adjudication Specialist.
DECISION:	Upon a motion by Mr. Kocot and duly seconded by Ms. Garvin, the Board unanimously voted (7-0) that, with the evidence presented, the practice as a pharmacy technician by Devon Keith poses a substantial danger to the public; and therefore, the registration of Mr. Keith shall be summarily suspended and with the Notice of formal hearing, a Consent Order shall be offered to Mr. Keith for the revocation of his registration.
ADJOURN:	With all business concluded, the meeting adjourned at 10:41 AM.
Dale St. Clair, Chair	Mykl Egan, Discipline Case Manager
Date	Date

VIRGINIA BOARD OF PHARMACY MINUTES OF FULL BOARD MEETING

Tuesday, December 6, 2022 Department of Health Professions

> Perimeter Center 9960 Mayland Drive Henrico, Virginia 23233

A full board meeting was called to order at 9:16am. CALL TO ORDER:

PRESIDING: Dale St. Clair, PharmD, Chairman

MEMBERS PRESENT: Larry Kocot, J.D.

> William Lee, DPh Wendy Nash, PharmD Kristopher Ratliff, DPh

Patricia Richards-Spruill, RPh

Ling Yuan, PharmD Cheryl Garvin, RPh

MEMBER ABSENT: Sarah Melton, PharmD

STAFF PRESENT: Caroline Juran, RPh, Executive Director

James Rutkowski, J.D., Assistant Attorney General

Arne W. Owens, Director, DHP

James Jenkins, Jr., RN, Chief Deputy Director, DHP

Erin Barrett, J.D., DHP Senior Policy Analyst

Annette Kelley, MS, CSAC, Deputy Executive Director

Ryan Logan, RPh, Deputy Executive Director Beth O'Halloran, RPh, Deputy Executive Director

Ellen B. Shinaberry, PharmD, Deputy Executive Director

Sorayah Haden, Executive Assistant

Patricia Mason, Individual Licensing Supervisor

PHARMACISTS AWARDED Wendy C. Nash, PharmD Ryan Logan, RPh

1-HOUR OF LIVE OR REAL-

Ellen B. Shinaberry, PharmD TIME INTERACTIVE

David Flammia, RPh CONTINUING EDUCATION

FOR ATTENDING MEETING:

QUORUM: With 8 members present, a quorum was established.

APPROVAL OF AGENDA:

An amended agenda was provided, along with handouts. A new item was inserted into the New Business section under Legislative/Regulatory/Guidance. The fourth bullet in the section was amended to read "Withdraw changes to Guidance Document 110-33 Pharmacy Interns as Pharmacy Technicians, Pharmacy Technician Ratio, and Pharmacy Technician Trainees and Amend Vaccine Protocol". Two handouts for this new item were provided, a copy of the current Guidance Document 110-33 and a copy of the Pharmacist Vaccine Statewide Protocol for adults with draft amendments.

Hearing no additional items, the chairman stated that the amended agenda was accepted as presented.

APPROVAL OF PREVIOUS BOARD MEETING MINUTES:

The chairman stated that on page 1 of the 9/6/22 full board meeting minutes, Mrs. Patricia Richards-Spruill should be listed as being awarded 1-hour of CE.

MOTION:

The Board voted unanimously to adopt the minutes for the meetings held between September 6, 2022 and November 17, 2022 as presented and amended as follows:

- Page 1 of the 9/6/22 full board meeting minutes, Mrs. Patricia Richards-Spruill should be listed as being awarded 1-hour of CE;
- Page 8 of the 9/6/22 full board meeting minutes should read "motion by Ratliff, seconded by Richards-Spruill". (motion by Ratliff, seconded by Garvin)

PUBLIC COMMENT:

Becky Hobden, Lab Director, Green Analytics Virginia provided comment that propane and butane should be considered for inclusion on the proposed list of approved hydrocarbon solvents (Guidance Document 110-45). While the solvents are not listed on the AHP list, she noted that the AHP states that it is not an exhaustive list. She believes supportive documentation exists. She stated Maryland and Pennsylvania allow use of the solvents, but testing thresholds may vary among the states. She commented that toxicology information needs to be reviewed.

Christina Barrille, Executive Director, VPhA, thanked Dr. David Brown for his service as former DHP Director and welcomed Arne W. Owens and Jim Jenkins on their new roles at DHP. She stated it is difficult to obtain an appointment in a primary care setting and that VPhA will introduce a bill to expand access by authorizing pharmacists to treat certain conditions. She also expressed concern for recent interpretations of the Department of Labor and Industry restricting use of pharmacy technician trainees under the age of 18. She commented that the DOE should be authorized to produce well-trained pharmacy technician trainees and not discourage high school students from seeking a career in healthcare. She invited everyone to participate in an

upcoming CE webinar regarding statewide protocols and the upcoming annual meeting in Roanoke in February.

Natalie Nguyen, PharmD, representing the Virginia Society of Health-Systems Pharmacists provided comment in support of exempting automated dispensing devices stocked solely with emergency or stat-use medications from certain requirements of 18VAC110-20-555. The public comment period for the NOIRA closes on 11/7/2022.

DHP DIRECTOR'S REPORT:

Mr. Arne W. Owens introduced himself as the newest appointed Director of the Department of Health Professions. He provided a brief overview of his career, including time spent as the former Chief Deputy Director of DHP. He acknowledged the important role of pharmacists and expressed appreciation for their role in the administration of COVID-19 vaccines. Mr. Owens then welcomed his Chief Deputy Director, James Jenkins, Jr., RN who will also serve as a special advisor for healthcare workforce matters.

UPDATES FROM THE HEALTH PRACTITIONER MONITORING PROGRAM:

Training updates on HPMP were requested since the Board has several new members. PowerPoint slides regarding the Health Practitioner Monitoring Program were provided by Christina C. Buisset, DHP Health Practitioners' Monitoring Program Manager and Amy Ressler, VCU Health Practitioners' Monitoring Program Administrative Director. Mrs. Buisset provided foundational facts of the program such as the history, purpose, and goal of the program. The goal of the HPMP is to assist and support the recovery process for licensees impaired by substance abuse or mental health and navigate the practitioner to return to safe and productive clinical practice.

The program resulted from legislation passed in 1997. There is no participation fee. DHP has an MOU with VCU Addiction Psychiatry. There are currently 6 case managers that make collective decisions and a medical review officer. HPMP makes referrals for treatment, drug toxicology screens, requires a daily check-in line, determines approval to work, and requires work-site monitoring. The HPMP Advisory Committee reviews noncompliance, dismissals, resignations, and successful completions. medication assisted treatment, participants will be referred to a physician to determines best form of treatment, e.g., naltrexone or buprenorphine. Completion of a participation contract happens quickly, and the licensee agrees to not practice until approved to work. Completion of the recovery monitoring contract can take longer as more information is needed. Dr. Nash requested that we assess prevalence of suicide, but that information is not required to be reported to HPMP or the Board.

As of December 31, 2021, the program consists of 349 participants in which Pharmacy licensees made up 4% of the program participants (7 pharmacists and 1 pharmacy technician). The most common drug of choice currently is

OLD BUSINESS:

PHARMACY TECHNICIAN TRAINEES WHO ARE MINORS: alcohol, followed by opioids. Mrs. Buisset and Mrs. Ressler explained the intake process of a participant joining the program through various methods. Details of the contract requirements were explained such as routine check-ins and toxicology monitoring.

The chairman reminded members that during the September board meeting, the Board tabled the adoption of a draft guidance document regarding minors working as pharmacy technician trainees that would have recommended trainees under the age of 18 handle only Schedule VI drugs in the course of their training. The document referenced concerns raised by the Department of Labor and Industry (DOLI) related to the application of Virginia Code 40.1-100(A)(4) and 16VAC15-30-200(4). The Board requested that staff invite a representative of DOLI to further discuss the issue.

Jay Withrow, Director of the Division of Legal Support, ORA, OPPPI, and OWP at the Virginia Department of Labor and Industry appeared in-person. He stated certain occupations are considered hazardous as they deal with "dangerous and poisonous chemicals" which may cause the child's life to be endangered. He stated that pharmacists serve in a custodial capacity when working with minors and can be criminally charged or fined civil penalties if the child is harmed. DOLI recently initiated rulemaking and entered into a MOA with DOE and DHP. The agreement requires pharmacy technician trainees under 18 to only handle Schedule VI drugs. There was reference to whether a youth apprenticeship could be used. There was discussion regarding the use of the term "handling" when the law references "preparing". Mr. Withrow stated that it is primarily concerned with the handling of "loose" pills. He indicated DOLI has previously addressed minors working as lifeguards and in kitchens. He stated this is the first healthcare professional training program to be addressed, but that it intends to address others such as licensed practical nurses and emergency medical technicians involving the training of minors.

MOTION

LEGISLATIVE/ REGULATORY/GUIDANCE

CHART OF CURRENT REGULATORY ACTIONS

ADOPTION OF FINAL REGULATIONS – PLACEMENT OF CHEMICALS IN SCHEDULE The Board voted unanimously to not adopt the draft Guidance Document on page 40 of the agenda packet regarding minors working as Pharmacy Technician Trainees. (motion by Garvin, seconded by Nash)

Erin Barret, J.D. briefly reviewed the regulatory action chart in the agenda packet and provided updated information.

The Board considered the adoption of the final regulations regarding the placement of chemicals in Schedule I.

I

MOTION

The Board voted unanimously to adopt the exempt final changes to 18VAC110-20-322 as presented regarding the placement of the following chemicals in schedule I:

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-methyl-N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide (other name: 2-methyl butyryl fentanyl), 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-(7-methoxy-1,3-benzodioxol-5-yl)propan-2-amine (other names: 5-methoxy-3,4-methylenedioxyamphetamine, 3-methoxy MDA, MMDA), 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. 1-[1-(3-chlorophenyl)cyclohexyl]-piperidine (other names: 3-Chloro Phencyclidine, 3Cl-PCP, 3-chloro PCP), 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.

Based on its chemical structure, the following compound is expected to have depressant properties. Compounds of this type have been placed in Schedule I (§ 54.1-3446(4)) in previous legislative sessions.

4. 7-bromo-5-phenyl-1,3-dihydro-1,4-benzodiazepin-2-one (other names: Desalkylgidazepam, Bromonordiazepam), 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 cannabimimetic agent. Compounds of this type have been placed in Schedule I (§ 54.1-3446(6)) in previous legislative sessions.

5. Methyl N-[(5-bromo-1H-indazol-3-yl)carbonyl]-3-methyl-valinate

(other name: MDMB-5Br-INACA), 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. (motion by Richards-Spruill, seconded by Yuan)

ADOPTION OF GUIDANCE DOCUMENT 110-45: APPROVED CHEMICALS FOR USE AS HYDROCARBON OR OTHER FLAMMABLE SOLVENTS BY PHARMACEUTICAL PROCESSORS The Board considered the adoption of Guidance Document 110-45 as approved chemicals for use as hydrocarbon or other flammable solvents in the cultivation, extraction, production, or manufacturing of cannabis products. There was discussion regarding the public comment received to consider adding butane and propane to the approved list.

ACTION ITEM:

It was determined that staff will further research which states authorize the use of these chemicals and the established testing thresholds for safety.

MOTION:

The Board voted unanimously to adopt Guidance Document 110-45 as presented in the agenda packet. (motion by Ratliff, seconded by Garvin)

WITHDRAW CHANGES TO GUIDANCE DOCUMENT 110-33: PHARMACY INTERNS AS PHARMACY TECHNICIANS, PHARMACY TECHNICIAN RATIO, AND PHARMACY TECHNICIAN TRAINEES AND AMEND VACCINE PROTOCOL Ms. Juran reminded the Board that at the September board meeting, the Board adopted amendments to Guidance Document 110-33 that would have prohibited a pharmacy technician trainee from administering vaccines. During the public comment period following adoption, the Board received comment that the proposed amendment appeared contrary to statutory changes effective July 1, 2022. Board counsel advised that the Board should withdraw the proposed amendments but could amend the Vaccine Protocol to include additional training requirements for personnel prior to administering vaccines.

MOTION:

The Board voted unanimously to withdraw the proposed amendments to Guidance Document 110-33 and revert back to the current language. (motion by Ratliff, seconded by Lee)

MOTION:

The Board voted unanimously to amend the vaccine protocol for adults as presented and listed below:

- Under "Pharmacist Education and Training", insert "The pharmacist shall also have a current certificate in basic cardiopulmonary resuscitation." at the end of the paragraph;
- Insert new section "Pharmacy Technician and Pharmacy Intern Training" with the following verbiage "Prior to administering a vaccine, a pharmacy technician, pharmacy technician trainee, or pharmacy intern shall have completed a practical training program of at least 20 hours that is approved by the

Accreditation Council for Pharmacy Education ("ACPE"). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines. The pharmacy technician, pharmacy technician trainee, or pharmacy intern shall also have a current certificate in basic cardiopulmonary resuscitation." (motion by Ratliff, seconded by Richards-Spruill)

It was acknowledged by the chairman that pharmacy technician trainees may administer adult vaccines pursuant to this statewide protocol but may not administer vaccines to patients under the age of 18 until the emergency regulations and the vaccine statewide protocol for minors becomes effective. Counsel has previously advised that the PREP Act does not authorize pharmacy technician trainees to administer vaccines.

PERIODIC REVIEW OF GUIDANCE DOCUMENTS

ADOPT REVISIONS TO GUIDANCE DOCUMENT 110-10: MOBILE UNITS FOR DISPENSING FOR THE INDIGENT OR UNDERSERVED POPULATION: The Board considered the adoption of Guidance Document 110-10 as presented.

MOTION:

ADOPT REVISIONS TO GUIDANCE DOCUMENT 110-11: PROOF OF IDENTITY WHEN DISPENSING SCHEDULE II DRUGS

The Board voted unanimously to amend Guidance Document 110-10 as presented. (motion by Garvin, seconded by Ratliff)

The Board considered the adoption of Guidance Document 110-11 as presented.

MOTION

The Board voted unanimously to amend Guidance Document 110-11 as presented (motion by Richards-Spruill, seconded by Yuan)

ADOPT REVISIONS TO GUIDANCE DOCUMENT

The Board considered the adoption of Guidance Document 110-24.

110-24: COMPETENCY EXAMINATION REQUIRED FOR LICENSURE AS A PHARMACIST NAPLEX PASSING SCORE

MOTION

The Board voted unanimously to amend Guidance Document 110-24 as presented. (motion by Lee, seconded by Garvin)

ADOPT REVISIONS TO GUIDANCE DOCUMENT 110-28: GUIDANCE FOR FREE CLINIC PHARMACY APPLICANTS The Board considered the adoption of Guidance Document 110-28.

MOTION

The Board voted unanimously to amend Guidance Document 110-28 as presented. (motion by Ratliff, seconded by Garvin)

REPEAL GUIDANCE DOCUMENT 110-37: CONDUCT OF AN INFORMAL CONFERENCE BY AN AGENCY SUBORDINATE The Board considered the repeal of Guidance Document 110-37, because the agency now has Guidance Document 76-10.01 that applies to all health regulatory boards and is consistent with current legal advice to the agency.

MOTION

The Board voted unanimously to repeal Guidance Document 110-37 as presented (motion by Yuan, seconded by Garvin)

ADOPT REVISIONS TO GUIDANCE DOCUMENT 110-43: DISPENSING WITH AN AUTHORIZED GENERIC The Board considered the adoption of Guidance Document 110-43 as presented.

MOTION

The Board voted unanimously to amend Guidance Document 110-43 as presented. (motion by Ratliff, seconded by Kocot)

ADOPT REVISIONS TO GUIDANCE DOCUMENT 110-47: GUIDELINES FOR PROVISION COUNSELING AND INFORMATION BY PHARMACISTS REGARDING PROPER DISPOSAL OF UNUSED DISPENSED DRUGS **MOTION:**

The Board voted unanimously to amend Guidance Document 110-47 as presented. (motion by Lee, seconded by Garvin)

REPORTS:

CHAIRMAN'S REPORT

Dr. St. Clair acknowledged former board members that recently left the board due to the end of their appointments: Jim Jenkins, Glenn Bolyard, Bernie Henderson, and Cheryl Nelson. Dr. St. Clair also congratulated James Jenkins, Jr., RN on his new appointment as the Chief Deputy Director of the Department of Health Professions.

BOARD OF HEALTH PROFESSIONS

Dr. St. Clair provided the Board of Health Professions report on behalf of Dr. Sarah Melton in her absence. The Board of Health Professions did not have any updates to provide as the Board has not met since the most recent full board meeting.

LICENSURE OF INDIVIDUALS AND IN-STATE FACILITIES Ryan Logan provided a verbal summary of the Licensure of Individuals and In-State Facilities report included in the agenda packet. As of November 17, 2022, the Virginia Board of Pharmacy has a total of 44,775 individual and instate facilities licensed.

LICENSURE OF NON-RESIDENT FACILITIES Beth O'Halloran provided a verbal summary of the Licensure of Non-Resident Facilities report included in the agenda packet. As of November 15, 2022, the Virginia Board of Pharmacy has a total of 2,484 non-resident facilities licensed.

INSPECTION PROGRAM

Melody Morton, Inspections Manager with the Enforcement Division presented the Inspections Report including data from July 1, 2022 through September 30, 2022. The report detailed the various types of inspections conducted as well as the deficiencies noted.

PHARMACEUTICAL PROCESSORS

Annette Kelley presented a handout containing the Pharmaceutical Processors Report. Three additional cannabis dispensing facilities have been permitted during the last quarter totaling 10 cannabis dispensing facilities. Due to the change in the requirements for patients/parents/legal guardians to register with the Board, the amount of applications received has decreased significantly. The Department of Health Professions and the Virginia Board of Pharmacy has completed contract negotiations for a new patient portal with BioTrack. The portal is anticipated to be operational in the first quarter of 2023.

DISCIPLINARY PROGRAM

Ellen B. Shinaberry presented a handout of the Disciplinary Program Report. The Virginia Board of Pharmacy currently has 414 disciplinary cases consisting of 186 patient care cases and 228 non-patient care cases.

EXECUTIVE DIRECTOR'S REPORT

Ms. Juran provided a verbal summary of the Executive Director's Report included in the agenda packet. The agency has implemented various IT upgrades such as the migration to Microsoft 365, Cardinal payroll system, Windows 11, and transitioned to digital case files via Box. Various meetings recently attended by Ms. Juran were mentioned. Ms. Garvin provided additional comments on the Tri-Regulator Symposium that she and Ms. Juran recently attended.

CONSIDERATION OF CONSENT ORDERS, SUMARY SUSPENSIONS, OR SUMMARY RESTRICTIONS

COAST QUALITY PHARMACY LLC PERMIT #0214000324

Sean Murphy, AAG presented a consent order for Board consideration regarding Coast Quality Pharmacy LLC (Permit #0214000324/ Case #194504).

DECISION:

Upon a motion by Ratliff and duly seconded by Yuan, the Board unanimously voted to accept the consent order for Coast Quality Pharmacy LLC as presented (Permit #0214000324/ Case #194504).

WARREN PAGE MCCANN LICENSE #0202204817

Ann Joseph, APD Specialist, presented a consent order for Board consideration regarding Warren Page McCann (License #0202204817/Case #218439).

DECISION:

Upon a motion by Garvin, and duly seconded Richards-Spruill, the Board unanimously voted to accept the consent order for Warren Page McCann as presented (License #0202204817/Case #218439).

Caroline D. Juran
Executive Director

DATE:



VIRGINIA BOARD OF PHARMACY MINUTES OF PUBLIC HEARINGS TO PLACE CERTAIN CHEMICALS INTO SCHEDULE I AND THE IMPLEMENTATION OF 2021 LEGISLATION FOR PHARMACISTS INITIATING TREATMENT

Tuesday, December 6, 2022 Department of Health Professions

Perimeter Center 9960 Mayland Drive Henrico, Virginia 23233

CALL TO ORDER: Public hearings were called to order at 9:08AM

PRESIDING: Dale St. Clair, PharmD, Chairman

MEMBERS PRESENT: Ling Yuan, PharmD

Wendy C. Nash, PharmD

Larry Kocot, J.D. Cheryl Garvin, RPh Kristopher Ratliff, DPh

Patricia Richards-Spruill, RPh

William Lee, DPh

MEMBER ABSENT: Sarah Melton, PharmD

STAFF PRESENT: Caroline Juran, RPh, Executive Director

James Rutkowski, J.D., Assistant Attorney General

Arne W. Owens, Director, DHP

James Jenkins, Jr., RN, Chief Deputy Director, DHP Erin Barrett, J.D., Senior Policy Analyst, DHP

Ellen B. Shinaberry, PharmD, Deputy Executive Director

Beth O'Halloran, RPh, Deputy Executive Director Annette Kelley, MS, CSAC, Deputy Executive Director

Ryan Logan, RPh, Deputy Executive Director

Sorayah Haden, Executive Assistant

Patricia Mason, Individual Licensing Supervisor

QUORUM: With 8 members present, a quorum was established.

PLACING CHEMICALS INTO

SCHEDULE I:

Pursuant to article § 54.1-3443(D), the Virginia Department of Forensic Science (DFS) identified the following five compounds for recommended

inclusion into Schedule I of the Drug Control Act. A public hearing was convened to receive public comment on the subject.

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-methyl-N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide (other name: 2-methyl butyryl fentanyl), 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-(7-methoxy-1,3-benzodioxol-5-yl)propan-2-amine (other names: 5-methoxy-3,4-methylenedioxyamphetamine, 3-methoxy MDA, MMDA), 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. 1-[1-(3-chlorophenyl)cyclohexyl]-piperidine (other names: 3-Chloro Phencyclidine, 3Cl-PCP, 3-chloro PCP), 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.

Based on its chemical structure, the following compound is expected to have depressant properties. Compounds of this type have been placed in Schedule I (§ 54.1-3446(4)) in previous legislative sessions.

4. 7-bromo-5-phenyl-1,3-dihydro-1,4-benzodiazepin-2-one (other names: Desalkylgidazepam, Bromonordiazepam), 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 cannabimimetic agent. Compounds of this type have been placed in Schedule I (§ 54.1-3446(6)) in previous legislative sessions.

5. Methyl N-[(5-bromo-1H-indazol-3-yl)carbonyl]-3-methyl-valinate (other name: MDMB-5Br-INACA), 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.

DATE:

December 6, 2022	ng Minutes
PHARMACISTS INITIATING TREATMENT:	A public hearing was convened to also receive public comment on proposed amendments to Chapters 20 and 21 of the Board's regulations regarding implementation of 2021 legislation for pharmacists initiating treatment. The proposed regulations will replace the emergency regulations which became effective on December 21, 2021 and expire June 21, 2023.
PUBLIC COMMENT:	Robyn Weimer, Chemistry Program Manager, DFS offered public comment addressing the five compounds. No other public comment was offered on this subject. Christina Barrille, Executive Director, Virginia Pharmacists Association offered public comment urging the passing of the proposed regulations for pharmacists initiating treatment. She thanked the Virginia Boards of Pharmacy and Medicine and stakeholder partners such as the Medical Society of Virginia. No other public comment was offered on this subject.
MEETING ADJOURNED:	9:16am
Caroline D. Juran, Executive Director	

VIRGINIA BOARD OF PHARMACY SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, December 7, 2022 Department of Health Professions Commonwealth Conference Center Perimeter Center Second Floor 9960 Mayland Drive, Suite 300 Board Room 1 Henrico, Virginia 23233-1463

CALL TO ORDER: A meeting of a Special Conference Committee of the

Board of Pharmacy was called to order at 9:12 am.

PRESIDING: Patricia Richards-Spruill, Committee Chair

MEMBERS PRESENT: Ling Yuan, Committee Member

STAFF PRESENT: Mykl Egan, Discipline Case Manager

> Ileita Redd, Discipline Case Specialist Jess Weber, DHP Adjudication Specialist

Christine Andreoli, DHP Adjudication Specialist

Health Star Pharmacy Garrett Yates, Pharmacy Operations Manager, Permit No. 0201-004932

appeared as a representative of Health Star Pharmacy to discuss allegations that the pharmacy may have violated certain laws and regulations governing the conduct of a pharmacy as stated in the September 23, 2022 Notice. The pharmacy was

represented by Jonathan Swichar, Esq. and Drew

Dorner, Esq.

Closed Meeting:

Upon a motion by Dr. Yuan, and duly seconded by Mrs. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Health Star Pharmacy. Additionally, she 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:

Decision:

GREEN LEAF MEDICAL OF VIRGINIA, LLC Permit No. 0240-000003

Closed Meeting:

Reconvene:

Decision:

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.

Upon a motion by Dr. Yuan and duly seconded by Mrs. Richards-Spruill, the Committee unanimously voted to assess a monetary penalty against Health Star Pharmacy and order additional terms and conditions placed on the Pharmacy.

Donald Moore, Compliance Case Manager and Jacob Crisco, General Manager and Responsible Party, appeared as representatives of Green Leaf Medical of Virginia, LLC ("Green Leaf Processing") to discuss allegations that it may have violated certain laws and regulations governing its conduct as a pharmaceutical processor as stated in the September 30, 2022, Notice. They were represented by Lindsay Sessa, Esquire.

Upon a motion by Dr. Yuan, and duly seconded by Mrs. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Green Leaf Processing. Additionally, she 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.

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.

Upon a motion by Dr. Yuan and duly seconded by Mrs. Richards-Spruill, the Committee voted unanimously to place Green Leaf Processing under terms and conditions.

Phoebe L. Roberts,

Phoebe Roberts appeared to discuss allegations that

Pharmacy Technician Trainee she may have violated certain laws and regulations Registration No. 0245-004634 governing her practice as a pharmacy technician trainee as stated in the September 16, 2022, Notice. Ms. Roberts was not represented by Counsel. Closed Meeting: Upon a motion by Dr. Yuan, and duly seconded by Mrs. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Phoebe Roberts. Additionally, she 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 Dr. Yuan and duly seconded by Richards-Spruill, the Committee voted unanimously to Committee unanimously voted to order that Ms. Roberts complete additional hours in continuing education. ADJOURNED: 2:35 p.m. Patricia Richards-Spruill, Chair Mykl D. Egan Discipline Case Manager Date Date

VIRGINIA BOARD OF PHARMACY SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, January 3, 2023 Department of Health Professions Commonwealth Conference Center Perimeter Center Second Floor 9960 Mayland Drive, Suite 300 Board Room 4 Henrico, Virginia 23233-1463

CALL TO ORDER: A meeting of a Special Conference Committee of the

Board of Pharmacy was called to order at 9:05 am.

PRESIDING: William Lee, Committee Chair

MEMBERS PRESENT: Wendy Nash, Committee Member

STAFF PRESENT: Mykl Egan, Discipline Case Manager

> Ileita Redd, Discipline Case Specialist Jess Weber, DHP Adjudication Specialist

David Robinson, DHP Adjudication Specialist

Anu George, appeared to discuss allegations that ANU R. GEORGE, M.D. License No. 0213-001011 she may have violated certain laws and regulations

governing her practice as a physician selling controlled substances as stated in the October 14,

2022, Notice. She was not represented by counsel.

Closed Meeting: Upon a motion by Dr. Nash, and duly seconded by

> Dr. Lee, 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 Dr. George. Additionally, she 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 Code 2.2-3712, the Committee § reconvened in open meeting and announced the

decision.

Decision:

Upon a motion by Dr. Nash, and duly seconded by Dr. Lee, the Committee unanimously voted to order that Dr. George be assessed a monetary penalty and order that additional terms and conditions be placed against the facility.

MEDICAP PHARMACY Permit No. 0201-004165 No one appeared as a representative of Medicap Pharmacy to discuss allegations that it may have violated certain laws and regulations governing the conduct of a pharmacy as stated in the November 18, 2022, Notice. The pharmacy was not represented by counsel.

Closed Meeting:

Upon a motion by Dr. Nash, and duly seconded by Dr. Lee, 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 Medicap Pharmacy Additionally, she 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 Dr. Nash and duly seconded by Dr. Lee, the Committee unanimously voted to assess a monetary penalty against Medicap Pharmacy and order additional terms and conditions placed on the pharmacy.

TAILAR HUDSON, Pharmacy Technician Trainee Applicant Registration No. Tailar Hudson did not appear to discuss her application for registration as a pharmacy technician trainee and to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy that could lead to the denial of her application as stated in the November 18, 2022 Notice. Ms. Hudson was not represented by counsel.

Closed Meeting:	Upon a motion by Dr. Nash, and duly seconded by Dr. Lee, 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 Tailar Hudson. Additionally, she 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 Dr. Nash, and duly seconded by Dr. Lee, the Committee unanimously voted to deny Ms. Hudson's application.
ADJOURNED:	10:52 a.m.
William Lee, Chair	Mykl D. Egan Discipline Case Manager
Date	Date

VIRGINIA BOARD OF PHARMACY SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, January 11, 2023

Commonwealth Conference Center

Second Floor

Board Room 4

Department of Health Professions

Perimeter Center

9960 Mayland Drive, Suite 300

Henrico, Virginia 23233-1463

CALL TO ORDER: A meeting of a Special Conference Committee of the

Board of Pharmacy was called to order at 9:11 am.

PRESIDING: Cheryl Garvin, Committee Chair

MEMBERS PRESENT: Wendy Nash, Committee Member

STAFF PRESENT: Mykl Egan, Discipline Case Manager

Ileita Redd, Discipline Case Specialist Jess Weber, DHP Adjudication Specialist

David Robinson, DHP Adjudication Specialist

MIKDAD MAROUF, Pharmacist

License No. 0202-210485

Mikdad Marouf, pharmacist, appeared to discuss allegations that he may have violated certain laws and regulations governing his practice as a pharmacist as stated in the December 12, 2022, Notice. He was not represented by counsel.

Closed Meeting:

Upon a motion by Dr. Nash, and duly seconded by Ms. Garvin, 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 Mikdad Marouf. Additionally, she 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 Dr. Nash, and duly seconded by Ms. Garvin, the Committee voted unanimously to refer the matter to a formal administrative hearing.
FRANK LUCAS, Pharmacist License No. 0202-004585	Frank Lucas did not appear to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the December 2, 2022, Notice. Mr. Lucas was not represented by counsel.
Closed Meeting:	Upon a motion by Dr. Nash, and duly seconded by Ms. Garvin, 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 Frank Lucas. Additionally, she moved that Myk 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 Dr. Nash and duly seconded by Ms. Garvin, the Committee voted unanimously to refer the matter to a formal administrative hearing.
ADJOURNED:	11:44 a.m.
Cheryl Garvin, Chair	Mykl D. Egan Discipline Case Manager
Date	 Date

VIRGINIA BOARD OF PHARMACY MINUTES OF SPECIAL CONFERENCE COMMITTEE

Wednesday, February 8, 2023

Commonwealth Conference Center

Second Floor

Board Room 1

Department of Health Professions

Perimeter Center

9960 Mayland Drive, Suite 300

Henrico, Virginia 23233

CALL TO ORDER: A meeting of a Special Conference Committee

(Innovative Pilot) of the Board of Pharmacy was

called to order at 9:08 AM.

PRESIDING: Dale St.Clair, Committee Chairman

MEMBER PRESENT: Cheri Garvin, Committee Member

STAFF PRESENT: Caroline D. Juran, Executive Director

Ellen Shinaberry, Deputy Executive Director Mykl Egan, Discipline Case Manager

Jess Weber, DHP Adjudication Specialist

WALGREENS CENTRAL FILL Derek Parvizi, Pharmacist in Charge,

#21420

Shawna Peterson, Senior Director of Operations, Jeenu Phillip, Director or Pharmacy Affairs, and Tolu Akinwale, Director of Patient Safety and Compliance, appeared in person to discuss the proposed innovative pilot program "Walgreens Central Fill #21420" as stated in the January 24, 2023

Notice.

DISCUSSION: Representatives of Walgreens presented information

about related to their application for a central fill pharmacy to be located in Mechanicsville, VA.

DECISION: Upon a motion by Dr. St. Clair, and duly seconded by

Ms. Garvin, 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

1:16PM.

Dale St. Clair Committee Chairman	Caroline D. Juran Executive Director	
Date	Date	

VIRGINIA BOARD OF PHARMACY

POSSIBLE SUMMARY SUSPENSION PRESENTATION & MINUTES OF A PANEL OF THE BOARD

Wednesday, February 15, 2023 Commonwealth Conference Center Second Floor Board Room 2

CASE NO. 221671

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 quorum of the Board of Pharmacy

("Board") was called to order at 9:02am for the purpose of two possible summary suspension

presentations.

PRESIDING: William Lee, Chair

MEMBERS PRESENT: Dr. Krisopher Ratliff

Mrs. Patricia Richards-Spruill

Ms. Cheri Garvin Dr. Ling Yuan Mr. Larry Kocot Dr. Sarah Melton

STAFF PRESENT: Caroline D. Juran, Executive Director

Ellen B. Shinaberry, Deputy Executive Director James Rutkowski, Assistant Attorney General Laura Booberg, Assistant Attorney General

Sorayah Haden, Executive Assistant

QUORUM: With seven (7) members of the Board present, a

quorum of the board was established.

PURPOSE: Wayne Halbleib, Assistant Attorney General, Division

Chief, presented a summary of the evidence in this case. Mr. Halbleib was assisted by Jess Weber,

Adjudication Specialist.

DECISION: Upon a motion by Dr. Melton and duly seconded by

Ms. Garvin, the Board unanimously voted (7-0) that with the evidence presented, Jennifer L. Nollie poses a substantial danger to the public; and therefore, the Board voted to summarily suspended Ms. Nollie's pharmacy technician trainee registration, to notice her for a formal hearing, and offer a consent order in lieu

of the formal hearing.

PURPOSE: Sean J. Murphy, Assistant Attorney General

Murphy was assisted by Jess Weber, Adjudication Specialist.

