COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

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

Tentative Agenda of Public Hearing and Full Board Meeting

March 26, 2019

9:00AM

TOPIC	PAGES

Call to Order of Public Hearing: Rafael Saenz, Chairman

- Welcome & Introductions
- Reading of Emergency Evacuation Script

Public Hearing:

- Possible Scheduling of Certain Chemicals in Schedule I of the Drug Control Act 1
- Pharmaceutical Processor Regulations – proposed text available at http://townhall.virginia.gov/L/viewstage.cfm?stageid=8484

Adjournment of Public Hearing

Call to Order of Full Board Meeting: Rafael Saenz, Chairman

- Approval of Agenda
- Approval of Previous Board Meeting Minutes:
  - December 18, 2018, Full Board Meeting 2-12
  - December 18, 2018, Public Hearing 13-14
  - December 18, 2018, Formal Hearing 15-16
  - January 9, 2019, Formal Hearing 17-19
  - January 9, 2019, Public Hearing 20
  - January 25, 2019, Special Conference Committee 21-26
  - February 13, 2019, Special Conference Committee (pilot) 27-28
  - February 27, 2019, Formal Hearing 29-31
  - February 28, 2019, Special Conference Committee 32-37

Call for Public Comment: The Board will receive public comment at this time. The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters.

DHP Director's Report: David Brown, DC

Legislative/Regulatory/Guidance: Elaine Yeatts/Caroline D. Juran

- Report of 2019 General Assembly 38-47
- Regulatory update 48-49
- Adoption of exempt regulation to schedule certain chemicals in Schedule I 50-58
- Adoption of proposed regulations on delivery of dispensed prescription devices 59-64
- Consideration of comment on periodic review regulations and adoption of final amendments 65-225

- Preliminary discussion of 2020 legislative proposals — 226-228
  - Pharmacy technician training requirements — 229-231
  - Compounding of essentially copies

Old Business:

- Request from Gates Healthcare Associates, Inc. regarding cGMP inspections

New Business:

- Presentation on telemedicine - Jessica Adams, PharmD, Manager, Regulatory Affairs, TelePharm — 232-241
- Overview of Pharmacists and Pharmacy Technician Workforce Survey Reports - Elizabeth A. Carter, PhD, Director, DHP Healthcare Workforce Data Center — Attachments 1 and 2
- Presentation on HPMP – Peggy Wood, Program Manager, DHP
- Training on disciplinary process, conduct during informal conferences and formal hearings - Shinaberry, Juran, and Rutkowski — Handout

Reports:

- Chairman's Report – Rafael Saenz
- Report on Board of Health Professions – Ryan Logan
- Report on Inspection and Licensure Program – J. Samuel Johnson, Jr./Beth O'Halloran — 242-253
- Report on Disciplinary Program – Ellen B. Shinaberry — 254
- Executive Director's Report – Caroline D. Juran — 255

Consideration of consent orders & summary suspension 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. *****

Notice of Public Hearing
Placement of Chemicals in Schedule I

Pursuant to subsection D of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act. The public hearing will be conducted at **9:00 a.m. on March 26, 2019** at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233. Public comment may also be submitted electronically or in writing prior to March 12, 2019 to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

Pursuant to article § 54.1-3443(D), The Virginia Department of Forensic Science (DFS) has identified three (3) compounds for recommended inclusion into the Code of Virginia. The following is a brief description, chemical name, and common name for each compound.

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

1. **3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-isopropyl-benzamide (other name: Isopropyl U-47700)**, 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.

The following compounds are classified as research chemicals. Compounds of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

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

3. **1-[1-(3-hydroxyphenyl)cyclohexyl]piperidine (other name: 3-hydroxy PCP)**, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING

December 18, 2018
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER: The meeting of the Board of Pharmacy was called to order at 9:11 am

PRESIDING: Rafael Saenz, Chairman

MEMBERS PRESENT:
Glenn L. Bolyard, Jr.
Melvin L. Boone, Sr.
James. L. Jenkins, Jr.
Ryan K. Logan
Cheryl H. Nelson
Kristopher S. Ratliff
Patricia Richards-Spruill
Rebecca Thornbury
Cynthia Warriner

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Ellen B. Shinaberry, Deputy Executive Director
Elaine Yeatts, Senior Policy Analyst, DHP
David Brown, Director, DHP
James Rutkowski, Assistant Attorney General

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

APPROVAL OF AGENDA: An amended agenda was provided as a handout. Amendments included: approval of draft minutes from the December 12, 2018 Special Conference Committee and the re-adoption of regulatory action regarding brown bagging and white bagging. **(motion by Thornbury, second by Boone)**

APPROVAL OF PREVIOUS BOARD MEETING MINUTES

MOTION: **The Board voted unanimously to approve the minutes as presented for the following meetings:**

- **September 24, 2018, Special Conference Committee**
- **September 25, 2018, Full Board Meeting**
- **September 25, 2018, Public Hearing**
- **October 9, 2018, Telephone Conference Call**
- **October 17, 2018, Special Conference Committee**

- **October 25, 2018, Formal Hearings**
- **November 27, 2018, Special Conference Committee**
- **November 28, 2018, Formal Hearings**
- **November 28, 2018, Full Board Meeting**
- **November 28, 2018, Public Hearing**
- **December 7, 2018, Telephone Conference Call**
- **December 12, 2018, Special Conference Committee**

(motion by Bolyard, second by Richards-Spruill)

PUBLIC COMMENTS:

Denise Frank with Gates Healthcare Associates offered comment regarding Gates' request for the Board to accept a cGMP inspection performed by Gates of outsourcing facilities for licensure purposes, in lieu of an FDA inspection. She stated Gates has provided an excerpt of a proposed inspection form checklist, that she has recently completed a cGMP certification program, and that Gates has hired a second former FDA inspector, Frank Minella. Mr. Minella also offered comment and later clarified that he is not a former FDA inspector, but has worked for many years with the pharmaceutical industry such as with submissions of New Drug Applications and is very familiar with the regulatory aspects imposed on the industry.

Farzanah Kennedy commented that the five pharmaceutical processors awarded conditional approval have recently established the Virginia Medical Cannabis Coalition and that she is serving as President. She stated Katie Hellebush and Caley Crawford will manage the Coalition.

Christina Barrille, Executive Director, Virginia Pharmacists Association, commented that VPhA has several 2019 legislative initiatives. The first contemplates authorizing the Boards of Medicine and Pharmacy to regulate a limited prescriptive authority for pharmacists to treat minor conditions that do not require a diagnosis or for which there is a CLIA-waived test to assist in assessing the patient. Other initiatives contemplate addressing PBM audit reform and carving out Medicaid pharmacy benefits from managed care organization control. She also stated the association has recently created an Academy for Medical Cannabis to assist in educating pharmacists on the subject.

Randall Eads, City Manager and Attorney for the City of Bristol, Virginia thanked the Board for its confidence in Dharma Pharmaceuticals. He stated they believe Dharma Pharmaceuticals will play a role in addressing the opioid addiction. He provided an explanation for the change of location application submitted by Dharma. The city realized, due to the nature of the business, that having a pharmaceutical processor located in the vacant mall may limit the other types of businesses that could be co-located in the mall. The city asked Dharma to consider relocating to another location within the city. Mr. Eads stated that while the city would prefer Dharma to not be located in the mall based on other possible economic opportunities, the city would support Dharma's efforts at a location approved by the Board. When questioned, Mr. Eads acknowledged that it is possible a casino could be located at the mall if legislation is passed.

Michael Johnson, owner of Michaels Pharmacy and tentative pharmacist-in-charge of Dharma Pharmaceuticals, stated that he has concerns for patient comfort if Dharma Pharmaceuticals is located in the mall, along with a casino.

Nathan Payne, pharmacist in Danville, Virginia and representing Wellness Pharmaceuticals, which submitted a pharmaceutical processor application in health service area III, urged the Board to deny the change of location application submitted by Dharma. He stated that location and site layout was part of the initial application evaluation process, that other applicants did not have the same luxury of extra time for finding a better location, and that the Board should deny the request as it denied Dalitso's change of location application at the last board meeting.

Delegate O'Quinn, representing the City of Bristol, thanked the Board for the initial awarding of conditional approval to Dharma Pharmaceuticals. He commented that Dharma Pharmaceuticals worked with the City of Bristol to determine the best placement of the pharmaceutical processor that would provide for the best economic impact and serve as a central location for patients to obtain the dispensed oils. Del O'Quinn requested that the Board approve the change of location application submitted by Dharma Pharmaceuticals.

Alexis Long, interim vice-chair of the Academy of Medical Cannabis, introduced herself to the Board and indicated that the Academy will partner with other providers to serve as an educational resource for pharmacists, pharmacy technicians, and patients and will assist with internship opportunities in the medical cannabis area.

Aaron Lopez, speaking on behalf of Dalitso, urged the Board to approve the change of location application submitted by Dharma Pharmaceuticals, stating that the request should be considered separately from the Board's previous consideration, and subsequent denial, of the change of location application submitted by Dalitso.

DHP DIRECTOR'S REPORT:

Dr. Brown stated there have been recent positive indicators surrounding the opioid addiction crisis. The overdose death rate has decreased and the dispensing of opioids have decreased by 50% in the past few years. Dr. Brown also indicated the availability of treatment opportunities have increased, especially for those who could not previously afford such treatment. He also stated that number of prescribers who have obtained a waiver to provide medication assisted treatment has increased as well.

LEGISLATIVE/REGULATORY/ GUIDANCE UPDATE

Regulatory Update

Ms. Yeatts reviewed the Chart of Regulatory Actions found in the agenda packet and provided updates to the following actions:

- Brown bagging and white bagging is on the agenda for consideration of readoption based on an amendment;
- A public hearing for placing Epidiolex in Schedule V has been set for February 6; and,

- A comment period on the delivery of Schedule VI devices will open on 12/24/18.

Adoption of Exempt Regulation to Schedule Certain Chemicals in Schedule I

There was a public hearing conducted at 9:07am this morning pursuant to requirements of §54.1-3443 of the Drug Control Act to receive comment on scheduling certain chemicals in Schedule I.

MOTION:

The Board voted unanimously to place the referenced drugs into Schedule I by amending 18VAC110-20-322 by inserting a new subsection D as listed below:

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

1. Synthetic opioid.

N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-benzamide (other names: Phenyl fentanyl, Benzoyl 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. Research chemicals.

a. 4-acetyloxy-N,N-diallyltryptamine (other name: 4-AcO-DALT), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 4-chloro-N,N-dimethylcathinone, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

c. 4-hydroxy-N,N-methylisopropyltryptamine (other name: 4-hydroxy-MiPT), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

d. 3,4-Methylenedioxy-alpha-pyrrolidinohexanophenone (other name: MDPHP), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Cannabimimetic agent.

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

The placement of drugs listed in this subsection shall remain in effect until (18 months from the effective date of the regulation), unless enacted into law in the Drug Control Act." (motion by Warriner, second by Thornbury)

Amend 18VAC110-20-10, Storage Temperature Definition Reference to Freezer

USP has revised the allowable temperature range for drug storage in a freezer, therefore, the Board should consider amending regulation to conform to this standard. Historically, USP's definition for storage temperature in a freezer was between 20 and 10 degrees Celsius. The definition now is a "controlled temperature between 25 and 10 degrees Celsius" and that in "some instances articles may have a recommended storage condition below 20 degrees Celsius. In such cases, the temperature of the storage location should be controlled to +/- 10 degrees."

MOTION:

The Board voted unanimously to adopt a fast-track action to amend the meaning of "cold" within the definition of "storage temperature" in 18VAC110-20-10 by striking "maintained thermostatically between -20° and -10°C (-4° and 14°F)" following the phrase "A freezer is a cold place in which the temperature is" and replacing with "controlled between –25° and –10°C (-13° and 14°F). In those instances in which articles may have a recommended storage condition below -20° C (-4°F), the temperature of the storage location should be controlled to +/-10°". (motion by Warriner, second by Jenkins)

Adoption of Final Regulations for E-Profile Requirement

Ms. Yeatts provided background on the proposed regulations and indicated that no public comment was received. The final regulations for consideration are identical to the proposed regulations. Applicants as well as renewal applicants would be required to provide the board with their e-profile ID number issued by NABP. Ms. Juran confirmed that most applicants already have an e-profile ID and there is no cost for obtaining the ID. Use of the e-profile ID will assist board staff in securely and efficiently communicating with NABP on licensure or disciplinary-related matters.

MOTION:

The Board voted unanimously to adopt final regulations to require pharmacists, pharmacy technicians and pharmacy interns to provide an e-profile ID number when applying for a new license or registration or renewing their license or registration. (motion by Nelson, second by Bolyard)

Adoption of Proposed Regulations for Labeling of Dispensed Medications

Ms. Yeatts reminded the Board that a petition for rulemaking was received on this subject and that the Board had adopted a NOIRA. She reported that comments received on the NOIRA generally favored rulemaking. One commenter did not support the petitioner's request for rulemaking. The Board now needed to consider the adoption of proposed regulations on the subject. The draft proposed regulations provided in the agenda packet amended 18VAC110-25-275(B) to clarify requirements for the policies and procedure manual when a pharmacy delivers a dispensed drug to another pharmacy. Additionally, it stated that the identity of the pharmacy solely involved in the holding of a prescription for pick-up or further delivery is not required on the

prescription label, or may be included in a unique identifier, when that pharmacy has not shared in other filling or dispensing functions. Ms. Warriner expressed concern for patients and other caregivers potentially not being able to identify both pharmacies on the prescription label. Ms. Thornbury agreed with Ms. Warriner's comments. It was stated that it may be confusing to the patient to have two phone numbers listed on the label and that it may be more appropriate to list only the number of the pharmacy that was involved in the dispensing of the drug. Ms. Yeatts reminded the Board that the action is still at the proposed stage so there will be an additional 60-day comment period for the public to provide comment on the proposed regulations.

MOTION:

The Board voted unanimously to refer the matter to the Regulation Committee for further consideration of the draft proposed regulatory language. (motion by Logan, second by Richards-Spruill)

Adoption of Fast-Track Regulation for Pharmacy Permit Recession

The Board previously adopted a proposed regulatory action to authorize the Board to rescind a pharmacy permit if the pharmacy did not become operational within a defined period. Counsel subsequently advised that the action was not consistent with statutory authority and needed to be revised. Ms. Juran reminded the Board that this action was intended to address concerns with what appears to be suspicious fraudulent activity. The revised language indicates that once a pharmacy permit is issued, a pharmacy must be operational within 90 days of issuance. The Board may grant an extension for good cause shown. If not operational and no extension is granted, the pharmacy would be subject to possible disciplinary action for violating the regulatory requirement.

MOTION:

The Board voted unanimously to adopt a fast track regulatory action to amend 18VAC110-20-140 by inserting a new subsection F that reads:

- **"Once a permit has been issued, the pharmacy shall be fully operational within 90 days of issuance. For good cause shown, such as circumstances beyond the control of the permit holder, the board may grant an extension." (motion by Warriner, second by Nelson)**

Review of Guidance Documents

The Board completed its review of guidance documents that have not been reviewed or re-adopted in the past 4 years. Ms. Juran indicated that Guidance Document 110-43 should be amended to accurately reflect the current edition of the FDA's Orange Book.

MOTION:

The Board voted unanimously to amend sentences within the first paragraph of Guidance Document 110-43 in accordance with the underlined additions and strikethroughs listed below:

- **"However, according to the preface of the ~~32nd~~ 38th edition of the FDA's Orange Book, ~~page vii,~~ "Any drug product in the ~~List~~ Orange Book repackaged and/or distributed by other than the ~~application~~**

~~holder~~ applicant is considered to be therapeutically equivalent to the ~~application holder's~~ applicant's drug product even if the ~~application holder's~~ applicant's drug product is single source or coded as non-equivalent (e.g., BN). ~~Also, distributors or repackagers of an application holder's drug product are considered to have the same code as the application holder.~~"

(motion by Logan, second by Warriner)

MOTION:

The Board voted unanimously to re-adopt the following Guidance Documents as presented, along with the amended Guidance Document 110-43:

- **110-3–Guidance on alternate delivery of prescriptions, pharmacy to physician or pharmacy to controlled substance registration type of delivery**
- **110-21 – Sanction Reference Points Manual**
- **110-28 – Guidance for Free Clinic Pharmacy Permit Applicants**
- **110-30 – Drugs within animal shelters and pounds**
- **110-32 – Use of a drop-box for the collection of prescriptions**
- **110-33 – Pharmacy interns as pharmacy technicians, Pharmacy technician ratio**
- **110-37 – Guidance for conducting informal fact-finding by an agency subordinate.**
- **110-40 – Storage of Schedule II drugs in a pharmacy**
- **110-41 – Changes a pharmacist may make to a Schedule II prescription**
- **110-42 – Continuing Education audit and recommended sanctions**
- **110-43 – Dispensing with an authorized generic**

(motion by Logan, second by Richards-Spruill)

Re-Adoption of White Bagging/Brown Bagging Regulations

Following the Board's adoption of proposed regulatory amendments to 18VAC110-20-275 in November 2018, staff received several comments expressing concern that the adopted language would prohibit hemophiliac patients from receiving blood factors delivered to their residence that may be needed for emergent treatment. A handout of the proposed regulatory amendment was provided to the Board for their consideration that included an exception in subsection G that would allow emergent blood factor treatment intended to be subsequently transported by the patient or patient's agent to a hospital, medical clinic, prescriber's office, or pharmacy for administration and that required special storage, reconstitution or compounding prior to administration, to be delivered to a patient's residence.

MOTION:

The Board voted 9 to 0 to readopt the proposed regulatory amendment to 18VAC110-20-275 as presented that inserted the following sentence at the end of subsection G, "An exception to this requirement may be made for patients with hemophilia who may require emergent blood factor treatment." (motion by Logan, second by Boone; abstention by Warriner)

OLD BUSINESS

MOTION FOR CLOSED MEETING:

Upon a motion by Ms. Warriner, and duly seconded by Mr. Logan, the Board unanimously voted to convene a closed meeting pursuant to § 2.2-2711 (A) (8) of the Code of Virginia to receive legal advice regarding the Virginia Freedom of Information Act and the consideration of the applications for pharmaceutical processor permits. In addition, Mr. Saenz moved that Caroline Juran, Jim Rutkowski, Elaine Yeatts, and Sammy Johnson attend the closed session because their presence is necessary and will reasonably aid the board.

MOTION TO RECONVENE:

Upon motion by Ms. Warriner, and duly seconded by Ms. Nelson, the board certified to the best of their knowledge, that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed session were heard, discussed, or considered during the closed session that just concluded.

Finalize Pharmaceutical Processor Conditional Approvals

Prior to the Board considering the finalizing of the conditional approval for the fifth pharmaceutical processor, Dharma Pharmaceuticals, and their submission of an application for change of location, Mr. Ratliff stated that he would recuse himself from the discussions since he wrote a letter of support for Dharma Pharmaceuticals prior to being appointed to the Board.

Ms. Nelson suggested that the Board consider denying the change of location application, consistent with the handling of Dalitso's change of location application, because the Board has completed an extensive RFA evaluation process and it may not be fair to other applicants to approve the change of location at this time. Ms. Warriner disagreed, because Dharma's request for a change of location involved concerns with patient issues, unlike the request from Dalitso. Ms. Thornbury agreed with Ms. Warriner that this request involved concerns with patient safety and the request from Dalitso was focused more on allowing the processor to open earlier. Ms. Warriner also commented that the alternate site is in the same municipality as the originally proposed site, there is broad support from the municipality and legislators, and valid reasons exist for supporting the change of location. Ms. Thornbury also commented that from the information the applicant provided with the change of location application that the alternate site might be a more secure location. Mr. Logan requested clarity from Board members that were advocating for the approval based on security. Ms. Warriner commented that since the alternate location is a stand-alone facility, there would be better security as opposed to being in a building with other businesses. Also, potentially being located next to a casino does not lend itself to mixing well with medical care from a security standpoint. Mr. Bolyard commented that he does not feel that the Board should consider approving another location other than what was considered initially during the awarding of the conditional approvals. Ms. Warriner commented that she thoroughly reviewed all 51 applications and feels the Board would have awarded the same conditional approvals even if Dharma had listed the alternate site on its initial application.

MOTION:

The board voted 3-4 to approve the change of location application for

Dharma Pharmaceuticals in Health Service Area 3, therefore, the motion failed. (motion by Warriner, seconded by Thornbury; opposed by Nelson, Bolyard, Jenkins, Saenz; abstentions by Logan and Boone; Ratliff recused).

MOTION:

The Board voted 7-3 to finalize the awarding of the conditional approval for Dharma Pharmaceuticals at the location listed on the original application. (motion by Nelson, seconded by Bolyard; abstentions by Warriner, Boone, and Logan; Ratliff recused)

Request from Gates Healthcare Associates, Inc. regarding cGMP Inspections

The board reviewed the information presented by Gates Healthcare Associates. There was some discussion regarding the allowance for accepting cGMP inspections performed by Bestech, in lieu of an FDA inspection for licensure purposes. Mr. Johnson confirmed that there have been no issues of concern thus far. There was some discussion regarding whether a need existed for approving a second entity to perform these inspections.

MOTION:

The Board voted 3-0 to deny the request by Gates Healthcare Associates, Inc. (motion by Nelson, seconded by Richards-Spruill; abstentions by Saenz, Warriner, Thornbury, Logan, Jenkins, Bolyard, and Boone. It was determined that the motion did not pass due to the number of abstentions.)

MOTION:

The Board voted unanimously to obtain and review, in consultation with Mr. Johnson and Ms. O'Halloran, additional information from Gates Healthcare regarding its proposed inspection report and to further consider the expertise of the persons who would be performing the cGMP inspections. (motion by Logan, second by Warriner)

NEW BUSINESS

Presentation on Sanction Reference Points

Mr. Neal Kauder and Ms. Kim Small from Visual Research provided a training presentation on the Sanction Reference Points, explaining its creation and how the Board is currently utilizing it.

MOTION:

The Board voted unanimously to amend letter D on the SRP Worksheet for Pharmacists within Guidance Document 110-21 to read "Violations associated with multiple cases". (motion by Warriner, second by Boone)

Review of Pharmaceutical Processor Inspection Report

Mr. Johnson provided an overview of the current draft of the pharmaceutical processor inspection report. Mr. Johnson, Melody Morton and two pharmacy inspectors will be traveling to Connecticut in January to visit three pharmaceutical processor locations and learn more about CT's inspection process which may lead to additional amendments to the document. Current Good Manufacturing Practices (cGMP) information may be added to the inspection report prior to use of the form.

REPORTS

Chairman's Report

Mr. Saenz provided a report regarding the ASHP mid-year meeting that he

attended. At the meeting, the discussions revolved around topics such as drug shortages, Board of Pharmacy meetings, pharmacy technician training, and the roles of the pharmacy technician.

Report on Board of Health Professions

Mr. Logan did not information to share with the board at this time.