Upon a motion by Dr. Melton and duly seconded by Ms. Richards-Spruill, the Board unanimously voted (7-0) that with the evidence presented, Cheryl W. Kegley poses a substantial danger to the public; and therefore,

DECISION:

the Board voted to summarily suspended Ms.

Kegley's pharmacist license, to notice her for a formal hearing, and offer a consent order in lieu of the formal hearing.

JAMES V. ETTARE License No. 0202-206317 A formal hearing was held in the matter of James V. Ettare to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia as provided in the notice dated September 27, 2022.

With seven (7) members of the Board present, a quorum of the board was established.

Christine Andreoli, Adjudication Specialist, presented the case.

James V. Ettare was represented by Edward Dawson, Esq.

Jessica Ackers, Lead Pharmacy Technician at Timberlake Health and Wellness, and Jennifer Walker, General Manager Peaks View Brew and Games, and Manager Timberlake Health and Wellness, testified in person on behalf of the Commonwealth.

Amy Ressler, Program Administrative Director for the Health Practitioners Monitoring Program, and Jodi Ettare, Pharmacist in Charge at Timberlake Health and Wellness, testified on behalf of the respondent. James V. Ettare testified on his own behalf.

CLOSED MEETING:

RECONVENE:

DECISION:

FEDAH S. ABOABDO License No. 0202-217102 Upon a motion by Ms. Richards-Spruill, and duly seconded by Dr. Yuan, 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 to reach a decision regarding the matter of James V. Ettare. Additionally, she moved that Ellen Shinaberry, Caroline Juran, Jim Rutkowski, Laura Booberg, and Sorayah Hayden attend the closed meeting.

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision. (Richards-Spruill/Garvin)

Upon a motion by Ms. Garvin, and duly seconded by Dr. Yuan, the Board voted 7-0 to accept the Findings of Fact and Conclusions of law as presented by the Commonwealth and amended by the Board.

Upon a motion by Dr. Ratliff, and duly seconded by Ms. Garvin, the board voted 7-0 to continue Mr. Ettare's pharmacist license on indefinite suspension of his right to renew, and stay the indefinite suspension of the right to renew, contingent upon certain terms and conditions.

Board member Richards-Spruill departed at the conclusion of this hearing.

A formal hearing was held in the matter of Fedah S. Aboabdo to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy in Virginia as provided in the notice dated September 2, 2022, David Robinson, Assistant Attorney General, represented the Commonwealth along with Jess Weber, Adjudication Specialist,

With six (6) members of the Board present, a quorum of the board was established.

Ms. Aboabdo was present and was represented by Karen Doner, Esq.

As a preliminary matter, Mr. Robinson presented a consent order in lieu of the formal hearing agreed upon by both the respondent and the Commonwealth for the Board's consideration to resolve the matter.

CLOSED MEETING:

Upon a motion by Ms. Garvin, and duly seconded by Dr. Ratliff, the Board 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 Fedah S. Aboabdo. Additionally, she moved that Ellen Shinaberry, Caroline Juran, Jim Rutkowski, Laura Booberg, and Sorayah Hayden 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 reconvened an open meeting and announced the decision. (Garvin/Ling)

DECISION:

Upon a motion by Mr. Kocot, and duly seconded by Dr. Melton, the Board voted 6-0 to accept the Consent Order in lieu of the formal hearing as presented by the Commonwealth and the respondent.

Board member Cheri Garvin departed at the conclusion of this proceeding.

DARRELLE MOSES Registration No. 0245-000331 A formal hearing was held in the matter of Darrelle Moses to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technician trainees in Virginia as provided in the notice dated December 6, 2022.

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

David Robinson, Assistant Attorney General, presented the case. He was assisted by Jess Weber, Adjudication Specialist.

Ms. Moses was not present for the hearing and was not represented by counsel.

Steven Keene, DHP Sr. Investigator, testified in person for the Commonwealth. **CLOSED MEETING:** Upon a motion by Dr. Melton, and duly seconded by Dr. Ratliff, the Board 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 Darrelle she moved Moses. Additionally, that Shinaberry, Caroline Juran, Jim Rutkowski, Laura Booberg, and Sorayah Hayden 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 reconvened an open meeting and announced the decision. (Melton/Kocot) **DECISION:** Upon a motion by Dr. Melton, and duly seconded by Mr. Kocot, the Board voted 5-0 to accept the Findings of Fact and Conclusions of law as presented by the Commonwealth and amended by the Board. Upon a motion by Dr. Yuan, and duly seconded by Dr. Ratliff, the board voted 5-0 to indefinitely suspend the technician trainee registration of Darrelle Moses for not less than 2 years. 3:28 PM ADJOURNED: Bill Lee, Chair Caroline D. Juran, Executive Director Date

VIRGINIA BOARD OF PHARMACY SPECIAL CONFERENCE COMMITTEE MINUTES

Thursday, February 16, 2023

Commonwealth Conference Center
Second Floor
Board Room 4

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

CALL TO ORDER:

A meeting of a Special Conference Committee of the

PRESIDING: Patricia Richards-Spruill, Committee Chair

MEMBERS PRESENT: Ling Yuan, Committee Member

STAFF PRESENT: Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Case Specialist

Jess Weber, DHP Adjudication Specialist

KENNEDY O. DONKOR, Pharmacist Kennedy Donkor, pharmacist, appeared to discuss allegations that he may have violated certain laws

icense No. 0202-214307 allegations that he may have violated certain laws and regulations governing his practice as a

pharmacist as stated in the January 13, 2023, Notice.

Board of Pharmacy was called to order at 9:11 am.

He was not represented by counsel.

Closed Meeting: Upon a motion by Dr. Yuan, and duly seconded by Mrs. Richards-Spruill, the Committee unanimously

voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Kennedy Donkor. Additionally, she 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 Dr. Yuan, and duly seconded by

Mrs. Richards-Spruill, the Committee unanimously

voted to order Mr. Donkor to comply with one term and condition.

SENTARA NORFOLK GENERAL HOSPITAL

Permit No. 0201-001014

Catherine Floroff, Pharmacist-in-Charge, Jon Horton, Pharmacy Operations Director, and Tim Jennings, Chief Pharmacy Officer, appeared as representatives of Sentara Norfolk General Hospital ("Sentara") to discuss it's request to be released form the terms of its probation placed on it by Order of the Board of Pharmacy entered May 18, 2021 ("Board's Order") as stated in the November 18, 2022 Notice. Sentara was represented by Jason Davis, Esq.

Closed Meeting:

Upon a motion by Dr. Yuan, and duly seconded by Mrs. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Sentara Norfolk General Hospital. Additionally, she 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 Dr. Yuan and duly seconded by Mrs. Richards-Spruill, the Committee voted unanimously to Grant Sentara Norfolk General Hospital's request to be released from its probation and all terms and conditions it was under pursuant to the Board's Order.

ADJOURNED:

12:30 p.m.

Patricia Richards-Spruill, Chair

Mykl D. Egan

Virginia Board of Pharmacy Minutes Special Conference Committee February 16, 2023		Page
	Discipline Case Manager	
Date	Date	

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Legislative Report Board of Pharmacy March 30, 2023

Agency Bills:

HB 1622 Health regulatory boards; delegation of authority to conduct informal fact-finding proceedings.

AGENCY BILL

Chief patron: Wright

Health regulatory boards; delegation of authority to conduct informal fact-finding proceedings. Removes the requirement that a health regulatory board receive information that a practitioner may be subject to a disciplinary action in order for the board to delegate to an appropriately qualified agency subordinate the authority to conduct informal fact-finding proceedings.

02/23/23 House: Signed by Speaker 02/25/23 Senate: Signed by President

HB 1638 DPOR, et al.; disclosure of certain information.

AGENCY BILL

Chief patron: Walker

Department of Professional and Occupational Regulation, Department of Health Professions, and related regulatory boards; disclosure of information regarding examinations, licensure, certification, registration, or permitting. Allows the Department of Professional and Occupational Regulation, the Department of Health Professions, and professional, occupational, and health regulatory boards to mail or email upon request records regarding applications for admission to examinations or for licensure, certification, registration, or permitting and the related scoring records to the individual to whom such records pertain. Under current law, such records may be made available for copying by the subject individual at the office of the Department or board that possesses the material during normal working hours. This bill is identical to SB 1060.

02/16/23 House: Signed by Speaker 02/16/23 Senate: Signed by President

SB 1054 Interjurisdictional compacts; criminal history record checks.

AGENCY BILL

Chief patron: Peake

Interjurisdictional compacts; criminal history record checks. Provides that when an interjurisdictional compact requires criminal history record checks as a condition of participation, the applicable health regulatory board shall require each applicant to submit to fingerprinting and provide personal descriptive information to be forwarded along with his fingerprints through the Central Criminal Records Exchange to the Federal Bureau of Investigation for the purpose of obtaining criminal history record information. This bill is identical to HB 2157.

02/22/23 House: Signed by Speaker

02/23/23 Senate: Signed by President

General Bills:

HB 1573 Mental health conditions & impairment; health regulatory board w/in DHP to amend its applications.

Chief patron: Walker

Department of Health Professions; applications for licensure, certification, and registration; mental health conditions and impairment; emergency. Directs each health regulatory board within the Department of Health Professions to amend its licensure, certification, and registration applications to remove any existing questions pertaining to mental health conditions and impairment and to include the following questions: (i) Do you have any reason to believe that you would pose a risk to the safety or well-being of your patients or clients? and (ii) Are you able to perform the essential functions of a practitioner in your area of practice with or without reasonable accommodation? The bill contains an emergency clause. This bill is identical to SB 970.

EMERGENCY

02/16/23 House: Signed by Speaker

02/16/23 Senate: Signed by President

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HB 1409 Drug Control act; distribution of hypodermic needles.

Chief patron: Brewer

Distribution of hypodermic needles, syringes, and insulin pens. Provides that the restrictions on the distribution of hypodermic needles and syringes do not prohibit the dispensing or distribution of hypodermic needles for the administration of insulin.

03/02/23 House: Enrolled Bill communicated to Governor on March 2, 2023

03/02/23 Governor: Governor's Action Deadline 11:59 p.m., March 27, 2023

HB 1447 Controlled substances; administration by emergency medical providers.

Chief patron: Orrock

Administration of controlled substances; emergency medical services providers. Allows persons who are employed or engaged at a medical care facility who have a valid emergency medical services provider certification issued by the Board of Health as a requirement of being employed or engaged at the medical care facility to administer drugs and devices at the medical care facility pursuant to an oral or written order or standing protocol. This bill is identical to SB1426.

03/02/23 House: Enrolled Bill communicated to Governor on March 2, 2023

03/02/23 Governor: Governor's Action Deadline 11:59 p.m., March 27, 2023

HB 1449 Emergency medical services providers; administration of prescription medication.

Chief patron: Orrock

Secretary of Health and Human Resources; administration of prescription medication by emergency medical services providers. Directs the Secretary of Health and Human Resources to consider adopting a process to allow emergency medical services providers to administer prescription medication to persons under certain circumstances.

02/27/23 House: Enrolled Bill communicated to Governor on February 27, 2023

02/27/23 Governor: Governor's Action Deadline 11:59 p.m., March 27, 2023

HB 1511 Midwifery; administration of medication.

Chief patron: Adams, D.M.

Midwifery; administration of medication. Allows licensed midwives to obtain, possess, and administer drugs and devices within the scope of their practice. The bill requires the Board of Medicine to develop and publish best practice and standards of care guidance for all such drugs. The bill limits the liability of entities that provide or dispense drugs or devices to a licensed midwife and that rely in good faith upon the license information provided by the licensed midwife. Under the bill, completing all Alliance for Innovation on Maternal Health patient safety bundles advanced by the Virginia Neonatal Perinatal Collaborative is required of any licensed midwife who obtains, possesses, and administers drugs and devices within the scope of his practice. This bill is identical to SB 1275.

03/02/23 House: Enrolled Bill communicated to Governor on March 2, 2023 03/02/23 Governor: Governor's Action Deadline 11:59 p.m., March 27, 2023

HB 1513 Psilocybin; possession or distribution for certain medical purposes permitted, penalty.

Chief patron: Adams, D.M.

** **DEAD BILL** **

Possession or distribution of psilocybin for certain medical purposes permitted; penalty. Allows possession of psilocybin pursuant to a valid prescription or order issued by a health care practitioner in the course of his professional practice for treatment of refractory depression or post-traumatic stress disorder or to ameliorate end-of-life anxiety. The bill prohibits prosecution of health care practitioners or pharmacists for dispensing or distributing psilocybin for such purposes. The bill makes possession of psilocybin without a valid prescription a Class 2 misdemeanor punishable by no longer than 30 days in jail and no more than a \$500 fine, either or both. The bill makes a second or subsequent offense a Class 1 misdemeanor.

01/18/23 House: Subcommittee recommends laying on the table (5-Y 3-N)

02/07/23 House: Left in Courts of Justice

HB 1521 Kratom products; prohibited acts, civil penalty.

Chief patron: Fowler

** DEAD BILL **

Kratom; prohibited acts; civil penalty. Provides that no person that sells, prepares, manufactures, distributes, or maintains kratom products, as defined in the bill, or advertises, represents, or holds itself out as selling, preparing, manufacturing, distributing, or maintaining kratom products shall prepare, distribute, sell, or expose for sale (i) any kratom product that includes or is packed with a substance that is not kratom and that affects the quality or strength of the kratom product or that contains any poisonous or otherwise deleterious ingredient; (ii) any kratom product that contains a level, as described in the bill, that is greater than two percent of the overall alkaloid composition of the product or any synthetic alkaloids or other synthetically derived compounds of the kratom plant; (iii) any kratom extract that contains levels of residual solvents that are higher than is allowed in Chapter 467 of current edition of the United States Pharmacopeia; or (iv) any kratom product that does not provide labeling directions necessary for safe and effective use by consumers, including a recommended serving size. The bill provides that any person that violates the provisions of the bill shall be subject to a civil penalty of \$100 for a first violation, \$200 for a second violation, and \$500 for a third or subsequent violation.

02/02/23 House: Subcommittee recommends reporting with substitute (5-Y 1-N)

02/02/23 House: Failed to report (defeated) in General Laws (7-Y 14-N)

HB 1787 Schedule VI controlled substance; practitioner-patient relationship.

Chief patron: Robinson

** **DEAD BILL** **

Prescription for controlled substance; practitioner-patient relationship. Allows a practitioner to establish a bona fide practitioner-patient relationship for the purpose of prescribing a Schedule VI controlled substance if the patient chooses not to seek reimbursement by a health plan or carrier for the prescribing and if such prescribing complies with federal requirements for the practice of telemedicine.

01/26/23 House: Subcommittee recommends striking from docket (10-Y 0-N)

02/07/23 House: Left in Health, Welfare and Institutions

HB 1814 Prescription Monitoring Program; exemptions, licensed narcotic maintenance treatment programs.

Chief patron: Wachsmann

** DEAD BILL **

Prescription Monitoring Program; exemptions; licensed narcotic maintenance treatment programs. Removes dispensing of covered substances within a licensed narcotic maintenance treatment program from the list of circumstances exempt from reporting requirements of the Prescription Monitoring Program. The bill has a delayed effective date of July 1, 2024.

02/06/23 House: VOTE: Block Vote Passage (100-Y 0-N)

02/16/23 Senate: Stricken at request of patron in Education and Health (14-Y 0-N)

HB 2139 Prescription refills; authority of pharmacists to refill prescriptions for insulin.

Chief patron: Delaney

Prescription refills; insulin; authority of pharmacists to refill prescriptions. Allows pharmacists to refill prescriptions for insulin without authorization from the prescriber in emergencies.

03/02/23 House: Enrolled Bill communicated to Governor on March 2, 2023

03/02/23 Governor: Governor's Action Deadline 11:59 p.m., March 27, 2023

HB 2147 Prescriptions; Bd. of Pharmacy to evaluate translated directions for use.

Chief patron: Guzman

Board of Pharmacy; translated directions for use of prescriptions; report. Directs the Board of Pharmacy to convene a work group to study the provision of translated directions for the use of prescriptions. The bill directs the work group to report its findings and recommendations to the Governor and the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by December 1, 2023.

02/21/23 Senate: Passed Senate (40-Y 0-N)

02/24/23 House: Enrolled

HB 2248 Substance use disorder; providers of treatment, use of methadone or opioid replacements.

Chief patron: Cordoza

** **DEAD BILL** **

Providers of treatment for substance use disorder; use of methadone or opioid replacements; biometric certification. Requires providers of treatment for substance use disorder who administer methadone or opioid replacements as treatments to utilize biometric certification to verify the identity of the clinician and patient. Biometric certification includes iris scans of patients and either iris scans or two-finger fingerprint scans of clinicians. The bill requires the Board of Pharmacy to establish a statewide data repository for the storage of records of every transaction involving the administration of methadone or opioid replacements to a patient, with such records being held for no fewer than 10 years.

01/26/23 House: Subcommittee recommends laying on the table (4-Y 0-N)

02/07/23 House: Left in Health, Welfare and Institutions

HB 2274 Pharmacist scope of practice; initiation of treatment for various diseases and conditions.

Chief patron: Kilgore

Pharmacist scope of practice; initiation of treatment for certain diseases and conditions. Allows pharmacists to initiate treatment with, dispense, or administer controlled substances or devices for the initiation of treatment of group A streptococcus bacteria infection, influenza virus infection, COVID-19 virus infection, and urinary tract infection to persons 18 years of age or older with whom the pharmacist has a bona fide pharmacist-patient relationship in accordance with regulations set forth by the Board of Pharmacy. The bill directs the Board of Pharmacy to adopt a statewide protocol for the initiation of treatment with and dispensing and administering of drugs and devices by pharmacists in accordance with the provisions of the bill by November 1, 2023. The bill provides that such protocol shall be developed by a work group consisting of representatives from the Board of Pharmacy, the Board of Medicine, and the Department of Health and directs the Board of Pharmacy to adopt emergency regulations to implement the provisions of the bill. This bill is identical to SB 948.

03/02/23 House: Enrolled Bill communicated to Governor on March 2, 2023 03/02/23 Governor: Governor's Action Deadline 11:59 p.m., March 27, 2023

HB 2364 Drug Control Act; adds certain chemicals to Schedule I of Act.

Chief patron: Wachsmann

Drug Control Act; Schedule I. Adds certain chemicals to Schedule I of the Drug Control Act. The Board of Pharmacy has added these substances in an expedited regulatory process. A substance added via this process is removed from the schedule after 18 months unless a general law is enacted adding the substance to the schedule. This bill is identical to SB 894.

03/02/23 House: Enrolled Bill communicated to Governor on March 2, 2023 03/02/23 Governor: Governor's Action Deadline 11:59 p.m., March 27, 2023

HB 2374 Pharmacies; prohibits refusal to fill prescription from telemedicine provider.

Chief patron: Davis

Prescriptions; telemedicine; refusal to fill prescription from telemedicine provider; prohibition. Prohibits pharmacists from refusing to fill prescriptions solely on the basis of a prescriber's use of a telemedicine platform to provide services. The bill also prohibits pharmacists from prioritizing dispensing prescriptions from a prescriber who does not use telemedicine over prescriptions from a prescriber who does use telemedicine based solely on the prescriber's use of a telemedicine platform to provide services.

03/02/23 House: Enrolled Bill communicated to Governor on March 2, 2023 03/02/23 Governor: Governor's Action Deadline 11:59 p.m., March 27, 2023

HB 2465 Prescription drugs; return of drugs past their expiration dates.

Chief patron: Hodges

** **DEAD BILL** **

Return of prescription drugs past their expiration dates. Permits prescription drugs in full or partial containers to be returned up to six months after the labeled expiration date for full credit or replacement.

02/07/23 House: Left in Health, Welfare and Institutions

SB 930 Health care; decision making, end of life, penalties.

Chief patron: Hashmi

** DEAD BILL **

Health care; **decision making**; **end of life**; **penalties**. Allows an adult diagnosed with a terminal condition to request and an attending health care provider to prescribe a self-administered controlled substance for the purpose of ending the patient's life in a humane and dignified manner.

01/26/23 Senate: Passed by indefinitely in Education and Health (9-Y 5-N)

SB 932 Virginia Psilocybin Advisory Board; established, report.

Chief patron: Hashmi

** **DEAD BILL** **

Virginia Psilocybin Advisory Board established; report; Drug Control Act reclassification of psilocybin. Establishes the Virginia Psilocybin Advisory Board to develop a long-term strategic plan for establishing therapeutic access to psilocybin services and monitor and study federal laws, regulations, and policies regarding psilocybin. The bill requires the Board to report annually by December 1 to the Governor and the General Assembly regarding its activities and recommendations. The bill reclassifies psilocybin under the Drug Control Act from a Schedule I to a Schedule III controlled substance.

02/07/23 Senate: Read third time and passed Senate (25-Y 15-N)

02/10/23 House: Referred to Committee on Rules

02/14/23 House: Tabled in Rules (13-Y 5-N)

SB 957 Prescription Drug Affordability Board and Fund; established, report, drug cost affordability review.

Chief patron: Petersen

Prescription Drug Affordability Board and Fund established; drug cost affordability review. Establishes the Prescription Drug Affordability Board for the purpose of protecting the

citizens of the Commonwealth and other stakeholders within the health care system from the high costs of prescription drug products.

The bill also creates the Prescription Drug Affordability Fund to be used for funding the operations of the Board and reimbursing state agencies for implementing the provisions of the bill. The bill requires the Board to report its findings and recommendations to the General Assembly twice annually, beginning on July 1, 2024, and December 31, 2024.

Provisions of the bill shall apply to state-sponsored and state-regulated health plans and health programs and obligate such policies to limit drug payment amounts and reimbursements to an upper payment limit amount set by the Board, if applicable, following an affordability review. The bill specifies that Medicare Part D plans shall not be bound by such decisions of the Board.

The bill has a delayed effective date of January 1, 2024.

02/16/23 House: Subcommittee recommends laying on the table (4-Y 2-N)

02/22/23 House: Left in Commerce and Energy

SB 1198 Drug Control act; distribution of hypodermic needles.

Chief patron: Saslaw

Drug Control Act; prohibition of distribution of hypodermic needles; exception. Provides an exception to the prohibition of distribution of hypodermic needles for the distribution of hypodermic needles that are designed to be used with a reusable injector pen for the administration of insulin.

02/24/23 Senate: Conference report agreed to by Senate (40-Y 0-N) 02/24/23 House: Conference report agreed to by House (95-Y 0-N)

Cannabis Legislation:

HB 1464 Cannabis control; establishes framework for creation of retail market, transitional sale, penalties.

Chief patron: Hodges

** **DEAD BILL** **

Cannabis control; retail market; transitional sales; penalties. Establishes a framework for the creation of a retail marijuana market in the Commonwealth, which would be administered by the Virginia Cannabis Control Authority. The bill allows the Authority to begin issuing marijuana licenses on July 1, 2024. The bill allows, beginning July 1, 2023, certain pharmaceutical and industrial hemp processors, pending establishment of the retail market, to cultivate, manufacture, and sell cannabis products to persons 21 years of age or older.

01/31/23 House: House subcommittee amendments and substitutes offered

01/31/23 House: Subcommittee recommends laying on the table (5-Y 3-N)

02/07/23 House: Left in General Laws

HB 1598 Medical cannabis program; transition from Board of Pharmacy to Virginia Cannabis Control Authority.

Chief patron: Robinson

Medical cannabis program; transition from Board of Pharmacy to Virginia Cannabis Control Authority. Transfers oversight and administration of the Commonwealth's medical cannabis program from the Board of Pharmacy to the Virginia Cannabis Control Authority. The bill has a delayed effective date of **January 1, 2024**, and is identical to SB 788.

03/02/23 House: Enrolled Bill communicated to Governor on March 2, 2023 03/02/23 Governor: Governor's Action Deadline 11:59 p.m., March 27, 2023

HB 1750 Cannabis control; establishes framework for creation of retail marijuana market.

Chief patron: Webert

** DEAD BILL **

Cannabis control; retail market; transitional sales; penalties. Establishes a framework for the creation of a retail marijuana market in the Commonwealth, which would be administered by the Virginia Cannabis Control Authority. The bill allows the Authority to begin issuing marijuana licenses on January 1, 2024, but provides that no marijuana sales may occur prior to January 1, 2025.

01/31/23 House: Subcommittee recommends laying on the table (8-Y 0-N)

02/07/23 House: Left in General Laws

HB 2265 Industrial hemp; increases maximum THC concentration.

Chief patron: Wilt

** DEAD BILL **

Industrial hemp; maximum THC concentration. Increases from 0.3 percent to one percent, in the definition of industrial hemp, the maximum concentration of tetrahydrocannabinol (THC) in the plant Cannabis sativa and excludes hemp products with a THC concentration of one percent or less from (i) the definition of marijuana and (ii) tetrahydrocannabinols as found on Schedule I of the Drug Control Act. The bill allows the Commissioner of Agriculture and Consumer Services to destroy Cannabis sativa found to have a THC concentration greater than one percent only if such Cannabis sativa is intended for human consumption; reduces the application and registration requirements for any person seeking to grow, deal in, or process industrial hemp; and prohibits the Board of Agriculture and Consumer Services and the Commissioner from adopting any regulation that prohibits the use of industrial hemp or hemp products in the production of any commercial feed product regulated by the Board.

01/31/23 House: Subcommittee recommends laying on the table (8-Y 0-N)

02/07/23 House: Left in General Laws

HB 2368 Medical marijuana program; product requirements, certifications.

Chief patron: Adams, D.M.

Medical marijuana program; product requirements; certifications; reporting. Requires cannabis product and botanical cannabis labels to be complete, accurate, easily discernable, and uniform among different products and brands and that each label, which shall be included on the product and on the pharmaceutical processor's website, include (i) the product name, (ii) all active and inactive ingredients, (iii) the total percentage and milligrams of

tetrahydrocannabinol and cannabidiol included in the product and the number of milligrams of tetrahydrocannabinol and cannabidiol in each serving, (iv) the amount of product that constitutes a single serving and the amount recommended for use by the practitioner or dispensing pharmacist, (v) information regarding the product's purpose and detailed usage directions, and (vi) child and safety warnings in a conspicuous font. The bill also requires that a pharmaceutical processor or cannabis dispensing facility shall maintain an adequate supply of cannabis products that (a) contain cannabidiol as their primary cannabinoid and (b) have low levels of or no tetrahydrocannabinol. The bill provides that a patient's registered agent is not required to register with the Board of Pharmacy when such registered agent is listed on the patient's written certification pursuant to the patient's request and in the discretion of the practitioner based on medical need.

02/24/23 House: Enrolled

02/24/23 House: Bill text as passed House and Senate (HB2368ER)

HB 2428 Marijuana; advertising restrictions, penalties.

Chief patron: Wilt

Marijuana; advertising restrictions; penalties. Makes it a Class 1 misdemeanor to advertise in or send any advertising matter into the Commonwealth regarding marijuana, marijuana products, or any substance containing a synthetic tetrahydrocannabinol unless the advertisement (i) is for a product that may be legally sold in the Commonwealth under certain Articles of the Drug Control Act or (ii) concerns the treatment of addiction or substance abuse or is part of a public health awareness campaign.

The bill also defines "tetrahydrocannabinol" or "THC" as any naturally occurring or synthetic tetrahydrocannabinol, including its salts, isomers, synthetic derivatives, salts of isomers, or salts of synthetic derivatives.

02/25/23 House: Conference report agreed to by House (92-Y 0-N)

02/25/23 Senate: Conference report agreed to by Senate (40-Y 0-N)

HB 2294 Industrial hemp; regulated hemp products, etc.

Chief patron: Kilgore

Tetrahydrocannabinol; industrial hemp; regulated hemp products. Establishes product packaging, labeling, and testing requirements for such products, and creates a civil penalty of up to \$1,000 for certain violations relating to such products. The bill requires that laboratories that test hemp products that are consumed orally or by inhalation have a registration with the U.S. Drug Enforcement Administration. The bill requires any person who manufactures an industrial hemp extract, as defined in the bill, or food containing an industrial hemp extract to obtain a permit from the Commissioner of Agriculture and Consumer Services and creates a Class 1 misdemeanor and a civil penalty of up to \$10,000 for certain violations.

The bill caps the total tetrahydrocannabinol in an industrial hemp extract product when offered for retail sale at a total tetrahydrocannabinol concentration that is no more than 0.3 percent and contains no more than two milligrams of total tetrahydrocannabinol per package. The bill also clarifies that the definition of marijuana does not include any substance containing tetrahydrocannabinol that has been placed by the Board of Pharmacy into one of the schedules set forth in the Drug Control Act. The bill increases the civil penalty for certain actions relating to sales of cigarettes and hemp products from \$50 to \$500. The bill also removes tetrahydrocannabinol from the Schedule I list of controlled substances and permits the Board of Pharmacy to schedule, deschedule, or reschedule a tetrahydrocannabinol isomer, ester, ether, salt, except delta-9-tetrahydrocannabinol, or salts of such isomer, ester, or ether in accordance with the provisions of the bill.

02/24/23 House: Conference report agreed to by House (85-Y 9-N)

02/24/23 House: VOTE: Adoption (85-Y 9-N)

02/24/23 Senate: Conference report agreed to by Senate (23-Y 17-N)

HB 2369 Medical marijuana program; dispensaries.

Chief patron: Adams, D.M.

** **DEAD BILL** **

Medical marijuana program; dispensaries. Removes the requirement that a cannabis dispensing facility be owned, at least in part, by a pharmaceutical processor and increases from five to 12 the number of cannabis dispensing facility permits the Board of Pharmacy may issue per year in each health service area.

02/02/23 House: Subcommittee recommends striking from docket (6-Y 0-N)

02/07/23 House: Left in Health, Welfare and Institutions

SB 903 Industrial hemp; regulated hemp products, etc.

Chief patron: Hanger

Tetrahydrocannabinol; industrial hemp; regulated hemp products. Establishes provisions for the registration of a retail facility for regulated hemp products, as defined in the bill, and establishes product packaging, labeling, and testing requirements for such products. The bill requires any person who manufactures an industrial hemp extract, as defined in the bill, or food containing an industrial hemp extract to obtain a permit from the Commissioner of Agriculture and Consumer Services. The bill creates a Class 1 misdemeanor and a civil penalty of up to \$10,000 for certain hemp-related violations and increases from \$50 to \$500 the civil penalty for certain actions relating to sales of cigarettes and hemp products. The bill requires topical hemp products, as defined in the bill, to include a bittering agent and imposes a \$500 penalty for violations of such requirement. The bill removes tetrahydrocannabinol from the Schedule I list of controlled substances and permits the Board of Pharmacy to schedule, deschedule, or reschedule a tetrahydrocannabinol isomer, except delta-9-tetrahydrocannabinol, or salts of such isomer in accordance with the provisions of the bill. The bill (i) provides that oversight of certain provisions of the bill, including provisions related to the registration requirement for retail facilities and packaging, labeling, and testing requirements, shall transfer from the Virginia Department of Agriculture and Consumer Services to the Virginia Cannabis Control Authority on July 1, 2024, and (ii) directs the Board of Directors of the Virginia Cannabis Control Authority to promulgate regulations regarding the maximum amount of tetrahydrocannabinol that may be contained in a regulated hemp product.

02/24/23 Conference: Amended by conference committee

02/24/23 Senate: Conference report agreed to by Senate (22-Y 18-N) 02/24/23 House: Conference report agreed to by House (78-Y 14-N)

SB 1090 Pharmaceutical processor or cannabis dispensing facility; increases number of permits issued.

Chief patron: Ebbin

** DEAD BILL **

Board of Pharmacy; permit to operate pharmaceutical processor or cannabis dispensing facility. Increases the limit on the number of permits that the Board of Pharmacy (the Board) may issue or renew in any year from one to two pharmaceutical processors for each health

service area established by the Board of Health. The bill also allows the Board to issue or renew permits in any year for up to five cannabis dispensing facilities per pharmaceutical processor for each health service area. Under current law, the Board may issue up to five cannabis dispensing facilities for each health service area. With the exception of pharmaceutical processors permitted prior to July 1, 2023, the bill prohibits a pharmaceutical processor from receiving more than one permit from the Board.

02/22/23 House: Left in Health, Welfare and Institutions

SB 1337 Medical marijuana program; product, registration, dispensing, and recordkeeping requirements.

Chief patron: Dunnavant

Medical marijuana program; product, registration, dispensing, and recordkeeping requirements; advertising. Allows a practitioner to issue a written certification via telemedicine to a patient who is located on the premises of a pharmaceutical processor or cannabis dispensing facility. The bill allows pharmaceutical processors and cannabis dispensing facilities to make available on its premises technology that uncertified persons may use to contact a practitioner of the person's choice to request a written certification. The bill amends and adds numerous provisions regarding the Commonwealth's medical marijuana program, including provisions related to recordkeeping, product registration, expiration dates, allowable deviations, dispensing, packing, labeling, and advertising. The bill requires pharmaceutical processors and cannabis dispensing facilities to collect and provide to the Board of Pharmacy by July 1, 2024, data regarding implementation of the bill. The bill also requires the Board of Pharmacy to make certain amendments to its regulations. This bill is the companion of HB1846.

02/22/23 Senate: House amendments agreed to by Senate (27-Y 13-N)

SB 1533 Medical marijuana program; additional cultivation facility.

Chief patron: Deeds

Medical marijuana program; additional cultivation facility. Allows a pharmaceutical processor that has obtained a permit to operate a pharmaceutical processing facility from the Board of Pharmacy to establish one additional location for the cultivation of cannabis plants, which must be located within the same health service area as the pharmaceutical processing facility.