Report on NABP Interactive Member Forum

Ms. Warriner provided a report on the NABP interactive member forum that discussed topics such as opioid lawsuits, competency exams, and suspicious ordering. Ms. Warriner indicated that it was very informative to meet with other state board members to ascertain the work being done in other states.

Report on Licensure Program

Mr. Johnson reported the Board currently licenses 38,773 individuals and facilities. The Board issued 1,100 licenses and registrations for the period of September 1, 2018 through November 30, 2018. Inspectors conducted 562 facility inspections including 222 routine inspections of pharmacies: 109 (49%) resulted in no deficiency, 64 (29%) with deficiencies and 49 (22%) with deficiencies and a consent order. Mr. Johnson commented that two factors may have contributed to the reduction in inspections with a consent order: 1) the implementation of not issuing a consent order for the "First Documented Occurrence" for certain deficiencies that began on July 1, 2018 and 2) improved compliance by pharmacies as a result of the inspection program.

Report on Disciplinary Program

Ms. Shinaberry indicated Ileita Redd and Rose DeMatteo continue to assist with administrative functions in the absence of our Discipline Program Specialist. As of November 15, 2018, the Board had a total of 289 open cases. There were 23 cases pending an Informal Conference or Formal Hearing. There were only 7 patient-care cases at the Board level that exceeded 250 work-days, substantially below the 10% threshold for open cases. The board continues to experience a decrease in the number of inspection-related cases that result in a pre-hearing consent order. It was noted, however, that the complexity of cases is increasing as the board is seeing more cases involving fraud and indiscriminant dispensing, and mandatory suspensions of outsourcing facilities. The Board is currently recruiting for a Disciplinary Case Manager to assist with the caseload.

Executive Director's Report

Ms. Juran listed the meetings attended and presentations recently provided by board staff. She also provided a summary of board-related accomplishments over the past year and thanked board members and staff for their hard work and dedication.

MOTION FOR CLOSED MEETING:

Upon a motion by Ms. Nelson, and duly seconded by Mr. Jenkins, the Board unanimously voted to convene a closed meeting pursuant to Section 2.2-3711(A)(27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Cantrell Drug Company. In addition, Mr. Nelson moved that Caroline Juran, Jim Rutkowski, and Ellen Shinaberry attend the closed session because their presence was necessary and would reasonably aid the board.

MOTION TO RECOVENE OPEN MEETING: **Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Board reconvened in open meeting and announced the decision.**

DECISION: **The Board voted to accept the Consent Order for Cantrell Drug Company.**

ADJOURN: With all business concluded, the meeting adjourned at approximately 2:15pm.

Rafael Saenz, Chairman

DATE:

Caroline D. Juran, Executive Director

DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY

PUBLIC HEARING FOR SCHEDULING CERTAIN CHEMICALS IN SCHEDULE I

December 18, 2018
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER: The public hearing was called to order at 9:07 a.m.

PRESIDING: Rafael Saenz, Chairman

MEMBERS PRESENT:
Glenn L. Bolyard, Jr.
Melvin L. Boone, Sr.
James. L. Jenkins, Jr.
Ryan K. Logan
Cheryl H. Nelson
Kristopher S. Ratliff
Patricia Richards-Spruill
Rebecca Thornbury
Cynthia Warriner

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Ellen Shinaberry, Deputy Executive Director
Elaine J. Yeatts, Senior Policy Analyst, DHP
James Rutkowski, Assistant Attorney General
David E. Brown, Director, DHP

CALL FOR PUBLIC COMMENT: Mr. Saenz called for comment to consider placement of the following chemical substances into Schedule I:

The following compound is classified as a powerful synthetic opioid:

- N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-benzamide (other names: Phenyl fentanyl, Benzoyl fentanyl)

The following compounds are classified as research chemicals:

- 4-acetyloxy-N,N-diallyltryptamine (other name: 4-AcO-DALT)
- 4-chloro-N,N-dimethylcathinone
- 4-hydroxy-N,N-methylisopropyltryptamine (other name: 4-hydroxy-MiPT)
- 3,4-Methylenedioxy-alpha-pyrrolidinohexanophenone (other name: MDPHP)

The following compound is classified as a cannabimimetic agent:

- Methyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 5-Fluoro-MDMB-PICA)

If approved by the Board of Pharmacy, the placement of these substances in Schedule I shall go into effect 30 days following publication of the proposed regulation and remain in effect for a period of 18 months. The chemicals will then be de-scheduled unless a general law is passed by the General Assembly placing the chemicals into Schedule I.

PULIC COMMENT: Scott May, Chemistry Program Manager at the Department of Forensic Science provided information regarding the 6 chemicals it has identified for the Board's consideration to place into Schedule I. All six chemicals have been found in seized form in their laboratory.

ADJOURN: The public hearing adjourned at 9:11am.

Rafael Saenz, Chairman

Caroline D. Juran, Executive Director

Date

Date

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

Tuesday, December 18, 2018
Commonwealth Conference Center
Second Floor
Board Room 2

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

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

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 2:31 pm.

PRESIDING: Rafael Saenz, Chairman

MEMBERS PRESENT:
Glenn Bolyard
Cindy Warriner
Melvin Boone
James Jenkins
Ryan Logan
Cheryl Nelson
Kris Ratliff
Patricia Richards-Spruill
Rebecca Thornbury

STAFF PRESENT:
Caroline D. Juran, Executive Director
Ellen B. Shinaberry, Deputy Executive Director
James Rutkowski, Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

QUORUM: With ten (10) members of the Board present, a panel of the board was established.

AGNES RUBIN
License No. 0202-208745

A formal hearing was held in the matter of Agnes Rubin to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy in Virginia and to consider her application for reinstatement.

Mykl D. Egan, DHP Adjudication Specialist, presented the case.

Ms. Rubin was present.

Me-Lien Chung, DHP Senior Investigator testified in person on behalf of the Commonwealth.

Ms. Rubin testified on her own behalf.

CLOSED MEETING:	Upon a motion by Ms. Warriner, and duly seconded by Mr. Bolyard, the panel voted 10-0, 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 Agnes Rubin. Additionally, he moved that Caroline Juran, Ellen Shinaberry and Jim Rutkowski attend the closed meeting.
RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened an open meeting and announced the decision.
DECISION:	Upon a motion by Mr. Jenkins, and duly seconded by Ms. Nelson, the panel voted 10-0 to accept the Findings and Facts and Conclusion of Law proposed by Mr. Egan and amended by the Board. Upon a motion by Mr. Ratliff, and duly seconded by Ms. Warriner, the panel voted 10-0 to reinstate the pharmacist license of Ms. Rubin and place her license on probation with certain terms and conditions.
ADJOURN:	With all business concluded, the meeting adjourned at 4:55 pm.

Rafael Saenz, Chair

Caroline D. Juran
Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

January 9, 2019
Commonwealth Conference Center
Second Floor
Board Room 4

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

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

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 9:12 a.m.

PRESIDING: Rafael Saenz, Chairman

MEMBERS PRESENT:
Ryan Logan
Kristopher Ratliff
James Jenkins
Cheryl Nelson
Cindy Warriner
Melvin Boone

STAFF PRESENT:
Caroline D. Juran, Executive Director
Ellen Shinaberry, Deputy Executive Director
James Rutkowski, Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist
Wayne Halbleib, Senior Asst. Attorney General/Chief
Claire Foley, DHP Adjudication Specialist

QUORUM: With seven (7) members of the Board present, a panel of the Board was established.

FAIZ A. OLEY, JR.
License No. 0202-010741

A formal hearing was held in the matter of Faiz A. Oley, Jr. to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia and to consider his application for reinstatement.

Wayne Halbleib, Senior Asst. Attorney General/Chief, presented the case, assisted by Mykl Egan, DHP Adjudication Specialist.

Patricia L. Dewey, DHP Senior Investigator, testified in person on behalf of the Commonwealth.

Mr. Oley testified on his own behalf.

CLOSED MEETING:	Upon a motion by Ms. Warriner, and duly seconded by Mr. Boone, the panel voted unanimously, 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 Faiz A. Oley, Jr. Additionally, she moved that Caroline Juran, Ellen Shinaberry, and Jim Rutkowski attend the closed meeting.
RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the quorum re-convened an open meeting and announced the decision.
DECISION:	Upon a motion by Mr. Logan, and duly seconded by Mr. Boone, the panel voted unanimously to accept the Findings of Fact and Conclusions of Law as presented by Mr. Halbleib and amended by the Board. Upon a motion by Mr. Boone, and duly seconded by Mr. Jenkins, the panel voted unanimously to deny Faiz A. Oley's request for reinstatement of his pharmacy license. Mr. Saenz and Ms. Shinaberry departed at 11:25 am.
PRESIDING:	Cindy Warriner, Vice Chairman
QUORUM:	With six (6) members of the Board present, a panel of the Board was established.
AMANDA K. GORE Registration No. 0230029035	A formal hearing was held in the matter of Amanda K. Gore to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia. Claire Foley, DHP Adjudication Specialist, presented the case. Ms. Gore was not present.

Megan Holstein, CVS Asset Protection Manager, and Cheryl Hodgson, DHP Senior Investigator, testified by telephone on behalf of the Commonwealth.

CLOSED MEETING:

Upon a motion by Mr. Boone, and duly seconded by Ms. Nelson, the panel voted unanimously, 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 Amanda K. Gore. Additionally, he moved that Caroline Juran and Jim Rutkowski attend the closed meeting.

RECONVENE:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened an open meeting and announced the decision.

DECISION:

Upon a motion by Mr. Logan, and duly seconded by Mr. Ratliff, the panel voted unanimously to accept the Findings and Facts and Conclusion of Law proposed by Ms. Foley. Upon a motion by Mr. Ratliff, and duly seconded by Mr. Jenkins, the panel voted unanimously to indefinitely suspend Ms. Gore's right to renew her pharmacy technician registration for no less than two years.

ADJOURNED:

With all business concluded, the meeting adjourned at 12:15 p.m.

Rafael Saenz, Chairman

Date

Cindy Warriner, Vice Chairman

Date

Caroline D. Juran
Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
PUBLIC HEARING FOR PERIODIC REVIEW OF REGULATIONS

January 9, 2019
Commonwealth Conference Center
Second Floor
Board Room 4

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

CALL TO ORDER:	The public hearing was called to order at 9:08 a.m.
PRESIDING:	Rafael Saenz, Chairman
MEMBERS PRESENT:	Ryan Logan Kristopher Ratliff James Jenkins Cheryl Nelson Cindy Warriner Melvin Boone
STAFF PRESENT:	Caroline D. Juran, Executive Director Ellen Shinaberry, Deputy Executive Director Elaine J. Yeatts, Senior Policy Analyst, DHP James Rutkowski, Assistant Attorney General
CALL FOR PUBLIC COMMENT:	Mr. Saenz called for comment on the periodic review of regulations in chapters 20, 50, and the promulgation of chapters 16 and 25.
PULIC COMMENT:	No public comment was offered. Mr. Saenz reminded everyone that a public comment period will remain open until February 22, 2019.
ADJOURN:	The public hearing adjourned at 9:11am.

Rafael Saenz, Chairman

Caroline D. Juran, Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Friday, January 25, 2019
Commonwealth Conference Center
Second Floor
Board Room 1

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 9:04 a.m.
PRESIDING:	Cindy Warriner, Committee Chair
MEMBERS PRESENT:	Melvin Boone, Committee Member
STAFF PRESENT:	Ellen B. Shinaberry, Deputy Executive Director Claire Foley, DHP Adjudication Specialist Mykl Egan, DHP Adjudication Specialist
AAMNA IKRAM Registration No. 0230-028089	Aamna Ikram, pharmacy technician, did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the November 8, 2018 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Ms. Warriner, 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 Aamna Ikram. Additionally, he moved that Ellen B. Shinaberry attend the closed meeting because her presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code §2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:	Upon a motion by Mr. Boone and duly seconded Ms. Warriner, the Committee unanimously voted to enter an Order for a Reprimand.
LARRY A. CALE License No.: 0202-010147	Larry A. Cale did not appear to discuss allegations that he may have violated certain laws governing the practice of pharmacy as stated in the December 5, 2018 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Ms. Warriner, 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 Larry A. Cale. Additionally, he moved that Ellen B. Shinaberry attend the closed meeting because her presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone and duly seconded Ms. Warriner, the Committee unanimously voted to refer the matter to a panel of the Board for a formal hearing and to offer a Consent Order for suspension of his right to renew his pharmacist license in lieu of the formal hearing.
LANSDOWNE PHARMACY Permit No. 0201-004183	Pascale El-Hayek, Pharmacist in charge, appeared on behalf of Lansdowne Pharmacy to discuss allegations that Lansdowne Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the August 31, 2018 and October 29, 2018 Notices.

Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Ms. Warriner, 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 Lansdowne Pharmacy. Additionally, he moved that Ellen B. Shinaberry attend the closed meeting because her presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision	Upon a motion by Mr. Boone and duly seconded Ms. Warriner, the Committee unanimously voted to issue a monetary penalty and place Lansdowne Pharmacy on probation with terms.
TERRY SMITH Registration No. 0230-029152	Terry Smith, pharmacy technician, did not appear to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the October 30, 2018 Notice.
Decision:	Upon a motion by Mr. Boone and duly seconded Ms. Warriner, the Committee unanimously voted to enter an Order for a reprimand.
BARBARA JACKSON Registration No.: 0230-009243	Barbara Jackson, pharmacy technician, did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the October 30, 2018 Notice.
Decision:	Upon a motion by Mr. Boone and duly seconded Ms. Warriner, the Committee unanimously voted to enter an Order for a reprimand.
KENNEDY HARVELL Registration No.: 0230-027152	Kennedy Harvell, pharmacy technician, did not appear to discuss allegations that he may have

violated certain laws and regulations governing the practice of pharmacy technicians as stated in the October 30, 2018 Notice.

Decision: Upon a motion by Mr. Boone and duly seconded Ms. Warriner, the Committee unanimously voted to enter an Order for a reprimand.

PATRICIA HARMON
Registration No.: 0230-026133

Patricia Harmon, pharmacy technician, did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the October 30, 2018 Notice.

Decision: Upon a motion by Mr. Boone and duly seconded Ms. Warriner, the Committee unanimously voted to enter an Order for a reprimand.

NYRA STATON
Registration No.: 0230-027638

Nyra Staton, pharmacy technician, did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the October 30, 2018 Notice.

Decision: Upon a motion by Mr. Boone and duly seconded Ms. Warriner, the Committee unanimously voted to enter an Order for a reprimand.

CRYSTAL AUSTIN
Registration No.: 0230-001045

Crystal Austin, pharmacy technician, did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the October 30, 2018 Notice.

Decision: Upon a motion by Mr. Boone and duly seconded Ms. Warriner, the Committee unanimously voted to enter an Order for a reprimand.

JOHN SNYDER
Registration No.: 0230-028325

John Snyder, pharmacy technician, did not appear to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the November 1, 2018 Notice.

Decision:	Upon a motion by Mr. Boone and duly seconded Ms. Warriner, the Committee unanimously voted to enter an Order for a reprimand.
KWAME BOATENG Registration No.: 0230-025106	Kwame Boateng, pharmacy technician, did not appear to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in November 1, 2018 Notice.
Decision:	Upon a motion by Mr. Boone and duly seconded Ms. Warriner, the Committee unanimously voted to enter an Order for a reprimand.
MAHLET LAKEW Registration No.: 0230-027789	Mahlet Lakew, pharmacy technician, did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in November 1, 2018 Notice.
Decision:	Upon a motion by Mr. Boone and duly seconded Ms. Warriner, the Committee unanimously voted to enter an Order for a reprimand.
KRYSTAL SETTLE Registration No.: 0230-029138	Krystal Settle, pharmacy technician, appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in November 1, 2018 Notice.
Decision:	Upon a motion by Mr. Boone and duly seconded Ms. Warriner, the Committee unanimously voted to not issue a sanction.
EDWARD OKATAH-BOI License No.: 0202-210931	Edward Okatah-Boi, pharmacist, appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in October 30, 2018 Notice.
Decision:	Upon a motion by Mr. Boone and duly seconded Ms. Warriner, the Committee unanimously voted to enter an Order for a reprimand.

GOOD HEALTH PHARMACY AT HARBOR VIEW Permit No.: 0201-004530	Good Health Pharmacy at Harbor View did not appear to discuss allegations that Good Health Pharmacy at Harbor View may have violated certain laws and regulations governing the conduct of pharmacy as stated in the December 17, 2018 Notice.
Decision:	Upon a motion by Mr. Boone and duly seconded Ms. Warringer, the Committee unanimously voted to refer the matter to issue a monetary penalty.
ADJOURNED:	2:49 PM

Cindy Warriner, Chair	Ellen B. Shinaberry Deputy Executive Director
Date	Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF INFORMAL CONFERENCE COMMITTEE

February 13, 2019
Second Floor
Hearing Room 5

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

CALL TO ORDER:	A meeting of an informal conference committee of the Board of Pharmacy was called to order at 9:07 AM.
PRESIDING:	Rafael Saenz, Committee Chairman
MEMBER PRESENT:	Ryan Logan
STAFF PRESENT:	Caroline D. Juran, Executive Director Sammy Johnson, Deputy Executive Director Ellen Shinaberry, Deputy Executive Director Mykl Egan, DHP Adjudication Specialist Kiara Christian, Executive Assistant
Partners Pharmacy Automatic Dispensing System AP Passport, Applicant	Nikki Bonas, pharmacist-in-charge of Partners Pharmacy; Jody Fenelon, Director of Compliance for Partners Pharmacy; and Frank Wang, Vice President of Operations for Partners Pharmacy were present to discuss the application, received October 17, 2018, for approval of an Innovative (Pilot) program from Partners Pharmacy of Virginia LLC. Partners Pharmacy is seeking to install a fully automated, remotely monitored medication dispensing center known as "AP PassPort" into long term care facilities located in the state of Virginia. Partners Pharmacy of Virginia LLC is seeking a waiver of 18 VAC 110-20-425 of the regulations governing the Practice of Pharmacy dealing with robotic pharmacy systems and any other regulations that would prevent the AP PassPort from being installed.
Discussion:	Representatives of Partners Pharmacy of Virginia, LLC presented information about the available technology that allows automated disbursement and medication management for use in skilled facilities interested in using the fully supported pharmacy platform AP Passport. Statements made by the applicant indicated that Partners Pharmacy of Virginia would use AP Passport to package and monitor the disbursement of oral solid medications given to patients at skilled nursing facilities.

Decision:	After consideration of the application and statements concerning the proposed Innovative (Pilot) program, Mr. Saenz moved, and the Committee voted in favor of the motion, that the application for an Innovative (Pilot) program be approved, under certain terms and conditions, for a period of three (3) years beginning 30 days from the date the Order is entered by the board. The Order summarizing the terms and conditions will be prepared and mailed to the applicant.
ADJOURN:	With all business concluded, the meeting adjourned at 11:45AM.

Rafael Saenz Committee Chairman	Caroline D. Juran Executive Director
Date	Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

February 27, 2019
Commonwealth Conference Center
Second Floor
Board Room 4

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

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

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 9:08 a.m.

PRESIDING: Rafael Saenz, Chair

MEMBERS PRESENT:
Melvin Boone
Glenn Bolyard
Jim Jenkins
Cheryl Nelson
Kris Ratliff
Patricia Richards-Spruill

STAFF PRESENT:
Ellen Shinaberry, Deputy Executive Director
James Rutkowski, Assistant Attorney General
Wayne Halbleib, Senior Assistant Attorney General (departed at 9:25 am)
Anne Joseph, Deputy Executive Director, APD (departed at 9:25 am)

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

POSSIBLE SUMMARY SUSPENSION

GWENDOLYN BOYKIN
License No. 0202-006898

Wayne Halbleib, Senior Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a summary suspension. Anne Joseph, Deputy Executive Director APD, was also present.

CLOSED MEETING: Upon a motion by Mr. Bolyard, and duly seconded by Mr. Boone, the panel 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 Gwendolyn Boykin. Additionally, he moved that Ellen Shinaberry

and Jim Rutkowski attend the closed meeting.

RECONVENE: Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the quorum re-convened an open meeting and announced the decision.

DECISION: Upon a motion by Mr. Jenkins and duly seconded by Ms. Richards-Spruill, the Board unanimously voted that, with the evidence presented, the practice as a pharmacist by Gwendolyn Boykin poses a substantial danger to the public; and therefore, the license of Ms. Boykin shall be summarily suspended, and that a Consent Order shall be offered to Ms. Boykin for the indefinite suspension of her license to practice as a pharmacist for not less than two years, in lieu of a formal administrative hearing.

FORMAL HEARING

ADDITIONAL MEMBERS ARRIVING: Cynthia Warriner (arrived at 9:25 am)

QUORUM: With eight (8) members of the Board present, a quorum was established.

ROBERT CLOUTIER
License #: 0202-006751

A formal hearing was held in the matter of Robert Cloutier, pharmacist, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia. Mr. Cloutier did not appear on his own behalf and was not represented by counsel.

Claire Foley, DHP Adjudication Specialist, presented the case.

Bradley Zaretsky, District Asset Protection Leader, CVS, testified in person on behalf of the Commonwealth.

Cheryl Hodgson, DHP Senior Investigator, testified by telephone on behalf of the Commonwealth.

CLOSED MEETING: Upon a motion by Ms. Warriner, and duly seconded by Ms. Nelson, the panel 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 Robert Cloutier. Additionally, she moved that Ellen Shinaberry and Jim Rutkowski attend the closed meeting.

RECONVENE: Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the quorum re-convened an open meeting and announced the decision.

DECISION: Upon a motion by Ms. Warriner and duly seconded by Ms. Nelson, the Board unanimously voted to suspend the pharmacist license of Robert Cloutier indefinitely for no less than 2 years .

CONSIDERATION OF CONSENT ORDER

AMEX PHARMACY
License No. 0214001251

Ms. Shinaberry presented a Consent Order for reinstatement of the pharmacy permit for AmEX Pharmacy.

DECISION: Upon a motion by Ms. Warriner and duly seconded by Mr. Boone, the Board unanimously voted to accept the Consent Order.

ADJOURNED: With all business concluded, the meeting adjourned at 10:48 am.

Rafael Saenz, Chair

Caroline D. Juran
Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Thursday, February 28, 2018
Commonwealth Conference Center
Second Floor
Board Room 1

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 09:08 a.m.
PRESIDING:	Patricia Richards-Spruill, Committee Chair
MEMBERS PRESENT:	Kris Ratliff, Committee Member
STAFF PRESENT:	Ellen B. Shinaberry, Deputy Executive Director Claire Foley, DHP Adjudication Specialist Mykl Egan, DHP Adjudication Specialist Jessica Kelley, DHP Adjudication Specialist
STEPHANIE SCHICK License No. 0202-213382	Stephanie Schick, Pharmacist and Nicholas Ballard, Attorney, appeared on behalf of Ms. Schick to discuss allegations that Ms. Schick may have violated certain laws and regulations governing the practice of pharmacy as stated in the October 29, 2018 Notice.
Closed Meeting:	Upon a motion by Mr. Ratliff, and duly seconded by Ms. Patricia 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 Stephanie Schick. Additionally, he moved that Ellen Shinaberry attend the closed meeting because her presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:	Upon a motion by Mr. Ratliff and duly seconded Ms. Richards-Spruill, the Committee unanimously to enter an Order to issue a Reprimand.
EXPRESS PHARMACY Permit No. 0201-004491	Joel Sarsah, Pharmacist and owner, and Felix Asamoah-Darko, appeared on behalf of Express Pharacy to discuss allegations that Express Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the October 29, 2018 Notice.
Closed Meeting:	Upon a motion by Mr. Ratliff, and duly seconded by Ms. 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 Express Pharmacy. Additionally, he moved that Ellen Shinaberry attend the closed meeting because her presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Ratliff and duly seconded Ms. Richards-Spruill, the Committee unanimously voted to enter an Order for the assessment of a monetary penalty.
AdKOA PHARMACY Permit No. 0201-004744	Adwoa Addai, Pharmacist, appeared on behalf of AdKOA Pharmacy to discuss allegations that AdKOA Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the November 1, 2018 Notice.

Closed Meeting:	Upon a motion by Mr. Ratliff, and duly seconded by Ms. 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 AdKOA Pharmacy. Additionally, he moved that Ellen Shinaberry attend the closed meeting because her presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Ratliff and duly seconded Ms. Richards-Spruill, the Committee unanimously voted to enter an Order with no sanction imposed.
GEORGETTE J. PRIESTER-GONZALEZ Registration No. 0230-014187	Georgette J. Priester-Gonzalez, appeared on her behalf to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the November 2, 2018 Notice.
Closed Meeting:	Upon a motion by Mr. Ratliff, and duly seconded by Ms. 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 Georgette J. Priester-Gonzalez. Additionally, she moved that Ellen Shinaberry attend the closed meeting because her presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee

reconvened in open meeting and announced the decision.

Decision: Upon a motion by Mr. Ratliff, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to enter an Order with no sanction imposed.

CAROLYN HUNT
Registration No. 0230-011628

Carolyn Hunt, did not appear on her behalf to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the November 2, 2018 Notice.

Decision: Upon a motion by Mr. Ratliff, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to enter an Order to impose a Reprimand.

KAREN L. WEBBER-HARRELL
Registration No. 0230-027925

Karen L. Webber-Harrell, did not appear on her behalf to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the November 2, 2018 Notice.

Decision: Upon a motion by Mr. Ratliff, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to enter an Order to impose a Reprimand.

PHILIP S. HUNKING
Registration No. 0230-021878

Philip S. Hunking, did not appear on his behalf to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the November 2, 2018 Notice.

Decision: Upon a motion by Mr. Ratliff, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to enter an Order to impose a Reprimand.

JANE Y. BINAS
Registration No. 0230-001846

Jane Y. Binas, did not appear on her behalf to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the November 2, 2018 Notice.

Decision: Upon a motion by Mr. Ratliff, and duly seconded

by Ms. Richards-Spruill, the Committee unanimously voted to enter an Order to impose a Reprimand.

KYLE RATHJE
Registration No. 0230-025175

Kyle Rathje, did not appear on his behalf to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the November 2, 2018 Notice.

Decision:

Upon a motion by Mr. Ratliff, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to enter an Order to impose a Reprimand.

MISTY D. HOKE
Registration No. 0230-021994

Misty D. Hoke, did not appear on her behalf to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the November 1, 2018 Notice.

Decision:

Upon a motion by Mr. Ratliff, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to enter an Order to impose a Reprimand.

VICKIE YATES
Registration No. 0230-006966

Vickie Yates, did not appear on her behalf to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the November 1, 2018 Notice.

Decision:

Upon a motion by Mr. Ratliff, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to enter an Order to impose a Reprimand.

KIRAN S. CHAUDHRY
Registration No. 0230-019334

Kiran S. Chaudhry, did not appear on her behalf to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the November 1, 2018 Notice.

Decision:

Upon a motion by Mr. Ratliff, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to enter an Order to impose a Reprimand.

SANDRA T. LAM Registration No. 0230-023544	Sandra T. Lam, did not appear on her behalf to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the November 1, 2018 Notice.
Decision:	Upon a motion by Mr. Ratliff, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to enter an Order to impose a Reprimand.
BRITTNEY D. HANCOCK Registration No. 0230-022802	Brittney D. Hancock, did not appear on her behalf to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the November 15, 2018 Notice.
Decision:	Upon a motion by Mr. Ratliff, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to enter an Order to impose a Reprimand.
JOSEPHINE SARSOUR Registration No. 0230-003575	Josephine Sarsour, did not appear on her behalf to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the November 19, 2018 Notice.
Decision:	Upon a motion by Mr. Ratliff, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to enter an Order to impose a Reprimand.
ADJOURNED:	3:31 PM

_____
Patricia Richards-Spruill, Chair

_____
Ellen B. Shinaberry
Deputy Executive Director

_____
Date

_____
Date

Report of the 2019 General Assembly

Board of Pharmacy

HB 1743 Pharmacist; counseling for new prescriptions, disposal of medicine.

Chief patron: Bulova

Summary as introduced:

Pharmacist; counseling for new prescriptions; disposal of medicine. Allows a pharmacist to include information regarding the proper disposal of medicine when giving counsel to a person who presents a new prescription for filling. This bill is identical to SB 1405.

HB 1803 Controlled substances; adds certain chemicals to Schedule I and Schedule II.

Chief patron: Garrett

Summary as passed House:

Controlled substances; Schedules I and II. Adds certain chemicals to Schedule I and Schedule II of the Controlled Substances Act.

HB 1839 Industrial hemp; federal Farm Bill.

Chief patron: Marshall

Summary as passed:

Industrial hemp; federal Farm Bill; emergency. Conforms Virginia law to the provisions of the federal 2018 Farm Bill by amending the definitions of cannabidiol oil, marijuana, and tetrahydrocannabinol (THC) to exclude industrial hemp in the possession of a registered person, hemp products, or an oil containing no more than 0.3% THC. The bill defines "industrial hemp" as any part of the plant Cannabis sativa that has a concentration of THC that is no greater than that allowed by federal law, and it defines "hemp product" as any finished product that is otherwise lawful and that contains industrial hemp. The bill it adds the category of "dealer" in industrial hemp to the existing registration categories of grower and processor.

The bill requires any registered grower, dealer, or processor who negligently violates the law to comply with a corrective action plan established by the Commissioner of Agriculture and Consumer Services (the Commissioner). The plan must identify a date by which the person is required to correct the violation and requires the person to report periodically for not less than two calendar years on his compliance with the law. No person who negligently violates the

industrial hemp law three times in a five-year period is eligible to grow, deal in, or process industrial hemp for a period of five years beginning on the date of the third violation.

The bill directs the Commissioner to (i) revoke the registration of any registered grower, dealer, or processor who violates the law with a culpable mental state greater than negligence and (ii) advise the Attorney General of the United States and the Superintendent of State Police, or the chief law-enforcement officer of the county or city, when such person grows, deals in, or processes any Cannabis sativa with a concentration of THC that is greater than that allowed by federal law with a culpable mental state greater than negligence.

The bill authorizes the Department of Agriculture and Consumer Services (the Department), if it obtains the approval of the U.S. Secretary of Agriculture, to refrain from requiring destruction of industrial hemp until the THC level is greater than 0.6%, and it authorizes the Department at that point to allow a re-test of the industrial hemp if the THC level is no greater than one percent.

The bill abolishes the higher education and Virginia industrial hemp research programs, along with the requirement that a grower or processor act exclusively within such a program. The bill authorizes the Commissioner to charge a fee for certain THC testing. Finally, the bill directs the Department to report by December 1, 2019, (a) to the General Assembly on the fiscal impact of the growth of the industrial hemp industry upon the Department's registration program and the existence of any need to alter the registration fee and (b) to the Chairmen of the House and Senate Agriculture Committees on the viability of markets for Virginia industrial hemp growers, the types of products made from industrial hemp that can be produced in Virginia, and the economic benefits and costs of production of such products. The bill also directs the Secretary of Agriculture and Forestry and the Secretary of Health and Human Resources to report by November 1, 2019, on the appropriate standards, if any, for the production of an oil with a THC concentration of no greater than 0.3 percent that is derived from industrial hemp. The bill contains an emergency clause.

EMERGENCY

HB 1841 Pharmaceutical processors; employment, misdemeanors.

Chief patron: Marshall

Summary as passed House:
Pharmaceutical processors; employment; misdemeanors. Allows pharmaceutical processors to employ or permit to act as an agent of such pharmaceutical processor persons who have been convicted of certain drug and drug paraphernalia misdemeanors, except in cases where such conviction occurred within the last five years. The bill also requires that pharmaceutical processors adopt policies for pre-employment drug screening and regular, ongoing, random drug screening of employees.

HB 1878 Naloxone; possession and administration by regional jail employees.

Chief patron: Garrett

Summary as introduced:
Possession and administration of naloxone; regional jail employees. Adds employees of regional jails to the list of individuals who may possess and administer naloxone or other opioid antagonist, provided that they have completed a training program.

HB 1952 Patient care teams; podiatrists and physician assistants.

Chief patron: Campbell, J.L.

Summary as passed House:

Patient care team podiatrist definition; physician assistant supervision requirements. Establishes the role of "patient care team podiatrist" as a provider of management and leadership to physician assistants in the care of patients as part of a patient care team. The bill modifies the supervision requirements for physician assistants by establishing a patient care team model. The bill directs the Board of Medicine to adopt emergency regulations to implement the provisions of the bill and is identical to SB 1209.

HB 1971 Health professions and facilities; adverse action in another jurisdiction.

Chief patron: Stolle

Summary as introduced:
Health professions and facilities; adverse action in another jurisdiction. Provides that the mandatory suspension of a license, certificate, or registration of a health professional by the Director of the Department of Health Professions is not required when the license, certificate, or registration of a health professional is revoked, suspended, or surrendered in another jurisdiction based on disciplinary action or mandatory suspension in the Commonwealth. The bill extends the time by which the Board of Pharmacy (Board) is required to hold a hearing after receiving an application for reinstatement from a nonresident pharmacy whose registration has been suspended by the Board based on revocation or suspension in another jurisdiction from not later than its next regular meeting after the expiration of 30 days from receipt of the reinstatement application to not later than its next regular meeting after the expiration of 60 days from receipt of the reinstatement application.

HB 2158 Naloxone; expands list of individuals who may dispense.

Chief patron: Plum

Summary as passed House:
Dispensing of naloxone. Expands the list of individuals who may dispense naloxone pursuant to a standing order to include health care providers providing services in hospital emergency departments and emergency medical services personnel and eliminates certain requirements. The bill establishes requirements for the dispensing of naloxone in an injectable formulation with a hypodermic needle or syringe. The bill also allows a person who dispenses naloxone on behalf of

an organization to charge a fee for the dispensing of naloxone, provided that the fee is no greater than the cost to the organization of obtaining the naloxone dispensed.

HB 2228 Nursing and Psychology, Boards of; health regulatory boards, staggered terms.

Chief patron: Bagby

Summary as introduced:
Composition of the Boards of Nursing and Psychology; health regulatory boards; staggered terms. Alters the composition of the Board of Nursing and replaces the requirement that the Board of Nursing meet each January with the requirement that it meet at least annually. The bill also removes specific officer titles from the requirement that the Board of Nursing elect officers from its membership. The bill replaces the requirement that a member of the Board of Psychology be licensed as an applied psychologist with the requirement that that position be filled by a member who is licensed in any category of psychology. The bill also provides a mechanism for evenly staggering the terms of members of the following health regulatory boards, without affecting the terms of current members: Board of Nursing, Board of Psychology, Board of Dentistry, Board of Long-Term Care Administrators, Board of Medicine, Board of Veterinary Medicine, Board of Audiology and Speech-Language Pathology, Board of Pharmacy, and Board of Counseling.

HB 2318 Naloxone; possession and administration by school nurses and local health department employees.

Chief patron: McGuire

Summary as passed House:

Possession and administration of naloxone; school nurses; local health department employees. Adds school nurses, local health department employees that are assigned to a public school pursuant to an agreement between the local health department and school board, and other school board employees or individuals contracted by a school board to provide school health services to the list of individuals who may possess and administer naloxone or other opioid antagonist, provided that they have completed a training program.

HB 2493 Topical drugs; administration by dental hygienists, physician assistants, and nurses.

Chief patron: Tran

Summary as introduced:
Administration of topical drugs; dental hygienists, physician assistants, and nurses. Authorizes a dental hygienist practicing under remote supervision to administer topical oral anesthetics, topical and directly applied antimicrobial agents for treatment of periodontal pocket lesions, and any other Schedule VI topical drug approved by the Board of Dentistry. Under current law, a dental hygienist must be practicing under general supervision to do so.

Additionally, the bill authorizes a physician assistant, nurse, or dental hygienist to possess and administer topical fluoride varnish pursuant to an oral or written order or a standing protocol. Under current law, such possession and administration is limited to administration to children aged six months to three years and is required to conform to standards adopted by the Department of Health.

HB 2556 Health Professions, Dept of, and health regulatory boards; information obtained in an investigation.

Chief patron: Plum

Summary as introduced:
Department of Health Professions and health regulatory boards; information obtained in an investigation or disciplinary proceeding; authorized disclosures. Provides that provisions protecting the confidentiality of information obtained during an investigation or disciplinary hearing do not prohibit the disclosure of information about a suspected violation of state or federal law or regulation to state law enforcement. Under current law, such disclosure is authorized only to agencies within the Health and Human Resources Secretariat or to federal law-enforcement agencies. The bill also provides that investigative staff of agencies to which disclosure is authorized are not prohibited from interviewing fact witnesses, disclosing to fact witnesses the identity of the subject of the complaint or report, or reviewing with fact witnesses any portion of records or other supporting documentation necessary to refresh the fact witnesses' recollection.

HB 2557 Drug Control Act; classifies gabapentin as a Schedule V controlled substance.

Chief patron: Pillion

Summary as passed:

Drug Control Act; Schedule V; gabapentin. Classifies gabapentin as a Schedule V controlled substance. Current law lists gabapentin as a drug of concern. The bill also removes the list of drugs of concern from the Code of Virginia and provides that any wholesale drug distributor licensed and regulated by the Board of Pharmacy and registered with and regulated by the U.S. Drug Enforcement Administration shall have until July 1, 2020, or within six months of final approval of compliance from the Board of Pharmacy and the U.S. Drug Enforcement Administration, whichever is earlier, to comply with storage requirements for Schedule V controlled substances containing gabapentin.

HB 2559 Electronic transmission of certain prescriptions; exceptions.

Chief patron: Pillion

Summary as passed House:

Electronic transmission of certain prescriptions; exceptions. Provides certain exceptions, effective July 1, 2020, to the requirement that any prescription for a controlled substance that contains an opioid be issued as an electronic prescription. The bill requires the licensing health regulatory boards of a prescriber to grant such prescriber a waiver of the electronic prescription requirement for a period not to exceed one year due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the prescriber, or other exceptional circumstances demonstrated by the prescriber. The bill provides that a dispenser is not required to determine whether one of the exceptions applies when he receives a non-electronic prescription for a controlled substances containing opioids. The bill requires the Boards of Medicine, Nursing, Dentistry, and Optometry to promulgate regulations to implement the prescriber waivers. Finally, the bill requires the Secretary of Health and Human Resources to convene a work group to identify successes and challenges of the electronic prescription requirement and offer possible recommendations for increasing the electronic prescribing of controlled substances and to report to the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2022.

HB 2561 Pharmacy audits; pharmacy benefits manager.

Chief patron: Pillion

Summary as passed:

Pharmacy audits; pharmacy benefits managers. Requires that any contract between a carrier and its intermediary pursuant to which the intermediary has the right or obligation to conduct audits of participating pharmacy providers and any provider contract between a carrier and a participating pharmacy provider or its contracting agent pursuant to which the carrier has the right or obligation to conduct audits of participating pharmacy providers contain certain terms and provisions relating to audits and that will apply in the absence of fraud. The terms and provisions (i) require at least 14 days written notice before conducting the initial audit for each audit cycle; (ii) prohibit the initiation or scheduling of an onsite audit during the first five calendar days of any month or on a Monday; (iii) prohibit an onsite audit of a particular pharmacy location on behalf of a particular carrier more than once in a 12-month period; (iv) require each pharmacy shall be audited under the same standards and parameters as every other similarly situated pharmacy; (v) require any audit issues that involve clinical or professional judgment to be conducted by a pharmacist who has available for consultation a pharmacist licensed by the Commonwealth; (vi) require each audit to be conducted by a field agent who possesses the requisite knowledge and experience in pharmacy practice; (vii) require audits to be conducted in the Commonwealth in compliance with federal and state laws, rules and regulations; (viii) require prescriptions to be considered valid prescriptions if they are compliant with the then-current Board of Pharmacy rules and regulations and have been successfully adjudicated upon a clean claim submission; (ix) require electronic records and documentation to be acceptable for auditing under the same terms, conditions, and validation and for the same purposes as their paper analogs; (x) permit a pharmacy to use the historical records of a hospital, physician, or other authorized practitioner of the healing arts for drugs or medicinal supplies written and transmitted by any documented means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug; (xi) require

validation and documentation at the time of dispensing of appropriate days' supply and drug dosing to be based on manufacturer guidelines and definitions or, in the case of topical products or titrated products, based on the professional judgment of the pharmacist in communication with the patient or prescriber; (xii) require a pharmacy's usual and customary price for compounded medications to be considered the reimbursable cost unless the pricing methodology is published in the provider contract and signed by both parties or their agents; (xiii) prohibit a carrier or its intermediary from making charge backs or seeking recoupment from a pharmacy, or assessing or collecting penalties from a pharmacy, until the time period for filing an appeal to an initial audit report has passed or until the appeals process has been exhausted, whichever is later; (xiv) establish requirements for a preliminary audit report; (xv) require a pharmacy to be allowed at least 60 calendar days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during an audit or to file an appeal; (xvi) establish time periods during which a final audit report containing claim level information for any discrepancy found and total dollar amount of claims subject to recovery is required to be delivered to the pharmacy or its pharmacy corporate office; (xvii) prohibit a carrier or its intermediary from recovering from the pharmacy payment of claims that is identified through the audit process to be the responsibility of another payer; (xviii) prohibit recoupment of amounts paid to a pharmacy for any claim shall be made solely on the basis of a prescriber's or patient's lack of response to a request made by a carrier or its intermediary; (xix) require a carrier or its intermediary to issue its initial audit findings in conformity with the laws of the Commonwealth; and (xx) prohibit a carrier or its intermediary from retroactively denying a claim in certain circumstances.

HB 2563 Drug paraphernalia and controlled paraphernalia; fentanyl testing products.

Chief patron: Robinson

Summary as passed House:

Drug paraphernalia and controlled paraphernalia; fentanyl testing products. Clarifies that narcotic testing products used to determine whether a controlled substance contains fentanyl or a fentanyl analog are not drug paraphernalia or controlled paraphernalia.

SB 1289 Pharmacy, Board of; seizure of controlled substances and prescription devices.

Chief patron: Edwards

Summary as introduced:
Board of Pharmacy: seizure of controlled substances and prescription devices. Establishes a process by which the Board of Pharmacy, an authorized agent of the Board, or law enforcement can seize and place under seal controlled substances and prescription devices that are owned or possessed by a person or entity when the registration, license, permit, or certificate authorizing such ownership or possession is suspended or revoked. The bill also provides procedures and requirements for the transfer and disposal of sealed controlled substances and prescription devices if subject to forfeiture. The bill provides that the period in which the Director of the Department of Health Professions, his authorized agent, or a law-enforcement officer may

properly dispose of the seized drugs and devices in the event the owner has not claimed and provided for the proper disposition of the property is 60 days from notice of seizure. Under current law, such period is six months from notice of seizure.

SB 1366 Health, Commissioner of; consolidation of inspections.

Chief patron: Cosgrove

Summary as introduced:
Commissioner of Health; consolidation of inspections. Requires the Commissioner of Health to identify any inspection of a medical care facility required by Title 32.1 (Health), Board of Health regulations, the Commissioner of Health, the Department of Health, or any other state regulatory boards or agencies and, in collaboration with any such inspecting entity, work to consolidate, as much as practicable, all such inspections in order to minimize the interruption of the provision of care in such medical care facilities.

SB 1516 DOC; disclosure of information, delivery of controlled substances to prisoners.

Chief patron: Carrico

Summary as passed Senate:

Department of Corrections; disclosure of information; delivery of controlled substances to prisoners. Requires the Director of the Department of Health Professions, upon receiving a request for information, to disclose to an investigator for the Department of Corrections who has completed the Virginia State Police Drug Diversion School and who has been designated by the Director of the Department of Corrections information relevant to a specific investigation of a specific individual into a possible unlawful delivery of a controlled substance.

SB 1557 Pharmacy, Board of; cannabidiol oil and tetrahydrocannabinol oil, regulation of pharmaceutical.

Chief patron: Dunnavant

Summary as passed:

Board of Pharmacy; cannabidiol oil and tetrahydrocannabinol oil; regulation of pharmaceutical processors. Authorizes licensed physician assistants and licensed nurse practitioners to issue a written certification for use of cannabidiol oil and THC-A oil. The bill requires the Board to promulgate regulations establishing dosage limitations, which shall require that each dispensed dose of cannabidiol oil or THC-A oil not exceed 10 milligrams of tetrahydrocannabinol. The bill requires the Secretary of Health and Human Resources and the Secretary of Agriculture and Forestry to convene a work group to review and recommend an appropriate structure for an oversight organization in Virginia and report its findings and recommendations to the Chairmen of the Senate Committees on Agriculture, Conservation and

Natural Resources and Education and Health and the House Committees on Agriculture, Chesapeake and Natural Resources and Health, Welfare and Institutions by November 1, 2019.

SB 1632 **Public elementary & secondary school students; possession or distribution at school.**

Chief patron: Sturtevant

Summary as introduced:
Cannabidiol oil and THC-A oil; use at school. Requires local school boards to adopt and implement policies permitting a student who has been issued a valid written certification for the use of cannabidiol oil or THC-A oil to use such oils while at school. The bill prohibits a school board from suspending or expelling such a student for such use. The bill prohibits a school nurse employed by a local school board, person employed by a local health department who is assigned to the public school pursuant to an agreement between the local health department and the school board, or other person employed by or contracted with a local school board to deliver health-related services from being prosecuted for possession or distribution of cannabidiol oil or THC-A oil or for storing, dispensing, or administering cannabidiol oil or THC-A oil, in accordance with the policy adopted by the local school board, to a student who has been issued a valid written certification for its use. Finally, the bill requires the Department of Health Professions, in coordination with the Department of Education, to develop and make available to school boards, a standardized form to be completed by the certification issuing physician and the dispensing pharmaceutical processor.