02/21/23 House: Passed House with amendments (78-Y 18-N)

02/22/23 Senate: House amendments agreed to by Senate (32-Y 8-N)

Board of Pharmacy Current Regulatory Actions As of March 10, 2023

In the Governor's Office

VAC	Stage	Subject Matter	Date submitted*	Office; time in office**	Notes
18VAC110- 20	Final	Prohibition against incentives to transfer prescriptions	5/23/2018	Governor 1,752 days; 6 years since submission for executive branch review	Addresses a patient safety concern.
18VAC110- 20	Emergency/ NOIRA	Pharmacy working conditions	2/27/2023	Governor 11 days	Implements emergency regulations related to work environments for pharmacy personnel

In the Secretary's Office

VAC	Stage	Subject Matter	Date submitted*	Office; time in office**	Notes
18VAC110-20	NOIRA	Implementation of 2021 Periodic Review	4/3/2022	Secretary 341 days	Implementation of changes identified during 2021 periodic review of regulations governing the practice of pharmacy
18VAC110-21	NOIRA	Implementation of 2021 Periodic Review	4/3/2022	Secretary 341 days	Implementation of changes identified during 2021 periodic review of regulations governing the licensure of pharmacists and

					registration of pharmacy technicians
18VAC110-20	Proposed	Centralized warehouser or wholesale distributor verification of Schedule VI drugs for ADDs in hospitals	8/31/2022	Secretary 191 days	Permits centralized warehousers or wholesale distributors to verify Schedule VI drugs for ADDs in hospitals

At DPB/OAG

VAC	Stage	Subject Matter	Date submitted*	Office; time in office**	Notes
18VAC110- 60	Exempt/ Final	Pharmaceutical processor regulations	10/5/2022	OAG 156 days	Implements changes to processor regulations pursuant to 2022 legislation

^{*} Date submitted to current location ** As of March 10, 2023

Recently effective or awaiting publication

VAC	Stage	Subject Matter	Publication date	Effective date
18VAC110- 20	Proposed	Implementation of 2021 legislation for pharmacists initiating treatment	11/21/2022	Public comment period ended 1/20/2023. Before Board for adoption of final regulations.
18VAC110- 30	NOIRA	Implementation of 2021 Periodic Review	12/5/2022	Public comment period ended 1/4/2023 with no comments. Board will consider proposed regulations.

18VAC110- 20	Exempt/Final	September 2022 action conforming schedules to federal scheduling actions	1/2/2023	2/1/2023
18VAC110- 21	Emergency/ NOIRA	2022 Pharmacists initiating treatment	3/13/2023	2/21/2023

Agenda Item: Adoption of exempt regulations - addition of chemicals from Schedule I

Included in your agenda package are:

- Recommendation from Department of Forensic Science to place certain chemicals in Schedule I.
- Amendments to 18VAC110-20-322.

Action needed:

• Motion to adopt exempt changes to 18VAC110-20-322 to add chemicals to Schedule I.



COMMONWEALTH of VIRGINIA

DEPARTMENT OF FORENSIC SCIENCE

OFFICE OF THE DIRECTOR
A Nationally Accredited Laboratory

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To: Caroline Juran, Executive Director, Board of Pharmacy

From: Robyn Weimer, Chemistry Program Manager, Virginia Department of Forensic Science

Date: January 13, 2023

RE: Recommendation for Expedited Scheduling of Controlled Substances

Ms. Juran,

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

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

- 1. N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)pentanamide (other names: para-fluoro valeryl fentanyl, para-fluoro pentanoyl fentanyl), 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. N-(4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (other name: para-fluoroacetyl fentanyl), 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.

- 3. 1-[1-(3-fluorophenyl)cyclohexyl]piperidine (other names: 3-fluoro Phencyclidine, 3F-PCP), 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. 2-(ethylamino)-2-(2-fluorophenyl)-cyclohexanone (other names: 2-fluoro-2-oxo PCE, 2-fluoro NENDCK), 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 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.

5. 2-(3-chlorophenyl)-3-methylmorpholine (other name: 3-chlorophenmetrazine), its salts, is omers (optical, position, and geometric), and salts of isomers.

Robyn Weimer

Chemistry Program Manager

Board of Pharmacy

March 2023 Schedule I adds pursuant to DFS notification

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. 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.

- 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 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, alphaethylaminopentiophenone), 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 stimulant. 4-methylmethamphetamine (other names: N-alpha,4-trimethyl-benzeneethanamine, 4-MMA), including its salts, isomers, and salts of isomers.
- 4. Cannabimimetic 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 March 14, 2024, unless enacted into law in the Drug Control Act.

- C. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:
 - 1. Synthetic opioid. N,N-diethyl-2-[5-nitro-2-(4-propoxybenzyl)-1H-benzimidazol-1-yl]ethanamine (other name: Protonitazene), 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. 1-(1,3-benzodioxol-5-yl)-2-(cyclohexylamino)butan-1-one (other names: Cybutylone, N-cyclohexyl 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. Compounds expected to have depressant properties. 8-bromo-6-(2-chlorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine (other names: Clobromazolam, Phenazolam), 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. Cannabimimetic agents.

- a. 5-bromo-N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1H-indazole-3-carboxamide (other name: ADB-5Br-INACA), 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)-5-bromo-1-butylindazole-3-carboxamide (other name: ADB-5'Br-BUTINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until July 31, 2024, 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 compounds.

- a. N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)pentanamide (other names: para-fluoro valeryl fentanyl, para-fluoro pentanoyl fentanyl), 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-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (other name: para-fluoroacetyl fentanyl), 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-fluorophenyl)cyclohexyl]piperidine (other names: 3-fluoro Phencyclidine, 3F-PCP), 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)-2-(2-fluorophenyl)-cyclohexanone (other names: 2-fluoro-2-oxo PCE, 2-fluoro NENDCK), 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. Central nervous system stimulant. 2-(3-chlorophenyl)-3-methylmorpholine (other name: 3-chlorophenmetrazine), its salts, isomers (optical, position, and geometric), and salts of isomers.

The placement of drugs listed in this subsection shall remain in effect until [September 30], 2024, unless enacted into law in the Drug Control Act.

Agenda Item: Adoption of exempt regulations – addition and removal of drugs and chemicals pursuant to federal changes

Included in your agenda package are:

- Summary of DEA scheduling changes July 7, 2022 February 3, 2023.
- Amendments to 18VAC110-20-323.

Action needed:

• Motion to adopt exempt changes to 18VAC110-20-323 pursuant to federal scheduling changes.

DEA Scheduling Actions July 7, 2022 through February 3, 2023

Removal of Fenfluramine From Schedule IV

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Drug Enforcement Administration, Department of Justice.

ACTION:

Final rule.

SUMMARY:

With the issuance of this final rule, the Drug Enforcement Administration removes fenfluramine (chemical name: N-ethyl- α -methyl-3-(trifluoromethyl)phenethylamine), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts is possible, from the schedules of the Controlled Substances Act. Prior to the effective date of this rule, fenfluramine was a schedule IV controlled substance. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule IV controlled substances, on persons who handle (manufacture, distribute, reverse distribute, dispense, engage in research, import, export, conduct instructional activities or chemical analysis with, or possess) or propose to handle fenfluramine.

DATES:

Effective December 23, 2022.

FOR FURTHER INFORMATION CONTACT:

Terrence L. Boos, Ph.D., Chief, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362-3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

Under the Controlled Substances Act (CSA), each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause. [L] The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c) and the current list of scheduled substances is published at 21 CFR part 1308.

Pursuant to <u>21 U.S.C. 811(a)(2)</u>, the Attorney General may, by rule, "remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule." The Attorney General has delegated scheduling

authority under <u>21 U.S.C. 811</u> to the Administrator of the Drug Enforcement Administration (DEA). [2]

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General on the petition of any interested party. This action was initiated by a petition to remove fenfluramine from the list of scheduled controlled substances of the CSA, and is supported by, *inter alia*, a recommendation from the Assistant Secretary for Health of the Department of Health and Human Services (HHS) and an evaluation of all relevant data by DEA. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule IV controlled substances, on persons who handle or propose to handle fenfluramine.

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Drug Enforcement Administration, Department of Justice.

ACTION:

Final rule.

SUMMARY:

With the issuance of this final rule, the Drug Enforcement Administration places *N* -methyl-1-(thiophen-2-yl)propan-2-amine (methiopropamine), including its salts, isomers, and salts of isomers in schedule I of the Controlled Substances Act. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle methiopropamine.

DATES:

Effective date: January 9, 2023.

Placing Mesocarb in Schedule I

AGENCY:

Drug Enforcement Administration, Department of Justice.
ACTION:
Final rule.
SUMMARY:
With the issuance of this final rule, the Drug Enforcement Administration places mesocarb (chemical name: N -phenyl- N' -(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate), including its salts, isomers, and salts of isomers, in schedule I of the Controlled Substances Act. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle mesocarb.
DATES:
Effective date: December 22, 2022.
Background
Mesocarb (chemical name: N -phenyl- N' -(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate) is a central nervous system (CNS) stimulant.
At its 38th session (March 1995), the United Nations Commission on Narcotic Drugs added mesocarb to Schedule IV of the 1971 Convention, thus notifying all parties to the 1971 Convention.
Placing Zipeprol in Schedule I
AGENCY:
Drug Enforcement Administration, Department of Justice.
ACTION:
Final rule.
SUMMARY:

With the issuance of this final rule, the Drug Enforcement Administration places zipeprol (chemical name: 1-methoxy-3-[4-(2-methoxy-2-phenylethyl)piperazin-1-yl]-1-phenylpropan-2-ol), including its isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation, in schedule I of the Controlled Substances Act. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle zipeprol.

DATES:

Effective December 21, 2022.

Background

Zipeprol (chemical name: 1-methoxy-3-[4-(2-methoxy-2-phenylethyl)piperazin-1-yl]-1-phenylpropan-2-ol) is pharmacologically an opioid drug with some hallucinogenic properties that has no approved medical use in the United States.

In March 1995, the United Nations Commission on Narcotic Drugs, on the advice of the Director-General of the World Health Organization, placed zipeprol in Schedule II of the 1971 Convention, thus notifying all parties to the 1971 Convention.

Placing Amineptine in Schedule I

AGENCY:

Drug Enforcement Administration, Department of Justice.

ACTION:

Final rule.

SUMMARY:

With the issuance of this final rule, the Drug Enforcement Administration places amineptine (chemical name: 7-[(10,11-dihydro-5 *H*-dibenzo[*a,d*]cyclohepten-5-yl)amino]heptanoic acid), including its salts, isomers, and salts of isomers, in schedule I of the Controlled Substances Act. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle amineptine.

DATES:

Effective date: December 19, 2022.

Background

Amineptine (chemical name: 7-[(10,11-dihydro-5 H-dibenzo[a,d]cyclohepten-5-yl)amino]heptanoic acid) is a synthetic tricyclic antidepressant with central nervous system (CNS) stimulating properties.

In April 2003, the United Nations Commission on Narcotic Drugs (CND), on the advice of the Director-General of the World Health Organization (WHO), added amineptine to Schedule II of the 1971 Convention, thus notifying all parties to the 1971 Convention.

Board of Pharmacy

March 2023 scheduling and de-scheduling of drugs and chemicals pursuant to federal scheduling changes July 2022 - February 2023

18VAC110-20-323. Scheduling for conformity with federal law or rule.

Pursuant to subsection E of § 54.1-3443 of the Code of Virginia and in order to conform the Drug Control Act to recent scheduling changes enacted in federal law or rule, the board:

- 1. Adds MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine) to Schedule I;
- 2. Adds Dronabinol ((-)-delta-9-trans tetrahydrocannabinol) in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration to Schedule II;
- 3. Deletes naldemedine from Schedule II;
- 4. Deletes naloxegol and 6β-naltrexol from Schedule II;
- 5. Replaces 4-anilino-N-phenethyl-4-piperidine (CASRN 21409-26-7) in Schedule II with 4-anilino-N-phenethylpiperidine (ANPP);
- 6. Adds 4-methyl-5-(4-methylphenyl)-4,5-dihydro-1,3-oxazol-2-amine (4,4'-Dimethylaminorex, 4,4'-DMAR) to Schedule I;
- 7. Adds 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)pyrrolo[2,3-b]pyridine-3-carboxamide (5F-CUMYL-P7AICA) to Schedule I;
- 8. Adds ethyl N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]carbamate (fentanyl carbamate) to Schedule I;
- 9. Adds N-(2-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]prop-2-enamide (ortho-fluoroacryl fentanyl) to Schedule I;

- 10. Adds N-(2-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (ortho-fluoroisobutyryl fentanyl) to Schedule I;
- 11. Adds N-(4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (para-fluoro furanyl fentanyl) to Schedule I;
- 12. Adds N-(2-fluorophenyl)-N-[1-[2-(2-fluorophenyl)ethyl]piperidin-4-yl]propanamide (2'-fluoro ortho-fluorofentanyl; 2'-fluoro 2-fluorofentanyl) to Schedule I;
- 13. Adds N-[1-[2-(4-methylphenyl)ethyl]piperidin-4-yl]-N-phenylacetamide (4'-methyl acetyl fentanyl) to Schedule I;
- 14. Adds N,3-diphenyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (β'-phenyl fentanyl; beta'-phenyl fentanyl; 3-phenylpropanoyl fentanyl) to Schedule I;
- 15. Adds N-phenyl-N-[1-(2-phenylpropyl)piperidin-4-yl]propanamide (β-methyl fentanyl) to Schedule I;
- 16. Adds N-(2-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide (ortho-fluorobutyryl fentanyl; 2-fluorobutyryl fentanyl) to Schedule I;
- 17. Adds N-(2-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (ortho-methyl acetylfentanyl; 2-methyl acetylfentanyl) to Schedule I;
- 18. Adds 2-methoxy-N-(2-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (ortho-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl) to Schedule I;
- 19. Adds N-(4-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (paramethylfentanyl; 4-methylfentanyl) to Schedule I;
- 20. Adds N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]thiophene-2-carboxamide (thiophene fentanyl) to Schedule I;

- 21. Adds N-(4-chlorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (para-chloroisobutyryl fentanyl) to Schedule I;
- 22. Adds 24. 2-[2-[(4-butoxyphenyl)methyl]-5-nitrobenzimidazol-1-yl]-N,N-diethylethanamine (Butonitazene) to Schedule I;
- 23. Adds N,N-diethyl-2-[2-[(4-fluorophenyl)methyl]-5-nitrobenzimidazol-1-yl] ethanamine (Flunitazene) to Schedule I;
- 24. Adds Oliceridine to Schedule II;
- 25. Deletes Samidorphan from Schedule II;
- 26. Adds Remimazolam to Schedule IV;
- 27. Adds Serdexmethylphenidate to Schedule IV;
- 28. Adds Lemborexant to Schedule IV;
- 29. Adds Daridorexant to Schedule IV; and
- 30. Adds Ganaxolone to Schedule V-;
- 31. Adds N-methyl-1-(thiophen-2-yl)propan-2-amine (other name: methiopropamine) to Schedule I;
- 32. Adds N -phenyl- N'-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate (other name: mesocarb) to Schedule I;
- 33. Adds 1-methoxy-3-[4-(2-methoxy-2-phenylethyl)piperazin-1-yl]-1-phenylpropan-2-ol (other name: zipeprol) to Schedule I;
- 34. Adds 7-[(10,11-dihydro-5 *H* -dibenzo[*a,d*]cyclohepten-5-yl)amino]heptanoic acid (other name: amineptine) to Schedule I; and
- 35. Deletes Fenfluramine from Schedule IV.

Agenda Item: Adoption of final regulations – implementation of 2021 legislation for pharmacists initiating treatment

Included in your agenda package are:

- Amendments to 18VAC110-21-46.
- Comments received via Regulatory Town Hall following publication of the proposed stage.
- Ch. 214 of the 2021 Acts of Assembly.

Action needed:

• Motion to adopt final regulatory changes as presented to implement Ch. 214 of the 2021 Acts of Assembly regarding pharmacists initiating treatment.

Board of Pharmacy

Implementation of 2021 legislation for pharmacists initiating treatment 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 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;
- 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. <u>Drugs and devices as defined in § 54.1-3401 of the Code of Virginia, controlled paraphernalia as defined in § 54.1-3466 of the Code of Virginia, and other supplies and equipment available over the counter 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</u>

over-the-counter equivalent of the same drug-, device, controlled paraphernalia, or other supplies or equipment;

- 7. Vaccines included on the Immunization Schedule published by the Centers for Disease

 Control and Prevention or that have a current emergency use authorization from the U.S.

 Food and Drug Administration;
- 8. Tuberculin purified protein derivative for tuberculosis testing; and
- 9. Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention.
- B. Pharmacists who initiate treatment with, dispense, or administer a drug or device pursuant to subsection A of this section shall:
 - 1. Follow the statewide protocol adopted by the board for each drug-or, device-, controlled paraphernalia, or other supplies or equipment.
 - 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, controlled paraphernalia, or other supplies or equipment have has 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. If the pharmacist is administering a vaccine pursuant to this section, the pharmacist shall report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01 of the Code of Virginia.

- 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.

Action	: Implement	tation of 2021 legislation for pharmacists initiating treatment [586]	61 / 9562]
Commenter	Title	Comment	Date/ID
Brad McDaniel, Virginia Society of Healthsystem Pharmacists	of	The Virginia Society of Healthsystem Pharmacists appreciates the Virginia legislature and the board of pharmacy's work on these new allowances that will benefit citizens by increasing access to convenient care through pharmacist services.	12/2/22 9:44 am CommentID:206466
Caitlin Prather		I am very pleased to see this proposal move towards more permanent status! This will greatly increase access to PrEP and PEP services across the state and move us closer to ending the HIV epidemic.	12/9/22 2:16 pm CommentID:206555

VIRGINIA ACTS OF ASSEMBLY -- 2021 SPECIAL SESSION I

CHAPTER 214

An Act to amend and reenact §§ 54.1-3300 and 54.1-3303.1 of the Code of Virginia, relating to pharmacists; initiation of treatment; certain drugs and devices.

[H 2079]

Approved March 18, 2021

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3300 and 54.1-3303.1 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3300. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Board" means the Board of Pharmacy.

"Collaborative agreement" means a voluntary, written, or electronic arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a single physical location where patients receive services and (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for delivery.

"Pharmacist" means a person holding a license issued by the Board to practice pharmacy.

"Pharmacy" means every establishment or institution in which drugs, medicines, or medicinal chemicals are dispensed or offered for sale, or a sign is displayed bearing the word or words "pharmacist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "medicine store," "drug sundries," "prescriptions filled," or any similar words intended to indicate that the practice of pharmacy is being conducted.

"Pharmacy intern" means a student currently enrolled in or a graduate of an approved school of pharmacy who is registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

"Pharmacy technician" means a person registered with the Board to assist a pharmacist under the

pharmacist's supervision.

"Pharmacy technician trainee" means a person registered with the Board for the purpose of performing duties restricted to a pharmacy technician as part of a pharmacy technician training program in accordance with the provisions of subsection G of § 54.1-3321.

"Practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging, and dispensing of drugs, medicines, and devices used in the diagnosis, treatment, or prevention of disease, whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include (i) the proper and safe storage and distribution of drugs; (ii) the maintenance of proper records; (iii) the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; (iv) the management of patient care under the terms of a collaborative agreement as defined in this section; and (v) the initiating of treatment with or dispensing or administering of certain drugs, devices, or controlled paraphernalia in accordance with the provisions of § 54.1-3303.1.

"Supervision" means the direction and control by a pharmacist of the activities of a pharmacy intern or a pharmacy technician whereby the supervising pharmacist is physically present in the pharmacy or in the facility in which the pharmacy is located when the intern or technician is performing duties restricted to a pharmacy intern or technician, respectively, and is available for immediate oral communication.

Other terms used in the context of this chapter shall be defined as provided in Chapter 34

(§ 54.1-3400 et seq.) unless the context requires a different meaning.

§ 54.1-3303.1. Initiating of treatment with and dispensing and administering of controlled substances by pharmacists.

A. Notwithstanding the provisions of § 54.1-3303, a pharmacist may initiate treatment with, dispense, or administer the following drugs and, devices, controlled paraphernalia, and other supplies and equipment to persons 18 years of age or older in accordance with a statewide protocol developed by the Board in collaboration with the Board of Medicine and the Department of Health and set forth in regulations of the Board:

1. Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in

§ 54.1-3466, 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 Drugs as defined in § 54.1-3401, devices as defined in § 54.1-3401, controlled paraphernalia as defined in § 54.1-3466, and other supplies and equipment available over-the-counter, 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, device, controlled paraphernalia, or other supplies or equipment;

7. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention or that have a current emergency use authorization from the U.S. Food and Drug

Administration;

8. Tuberculin purified protein derivative for tuberculosis testing; and

9. Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention.

- B. A pharmacist who initiates treatment with or dispenses or administers a drug or device pursuant to this section shall notify the patient's primary health care provider that the pharmacist has initiated treatment with such drug or device or that such drug or device has 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.
- C. A pharmacist who administers a vaccination pursuant to subdivision A 7 shall report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.
- 2. That the Board of Pharmacy, in collaboration with the Board of Medicine and the Department of Health, shall establish protocols for the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment available over-the-counter by pharmacists in accordance with § 54.1-3303.1 of the Code of Virginia, as amended by this act, by November 1, 2021. The Board of Pharmacy shall convene a work group composed of an equal number of representatives of the Boards of Pharmacy and Medicine to recommend protocols to the Board of Pharmacy for review and implementation. No pharmacist shall initiate treatment with or dispense or administer such drug, device, controlled paraphernalia, or supply or equipment until such protocols have been adopted. Such protocols shall address training and continuing education for pharmacists regarding the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment pursuant to § 54.1-3303.1 of the Code of Virginia, as amended by this act.

3. That the Board of Pharmacy, in collaboration with the Board of Medicine, shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment. Such regulation shall include authorization for a pharmacist to initiate treatment with or dispense or administer drugs, devices, controlled paraphernalia, and supplies and equipment described in § 54.1-3303.1 of the Code of Virginia, as amended by this act, in accordance with protocols adopted by the Board of Pharmacy. The Board of Pharmacy shall convene a work group composed of an equal number of representatives of the Boards of Pharmacy and Medicine to develop recommendations and propose language for inclusion in such regulations.

4. That the Board of Pharmacy shall convene a work group composed of an equal number of

representatives of the Boards of Pharmacy and Medicine as well as representatives of the Board of Medicine, the Department of Health, schools of medicine and pharmacy located in the Commonwealth, and such other stakeholders as the Board of Pharmacy may deem appropriate to provide recommendations regarding the development of protocols for the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment by pharmacists to persons 18 years of age or older, including (i) controlled substances, devices, controlled paraphernalia, and supplies and equipment for the treatment of diseases or conditions for which clinical decision-making can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988, including influenza virus, urinary tract infection, and group A Streptococcus bacteria, and (ii) drugs approved by the U.S. Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy. The work group shall focus its work on developing protocols that can improve access to these treatments while maintaining patient safety and report its recommendations to the Governor and the Chairmen of the Joint Commission on Health Care, the House Committee on Health, Welfare and Institutions, and the Senate Committee on Education and Health by November 1, 2021.

Agenda Item: Adoption of proposed regulations to Chapter 30 following periodic review Included in your agenda package are:

- Amendments to Chapter 30 based on the Notice of Intended Regulatory Action.
- Regulatory Town Hall action page showing no comments on the NOIRA stage.

Action needed:

• Motion to adopt proposed regulatory changes as presented to Chapter 30.

Project 7073 - Proposed

Board of Pharmacy

Implementation of 2021 Periodic Review

Chapter 30

Regulations for Practitioners of the Healing Arts to Sell Controlled Substances

18VAC110-30-21. Application for facility permit.

A. After June 7, 2016, any Any location at which practitioners a practitioner of the healing arts sell sells controlled substances shall have a permit issued by the board in accordance with § 54.1-3304.1 of the Code of Virginia. A licensed practitioner of the healing arts shall apply for the facility permit on a form provided by the board on which the applicant shall designate the hours of operation the location will be open to service the public.

- B. For good cause shown, the board may issue a limited-use facility permit when the scope, degree, or type of services provided to the patient is of a limited nature. The permit to be issued shall be based on conditions of use requested by the applicant or imposed by the board in cases where certain requirements of this chapter may be waived.
 - 1. The limited-use facility permit application shall list the regulatory requirements for which a waiver is requested, if any, and a brief explanation as to why each requirement should not apply to that practice.
 - 2. A policy and procedure manual detailing the type and volume of controlled substances to be sold and safeguards against diversion shall accompany the application.
 - 3. The issuance and continuation of a limited-use facility permit shall be subject to continuing compliance with the conditions set forth by the board.

- 4. A limited-use facility permit may be issued to a nonprofit facility for the purpose of dispensing Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances.
- C. The executive director may grant a waiver of the security system when storing and selling multiple strengths and formulations of no more than five different topical Schedule VI drugs intended for cosmetic use.

18VAC110-30-55. Change of hours in a permitted facility.

The practitioner designated pursuant to 18VAC110-30-70 shall be responsible for providing notice for a change in the hours of operation, which is expected to last more than one week, to the public and to the board. At least 14 days prior to the anticipated change, notice shall be posted in a conspicuous place to provide notice to the public and provided to the board in writing unless the change is necessitated by emergency circumstances beyond the control of the practitioner, or unless the change will result in an expansion of the current hours of operation. If the facility is not able to post the changes 14 days in advance, the practitioner shall ensure that the board is notified as soon as he knows of the change and disclose the emergency circumstances preventing the required notification.

18VAC110-30-80. Inspection and notice required.

A. The area designated for the storage and selling of controlled substances shall be inspected by an agent of the board prior to the issuance of the first license to sell controlled substances from that site. Inspection prior to issuance of subsequent licenses at the same location shall be conducted at the discretion of the board.

- B. Applications for facility permits that indicate a requested inspection date, or requests that are received after the application is filed, shall be honored provided a 14-day notice to the board is allowed prior to the requested inspection date.
- C. Requested inspection dates that do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.

D. At the time of the inspection, the controlled substance selling and storage area shall comply with 18VAC110-30-90, 18VAC110-30-100, 18VAC110-30-110, 18VAC110-30-120, and 18VAC110-30-130.

E. If an applicant substantially fails to meet the requirements for issuance of a facility permit and a reinspection is required, or if the applicant is not ready for the inspection on the established date and fails to notify the inspector or the board at least 24 hours prior to the inspection, the applicant shall pay a reinspection fee as specified in 18VAC110-30-15 prior to a reinspection being conducted.

F. No facility permit shall be issued to sell controlled substances until adequate safeguards against diversion have been provided for the controlled substance storage and selling area and approved by the inspector or board staff.

G. No facility permit shall be issued to a private dwelling or residence for the purpose of selling controlled substances.

<u>H.</u> The licensee shall notify the board of any substantive changes to the approved selling and storage area including moving the location of the area, making structural changes to the area, or making changes to the alarm system for the area prior to the changes being made and pay a reinspection fee. An inspection shall be conducted prior to approval of the new or altered selling and storage area.

Virginia.gov

Agencies | Governor



Agency

Department of Health Professions

Board

Board of Pharmacy

Chapter

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

Action: Implementation of 2021 Periodic Review

Notice of Intended Regulatory Action (NOIRA) 💿

Action 5927 / Stage 9565

Edit Stage
Withdraw Stage
Go to RIS Project

Documents		
Preliminary Draft Text	None submitted	Sync Text with RIS
Agency Background Document	3/21/2022	<u>Upload / Replace</u>
Governor's Review Memo	11/4/2022	
Registrar Transmittal	11/4/2022	

Status	
Public Hearing	Will be held at the proposed stage
DPB Review	Submitted on 3/21/2022
	Policy Analyst: <u>Jerry Gentile</u>
	Review Completed: 3/29/2022
Governor's Review	ORM Review: ORM Approved 11/4/2022 Governor Review Completed: 11/4/2022
	Result: Approved
Virginia Registrar	Submitted on 11/4/2022
	The Virginia Register of Regulations
	Publication Date: 12/5/2022 Volume: 39 Issue: 8
Comment Period	Ended 1/4/2023
	0 comments

Contact Inform	ation
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Telephone: (804)527-4456 FAX: (804)527-4472 TDD: ()-

This person is the primary contact for this chapter.

This stage was created by Erin Barrett on 03/21/2022 at 1:45pm This stage was last edited by Erin Barrett on 03/21/2022 at 1:45pm Agenda Item: Adoption of proposed regulatory changes to exempt ADDs exclusively stocked with emergency or stat-use medications from certain requirements

Included in your agenda package is:

- Proposed regulatory changes to 18VAC110-20-555;
- Agency background document filed with the Notice of Intended Regulatory Action;
- Public comments received during the comment period for the NOIRA.

Staff Note: This regulatory action was initiated in response to a petition for rulemaking in 2022.

Action needed:

• Motion to adopt proposed regulatory changes as presented or amended.

Board of Pharmacy

Exemption of automated dispensing devices stocked solely with emergency or stat-use medications from certain requirements of 18VAC110-20-555

Chapter 20

Regulations Governing the Practice of Pharmacy

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, Except for automated dispensing devices exclusively stocked with drugs that would be stored in an emergency drug kit or stat-drug box for emergency or stat administration, a drug 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.

Form: TH-01
April 2020



townhall.virginia.gov

Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC110-20
VAC Chapter title(s)	Regulations Governing the Practice of Pharmacy
Action title	Exemption of automated dispensing devices stocked solely with emergency or stat use medications from certain requirements of 18VAC110-20-555
Date this document prepared	June 6, 2022

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of the subject matter, intent, and goals of this this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation.

In response to a petition for rulemaking, the Board is issuing a Notice of Intended Regulatory Action to consider an amendment to section 555 to exempt an automated dispensing device ("ADD") from the requirements of 18VAC110-20-555 when that ADD is exclusively stocked with certain drugs that may 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.

Acronyms and Definitions

Define all acronyms or technical definitions used in this form.

ADD = automated dispensing device

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

The impetus for change is a petition for rulemaking requesting an amendment to regulations for ADDs stocked solely with stat or emergency use drugs. As presented by the petitioner, it would be more secure for such drugs to be stored in an ADD than a "tackle-box" style mechanism which is currently used.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Regulations of the Board of Pharmacy are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Virginia Code § 54.1-2400(6) specifically states that the general powers and duties of health regulatory boards shall be "[t]o promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system."

Purpose

Describe the specific reasons why the agency has determined that this regulation is essential to protect the health, safety, or welfare of citizens. In addition, explain any potential issues that may need to be addressed as the regulation is developed.

The Board determined that the petitioner correctly identified a potential hazard in storage of stat or emergency use only medications under 18VAC110-20-540 or 18VAC110-20-550. Stat or emergency use drugs stored in an ADD would contain an electronic record of access to those drugs, while the current tackle-box style storage systems do not. For some facilities, such as nursing homes, ADDs are not used because the only drugs stored on the premises are stat or emergency use medication. Patient and drug security may be increased through utilization of ADDs when exempted from certain requirements that would unacceptably delay the administration of life-saving drugs for patients.

Substance

Briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

Form: TH-01

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

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

The Board of Pharmacy regulates both the use of ADDs and the use of emergency or stat drugs. There is no alternative to regulation to create this exemption.

Periodic Review and Small Business Impact Review Announcement

This NOIRA is not being used to announce a periodic review or a small business impact review.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below. In addition, as required by § 2.2-4007.02 of the Code of Virginia describe any other means that will be used to identify and notify interested parties and seek their input, such as regulatory advisory panels or general notices.

The Board of Pharmacy is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, and (iii) the potential impacts of the regulation.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Erin Barrett, 9960 Mayland Drive, Suite 300, Henrico, Virginia 23233, erin.barrett@dhp.virginia.gov, or by fax at (804) 915-0382. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will not be held following the publication of the proposed stage of this regulatory action.

Form: TH-01

Commenter: Ben Traynham, Hancock, Daniel & Johnson, P.C.

Comments by PharmScript, LLC

Dear Mr. St. Clair:

Please accept this letter on behalf of PharmScript, LLC as comments on the proposed rulemaking to exempt automated dispensing devices stocked solely with emergency or stat-use medications from certain requirements of 18VAC110-20-555. PharmScript <u>supports</u> the rulemaking because it will eliminate a hurdle to speedy patient care and ultimately lower risk of patient harm.

PharmScript is one of several long-term care pharmacy services companies who provide remote pharmacy services such as distributing and dispensing emergency and stat-use pre-packaged drugs via automated dispensing devices (ADDs) to nursing homes in Virginia.

18VAC110-20-555 presents an issue that is unique to our operation in Virginia, and that is the required extra-step pharmacist authorization (PV1 order verification) of stat-drugs being dispensed from an ADD. Requiring the pharmacist to review and electronically authorize each stat-drug *prior* to administration is a time-consuming and unnecessary task during a critical period in patient care when the patient needs medication.

PharmScript operates in twenty-three states and the District of Columbia, and Virginia is the only jurisdiction that requires this authorization prior to administration. Other states, including neighbors DC, Maryland, Tennessee, and North Carolina, allow for the pharmacist verification of stat drugs (also referred to as "starter drugs" or "emergency drugs") after administration, usually within 24 hours.

Stat-drugs, synonymous and used as a term interchangeable with emergency drugs, are drugs that should be administered immediately to avoid or reduce patient harm. Stat-drug boxes contain prepackaged drugs that are ready for administration. The risk of improper administration by the caregiver accessing the ADD is extremely low to nonexistent as there are many safeguards, including electronic controlled access, already built into the ADD system.

In short, the net effect of this requirement is delayed patient care. Delayed care increases the risk of harm to the patient. The increased risk of harm due to delayed care significantly outweighs any potential risk associated with eliminating the PV1 authorization prior to removing stat drugs from an ADD.

Accordingly, PharmScript strongly supports the proposed rulemaking as it would provide patients faster access to the medication they need while reducing potential risk of harm. Please feel free to contact me if you or any Board member wishes to discuss the operational effect of this regulation further.