SB 1653 **Prescription Monitoring Program; veterinarians.**

Chief patron: Stanley

Summary as passed:

Prescription Monitoring Program; veterinarians. Exempts the dispensing of feline buprenorphine or canine butorphanol from the requirement that the dispensing veterinarian report certain information about the animal and the owner of the animal to the Prescription Monitoring Program. The bill also requires that every veterinary establishment licensed by the Board of Veterinary Medicine maintain records of the dispensing of feline buprenorphine and canine butorphanol, reconcile such records monthly, and make such records available for inspection upon request.

SB 1719 **Cannabidiol oil and THC-A oil; registered agents and pharmaceutical processors.**

Chief patron: Marsden

Summary as passed Senate:

Cannabidiol oil and THC-A oil; registered agents and pharmaceutical processors. Authorizes a patient or, if such patient is a minor or an incapacitated adult, such patient's parent

or legal guardian to designate an individual to act as his registered agent for the purposes of receiving cannabidiol oil or THC-A oil pursuant to a valid written certification. Such designated individual is required register with the Board of Pharmacy (Board). The bill authorizes the Board to set a limit on the number patients for whom any individual is authorized to act as a registered agent. The bill authorizes a pharmaceutical processor to dispense cannabidiol oil or THC-A oil to such registered agent and provides such registered agent an affirmative defense for possession of cannabidiol oil or THC-A oil.

The bill authorizes a pharmaceutical processor, in addition to other employees authorized by the Board, to employ individuals (i) to perform cultivation-related duties under the supervision of an individual who has received a degree in horticulture or a certification recognized by the Board or who has at least two years of experience cultivating plants and (ii) to perform extraction-related duties under the supervision of an individual who has a degree in chemistry or pharmacology or at least two years of experience extracting chemicals from plants.

The bill directs the Board to promulgate regulations regarding the wholesale distribution of and transfer of cannabidiol oil or THC-A oil between pharmaceutical processors and removes a requirement that a pharmaceutical processor only dispense cannabidiol oil or THC-A oil cultivated and produced on-site. The bill provides that a pharmaceutical processor may begin cultivation upon being issued a permit by the Board.

The bill provides that the concentration of tetrahydrocannabinol in any THC-A oil on site at a pharmaceutical processor may be up to 10 percent greater than or less than the level of tetrahydrocannabinol measured for labeling. Finally, the bill requires the Board of Pharmacy to promulgate regulations to implement the provisions of the bill within 280 days of its enactment.

Board of Pharmacy

Chart of Regulatory Actions as of March 4, 2019

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Brown bagging and white bagging [Action 4968] NOIRA - *Register Date: 8/6/18* *Proposed stage to be submitted*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Delivery of dispensed prescriptions; labeling [Action 5093] NOIRA - *Register Date: 10/29/18* *Referred to Regulation Committee*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Periodic review result of Chapters 20 and 50; Promulgation of Chapters 16 and 25 [Action 4538] Proposed - *Register Date: 12/24/18* *Board to adopt Final: 3/26/19*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Increase in fees [Action 4938] Proposed - *At Governor's Office for 99 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Requirement for pharmacy to be operational within 90 days [Action 5080] Fast-Track - *DPB Review in progress*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Amending definition of "cold" [Action 5210] Fast-Track - *DPB Review in progress*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Final - *At Governor's Office for 285 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	(E) Scheduling of drug in Schedule V [Action 5186] Final - *Register Date: 1/7/19* *Effective: 2/6/19*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Requirement for applicants and licensees to have an e-profile ID number [Action 4909] Final - *At Secretary's Office for 39 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	(E) Scheduling chemicals in Schedule I [Action 5211] Final - *Register Date: 3/4/19* *Effective: 4/3/19*
[18 VAC 110 - 50]	Regulations Governing Wholesale Distributors, Manufacturers and	Delivery of Schedule VI prescription devices

	Warehousers	[Action 5084] Emergency/NOIRA - *Register Date: 12/24/18* *Comment on NOIRA closed 2/6/19* *Adoption of proposed: 3/26/19*
[18 VAC 110 - 50]	Regulations Governing Wholesale Distributors, Manufacturers and Warehousers	Registration of nonresident warehousers and nonresident third party logistics providers [Action 5083] Fast-Track - *Register Date: 2/4/19* *Effective: 3/22/19*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	New regulations [Action 4695] Proposed - *Register Date: 3/18/19* *Comment: 3/18/19 to 5/17/19*

Agenda Item: Adoption of Regulation to Schedule certain chemicals in Schedule I of the Drug Control Act

Staff Note:

There was a Public Hearing conducted this morning pursuant to requirements of § 54.1-3443 of the Drug Control Act.

Included in your packet:

Notice of hearing and request for comment (none received)

Copy of regulation to schedule certain chemicals

Board action:

Adoption of amendments to section 18VAC110-20-322 for placement of chemicals in Schedule I. (Note: the action is exempt from the requirements of the Administrative Process Act pursuant to §2.2-4006)

BOARD OF PHARMACY

Scheduling chemicals in Schedule I

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

2. 2-methyl-1-(4-(methylthio)phenyl)-2-morpholinopropiophenone (other name: MMMP), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Alpha-ethylaminohexanophenone (other name: N-ethylhexedrone), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

5. 4-fluoro-alpha-pyrrolidinohexiophenone (other name: 4-fluoro-alpha-PHP), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of

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

6. N-ethyl-1,2-diphenylethylamine (other name: Ephenidine), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

7. Synthetic opioids:

a. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-1,3-benzodioxole-5-carboxamide (other name: Benzodioxole 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. 3,4-dichloro-N-[2-(diethylamino)cyclohexyl]-N-methylbenzamide (other name: U-49900), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

c. 2-(2,4-dichlorophenyl)-N-[2-(dimethylamino) cyclohexyl]-N-methylacetamide (other name: U-48800), 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.

8. Central nervous system stimulants:

a. Methyl 2-(4-fluorophenyl)-2-(2-piperidinyl)acetate (other name: 4-fluoromethylphenidate), including its salts, isomers, and salts of isomers.

b. Isopropyl-2-phenyl-2-(2-piperidinyl)acetate (other name: Isopropylphenidate), including its salts, isomers, and salts of isomers.

The placement of drugs listed in this subsection shall remain in effect until August 21, 2019, 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. Research chemicals:

a. 2-(ethylamino)-2-phenyl-cyclohexanone (other name: deschloro-N-ethyl-ketamine), its optical, position, and geometric isomers, salts, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 3,4-methylenedioxy-N-tert-butylcathinone, its optical, position, and geometric isomers, salts, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

c. 4-fluoro-N-ethylamphetamine, its optical, position, and geometric isomers, salts, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

d. Beta-keto-4-bromo-2,5-dimethoxyphenethylamine (other name: bk-2C-B), its optical, position, and geometric isomers, salts, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

2. Synthetic opioids:

a. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2butenamide (other name: Crotonyl 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. 2-(3,4-dichlorophenyl)-N-[2-(dimethylamino) cyclohexyl]-N-methylacetamide (other name: U-51754), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

c. N-phenyl-N-[4-phenyl-1-(2-phenylethyl)-4piperidinyl]-propanamide (other name: 4phenylfentanyl), 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.

The placement of drugs listed in this subsection shall remain in effect until December 12, 2019, 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. 2,5-dimethoxy-4-chloroamphetamine (other name: DOC), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

2. Synthetic opioids:

a. N-(2-fluorophenyl)-2-methoxy-N-[1-(2-phenylethyl)-4-piperidinyl]-acetamide (other name: Ocfentanil), 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-methoxyphenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: 4-methoxybutyrylfentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

c. N-phenyl-2-methyl-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: Isobutyryl 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.

d. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-cyclopentanecarboxamide (other name: Cyclopentyl 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.

e. N-phenyl-N-(1-methyl-4-piperidinyl)-propanamide (other name: N-methyl norfentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

3. Cannabimimetic agent: 1-(4-cyanobutyl)-N-(1-methyl-1-phenylethyl)-1H-indazole-3-carboxamide (other name: 4-cyano CUMYL-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.

4. Benzodiazepine: Flualprazolam, 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 4, 2020, unless enacted into law in the Drug Control Act.

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

1. Synthetic opioid: N-[2-(dimethylamino)cyclohexyl]-N-methyl-1,3-benzodioxole-5-carboxamide (other names: 3,4-methylenedioxy U-47700 or 3,4-MDO-U-47700), 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. Cannabimimetic agent: N-(adamantanyl)-1-(5-chloropentyl) indazole-3-carboxamide (other name: 5-chloro-AKB48), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until May 27, 2020, unless enacted into law in the Drug Control Act.

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

1. Synthetic opioid: N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-benzamide (other names: Phenyl fentanyl, Benzoyl 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. Research chemicals:

a. 4-acetyloxy-N,N-diallyltryptamine (other name: 4-AcO-DALT), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 4-chloro-N,N-dimethylcathinone, its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

c. 4-hydroxy-N,N-methylisopropyltryptamine (other name: 4-hydroxy-MiPT), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

d. 3,4-Methylenedioxy-alpha-pyrrolidinohexanophenone (other name: MDPHP), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

The placement of drugs listed in this subsection shall remain in effect until October 2, 2020, unless enacted into law in the Drug Control Act.

F. 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. 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-isopropyl-benzamide (other name: Isopropyl U-47700), 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. alpha-pyrrolidinoisohexiophenone (other name: alpha-PiHP), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. 1-[1-(3-hydroxyphenyl)cyclohexyl]piperidine (other name: 3-hydroxy PCP), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until (18 months after the effective date of the regulation), unless enacted into law in the Drug Control Act.

Agenda Item: Proposed action on Delivery of Dispensed Prescription Devices – replacement of emergency regulations

Included in your package are copies of:

Copy of the posting on the Virginia Regulatory Townhall

(No comment was received)

Draft of Proposed regulations – identical to emergency regulations currently in effect

Action:

Motion to adopt the proposed regulations as drafted or as amended by the Board

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VIRGINIA REGULATORY TOWN HALL

Logged in as
Elaine J. Yeatts

Agency Department of Health Professions

Board Board of Pharmacy

Chapter

Regulations Governing Wholesale Distributors, Manufacturers and Warehousers [18 VAC 110 - 50]

Action: Delivery of Schedule VI prescription devices

Emergency/NOIRA Stage

Action 5084 / Stage 8333

Edit Stage | Go to RIS Project | Request Emergency Extension

Documents		
Emergency Text	8/27/2018 11:59 am	Sync Text with RIS
Agency Statement	7/9/2018	Upload / Replace
Attorney General Certification	8/27/2018	
Governor's Review Memo	12/12/2018	
Registrar Transmittal	12/12/2018	

Status	
Public Hearing	Will be held at the **proposed** stage
Emergency Authority	2.2-4011
Exempt from APA	No, this stage/action is subject to article 2 of the *Administrative Process Act* and the standard executive branch review process.
Attorney General Review	Submitted to OAG: 7/9/2018 Returned to Agency: 7/20/2018 Resubmitted to OAG: 7/30/2018 Review Completed: 8/27/2018 Result: Certified
DPB Review	Submitted on 8/27/2018 Policy Analyst: Jeannine Rose Review Completed: 9/10/2018 *DPB's policy memo is "Governor's Confidential Working Papers"*
Secretary Review	Secretary of Health and Human Resources Review Completed: 11/14/2018
Governor's Review	Review Completed: 12/12/2018 Result: Approved
Virginia Registrar	Submitted on 12/12/2018 The Virginia Register of Regulations Publication Date: 12/24/2018 Volume: 35 Issue: 9

Comment Period	Ended 2/6/2019 0 comments
Effective Date	12/13/2018
Expiration Date	6/12/2020

Contact Information	
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This person is the primary contact for this chapter.
This stage was created by Elaine J. Yeatts on 07/09/2018
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Project 5526 - Emergency/NOIRA

BOARD OF PHARMACY

Delivery of Schedule VI prescription devices

18VAC110-50-55. Delivery of Schedule VI devices.

A. In accordance with the provisions of subsection A of § 54.1-3415.1 of the Code of Virginia, a manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesaler distributor, third-party logistics provider, nonresident third-party logistics provider, warehouser, or nonresident warehouser licensed, permitted, or registered in Virginia may deliver Schedule VI prescription devices directly to an ultimate user or consumer on behalf of a medical equipment supplier.

1. Such delivery shall only occur in accordance with an agreement between a delivering entity named in this subsection and a medical equipment supplier in compliance with law and regulation.

2. The agreement shall be between an individual delivering entity or multiple delivering entities under shared ownership and an individual medical equipment supplier or multiple medical equipment suppliers under shared ownership. The agreement shall be applicable to all ultimate users or consumers receiving services from the medical equipment supplier who require delivery of Schedule VI prescription devices.

3. The medical equipment supplier shall represent to the delivering entity that it has complied with the provisions of § 54.1-3415.1 of the Code of Virginia regarding the existence of a valid order from a prescriber for the delivery of a Schedule VI prescription device to an ultimate user or consumer. Validation of orders of prescribers shall be the

responsibility of the medical equipment supplier upon request of the board or delivering entity.

B. In accordance with the provisions of subsection B of § 54.1-3415.1 of the Code of Virginia, a manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesaler distributor, third-party logistics provider, nonresident third-party logistics provider, warehouser, or nonresident warehouser licensed, permitted, or registered in Virginia may deliver Schedule VI prescription devices directly to an ultimate user's or consumer's residence to be administered by persons authorized to administer such devices, provided that (i) such delivery is made on behalf of a medical director of a home health agency, nursing home, assisted living facility, or hospice who has requested the distribution of the Schedule VI prescription device and directs the delivery of such device to the ultimate user's or consumer's residence and (ii) the medical director on whose behalf such Schedule VI prescription device is being delivered has entered into an agreement with the manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider for such delivery.

1. Such delivery shall only occur in accordance with an agreement between a delivering entity authorized in this subsection and a medical director of a home health agency, nursing home, assisted living facility, or hospice and in compliance with law and regulation.

2. The agreement shall be between an individual delivering entity or multiple delivering entities under shared ownership and the medical director of an individual home health agency, nursing home, assisted living facility, or hospice, or multiple such entities under shared ownership. The agreement shall be applicable to all ultimate users or consumers of the home health agency, nursing home, assisted living facility, or hospice who require delivery of Schedule VI prescription devices.

3. The home health agency, nursing home, assisted living facility, or hospice shall represent to the delivering entity that it has complied with provisions of § 54.1-3415.1 of the Code of Virginia regarding the existence of a request from a prescriber for the delivery of a Schedule VI prescription device to an ultimate user or consumer. Validation of the request from a prescriber shall be the responsibility of the home health agency, nursing home, assisted living facility, or hospice upon request of the board or delivering entity.

C. The agreement, as required by subdivisions A 1 and B 1 of this section, shall be in written or electronic format and shall be retained in a format available upon request to the board at all times the agreement is in effect and for two years after the date the agreement is terminated or concluded.

D. An agreement shall not contain any patient specific or patient health information that would be subject to the provisions of the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191).

Agenda Item: Adoption of final amendments for Periodic Review of:

Chapter 20 (Regulations Governing the Practice of Pharmacy) and Chapter 50 (Regulations Governing Wholesale Distributors, Manufacturers and Warehousers)

and adoption of:

New Chapter 21 (Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians) and Chapter 15 (Regulations Governing Delegation to an Agency Subordinate)

Included in your agenda package is:

Copy of regulations as published in the *Register or Regulations*

Copy of summary of public comment

Copy of public comment – received on Townhall or by email

Board action:

To amend the respond to comment on proposed regulations and to adopt final amendments pursuant to a periodic review of regulations

Summary of Comment on Proposed Regulations

Periodic Review

Board of Pharmacy

The Administrative Process Act requires that a summary of public comment be sent to all commenters at least five days prior to the adoption of a final regulation. The Board of Pharmacy will meet on March 26, 2019 to consider comment and adopt a final regulation.

Proposed amendments to regulations were published in the Virginia Register of Regulations on December 24, 2018. Public comment was requested for a 60-day period ending February 22, 2019. A Public Hearing before the Board of Pharmacy was held on January 9, 2019. There was no comment at the hearing.

There were 189 comments posted on Townhall.

133 of those were in opposition to a requirement of five hours of "live" continuing education for each renewal year. Commenters noted the additional time and expense involved in obtaining live or real-time interactive CE and the problem with availability, particularly in more rural areas of the state. Several people commented that they could support fewer hours than five each renewal cycle.

Seventeen commenters were in support of live CE, noting the positive impact of interaction with one's peers.

Several people were confused by the overstrikes of requirements that resulted from the division of Chapter 20 into two chapters, so it appeared that certain regulations, such as those relating to registration of pharmacy technicians, were being eliminated.

One person questioned how often an inventory of Schedule III-V drugs is required and whether the Board intends to go back to administering its own examination for pharmacy technicians.

One person supported the changes to: 1) allow a back-up pharmacy for issuing a seven-day supply of a drug to a long-term care facility; and 2) allow the pharmacist the discretion of whether to return a forged prescription to the customer.

An undergraduate student questioned the 15-hour continuing education requirement at the same time she is trying to complete his degree.

Several people concurred with the division into two chapters, so the requirements for pharmacists, interns, and technicians are more clearer set out separately.

Several people commented in support of the changes proposed as being pro-active in addressing outdated procedures and rules. Several particularly noted support for long term care patients, making it easier for them to get necessary medications.

One person objected to specific wording mentioning RobotRX and recommended more vague wording to allow other automation devices.

One person commented that the limitation on the number of times a facility can change a PIC seems to be based on a fee limitation rather than a number of times cap that may or may not appropriately fix the solution.

A number of commenters simply acknowledged that they had read the proposed amendments; this was in response to an alert that was sent from the Board to licensees informing them of the amended regulations posted on Townhall with the opportunity to comment during the 60-day comment period.

The following written comment was received from Kaiser Permanente:

In section 140, which proposes to authorize the Board to rescind a pharmacy permit if the pharmacy is not operational within 90 days, extend the time to 120 days to allow more time for extenuating circumstances.

In section 425, eliminate the requirement for a "root cause analysis" if a robot picks an incorrect medication in a robotic pharmacy system but require an investigation and the outcome of the corrective action plan to be summarized and documented.

In section 120, support the allowance of one hour of continuing education for a pharmacist serving as preceptor for a pharmacy student or resident.

The following written comment was received from the National Association of Chain Drug Stores (NACDS):

In section 10, amend definition of "faxed prescription" to allow an electronic image.
*Delete definition of "personal supervision" to allow audio-visual technology supervision of compounding in retail pharmacies.

In section 25, delete the ability of the Board to take disciplinary action based on a restriction on a license or permit in another U. S. jurisdiction.

In section 110, delete the proposed requirement for a minimum of two years of experience as a licensed pharmacist before someone could be named as pharmacist-in-charge (PIC) responsible for the pharmacy's compliance with law and regulation.

*In section 112, eliminate the current ratio of four pharmacy technicians to one pharmacist. Possibly allow the "prescription department manager" or "consultant pharmacist" to determine the number of technicians.

In section 270, allow a failed electronic prescription of a Schedule VI utilize an electronic signature on a faxed prescription.

In section 270, allow for a "two-step" verification process for an on-hold prescription.

**In section 360, amend the regulation to allow pharmacy technicians to be involved in prescription transfers; pharmacist on duty should be able to delegate that task.

**In new chapter 21, section 10, strike the definition of PTCB and insert new definition for certification meaning any individual who has passed a certification exam administered by an organization accredited by the National Commission for Certifying Agencies.

The following written comment was received from Remedi Senior Care:

In section 10, clarify the definition of "initials."

In section 110, delete the proposed requirement for a minimum of two years of experience as a licensed pharmacist before someone could be named as pharmacist-in-charge (PIC) responsible for the pharmacy's compliance with law and regulation.

In section 530, amend the requirement for the pharmacy providing services to the long-term care facility to have a written contract with the other pharmacy outlining services to be provided, the recordkeeping associated with dispensing, and the responsibilities of each pharmacy.

In section 25 on unprofessional conduct, change the "shall" to "may" in listing the practices that are considered to be unprofessional conduct within the meaning of § 54.1-3316 of the Code of Virginia. The current language uses the word "shall."

The following written comment was received from CVSHealth (it was also posted electronically on the Townhall):

*In section 10, amend the definition of personal supervision to allow a pharmacist to not be physically present in the pharmacy but to supervise through the use of "real-time, two-way technology communication" between the pharmacist and the technician.

*In section 112, eliminate the current ratio of four pharmacy technicians to one pharmacist.

**In section 360, amend the regulation to allow pharmacy technicians to be involved in prescription transfers; pharmacist on duty should be able to delegate that task.

*In section 150, delete the square footage requirement and allow pharmacies to decide the amount of space "adequate to perform the practice of pharmacy." Allow for trailers or other moveable facilities in a declared emergency.

*In section 270, except for electronic prescriptions, only require written prescriptions for "controlled substances" to have a signature.

*In section 270, allow a pharmacist to use his professional judgment to alter or adapt a prescription, to change dosage, dosage form or directions, to complete missing information, or to extend a maintenance drug.

*In section 270, amend the rule to not require data entry verification and prospective drug utilization review by a pharmacist who is dispensing an on-hold prescription at a future date.

In section 110, delete the requirement that a pharmacist have two years of experience before serving as the pharmacist-in-charge.

*In section 355, amend to allow for using returns of dispensed drugs to be restocked for reuse in an automated counting device.

***In section 240, allow for chart orders in correctional facilities.

In section 530, allow pharmacies with shared ownership to provide services with long-term care facilities without written contracts.

**In section 420, change the provision of a seven-day supply of a drug in a unit dose systems in hospitals or long-term care facilities to allow for dispensing of a 14-day supply.

* = Issue was not addressed in the Notice of Intended Regulatory Action or proposed regulations

** = Section was not amended in the proposed regulatory action

*** = Requires a change in the Code of Virginia

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VIRGINIA REGULATORY TOWN HALL

Logged in as
Elaine J. Yeatts

Agency Department of Health Professions

Board Board of Pharmacy

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

Action	**Periodic review result of Chapters 20 and 50; Promulgation of Chapters 16 and 25**
Stage	**Proposed**
Comment Period	Ends 2/22/2019

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

Back to List of Comments

Commenter: Elizabeth Scott Russell, speaking on my own behalf. 1/17/19 7:42 pm

Change in CE requirements to require 5 hours a year be live.