Sincerely,

John Camperlengo Chief Legal Officer, PharmScript LLC CommentID: 206471

12/7/22 1:42 pm

Commenter: Brad McDaniel, Virginia Society of Health-system Pharmacists

Emergent Medication Access vis ADCs

VSHP supports the access to medications that are required in emergent circumstances and waiting for a pharmacist to review the order could adversely impact the patient's condition. The Institute for Safe Medication Practice's "Guidelines for the Safe Use of Automated Dispensing Cabinets" includes that such circumstances would include antidotes, rescue agents, and reversal agents, life-sustaining medications, and urgent comfort medications such as managing acute pain or intractable nausea and vomiting.

Condition 1. VSHP requests that the Board consider the following exemptions to support timely access to medications outside of pharmacy service hours, when access to medications from a STAT box is needed:

- Outside of pharmacy service hours
- Nurse removes the medication under a patient profile (meaning that the ADC is configured as a "profiled" machine) this is called an "override" function in the ADC
- Medications provided for this indication are for emergent use (such as criteria outlined in ISMP's guidelines)
- Overrides are assessed periodically by the pharmacy provider for appropriate use of emergent medications

We believe these exemptions will support after-hours emergent access to medications and still allow for pharmacist review and verification of orders during pharmacy service hours.

Conditions 4(a) and 4(b) are appropriate exemptions to accomplish this objective.

Brad McDaniel, PharmD, MBA, BCCCP

Chair, Legislative Affairs Committee

Virginia Society of Health-systems Pharmacists

Agenda Item: Adoption of fast-track regulatory change to remove provisions no longer effective regarding pharmacy technician trainees

Included in your agenda package are:

- Repeal of 18VAC110-21-140 and 18VAC110-21-150.
- Copy of 18VAC110-21-141, currently in effect.

Staff Note: 18VAC110-21-140 and 18VAC110-21-150 were only effective until July 1, 2022. Repealing these provisions will alleviate confusion.

Action needed:

• Motion to repeal 18VAC110-21-140 and 18VAC110-21-150 by fast-track regulatory action.

Board of Pharmacy

Repeal of Outdated Sections

18VAC110-21-140. Application for registration as a pharmacy technician. (Repealed.)

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.

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

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.

Virginia Administrative Code

Title 18. Professional And Occupational Licensing

Agency 110. Board of Pharmacy

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

Part IV. Requirements for Pharmacy Technician Registration

18VAC110-21-141. Requirements for pharmacy technician training.

- 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.

Statutory Authority

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

Historical Notes

Derived from Virginia Register Volume 39, Issue 7, eff. December 21, 2022.

Agenda Item: Amendment of Guidance Document 110-9 to include pharmacy technician trainees

Included in your agenda package is:

• Redline of changes to Guidance Document 110-9 (only changes on page 1).

Action needed:

• Motion to adopt the revisions to Guidance Document 110-9 as presented.

Revised: September 24, 2021March 30, 2023 Effective: TBDNovember 25, 2021

Pharmacy Inspection Deficiency Monetary Penalty Guide Virginia Board of Pharmacy

Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty
1. No Pharmacist-in-Charge or Pharmacist-in-			
Charge not fully engaged in practice at	54.1-3434 and	must have	
pharmacy location	18VAC110-20-110	documentation	2000
2. Pharmacist-in-Charge in place, inventory			
taken, but application not filed with Board	54.1-3434 and		
within the required timeframe	18VAC110-20-110		1000
			First documented occurrence = no penalty
			Repeat = \$ penalty
3. Unregistered persons performing duties			
restricted to pharmacy technician without			
first becoming registered as a pharmacy	,		
technician trainee	54.1-3321 and	;	
	18VAC110-20-111	per ındıvıdual	250
4. Pharmacists/pharmacy technicians/pharmacy			First documented occurrence = no penalty
interns/pharmacy technician trainees			Repeat = \$ penalty
performing duties on an expired	18VAC110-21-60,		
license/registration	18VAC110-21-110,		
	18VAC110-21-141, and		100
	18VAC110-21-170	per individual	

Page 1 of 16

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Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty
5. Pharmacy technicians, pharmacy interns, or pharmacy technician trainees performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists	54.1-3320 18VAC110-20-112		200
A Expende whomsoid to whomson teachnicion		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	First documented occurrence = no penalty Repeat = \$ penalty
ratio	54.1-3320 18VAC110-20-112	per each technician over the ratio	100
7. Change of location or remodel of pharmacy without submitting application or Board approval		must submit an	
	18VAC110-20-140	application and fee	250
8. Refrigerator/freezer temperature out of range		determined using inspector's or	First documented occurrence = no penalty; drugs may be embargoed Repeat = \$ penalty
greater than +/- 4 degrees Fahrenheit.	18VAC110-20-150 and 18VAC110-20-10	pharmacy's calibrated thermometer	100 Drugs may be embargoed
9. The alarm is not operational. The enclosure is not locked at all times when a pharmacist			
is not on duty. The alarm is not set at all times when the pharmacist is not on duty.	18VAC110-20-180 and 18VAC110-20-190		1000

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Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty
9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. The alarm system does not include a feature by which any breach shall be communicated to the PIC or a pharmacist working at the pharmacy.	18VAC110-20-180		250
10. Unauthorized access to alarm or locking device to the prescription department	18VAC110-20-180 and 18VAC110-20-190		1000
			First documented occurrence and no drug loss = no penalty Drug loss or repeat = \$ penalty
11. Insufficient enclosures or locking devices	18VAC110-20-190		500
12. Storage of prescription drugs not in the prescription department	18VAC110-20-190		500

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\$ Monetary Penalty	First documented occurrence and no drug loss of Schedule II = no penalty Drug loss or repeat = \$ penalty		250	Over 30 days late and first documented occurrence = no penalty Over 30 days late and repeat = \$ penalty	200		200
Conditions				Cite Deficiency 113 if only	expired drugs not included in inventory.	Per occurrence. Cite Deficiency 113 if only	expired drugs not included in inventory.
Law/Reg Cite			18VAC110-20-200		54.1-3404 and 18VAC110-20-240		54.1-3434 and 18VAC110-20-240
Deficiency		12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe, or maintained in a manner that combines the two methods.		13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V.		14. No incoming change of Pharmacist-in-Charge inventory, inventory taken or over 5 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V	

Penalty	250	250	250	250
\$ Monetary Penalty				
Conditions	Review 10 drugs for six consecutive months. Includes expired drugs. Deficiency if more than 5 drugs not compliant.	per report/theft-loss		
Law/Reg Cite	18VAC110-20-240	54.1-3404 and 18VAC110-20-240	54.1-3404 and 18VAC110-20-240	54.1-3404, 18VAC110- 20-240, 18VAC110-20- 250, 18VAC110-20- 420, and 18VAC110-20- 425
Deficiency	 15. Perpetual inventory not being maintained as required as it does not: Include all Schedule II drugs received or dispensed; Accurately indicate the physical count of each Schedule II drug "on-hand" at the time of performing the inventory; Include a reconciliation of each Schedule II drug at least monthly; or Include a written explanation of any difference between the physical count and the theoretical count. Monthly perpetual inventory is performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required. 	16. Theft/unusual loss of drugs not reported to the Board as required	17. Hard copy prescriptions not maintained or retrievable as required (i.e. hard copy of fax for Schedule II, III, IV & V drugs and refill authorizations)	18. Records of dispensing not maintained as required

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Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty
19. Pharmacists not verifying or failing to	18VAC110-20-270,		
document verification of accuracy of dispensed prescriptions	18VAC110-20-420 and 18VAC110-20-425	10% threshold tor documentation	500
		Review all entries for 5 drugs	
		for six consecutive	
		months.	
20. Pharmacist not checking and documenting	54.1-3410.2, 18VAC110-20-355 and	Deficiency if 10% or more are not	
repackaging or bulk packaging	18VAC110-20-425	compliant.	250
20a. Pharmacist not documenting verification of accuracy of non-sterile compounding			
process and integrity of compounded	54.1-3410.2,	100/ 4/1004/2	003
20b. Pharmacist not documenting verification of	10 VICTOR 10 200	ומיים מווכאוומים	
accuracy of sterile compounding process	54.1-3410.2,		
and integrity of compounded products	18VAC110-20-355		5000
21. No clean room	54.1-3410.2		10000
		Compliant clean room present but	
		not utilized for	
		preparation of	
21a. Performing sterile compounding outside of	>	sterile drug	
	54.1-3410.2	products.	3000

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21. Presterilization procedures for high-risk completed in areas not classified as ISO Class (a completed in areas not classified as ISO Class (b) of compounded sterile preparation structure of the direct compounding area or better. 22. Certification of the direct compounding area indicating ISO Class S not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed. 23. Certification of the buffer or clean room and an area room individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed by a qualified and individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed in an area not physically separated whenever the device or room is relocated, altered, or major service to the facility is performed in an area not physically separated structure or major service to the facility is even compounded sterile preparations assigned to compounded sterile preparations assigned compounded sterile preparations assigned compounded sterile preparations assigned in an area not physically separated compounded sterile preparations assigned compounded sterile preparations assigned compounded sterile preparations assigned in an area not physically separated sterile preparations are signed compounded sterile preparations are signed in an area not physically separated sterile preparations are signed in an area not physically separated sterile preparations are signed and individual not be sterile preparations are signed and individual not be sterile preparations are signed and individual not be sterile preparations area not physically sparated sterile preparations are signed and sterile preparations are signed and individual sparated sterile preparations are signed and individual sparated sterile preparations are signed and individual sparated sterile preparations are s	Deficiency	Ŋ	Law/Reg Cite	Conditions	\$ Monetary Penalty	>
S4.1-3410.2 Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous sertification S4.1-3410.2 S4.1-3410.2 S4.1-3410.2	21b. Presterilization proced level CSPs, such as weighir completed in areas not classic	lures for high-risk ng and mixing, are fied as ISO Class 8				,
S4.1-3410.2 S4.1-3410.2 S4.1-3410.2 S4.1-3410.2 S4.1-3410.2 SA.1-3410.2 SAL1-3410.2	or better.		54.1-3410.2	Daviour, 7 most	200	2
54.1-3410.2 54.1-3410.2 54.1-3410.2 54.1-3410.2 54.1-3410.2 54.1-3410.2 54.1-3410.2 54.1-3410.2 54.1-3410.2 54.1-3410.2 55.11-3410.2 55.11-3410.2 55.11-3410.2 55.11-3410.2 55.11-3410.2	22 Contification of the direct.	on Suitain		recent reports;		
later than the last day of the sixth month from the previous certification Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification 54.1-3410.2 certification 54.1-3410.2	(DCA) for compounded so	terile preparations		be performed no		
day of the sixth month from the previous 54.1-3410.2 Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous 54.1-3410.2 certification 54.1-3410.2	indicating ISO Class 5 not	t performed by a		later than the last		
month from the previous certification Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification 54.1-3410.2 certification 54.1-3410.2 certification 54.1-3410.2	qualified individual no les	ss than every 6		day of the sixth		
previous certification Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification 54.1-3410.2 certification 54.1-3410.2	months and whenever the	device or room is		month from the		
S4.1-3410.2 certification Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification S4.1-3410.2 certification	relocated, altered, or majo	or service to the		previous		,
Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification certification 54.1-3410.2	facility is performed.		54.1-3410.2	certification	3000	0
sertification must be performed no later than the last day of the sixth month from the previous certification certification 54.1-3410.2 54.1-3410.2				Review 2 most		
54.1-3410.2 S4.1-3410.2 S4.1-3410.2 S4.1-3410.2 S4.1-3410.2 S5.1-3410.2 S6.1-3410.2	23. Certification of the buffer	or clean room and		recent reports;		
54.1-3410.2 be performed no later than the last day of the sixth month from the previous certification 54.1-3410.2 certification 54.1-3410.2	ante room indicating ISO	Class // ISO Class		certification must		
54.1-3410.2 54.1-3410.2 54.1-3410.2 54.1-3410.2	s or better not performed individual no less than ever	by a qualified		be periormed no		
54.1-3410.2 month from the previous certification 54.1-3410.2 certification 54.1-3410.2	whenever the device or ro	om is relocated.		day of the sixth		
54.1-3410.2 previous 54.1-3410.2 54.1-3410.2	altered, or major service to	o the facility is		month from the		
54.1-3410.2 certification 54.1-3410.2 54.1-3410.2	performed.			previous		
54.1-3410.2 54.1-3410.2				certification	1000	0
54.1-3410.2 54.1-3410.2	24. Sterile compounding of ha	azardous drugs				
54.1-3410.2 54.1-3410.2	performed in an area not p	physically separated				
54.1-3410.2	from other preparation are	sas	54.1-3410.2		2000	9
sk 54.1-3410.2	25. No documentation of steri	ilization methods or				
sk 54.1-3410.2	endotoxin pyrogen testing	for high-risk level				
54.1-3410.2	compounded sterile prepa	rations or high risk				
4C	compounded sterile prepa	rations assigned	54 1 3410 3		2000	9
	inappropriate beyond use	date (BUD)	54.1-5410.2			

Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty
25a. No documentation of initial and semiannual (6 months) media-fill testing or gloved fingertip testing for persons performing high-risk level compounding of sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing and gloved fingertip testing must be performed no later than the last day of the sixth month from the date the previous media-fill test and gloved fingertip testing was initiated.	2000
25b. High-risk compounded sterile preparations intended for use are improperly stored	54.1-3410.2		5000
25c. Documentation that a person who failed a media-fill test or gloved fingertip test has performed high-risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill and gloved fingertip test	54.1-3410.2		2000

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26. No documentation of initial and annual (12 months) media-fill testing or gloved fingertip testing must be performed no later than the last day of the welfith months media-fill testing or gloved fingertip was mediaming low and mediaming low at mediam risk level compounding of sterile peparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill states and gloved fingertip test salt and prior to retraining and receipt of passing media-fill salt lost of far failed test result and prior to retraining and receipt of passing media-fill salt lost of far failed test result and prior to retraining and receipt of passing media-fill salt lost of far failed test result and prior to retraining and receipt of passing media-fill salt lost of far failed test result and prior to retraining and receipt of passing media-fill salt lost lost lost lost lost lost lost lo		Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty	
b media-fill test and gloved fingertip testing was initiated. 54.1-3410.2 54.1-3410.2 per Rx dispensed up to maximum of 100 RX or \$5000				Review 2 most recent reports. Media-fill testing and gloved finger-tip testing must be performed no later than the last day of the twelfth month from the date the previous		
led a has has has of to a-fill s410.2 s4.1-3410.2 ber Rx dispensed up to maximum of 100 RX or \$54.1-3410.2 \$54.1-3410.2 \$54.1-3410.2 \$5000		26. No documentation of initial and annual (12 months) media-fill testing or gloved fingertip testing for persons performing low and medium-risk level compounding of sterile		media-fill test and gloved fingertip testing was initiated.		
led a has has has lifer or to a-fill 54.1-3410.2 ber Rx dispensed up to maximum of 100 RX or \$54.1-3410.2 \$5000		preparations.	54.1-3410.2		500	_
or to or to lation 54.1-3410.2 per Rx dispensed		26a. Documentation that a person who failed a media-fill test or gloved fingertip test has performed low or medium risk level				
lation 54.1-3410.2 per Rx dispensed up to maximum of 100 RX or \$54.1-3410.2 \$5000		compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill				
lation 54.1-3410.2 per Rx dispensed up to maximum of 100 RX or \$54.1-3410.2 \$5000		and gloved fingertip test	54.1-3410.2		500	\neg
per Rx dispensed up to maximum of 100 RX or \$54.1-3410.2 \$5000		27. Compounding using ingredients in violation of 54.1-3410.2.	54.1-3410.2		1000	_
54.1-3410.2 \$5000	1	28. Compounding copies of commercially		per Rx dispensed up to maximum of 100 RX or		
	16	available products	54.1-3410.2	\$5000	50	_

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	Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty
	29. Unlawful compounding for further distribution by other entities	54.1-3410.2		200
	30. Security of after-hours stock not in compliance		(First documented occurrence and no drug loss = no penalty Drug loss or repeat = \$ penalty
		18VAC110-20-450		500
	31. Drugs removed and administered to a patient		Except for drugs that would be stocked in an	First documented occurrence and no known patient harm = no penalty Repeat = \$ penalty
	from an automated dispensing device in a nursing home prior to review of the order and authorization by a pharmacist.		emergency drug kit as allowed by 18VAC110-20-	
		18VAC110-20-555	555 (3)(C)	250
	32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	54.1-3410.2		2000
	33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	54.1-3410.2		1000
	34. Combined with Deficiency 142 – 12/2013.			
	35. Schedule II through VI drugs are being purchased from a wholesale distributor or			
	warehouse not licensed or registered by the board or from another pharmacy in a non-	10X7 A C 1110 20 205		030
, l	compinant manner	16 V AC 110-20-393		0.07

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Other Deficiencies

Guidance Document: 110-9

If five (5) or more deficiencies in this category are cited, a \$250 monetary penalty shall be imposed. Another \$100 monetary penalty will be added for each additional deficiency cited in this category, over the initial five.

101.		Law/Regulation Cite	Conditions
	Repealed 6/2011		
102.	Special/limited-use scope being exceeded without approval	18VAC110-20-120	
103.	Repealed 12/2013		
104.	Sink with hot and cold running water not available within the prescription department.	18VAC110-20-150	
105.	No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit. Temperature not being recorded daily or record of such not maintained properly.	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's calibrated thermometer
106.	Prescription department substantially not clean and sanitary and in good repair	18VAC110-20-160	must have picture documentation
107.	Current dispensing reference not maintained	18VAC110-20-170	
108.	Emergency access alarm code/key not maintained in compliance	18VAC110-20-190	
118	Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs	54.1-3457 18VAC110-20-200	10% threshold

	Deficiency	Law/Regulation Cite	Conditions
retui not i place stocl	returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container)	18VAC110-20-355	
Sto	Storage of paraphernalia/Rx devices not in compliance	18VAC110-20-200	
Sto pre	Storage of prescriptions awaiting delivery outside of the prescription department not in compliance	18VAC110-20-200	
Bie	Biennial taken late but within 30 days	54.1-3404 and 18VAC110-20-240	
Inv sig seg	Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, Schedule II drugs not separate, failure to include expired drugs.	54.1-3404, 54.1-3434 and 18VAC110-20-240	
Re	Records of receipt (e.g. invoices) not on site or retrievable	54.1-3404 and 18VAC110-20-240	
Õ	Other records of distributions not maintained as required	54.1-3404 and 18VAC110-20-240	
Pr Pr fa	Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	54.1-3408.01, 54.1-3408.02, 54.1-3410, 18VAC110-20-280 and 18VAC110-20-285 18VAC110-20-270	10% threshold
Ď	Deficiency 117 combined with Deficiency 116 – 6/2011		
S S	Schedule II emergency oral prescriptions not dispensed in compliance	54.1-3410 and 18VAC110-20-290	>3

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128. Unit dose procedures or records not in compliance 18VAC110-20-420 129. Robotic pharmacy systems not in compliance 18VAC110-20-425
Robotic pharmacy systems not in compliance

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		Deficiency	Law/Regulation Cite	Conditions	
	130.	Required compounding/dispensing/distribution records not complete and properly maintained	54.1-3410.2		
	130a	Compounded products not properly labeled	54.1-3410.2		
	131.	Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	54.1-3410.2		
	132.	Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	54.1-3410.2		
	133.	Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2	54.1-3410.2		
	134.	Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	18VAC110-20-440		1
	135.	Policies and procedures for drug therapy reviews not maintained or followed	18VAC110-20-440		
	136.	After hours access to a supply of drugs or records not in compliance	18VAC110-20-450	10% threshold	I
	137.	Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	18VAC110-20-460	10% threshold	Ī
121	138.	Automated dispensing device loading, records, and monitorino/reconciliation not in compliance	54.1-3434.02, 18VAC110-20-490	Cite if no documentation of monitoring. Review ADD in areas that do not utilize patient specific profile. Review 3 months of records – 30% threshold. Cite if exceeds threshold.	
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		Deficiency	Law/Kegulation Cite	Conditions
				comment section steps pharmacy is taking to comply. Educate regarding requirements.
	139.	Emergency medical services procedures or records not in compliance	18VAC110-20-500	10% threshold
	140.	Emergency kit or stat-drug box procedures or records not in compliance	18VAC110-20-540 and 18VAC110-20-550	10 % threshold
	141.	Maintaining floor stock in a long-term care facility when not authorized	18VAC110-20-520 and 18VAC110-20-560	
	142.	No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization	18VAC110-20-418	
	143.	Repealed 6/21/2018		
	144.	Repealed 6/21/2018		
	145.	Repealed 6/21/2018		
	146.	Repealed 6/21/2018		
122	147.	Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions.	54.1-3410.2	
<u>)</u>				Page 15 of 16

	Deficiency	Law/Regulation Cite	Conditions	
148.	Theft/unusual loss of drugs reported to board but report not maintained by pharmacy	54.1-3404 and 18VAC110-20-240		1

NOTE: A "repeat" deficiency is a deficiency that was cited during the routine or focused inspection performed immediately prior to the current routine inspection and after July 1, 2018.

Examples:

Routine inspection on 7/1/18 – Cited for Deficiency 3. No monetary penalty. Routine inspection on 7/1/20. Cited for Deficiency 3. Monetary penalty.

Routine inspection on 7/1/18 - Cited for deficiency 3. No monetary penalty.

Routine inspection on 7/1/20 – No deficiency.

Routine inspection on 7/1/22 – Cited for deficiency 3. No monetary penalty. Routine inspection on 7/1/24 – Cited for deficiency 3. Monetary penalty.

Agenda Item: Adoption of Guidance Document 110-37 regarding access to prescriptions during unanticipated shortened hours

Included in your agenda package is:

■ Draft Guidance Document 110-37.

Action needed:

• Motion to adopt Guidance Document 110-37 as presented or revised.

Adopted March 30, 2023 Effective: TBD

Virginia Board of Pharmacy

Access to Prescriptions During Unanticipated Shortened Hours of Pharmacy Operation

Notwithstanding Virginia Code § 54.1-3434 and 18VAC110-20-135, a pharmacy operating with repeatedly shortened hours of operation that are not expected to last more than one week but that prevent patients from accessing prescriptions may be in violation of Virginia Code § 54.1-3316(2), (3), and 18VAC110-20-25(11). The Board strongly encourages pharmacies unable to operate according to designated hours of operation to formally change hours of operation to establish realistic expectations for the public or provide as much notice as possible to the public using various methods of communication. Such pharmacies should also inform patients of how they may access their prescriptions during the time in which the pharmacy is not operating. Pharmacies at risk of unanticipated shortened hours of operation should exercise caution when performing data-entry of prescriptions or adjudicating third-party claims without completing the dispensing process as this may prevent a patient from obtaining the drug from another pharmacy.

For any change in hours of operation expected to last more than one week, the requirements of Virginia Code § 54.1-3434 and 18VAC110-20-135 apply, which require the pharmacy to notify the Board and provide notice to the public pursuant to the provisions of those laws.

For closure of a pharmacy, defined in 18VAC110-20-10, the requirements of Virginia Code § 54.1-3434.01 and 18VAC20-130 apply.

Applicable Statutes:

Va. Code § 54.1-3316 Va. Code § 54.1-3434 Va. Code § 54.1-3434.01

Applicable Regulations:

18VAC110-20-10 (definition of "pharmacy closing") 18VAC110-20-25 18VAC110-20-130 18VAC110-20-135

Agenda Item: Adoption of Guidance Document 110-50 to address pharmacy administration records

Included in your agenda package is:

• Proposed Guidance Document 110-50.

Action needed:

• Motion to adopt the Guidance Document 110-50 as presented or amended.

Adopted: March 30, 2023 Effective Date: TBD

Virginia Board of Pharmacy

Pharmacy Administration Records

Under Virginia Code § 54.1-3401, the administration of a drug is included in the definition of "dispense." Therefore, administration of a drug is subject to the requirements under Virginia Code § 54.1-3412 and 18VAC110-20-255. A pharmacy should maintain a separate record of administration when the person administering the drug, or the date of administration is different than the pharmacist or date identified in the record of dispensing. Pursuant to § 54.1-3412, the initials or identity of the person administering the drug and the date of administration may be recorded in the automated data processing system used for the storage and retrieval of dispensing information for prescriptions or on another record in compliance with 18VAC110-20-255.

References

<u>Va. Code § 54.1-3401</u> <u>Va. Code § 54.1-3412</u> 18VAC110-20-255

Agenda Item: Revision of Guidance Document 110-44, Naloxone Protocols

Included in your agenda package is:

- Clean version of revised Guidance Document 110-44.
- Redline of changes to Guidance Document 110-44.

Staff Note: The Virginia Department of Health intends to amend the Commissioner's standing order for naloxone to include new drug products. The Board must amend its naloxone protocol prior to the Commissioner issuing the amendment.

Action needed:

• Motion to revise Guidance Document 110-44 as presented.

Virginia Board of Pharmacy

Naloxone Protocols

Virginia Code § 54.1-3408(X) and (Y) authorize certain persons to dispense naloxone pursuant to an oral, written, or standing order and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. This document contains the protocols which must be followed when dispensing naloxone pursuant to these subsections of law. The protocols include information on the required elements of a standing order, instruction the recipient must receive, and labeling and recordkeeping requirements.

I. Protocol for the Prescribing and Dispensing of Naloxone by Persons Listed in 54.1-3408 (X)

a. Authorized Dispensers

The following individuals may dispense naloxone pursuant to an oral, written or standing order to a person to administer to another person believed to be experiencing or about to experience a life-threatening opioid overdose and shall follow this protocol when dispensing naloxone as authorized in subsection X of §54.1-3408:

- Pharmacists,
- Health care providers providing services in a hospital emergency department,
- Emergency medical services personnel as defined in § 32.1-111.1

And the following persons who have completed a training program:

- Law-enforcement officers as defined in § 9.1-101,
- Employees of the Department of Forensic Science,
- Employees of the Office of the Chief Medical Examiner,
- Employees of the Department of General Services Division of Consolidated Laboratory Services,
- Employees of the Department of Corrections designated as probation and parole officers or as correctional officers as defined in § 53.1-1,
- Employees of regional jails,
- School nurses,
- Local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board,
- Other school board employees or individuals contracted by a school board to provide school health services,
- Firefighters, and
- Employees or other persons acting on behalf of a "public place" which means any enclosed area that is used or held out for use by the public, whether owned or operated by a public or private interest.

b. Required Training

i. Those persons listed above who must first complete a training program prior to dispensing naloxone shall complete training in accordance with policies and procedures of their employer or governing entity. Selection of or development of the training program is at the discretion of the employer or governing entity. The REVIVE! training program developed by the Department of Behavioral Health and Developmental Services is an available option.

c. Required Order

i. Prior to dispensing naloxone, the dispenser shall receive an oral or written order issued by a prescriber for a specific person to receive naloxone or a standing order issued by an individual prescriber or the Health Commissioner that authorizes the dispenser to dispense naloxone. The prescriber may indicate on such orders that the order is valid and may be refilled for up to two years from the date of issuance. Except for pharmacists, persons authorized in 54.1-3408(X) shall only dispense formulations for intranasal administration or an autoinjector formulation.

- ii. If the naloxone is dispensed pursuant to a standing order, the standing order must contain the following information at a minimum:
 - 1. Name of entity or group of entities authorized to dispense naloxone pursuant to standing order;
 - 2. Name of drug, strength, quantity to be dispensed, and directions for administration, as indicated in the chart below;
 - 3. Prescriber's signature;
 - 4. Date of issuance; and
 - 5. Amount of time, up to two years from date of issuance, for which the order is valid.

Intranasal	Auto-Injector	Intranasal	<u>Intranasal</u>
Naloxone 2mg/2ml	Naloxone 2 mg or 5mg	Naloxone Nasal Spray 4mg, #1	Naloxone nasal spray 8mg, #1
prefilled syringe, # 2	#1 twin pack	twin pack	twin pack
syringes			
	Directions: Use one	Directions: Administer a single	Directions: Administer a single
Directions: Spray one-	auto-injector upon	spray intranasally into one	spray intranasally into one nostril
half of the syringe into	signs of opioid	nostril. Administer additional	upon signs of opioid overdose.
each nostril upon signs	overdose. Call 911.	doses using a new nasal spray	Administer additional dose in
of opioid overdose.	Additional doses may	with each dose, if patient does	other nostril using a new nasal
Call 911. Additional	be given every 2 to 3	not respond or responds and then	spray with each dose, if patient
doses may be given	minutes until	relapses into respiratory depression. Call 911.	does not respond or responds and
every 2 to 3 minutes	emergency medical	depression. Call 911. Additional doses may be given	then relapses into respiratory
until emergency medical assistance	assistance arrives.	every 2 to 3 minutes until	depression. Call 911. Additional
arrives.		emergency medical assistance	doses may be given every 2 to 3 minutes until emergency medical
allives.		arrives.	assistance arrives.
Mucosal Atomization		ullives.	assistance arrives.
Device (MAD) # 2			
SIG: Use as directed			
for naloxone			
administration.			
Must dispense with 2			
prefilled syringes and 2			
atomizers and			
instructions for			
administration.			

d. Required Labeling and Recordkeeping

i. The dispenser shall affix a label to the naloxone container that bears the name and strength of the dispensed naloxone, directions as indicated on the oral, written, or standing order, name of prescriber, date of dispensing, and name and address or telephone of dispensing entity. The name of the recipient does not have to appear on the label. Optional items that may be dispensed that do not require labeling include rescue breathing masks and latex-free gloves.

- ii. The dispenser shall maintain a record of dispensing indicating the name of the recipient, the name, strength, and quantity of naloxone dispensed, date of dispensing, and name or initials of dispenser. Such record shall be maintained for two years from the date of dispensing.
- iii. The oral, written, or standing order must be maintained for two years from the last date of dispensing.
- iv. Unless a waiver has been granted by the Prescription Monitoring Program, pharmacies and physicians licensed to dispense shall report the dispensing to the Prescription Monitoring Program.

e. Required Instruction

i. The dispenser shall provide instruction to the recipient on opioid overdose prevention, overdose recognition, proper administration and dosing of naloxone, effectiveness and response following administration, adverse effects, safety, storage conditions, and expiration date. If the recipient refuses instruction, the instruction may be accomplished by providing the recipient with the current REVIVE! Pharmacy dispensing brochure available on the Department of Behavioral Health and Developmental Services website or by clicking on the link. If the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time, information or referrals to appropriate resources may be provided.

II. Protocol for the Prescribing of Naloxone and Dispensing by Persons Listed in 54.1-3408 (Y)

a. Authorized Dispensers

The following individuals who are acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone, e.g., non-profit organization, community service board, or behavioral health authority, may dispense naloxone pursuant to a standing order to a person to administer to another person believed to be experiencing or about to experience a life-threatening opioid overdose and shall follow this protocol when dispensing naloxone as authorized in subsection Y of §54.1-3408:

- A person who is acting on behalf of such organization may dispense formulations for intranasal administration or an autoinjector formulation;
- A person who is authorized by the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe may dispense formulations for intranasal administration, autoinjector formulation, or an injectable naloxone formulation with a hypodermic needle or syringe, if the organization has obtained a controlled substances registration from the Board of Pharmacy at no charge.

b. Training

• While it is recommended that those persons acting on behalf of such organization and who are dispensing naloxone formulations for intranasal administration or autoinjectors complete training in accordance with policies and procedures of their employer or governing entity, it is not a requirement of law. Selection of or development of the training program is at the discretion of the employer or governing entity. The REVIVE! training program developed by the Department of Behavioral Health and Developmental Services is an available option.

• Those persons acting on behalf of such organization and who intend to dispense injectable naloxone formulation with a hypodermic needle or syringe, must first complete training developed by and be authorized by the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe

c. Required Order

- i. Prior to dispensing naloxone, the dispenser shall receive a standing order issued by an individual prescriber that authorizes the dispenser to dispense naloxone. The standing order must contain the following information at a minimum:
 - 1. Name of organization authorized to dispense naloxone pursuant to standing order;
 - 2. Name of drug, strength, quantity to be dispensed, and directions for administration, as indicated in the chart below;
 - 3. If hypodermic needles and syringes are to be dispensed by an authorized trainer for administering such naloxone, the standing order must also specify the kind and quantity of hypodermic needles and syringes to be dispensed as outlined in the chart below;
 - 4. Prescriber's signature;
 - 5. Date of issuance; and
 - 6. Amount of time, up to two years from date of issuance, for which the order is valid.

Intranasal	Auto- Injector	Intranasal	Injection*	<u>Intranasal</u>
Naloxone 2mg/2ml prefilled syringe, # 2 syringes SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Dispenser must dispense 2 prefilled syringes and 2 atomizers and instructions for administration.	Naloxone 2 mg or 5mg, #1 twin pack SIG: Use one auto- injector upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Naloxone Nasal Spray 4mg, #1 twin pack SIG: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Naloxone 0.4mg/ml #2 single-use 1ml vials SIG: Inject 1ml in shoulder or thigh upon signs of opioid overdose. Call 911. Repeat after 2-3 minutes if no or minimal response. #2 (3ml) syringe with 23-25 gauge 1-1.5 inch IM needles SIG: Use as directed for naloxone administration. Dispenser must dispense 2 single-use 1ml vials, 2 (3ml) syringes and 2 (23- 25 gauge) hypodermic needles for administration.	Naloxone nasal spray 8mg, #1 twin pack SIG: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional dose in other nostril using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.

d. Registration

An organization that intends to dispense an injectable naloxone formulation with a hypodermic needle or syringe must first obtain a controlled substances registration from the Board of Pharmacy at no charge. The application may be downloaded at http://www.dhp.virginia.gov/pharmacy/pharmacy/forms.htm The person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and dispense naloxone for opioid overdose reversal must serve as the responsible party on the application. The prescriber issuing the standing order must serve as the supervising practitioner. An alarm system is not required for the controlled substances registration.

e. Required Labeling, Recordkeeping, and Storage

- i. The dispenser shall affix a label to the naloxone container that bears the name and strength of the dispensed naloxone, directions as indicated on the standing order, name of prescriber, date of dispensing, and name and address or telephone of dispensing entity. The name of the recipient does not have to appear on the label. Optional items that may be dispensed that do not require labeling include rescue breathing masks and latex-free gloves.
- ii. The dispenser shall maintain a record of dispensing indicating the name of the recipient, the name, strength, and quantity of naloxone dispensed, date of dispensing, and name or initials of dispenser. Such record shall be maintained for two years from the date of dispensing.
- iii. The standing order must be maintained for two years from the last date of dispensing.

iv. If the dispenser is dispensing an injectable naloxone formulation with a hypodermic needle or syringe, the dispenser shall comply with the requirements of Board of Pharmacy Regulation 18VAC110-20-735, in lieu of the requirements listed above in section (i) and (ii).

v. The naloxone, hypodermic needles, and syringes shall be stored and transported under appropriate storage conditions in accordance with the manufacturer's directions to protect from adulteration and unlawful use.

f. Required Instruction

- i. The dispenser shall provide instruction to the recipient on opioid overdose prevention, overdose recognition, proper administration and dosing of naloxone, effectiveness and response following administration, adverse effects, safety, storage conditions, and expiration date. If the recipient refuses instruction, the instruction may be accomplished by providing the recipient with the current <u>REVIVE! Pharmacy dispensing brochure</u> available on the Department of Behavioral Health and Developmental Services website or the link above. If the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time, information or referrals to appropriate resources may be provided.
- ii. If the dispenser is dispensing an injectable naloxone formulation with a hypodermic needle or syringe, the dispenser shall also train the individual on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe.

III. Protocol for Pharmacies to Distribute Naloxone to Entities Authorized to Possess, Administer, and Dispense Naloxone

- **a.** In addition to a wholesale distributor, third party logistics provider, or manufacturer, a pharmacy may distribute naloxone via invoice to:
 - i. Designated health care providers providing services in a hospital emergency department and emergency medical services personnel, as that term is defined in § 32.1-111.1;
 - ii. Designated law enforcement officers, firefighters, employees of the Department of Corrections designated as probation and parole officers or as correctional officers as defined in § 53.1-1, and employees of regional jails, employees of the Department of Forensic Science, employees of the Office of the Chief Medical Examiner, employees of the Department of General Services Division of Consolidated Laboratory Services, school nurses, local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board, and other school board employees or individuals contracted by a school board to provide school health services who have successfully completed a training program; or
- iii. Persons who are acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal and who are authorized to dispense naloxone pursuant to §54.1-3408 (Y). Examples of such an organization may include non-profit entities, a community service board, or behavioral health authority. Such organization is not required to obtain a controlled substances registration (CSR) from the Board of Pharmacy if only dispensing intranasal or autoinjector formulations. If dispensing injectable formulations, along with hypodermic needles and syringes, then the organization must first obtain a CSR and the person dispensing such items shall first obtain authorization from the Department of Behavioral Health and

Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe.

It is recommended that the wholesale distributor, third party logistics provider, manufacturer, or pharmacy distributing naloxone first obtain confirmation from the entity that designated persons have completed any required training and that the entity has obtained a standing order, if necessary.

IV. Resources

- a. REVIVE! Pharmacy dispensing brochure
- b. Substance Abuse Mental Health Services Administration's "Opioid Prevention Toolkit" (2014), available at http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742
- c. Prescribe to Prevent, http://prescribetoprevent.org/pharmacists
- d. Harm Reduction Coalition, http://harmreduction.org/issues/overdose-prevention/tools-best-practices/od-kit-materials
- e. <u>Dispensers</u> may obtain kits to have on-hand for dispensing naloxone from the REVIVE! program at the Department of Behavioral Health and Developmental Services. To request kits, contact <u>REVIVE@dbhds.virginia.gov</u>

Virginia Board of Pharmacy

Naloxone Protocols

Virginia Code § 54.1-3408-(X) and (Y) authorize certain persons to dispense naloxone pursuant to an oral, written, or standing order and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. -This document contains the protocols which must be followed when dispensing naloxone pursuant to these subsections of law. -The protocols include information on the required elements of a standing order, instruction the recipient must receive, and labeling and recordkeeping requirements.

§54.1-3408

X. Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, a pharmacist, a health care provider providing services in a hospital emergency department, and emergency medical services personnel, as that term is defined in § 32.1-111.1, may dispense naloxone or other opioid antagonist used for overdose reversal and a person to whom naloxone or other opioid antagonist has been dispensed pursuant to this subsection may possess and administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life threatening opioid overdose. Lawenforcement officers as defined in § 9.1-101, employees of the Department of Forensic Science, employees of the Office of the Chief Medical Examiner, employees of the Department of General Services Division of Consolidated Laboratory Services, employees of the Department of Corrections designated as probation and parole officers or as correctional officers as defined in § 53.1-1, employees of regional jails, school nurses, local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board, other school board employees or individuals contracted by a school board to provide school health services, and firefighters who have completed a training program may also possess and administer naloxone or other opioid antagonist used for overdose reversal and may dispense naloxone or other opioid antagonist used for overdose reversal pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, an employee or other person acting on behalf of a public place who has completed a training program may also possess and administer naloxone or other opioid antagonist used for overdose reversal other than naloxone in an injectable formulation with a hypodermic needle or syringe in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

Notwithstanding any other law or regulation to the contrary, an employee or other person acting on behalf of a public place may possess and administer naloxone or other opioid antagonist, other than naloxone in an injectable formulation with a hypodermic needle or syringe, to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose if he has completed a training program on the administration of such naloxone and

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administers naloxone in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

For the purposes of this subsection, "public place" means any enclosed area that is used or held out for use by the public, whether owned or operated by a public or private interest.

Y. Notwithstanding any other law or regulation to the contrary, a person who is acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal may dispense naloxone to a person who has received instruction on the administration of naloxone for opioid overdose reversal, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber and (ii) in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. If the person acting on behalf of an organization dispenses naloxone in an injectable formulation with a hypodermic needle or syringe, he shall first obtain authorization from the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a odermic needle or syringe, and he shall obtain a controlled substance registration from the Board of Pharmacy. The Board of Pharmacy shall not charge a fee for the issuance of such controlled substance registration. The dispensing may a site other than that of the controlled substance registration provided the entity possessing the controlled substances registration maintains records in accordance with regulations of the Board of Pharmacy. No person who dispenses naloxone on behalf of an organization pursuant to this subsection shall charge a fee for the dispensing of naloxone that is greater than the cost to the organization of obtaining the naloxone dispensed. A person to whom naloxone has been dispensed pursuant to this subsection may possess naloxone and may administer naloxone to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

I. Protocol for the Prescribing and Dispensing of Naloxone by Persons Listed in 54.1-3408 (X)

a. Authorized Dispensers

The following individuals may dispense naloxone pursuant to an oral, written or standing order to a person to administer to another person believed to be experiencing or about to experience a life-threatening opioid overdose and shall follow this protocol when dispensing naloxone as authorized in subsection X of §54.1-3408:

- Pharmacists.
- Health care providers providing services in a hospital emergency department,
- Emergency medical services personnel as defined in § 32.1-111.1

And the following persons who have completed a training program:

- Law-enforcement officers as defined in § 9.1-101,
- Employees of the Department of Forensic Science,
- Employees of the Office of the Chief Medical Examiner,
- Employees of the Department of General Services Division of Consolidated Laboratory Services,
- Employees of the Department of Corrections designated as probation and parole officers or as correctional
 officers as defined in § 53.1-1,
- · Employees of regional jails,
- · School nurses,

Guidance Document: -110-44 Revised: March 30, 2023

Local health department employees that are assigned to a public school pursuant to an agreement between
the local health department and the school board,

- Other school board employees or individuals contracted by a school board to provide school health services,
- Firefighters, and
- Employees or other persons acting on behalf of a "public place" which means any enclosed area that is used
 or held out for use by the public, whether owned or operated by a public or private interest.

b. Required Training

i. Those persons listed above who must first complete a training program prior to dispensing naloxone shall complete training in accordance with policies and procedures of their employer or governing entity. Selection of or development of the training program is at the discretion of the employer or governing entity. The REVIVE! training program developed by the Department of Behavioral Health and Developmental Services is an available option.

c. Required Order

- i. Prior to dispensing naloxone, the dispenser shall receive an oral or written order issued by a prescriber for a specific person to receive naloxone or a standing order issued by an individual prescriber or the Health Commissioner that authorizes the dispenser to dispense naloxone. The prescriber may indicate on such orders that the order is valid and may be refilled for up to two years from the date of issuance. Except for pharmacists, persons authorized in 54.1-3408(X) shall only dispense formulations for intranasal administration or an autoinjector formulation.
- ii. If the naloxone is dispensed pursuant to a standing order, the standing order must contain the following information at a minimum:
 - 1. Name of entity or group of entities authorized to dispense naloxone pursuant to standing order;
 - Name of drug, strength, quantity to be dispensed, and directions for administration, as indicated in the chart below;
 - 3. Prescriber's signature;
 - 4. Date of issuance; and
 - 5. Amount of time, up to two years from date of issuance, for which the order is valid.

Intranasal	Auto-Injector	Intranasal	<u>Intranasal</u>
Naloxone 2mg/2ml prefilled syringe, # 2	Naloxone 2 mg or 5mg #1 twin pack	Naloxone Nasal Spray 4mg, #1 twin pack	Naloxone nasal spray 8mg, #1 twin pack
syringes Directions: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Directions: Use one auto-injector upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Directions: Administer a single spray intranasally into one nostril. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Directions: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional dose in other nostril using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.
Mucosal Atomization Device (MAD) # 2			

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SIG: Use as directed		
for naloxone		
administration.		
Must dispense with 2		
prefilled syringes and 2		
atomizers and		
instructions for		
administration.		

d. Required Labeling and Recordkeeping

- i. The dispenser shall affix a label to the naloxone container that bears the name and strength of the dispensed naloxone, directions as indicated on the oral, written, or standing order, name of prescriber, date of dispensing, and name and address or telephone of dispensing entity. The name of the recipient does not have to appear on the label. Optional items that may be dispensed that do not require labeling include rescue breathing masks and latex-free gloves.
- ii. The dispenser shall maintain a record of dispensing indicating the name of the recipient, the name, strength, and quantity of naloxone dispensed, date of dispensing, and name or initials of dispenser. Such record shall be maintained for two years from the date of dispensing.
- iii. The oral, written, or standing order must be maintained for two years from the last date of dispensing.
- iv. Unless a waiver has been granted by the Prescription Monitoring Program, pharmacies and physicians licensed to dispense shall report the dispensing to the Prescription Monitoring Program.

e. Required Instruction

i. The dispenser shall provide instruction to the recipient on opioid overdose prevention, overdose recognition, proper administration and dosing of naloxone, effectiveness and response following administration, adverse effects, safety, storage conditions, and expiration date. If the recipient refuses instruction, the instruction may be accomplished by providing the recipient with the current <u>REVIVE!</u> <u>Pharmacy dispensing brochure</u> available on the Department of Behavioral Health and Developmental Services website or by clicking on the link. If the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time, information or referrals to appropriate resources may be provided.

II. Protocol for the Prescribing of Naloxone and Dispensing by Persons Listed in 54.1-3408 (Y)

a. Authorized Dispensers

The following individuals who are acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone, e.g., non-profit organization, community service board, or behavioral health authority, may dispense naloxone pursuant to a standing order to a person to administer to another person believed to be experiencing or about to experience a life-threatening opioid overdose and shall follow this protocol when dispensing naloxone as authorized in subsection Y of §54.1-3408:

 A person who is acting on behalf of such organization may dispense formulations for intranasal administration or an autoinjector formulation;

A person who is authorized by the Department of Behavioral Health and Developmental Services to
train individuals on the proper administration of naloxone by and proper disposal of a hypodermic
needle or syringe may dispense formulations for intranasal administration, autoinjector formulation, or
an injectable naloxone formulation with a hypodermic needle or syringe, if the organization has
obtained a controlled substances registration from the Board of Pharmacy at no charge.

b. Training

- While it is recommended that those persons acting on behalf of such organization and who are dispensing naloxone formulations for intranasal administration or autoinjectors complete training in accordance with policies and procedures of their employer or governing entity, it is not a requirement of law. Selection of or development of the training program is at the discretion of the employer or governing entity. The REVIVE! training program developed by the Department of Behavioral Health and Developmental Services is an available option.
- Those persons acting on behalf of such organization and who intend to dispense injectable naloxone
 formulation with a hypodermic needle or syringe, must first complete training developed by and be
 authorized by the Department of Behavioral Health and Developmental Services to train individuals on
 the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe

c. Required Order

- i. Prior to dispensing naloxone, the dispenser shall receive a standing order issued by an individual prescriber that authorizes the dispenser to dispense naloxone. The standing order must contain the following information at a minimum:
 - 1. Name of organization authorized to dispense naloxone pursuant to standing order;
 - Name of drug, strength, quantity to be dispensed, and directions for administration, as indicated in the chart below;
 - If hypodermic needles and syringes are to be dispensed by an authorized trainer for administering such naloxone, the standing order must also specify the kind and quantity of hypodermic needles and syringes to be dispensed as outlined in the chart below;
 - 4. Prescriber's signature;
 - 5. Date of issuance; and
 - 6. Amount of time, up to two years from date of issuance, for which the order is valid.

Intranasal	Auto-	Intranasal	Injection*	<u>Intranasal</u>
Intranasal Naloxone 2mg/2ml prefilled syringe, # 2 syringes SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Dispenser must dispense 2 prefilled syringes and 2 atomizers and instructions	Auto-Injector Naloxone 2 mg or 5mg, #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Intranasal Naloxone Nasal Spray 4mg, #1 twin pack SIG: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Naloxone 0.4mg/ml _ #2 single-use 1 ml vials SIG: Inject 1 ml in shoulder or thigh upon signs of opioid overdose. Call 911. Repeat after 2-3 minutes if no or minimal response. #2 (3ml) syringe with 23-25 gauge 1-1.5 inch IM needles SIG: Use as directed for naloxone administration. Dispenser must dispense 2 single-use 1 ml vials, 2 (3ml) syringes and 2 (23-	Intranasal Naloxone nasal spray 8mg, #1 twin pack SIG: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional dose in other nostril using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may
for administration.		assistance arrives.	25 gauge) hypodermic needles for administration.	be given every 2 to 3 minutes until emergency medical assistance arrives.

d. Registration

An organization that intends to dispense an injectable naloxone formulation with a hypodermic needle or syringe must first obtain a controlled substances registration from the Board of Pharmacy at no charge. The application may be downloaded at http://www.dhp.virginia.gov/pharmacy/pharmacy forms.htm The person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and dispense naloxone for opioid overdose reversal must serve as the responsible party on the application. The prescriber issuing the standing order must serve as the supervising practitioner. An alarm system is not required for the controlled substances registration.

e. Required Labeling, Recordkeeping, and Storage

- i. The dispenser shall affix a label to the naloxone container that bears the name and strength of the dispensed naloxone, directions as indicated on the standing order, name of prescriber, date of dispensing, and name and address or telephone of dispensing entity. The name of the recipient does not have to appear on the label. Optional items that may be dispensed that do not require labeling include rescue breathing masks and latex-free gloves.
- ii. The dispenser shall maintain a record of dispensing indicating the name of the recipient, the name, strength, and quantity of naloxone dispensed, date of dispensing, and name or initials of dispenser. Such record shall be maintained for two years from the date of dispensing.
- iii. The standing order must be maintained for two years from the last date of dispensing.

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iv. If the dispenser is dispensing an injectable naloxone formulation with a hypodermic needle or syringe, the dispenser shall comply with the requirements of Board of Pharmacy Regulation 18VAC110-20-735, in lieu of the requirements listed above in section (i) and (ii).

v. The naloxone, hypodermic needles, and syringes shall be stored and transported under appropriate storage conditions in accordance with the manufacturer's directions to protect from adulteration and unlawful use.

f. Required Instruction

- i. The dispenser shall provide instruction to the recipient on opioid overdose prevention, overdose recognition, proper administration and dosing of naloxone, effectiveness and response following administration, adverse effects, safety, storage conditions, and expiration date. If the recipient refuses instruction, the instruction may be accomplished by providing the recipient with the current REVIVE! Pharmacy dispensing brochure available on the Department of Behavioral Health and Developmental Services website or the link above. If the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time, information or referrals to appropriate resources may be provided.
- ii. If the dispenser is dispensing an injectable naloxone formulation with a hypodermic needle or syringe, the dispenser shall also train the individual on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe.

III. Protocol for Pharmacies to Distribute Naloxone to Entities Authorized to Possess, Administer, and Dispense Naloxone

- a. In addition to a wholesale distributor, third party logistics provider, or manufacturer, a pharmacy may distribute naloxone via invoice to:
 - Designated health care providers providing services in a hospital emergency department and emergency medical services personnel, as that term is defined in § 32.1-111.1;
- ii. Designated law enforcement officers, firefighters, employees of the Department of Corrections designated as probation and parole officers or as correctional officers as defined in § 53.1-1, and employees of regional jails, employees of the Department of Forensic Science, employees of the Office of the Chief Medical Examiner, employees of the Department of General Services Division of Consolidated Laboratory Services, school nurses, local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board, and other school board employees or individuals contracted by a school board to provide school health services who have successfully completed a training program; or
- Persons who are acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal and who are authorized to dispense naloxone pursuant to §54.1-3408 (Y). Examples of such an organization may include non-profit entities, a community service board, or behavioral health authority. Such organization is not required to obtain a controlled substances registration (CSR) from the Board of Pharmacy if only dispensing intranasal or autoinjector formulations. If dispensing injectable formulations, along with hypodermic needles and syringes, then the organization must first obtain a CSR and the person dispensing such items shall first obtain authorization from the Department of Behavioral Health and

Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe.

It is recommended that the wholesale distributor, third party logistics provider, manufacturer, or pharmacy distributing naloxone first obtain confirmation from the entity that designated persons have completed any required training and that the entity has obtained a standing order, if necessary.

IV. Resources

- a. REVIVE! Pharmacy dispensing brochure
- b. Substance Abuse Mental Health Services Administration's "Opioid Prevention Toolkit" (2014), available at http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742
- c. Prescribe to Prevent, http://prescribetoprevent.org/pharmacists
- d. Harm Reduction Coalition, http://harmreduction.org/issues/overdose-prevention/tools-best-practices/od-kit-materials
- e. <u>Dispensers</u> may obtain kits to have on-hand for dispensing naloxone from the REVIVE! program at the Department of Behavioral Health and Developmental Services. To request kits, contact REVIVE@dbhds.virginia.gov

Agenda Item: Amend Statewide Protocols for Vaccines for Adults and Three Years of Age or Older

Included in your agenda package are:

- Draft amendments of Vaccine Statewide Protocol for Persons Three Years of Age or Older
- Draft amendments of Vaccine Statewide Protocol for Persons Eighteen Years of Age or Older

Staff Note:

• Following the last meeting, staff received feedback that the 20 hours of ACPE-accredited vaccine training required in the PREP Act is specifically for pharmacists, not pharmacy technicians or pharmacy interns. The suggested amendments conform the language to the training requirements in the PREP Act for pharmacy technicians and pharmacy interns.

Action Needed:

 Motion to amend Vaccine Statewide Protocol for Persons Three Years of Age or Older and Vaccine Statewide Protocol for Persons Eighteen Years of Age or Older as presented or amended.

Adopted: 9/24/2021 Revised: 3/30/2023

Effective:

VIRGINIA BOARD OF PHARMACY

Pharmacist Vaccine Statewide Protocol <u>for Persons</u> <u>Eighteen Years of Age or Older</u>

Consistent with the Immunization Schedule published by the Centers for Disease Control and Prevention (CDC) or current emergency use authorization from the U.S. Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the vaccines to persons 18 years of age or older.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering vaccine under this protocol, the pharmacist shall be knowledgable of the manufacturer's instructions for use or instructions indicated in the emergency use authorization, the current Immunization Schedule published by the CDC, how to properly identify which vaccines a patient may require, storage and handling requirements, and how to counsel the patient on possible adverse reactions. The pharmacist shall also have a current certificate in basic cardiopulmonary resuscitation.

PHARMACY TECHNICIAN AND PHARMACY INTERN TRAINING

Prior to administering a vaccine, a pharmacy technician, pharmacy technician trainee, or pharmacy intern shall have completed a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education ("ACPE"). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines. The pharmacy technician, pharmacy technician trainee, or pharmacy intern shall also have a current certificate in basic cardiopulmonary resuscitation.

PATIENT INCLUSION CRITERIA

Pharmacist shall review applicable medical history prior to administering vaccine to ensure vaccine administration is appropriate for patient's medical condition(s), e.g., pregnancy, immunocompromised state. Patients eligible for vaccine under this protocol:

- An individual, 18 years of age or older, whose immunization history is incomplete or unknown and for whom a vaccine is recommended at his or her age in accordance with the most current Child and Adolescent Immunization Schedule or the Adult Immunization Schedule <u>published by the CDC</u> inclusive of additional information for COVID-19 vaccination;
- An individual, 18 years of age or older, whose immunization history is incomplete or unknown and for whom a vaccine with current emergency use authorization from the U.S. Food and Drug Administration is recommended by the CDC; and,
- An individual, 18 years of age or older, preparing to travel to a destination for which immunization history is incomplete or unknown and for whom a vaccine is recommended by the CDC prior to traveling to the specific destination.

Adopted: 9/24/2021 Revised: 3/30/2023

Effective:

PATIENT EXCLUSION CRITERIA

Patients NOT eligible for vaccine under this protocol:

- An individual less than 18 years of age;
- An individual for whom a vaccine is not recommended by the CDC such as based on the patient's medical condition(s); or
- An individual who has received all CDC recommended doses for their age, medical condition or other indicators.

COUNSELING

The pharmacist shall ensure the patient or patient's agent is provided with written information regarding the vaccine and possible adverse reactions.

RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46 and report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and 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.

Effective: Upon Expiration of PREP Act -10/1/2024

VIRGINIA BOARD OF PHARMACY

Vaccine Statewide Protocol <u>for Persons</u> <u>Three Years of Age or Older</u>

(Effective upon the expiration of the provisions of the federal Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 related to the vaccination and COVID-19 testing of minors.)

Consistent with the Immunization Schedule published by the Centers for Disease Control and Prevention ("CDC") or current emergency use authorization from the U.S. Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer, or may direct a pharmacy technician or pharmacy intern under the supervision of the pharmacist to administer vaccines to persons 3 years of age or older.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with a patient, dispensing, or administering vaccines under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use or instructions indicated in the emergency use authorization, the current Immunization Schedule published by the CDC, how to properly identify which vaccines a patient may require, storage and handling requirements, and how to counsel the patient on possible adverse reactions. The pharmacist shall also have a current certificate in basic cardiopulmonary resuscitation.

PHARMACY TECHNICIAN AND PHARMACY INTERN TRAINING

Prior to administering a vaccine, a pharmacy technician, pharmacy technician trainee, or pharmacy intern shall have completed a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education ("ACPE"). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines. The pharmacy technician, pharmacy technician trainee, or pharmacy intern shall also have a current certificate in basic cardiopulmonary resuscitation.

a practical training program that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines.

PATIENT INCLUSION CRITERIA

The pharmacist shall review applicable medical history prior to administering a vaccine to ensure the vaccine administration is appropriate for the patient's medical condition(s) (e.g., pregnancy or immunocompromised state). The following patients are eligible for vaccines under this protocol:

- An individual 3 years of age or older whose immunization history is incomplete or unknown and for whom a vaccine is recommended at his or her age in accordance with the most current Child and Adolescent Immunization Schedule or the Adult Immunization Schedule published by the CDC inclusive of additional information for COVID-19 vaccination.
- An individual 3 years of age or older whose immunization history is incomplete or unknown

1

- and for whom a vaccine with current emergency use authorization from the U.S. Food and Drug Administration is recommended by the CDC; and,
- An individual 3 years of age or older preparing to travel to a destination for which immunization history is incomplete or unknown and for whom a vaccine is recommended by the CDC prior to traveling to the specific destination.



Effective: Upon Expiration of PREP Act -10/1/2024

PATIENT EXCLUSION CRITERIA

The following patients are NOT eligible for vaccines under this protocol:

- An individual less than 3 years of age;
- An individual for whom a vaccine is not recommended by the CDC for reasons such as based on the patient's medical condition(s); or
- An individual who has received all CDC recommended doses for their age, medical condition or other indicators.

COUNSELING

The pharmacist shall ensure the patient or patient's agent is provided with written information regarding the vaccine and possible adverse reactions.

RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46 and report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and 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. A pharmacist who administers a vaccination to a minor shall provide written notice to the minor's parent or guardian that the minor should visit a pediatrician annually.



Virginia's Pharmacist Workforce: 2022

Healthcare Workforce Data Center

February 2022

Virginia Department of Health Professions
Healthcare Workforce Data Center
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233
804-597-4213, 804-527-4466 (fax)
E-mail: HWDC@dhp.virginia.gov

Follow us on Tumblr: www.vahwdc.tumblr.com

Get a copy of this report from:

http://www.dhp.virginia.gov/PublicResources/HealthcareWorkforceDataCenter/ProfessionReports/

15,296 Pharmacists voluntarily participated in this survey. Without their effort, the work of the center would not be possible. The Department of Health Professions, the Healthcare Workforce Data Center, and the Board of Pharmacy express our sincerest appreciation for their ongoing cooperation.

Thank You!

Virginia Department of Health Professions

Arne W. Owens, MS *Director*

James L. Jenkins, Jr., RN Chief Deputy Director

Healthcare Workforce Data Center Staff:

Yetty Shobo, PhD Director Barbara Hodgdon, PhD Deputy Director Rajana Siva, MBA Data Analyst Christopher Coyle, BS Research Assistant

The Board of Pharmacy

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Patricia Lynn Richards-Spruill Suffolk

> Ling Yuan Glen Allen

Executive Director

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The Pharmacist Workforce: At a Glance:

The Workforce
Licensees: 16,671
Virginia's Workforce: 8,965

FTEs: 7,394

Survey Response Rate

All Licensees: 92% Renewing Practitioners: 97%

Demographics

Female: 67% Diversity Index: 54% Median Age: 44

Background

Rural Childhood: 32% HS Degree in VA: 47% Prof. Degree in VA: 48%

Education

Baccalaureate: 29% Pharm.D./Professional: 71%

Finances

Median Inc.: \$120k-\$130k Health Benefits: 69% Under 40 w/ Ed debt: 69%

ource: Va. Healthcare Workforce Data Center

Current Employment

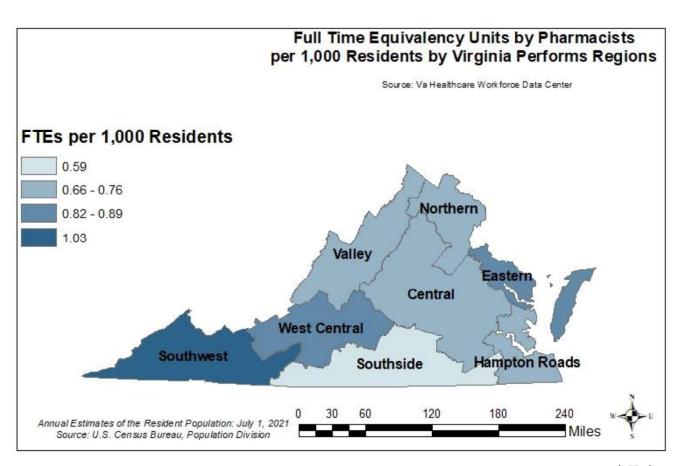
Employed in Prof.: 91% Hold 1 Full-time Job: 73% Satisfied?: 86%

Job Turnover

Switched Jobs in 2022: 6% Employed over 2 yrs.: 58%

Primary Roles

Patient Care: 73% Administration: 8% Education: 1%



Results in Brief

A total of 15,296 pharmacists voluntarily took part in the 2022 Pharmacist Workforce Survey. The Virginia Department of Health Professions' Healthcare Workforce Data Center (HWDC) administers the survey during the license renewal process, which takes place every December for pharmacists. These survey respondents represent 92% of the 16,671 pharmacists who are licensed in the state and 97% of renewing practitioners. The HWDC estimates that the 8,965 pharmacists in the Virginia's workforce during the survey period provided 7,394 full-time equivalency units (FTE).

The majority of Virginia's pharmacists are female, and the median age among those in the workforce is 44. Almost one-third of pharmacists grew up in a rural area, and close to one-quarter of these professionals currently work in non-metro areas of the state. Overall, 11% of Virginia's pharmacists work in a non-metro area. 71% of Virginia's pharmacist workforce have earned a doctorate or other professional degree as their highest educational attainment. Further, 42% of pharmacists currently carry educational debt. Furthermore, nearly seven out of ten of those under the age of 40 carry education debt. The median debt for those pharmacists with educational debt is between \$120,000 and \$130,000.

More than nine out of every ten pharmacists are currently employed in the profession, with 73% holding one full-time position. Over the past year, 1% of pharmacists were involuntarily unemployed, while another 2% were underemployed. The typical pharmacist earned between \$120,000 and \$130,000 in 2022. Around 86% of all pharmacists are satisfied with their current employment situation, including 44% who indicated that they are "very satisfied".

About 91% of all pharmacists work in the private sector, including 63% who work at a for-profit organization. Large chain pharmacies (i.e., pharmacies with more than 11 stores) were the most common working establishment type for Virginia's pharmacist workforce, employing 26% of all professionals. Hospital systems and smaller pharmacies were also common employers. About 48% of pharmacists expect to retire by the age of 65 and 7% of the current workforce expect to retire in the next two years. Half of the current workforce expect to retire by 2047.

Summary of Trends

The total number of licensed pharmacists has grown by almost 31% since 2013. Of these, the number working in the state workforce has also increased but the increase of 13% is modest by comparison. Additionally, the 8% increase in FTE provided in state by pharmacists between 2013 and 2022 is an even more modest increase.

The diversity index of Virginia's pharmacists increased from 47% in 2013 to 53% in 2021 and increased slightly in 2022 to 54%. The percentage of pharmacists who are female also continued increasing, from 62% in 2013 to 67% in 2022, though the percentage of female pharmacists did not change between 2021 and 2022. Median age has been relatively stable between 44 to 45 years in the past eight surveys. The percent under age 40, increased from 37% in 2013 to 40% in 2016, and stayed the same until 2021. Then, from 2021 to 2022 the percentage decreased from 40% to 39%.

Educational attainment continues to increase in the pharmacist workforce. In 2013, only 51% had a pharmacy doctorate compared to 71% in 2022. Alongside increasing educational attainment, the percent reporting educational debt has also increased from 35% in 2013 to 42% in 2021. Further, the median educational debt, which increased from \$90K-\$100K in 2013 to \$110K-\$120K in 2018, is now \$120K-\$130K.

The percent involuntarily unemployed has remained at 1% since 2021, which suggests a recovery of the impact of the pandemic. Further, around 91% reported being employed in the profession and the current involuntary unemployment rate in December 2021, when the survey took place, was 1%. Median income has been stable at \$120K to \$130K between 2016 and 2022 after increasing from \$110K-\$120K in 2013. However, the percent earning above \$140,000 increased from 17% in 2016 to 31% in 2022; only 12% were in that income range in 2013. Job satisfaction has increased to 86% in 2022 when it had previously been at its lowest level (83%) in 2021. This was driven by pharmacists who reported being very satisfied with their job who increased from 42% in 2021 to 44% in 2022.

Pharmacists intending to retire in the next decade increased from 22% in the pre-2017 surveys to 25% in 2022. Regarding future plans, only 7% intended to pursue additional education in 2022 compared to 13% in 2013.

Licensee Counts						
License Status	#	%				
Renewing Practitioners	15,079	90%				
New Licensees	811	5%				
Non-Renewals	781	5%				
All Licensees	16,671	100%				

Source: Va. Healthcare Workforce Data Center

HWDC surveys tend to achieve very high response rates. 97% of renewing pharmacists submitted a survey. These represent 92% of pharmacists who held a license at some point in 2022.

Response Rates						
Statistic	Non Respondents	Respondent	Response Rate			
By Age						
Under 30	102	705	87%			
30 to 34	195	2,253	92%			
35 to 39	197	2,709	93%			
40 to 44	172	2,182	93%			
45 to 49	132	1,824	93%			
50 to 54	127	1,761	93%			
55 to 59	98	1,416	94%			
60 and Over	352	2,446	87%			
Total	1,375	15,296	92%			
New Licenses						
Issued in 2022	223	588	73%			
	Metro Sta	atus				
Non-Metro	88	1,063	92%			
Metro	582	8,242	93%			
Not in Virginia	705	5,991	89%			

Source: Va. Healthcare Workforce Data Center

At a Glance:

Licensed Pharmacists

Number: 16,671 New: 5% Not Renewed: 5%

Survey Response Rates

All Licensees: 92% Renewing Practitioners: 97%

Source: Va. Healthcare Workforce Data Cente

Response Rates	
Completed Surveys	15,296
Response Rate, all licensees	92%
Response Rate, Renewals	97%

Source: Va. Healthcare Workforce Data Center

Definitions

- **1. The Survey Period:** The survey was conducted in December 2022.
- 2. Target Population: All pharmacists who held a Virginia license at some point in 2022.
- 3. Survey Population: The survey was available to those who renewed their licenses online. It was not available to those who did not renew, including some pharmacists newly licensed in 2022.