I am very opposed to the Board's requiring any portion of the CE requirement for pharmacists to be live. I feel that in order for the board to impose this new requirement, it should have to provide some evidence showing that live or interactive CE is a better educational experience than self study coursework. The Board has not provided this evidence in the documents I have reviewed thus far, but is merely expressing its opinion. In my own experience, I have found that having to review home-study coursework and pass a substantial post-test requires much more attention to and retention of course material than sitting through a live lecture where all you have to do is wait for a CE code at the end and complete an evaluation, with nothing to prevent participants from spending the entire time on their phone or some other distraction. Typically, live CE is a lot more expensive and inconvenient than home-study courses. There is a plethora of home-study coursework available to pharmacists at minimal to no cost, and pharmacists can choose coursework that is relevant to their area of practice and interest, or where they may be weak and need additional education. There is not even close to the same availability of live or interactive courses, forcing pharmacists to attend meetings or "interactive" courses that may not be offered at a time convenient to them, possibly even forcing them to take time off work or away from home/family. Again, without a solid argument that live CE is more effective in maintaining pharmacist competency, I do not believe that the Board should be allowed to require this. This new requirement will add substantial costs to renewing a pharmacist license, both in course costs as well as pharmacist time to attend a live or interactive program, without any stated basis or evidence shown for increased protection of the public health, safety and welfare.

Commenter: Vicki Gwaltney Garrison 1/23/19 1:42 pm

Requirement for 5 Hours of Live CE Credits for License Renewal

I have recently retired following almost 40 years.....yikes....from a regulatory pharmacy inspector/investigator position with VA Department of Health Professions. I maintain an active pharmacist license and hope to continue my annual renewal. I think pharmacists attempt to locate CE courses that are applicable to their practice setting. The majority of courses are related to clinical practice. If practicing in a hospital setting, pharmacists have many opportunities to obtain

education via onsite pharmacology seminars, association meetings, journals and online courses. Retail and specialty pharmacists can obtain education through online courses, association meetings and corporate training. I have struggled each year to find courses that provide additional education for my practice including drug security, excessive opioid dispensing and risks for dispensing errors. However, I feel that when access to CE courses is easily accessible and affordable, a pharmacist with an active license will search for education that will keep them current with the requirements of their practice. At least completion of an online course requires the successful passing of a follow-up test. I am not sure that connecting a laptop to participate in a live webinar or attending a speech assures that education has been obtained. Pharmacists who no longer practice, but enjoy the pride in maintaining an active license, may choose to go inactive if expensive education costs are involved.

Commenter: Jennifer Chang 1/31/19 8:26 pm

Live CE

Unless there is significant evidence to show that all pharmacists need live CE, live CE should NOT be a requirement. Employers do not pay for it and drug companies that provide it can be biased. This is a bad idea for a career path that is experiencing too many graduates, decreasing salaries and more/more work load that is below our already over qualifications

Commenter: Krista 1/31/19 8:36 pm

Live CE

I do not think it is wise in the least to require live CE. Live CE is very difficult for people with busy lives to get, and as such it is usually attended at work where we are surrounded by distractions, or at home surrounded by distractions, or at other such places and times unconducive to learning. Quite often pharmacists will simply pick a live CE based on what best fits their schedule, rather than which topic they feel will benefit them. I have personally attended several targeted at inpatient pharmacists, even though I never have and likely never will work inpatient, simply because that was the most convenient time. None of this is helpful. Non-live CEs have a much broader array of selections, so pharmacists can pick the topics they feel they need to hone in on. And they can complete them when they have the time and focus to truly absorb and learn the material.

Commenter: Elizabeth 1/31/19 8:48 pm

Live CE

I am against the Live CE proposal. I agree with other commenters that we are all busy and will only pick live CEs that fit in our schedule and price range and will not necessarily have anything to do with our area of practice (ie waste of time). I would rather select CEs that are a topic that pertains to my every day job, which is much easier to do when not live. I don't know of any evidence that shows Live is any more beneficial than not. I think it's unnecessary and don't see the point. I believe it would only serve to make my CE experiences less meaningful.

Commenter: Marcella R Brown, Enclara Pharmacia 1/31/19 8:58 pm

Live CEs for pharmacists

Good evening,

The expectation of 5 live CEs is not much to ask for and should be supported.

Thank you,

Marcella R Brown, PharmD

Commenter: Michael azab 1/31/19 9:04 pm

More obstacles

With all due respect to the changes in the laws in regards to the continuing education .I feel that this will put more impact and stress on us as a pharmacist in charge , for example the change in hours is been changed when we converted from Rite Aid to walgreens from 78 hours per 2 week to 84 hours every two weeks with no pay Increases . I feel like any more regulations will make our job harder . Big part of our job description working for big corporate is also engaging into MTM's and Mirixa which takes most of our time .Also we are part of the business plan to meet is increasing immunization. There should be a regulations to help us do our job better and more save . Like but not limited to the amount we spend ring people up on the register due to cutting labor hours , instead on focusing on filling rxs and catch possible drug interactions .

Commenter: Jeffrey Shearin 1/31/19 9:07 pm

Live CE

I did my training in another state that required live CE so I was surprised that VA BOP did not require this. I feel that this would increase regional and state meetings from our pharmacy organizations and provide better networking opportunties for our pharmacist to share our ideas and struggles. I worlk as in-patient pharmacist and at the very least this should increase the number of staff pharmacist that attend the monthly Interprofessional education events which I feel would be a benefit to our entire organization.

Commenter: Fran Warren, West Point Pharmacy 1/31/19 9:11 pm

Clarification

In reading through the proposed changes, I was unclear on two things. In the section on Inventory, the board requires inventory of C3-5 but with approximate counts. However, there is no reference as to how often. Previously we were required to have a biannual inventory of these drugs. Also, under pharmacy technician examination: there is no specific test mentioned. Is the state going back to administering their own exam? I am in charge of a training program at my store. This is important information for me to know for my trainees.

Commenter: Sabrina Vadehra 1/31/19 9:12 pm

Live CE

I would like to see studies that prove that Live CEs provide pharmacists with significant learning outcomes versus self study CE courses. I do feel it is difficult to find and schedule live CE courses that accomadate our busy professional schedules along with family duties. Also, the expenses do add up. I am a pharmacist carrying a few state pharmacist licenses. I do not practice in Virginia but

would like to keep my license active and if this increases my costs I would have to reconsider maintaining my license there.

Commenter: Jeremy Counts, Main Street Pharmacy 1/31/19 9:13 pm

Live hours are a bad idea

The entire world is moving toward easy online education, and we now will have to fit live hours into our schedule? Waste of time and money for everyone except those selling live classes

Commenter: Rimma Wolfe 1/31/19 9:13 pm

Live CE

Like others have mentioned previously, I do not see a reason to require pharmacists to obtain live CE hours. I currently am able to obtain CE hours online that are free/affordable and in subjects that pertain to my career. If I am required to obtain live CE hours, then I would choose these classes based on time and affordability. Neither of those reasons would help progress my career or proactively impact my knowledge in my specialty. I dont feel that the purpose of CEs is to mark a check box off that we have completed them, but to increase our knowledge so that we can have an impact in our practice. By requiring live CEs, a majority of pharmacists will look at this as just a check box we need to check.

Commenter: Lisa H 1/31/19 9:14 pm

Pharmacy Technicians

I am confused. Do Pharmacy Technicians need to bed certified anymore? Everything was lined out. Please advise.

Commenter: Kassandra King, pharmacy tech 1/31/19 9:16 pm

Chapters 20 and 50 regulations review

With the new stated regulations, I believe the focus of care provided to patients in long term care facilities have been acknowledged and met with allowing a back up pharmacy to issue a 7 day supply to patients when primary pharmacy does not have medication readily available. It keep patients on track with the care they need.

When it comes to the safety of the pharmacist and and the care of patients, the ability of allowing the pharmacist to recover a forged perscription or returning it to patient at his discreation under the circumstances will not only keep the pharmacist safe but the patients and other pharmacy staff out of harms way and trust with the pharmacist.

Commenter: Graham Price, Poquoson Compounding 1/31/19 9:21 pm

Continued Education Amendments

As a full time undergraduate student, and managing to work 30 hours a week at the same time is stressful and leaves me with little time for my studies. To require 15 hours of in class continued education further takes away from my studies. Furthermore, the stress of having the hour

requirements would hinder my grades in the classroom which I place a higher priority on. Due to the previously stated reasons, I do not agree with this amendment because it is unfair to undergraduates like myself that are trying to succee in pharmacology.

Commenter: Renee 1/31/19 9:23 pm

Ch 20 and 50

The revisions made seem fine. As this is my first time having to review any sort of official revisions, I am somewhat confused at what the crossings out mean. As I am a pharmacy technician, I especially looked at the parts related and found most of those parts crossed out. The non-crossed out sections seem fine.

Commenter: Enad 1/31/19 9:55 pm

Live CE

I am against live CE. It is a waste of time and money. I can find free and useful online courses that offer many and variable topics.

Commenter: Enas 1/31/19 9:56 pm

Live CE

I am against live CE. It is a waste of time and money. I can find free and useful online courses that offer many and variable topics.

Commenter: Sam cosnotti 1/31/19 10:16 pm

5hours of live c.e.

What's the logic? Live c.e. Is a step back in the education process. As everyone else has stated, it does not allow the pharmacist to rationally choose what type of c.e. Is needed in their practice. I am already visualizing the all day seminars offering six hours of c.e. That can be attended, no matter what the subject matter entails.

Commenter: Tyler Dymond 1/31/19 10:22 pm

No Live CEs

I am against the live CE requirment for pharmacists. It is a step back in learning availibility where the pharmacist can focus their CEs on matters that pertain to their pharmacy rather than what live courses are available in their area.

Commenter: Farisa Ali 1/31/19 11:24 pm

I am against Live CE's as a requirement to renew license in the Commonwealth of Virginia

I am not in favor of live CE as a requirement to renew Pharmacist license in the Commonwealth of Virginia. It is difficult to find free live CE's from websites and the times may not be good for many fulltime working pharmacists. Live CE's may not present topics that are interesting or relavent to the many areas a pharmacist may work at. I recommend against Live CE requirements for pharmacists.

Commenter: Susan 1/31/19 11:38 pm

No live CE

There is nothing to be gained with a live CE. Pharmacists have no time with their already over loaded work schedules rendering it difficult to find; the time, conveniently located site, an a topic relevent to practice area. There are many no cost CE's with many topics that benefit many practice areas.

Commenter: Quin 2/1/19 12:12 am

Live CE

I oppose this change to incorporate 5 Live CE's in order to meet the Pharmacist renewal requirement. It should continue to be an option so that Pharmacists can choose topics that best relate to their pharmacy setting. In addition I live in a small town, so I will have to travel far to attend a live CE. I don't see the benefit in this, it would be very time consuming for some, an un-needed expense of travel and stress- such as making arrangements for children, tired from the commute, and having to go into work the next day, trying to even locate a CE symposium if you live in a small town , just to name a few! Furthermore, there are so many changes that could be made in our field, and this should not be the one on the table, again I oppose this change!

Commenter: V 2/1/19 12:30 am

Live CE should be optional, not a requirement

I attended one live CE once and honestly I didn't absorb the information as well as I would like. I regretted afterwards, since it was unrelated to my field of practice yet I had to put quite an amount of efforts scheduling the time for it. I found that it didn't help expand my scope of knowledge on the topic as I would attained in a self-study coursework. Normally, I studied/updated certain materials based on my own available timing thus enabled me that flexibility to do more research on it.

From my own experience, I can conclude that Live CEs are costly, not conducive to my learning objectives, as well as being a time constraint to my already busy schedule.

Commenter: Amanda M Pelletier 2/1/19 1:10 am

I am against Live CE's

Please don't do live CE's. Being a pharmacy technician is my job. I have job to make money. My job costs me money. Yes you have to spend money to make money, but listen to this, the Pharmacy Technician Certification exam costs me $129 then the state licensure costs me $25 a year. Finding free or cheap CE's is hard enough. I work full time at 40 hours a week and I go to Nursing school full time. Being a technician is not an easy job. Down with live CE's Down with more regulation!

Commenter: Sara jamal 2/1/19 4:49 am

I'm against LIVE CEs. What purpose will it accomplish beyond filling the purses of the sponsors of

Commenter: Deanna McBrayer, Cvs Pharmacy 2/1/19 5:01 am

Periodic Review

I believe Pharmacists & Pharmacy Technician's should complete as many hours of continuing education courses as possible to stay current with today's issues. I agree on separating chapters for Pharmacists & Pharmacy Technician's.

Commenter: Rick Good 2/1/19 5:48 am

Comment on changes to Board of Pharmacy reqirements

I am not in favor of changing the annual continuing education requirement to include five hours of live interactive continuing education.

Commenter: Francis Jones 2/1/19 7:25 am

Proposed changes to Current Board of Pharmacy Rules and Regulations

I have read, in its entirety, the proposed changes to Board of Pharmacy Rules and Regs and the Statutes of the Commonwealth...and AGREE with ALL proposed changes...Once again, the Virginia Board has shown to be "pro-active" in making important changes to existing out-dated procedures...Keep up the Good Work..... Boards in the other 7 states that I am Registered IN...are still operating under out-dated and often Inadequate Laws and Rules.

Commenter: Katie S 2/1/19 7:34 am

Live CE

Live CEs are a waste of time and should not be implemented. I am a full time graduate student and do not have the money or time to do live CE's. The board should provide some evidence that live CE's provide better training than other CE's if they really want to implement this. Also, I am confused as to how acting as a preceptor would count as a live CE. I don't have the opportunity to do this and so it places me at an unfair advantage and would require me to spend a lot of money on live CE's.

Commenter: Melanie Baker 2/1/19 7:45 am

I disagree with LIVE CE and/or interactive CE

Most of us are working full time and raising families. We don't have time off to attend presentations. It costs money and time away from our families - if we can get the time off at work.

I understand why live CE sounds good - sharing time with colleagues etc. This is negated as most of us prefer to get the work done so we can go home to our familes.Thank you for understanding that work and pharmacy are not the primary reason we live.

Commenter: Martha M Talley 2/1/19 8:37 am

pharmacist continuing education

Live CE should not be a requirement for Pharmacist licensure. Pharmacists should have the choice of how to receive their continuing educations requirements.

Commenter: Anoop Joseph, Pharmacist 2/1/19 8:41 am

Live / Interactive CE should NOT be required

Live or Interactive continuing education should NOT be a requirement. Live CEs are expensive, time wasting, and an ineffective way of transmitting information to Pharmacists. Traditional CEs are much better and more than sufficient in furthering the education of Pharmacy members. If it ain't broke, don't fix it.

Commenter: bf 2/1/19 8:49 am

live ce optional or not

i have attended some very good live ce classes relating to my practice of pharmacy.some were lacking in regards to our actual duties and responsibilities.i also noticed some attendees only came for the free meals!!!!

Commenter: Andy C Starkey, Wesley long Outpatient Pharmacy/Cone Health 2/1/19 9:09 am

Periodic Review of Regulations

Reviewed and understood.

Commenter: Jonathan Mendonsa 2/1/19 9:20 am

Comment on LIVE CE Requirement for pharmacist

For community Pharmacist, I believe this requirement would be an unreasonable burden. I know for myself and my fellow community pharmacist friends we would struggle to find these opportunities and would have to potentially pay far more to get these hours.

Commenter: Brian Morris, Buena Vista Family Pharmacy 2/1/19 9:20 am

Live CE

I do not agree with the change to require 5 live CE hours. It is not practical for pharmacists, many of whom work more than 40 hours per week, to attend 2 or more courses throughout the year to

remain licensed. In the past, the Board has required CE in a specific subject area in some years. I believe that would be the more prudent measure to ensure that pharmacists maintain current knowledge.

Commenter: Annette Paul 2/1/19 9:27 am

Requirement for live CE

Dear Madam/Sirs:

I would like to respectively request that the addition of the requirement for live continuing be reconsidered. Pharmacists do not always work hours that are flexibile enought to allow for live attendance at a particular time and/or place to receive their continuing education. The internet has allowed me, and I'm sure other pharmacists, the ability to obtain good qualilty continuing pharmacy education at times that are convenient to my schedule and also allows me to choose topics that are both of interest to me and of particular utility to my practice. A requirement to obtain a third of my annual requirement as live or interactive content would likely force me to take "something" that I could squeeze into my schedule, rather than a topic that was relavant.

Thank you for taking the time to consider my feedback.

Annette L. Paul, RPh

Director, Clinical Services, Magellan Health Services

Glen Allen, VA

Commenter: Christine Norris 2/1/19 9:27 am

Live CE Requirement

I am opposed to the proposed changes to the CE requirements. I do not feel there is any added benefit to requiring 5 of the hours to be live. It puts an undue scheduling burden on the pharmacists and increases the expense of maintaining a license. Would Webinars or video teleconferences count as live CE?

Commenter: Lauren Caldas 2/1/19 9:38 am

Requirement for Live CE

I am in full support for a requirement of live CE. Pharmacists in other states have this requirement and it increases the professional network and knowledge through live CE. I was able to personally witness this through a pharmacist looking for live CE for her NC requirement. She joined the local organization and has become a more involved pharmacist in the profession. She has become an expert in her field and a role model for other pharmacists. I look forward to this and think it will improve our quality of Virginia Pharmacist and the profession.

Commenter: Mozlifa, CVS 2/1/19 9:42 am

No live CE

I am against it because no one has 5hours to waste. The CE live can be made to 1 hour or 2 hours max.

Commenter: Brenda J Birney 2/1/19 10:00 am

Changing mandatory pharmacists licensure CE requirements.

February 1, 2019

I have read the Agency Statement. I'm still unclear as to what the goal is for requiring mandatory five continuing education credits (out of the total fifteen). This will be a huge burden to most pharmacists. What is the goal? Please keep it simple if you reply.

Respectfully yours,

Brenda Birney, R. Ph.

Commenter: TERRI COULTER 2/1/19 10:02 am

DISAGREE WITH REQUIRED 5 LIVE CE'S

C. Of the 15 contact hours required for annual renewal, at least five hours shall be obtained in courses or programs that are live or real-time interactive. Included in the five hours, the following may be credited:

1. A maximum of one hour for attendance at a board meeting or formal hearing; or

2. A maximum of one hour for serving as a preceptor for a pharmacy student or resident in an accredited school or program or for a foreign-trained student obtaining hours of practical experience.

I disagree with requiring Pharmacists to have 5 LIVE CE hours annually, when none are required at the moment. If webinars are included in the LIVE CE hours, then I can understand 1-2 LIVE CE hours annually to get us use to doing them. Then you can increase 1 hour per year at a time if necessary. However there also needs to be more readily available CHOICES of LIVE CE hour courses offered during NON-WORK hours. Please remember when LIVE CE hours are required, the costs will increase due to having a live presentation.

Thank you.

Commenter: Susan McCoy 2/1/19 10:09 am

required live ce

I do not agree with the required 5 hours of live continuing education. This may be a nice option for some but should not be requied. If more people are going to need to attend the same conference, there are issues with getting off from work. Most of these conferences are quite costly.

Commenter: Niyati Amin, Pharm D 2/1/19 10:14 am

No Live CE requirement

I reviewed the new policies outlined by the board. I do not agree to requiring pharmacist to do 5 live CE hours. I believe the CE can do done on an array of subjects online. I do not agree that doing live CE hours is better than online courses. I urge the board to reconsider this requirement. Thank you for your time.

Commenter: Christina Lewis, Provdence St Joseph Health 2/1/19 10:26 am

RE: Live CE requirement for pharmacists

While, in my experience, live CE has been no more effective as a learning tool than reading an article and completing a quiz, I'm not opposed to this potential requirement however, pharmacists are likely going to have to take time away from work to attend live CE. Due to limited availability of events and many pharmacist schedules including late evening and weekend hours, it may be difficult to make arrangements to attend during non-work hours. If this becomes a requirement in order to maintain a pharmacist license, will employers be required to allow separate paid time off for pharmacists to attend live CE events, sufficient to account for travel time, etc? I am currently living and working outside of Virginia and will continue to do so at least until my daughter graduates from high school. I am also fortunate enough to have an employer who does allow paid time off for live CE. If I were to return to VA with live CE as a requirement, this would be a significant concern.

Commenter: Lezli Jeter Magellan Rx Services, Glen Allen, VA 2/1/19 10:27 am

Proposed regulations changes for pharmacists' continuing education requirements

I disagree with requiring pharmacists with active licenses to have to include 5 hours of live/interactive continuing education annually. I understand the need for continuing education, in general, but how the pharmacist gets the requirement fulfilled, and how much of their personal time is required, should be at the discretion of the pharmacist. I think this suggestion for change is too invasive, as it imposes significant inconvenience on the pharmacists, who, in most cases, already work long hours and give up a lot of opportunity for personal time activities with normal job requirements.

Commenter: Travis Hale, Remington Drug Co 2/1/19 10:37 am

5hrs Live/Interactive CE for Pharmacists

I do not feel this should be a mandatory requirement for pharmacists as many of us smaller independents are tied to our stores and it would make it extremely worrisome for us to try to find another pharmacist to cover our store in order to get away for a live CE and 5hrs of live CE at that. Many live CEs have an expense involved and if by chance they are free, there will be an expense on the business itself for what I just described in having to get another pharmacist to cover the store as well as the travel expense associated with getting to a live CE which is hopefully not an overnight stay. I have not heard the purpose or reason behind why live CE is better than CE that isn't live. I would like to know that reasoning and maybe it would change my perspective, but as of now, I feel this is more of a hindrance for not a lot of benefit and one more expense tied to a regulation that pharmacists or their respective businesses have to fund.

Commenter: Sherri Francisco, Sovah Health Danville 2/1/19 10:53 am

Regarding verbiage on use of robotics

Regarding the verbiage on the use of robotics with the specific wording mentioning RobotRX, there are many more pharmacy automation options available now---example, the Omnicell Carousel

technology--which also has bar code scanning as a safety feature... Sovah Danville suggests more vague wording here to allow other available automation options---pending board approval.

Sovah Health Danville will remove our robot by the end of 2019 and move to the Omnicell Carousels. We will request Board review and approval of this technology so that the pharmacist will not need to check each individual dose dispensed. Thank you for the consideration.

Commenter: KS 2/1/19 10:54 am

DO NOT REQUIRE 5 LIVE CES

I do not agree with the requirement of 5 live CEs. This is not feasible for many who have to work 40+ hours a week. There are not enough classes available for people to attend. The classes are not paid for by employers and most of them are biased so they are not even beneficial.

Commenter: Robert McDonald 2/1/19 10:56 am

Live CE requirement

As I have not been invited or even seen any opportunity to participate in Live CE in the Roanoke area for at least 15 years (ever since it was deemed a conflict of interest when drug companies offered them) I believe we are putting the cart before the horse. Let's first get sponsors to offer the Live CE and then make the requirement of the professionals. I do not believe pharmacists should be required to travel hours to obtain CE nor should they have limited options. In the 80's we had many opportunities during the year to attend CE presentations but now if there is an educational presentation we are prevented from receiving the CE. I am not an advocate of online live CE. You do not have the live interaction with the presenter ad well as with other attendees at the same time for forfeiting one huge advantage of the experience.