Workforce

Pharmacist Workforce: 8,965 FTEs: 7,394

Utilization Ratios

Licensees in VA Workforce: 54% Licensees per FTE: 2.25 Workers per FTE: 1.21

Source: Va. Healthcare Workforce Data Center

Virginia's Pharmacist Workforce					
Status	#	%			
Worked in Virginia in Past Year	8,715	97%			
Looking for Work in Virginia	250	3%			
Virginia's Workforce	8,965	100%			
Total FTEs	7,394				
Licensees	16,671				

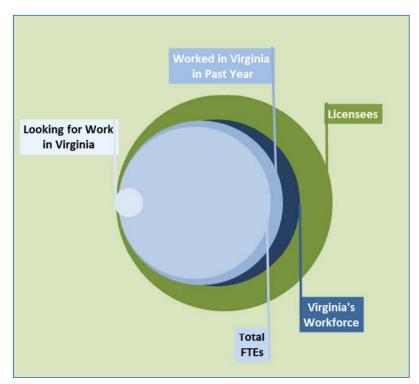
Source: Va. Healthcare Workforce Data Center

This report uses weighting to estimate the figures in this report. Unless otherwise noted, figures refer to the Virginia Workforce only. For more information on HWDC's methodology visit:

www.dhp.virginia.gov/hwdc

Definitions

- 1. Virginia's Workforce: A licensee with a primary or secondary work site in Virginia at any time in the past year or who indicated intent to return to Virginia's workforce at any point in the future.
- **2. Full Time Equivalency Unit (FTE):** The HWDC uses 2,000 hours (40 hours for 50 weeks with 2 weeks off) as its baseline measure for FTEs.
- **3.** Licensees in VA Workforce: The proportion of licensees in Virginia's Workforce.
- **4.** Licensees per FTE: An indication of the number of licensees needed to create 1 FTE. Higher numbers indicate lower licensee participation.
- 5. Workers per FTE: An indication of the number of workers in Virginia's workforce needed to create 1 FTE. Higher numbers indicate lower utilization of available workers.



Source: Va. Healthcare Workforce Data Center

Age & Gender							
	Ma	ale	Fe	male	To	Total	
Age	#	% Male	#	% Female	#	% in Age Group	
Under 30	128	24%	398	76%	526	7%	
30 to 34	300	28%	791	73%	1,091	15%	
35 to 39	362	32%	786	69%	1,148	16%	
40 to 44	257	28%	661	72%	918	13%	
45 to 49	250	32%	524	68%	774	11%	
50 to 54	221	28%	569	72%	789	11%	
55 to 59	230	34%	445	66%	675	9%	
60 +	590	49%	605	51%	1,195	17%	
Total	2,339	33%	4,778	67%	7,117	100%	

Source: Va. Healthcare Workforce Data Center

Race & Ethnicity						
Race/	Virginia*	Pharmacists		Pharmacists Under 40		
Ethnicity	%	#	%	#	%	
White	60%	4,543	64%	1,638	59%	
Black	19%	816	11%	305	11%	
Asian	7%	1,387	19%	647	23%	
Other Race	0%	118	2%	43	2%	
Two or more races	3%	123	2%	61	2%	
Hispanic	10%	133	2%	66	2%	
Total	100%	7,120	100%	2,760	100%	

^{**} Population data in this chart is from the U.S. Census, Annual Estimates of the Resident Population by Sex, Race, and Hispanic Origin for the United States, States, and Counties: July 1, 2021.

Source: Va. Healthcare Workforce Data Center

39% of pharmacists are under the age of 40, and 71% of these professionals are female. In addition, pharmacists who are under the age of 40 are just as diverse as Virginia's overall population.

At a Glance:

Gender

% Female: 67% % Under 40 Female: 71%

Age

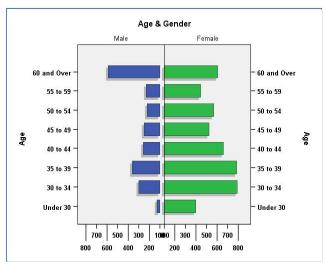
Median Age: 44 % Under 40: 39% % 55+: 26%

Diversity

Diversity Index: 54% Under 40 Div. Index: 58%

Source: Va. Healthcare Workforce Data Centi

In a chance encounter between two pharmacists, there is a 54% chance that they would be of a different race/ethnicity (a measure known as the Diversity Index). For Virginia's population as a whole, the comparable number is 58%.

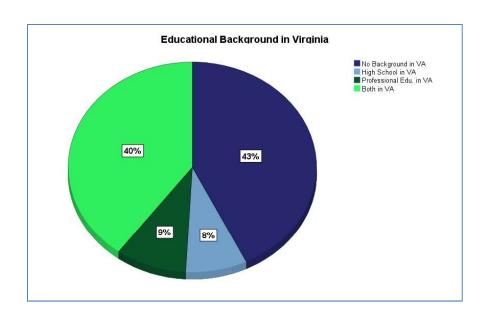


At a Glance: **Childhood Urban Childhood:** 16% Rural Childhood: 32% Virginia Background HS in Virginia: 47% Prof. Education in VA: 48% HS/Prof. Educ. in VA: 57% **Location Choice** % Rural to Non-Metro: 23% % Urban/Suburban to Non-Metro: 5%

A Closer Look:

Primary Location: Rural Status of Childhoo						
USE	OA Rural Urban Continuum		Location			
Code	Description	Rural	Suburban	Urban		
	Metro Cour	nties				
1	Metro, 1 million+	21%	59%	20%		
2	Metro, 250,000 to 1 million	53%	41%	6%		
3	Metro, 250,000 or less	41%	46%	12%		
	Non-Metro Counties					
4	Urban pop 20,000+, metro adjacent	56%	34%	10%		
6	Urban pop, 2,500-19,999, metro adjacent	61%	30%	8%		
7	Urban pop, 2,500-19,999, non adjacent	89%	8%	4%		
8	Rural, metro adjacent	57%	39%	4%		
9	Rural, non adjacent	72%	23%	5%		
	Overall	32%	52%	16%		

Source: Va. Healthcare Workforce Data Center



32% of pharmacists grew up in self-described rural areas, and 23% of these professionals currently work in nonmetro counties. Overall, 11% of Virginia's pharmacist workforce currently work in nonmetro counties.

Top Ten States for Pharmacy Recruitment

Rank	All Pharmacists					
Nalik	High School	#	Professional School	#		
1	Virginia	3,307	Virginia	3,339		
2	Outside U.S./Canada	865	Pennsylvania	467		
3	Pennsylvania	406	Outside U.S./Canada	337		
4	New York	330	North Carolina	321		
5	Maryland	209	Maryland	242		
6	North Carolina	197	New York	232		
7	West Virginia	189	West Virginia	201		
8	New Jersey	140	Massachusetts	193		
9	Ohio	131	Washington, D.C.	174		
10	Florida	116	Tennessee	140		

47% of Virginia's pharmacists received their high school degree in Virginia, and 48% received their initial professional degree in the state.

Source: Va. Healthcare Workforce Data Center

Among pharmacists who have been licensed in the past five years, 41% received their high school degree in Virginia, and 42% received their initial professional degree in the state.

Pank	Licensed in the Past 5 Years				
Naiik	High School	#	Professional School	#	
1	Virginia	678	Virginia	678	
2	Outside U.S./Canada	210	Pennsylvania	108	
3	Pennsylvania	89	North Carolina	101	
4	North Carolina	70	Maryland	81	
5	New York	66	Tennessee	78	
6	Maryland	65	Outside U.S./Canada	76	
7	Florida	41	West Virginia	55	
8	Ohio	34	New York	43	
9	Tennessee	33	Massachusetts	39	
10	West Virginia	32	Ohio	36	

Source: Va. Healthcare Workforce Data Center

46% of Virginia's licensed pharmacists did not participate in Virginia's workforce in 2022. 92% of these professionals worked at some point in the past year, including 84% who currently work as pharmacists.

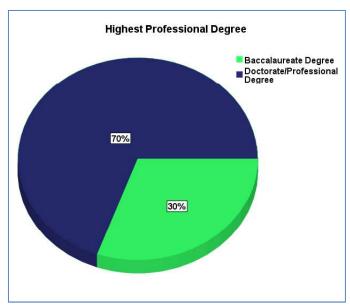
At a Glance:

Not in VA Workforce

Total: 7,705 % of Licensees: 46% Federal/Military: 8% VA Border State/DC: 16%

Highest Professional Degree						
Degree # %						
B.S. Pharmacy	1,968	29%				
Pharm.D. 4,855 71%						
Total 6,823 100%						

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

42% of pharmacists currently have educational debt, including 69% of those under the age of 40. For those with educational debt, the median debt is between \$120,000 and \$130,000. Among those under the age of 40 with debt, median is \$150,000 to \$160,000.

At a Glance:

Education

B.S. Pharmacy: 29% Pharm.D.: 71%

Educational Debt

Carry debt: 42% Under age 40 w/ debt: 69% Median debt: \$120k-\$130k

Cource: Va. Healthcare Workforce Data Center

71% of pharmacists hold a Doctorate in Pharmacy as their highest professional degree, while all remaining professionals have earned a Bachelor's degree in Pharmacy.

Educational Debt						
	All			Pharmacists		
Amount Carried	Pharm	nacists	Unde	er 40		
	#	%	#	%		
None	3,258	58%	654	31%		
\$20,000 or less	157	3%	55	3%		
\$20,001-\$40,000	192	3%	58	3%		
\$40,001-\$60,000	201	4%	89	4%		
\$60,001-\$80,000	166	3%	79	4%		
\$80,001-100,000	182	3%	108	5%		
\$100,001-\$120,000	154	3%	105	5%		
\$120,001-\$140,000	164	3%	114	5%		
\$140,001-\$160,000	165	3%	126	6%		
\$160,001-\$180,000	165	3%	127	6%		
\$180,001-\$200,000	143	3%	116	5%		
Over \$200,000	650 12%		502	24%		
Total	5,597	100%	2,133	100%		

Top Specialties

Immunization: 15%
Community Pharmacy: 8%
Ambulatory Care: 4%

Top Board Certifications

BPS - Pharmacotherapy: 6%BPS - Ambulatory Care: 1%BCGP - Geriatrics: 1%

Top Residencies (PGY1)

Pharmacy Practice

(Post 1993): 12% Community Pharmacy: 5%

Pharmacy Practice

(Pre 1993): 3%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

PGY1		
Residency	#	%
Pharmacy Practice (Post 1993)	1,041	12%
Community Pharmacy	434	5%
Pharmacy Practice (Pre 1993)	277	3%
Managed Care Pharmacy	35	<1%
Total	1,787	20%
PGY2		
Ambulatory Care	113	1%
Critical Care	61	1%
Internal Medicine/Cardiology	45	1%
Infectious Disease	40	<1%
Pediatrics	34	<1%
Oncology	33	<1%
Health-system Pharmacy Administration	32	<1%
Psychiatry	26	<1%
Drug Information	21	<1%
Solid Organ Transplant	20	<1%
Emergency Medicine	18	<1%
Pharmacotherapy	17	<1%
Geriatrics	17	<1%
Other	147	2%
At Least One	624	7%

Source: Va. Healthcare Workforce Data Center

Board Certifications			
Certification	#	%	
BPS-Pharmacotherapy	535	6%	
BPS-Ambulatory Care	107	1%	
BCGP-Geriatrics	83	1%	
BPS-Oncology	41	<1%	
BPS- Psychiatric	25	<1%	
BPS- Nutrition	10	<1%	
BPS-Nuclear Pharmacy	9	<1%	
ABAT-Applied Toxicology	3	<1%	
Other Board Certification	261	3%	
At Least One Certification	976	11%	

Source: Va. Healthcare Workforce Data Center

11% of pharmacists hold a board certification, including 6% who hold a certification in Pharmacotherapy. 31% also have a self-designated specialty area, including 15% who have a specialization in immunization.

Top ServicesImmunization:31%Medication Management:26%Compounding:21%

Disease Management

Anticoagulation: 15% Diabetes: 1%

Source: Va. Healthcare Workforce Data Center

Services Provided				
Services	Primary		Secon	dary
	#	%	#	%
Primary Service, Immunization	2,751	31%	2,751	31%
Primary Service, Medication Therapy Management	2,332	26%	305	3%
Primary Service, Compounding	1,895	21%	209	2%
Primary Service, Central Filling	1,077	12%	151	2%
Primary Service, Remote Order Processing	986	11%	103	1%
Primary Service, Collaborative Practice Agreement	594	7%	90	1%
At Least One	4,428	49%	2,987	33%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Disease Management in Collaborative Practice			
	#	%	
Anticoagulation	249	42%	
Diabetes	239	40%	
Hypertension	216	36%	
Hypercholesterolemia	200	34%	
Tobacco Cessation	162	27%	
Asthma	128	22%	
Travel Medications	74	12%	
At least one	383	64%	

Source: Va. Healthcare Workforce Data Center

64% of the 383 pharmacists with a collaborative practice agreement were involved in providing at least one disease management service; anticoagulation management was the most commonly reported by 42% of those with the agreement. 19% of pharmacists in the state workforce also utilized at least one of the listed statewide protocols.

Statewide Protocols				
	#	%		
Naloxone	1,589	18%		
Lowering Out-of-Pocket Expenses	356	4%		
Epinephrine	272	3%		
Emergency Contraception	198	2%		
Hormonal Contraception	145	2%		
Prenatal Vitamins	129	1%		
At Least One	1,729	19%		

Employment

Employed in Profession: 91% Involuntarily Unemployed: 1%

Positions Held

1 Full-time: 73% 2 or More Positions: 8%

Weekly Hours:

40 to 49: 52% 60 or more: 5% Less than 30: 12%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Current Work Status			
Status	#	%	
Employed, capacity unknown	2	<1%	
Employed in a pharmacy-related capacity	6,227	91%	
Employed, NOT in a pharmacy-related capacity	277	4%	
Not working, reason unknown	0	0%	
Involuntarily unemployed	36	1%	
Voluntarily unemployed	177	3%	
Retired	136	2%	
Total	6,855	100%	

Source: Va. Healthcare Workforce Data Center

91% of Virginia's pharmacists are currently employed in the profession, and 1% of all pharmacy professionals are involuntarily unemployed at the survey period. 73% of the state's pharmacist workforce have one full-time job, while 8% of pharmacists have multiple positions. 52% of pharmacists work between 40 and 49 hours per week, while 5% of pharmacy professionals work at least 60 hours per week.

Current Positions			
Positions	#	%	
No Positions	349	5%	
One Part-Time Position	909	14%	
Two Part-Time Positions	128	2%	
One Full-Time Position	4,895	73%	
One Full-Time Position & One Part-Time Position	393	6%	
Two Full-Time Positions	5	0%	
More than Two Positions	34	1%	
Total	6,713	100%	

Source: Va. Healthcare Workforce Data Center

Current Weekly Hours			
Hours	#	%	
0 hours	349	5%	
1 to 9 hours	164	2%	
10 to 19 hours	235	4%	
20 to 29 hours	413	6%	
30 to 39 hours	1,285	19%	
40 to 49 hours	3,428	52%	
50 to 59 hours	481	7%	
60 to 69 hours	180	3%	
70 to 79 hours	61	1%	
80 or more hours	59	1%	
Total	6,655	100%	

Inc	ome	
Annual Income	#	%
Volunteer Work Only	51	1%
\$50,000 or less	376	8%
\$50,001-\$60,000	115	2%
\$60,001-\$70,000	99	2%
\$70,001-\$80,000	128	3%
\$80,001-\$90,000	128	3%
\$90,001-\$100,000	208	4%
\$100,001-\$110,000	448	9%
\$110,001-\$120,000	489	10%
\$120,001-\$130,000	713	14%
\$130,001-\$140,000	687	14%
\$140,001-\$150,000	552	11%
More than \$150,000	1,013	20%
Total	5,007	100%

At a Glance:

Annual Income

Median Income: \$120k-130k

Benefits

Employer Retirement: 69%

Employer Health

Insurance: 69%

Satisfaction

Satisfied: 86% Very Satisfied: 44%

Source: Va. Healthcare Workforce Data Cente

Source: Va. Healthcare Workforce Data Center

Job Satisfaction			
Level	#	%	
Very Satisfied	2895	44%	
Somewhat Satisfied	2781	42%	
Somewhat Dissatisfied	628	10%	
Very Dissatisfied	292	4%	
Total	6,596	100%	

Source: Va. Healthcare Workforce Data Center

The typical pharmacist earned between \$120,000 and \$130,000 in 2022. Among pharmacists who received either an hourly wage or a salary as compensation at their primary work location, 69% received health insurance and 69% also had access to a retirement plan.

Employer-Sponsored Benefits				
Benefit	#	%	% of Wage/Salary Employees	
Paid Vacation Leave	4,650	75%	78%	
Retirement	4,149	67%	69%	
Health Insurance	4,108	66%	69%	
Dental Insurance	3,986	64%	67%	
Paid Sick Leave	3,513	56%	59%	
Group Life Insurance	2,886	46%	49%	
Signing/Retention Bonus	521	8%	9%	
Received At Least One Benefit	4,948	79%	82%	

^{*}From any employer at time of survey.

Source: Va. Healthcare Workforce Data Center

Underemployment in Past Year		
In the past year did you?	#	%
Experience Involuntary Unemployment?	80	1%
Experience Voluntary Unemployment?	280	3%
Work Part-time or temporary positions, but would have preferred a full-time/permanent position?	220	2%
Work two or more positions at the same time?	723	8%
Switch employers or practices?	541	6%
Experienced at least 1	1,532	17%

Source: Va. Healthcare Workforce Data Center

1% of Virginia's pharmacists experienced involuntary unemployment at some point in 2022. By comparison, Virginia's average monthly unemployment rate was 2.9%.¹

Location Tenure							
Tanuna	Prin	nary	Seco	ndary			
Tenure	#	%	#	%			
Not Currently Working at this Location	129	2%	71	8%			
Less than 6 Months	632	10%	118	13%			
6 Months to 1 Year	625	10%	106	12%			
1 to 2 Years	1,244	20%	168	19%			
3 to 5 Years	1,225	19%	200	22%			
6 to 10 Years	951	15%	111	12%			
More than 10 Years	1,521	24%	128	14%			
Subtotal	6,326	100%	902	100%			
Did not have location	312		8,022				
Item Missing	2,327		40				
Total	8,965		8,965				

Source: Va. Healthcare Workforce Data Center

Half of all pharmacists receive a salary or commission at their primary work location, while 44% receive an hourly wage.

At a Glance:

Unemployment Experience

Involuntarily Unemployed: 1% Underemployed: 2%

Stability

Switched: 6%
New Location: 23%
Over 2 years: 58%
Over 2 yrs, 2nd location: 49%

Employment Type

Salary or Wage: 94%

Source: Va. Healthcare Workforce Data Cente

58% of pharmacists have worked at their primary location for more than 2 years—the job tenure normally required to get a conventional mortgage loan.

Employment Type					
Primary Work Site	#	%			
Salary/ Commission	2,865	50%			
Hourly Wage	2,503	44%			
By Contract	54	1%			
Business/ Practice Income	245	4%			
Unpaid	26	0%			
Subtotal	5,692	100%			

¹ As reported by the U.S. Bureau of Labor Statistics. The non-seasonally adjusted monthly unemployment rate fluctuated between a low of 2.5% and a high of 3.4%. The unemployment rate from December 2022 was still preliminary at the time of publication.

Concentration

Top Region:26%Top 3 Regions:71%Lowest Region:1%

Locations

2 or more (2021): 10% 2 or more (Now*): 13%

Source: Va. Healthcare Workforce Data Cente

Over half of all pharmacists in the state work in either Northern Virginia or Central Virginia.

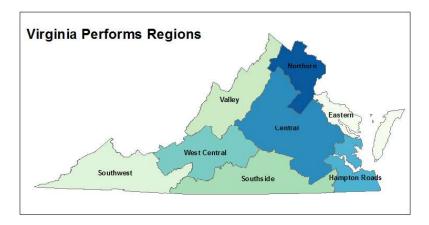
Number of Work Locations						
Locations	Wo Locati 20	ons in	Work Locations Now*			
	#	%	#	%		
0	308	3%	340	5%		
1	7,717	86%	5,373	82%		
2	524	6%	513	8%		
3	280	3%	227	4%		
4	23	0%	15	0%		
5	23	0%	12	0%		
6 or More	90	1%	73	1%		
Total	8,965	100%	6,554	100%		

*At the time of survey completion, December 2022. Source: Va. Healthcare Workforce Data Center

A Closer Look:

Regional Distribution of Work Locations							
Virginia Performs		nary ation	Secondary Location				
Region	#	%	#	%			
Central	1,643	26%	183	20%			
Eastern	88	1%	16	2%			
Hampton Roads	1,133	18%	162	18%			
Northern	1,714	27%	206	23%			
Southside	204	3%	32	4%			
Southwest	367	6%	57	6%			
Valley	371	6%	53	6%			
West Central	678	11%	100	11%			
Virginia Border State/DC	31	0%	34	4%			
Other US State	58	1%	64	7%			
Outside of the US	1	0%	1	0%			
Total	6,288	100%	908	100%			
Item Missing	2,364		35				

Source: Va. Healthcare Workforce Data Center



Over the past year, 10% of Virginia's pharmacists worked at multiple locations.

Location Sector						
	Prin	nary	Seco	ndary		
Sector	Loca	ition	Loca	ition		
	#	%	#	%		
For-Profit	3,682	63%	575	68%		
Non-Profit	1,604	28%	212	25%		
State/Local Government	218	4%	33	4%		
Veterans Administration	135	2%	2	0%		
U.S. Military	104	2%	11	1%		
Other Federal Gov't	88	2%	9	1%		
Total	5,831	100%	842	100%		
Did not have location	312		8,022			
Item Missing	2,821		101			

Source: Va. Healthcare Workforce Data Center

At a Glance: (Primary Locations)

Sector

For Profit: 63% Federal: 6%

Top Establishments

Large Chain Pharmacy: 26%

(11+ Stores)

Hospital/Health System: 26%

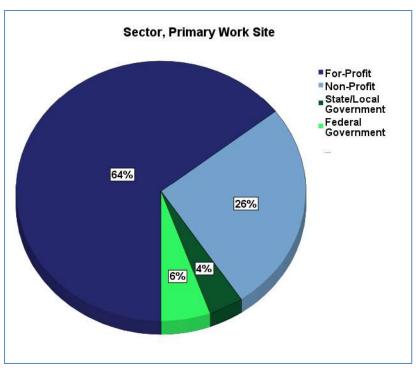
(Inpatient)

Independent Pharmacy: 9%

(1-4 Stores)

Source: Va. Healthcare Workforce Data Cente

91% of all pharmacists work in the private sector, including 63% who work at a for-profit company. Another 2% of pharmacists work for the federal government, while 4% work for a state or local government.

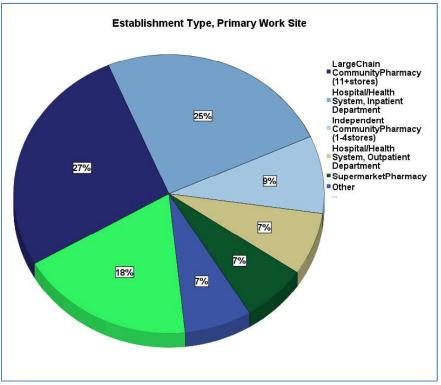


Top Location Types						
Establishment Type	Prim Loca	nary tion	Secondary Location			
	#	%	#	%		
Large Chain Community Pharmacy	1,469	26%	204	25%		
Hospital/Health System, Inpatient Department	1,466	26%	175	21%		
Hospital/Health System, Outpatient Department	508	9%	102	12%		
Supermarket Pharmacy	443	8%	41	5%		
Clinic-Based Pharmacy	352	6%	46	6%		
Mass Merchandiser (i.e., Big Box Store)	228	4%	28	3%		
Nursing Home/Long-Term Care	193	3%	53	6%		
Benefit Administration	173	3%	11	1%		
Independent Community Pharmacy	158	3%	29	3%		
Academic Institution	115	2%	27	3%		
Home Health/Infusion	75	1%	8	1%		
Mail Service Pharmacy	73	1%	10	1%		
Manufacturer	58	1%	3	0%		
Small Chain Community Pharmacy	30	1%	10	1%		
Wholesale Distributor	5	0%	0	0%		
Other	390	7%	83	10%		
Total	5,736	100%	830	100%		
Did Not Have a Location	312		8,022			

Large chain
community pharmacies of
more than 10 stores and
hospital, health system,
inpatient departments
are the most common
establishment type in
Virginia, employing over a
quarter of the state's
pharmacist workforce.

Source: Va. Healthcare Workforce Data Center

Large chain community pharmacies of more than 10 stores were also the most common establishment type among pharmacists who had a secondary work location.



At a Glance: (Primary Locations)

Typical Time Allocation

Patient Care: 80%-89% Administration: 1%-9%

<u>Roles</u>

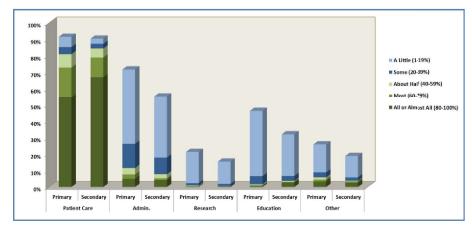
Patient Care: 73% Administration: 8% Education: 1%

Patient Care Pharmacists

Median Admin Time: 1%-9% Ave. Admin Time: 1%-9%

Source: Va. Healthcare Workforce Data Center

A Closer Look:



Source: Va. Healthcare Workforce Data Center

A typical pharmacist spends most of her time in patient care activities. In fact, almost three-quarters of pharmacists fill a patient care role, defined as spending at least 60% of their time in that activity.

	Time Allocation									
T	Pati Ca		Admin.		Research		Education		Other	
Time Spent	Pri. Site	Sec. Site	Pri. Site	Sec. Site	Pri. Site	Sec. Site	Pri. Site	Sec. Site	Pri. Site	Sec. Site
All or Almost All (80-100%)	55%	67%	6%	3%	0%	0%	1%	3%	4%	2%
Most (60-79%)	18%	13%	2%	1%	0%	0%	0%	0%	1%	1%
About Half (40-59%)	8%	6%	4%	3%	0%	0%	1%	1%	1%	0%
Some (20-39%)	4%	3%	14%	9%	2%	2%	5%	3%	2%	2%
A Little (1-20%)	6%	3%	44%	42%	18%	12%	40%	26%	16%	12%
None (0%)	9%	9%	29%	41%	79%	86%	53%	68%	76%	83%

Retirement Expectations						
Expected Retirement	А	.II	Over 50			
Age	#	%	#	%		
Under age 50	228	4%	-	-		
50 to 54	261	5%	0	0%		
55 to 59	655	12%	158	8%		
60 to 64	1,427	27%	521	26%		
65 to 69	1,804	34%	817	40%		
70 to 74	479	9%	282	14%		
75 to 79	145	3%	88	4%		
80 or over	86	2%	47	2%		
I do not intend to retire	273	5%	108	5%		
Total	5,357	100%	2,021	100%		

Source: Va. Healthcare Workforce Data Center

At a Glance:

Retirement Expectations

All Pharmacists

Under 65: 48% Under 60: 21%

Pharmacists 50 and over

Under 65: 34% Under 60: 8%

Time until Retirement

Within 2 years: 7%
Within 10 years: 25%
Half the workforce: By 2047

Source: Va. Healthcare Workforce Data Center

48% of Virginia's pharmacists expect to retire before the age of 65, while 19% plan on working until at least age 70. Among pharmacists who are age 50 and over, 34% still plan on retiring by age 65, while a quarter expect to work until at least age 70.

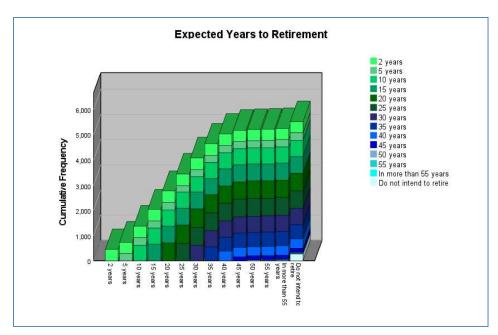
Within the next two years, 3% of Virginia's pharmacists plan on leaving the profession and 2% expect to leave the state. Meanwhile, 7% of pharmacists expect to pursue additional educational opportunities, and 6% plan on increasing the number of hours that they devote to patients.

Future Plans					
2 Year Plans:	#	%			
Decrease Participation	on				
Leave Profession	225	3%			
Leave Virginia	219	2%			
Decrease Patient Care Hours	292	3%			
Decrease Teaching Hours	31	0%			
Increase Participation	on				
Increase Patient Care Hours	537	6%			
Increase Teaching Hours	318	4%			
Pursue Additional Education	655	7%			
Return to Virginia's Workforce	111	1%			

By comparing retirement expectation to age, we can estimate the maximum years to retirement for pharmacists. Only 7% of pharmacists plan on retiring in the next two years, while 25% plan on retiring in the next ten years. More than half of the current pharmacist workforce is expected to retire by 2047.

Time to R	etireme	nt	
Expect to retire within	#	%	Cumulative %
2 years	387	7%	7%
5 years	253	5%	12%
10 years	685	13%	25%
15 years	672	13%	37%
20 years	662	12%	50%
25 years	650	12%	62%
30 years	682	13%	75%
35 years	524	10%	84%
40 years	366	7%	91%
45 years	124	2%	93%
50 years	40	1%	94%
55 years	18	0%	95%
In more than 55 years	21	0%	95%
Do not intend to retire	273	5%	100%
Total	5,357	100%	

Source: Va. Healthcare Workforce Data Center



Using these estimates, retirement will begin to reach 10% of the current workforce starting in 2026. Retirement will peak at 13% of the current workforce around 2041 before declining to under 10% of the current workforce again around 2061.

FTEs

Total: 7,394 FTEs/1,000 Residents²: 0.856 Average: 0.85

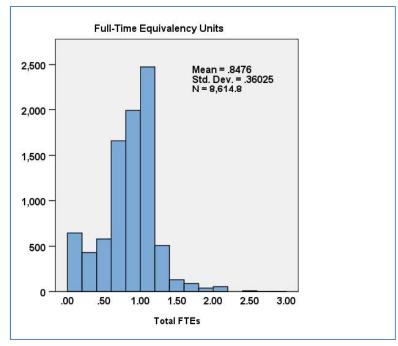
Age & Gender Effect

Age, Partial Eta³: Small Gender, Partial Eta³: Negligible

Partial Eta³ Explained: Partial Eta³ is a statistical measure of effect size.

Source: Va. Healthcare Workforce Data Center

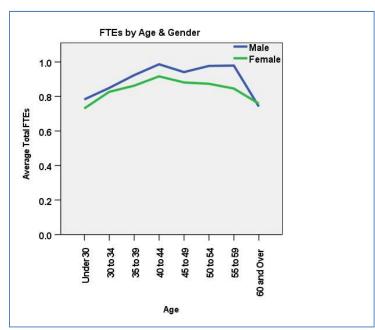
A Closer Look:



Source: Va. Healthcare Workforce Data Center

The typical pharmacist provided 0.85 FTEs in 2022, or about 34 hours per week for 52 weeks. Although FTEs appear to vary by both age and gender, statistical tests did not verify that a difference exists.³

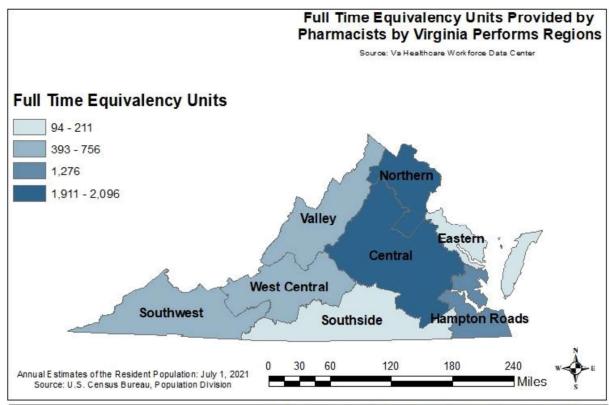
Full-Time Equivalency Units						
Age						
	Average	Median				
Under 30	0.86	0.96				
30 to 34	0.84	0.82				
35 to 39	0.85	0.84				
40 to 44	0.83	0.83				
45 to 49	0.85	0.78				
50 to 54	0.96	1.08				
55 to 59	0.86	0.83				
60 and Over	0.81	0.97				
Gender						
Male	0.88	0.97				
Female	0.84	0.93				
Source: Va. Healthcare	Workforce Data Cent	er				

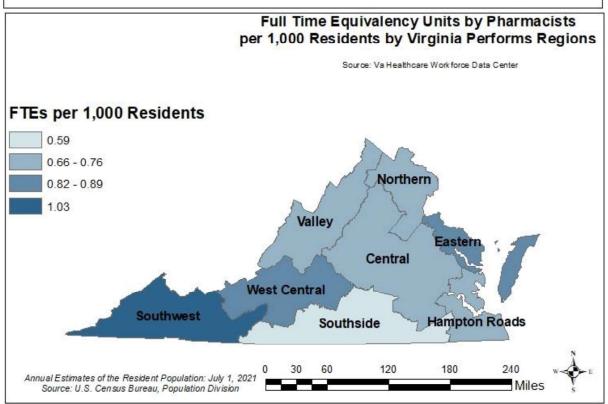


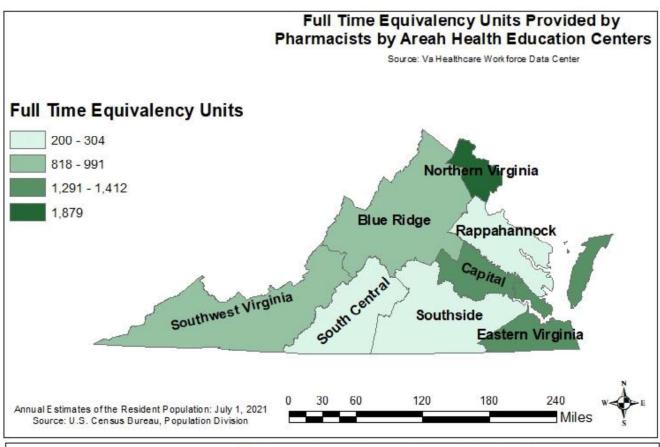
² Number of residents in 2020 was used as the denominator.