Commenter: Kristi 2/1/19 11:40 am

No live CE

I am against live ce training. There is not enough time and employers would not be able to reimburse for the time missed from work and the mileage out on the vehicle. There are also a limited amount of live CE to choose from and it doesn't concern my job. It would be a waste of my time and my money to be going. I am against this.

Commenter: Mark Gravitt, Magellan Health 2/1/19 11:55 am

Comment on "live" CE

I do not feel that live CE are necessary. In many cases, obtaining by written methods allows the pharmacists to select topics pertinent to his area of practice. With the live/interactive CE requirements, pharmacist my look to find the first thing to meet the requirement, even if not pertinent to their chosen area of practice.

Commenter: Carissa 2/1/19 12:12 pm

No live CE

As a community pharmacist I am against a live CE requirement. We are not reimbursed for this and would have to take PTO or use our time off to travel to these events. I am able to get all of the CE I need in the comfort of my own home for free. Thanks for your consideration.

Commenter: Anisa 2/1/19 12:37 pm

Live CEs

It is a step backward in education for professionals when elementary school students have already moved to online education. Not only a step backward in education but more cost and irrelevant topics for the pharmacists to choose from. Are we trying to ensure that the already skeptical students (not wanting to pursue this field because of saturation of colleges and students with huge loans not able to pay off because of saturated job market) will think twice of becoming pharmacist because of the added financial crisis? Live CEs are certainly not going to improve learning or be cost effective or helpful in any other way.

Commenter: Charlotte Johnson 2/1/19 12:45 pm

Live CE REQUIREMENT

No live or interactive CE REQUIREMENT ! Please! Even Online videos difficult for us country dwellers with limited internet. The amount of time spent at work (& in transit) already takes Pharmacists away from personal or family time and being available at specific times when live programs given is difficult. Optional live programs fine for those who want to attend but please do not make that a requirement.

Commenter: Amanda Holley; Chilhowie Drug Company, Inc. 2/1/19 1:25 pm

Public Comment on Chapters 20 & 50

Personally, I agree with adding chapter 25 in order to reduce the size of the other chapter regarding regulations governing pharmacy. This allows pharmacists to help our student pharmacists to explain the regulations during their rotations.

Commenter: Brittany smith, 2/1/19 1:44 pm

Town hall user policy

I've read the review and have no comments at this time

Commenter: Kevin 2/1/19 2:01 pm

No Live CE

I am opposed to live CE. Live CE should continue as an option rather than a requirement.

Commenter: Judith Giordano 2/1/19 2:58 pm

I am licensed in several states and greatly exceed the 5 hours of live CE now being proposed in VA.

As such, I find the self-studies more beneficial than the live CE programs.

Commenter: Stacy Chen, Indian Health Service 2/1/19 2:58 pm

Re: pharmacist CE regulations

It would be very hard to obtain 5 live CE as I do not live in the state. Please keep it at 15 CE annually as required without the 5 hours life CE requirement.

Sincerely,

Stacy

Commenter: Anthony J. Oley 2/1/19 3:08 pm

Review of regulations

I have no problem with the 5 hours of interactive/live CE hours as long as there are enough locally available in Richmond because scheduling out of town is a logistical nightmare.

Commenter: Mary Shepperson 2/1/19 3:50 pm

no live CE

Requiring live CE credits would pose a hardship for me due to my work schedule and a sick husband at home (transplant needed) Please do NOT change the requirements. Thank you.

Commenter: Ashley W, Walgreens 2/1/19 3:59 pm

No Live CE

Please no live CE's. It is already hard to find time for other duties, Mirixa, MTM, etc. Adding this restriant will take away time from patients and family.

Commenter: Allison M, Lifepoint Health 2/1/19 4:03 pm

No life CEs

No Live CEs

Commenter: Amir A 2/1/19 4:16 pm

No live CE requirement

Please do not make this a requirement. Pharmacists have to handle lots of other responsibilities and requirements, this would take away from much needed time with family. This should be optional but ultimately not a requirement.

Commenter: H.Delu 2/1/19 4:45 pm

Keep it how it is

Commenter: Jennifer Freeman, Biologics 2/1/19 4:55 pm

CE

Please keep the CE as it is.

Commenter: Megan C 2/1/19 5:19 pm

No live CEs

It would be a large burden on pharmacists to have to do live CEs on top of their already growing workload. Time with family or to themselves is already dwindling due to increasing demand for medication therapy management, data management, immunization services, health testing services, as well as additional tasks in their communities. Adding on an additional live education requirement for licensure would bog pharmacists down for time and energy better spent elsewhere.

Commenter: Kirsten McCormick 2/1/19 5:36 pm

Live/interactive CE requirement for pharmacists

I would like to disagree with this proposed change in the regulation governing the practice of pharmacy. I am a full time pharmacist and I live and practice in South Boston VA. I was previously dual licensed in North Carolina where they have a requirement for live CE. I have let that license expire as I found it very difficult to find live CE to attend. Most live classes are a minimum of a 2 hour drive for me (one way) which requires a large time commitment and expenses for travel, food or lodging. This is a rural part of our commonwealth and I can remember only a handful of live options in which I was able to go over the past 23 years. The online option is what many practitioners would be limited to, and if that is the case, is there any real benefit to being "live". I have had students on several occasions, and, while I appreciate that option, one hour seems to be lacking.

I appreciate the opportunity to respond.

Kirsten McCormick

Commenter: Betsy Stickley 2/1/19 6:17 pm

CE requirements

I do not see a benefit to live CE. Leave it as is.

Commenter: Keller A 2/1/19 6:36 pm

No live CE please!

It is very difficult to find meaningful (useful to my practice) live CE in rural Virginia. It is also very complicated to re-arrange multiple pharmacist's schedules in order to miss work to take live CE courses. Please keep the 15 hours as they are!

Commenter: Marie 2/1/19 7:06 pm

No Live CE

Live CE should not be a requirement for license renewal. I am licensed in Maryland and DC as well, so I would be well over the limit of 5 CE hours but I am already struggling to get the live CE for these regions. I am finding that I have to **pay** to get live CE, I have to **travel far** to get live CE, and I have to **take time off** an already full time job to get live CE. Live CE does not provide anything additional than self-study. Some of the free CE online is a video of an instructor (pharmacist, professor, MD, etc.) teaching the CE course with a powerpoint, but that is not registered as live CE with NABP it is still self-study. There is usually a quiz to make sure you get the main points of the presentation through these online courses. At live CE I would say 95% of the attendees don't speak to or interact with the instructor. You sit and listen. There is no difference whether we are face to face or through a computer. Content and takeaway is the same. Don't strain your pharmacists who I already working hard.

Commenter: Will 2/1/19 7:23 pm

Live CE Requirement

If you make live CE a requirement, you should make it a requirement that employers provide live CE and paid time off to complete the live CE. You have to factor in the time, travel, gas, and any additional stress.

Commenter: Eric 2/1/19 7:39 pm

No live ce

Please do not make live ce a requirement. I already put in 42 hours plus a week and have young children i am missing time with. Requiring live ce would take even more time away from my family.

Commenter: Tina S. Kim, PharmD, Kaiser Permanente, MAS 2/1/19 8:53 pm

Continuing Education requirements for Pharmacists

Virginia Pharmacy Board, I am required by my employer to maintain 3 concurrent state licenses for my work (tri-states, Mid-Atlantic Region). I have been so appreciative of Virginia's simple straightforward CPE requirements. Please do not complicate Virginia's requirements if possible. It's difficult enough now to keep all the numerous requirements straight for each different states, also the fact that they keep changing. Please keep the requirements the same, straigtforward as before. Thank you for your time.

Commenter: Engy Herakly, CVS 2/1/19 10:09 pm

No live CE

Live CE is not only unnecessary but also takes away valuable time from pharmacists.

Commenter: Ron Lyon, Hampton University School of Pharmacy 2/1/19 10:27 pm

Preceptor activities counting towards live CE requirement

I'm not clear on the language. Does precepting have a limit of one hour for live CE purposes? For example, would precepting a student for 200 hours count as one hour or more than one hour?

"The requirements in Section 120 are identical to those currently found in Chapter 20 with the exception of subsection C, which proposes to require that five of the required 15 hours be obtained in courses or programs that are live or interactive. There are two new activities that may be used to fulfill live CE, including one hour for attendance at a board meeting or hearing and one hour for serving as a preceptor for someone gaining practical experience. "

P.S. Lots of nice changes. The MTM facility requirements (e.g., sink) should help many pharmacists offer better services to their patients.

Commenter: Kalid Ahmed 2/1/19 11:17 pm

No comment

I aver all it is good step.

Commenter: SylviaDe Leon Beltrán 2/2/19 12:03 am

NO CHANGES TO CURRENT CEU REQUIREMENTS

I personally would not like the method of live CEUs. The current method is more convenient. I don't think it is necessary to change something that already works. I share the same difficulty as others to do live CEUs especially when you have to balance School, work, family, and more.

2/2/19 6:45 am

Commenter: Latausia Williams

No changes should be made

I've been a pharmacy technician for 14 years and have worked in all pharmacy settings. Pharmacists experience enough Live situations through out their work day that, they should not have to attend 5 hours of Live CE. I don't know how they survive their work day most of the time. They made it through school, and still paying their dues on a daily basis from what I've been seeing for 14 years. Give them a break. Keep it like it is.

Commenter: Michelle Phipps 2/2/19 9:17 am

Live CE

Please do not require live CEs, especially so many per year. This adds an unecessary burden to pharmacists and adds no value. It is difficult to find time for live CEs that fit into extremely busy schedules and adds expense. I have to do 2 hours of live CEs per every 2 year renewal for Maryland, and it ends up being whatever fits into my schedule and does not add any benefit or value over other CEs.

Thank you for your consideration

Commenter: Russell 2/2/19 9:36 am

Opposed to live CE requirement

I am opposed to a change in Regulations Governing the Practice of Pharmacy [18 VAC 110 ? 20] that would require any portion of the CE requirement for pharmacists to be live.

Commenter: Susan Gladfelter 2/2/19 10:16 am

Pharmacist live CE

I do not think that pharmacists should be required to have 5 live hours of CE per year. This could be difficult for some pharmacist to obtain depending on their location of practice.

Commenter: Carol Carson 2/2/19 10:23 am

Live/Interactive CE for Pharmacists

I **strongly oppose** a requirement for all current active pharmacists to obtain 5 hours of live or interactive continuing education annually. This places undue burdens on pharmacists for the following reasons:

1. This rule would require some pharmcists, e.g. those who work nights or evenings, to **schedule time off from work** to attend live CE.
2. Learning styles differ from pharmacist to pharmacist. Live CE would **hinder learning** by those pharmacists who learn better by reading and studying material in the quiet of their office or home.
3. These **CEs may not be accepted by the Board of Pharmaceutical Specialties** as meeting requirements for certification, causing board certified pharmacists to have to seek additional annual CE opportunities.
4. Because there are limited live CE opportunities, it would be **difficult to find live CE in areas of professional interest.**
5. Pharmacists would **incur travel expenses** by attending live CE.

Commenter: Marie Lops 2/2/19 11:00 am

Live continuing education

Yes, I think live continuing education will be very beneficial to us Virginian Pharmacists and the patients that we serve. When we go to live CE, we discuss the information with our peers and we ask questions and they give us handsout. We understand better and we retain the information for a longer period of time.

Marie

Commenter: Richard Clark, Kroger 2/2/19 12:28 pm

chapters 20 and 50

I reviewed the information that you sent to me that is about chapters 20 and 50.

Commenter: Carol 2/2/19 2:10 pm

No to live CE

For the very few preferring live CE, that is an option available as in current pharmacy regulation. But why is it necessary to make live CE a requirement when mass majority are not in favor (for all the right reasons as I have read), and when self-study can provide similar, if not, a better option for continued education? I also don't believe in an individual's opinion speaking on behalf for other than herself/himself. If one pharmacist found to have better learning experience with live CE then that's her/his prerogative, but is it necessary to enforce their preferences on others? No individual should be stating "we pharmacists" while commenting on this section, because I am not part of that "we". I am not in favor of the live CE.

Commenter: Shaira O 2/2/19 5:37 pm

No Live CE

It will be a huge burden to squeeze in required live CE into busy work schedules. Live CE should remain as an option for people who has the time for it.

Commenter: Jennifer Sanders 2/2/19 7:52 pm

ce

I would prefer the ce requirements stay the same; with no live ce required.

Commenter: Gregg 2/2/19 10:09 pm

Live CE

If live CE proposal is approved, please be sure it continues to extend to either ACPE **and CME**. CME is as valuable of a resource, possibly more, than ACPE. My personal opinion, the changing pharmacist landscape makes this proposal more of a financial burden than an educational benefit. Local pharmacist organizations, other than their state-wide meetings, rarely provide ACPE credit due to these meetings being sponsored by pharmaceutical manufacturers. Meeting registration cost, accomodations, meals, and time off from work (likely vacation time) makes this an overly burdensome requirement.

Commenter: Samuel M Conteh 2/2/19 11:24 pm

Live CE

Commenter: Stephen Todd Shearon 2/3/19 2:07 am

No to live CE

Commenter: Robert Karim, Salem VAMC 2/3/19 8:20 am

Live CE Credits and Change to PIC

In regards to the change in PIC documentation, the organization of the form is a bit difficult to read given the track changes. From what I have extracted from it, the limitation to the number of times a facility can change a PIC seems to be based on a fee limitation rather than a number of times cap that may or may not appropriately fix the solution. In addition, the submission of a number of

fees for changing the PIC is fair, but at the low price seems to allow for an infinite number of PIC which will punish facilities who cannot find a permanent PIC. I did not see any clear grounds on how to handle a facility requiring temporary PIC coverage, or grounds to bypass fee punishments or grounds for filing in an expedited manner given appropriate grounds, (PIC passes away suddenly, PIC moving etc.)

In regards to the hours, live CE may be available, but in changing to nearly a third of the time for Live CE may be too much of a change. LIve CEs are often difficult to schedule during work hours, sometimes have technical difficulties, and in regards to attending meetings not every job alots a pharmacist to accomplish visiting live CEs, not to mention increased costs for either paying or visiting live CE. As such, switching to mandatory hours may not be received well given such a demand. If Live CE to be pushed, then suggest switching to 2 hours for the first few years to assess how compliance goes, and from there can adjust the time. Should 5 hours be passed, the board should redobule the efforts to then provide a planned list of live CEs on a monthly or bimonthly basis to assist and help pharmacists begin developing resources to meet this demand. This way the board and the ASHP ca begin to work out an understanding that will benefit all parties involved.

Commenter: Nazila Ghasemi 2/3/19 10:37 am

5 credits Live CE

I believe it's a great idea to assign 5 live CE as part of the 15 CE.

Commenter: Susan Reynolds 2/3/19 11:10 am

No changes to current CEU requirements.

Commenter: Susan Reynolds 2/3/19 11:12 am

No Changes!!!

Tyl would like no changes to the current CEU requirements. Thanks so much for letting me express what I think.pe over this text and enter your comments here. You are limited to approximately 3000 words.

Commenter: Diane Weakley 2/3/19 12:14 pm

Requirement for 5 hours of live or interactive CE for pharmacists per year

I believe that the 15 hours of CE required annually for pharmacists should be accomplished through either live or written programs, but there should be no requirement for 5 hours of live or interactive CE. There is no evidence to substantiate the benefit of live instruction over written programs. I have personally witnessed pharmacists that attend a live program but are distracted by their cell phones or personal conversations, thereby not paying attention or learning any information, yet receiving credit for simply being present. The quality of a speaker can also affect learning, as some programs are written by one person and presented by another. I've witnessed participants nodding off when the speaker was ineffective. Written presentations followed by examinations at least require some effort from the participant. In addition, there is a financial burden to attend 5 hours of live CE, as well as the inconvenience of finding approved programs

within a reasonable distance or that will fit into the participant's schedule. This is especially burdensome to single parents(most of whom are female) who work long hours and then must pay the cost of babysitters in addition to the cost of the live program. I see no need to change a system that has worked well for years unless there is some benefit that has been proven by other states that have such a requirement.

Commenter: Audrey Neel 2/3/19 1:33 pm

Requirement of 5 hours of live or interactive continuing education

To the Governing Body,

As a resident of southwestern Virginia, I find it difficult to attend live seminars in our area. I do not agree with the new requirement of five hours of continuing education to be obtained via live or interactive means. It would create a hardship on me on having to travel out of my area to attend such events. I would have to travel to the far end of Roanoke from where I live, which would be over an hour of travel each way.

Additionally, requiring 5, not 4 or 3, would require more fees to be paid. Most continuing education offering are in increments of two hours. A basic search on the internet to participate in live webinars proved that many of these seminars are priced $30 or above each. For me personally, that would require the payment of three of these seminars to fill this requirement. If there are seminars offered for 'free', the offering body requires one to become a member of their association. This is an underhanded technique to pad their membership rolls and obtain registration fees.

I practice as a part-time pharmacist, or as a relief one when not employed as the former. This does put a pinch in our family budget to have to pay these additional fees.

So again I will state, I do not agree with the proposal to require five hours of live or interactive continuing education.

Sincerely,

Audrey Neel, RPh

Commenter: Paula Schwarz, RPh 2/3/19 1:58 pm

Continuing

Commenter: Paula Schwarz, RPh 2/3/19 2:08 pm

5 hours live continuing education requirements

I would like to express my dismay and opposition to the proposed requirement that 5 of the 15 CE hours required for license renewal be live or "live interactive". As a resident of rural SW Virginia, I find it hard or impossible to find live programs in the area. Attending some would involve high expenditure of money and time because travel would be required. Also, internet service in these parts is very inadequate and expensive, making live interactive programs almost impossible to conduct. This proposal is basically discriminatory against rural pharmacists! Please reconsider.

Sincerely,

Paula Schwarz, RPh, Pearisburg, Giles County

Commenter: Debra Ovall 2/3/19 5:06 pm

No comment

Thank you.

Commenter: Joel Clark 2/3/19 7:32 pm

ok

ok

Commenter: Rebecca Shearon 2/3/19 8:40 pm

no live CE requirement please

I do not agree with the proposal to add 5 hours of mandatory CE annually. I do not see where this offers additional value over on-line/written CE courses.

Commenter: Carol 2/3/19 10:37 pm

Town hall user policy

No live ce

Commenter: Bon serours memorial regional 2/4/19 12:03 am

No live ce

No live ce please

Commenter: Diane Fonner 2/4/19 12:10 am

Please do not REQUIRE live CE

I am opposed to the requirement for live CE. There are several reasons that other people have elaborated on - lack of availability, cost, worthiness and learning styles.

I don't care if you live in the most rural part of southwest VA or in downtown Richmond; it is difficult to find live CE. There are a couple of conventions by VPhA but most pharmacists work weekends and can't be guaranteed to have those weekends off. Also, they are held on opposite ends of the

state and one is in the dead of winter in snow country. **IF ** we are lucky enough to go to a national convention, there are hours upon hours of CE to be had.

Generally speaking, we have to pay for CE in some form. Live CE often costs more and may also require hotel, gas, meals, airfare. Unless I can get 5-10 CE at one time, live CE just isn't worth it to me....

CE is only useful if you learn something from it. Obviously, I prefer to do CE on topics I find interesting, but sometimes I go out of my comfort zone. If a speaker is boring or I don't understand the presentation, it's a waste of my time and money (but I got CE!).

Finally, I don't learn best by just listening. I get distracted easily. So having words in front of me is better for ME. No one is saying the next person can't get all 15 hours live, Just let me do mine thru a journal or online.

Commenter: Ricky Clary 2/4/19 7:33 am

Live CE

Please don't require Live CE in Virginia. It would be an undue burden on many pharmacists who may have to travel to obtain the Live CE. There are plenty of online CE programs that meet the current CE requirements and changes to the regulations are not necessary.

Commenter: Andrew Gunn 2/4/19 8:55 am

Live CE

Sure I would be willing to attend 5 hours of live ce as long as the Board of Pharmacy reimbursed me for ALL my expenses. Pharmacists are not like Physicians who write these expenses off underneath their corporate umbrella. Don't you think 15 hours of ce, no matter how attained is suffcient concidering all the other services that the pharmacists of today are being required to perform. I realize the board exists to protect the public, but it certainly should serve as a advocate for the pharmacist in order for him to perform at the high expections expected of him, and cost aside, asking a pharmacist to spend a undetermined amount of time to obtain 5 hours of live ce is unreasonable. Why do you not stop cowtailing to the CVS's of the world and act in a manner to aide the pharmacist on a daily basis to do his job.

Commenter: Katheryne Richardson, Self 2/4/19 9:02 am

CE Comment, live requirement

This comment is regarding:

"C. Of the 15 contact hours required for annual renewal, at least five hours shall be obtained in courses or programs that are live or real-time interactive. Included in the five hours, the following may be credited:"

I do not support this new an onerous requirement. Mandating live CE is simply adding additional regulatory interference/burden, as there is no justification provided for why live CE is beneficial for the pharmacist, government, or patient safety. If there was research supporting live CE in association with better/safer pharmacy practice, I would support this. Having been a pharmacist for over 20 years, and completing various types of CE for licenses in different states, I find no association with live vs. written CE and better education outcomes. The impact of CE is unlikely associated with live vs. written CE, and much more likely to be associated with the professional's

committment to learning. Why would this new requirement be instituted? There is no rationale, and it will result in greater work on the pharmacists, the government officials keeping track of all of this, and there is no proof of any difference in outcome. More work and more rules---without evidence of improved results (nor a citation to postulate impiroved results)---sounds inefficient and wasteful. Please remove this requirement and focus on priority issues (opioid crisis, etc.)

Commenter: David Hetrick 2/4/19 9:44 am

Live CE

I do not support the Live CE proposed requirement. The current process for obtaining CE is adequate and serves the necessary purpose. Attending a Live CE is not going to change the level of knowledge I receive. Also most of the live CEs have an associated cost to attend. This is not something we should be required to do.

Commenter: Andew Gunn 2/4/19 9:47 am

LIve CE

If the Board of Pharmacy would truly be interested in the health of the citizens of Virginia why not mandate that all Pharmaceutical Companies be responsibible for conducting a LIVE program for all active Pharmacists on any and all new drugs they are introducing ***PRIOR*** to their being made any public awareness of the drug. This would certainly provide far more than 5 hours of live ce. , or is the Board to intimidated by these companies.

Commenter: Julie Saunders 2/4/19 11:05 am

Live CE

I do not support the Live CE proposed requirement. The current process for obtaining CE is adequate and serves the necessary purpose. Attending Live CE does not enhance learning. There are limited options for live CE and there is typically a significant cost to attend which would place an undue burden on Virginia pharmacists.