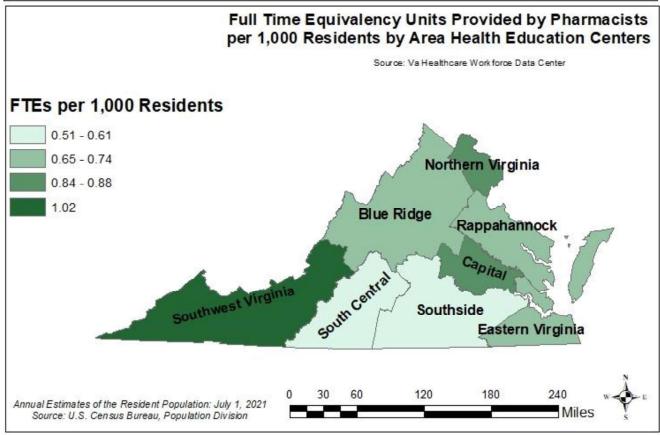
³ Due to assumption violations in Mixed between-within ANOVA (Levene's Test & Interaction effect are significant).

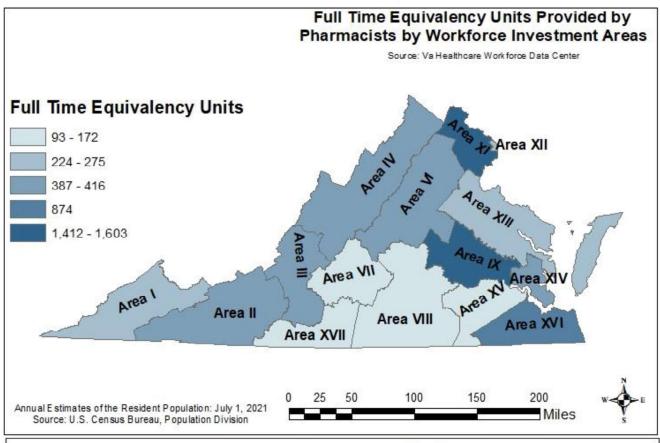
Virginia Performs Regions

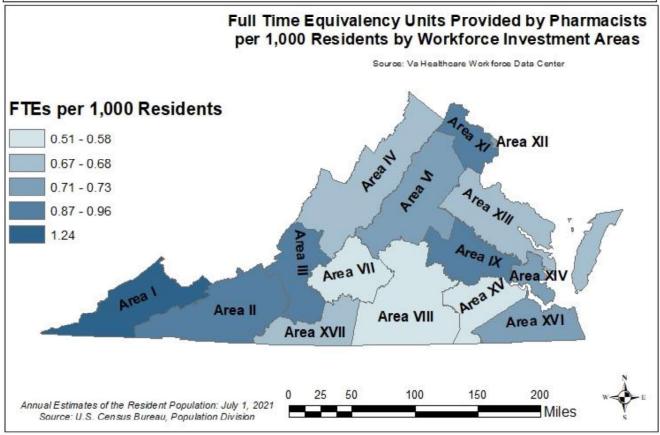


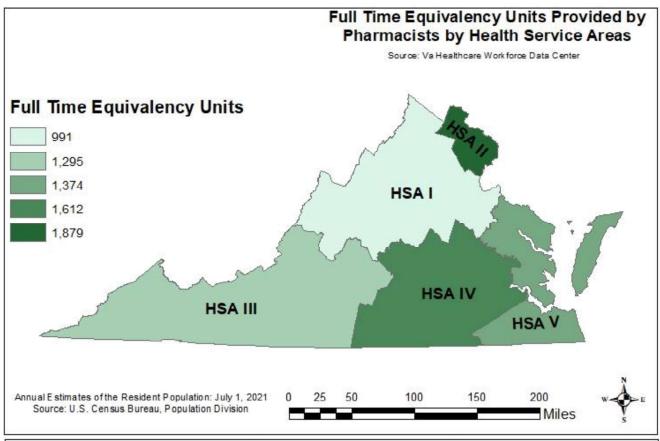


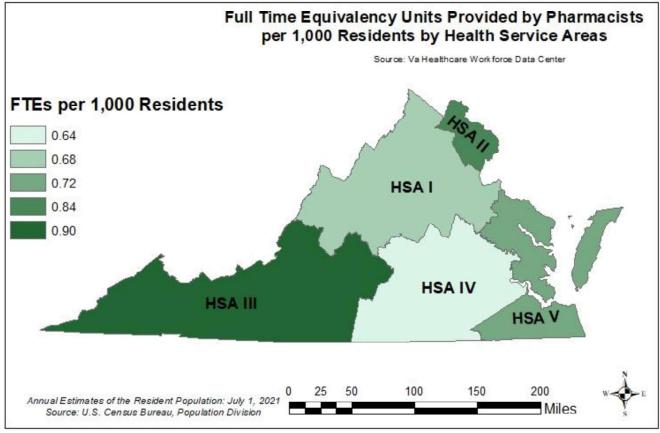


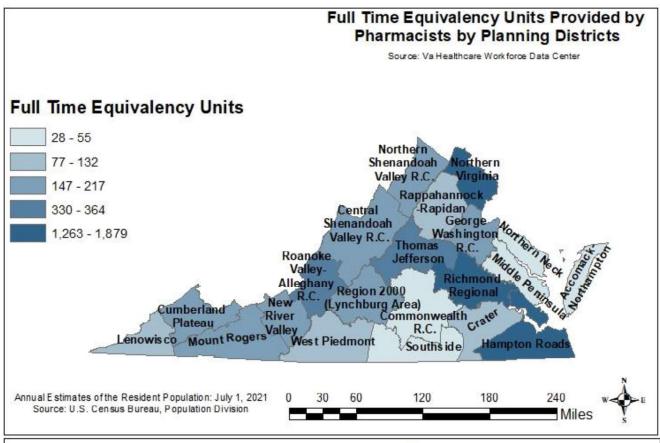


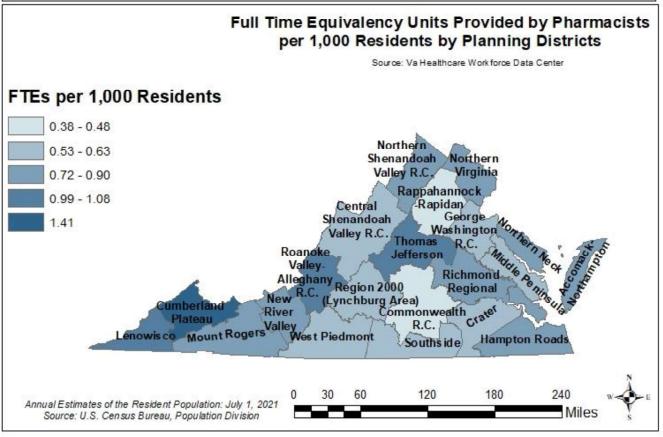












Weights

Rural		Location W	eight eight	Total V	Veight
Status	#	Rate	Weight	Min	Max
Metro, 1 million+	6,760	93.43%	1.0703	1.0500	1.1241
Metro, 250,000 to 1 million	952	93.17%	1.0733	1.0529	1.1272
Metro, 250,000 or less	1,112	93.44%	1.0703	1.0499	1.1241
Urban pop 20,000+, Metro adj	119	94.12%	1.0625	1.0423	1.1159
Urban pop 20,000+, nonadj	0	NA	NA	NA	NA
Urban pop, 2,500- 19,999, Metro adj	358	92.74%	1.0783	1.0578	1.1325
Urban pop, 2,500- 19,999, nonadj	302	92.05%	1.0863	1.0657	1.1409
Rural, Metro adj	242	90.91%	1.1000	1.0791	1.1553
Rural, nonadj	130	93.08%	1.0744	1.0540	1.1284
Virginia border state/DC	2,948	90.88%	1.1004	1.0795	1.1557
Other US State	3,748	88.37%	1.1316	1.1102	1.1885

Source: Va. Healthcare Workforce Data Center

Age Weight **Total Weight** Age Weight 807 87.36% Under 30 1.1447 1.1159 1.1885 30 to 34 2,448 92.03% 1.0866 1.0592 1.1282 93.22% 35 to 39 2,906 1.0727 1.0458 1.1138 40 to 44 2,354 92.69% 1.0788 1.1202 1.0517 45 to 49 1,956 93.25% 1.0724 1.0454 1.1134 50 to 54 1,888 93.27% 1.0721 1.0452 1.1132 55 to 59 1,514 93.53% 1.0692 1.0423 1.1102 60 and 2,798 87.42% 1.1439 1.1152 1.1877 Over

Source: Va. Healthcare Workforce Data Center

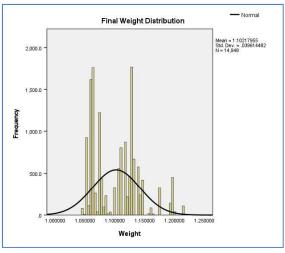
See the Methods section on the HWDC website for details on HWDC Methods:

www.dhp.virginia.gov/hwdc/

Final weights are calculated by multiplying the two weights and the overall response rate:

Age Weight x Rural Weight x Response Rate = Final Weight.

Overall Response Rate: 0.9175





Virginia's Pharmacy Technician Workforce: 2022

Healthcare Workforce Data Center

February 2023

Virginia Department of Health Professions Healthcare Workforce Data Center Perimeter Center 9960 Mayland Drive, Suite 300 Henrico, VA 23233 804-597-4213, 804-527-4434 (fax)

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Get a copy of this report from:

https://www.dhp.virginia.gov/PublicResources/HealthcareWorkforceDataCenter/ProfessionReports/

More than 10,000 Pharmacy Technicians voluntarily participated in this survey. Without their efforts, the work of the center would not be possible. The Department of Health Professions, the Healthcare Workforce Data Center, and the Board of Pharmacy express our sincerest appreciation for their ongoing cooperation.

Thank You!

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The Pharmacy Technician Workforce At a Glance:

The Workforce

Registrants: 13,893 Virginia's Workforce: 12,819 FTEs: 9,881

Survey Response Rate

All Registrants: 77% Renewing Practitioners: 99%

Demographics

Female: 85% Diversity Index: 61% Median Age: 36

Background

Rural Childhood: 39% HS Degree in VA: 74% % Work Non-Metro: 14%

Education

High School/GED: 56% Associate Degree: 21%

Finances

Median Income: \$30k-\$35k Health Insurance: 62% Under 40 w/ Ed. Debt: 47%

ource: Va. Healthcare Workforce Data Center

Current Employment

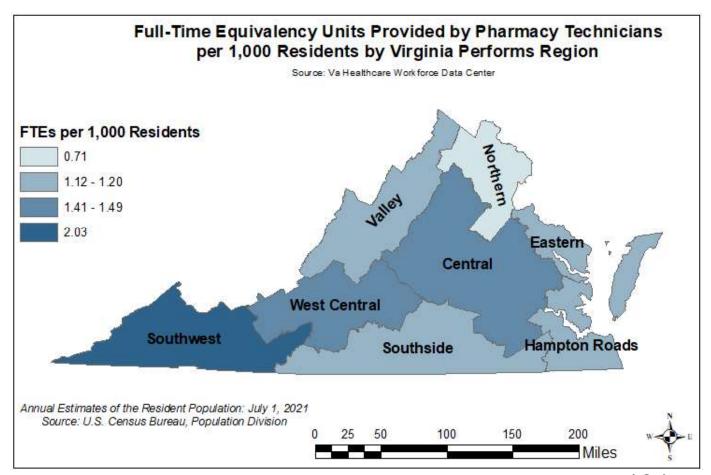
Employed in Prof.: 81% Hold 1 Full-Time Job: 69% Satisfied?: 90%

Job Turnover

Switched Jobs: 5% Employed Over 2 Yrs.: 53%

Primary Roles

Medication Disp.: 57%
Administration: 5%
Supervision: 2%



This report contains the results of the 2022 Pharmacy Technician Workforce survey. A total of 10,673 pharmacy technicians voluntarily participated in this survey. The Virginia Department of Health Professions' Healthcare Workforce Data Center (HWDC) administers the survey during the registration renewal process, which takes place every December for pharmacy technicians. These survey respondents represent 77% of the 13,893 pharmacy technicians who are registered in the state and 99% of renewing practitioners.

The HWDC estimates that 12,819 pharmacy technicians participated in Virginia's workforce during the survey period, which is defined as those who worked at least a portion of the year in the state or who live in the state and intend to return to work in the profession at some point in the future. Virginia's pharmacy technician workforce provided 9,881 "full-time equivalency units," which the HWDC defines simply as working 2,000 hours per year.

More than four out of every five pharmacy technicians are female, and the median age of this workforce is 36. In a random encounter between two pharmacy technicians, there is a 61% chance that they would be of different races or ethnicities, a measure known as the diversity index. This makes the pharmacy technician workforce more diverse than the state's overall population, which has a comparable diversity index of 58%. Nearly 40% of pharmacy technicians grew up in a rural area, and 28% of pharmacy technicians who grew up in a rural area currently work in a non-metro area of Virginia. In total, 14% of all pharmacy technicians work in a non-metro area.

More than 80% of all pharmacy technicians are currently employed in the profession, 69% hold one full-time job, and 51% work between 40 and 49 hours per week. Nine out of every ten pharmacy technicians work in the private sector, including 73% who work in the for-profit sector. The median annual income for pharmacy technicians is between \$30,000 and \$35,000. In addition, 81% of all pharmacy technicians receive at least one employer-sponsored benefit, including 62% who have access to health insurance. Nine out of every ten pharmacy technicians indicated that they are satisfied with their current work situation, including 49% who indicated that they are "very satisfied."

Summary of Trends

In this section, all statistics for the current year are compared to the 2012 pharmacy technician workforce. The number of registered pharmacy technicians has increased by 2% (13,893 vs. 13,610). However, the size of Virginia's pharmacy technician workforce has remained essentially constant (12,819 vs. 12,843), while the number of FTEs provided by this workforce has fallen by 7% (9,881 vs. 10,568). Renewing pharmacy technicians are more likely to respond to the survey (99% vs. 88%).

The percentage of pharmacy technicians who are female has increased slightly (85% vs. 84%), and the median age of this workforce has risen (36 vs. 34). The diversity index of this workforce has also risen (61% vs. 56%) during a time in which Virginia's overall population has also become more diverse (58% vs. 54%). The percentage of pharmacy technicians who grew up in a rural area has declined (39% vs. 42%). In addition, the percentage of all pharmacy technicians who work in a non-metro county has fallen slightly (14% vs. 15%).

Pharmacy technicians are more likely to work in the profession (81% vs. 79%), hold one full-time job (69% vs. 62%), and work between 40 and 49 hours per week (51% vs. 39%). The one-year rates of involuntary unemployment (1% vs. 3%) and underemployment (3% vs. 7%) have both declined. Pharmacy technicians are relatively more likely to work in the non-profit sector (17% vs. 12%) instead of the for-profit sector (73% vs. 76%). Although the percentage of pharmacy technicians who work in large chain community pharmacies has fallen (31% vs. 36%), they remain the most common establishment type in the state for this workforce.

Pharmacy technicians are more likely to receive at least one employer-sponsored benefit (81% vs. 73%), including those pharmacy technicians who have access to health insurance (62% vs. 58%). The percentage of pharmacy technicians who indicated that they are satisfied with their current work situation has increased (90% vs. 88%), and this is also the case among those pharmacy technicians who indicated that they are "very satisfied" (49% vs. 46%).

A Closer Look:

Registrant Counts				
Registration Status	#	%		
Renewing Practitioners	10,202	73%		
New Registrants	1,567	11%		
Non-Renewals	2,124	15%		
All Registrants	13,893	100%		

Source: Va. Healthcare Workforce Data Center

HWDC surveys tend to achieve very high response rates. Among all renewing pharmacy technicians, 99% submitted a survey. These represent 77% of all pharmacy technicians who were registered at some point in 2022.

Response Rates					
Statistic	Non Respondents	Respondents	Response Rate		
By Age					
Under 30	1,393	2,564	65%		
30 to 34	506	1,732	77%		
35 to 39	380	1,563	80%		
40 to 44	246	1,219	83%		
45 to 49	189	962	84%		
50 to 54	171	1,014	86%		
55 to 59	123	715	85%		
60 and Over	212	904	81%		
Total	3,220	10,673	77%		
New Registratio	ns				
Issued in 2022	1,035	532	34%		
Metro Status					
Non-Metro	391	1,594	80%		
Metro	2,356	8,363	78%		
Not in Virginia	473	716	60%		

Source: Va. Healthcare Workforce Data Center

Definitions

- **1. The Survey Period:** The survey was conducted in December 2022.
- **2. Target Population:** All professionals who held a Virginia registration at some point in 2022.
- 3. Survey Population: The survey was available to those who renewed their registration online. It was not available to those who did not renew, including some professionals newly registered in 2022.

Response Rates	
Completed Surveys	10,673
Response Rate, All	77%
Registrants	1170
Response Rate, Renewals	99%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Registered Pharmacy Tech.

Number: 13,893 New: 11% Not Renewed: 15%

Survey Response Rates

All Registrants: 77% Renewing Practitioners: 99%

At a Glance:

Workforce

Pharmacy Tech. Workforce: 12,819 FTEs: 9,881

Utilization Ratios

Registrants in VA Workforce: 92% Registrants per FTE: 1.41 Workers per FTE: 1.30

Source: Va. Healthcare Workforce Data Center

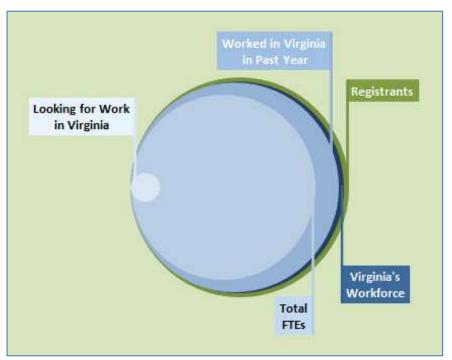
Pharmacy Tech. Workforce				
Status	#	%		
Worked in Virginia in Past Year	12,575	98%		
Looking for Work in Virginia	244	2%		
Virginia's Workforce	12,819	100%		
Total FTEs	9,881			
Registrants	13,893			

Source: Va. Healthcare Workforce Data Center

Weighting is used to estimate
the figures in this report.
Unless otherwise noted, figures
refer to the Virginia workforce
only. For more information on
the HWDC's methodology, visit:
https://www.dhp.virginia.gov/
PublicResources/HealthcareW
orkforceDataCenter/

Definitions

- 1. Virginia's Workforce: A registrant with a primary or secondary work site in Virginia at any time in the past year or who indicated intent to return to Virginia's workforce at any point in the future.
- **2. Full-Time Equivalency Unit (FTE):** The HWDC uses 2,000 (40 hours for 50 weeks) as its baseline measure for FTEs.
- **3. Registrants in VA Workforce:** The proportion of registrants in Virginia's Workforce.
- **4. Registrants per FTE:** An indication of the number of registrants needed to create 1 FTE. Higher numbers indicate lower registrant participation.
- 5. Workers per FTE: An indication of the number of workers in Virginia's workforce needed to create 1 FTE. Higher numbers indicate lower utilization of available workers.



Source: Va. Healthcare Workforce Data Center

A Closer Look:

Age & Gender						
	Ma	ale	Fer	nale	T	otal
Age	#	%	#	%	#	% in Age
		Male		Female		Group
Under 30	566	17%	2,736	83%	3,302	31%
30 to 34	272	16%	1,472	84%	1,744	16%
35 to 39	192	13%	1,245	87%	1,437	13%
40 to 44	137	13%	924	87%	1,061	10%
45 to 49	133	15%	736	85%	869	8%
50 to 54	110	13%	770	88%	880	8%
55 to 59	72	12%	557	89%	630	6%
60 and Over	102	13%	678	87%	780	7%
Total	1,584	15%	9,118	85%	10,702	100%

Source: Va. Healthcare Workforce Data Center

Race & Ethnicity						
Race/	Virginia* Pharmacy Pharmacy Tech. Under		·		-	
Ethnicity	%	#	%	#	%	
White	60%	6,192	57%	3,500	54%	
Black	19%	2,373	22%	1,485	23%	
Asian	7%	969	9%	568	9%	
Other Race	0%	140	1%	89	1%	
Two or More Races	3%	416	4%	327	5%	
Hispanic	10%	707	7%	551	8%	
Total	100%	10,797	100%	6,520	100%	

*Population data in this chart is from the U.S. Census, Annual Estimates of the Resident Population by Sex, Race, and Hispanic Origin for the United States, States, and Counties: July 1, 2021.

Source: Va. Healthcare Workforce Data Center

Among the 61% of pharmacy technicians who are under the age of 40, 84% are female. In addition, the diversity index among pharmacy technicians who are under the age of 40 is 64%.

At a Glance:

Gender

% Female: 85% % Under 40 Female: 84%

Age

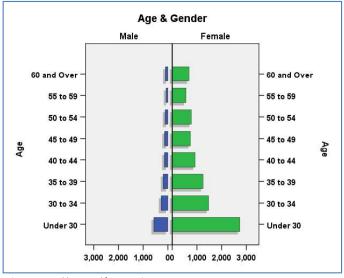
Median Age: 36 % Under 40: 61% % 55 and Over: 13%

Diversity

Diversity Index: 61% Under 40 Div. Index: 64%

Source: Va. Healthcare Workforce Data Cente

In a chance encounter between two professionals, there is a 61% chance that they would be of different races or ethnicities (a measure known as the diversity index). For Virginia's population as a whole, the comparable diversity index is 58%.



At a Glance:

Childhood

Urban Childhood: 20% Rural Childhood: 39%

Virginia Background

HS in Virginia: 74% HS in VA, Past 5 Years: 70%

Location Choice

% Work Non-Metro: 14% % Rural to Non-Metro: 28%

% Urban/Suburban

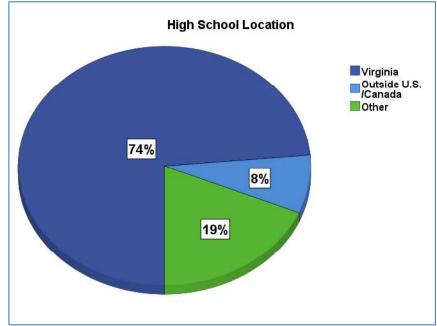
to Non-Metro: 5%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

USE	Primary Location: USDA Rural Urban Continuum		Rural Status of Childhood Location		
Code	Description	Rural	Suburban	Urban	
	Metro Cour	nties			
1	Metro, 1 Million+	22%	52%	26%	
2	Metro, 250,000 to 1 Million	60%	30%	11%	
3	Metro, 250,000 or Less	65%	25%	10%	
	Non-Metro Counties				
4	Urban, Pop. 20,000+, Metro Adjacent	61%	28%	10%	
6	Urban, Pop. 2,500-19,999, Metro Adjacent	81%	14%	5%	
7	Urban, Pop. 2,500-19,999, Non-Adjacent	93%	5%	3%	
8	Rural, Metro Adjacent	75%	16%	9%	
9	Rural, Non-Adjacent	72%	18%	10%	
	Overall	39%	41%	20%	

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

Among all pharmacy technicians, 39% grew up in a self-described rural area, and 28% of pharmacy technicians who grew up in a rural area currently work in a non-metro county. In total, 14% of all pharmacy technicians are employed in a non-metro area of the state.

Top Ten States for Pharmacy Technician Recruitment

	High School Location				
Rank	All Pharmacy Technicians	#	Registered in the Past Five Years	#	
1	Virginia	7,801	Virginia	2,735	
2	Outside U.S./Canada	833	Outside U.S./Canada	303	
3	North Carolina	183	Maryland	87	
4	Maryland	177	North Carolina	82	
5	New York	159	Florida	66	
6	Florida	143	Pennsylvania	62	
7	West Virginia	131	New York	57	
8	Pennsylvania	128	West Virginia	51	
9	California	121	California	50	
10	New Jersey	88	Tennessee	36	

Among all pharmacy technicians, 74% received their high school diploma in Virginia. Among those pharmacy technicians who obtained their initial registration in the past five years, 70% received their high school degree in the state.

Source: Va. Healthcare Workforce Data Center

In total, 8% of Virginia's registered pharmacy technicians did not participate in the state's workforce in 2022. However, 81% of these professionals worked at some point in the past year, including 62% who currently work as pharmacy technicians.

At a Glance:

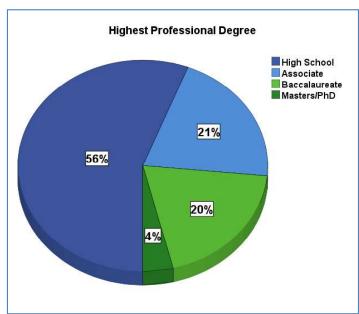
Not in VA Workforce

Total: 1,068 % of Registrants: 8% Federal/Military: 6% VA Border State/DC: 28%

A Closer Look:

Highest Professional Degree				
Degree	#	%		
High School/GED	5,842	56%		
Associate	2,159	21%		
Baccalaureate	2,040	20%		
Masters	365	3%		
PhD	46	0%		
Total	10,453	100%		

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

More than one-third of all pharmacy technicians currently carry education debt, including 47% of those pharmacy technicians who are under the age of 40. For those pharmacy technicians with education debt, the median debt amount is between \$18,000 and \$20,000.

At a Glance:

Education

High School/GED: 56% Associate Degree: 21%

Education Debt

Carry Debt: 37% Under Age 40 w/ Debt: 47% Median Debt: \$18k-\$20k

Cource: Va. Healthcare Workforce Data Center

More than half of all pharmacy technicians hold either a high school degree or a GED as their highest professional degree.

Education Debt					
Amount Carried	All Pharm. Tech.		Pharm. Tech. Under 40		
	#	%	#	%	
None	5,153	63%	2,588	53%	
Less than \$10,000	919	11%	716	15%	
\$10,000-\$19,999	622	8%	493	10%	
\$20,000-\$29,999	541 7%		413	8%	
\$30,000 or More	956 12%		675	14%	
Total	8,191	100%	4,885	100%	

At a Glance:

Top Certifications

PTCB: 64% ExCPT: 12% Total w/ Cert.: 76%

National Certifications

Required: 61% Pay Raise w/ Cert.: 46%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Professional Certifications					
Certification	#	% of Workforce			
Pharmacy Technician Certification Board (PTCB)	8,230	64%			
Exam for Certification of Pharmacy Technicians (ExCPT)	1,499	12%			
Total with Certification	9,728	76%			

Source: Va. Healthcare Workforce Data Center

More than three-quarters of Virginia's pharmacy technicians hold a professional certification, including 64% who hold a Pharmacy Technician Certification Board (PTCB) credential.

More than three out of every five pharmacy technicians work for an employer that requires a national certification as a condition of employment. Meanwhile, 46% of pharmacy technicians work for an employer that offers a pay raise for those who have obtained a national certification.

National Certifications					
Required for Employment? # %					
Yes	6,331	61%			
No	4,006	39%			
Pay Raise with Certification?	#	%			
Yes	4,431	46%			
No	4,663	49%			
No Certification Held 475 5%					

At a Glance:

Employment

Employed in Profession: 81% Involuntarily Unemployed: 1%

Positions Held

1 Full-Time: 69% 2 or More Positions: 9%

Weekly Hours:

40 to 49:51%60 or More:3%Less than 30:15%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Current Work Status				
Status	#	%		
Employed, Capacity Unknown	19	< 1%		
Employed in a Pharmacy Technician- Related Capacity	8,466	81%		
Employed, NOT in a Pharmacy Technician-Related Capacity	1,549	15%		
Not Working, Reason Unknown	0	0%		
Involuntarily Unemployed	79	1%		
Voluntarily Unemployed	281	3%		
Retired	51	1%		
Total	10,445	100%		

Source: Va. Healthcare Workforce Data Center

Among all pharmacy technicians, 81% are currently employed in the profession, 69% hold one full-time job, and 51% work between 40 and 49 hours per week.

Current Positions				
Positions	#	%		
No Positions	411	4%		
One Part-Time Position	1,864	18%		
Two Part-Time Positions	148	1%		
One Full-Time Position	7,090	69%		
One Full-Time Position & One Part-Time Position	684	7%		
Two Full-Time Positions	38	0%		
More than Two Positions	31	0%		
Total	10,266	100%		

Source: Va. Healthcare Workforce Data Center

Current Weekly Hours					
Hours # %					
0 Hours	411	4%			
1 to 9 Hours	289	3%			
10 to 19 Hours	470	5%			
20 to 29 Hours	758	8%			
30 to 39 Hours	2,330	23%			
40 to 49 Hours	5,044	51%			
50 to 59 Hours	359	4%			
60 to 69 Hours	111	1%			
70 to 79 Hours	72	1%			
80 or More Hours	132	1%			
Total	9,976	100%			

A Closer Look:

Annual Income						
Income Level # %						
Volunteer Work Only	78	2%				
Less than \$10,000	347	8%				
\$10,000-\$14,999	189	4%				
\$15,000-\$19,999	228	5%				
\$20,000-\$24,999	358	8%				
\$25,000-\$29,999	418	9%				
\$30,000-\$34,999	702	15%				
\$35,000-\$39,999	641	14%				
\$40,000-\$44,999	653	14%				
\$45,000-\$49,999	430	9%				
\$50,000 or More	591	13%				
Total	4,636	100%				

Source: Va. Healthcare Workforce Data Center

Annual Income

Median Income: \$30k-\$35k

Benefits

Health Insurance: 62% Retirement: 59%

Satisfaction

Satisfied: 90% Very Satisfied: 49%

Source: Va. Healthcare Workforce Data Cente

Job Satisfaction				
Level	#	%		
Very Satisfied	5,013	49%		
Somewhat Satisfied	4,176	41%		
Somewhat Dissatisfied	711	7%		
Very Dissatisfied	351	3%		
Total	10,250	100%		

Source: Va. Healthcare Workforce Data Center

The typical pharmacy technician earns between \$30,000 and \$35,000 per year. In addition, 81% of all pharmacy technicians receive at least one employer-sponsored benefit, including 62% who have access to health insurance.

Employer-Sponsored Benefits				
Benefit	#	%	% of Wage/Salary Employees	
Paid Leave	5,637	67%	61%	
Health Insurance	5,261	62%	57%	
Dental Insurance	5,086	60%	55%	
Retirement	4,973	59%	54%	
Group Life Insurance	3,042	36%	33%	
Signing/Retention Bonus	699	8%	8%	
At Least One Benefit	6,829	81%	74%	

^{*}From any employer at time of survey.

A Closer Look:

Employment Instability in the Past Year				
In The Past Year, Did You?	#	%		
Experience Involuntary Unemployment?	100	1%		
Experience Voluntary Unemployment?	382	3%		
Work Part-Time or Temporary Positions, but Would Have Preferred a Full-Time/Permanent Position?	361	3%		
Work Two or More Positions at the Same Time?	1,192	9%		
Switch Employers or Practices?	612	5%		
Experience At Least One?	2,224	17%		

Source: Va. Healthcare Workforce Data Center

Only 1% of pharmacy technicians were involuntarily unemployed at some point in the past year. By comparison, Virginia's average monthly unemployment rate was 2.9%.

Location Tenure					
Tenure	Primary		Secondary		
Tellure	#	%	#	%	
Not Currently Working at This Location	256	3%	173	11%	
Less than 6 Months	920	10%	226	14%	
6 Months to 1 Year	1,042	11%	179	11%	
1 to 2 Years	2,257	24%	344	21%	
3 to 5 Years	2,136	22%	314	19%	
6 to 10 Years	1,294	14%	184	11%	
More than 10 Years	1,591	17%	217	13%	
Subtotal	9,497	100%	1,638	100%	
Did Not Have Location	665		10,951		
Item Missing	2,658		231		
Total	12,819		12,819		

Source: Va. Healthcare Workforce Data Center

More than 90% of pharmacy technicians receive an hourly wage at their primary work location.

At a Glance:

Unemployment Experience

Involuntarily Unemployed: 1% Underemployed: 3%

Turnover & Tenure

Switched Jobs: 5%
New Location: 25%
Over 2 Years: 53%
Over 2 Yrs., 2nd Location: 44%

Employment Type

Hourly Wage: 91% Salary/Commission: 8%

Source: Va. Healthcare Workforce Data Cente

More than half of all pharmacy technicians have worked at their primary work location for more than two years.

Employment Type				
Primary Work Site	#	%		
Salary/Commission	744	8%		
Hourly Wage	8,163	91%		
By Contract/Per Diem	42	0%		
Business/Practice Income	8	0%		
Unpaid	16	0%		
Subtotal	8,973	100%		

¹ As reported by the U.S. Bureau of Labor Statistics. The non-seasonally adjusted monthly unemployment rate fluctuated between a low of 2.5% and a high of 3.4%. The unemployment rate from December 2022 was still preliminary at the time of publication.

At a Glance:

Concentration

Top Region: 24%
Top 3 Regions: 68%
Lowest Region: 2%

Locations

2 or More (Past Year): 19% 2 or More (Now*): 15%

Source: Va. Healthcare Workforce Data Center

More than two-thirds of all pharmacy technicians work in Central Virginia, Northern Virginia, and Hampton Roads.

Number of Work Locations				
Locations	Work Locations in Past Year		Wo Locat No	tions
	#	%	#	%
0	243	3%	408	4%
1	7,586	78%	7,791	81%
2	1,176	12%	929	10%
3	556	6%	486	5%
4	40	0%	27	0%
5	22	0%	13	0%
6 or More	56	1%	27	0%
Total	9,679	100%	9,679	100%

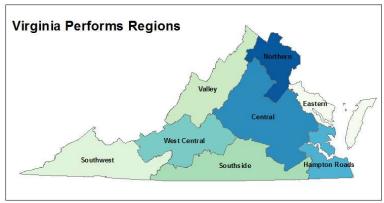
^{*}At the time of survey completion, December 2022.