Commenter: Lynn Cox 2/4/19 11:38 am

Live CE requirements

I am opposed to the Board's requiring any portion of the CE requirement for pharmacists to be live. Most if not all live CE has a cost involved whereby online/journals are often free. Pharmacists have to juggle work, home life, children and home study allows one to be flexible with time in order to complete. Live CE is usuallly not flexible with times of presentations. The board has not provided evidence that live/interactive CE is more beneficial than home study CE. The costs and lack of flexibility of live CE does not facilitate but rathers hinder a pharmacist completing required hours.

2/4/19 6:26 pm

Commenter: Amy cpht

Live ce

I am against more live CE that is not directly involved with my job. The cost alone is a problem.

Commenter: Elisabeth P 2/4/19 8:43 pm

Live CE

I am opposed to the live CE requirement. I would consider it if Board could show live CE to be of more benefit, however I find when attending live CE the majority of participants are either drifting off to sleep or on mobile device. It is also a more costly alternative and often unable to schedule due to offering restraints.

Commenter: debbie reed Bon Secours 2/4/19 10:48 pm

live CE requirements

thank you for the opportunity to comment on this issue. I support a live CE requirement but I would prefer 2 credits annually or a 2 year renewal period with 5 live credit hours. attending a program with 5-10 credit hours offered typically requires a time commitment and potential cost that may be incompatible with full time employment and home life.

Commenter: Tanner Seitter, Bon secours pharmacy tech 2/5/19 1:20 am

Perfect!

I feel like it would it be a great benefit doing this.

Commenter: Joseph E Manno 2/5/19 8:25 am

Proposed changes to CEU's requirements

Regarding proposed changes to 18VAC110-21-120. requirements for continuing education subsection C

"Of the 15 contact hours required for annual renewal, at least five hours shall be obtained in courses or programs that are live or real-time interactive."

While I support the Board requiring specific CEU's (e.g. opioid related material) as part of the annual 15 hour renewal, I see no need to require 5 hours of live or real-time programming. Some of us, myself included, learn more from the written lessons. After all, a CEU is a CEU.

Commenter: Dr. Maria Teresa Ambrosini, B.S.,Pharm.D.,BCPS 2/5/19 8:50 am

Ammendents to pharmacy law read

Commenter: Dave Dixon, VCU School of Pharmacy Center for Pharmacy Practice Innovation 2/5/19 12:09 pm

In support of live CE requirement

To Whom It May Concern:

On behalf of the VCU School of Pharmacy Center for Pharmacy Practice Innovation, I am writing in support of the proposed regulation to require 5 live CE hours for pharmacists to maintain licensure. Continuing Education is critical for sharing best practices and to improve patient outcomes. This is best achieved when CE is earned live as it promotes professional engagement in a way that other types of CE do not. Home study is certainly more convenient but it does come at the cost of person-person interaction and significantly limits the dynamics of CE delivery, which is much more engaging when delivered live as speakers can utilize role-playing, simulation, and other types of active learning to engage participants. Additionally, live CE provides a platform for open engagement and inquiry, which is important for participants to walk away with a richer and deeper understanding of the content. Other nearby states (e.g., NC) and professions in the Commonwealth (e.g., medicine) also require live CE so it seems reasonable for Virginia to do the same as this can create opportunities for live, interprofessional CE that brings various disciplines together to see how we can improve the care we provide to our patients. This also allows pharmacists the opportunity to engage with other disciplines and educate them on the important role pharmacists play in the healthcare system. If we want a seat at the table then we must put ourselves out there and be seen by our colleagues in medicine, nursing, etc.

In closing, if we aim to continue advancing the profession of pharmacy, it is imperative that we engage in a more meaningful way and requiring live CE is one way to achieve this goal.

Sincerely,

Dave L. Dixon, PharmD, FCCP, FNLA, FACC, BCPS, BCACP, CDE, CLS

Director, Center for Pharmacy Practice Innovation

Associate Professor, VCU School of Pharmacy

Commenter: Joseph McCloskey, Magellan Health 2/5/19 1:28 pm

RE: Proposed Live CE

To Whom It May Concern:

I do not feel that Live CE is needed for pharmacy licensure renewal. This creates an unnecessary burden for those folks with a very tight work schedule and may incur extra costs that some of us do not have luxury to afford.

Regards,

Joseph McCloskey

Commenter: Esther K, Compounding 2/5/19 3:04 pm

5 hours of live or interactive continuing education

Live CE's should be available for those who are supportive of its learning experience but should not be a requirement. There are those who search for free or cheap CE's in order to complete them. The requirement of the live CE's would make it very inconvenient for those who aren't as flexible with their schedules.

Commenter: Tina 2/5/19 10:29 pm

No live CE please

Like others, I against live CE. We have already overloaded at work and have to work extra hours without paid. If you can't help us out by requiring to have more tech help for pharmacist, PLEASE PLEASE PLEASE don't make it worse. Thanks a lot!

Commenter: Nan Dunaway 2/6/19 3:12 pm

LIVE CE

I do not agree with the requirement for live CE. I have obtained CE in various formats over the years and feel that I learn just as much, if not more, through the CE that is delivered in writing. I am a retired pharmacist, and have spoken with other retired pharmacists who tell me they have let their licenses in other states lapse when the states began requiring live CE. I believe the Board will lose revenue if live CE is required,

Commenter: Victoria Nordin 2/6/19 4:44 pm

Response

No Change

Commenter: Elizabeth Welch 2/6/19 5:33 pm

18VAC110-21-120

I strongly object to an annual requirement of 5 live contact hours of Continuing Education. There is no justification for this requirement. The quality of education obtained from a live event is not better than an online or written CE program. And the unprecedented requirement for fully one third of the required hours to be live is unconscionable. Pharmacists in a typical working environment do not have the leisure time to spend pursuing a live CE event, nor are many of these events available within the pharmacist's available time.

I have participated in live webinar events, as required by the Maryland Board of Pharmacy, where I am also licensed, and I can honestly say that I learn more from the written CE lessons because I can go back and re-read, or spend as much time as needed to learn the material.

I cannot stress enough how inconvenient, unnecessary, and useless it is to have one third of the CE hours be required to be live. If it were to be proposed that 1 or 2 hours annually be at a live event, that would be more in line with other states' requirements, and less of a time burden to Virginia's already overburdened pharmacists.

2/6/19 5:36 pm

Commenter: Elizabeth Welch

No live CE!

I strongly object to an annual requirement of 5 live contact hours of Continuing Education. There is no justification for this requirement. The quality of education obtained from a live event is not better than an online or written CE program. And the unprecedented requirement for fully one third of the required hours to be live is unconscionable. Pharmacists in a typical working environment do not have the leisure time to spend pursuing a live CE event, nor are many of these events available within the pharmacist's available time.

I have participated in live webinar events, as required by the Maryland Board of Pharmacy, where I am also licensed, and I can honestly say that I learn more from the written CE lessons because I can go back and re-read, or spend as much time as needed to learn the material.

I cannot stress enough how inconvenient, unnecessary, and useless it is to have one third of the CE hours be required to be live. If it were to be proposed that 1 or even 2 hours annually be at a live event, that would be more in line with other states' requirements, and less of a time burden to Virginia's already overburdened pharmacists.

Commenter: Dianne G 2/6/19 5:37 pm

Live CE

I do not support the Live CE requirement as proposed. The current CE requirement is sufficient and cost effective for everyone.

Commenter: Krystal Gulbransen. Walgreens 2/6/19 7:02 pm

The Board of Pharmacy is conducting a required periodic review of regulations in chapters 20 and 50

Why 5 live CE, now? Who is benefiting from requiring 5 live CEs? Live CEs usually cost money and are difficult to schedule. How does this benefit the pharmacist learning?

Commenter: Logan Chase Archer 2/7/19 5:50 am

No Live CE

I work night shift. It would be impossible for me to attend a live CE. With my current position, I would not even be able to take PTO in order to attend a live CE.

Commenter: Reem Kastoon 2/7/19 9:36 am

Chapters 20 and 50

I agree with the recommendations. Thank you

Commenter: Alan Dow, VCU Health, responding my own behalf 2/7/19 11:47 am

Continuing Education Requirements

Continuing education's (CE's) primary purpose is to ensure that healthcare practitioners better meet the needs of society. Part of fulfilling this pupose is learning new skills or knowledge while part of the fulfilling this purpose is developing collaborative relationships to create a stronger network of care. It is this latter purpose that live CE requirements support.

Knowledge and skills can be learned online, and I agree that a middle gound of having only a partial requirement for live CE makes sense. However, pharmacists are imporant members of the healthcare team and often not included in care in the way that most benefits patients and other healthcare practitioners. A live CE requirements supports education of the team and for the team to best meet the needs of patients. This meets the strategic guidance of major CE accreditors and policy makers including the Accreditation Council of Pharmacy Education.

We need knowledgable, skilled, and engaged healthcare practitioners. This last part--engagement--is why live CE is so important. Only with engaged practitioners can we build a stronger health workforce and a healthier society.

Alan Dow, MD, MSHA

Commenter: Lisa Leonard, Pharm.D., BCPS, BCPPS 2/7/19 11:52 am

Live CE

Please do not mandate that 5 hours of live or real-time interactive CE to be part of the annual requirements to maintain pharmacist licensure. If live CE is non-negotioable please consider reducing the number of hours.

Live CE does not meet the needs or wants or the majority of Virginia pharmacists. Instead, it caters to the visions of a few. Please provide evidence that live CE enhances the practice of every day pharmacists in retail pharmacy or non-academic hospital-based settings.

In my experience live CE is not as useful as high quality, self-study CE activities. I do believe that pharmacists have the option of choosing easier activities that may not enhance their knowledge to the degree that the BOP desires. Surely this can be addressed in a less exspensive and time consuming manner.

Commenter: Dan Orenzuk Valley Health Winchester Medical Center 2/7/19 12:53 pm

Comment on proposed live ce requirement for Pharmacists

I do not see the value in requiring live ce credits as a condition to renew a license. If the proposal is based on the assumption that the practitioner will learn more or be less inclined to "cheat" then I have to disagree. I feel I get less from listening to a webcast than from a written module where I can go back and review concepts I do not quite understand. Having to attend a planned live program entails added time away from my family and is expensive. Learning is a very different process for different individuals and leglislating a specific medium for all to learn by just makes no sense. Even If I already have the answers for a print course, I still have to read the questions and answers to complete the test; at many of the live events I have attended over the years, I just show up, maybe get something to eat or drink, maybe get to listen to a qualified presenter just to fill out an evaluation form at the end to claim my credit. My online experience often consists of having the program running in the background while I do other work and seldom are required to complete a test that actually quizzes me on the concepts presented. Please reconsider this proposal or at the least require the courses to be them to be free or reasonably priced, available at convenient times and to be free of the biases that are often the result of either a sponsored program or the for profit ce privateers.

Commenter: Francis Lucas 2/8/19 9:47 am

Proposal for 5 hr live/interactive contact hours for Pharmacists

I would ask for a clear definition of real time interactive vs live. I participate in some of the CDC train programs for Antimicrobial Stewardship. These programs require responses to questions throughout the program, but is not "live". Also, the NABP currently reports CPE activity as Live or Home Hours. Will another category be added for real time interactive? It would nice to have all CE programs identified as Live, Real Time Interactive, or Home based in the description of continuing education. For example, when obtaining ACPE credit, the description could state "pharmacists will receive 0.25 CEU's of *real time interactive* pharmacy education.

Commenter: Racheal Lowry 2/8/19 3:04 pm

Amendments

These amendments seem well thought out and necessary, and I particularly appreciate the rearranging of certain subjects to a more appropriate chapter. It seems as though the agency has done a great job in keeping up with issues which have an impact on both the pharmacy and the patient. Several of the proposed changes seem as though they will have a very positive effect on long term care patients in particular, and make it easier to provide them with the necessary medications while taking into account their unique situation.

Commenter: Maria J. Paccioretti 2/8/19 8:03 pm

New regulation for pharmacy continuing education

I believe that it is imperative that "live" and "interactive" be more clearly defined, as this will impact my comments. I live and practice pharmacy on Chincoteague Island on the Eastern Shore of Virginia. This is a sparsely populated rural area. As such, we are not privy to live presentations or symposiums. In fact, very few pharmaceutical representatives ever visit. Personally, I receive my continuing education credits through articles with on-line questions and "live" webinars, which are interactive, in that comments can be submitted and questions answered. The nearest towns where presentations might be held are Salisbury, Maryland (a 60 mile distance) or Norfolk-Virginia Beach, Virginia - an hour and a half to 2 hour drive. The travel time, as well as the expense of gasoline and tolls, would present a hardship for many pharmacists, and especially technicians. I hope that these concerns will factor into any decision the Board makes.

Thank you.

Commenter: Shabeen Ali 2/9/19 7:40 am

No live CE's!

I strongly object to the proposal of live CE's. With the convenience of modern technology, online CE's provide pharmacists with the opportunity to fact check, investigate further, and revisit topics of interest. In the age of technological advances, forcing pharmacists to take live CE's is a step backward, not forward. Furthermore, for many working pharmacists, the timings and schedule of live CE's is not conducive to their work week schedule. Weekend classes would force them away from their families, and would impede on what little personal time they have. Live CE's also open the door for sponsoring companies to fill their own pockets, which paves the way to biased content. There is absolutely no benefit to live CE's. It will only prove to be a burden on us pharmacists.

Commenter: Mahpara Khokar 2/9/19 12:21 pm

No Live CE

I don't support the Live CE requirement due to time constraints and cost. It should be an option for those who are interested in a particular topic but it should not be a requirement for everyone.

Commenter: Charity Deters 2/9/19 2:18 pm

Pharmacist renewal requirement for live CE

I am not opposed to a live CE requirement. However, 5 hours could be time prohibitive to many practitioners. Most live programs are only available during business hours and practitioners can not take off time to attend. Night shift practitioners may not be able to schedule or attend live CE. The other option is to give up their family/free time to attend, which many times, are costly programs (eg; travel, hotel, the live program, meals, etc).

If live CE is to be required, the requirement should not exceed 2 hours per renewal year.

Commenter: Bi Ntumngia 2/9/19 4:12 pm

CE requirements

Please no changes to current CE requirements hence i think no Live CE is needed. Thanks.

Commenter: Mark Zingelmann 2/9/19 8:00 pm

Live CE

Five hours of live CE is not much to ask. North Carolina required 8 hours of live up until last year when it was reduced to 5. It's not hard to obtain and is actually fun getting together with other pharmacists .

Commenter: Joanne M. Hawley, VAMC Salem 2/10/19 12:27 pm

Requirement for 5 hours live CE/year

Having read some of the comments, and knowing that VIrginia has some substantial rural areas, I would support limiting the required amount of live CE to 4 hours/year, about 1 hr per quarter. Working for the VA live programming thru teleconference is not a problem as there are many interactive offerings on a regular basis. Folks without that sort of contact or without coverage for the daytimes in which many interactive programs would occur may find themselves in more of a bind. Therefore, I support some interactive "live" CE and also ask that you put yourselves in the shoes of rural area pharmacists, too.

Commenter: GEORGE ROBERTS JR (Remington Drug Co) 2/10/19 1:52 pm

LIVE/LIVE-INTERACTIVE CE

I am in favor of the live CE requirement with reservations. I want to know the origin/reason for the requirement as well as evidence that the live/live-interactive programs provides added benefits. I would also appreciate a definition of what the Board would consider as "live-interactive". I believe the opportunity to interact and network with other pharmacists has value and this requirement would serve as a platform to accomplish this. I also think an opportunity to learn in a different way sometimes is a welcome change to the home study, printed materials. I also see this opportunity as a little nudge to promote joining organizations providing this form of CE. NCPA, APhA, and I suspect others offer live CE through membership and the cost of membership is cheaper than traveling to an onsite program. I am hesistant to lend full and complete support given two former Board of Pharmacy employees, Elizabeth Russell and Vicky Gwaltney, spoke convincing against this proposed change. Since this is a comment period, I hope this gives the Board reason to share details and explain the reasoning behind this significant change in CE requirements. I can see the valid points on time constraints, cost, and the real value of this requirement. I believe some live CE should be required but agree a phasing in or just a reduced requirement of say 2 hours instead of 5 may be a workable end result. Thank you for allowing me the opportunity to share my comments and concerns.

Commenter: Kathryn Dobski 2/10/19 3:49 pm

Review of Regulations

I have read and reviewed chapters 20 and 50 of the Virginia Regulations. I am an out of state pharmacist and have read over the new proposed regulations on the continuing education and now requiring 5 hours of live CE each year. Also the proposed changes in Pharmacist:Tech ratio.

Commenter: Ryan Jones, Department of Veterans Affairs 2/11/19 1:50 pm

Comment on Board of Pharmacy chapters 20 and 50 review

The proposed regulation involving the requirement of 5 hours of live CE out of 15 required hours for pharmacist license renewal will put an undue burden on federal employees and contribute to workplace dysfunction. As a federal employee, I work regularly with pharmacists who are licensed in different states. We have limited opportunities to attend live CE presentations, as these opportunities are often granted on a rotating basis for fairness and to ensure adequate pharmacist coverage. When live CE events are announced, multiple pharmacists are usually interested and depending on the number of pharmacists employed at the institution, as well as seniority, a single pharmacist may only be approved to attend 1-2 live CE events per year.

If this regulation is approved, it creates a situation where federal pharmacists licensed in Virginia MUST attend live CE events to maintain licensure and therefore employment. Thus, there will be pressure on management to allow pharmacists like myself to attend these events preferentially over those who have no such requirement. This may contribute to a sense of inequity and lead to strained workplace relationships.

Although I understand that live CE is desirable in many ways, this requirement is impractical and will create unnecessary personnel conflicts for those of us employed in federal institutions where many competing CE interests and various requirements are already in play. Live CE should continue to be optional toward the requirement to maintain pharmacist licensure in the Commonwealth of Virginia.

2/11/19 1:59 pm

Commenter: Ryan Jones, responding on behalf of myself

Addendum to previous comment

I need to add to my previous comment that I am responding on my own behalf, not as a spokesperson for the aforementioned government agency. My words should not be taken as an official statement or stance from any entity other than myself. Thank you.

Commenter: Adam Bateman 2/11/19 5:22 pm

Live CE Requirement

I am opposed to the Board's requiring any portion of the CE requirement for pharmacists to be live. I feel that in order for the board to impose this new requirement, it should have to provide some evidence showing that live or interactive CE is a better educational experience than self-study coursework. The Board has not provided this evidence in the documents made available thus far but is merely expressing its opinion. From experience, I have found that having to review home-study coursework and pass a substantial post-test requires much more attention to and retention of course material than sitting through a live lecture where all you have to do is wait for a CE code at the end and complete an evaluation. Typically, live CE is a lot more expensive and inconvenient than home-study courses. There is a lot of home-study coursework available to pharmacists at minimal to no cost, and pharmacists can choose coursework that is relevant to their area of practice and interest, or where they may be weak and need additional education. There is not even close to the same availability of live or interactive courses, forcing pharmacists to attend meetings or "interactive" courses that may not be offered at a time convenient to them, possibly even forcing them to take time off work or away from home/family. Again, without a solid argument that live CE is more effective in maintaining pharmacist competency, I do not believe that the Board should be allowed to require this. This new requirement will add substantial costs to renewing a pharmacist license, both in course costs as well as pharmacist time to attend a live or interactive program, without any stated basis or evidence shown for increased protection of the public health, safety, and welfare.

Thanks,

Adam

Commenter: CRAIG A STILTNER, FOREST PHARMACY 2/12/19 2:34 pm

5 HOURS OF LIVE CE

WE BARELY HAVE TIME TO DO OUR CE AFTER WORK, ESPECIALLY IF YOU OWN YOUR OWN PHARMACY. I HATE HAVING TO GO TO ROANOKE OR OTHER PLACES OF VENUE FOR MEETINGS, IT SEEMS SO CHAIN ORIENTED. I HOPE YOU WILL CONSIDER LEAVING THE CE LAW INTACT. LIVE CE IS JUST SIMPLY NOT NECESSARY.

Commenter: Cardinal Health Nuclear and Precision Health Solutions 2/13/19 9:24 am

Live CE

I have practiced as a nuclear pharmacist for 21 years and have completed Nuclear Pharmacy online CE from Purdue University to maintain my BCNP certification. This CE is very informative and practical for me to complete each year. Live CE for nuclear pharmacy would require long distance travel across the country. The current CE program works very well educating me on

nuclear pharmacy topics and is sufficient for maintaining my Board Certification in Nuclear Pharmacy which is a national program.

Commenter: John Nett, Lackey Free Clinic 2/14/19 10:01 am

Live CE

I am writing to voice opposition to the proposed live CE requirement change. Unless there is substantial evidence proving live CE is superior to other forms, this measure appears unwarranted and arbitrary. As a retired pharmacist, I maintain my license in order to provide pharmacy services at a local free clinic. As such, under the present system, I am able to select CE courses applicable to my practice setting. Regrettably if I am forced to take live CE, it will be whatever I can find. Additionally, the added costs associated with live CE may make continuing to maintain my license an untenable proposition. I hope you will reconsider the broad impacts of this proposed requirement change. Thank you for the opportunity to comment.

Commenter: Ginger, technician 2/14/19 10:20 am

Do pharmacy tech renewal licenses need live CE's too?

Commenter: Deborah A Sanborn 2/14/19 12:30 pm

Live CE--for pharmacists

Regarding the requirement for all current active pharmacists to obtain 5 hours of live or interactive continuing education annually. This is difficult to impossible for me as I live in Texas. Why the need for live CE? Even if it is a webinar, people can turn it on, walk off and do something else. I don't have the privilege of sitting through a live program as my job and family take up all of my time. I prefer to squeeze in home study CE when and where I can and actually read it. Adding the requirement of a live CE program puts an unnecessary burden on already stressed out pharmacists.

Commenter: Tuyet-Hoa Nguyen 2/14/19 10:04 pm

Live CE should be an option only.

No live CE requirement for Pharmacist please! There should be an easier way for Pharmacist to complete required CE courses due to their busy schedule especially if they are the owner of an independent pharmacy. Live CE should not be required but an option only.

Commenter: Jeffrey Martin, Bioscrip 2/15/19 9:18 am

Live CE requirements

I am **very opposed** to the Board's requiring any portion of the CE requirement for pharmacists to be live. I feel that in order for the board to impose this new requirement, it should have to provide some evidence showing that live or interactive CE is a better educational experience than self-study coursework. The Board has not provided this evidence in the documents made available thus far but is merely expressing its opinion. In my own experience, I have found that having to

review home-study coursework and pass a substantial post-test requires much more attention to and retention of course material than sitting through a live lecture where all you have to do is wait for a CE code at the end and complete an evaluation, with nothing to prevent participants from spending the entire time on their phone or some other distraction. Typically, live CE is a lot more expensive and inconvenient than home-study courses. There is a plethora of home-study coursework available to pharmacists at minimal to no cost, and pharmacists can choose coursework that is relevant to their area of practice and interest, or where they may be weak and need additional education. There is not even close to the same availability of live or interactive courses, forcing pharmacists to attend meetings or "interactive" courses that may not be offered at a time convenient to them, possibly even forcing them to take time off work or away from home/family. Again, without a solid argument that live CE is more effective in maintaining pharmacist competency, I do not believe that the Board should be allowed to require this. This new requirement will add substantial costs to renewing a pharmacist license, both in course costs as well as pharmacist time to attend a live or interactive program, without any stated basis or evidence shown for increased protection of the public health, safety, and welfare.