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Regional Distribution of Work Locations							
Virginia Performs		nary ation	Secondary Location				
Region	#	%	#	%			
Central	2,296	24%	414	23%			
Eastern	177	2%	35	2%			
Hampton Roads	2,029	22%	410	23%			
Northern	2,112	22%	389	22%			
Southside	388	4%	59	3%			
Southwest	711	8%	90	5%			
Valley	612	6%	93	5%			
West Central	1,062	11%	205	12%			
Virginia Border State/D.C.	17	0%	21	1%			
Other U.S. State	15	0%	44	2%			
Outside of the U.S.	0	0%	5	0%			
Total	9,419	100% 1,765 100					
Item Missing	2,737		103				

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

Among all pharmacy technicians, 15% currently have multiple work locations, while 19% have had multiple work locations over the past year.

A Closer Look:

Location Sector									
Sector	Prim Loca		Secondary Location						
	#	%	#	%					
For-Profit	6,485	73%	1,098	73%					
Non-Profit	1,524	17%	244	16%					
State/Local Government	562	6%	97	6%					
Veterans Administration	54	1%	8	1%					
U.S. Military	150	2%	31	2%					
Other Federal Gov't	118	1%	36	2%					
Total	8,893	100%	1,514	100%					
Did Not Have Location	665		10,951						
Item Missing	3,262		355						

Source: Va. Healthcare Workforce Data Center

At a Glance: (Primary Locations) Sector

For-Profit: 73% Federal: 4%

Top Establishments

Large Chain Pharmacy: 31%

(11+ Stores)

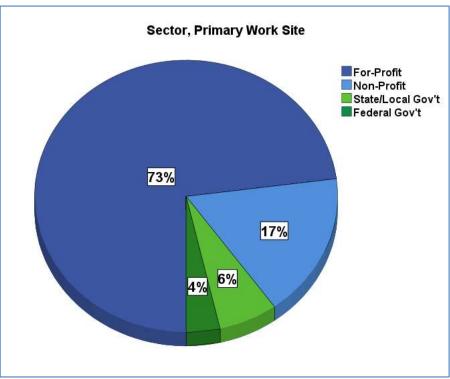
Hospital/Health System: 16%

(Inpatient)

Supermarket Pharmacy: 10%

Source: Va. Healthcare Workforce Data Cente

Nine out of every ten pharmacy technicians work in the private sector, including 73% who work in the for-profit sector. Another 6% of pharmacy technicians work for a state or local government.

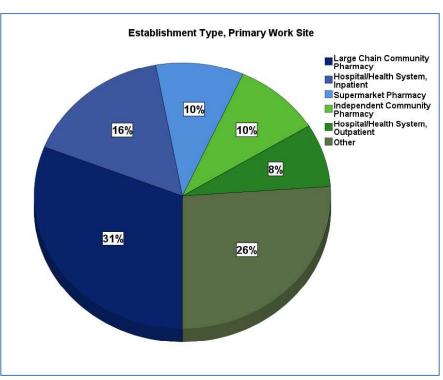


Location Type								
Establishment Type	Prim Locat		Secon Loca					
	#	%	#	%				
Large Chain Community Pharmacy (11+ Stores)	2,728	31%	481	33%				
Hospital/Health System, Inpatient Department	1,423	16%	191	13%				
Supermarket Pharmacy	845	10%	143	10%				
Independent Community Pharmacy (1-4 Stores)	843	10%	135	9%				
Hospital/Health System, Outpatient Department	672	8%	80	5%				
Mass Merchandiser (i.e., Big Box Store)	349	4%	45	3%				
Nursing Home/Long-Term Care	274	3%	43	3%				
Clinic-Based Pharmacy	274	3%	33	2%				
Pharmacy Benefit Administration (e.g., PBM, Managed Care)	265	3%	20	1%				
Mail Service Pharmacy	148	2%	24	2%				
Home Health/Infusion	138	2%	17	1%				
Other	856	10%	263	18%				
Total	8,815	100%	1,475	100%				
Did Not Have Location	665		10,951					

Nearly one-third of all pharmacy technicians in Virginia work in a large chain community pharmacy, while another 16% work in the inpatient department of a hospital.

Source: Va. Healthcare Workforce Data Center

For pharmacy technicians who also have a secondary work location, 33% work in a large chain community pharmacy, while 13% work in the inpatient department of a hospital.



At a Glance: (Primary Locations)

Typical Time Allocation

Medication Disp.: 70%-79% Administration: 10%-19% Teaching: 1%-9%

Roles

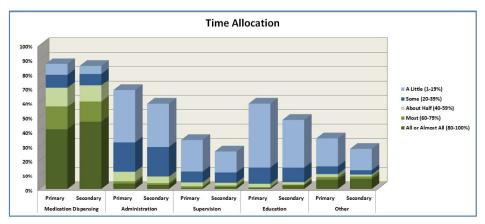
Medication Disp.: 57%
Administration: 5%
Supervision: 2%
Education: 1%

Patient Care Pharm. Tech.

Median Admin. Time: 1%-9% Avg. Admin. Time: 10%-19%

Source: Va. Healthcare Workforce Data Center

A Closer Look:



Source: Va. Healthcare Workforce Data Center

Nearly 60% of all pharmacy technicians fill a medication dispensing and customer service role, defined as spending 60% or more of their time in that activity.

Time Allocation										
Time Sport	Medic Dis		Admin.		Supervision		Educ	ation	Other	
Time Spent	Pri. Site	Sec. Site								
All or Almost All (80-100%)	42%	47%	4%	3%	1%	1%	1%	2%	6%	7%
Most (60-79%)	15%	14%	2%	1%	1%	1%	0%	1%	2%	2%
About Half (40-59%)	13%	11%	7%	5%	3%	2%	2%	2%	2%	2%
Some (20-39%)	9%	8%	20%	21%	8%	7%	11%	10%	5%	3%
A Little (1-19%)	7%	5%	36%	30%	22%	15%	44%	33%	19%	15%
None (0%)	13%	15%	31%	41%	66%	74%	41%	52%	65%	72%

A Closer Look:

Retirement Expectations									
Expected Retirement	А	II	50 and	50 and Over					
Age	#	%	#	%					
Under Age 50	1,816	23%	-	-					
50 to 54	385	5%	40	2%					
55 to 59	562	7%	123	7%					
60 to 64	1,252	16%	384	22%					
65 to 69	2,088	26%	726	42%					
70 to 74	554	7%	240	14%					
75 to 79	142	2%	58	3%					
80 and Over	89	1%	27	2%					
I Do Not Intend to Retire	1,010	13%	134	8%					
Total	7,898	100%	1,732	100%					

Source: Va. Healthcare Workforce Data Center

At a Glance:

Retirement Expectations

All Pharmacy Technicians

Under 65: 51%
Under 60: 35%
Pharm. Tech. 50 and Over

Under 65: 32% Under 60: 9%

Time Until Retirement

Within 2 Years: 4%
Within 10 Years: 15%
Half the Workforce: By 2047

Source: Va. Healthcare Workforce Data Cente

More than half of all pharmacy technicians expect to retire by the age of 65. Among pharmacy technicians who are age 50 and over, nearly one-third expect to retire by the age of 65.

Within the next two years, 19% of all pharmacy technicians expect to pursue additional educational opportunities, and 6% expect to increase their patient care hours.

Future Plans									
Two-Year Plans: # %									
Decrease Participation	on								
Leave Profession	1,097	9%							
Leave Virginia	441	3%							
Decrease Patient Care Hours	218	2%							
Decrease Teaching Hours	133	1%							
Increase Participation	on								
Increase Patient Care Hours	833	6%							
Increase Teaching Hours	757	6%							
Pursue Additional Education	2,445	19%							
Return to the Workforce	127	1%							

By comparing retirement expectation to age, we can estimate the maximum years to retirement for pharmacy technicians. While 4% of pharmacy technicians expect to retire in the next two years, 15% expect to retire within the next ten years. Half of the current workforce expect to retire by 2047.

Time to R	etireme	ent	
Expect to Retire Within	#	%	Cumulative %
2 Years	346	4%	4%
5 Years	200	3%	7%
10 Years	611	8%	15%
15 Years	717	9%	24%
20 Years	914	12%	35%
25 Years	1,181	15%	50%
30 Years	1,159	15%	65%
35 Years	647	8%	73%
40 Years	549	7%	80%
45 Years	334	4%	84%
50 Years	155	2%	86%
55 Years	48	1%	87%
In More than 55 Years	27	0%	87%
Do Not Intend to Retire	1,010	13%	100%
Total	7,898	100%	

Source: Va. Healthcare Workforce Data Center



Using these estimates, retirement will begin to reach 10% of the current workforce every five years by 2042. Retirement will peak at 15% of the current workforce around 2047 before declining to below 10% of the current workforce again around 2057.

Source: Va. Healthcare Workforce Data Center

At a Glance:

FTEs

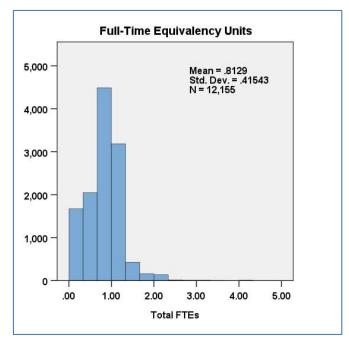
Total: 9,881 FTEs/1,000 Residents²: 1.143 Average: 0.81

Age & Gender Effect

Age, Partial Eta²: **Small** Gender, Partial Eta²: Negligible

> Partial Eta² Explained: Partial Eta² is a statistical measure of effect size.

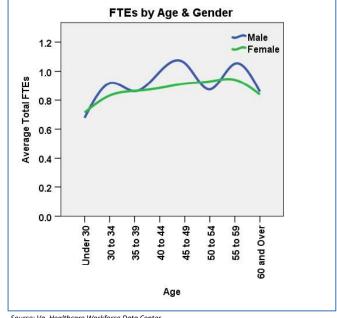
A Closer Look:



Source: Va. Healthcare Workforce Data Center

The typical pharmacy technician provided 0.85 FTEs in 2022, or approximately 34 hours per week for 50 weeks. Although FTEs appear to vary by age and gender, statistical tests did not verify that a difference exists.³

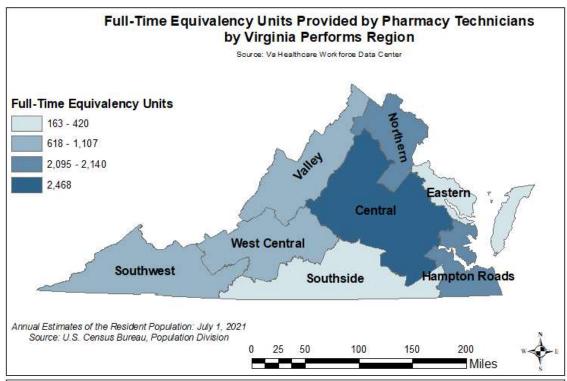
Full-Time Equivalency Units					
	Average	Median			
	Age				
Under 30	0.68	0.64			
30 to 34	0.85	0.88			
35 to 39	0.83	0.80			
40 to 44	0.88	0.84			
45 to 49	0.91	0.92			
50 to 54	0.89	0.90			
55 to 59	0.90	0.93			
60 and Over	0.87	0.99			
	Gender				
Male	0.84	0.93			
Female	0.83	0.91			
Source: Va. Healthcare Wor	kforce Data Center				

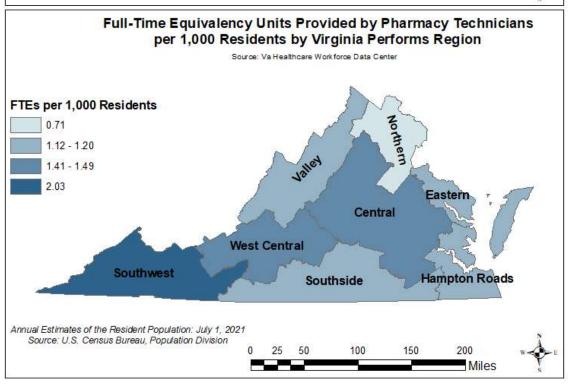


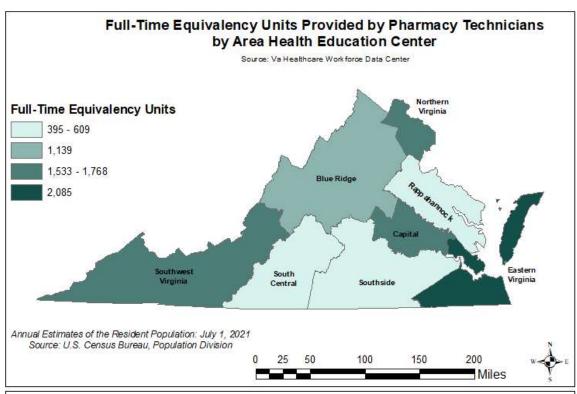
² Number of residents in 2021 was used as the denominator.

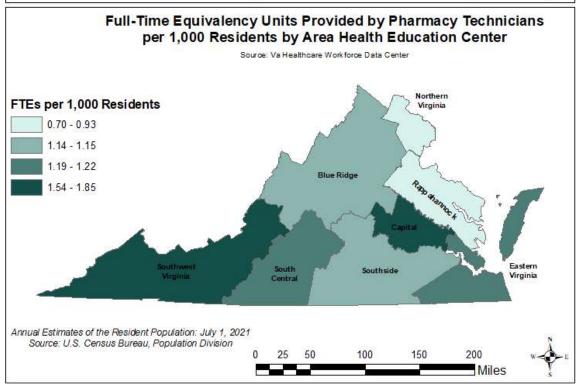
³ Due to assumption violations in Mixed between-within ANOVA (Levene's Test and Interaction effect were significant).

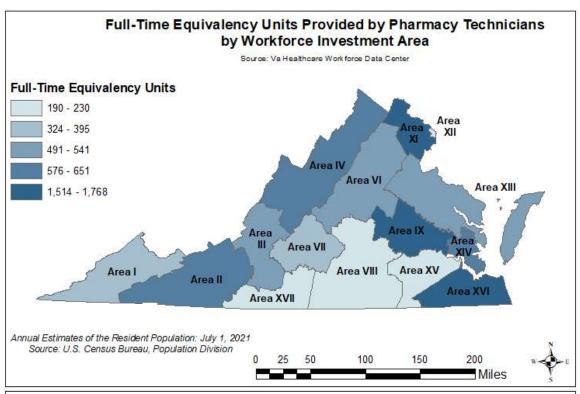
Virginia Performs Regions

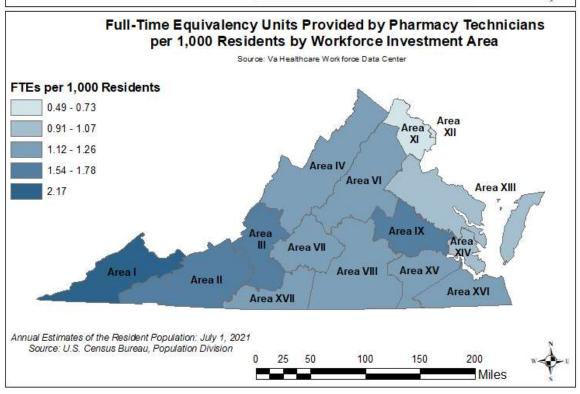


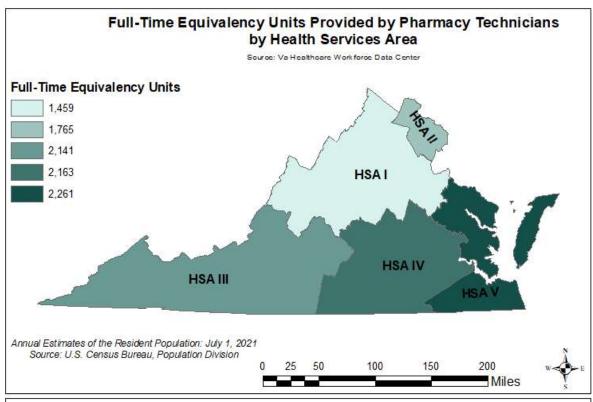


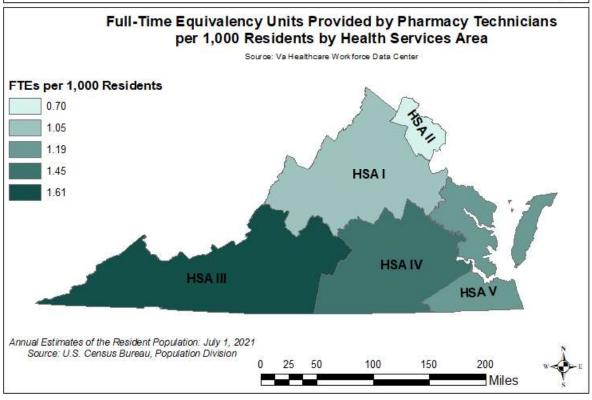


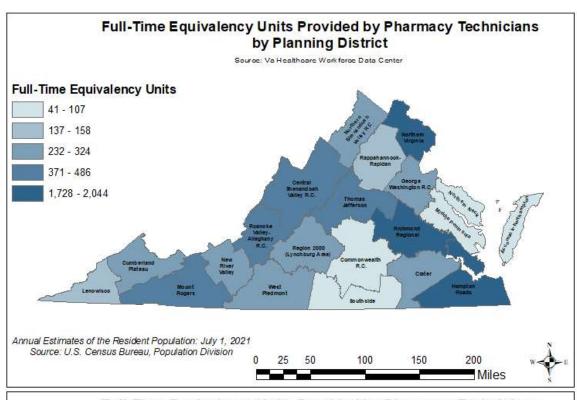


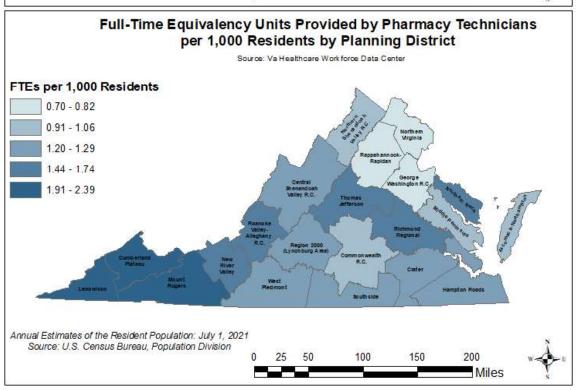












Weights

Dural Chatus	Lo	cation We	ight	Total \	Total Weight		
Rural Status	#	Rate	Weight	Min.	Max.		
Metro, 1 Million+	8,208	77.60%	1.289	1.157	1.528		
Metro, 250,000 to 1 Million	1,243	80.37%	1.244	1.117	1.475		
Metro, 250,000 or Less	1,268	78.47%	1.274	1.144	1.511		
Urban, Pop. 20,000+, Metro Adj.	289	82.01%	1.219	1.095	1.446		
Urban, Pop. 20,000+, Non- Adj.	0	NA	NA	NA	NA		
Urban, Pop. 2,500-19,999, Metro Adj.	683	82.28%	1.215	1.091	1.441		
Urban, Pop. 2,500-19,999, Non-Adj.	526	78.14%	1.280	1.149	1.517		
Rural, Metro Adj.	291	80.41%	1.244	1.116	1.474		
Rural, Non-Adj.	196	76.53%	1.307	1.173	1.549		
Virginia Border State/D.C.	797	62.99%	1.588	1.425	1.882		
Other U.S. State	392	54.59%	1.832	1.645	2.172		

Source: Va. Healthcare Workforce Data Center

A 50		Age Weigh	Total Weight		
Age	#	Rate	Weight	Min.	Max.
Under 30	3,957	64.80%	1.543	1.441	2.172
30 to 34	2,238	77.39%	1.292	1.206	1.818
35 to 39	1,943	80.44%	1.243	1.161	1.749
40 to 44	1,465	83.21%	1.202	1.122	1.691
45 to 49	1,151	83.58%	1.196	1.117	1.684
50 to 54	1,185	85.57%	1.169	1.091	1.645
55 to 59	838	85.32%	1.172	1.094	1.649
60 and Over	1,116	81.00%	1.235	1.153	1.737

Source: Va. Healthcare Workforce Data Center

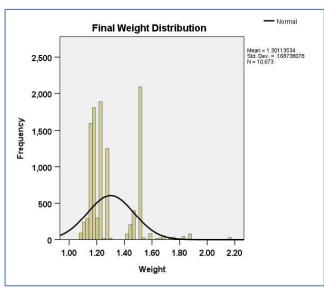
See the Methods section on the HWDC website for details on HWDC methods:

https://www.dhp.virginia.gov/PublicResources/Heal https://www.dhp.virginia.gov/PublicResources/Heal https://www.dhp.virginia.gov/PublicResources/Heal

Final weights are calculated by multiplying the two weights and the overall response rate:

Age Weight x Rural Weight x Response Rate = Final Weight.

Overall Response Rate: 0.768229



Source: Va. Healthcare Workforce Data Center

Virginia Board of Pharmacy March 30, 2023 Licenses Issued

	8/1/21 - 10/31/21	11/1/21 - 1/31/22	2/1/22 - 4/30/22	5/1/22 - 7/31/22	8/1/22 - 10/31/22	11/1/22 - 1/31/23	License Count 3/6/2023
Business CSR	25	28	35	30	32	25	1,379
CE Courses	1	0	1	0	0	0	9
Limited Use Pharmacy Technician	0	0	0	0	0	0	7
Medical Equipment Supplier	6	0	0	4	3	3	207
Non-restricted Manufacturer	1	2	0	2	1	1	31
Outsourcing Facility	0	0	0	0	0	1	1
Permitted Physician	0	0	1	0	0	0	1
Pharmacist	279	157	187	265	252	164	15,999
Pharmacist Volunteer Registration	1	0	1	0	2	1	1
Pharmacy	9	16	9	11	10	11	1,765
Pharmacy Intern	179	87	88	56	96	179	1,131
Pharmacy Technician	353	360	360	531	430	311	12,155
Pharmacy Technician Trainee	1280	1385	1042	777	1,226	1,185	8,386
Physician Selling Controlled Substances	39	14	17	33	27	43	533
Limited Use Practitioner Dispensing	0	0	0	1	1	0	3
Physician Selling Drugs Location	1	4	2	6	2	3	122
Pilot Programs	0	0	2	1	1	0	15
Registered Practitioner For Medical Cannabis	66	81	106	56	147	84	
Repackaging Training Program	0	0	0	0	0	0	2
Restricted Manufacturer	0	0	0	0	0	0	33
Third Party Logistics Provider	0	0	1	1	0	0	6
Warehouser	1	1	1	1	0	2	122
Limited Use Facility Dispensing	0	0	0	0	0	2	2
Wholesale Distributor	1	0	0	0	0	0	58
Total	2,242	2,135	1,853	1,775	2,230	2,015	41,968

Virginia Board of Pharmacy March 30, 2023 Nonresident Licenses Issued

	8/1/21 - 10/31/22	11/1/21 - 1/31/22	2/1/22 - 4/30/22	5/1/22 - 7/31/22	8/1/22 - 10/31/22	11/1/22 - 1/31/23	License Count 2/21/2023
Nonresident Manufacturer	10	1	12	4	6	6	227
Nonresident Medical Equipment Supplier	10	5	5	7	11	4	371
Nonresident Outsourcing Facility	1	1	0	2	2	1	34
Nonresident Pharmacy	17	22	25	27	18	21	925
Nonresident Third Party Logistics Provider	4	7	1	8	11	10	209
Nonresident Warehouser	4	5	6	0	8	7	114
Nonresident Wholesale Distributor	14	14	6	7	9	2	644
Total	60	55	55	55	65	51	2,524

Quarterly Review – Date Range 10/01/2022 ending 12/31/2022

Numbers of Inspections Completed by License Type

Insp Status	License Type	Change of Location	Focus	New	Pilot	Reinspection	Remodel	Routine	Grand Total
Completed	Business CSR	5	1	27			5	134	172
	Cannabis Dispensing Facility			3		1			4
	Limited Use Facility Dispensing			2					2
	Medical Equipment Supplier	2		3				13	18
	Non-restricted Manufacturer			1					1
	Outsourcing Facility			1					1
	Pharmaceutical Processor Permit						1		1
	Pharmacy	8		12		13	42	141	216
	Physician Selling Drugs Location			2			1	12	15
	Pilot Programs				1				1
	Third Party Logistics Provider	1						1	2
	Warehouser	1		2			1	10	14
	Wholesale Distributor	3					1	3	7
Completed Total		20	1	53	1	14	51	314	454
Completed Virtual	Business CSR			2		1	2	14	19
	Non-restricted Manufacturer						1		1
	Pharmacy					4	1		5
	Physician Selling Drugs Location			1					1
Completed Virtual Total				3		5	4	14	26
Grand Total		20	1	56	1	19	55	328	480

Date Range: 10/01/2022 ending 12/31/2022 Routine Inspections, Deficiencies by License Type

License Type	Attempted-No Inspection Required	Deficiency	Deficiency & IPHCO	No Deficiency	Grand Total
Business CSR	1	82		65	148
Business CSR Total	1	82		65	148
Medical Equipment Supplier		7		6	13
Medical Equipment Supplier Total		7		6	13
Pharmacy		38	68	35	141
Pharmacy Total		38	68	35	141
Physician Selling Drugs Location		8		4	12
Physician Selling Drugs Location Total		8		4	12
Third Party Logistics Provider				1	1
Third Party Logistics Provider Total				1	1
Warehouser		4		6	10
Warehouser Total		4		6	10
Wholesale Distributor		1		2	3
Wholesale Distributor Total		1		2	3
Grand Total	1	140	68	119	328

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

Date Range: 07/01/2022 ending 09/30/2022
Categories of Deficiencies for Occurrences, Routine Inspections Only Recorded >20 Times with Examples

Description	Number of times for occurrence
1	

110-20-180 27

Security: The alarm system does not include a feature by which any breach in the alarm shall be communicated by the monitoring entity to the PIC

The security system only has a cellular line of transmission. There is not a hard-wired line or a secondary line of communication Deficiency 9a: The alarm system does not include a feature by which any breach shall be communicated to the PIC Deficiency 7: Remodel of pharmacy without submitting application or Board approval

110-20-240 43

Deficiency 14: The Pharmacist-in-Charge inventory was taken 4 days prior to the effective date of change

Deficiency 15: Perpetual inventory not being maintained as required

Deficiency 17: Hard copy prescriptions not maintained or retrievable as required

Deficiency 113: Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close

Deficiency 148: Theft/unusual loss of drugs reported to board but report not maintained by pharmacy

110-20-275 26

A written contract between the facility and the provider pharmacy could not be located during the course of the inspection Deficiency 122: Engaging in alternate delivery not in compliance

No procedure for informing the patient and obtaining consent if required by law for using such a delivery process

110-20-418 26

Deficiency 142: No record maintained and available for 12 months from date of analysis of dispensing errors/ patient safety Deficiency 142. CQI - No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety

Description Number of times for occurrence

110-20-700 57

The facility did not maintain a complete list of drugs which may be ordered by the holder of the controlled substances registration that are approved by the supervising practitioner

Responsible party on CSR is incorrect

No report to the BOP of the change of RP

Access to the controlled substances shall be limited to the responsible party or to those persons who are authorized Key to medication cabinet in Room 123 is kept in an unlocked drawer behind receptionist desk, accessible by all staff

110-20-710 32

Expired drugs in working stock.

Any drug that has exceeded the expiration date shall not be administered

The security system does not have a secondary line of communication. It can send a signal to the monitoring entity if the primary line is breached

Refrigerator temperatures were not maintained within normal limits

110-20-190(G) 25

Eight expired drugs (C-VI) found in the working stock

88 expired drugs found in the working stock, which included 11 drugs without a first puncture/use date.

The following 15 expired drugs were found in the working stock:

110-20-190(J) 25

The 2019 and 2021 biennial inventories do not specify if they were taken at the opening or closing of business Biennial inventories did not contain expired Scheduled II-V drugs still on premises

Expired controlled substances maintained on premises was not included on the Biennial Inventory taken on 12-08-2022 No Biennial Inventory

Description Number of times for occurrence 39

54.1-3404

Deficiency 13: No biennial inventory, or over 30 days late, or substantially incomplete

Deficiency 16: Theft/unusual loss of drugs not reported to the Board as required

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

54.1-3410.2 83

59 Occurrences -No counted as a deficiency

800: Assessment of Risk has not been performed - Separated from the Section upon Board Request - Is not in full effect -Inspectors note to heighten preparedness

ADJUSTED TOTAL 24

Deficiency 130: Required compounding records not complete

Records are maintained within the pharmacy software system

The fungal results from the most recent certification have not come back yet. The PIC will send those results to the Board was received.

Sterile compounding; have clean room, but not all physical standards in compliance

54.1-3434 23

Deficiency 1: Pharmacist-in-Charge at pharmacy location

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: Two incoming change of Pharmacist-in-Charge (PIC) inventories were taken early. REPEAT

Two Year Review - Date Range: 09/30/2020 ending 09/30/2022

Number of Inspections Completed by License Type

	er mepeetiene cempi	0100 0	, =:	. , , , ,						
Insp Status	License Type	Change Location	Compliance	Focus	New	Pilot	Reinspection	Remodel	Routine	Grand Total
Completed	Business CSR	53		1	179		10	21	685	949
Completed	Cannabis Dispensing	"			12		4		- 000	16
	Limited Use Facility Dispensing				3		<u> </u>			3
	Medical Equipment Supplier	15			18				95	128
	Non-resident Medical Equipment Supplier				1					1
	Non-restricted Manufacturer	1			8		5	1	3	18
	Outsourcing Facility				1					1
	Pharmaceutical Processor	1					1	13	13	28
	Pharmacy	33	8	6	82	1	44	288	1459	1921
	Physician Selling Drugs	5	1		24		4	2	119	155
	Pilot Programs					9				9
	Restricted Manufacturer	1			1				1	3
	Third Party Logistics	1			2				5	8
	Warehouser	10			10		3	4	71	98
	Wholesale Distributor	6			2			3	34	45
Completed ⁻		126	9	7	343	10	71	332	2485	3383
Completed Virtual	Business CSR	14			59	1	6	12	160	252
	Medical Equipment Supplier	2			4			1	5	12
	Non-restricted Manufacturer						1	1		2
	Pharmacy	1		1	3		18	47	1	71
	Physician Selling Drugs	1			2		2	1	5	11
	Pilot Programs					4				4
	Third Party Logistics				1					1
	Warehouser	1			1		1	1	4	8
	Wholesale Distributor				1		1	1		3
Completed \	Completed Virtual Total 19			1	71	5	29	64	175	364
Grand Total		145	9	8	414	15	100	396	2660	3747

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

Reports Extracted on 02/27/2023

• Data extrapolated from My License Office (MLO) / Inspection Completed Detail Reports /Inspection Result Detail Reports

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

Pharmaceutical Processors Report-March 30, 2023

- Three additional cannabis dispensing facility haves been permitted during the last quarter, for a total of 13 cannabis dispensing facilities.
- 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 Virginia Court of Appeals heard oral arguments on the PharmaCann appeal on January 10, 2023. The Board is now awaiting the decision of the Court.
- ➤ With the July 1, 2022 change to the requirement for patients/parents/legal guardians to register with the Board, the number of applications received has decreased significantly. The Board has seen an 89% decrease in patient applications. Registration renewals have also significantly decreased.
- Board and agency staff continue work to develop specific components of the new patient/product registration platform. It is anticipated that the platform will be operational in late March/early April.
- ➤ Board and agency staff continue to meet with the Virginia Cannabis Control Commission to address the anticipated transition of the medical cannabis program to the VCCA on January 1, 2024. The bill authorizing this transition is currently awaiting the Governor's signature. Board staff have developed an initial transition plan to facilitate discussions with the VCCA.
- ➤ Board and agency staff continue to review bills that passed in the General Assembly with anticipated signature by the Governor to address changes that will need to be made to program regulations and operations.

Pharmaceutical Processors Program-By the Numbers As of 3/7/2023

Registered Practitioners	881
Registered Patients	28,958
Registered Parents/Guardians	130
Registered Agents	154
Registered Cannabis Oil Products	2,627
(cumulative)	

Discipline Program Report

Open Cases as of 3/7/23:

	PC	APD	Investigation	FH	IFC	Other	OAG	Pending Closure	Entry	TOTALS
Patient Care Cases	70	11	101	3	6	1	1	0	2	195
Non- Patient Care Cases	134	21	56	4	7	1	0	10	0	233
						TOTAL:				428

- The Board has two cases currently being appealed in circuit court (Category: Other).
 Total caseload continues to trend upward.

Upcoming Disciplinary Proceedings:

April 21, 2023	Full Board	Formal Hearings
April 28, 2023	Richards-Spruill/Yuan	Informal Conferences
May 9, 2023	Ratliff-Yuan	Informal Conferences
May 18, 2023(tentative)	St.Clair/Garvin	Pilot Committee
May 23, 2023	Lee,Ratliff,Melton,Kocot	Regulation Committee
	Richards-Spruill, St.Clair	
May 24, 2023	Garvin/Nash	Informal Conferences
June 13, 2023	Full Board	Full Board Meeting/Formal Hearing

Executive Director's Report – March 30, 2023

Recent Meetings Attended:

- * Right Help, Right Now Meetings
- ❖ SAMHSA Region 3 Meetings regarding Buprenorphine Access
- ❖ NABP Medication Safety Academy
- ❖ Virginia Pharmacy Association 142nd Annual Convention
- ❖ NABP Executive Committee Meeting
- ❖ Forensic Science Board Meeting
- * RxPartnership Board Meeting
- ❖ Monthly DHP Executive Directors' Meeting
- DHP Strategic Planning Meetings

Upcoming Meetings:

- Opioid Regulatory Collaborative
- Virginia Pharmacists Association Annual Meeting, Roanoke
- ❖ NABP Executive Committee Meeting
- * NABP .Pharmacy Executive Board Meeting
- ❖ DHP All-Staff Training Day
- ❖ NABP 119th Annual Meeting