Thanks very much,

Jeffrey Martin

Commenter: Stephanie G. Elliott 2/15/19 9:45 am

Including live hours in CE requirements

I agree to include live hours as part of the CE requirement for license renewal. 5/15hrs live per year.

Commenter: David Pinkston 2/15/19 1:24 pm

NO to Live C.E.

Requiring live C.E. would be a terrible mistake. I have attended live CE in the past and I have found that you gain very little if any educational value, it also makes it harder to understand and learn about the topic. On line courses allow each participant to learn about the topic at their own speed. They can review the information as often as they like and there are many more topics available that will allow them to select a topic that is more valuable to their needs. It appears that requiring live CE is taking a step backwards. There are many more disadvantages and no advantages for all involved.

Commenter: Anna Frazier 2/16/19 12:41 pm

live CE hours

I do not agree with requiring us to do live CE hours. Online CE hours are more beneficial, becuase it allows us to do them on our own time. Live CE hours would be an inconvience and would be hard for many people to attend.

Commenter: Margaret Frazier 2/16/19 12:49 pm

No live CE hours

Requiring us to do live CE hours would be a huge mistake. Online CE's are much more beneficial and can work well with the busy schedules of people who work or our going through school. Online CE hours also give us the time and material making it easier to learn and review material at our own pace, where as it is much harder to learn and review material if it was a live CE.

Commenter: Adikali H Kamara 2/16/19 9:34 pm

Pharmacist

I think that the self-study CE courses are convenient and easy to understand, and you can read the material over and over again. Except there are evidence to prove that Live CE are better than self study, I do not think that they should be a requirement. Live CE can be optional for those who want to pay for them and think that it is a better way of learning for them but it should not be a requirement.

Commenter: JANET KAY HAUN 2/17/19 8:46 am

REVIEW

INFO REVIEWED

Commenter: Jadore Douglas, Retail Pharmacy 2/18/19 9:28 am

Live CE

To Whom It May Concern,

I belive that a live CE would be a good way to debate ideas as well as think of options for patients that you originally would not think of. Pharmacists in different settings can come together and think of best options for patient outcomes.

Commenter: Morgan Crooks 2/18/19 6:39 pm

No Live CE!

I do not think live CE would be beneficial. Everyone learns differently and I think that the online CEs offer a better opportunity for everyone to learn at their own pace and how they best learn. Not everyone does well with live learning, so I do not think it would be a good option.

Commenter: Richard Blessing 2/18/19 9:16 pm

No Live CE's

I do not support the proposal of making Live CE's mandatory for all by the board. We all learn differently due to individual differences. Besides, live CE's require additional time and cost which is mostly not reimbursed by employers. Moreover, I don't think that there is any current research proving that Live CE's help pharmacist retain the material any longer than all the other forms of obtaining CE's.

Commenter: Joscelyn Huson 2/19/19 3:13 am

No changes

Commenter: Francis Buckman 2/19/19 12:06 pm

No change to CE requirement

Please do not make changes to the current CE requirement for pharmacists. Live CE does not improve the quality of the information but does place an undue burden on licenced individuals. Thanks to technology continuing education is available to pharmacists 24/7 with quality information at our finger tips. Please do not punish the thousands of pharmacists across the state by adding a requirement for an expenseive and time consuming prcocess that does nothing to add to pharmacists education.

Commenter: Sharon Gatewood 2/19/19 2:53 pm

Live CE support

I am in full support of live CE. Not all CE but some. It encourages people to become more active in their profession. There are so many pharmacists in VA that have become unengaged in the profession. This would allow pharmacists to expose themselve to topics outside of there scope and broaden their expertise. I have heard from several pharmaicsts that live in VA and need live CE for other states that this would be a benefit.

Commenter: CARVAJAL PHARMACY 2/19/19 3:35 pm

No change to CE requirements

Live CE should remain optional.

Commenter: E. Kim Swiger 2/19/19 4:28 pm

Live CE requirement

I respectfully share my strong opposition to the Board's proposal for five hours of live or real-time interactive to be part of the continuing education requirements. In my experience, live CE courses are often far too basic and do not serve to expand relevant knowledge. The only exceptions being those comprehensive live training courses such as immunization certification, dyslipidemia certification, diabetes certification, etc. which often require "home study" as well as live, and true interactive learning session(s). The variety and abundance of quality home study CE options allows a pharmacist to select coursework in an area that will benefit his/her practice and/or focus on a topic which he/she may be weak or need reinforcement. The required post-tests are valuable assessment tools to confirm knowledge and the articles/courses provide a valuable resource for future reference. Again, in my experience this is not the case with many/most live CE sessions as they often do not support level of knowledge expansion desired nor do they support retention of information or provide any detailed reference(s) for future use. While I still seek and participate in live CE courses whenever I am fortunate to attend conferences, I believe there are significant barriers to access to **quality** live CE such as lack of practice relevant and detailed programming, affordability, and time and travel constraints. Additionally, and unfortunately, one can look around

the room during live CE sessions and see that often times some of the participants are merely in attendance rather than fully engaged in a valuable, live and interactive CE session promoting new ideas, or expanding existing knowledge.

Commenter: Dr. Kristina Angelone, Pharmacist 2/19/19 4:51 pm

An addition of live CE hours

Live CE hours can be very difficult to schedule and very expensive. Going from zero hours per year to 5 places an unfair hardship on pharmacist. As it is, the board doesn't mind that we work 15+ hour days with no breaks but to add trying to fit 5 live CE hours into that schedule will be extremely difficult. Live CE do not provide any additional benefit to learning and nor does it increase understanding of a given subject matter. I see no reason the board should add this requirement to our annual CE hours.

Commenter: Candice Simpson 2/19/19 7:43 pm

5 Live CE Hours

Being a board certified pharmacist with licensure in three states, including Virginia, I have found that the impactful knowledge I gain is far greater with the non-live CE credits. I am able to choose a plethora of non-live CE topics that pertains to my focused area of practice and work at a pace conducive to my learning (I always spend more time on the CE material than the number of credits the CE provides.) . During live CE credits I often find that there is too much information cramed into the amount of time required and often presenters do not provide useful information. It seems a large majority of live CE credits are more focused on gaining money from participants than providing impactful educational opportunities.

Commenter: Medicine Shoppe, Julia W Jones, Pharmd 2/21/19 12:07 pm

comment on regulatory action

I have reviewed the regulations in chapters 20 and 50.

Sincerely,

Julia W Jones, PharmD.

Commenter: Brittany brace, Walgreens 2/21/19 1:54 pm

I vote not in favor

I vote not in favor of the five live continuing education hours.

Commenter: Jennie Tran 2/21/19 5:28 pm

Comment on Periodic Review of Regulations

After reviewing the Agency Statement and Proposed Text, there were several information from the chapters that were important to review and look over. The possible changes and proposed

amendments that were brought up seems effective. In providing excessive information into just one chapter, it wouldn't be as effective as if the information was splitted up. These amendments seem fair and reasonable.

Commenter: Retired Pharmacist 2/21/19 7:05 pm

Live CE

I am a retired pharmacist who during my career held licenses in several states, several of which required live CE. Over the years, I have found that live CE has not provided any more educational benefits than other forms of continuing education. With this in mind, I oppose adding live CE to the CE requirements for pharmacists licensed in Virginia.

Commenter: Keona Mack, va board pharmacy 2/21/19 8:10 pm

I read it and it was very comprehensive, thanks

Commenter: Keona Mack 2/21/19 8:54 pm

Registry

I have read about pharmacy regulations and fully understand what is expected of us pharmacy technicians.

Commenter: Kris, Va BoP 2/22/19 7:16 am

NO LIVE CE!!!!

No live CE!!! There is no benefit to live CE and they are more expensive and time consuming! Do not add live CE as requirement for license renewals!!!

Commenter: June 2/22/19 8:31 am

Comment

No live CE's

Commenter: Ghazaleh Mostafaei 2/22/19 9:57 am

Optional Live CE

As a practicing pharmacy technician, I believe self-study CE works better for me. However, an optional live CE would be a great idea for people who have a different style of learning.

Commenter: Mareese Guelig, retired from walmart 2/22/19 10:24 am

Please keep the CE requirement as it stands. Since a lot of pharmacist work long extra hr.Mareese

Commenter: Mareese Guelig, retired from walmart 2/22/19 10:29 am

Please keep the CE requirement as it stands. Since a lot of pharmacist work long extra hr.Mareese

Please keep the current CE requirement as it stands, many pharmacist work hours longer than their scheduled shifts. The don't get paid for going to live CE. Thanks Mareese G.

Commenter: CVS Health 2/22/19 11:16 am

CVS Health's comments (1 of 2) on Virginia Board of Pharmacy periodic review of regulations

February 22, 2019

Caroline Juran, RPh

Executive Director

Virginia Board of Pharmacy

9960 Mayland Drive

Suite 300

Richmond, VA 23233-1463

Caroline.juran@dhp.virginia.gov

Re: CVS Health's comments on Virginia Board of Pharmacy periodic review of regulations in chapter 20 and 50.

Dear Executive Director Juran:

I am writing to you in my capacity as Senior Director of Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points of care to patients in the state of Virginia through our integrated offerings across the spectrum of pharmacy care. CVS Health appreciates the opportunity to submit comments on the Virginia Board of Pharmacy periodic review of regulations in chapter 20 and 50. Our suggested rule language changes are listed in red and *italicized* throughout this letter. We would also like to thank the Board for their vigilance to

continuously improve the laws and regulations that guide pharmacists, pharmacy interns, and pharmacy technicians serving Virginia patients.

Supporting the Pharmacist

Community pharmacists provide high quality, accessible patient care services, including medication management, immunizations, preventive screenings, and chronic care management. Despite a growing need for increased access to patient care services, community pharmacists spend only 21% of their professional time performing patient care services that are not associated with dispensing prescriptions.1 To further enhance and optimize patient care services delivered at community pharmacies, leveraging and expanding current roles of the pharmacy technician should be considered in community pharmacies. This means working towards a unified vision for pharmacy technician practice, which includes removing antiquated supervision requirements and expanding technician roles related to dispensing medications and supporting patient care services.2 Increasing the scope of pharmacy technicians to include administrative and supportive tasks for pharmacist-provided patient care services will allow pharmacists to more effectively and efficiently provide for patients' medication-related needs.3 Most importantly, some states have a patient safety track record of success with expanded pharmacy technicians roles that spans over four decades.4

- We request that the Board amend the definition of personal supervision in 18VAC110-20-10 to allow for emerging technology to safely assist pharmacists in the communication and observation of pharmacy technicians.5
- We request the that the Board follow the lead of the National Association of Boards of Pharmacy (NABP) Model Act and 21 other states to remove the ratio supervision requirements proposed in 18VAC110-20-112(A).6
- We request that the Board amend 18VAC110-20-360 to permit pharmacy technicians to transfer prescriptions.4

Suggested language:

18VAC110-20-10. Definitions.

"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act being performed. ~~*Neither prior nor future instructions shall be sufficient nor shall supervision rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.*~~ *or must be readily and immediately available through the use of real time, two-way technology communications between the pharmacist and technician(s).*

1. A pharmacist using technology as an adjunct to assist in the personal supervision of the pharmacy technician shall make certain all applicable state and federal laws, including, but not limited to confidentiality, are fully observed when employing technological means of communication and observation.

2. If technology is being used to provide personal supervision of pharmacy technician(s), such technology shall be sufficient to provide the personal assistance, direction and approval required to meet the standard of practice for the delegated tasks.

Suggested language:

18VAC110-20-112. Supervision of pharmacy technicians.

A. A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time. ~~; however, no pharmacist shall supervise more than four persons performing the duties of a pharmacy technician at one time.~~

B. In addition to the acts restricted to a pharmacist in §54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians.

Suggested language:

18VAC110-20-360. Issuing a copy of a prescription that can be filed or refilled.

A. Consistent with federal laws and regulations, a copy of a prescription shall be given upon request by one pharmacy to another pharmacy provided the drug can be filled or refilled pursuant to §§ 54.1-3410 and 54.1-3411 of the Code of Virginia and provided the patient has given permission for the transfer.

B. The transfer of original prescription information for a drug listed in Schedules III through VI for the purpose of dispensing is permissible between pharmacies if the transfer is communicated directly between the two pharmacies either orally by direct communication ~~between the transferring pharmacist and the receiving pharmacist~~, or by facsimile machine or by electronic transmission, provided:

1. The transferring pharmacy:

a. Records the word "VOID" on the face of the invalidated prescription;

b. Records on the reverse of the invalidated prescription the name, address, and, except for a prescription for a Schedule VI drug, the DEA number of the pharmacy to which it was transferred, and, for an oral transfer, the name of the *pharmacist or pharmacy technician* receiving the prescription information;

c. Records the date of the transfer and, in the case of an oral transfer, the name of the *pharmacist or pharmacy technician* transferring the information; and

2. The receiving pharmacy:

a. Writes the word "TRANSFER" on the face of the transferred prescription.

b. Provides all information required to be on a prescription to include:

(1) Date of issuance of original prescription;

(2) Original number of refills authorized on the original prescription;

(3) Date of original dispensing, if applicable;

(4) Number of valid refills remaining and date of last dispensing;

(5) Pharmacy name, address, DEA registry number, except for Schedule VI prescriptions, and original prescription number from which the prescription information was transferred; and

(6) Name of transferring pharmacist~~,~~ *or pharmacy technician* if transferred orally.

Both the original and transferred prescription shall be maintained for a period of two years from the date of last refill.

C. Nothing in this chapter shall prevent the giving of a prescription marked "For Information Only" to a patient.

D. In lieu of recording the required information in subsection B of this section on a hard copy prescription, a pharmacy may record all required information in an automated data processing

system used for storage and retrieval of dispensing information in accordance with 18VAC110-20-250.

E. For prescriptions transferred between pharmacies using a common database, the pharmacy receiving the prescription shall not be required to maintain a hard copy pursuant to 18VAC110-20-240 B provided that the system used is capable of generating a hard copy of the transferred prescription upon request or except as required by federal law.

Supporting the Community

There are a variety of situations or natural disasters that can directly effect the temporary closing of community pharmacies across Virginia. In these events, patients can lose critical access to pharmacy services resulting in a fragmentation of their prescription medication management care. Mobile and temporary pharmacies have played a key role in other jursidictions in aiding patients to maintain or stabilize their health as they recover from the disaster's impact on other areas of their lives.[7-8]

- We request the Board amend 18VAC110-20-150(A) and (C) to permit pharmacies to aid Virginia communities with temporary pharmacy services during emergency situations.

Suggested Language:

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

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

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

C. The pharmacy shall be constructed of permanent and secure materials. Trailers or other moveable facilities or temporary construction shall ~~not~~ *only* be permitted *in a declared emergency pursuant to §54.1-3307.3 of the Code of Virginia*.

Dispensing of Prescriptions

CVS Health commends the Board for the proposed changes in in 18VAC110-20-270(D) and (F). We support all efforts that increase patient access to pharmacy services by allowing patients to utilize a drop box at their local pharmacy for the collection of written prescriptions and refill requests. We support the Board allowing pharmacists to use their professional judgment when determining whether or not to refuse to return forged prescriptions to patients. We believe the proposed changes align with the Drug Enforcement Admininstration (DEA) guidance publication to pharmacists on prescription fraud.[9] Empowering pharmacists to engage in all aspects of the prescription adaptation process can lead to improved medication management while promoting efficiencies between pharmacists and prescribers.[10-11] As the pharmacist's role in community pharmacies continues to transition to delivering a higher order of clinical care, it is vital to allow pharmacists the professional judgment to determine what practice models of the dispensing process best assist the needs of our patients.[1]

- We recommend the Board amend the title of 18VAC110-20-270 to remove supervision of pharmacy technicians, as the proposed supervision of pharmacy technician rule now rests in 18VAC110-20-112.
- We request the Board amend 18VAC110-20-270(B) for alignment with the DEA signature requirements for written prescriptions.10
- We request the Board amend proposed rule 18VAC110-20-270(E)(1-4) allowing adaptation of an existing prescription when, in the pharmacist professional judgment, the action is intended to optimize the therapeutic outcome of patient treatment.11-12
- We request the Board continue requiring both data entry verification and prospective drug utilization review as required by 18VAC110-20-270(F), but request that the Board amend the rule to allow for technical workflow efficiencies for on-hold prescriptions that increase pharmacists ability to spend time with patients.
- We request the Board strike 18VAC110-20-110(D) as is there is no published evidence that suggests a pharmacist graduating from an ACPE accredited college of pharmacy is not prepared and professionally capable to safely fulfill the duties of a PIC immediately upon passing the MPJE jurisprudence exam and licensure.

Suggested Language:

18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions.~~; supervision of pharmacy technicians.~~

A. In addition to the ~~acts restricted to a pharmacist in § 54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians.~~

~~B. A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time; however, no pharmacist shall supervise more than four persons acting as pharmacy technicians at one time~~ requirements in §54.1-3408.01 of the Code of Virginia for an oral prescription or written prescription, including those transmitted via facsimile or electronically, a prescription shall include a quantity, or duration of the order by which the pharmacist can calculate the authorized quantity using directions for use. Except for prescriptions transmitted electronically in compliance with 18VAC110-20-285, written prescriptions *for controlled substances* shall also include the prescriber's manual signature.

~~C.~~B. After the prescription has been prepared and prior to the delivery of the order, a pharmacist shall inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction. If more than one pharmacist is involved in verifying the accuracy of the prescription product, a record shall be maintained identifying the date of dispensing, each pharmacist involved in the process, and the individual task for which he is responsible for verifying the accuracy. Such record showing verification of accuracy shall be maintained on a pharmacy record and, if necessary, an alternate record consistent with 18VAC110-20-255 for the required time period of two years, unless otherwise specified in regulation. If the dispensing involves central or remote processing, records of pharmacist verification shall be maintained in a manner consistent with 18VAC110-20-276 and 18VAC110-20-515.

~~D.~~C. If a pharmacist declines to fill a prescription for any reason other than the unavailability of the drug prescribed, he shall record on the back of the prescription the word "declined"; the name, address, and telephone number of the pharmacy; the date filling of the prescription was declined; and the signature of the pharmacist.

~~E.~~D. If a pharmacist determines from a prescriber or by other means, including the use of his professional judgment, that a prescription presented for dispensing is a forgery, the pharmacist shall not may refuse to return the forged prescription to the person presenting it. The

forged prescription may be given to a law-enforcement official investigating the forgery; or it shall be retained for a minimum of 30 days before destroying it, in the event it is needed for an investigative or other legitimate purpose.

E. Upon patient consent, a pharmacist using professional judgement and acting in the best interest of patient care may adapt a prescription as specified in this rule, provided the drug is not for a controlled substance, and provided that the prescriber has not indicated by any means necessary that adaptation is not permitted.

1. A pharmacist may change the quantity, dosage, dosage form, or direction of medication dispensed if it meets the intent of the prescriber.

2. A pharmacist may complete missing information on a prescription if there is sufficient evidence to support the change.

3. A pharmacist may extend a maintenance drug for the limited quantity necessary to coordinate a patient's refills in medication synchronization program.

4. A pharmacist who adapts a prescription in accordance with these rules must document the adaptation in the patient's record.

~~F.~~E.*F.* An on-hold prescription shall be entered into the automated data processing system if such system is employed by the pharmacy, and the pharmacist ~~*on-duty*~~ shall verify the accuracy of the data entry ~~*at that time. The pharmacist subsequently dispensing the on-hold prescription on a future date shall, at a minimum,*~~ *and* conduct a prospective drug review consistent with § 54.1-3319 A of the Code of Virginia. If an on-hold prescription is returned to a patient prior to the initial dispensing of the drug, the pharmacist shall delete the entry in the automated data processing system.

~~*F.*~~*G.* A pharmacy may utilize a drop box for the collection of written prescriptions and refill requests. The drop box shall be located in a visible area within the permitted facility and shall be locked at all times with access to the items placed in the drop box restricted to pharmacists practicing at the pharmacy or an authorized pharmacy technician practicing at the pharmacy when a pharmacist is on duty. The drop box shall be constructed in a manner to prevent the theft or loss of a written prescription or confidential information and shall be bolted to the floor or a fixed structure. Pharmacists shall in some manner inform the public that containers left in a drop box for refill should not contain unused drugs.

18VAC110-20-110. Pharmacy permits generally.

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.

B. Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day and shall allow at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break.

C. The pharmacist-in-charge (PIC) PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

~~*D. A pharmacist shall not be eligible to serve as PIC until after having obtained a minimum of two years of experience practicing as a pharmacist in Virginia or another U.S. jurisdiction. The board may grant an exception to the minimum number of years of experience for good cause shown.*~~

(Comment 1 of 2)

Sincerely,

Mark Johnston, PharmD

Senior Director, Pharmacy Regulatory Affairs

CVS Health

200 Highland Corporate Drive

Woonsocket, RI 02895

(401)601-1968

Mark.Johnston@CVSHealth.com

Commenter: CVS Health 2/22/19 11:17 am

CVS Health's comments (2 of 2) on Virginia Board of Pharmacy periodic review of regulations

Dispensing of Prescriptions (Continued)

In 2008, NABP convened the task force on Medication Collection Programs. Based on research conducted and task force recommendation, NABP developed a position statement and model rules for the safe return and resuse of prescription medications in community pharmacy settings.6,13 CVS Health commends the Board of years ago for incorporating many of the recommendations set forth by NABP in 18VAC110-20-355(E) which are paramount for ensuring the integrity and stability of the medications are maintained. While it is not recommended in the NABP position statement and model rules, we acknowledge the best practices reasoning for 18VAC110-20-355(E)(2) and requiring restocked drugs to be dispensed as soon as possible. However, we believe the current rule does not account for automated counting device and dispensing processes which are stocked with medications that would qualify as fast-moving or high volume and therefore meet the intentions of current community pharmacy restock and reuse best practices.

- We request the Board amend 18VAC110-20-355(E)(2) to permit using returns of dispensed medication that never left the pharmacy or the control of the pharmacy delivery agent to be restocked for resuse in an automated counting device.

Suggested Language:

18VAC110-20-355. Pharmacy repackaging of drug; records required; labeling requirements.

~~D.~~E. A pharmacy may return a dispensed drug to stock for redispensing that has never left the pharmacy premises or the control of the pharmacy delivery agent pursuant to § 54.1-3411.1 A 3 of the Code of Virginia under the following conditions:

1. An expiration date shall be placed on the label prior to returning the drug to stock. In the absence of stability data to the contrary, the date on the label may not exceed the expiration date on the manufacturer's container or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier.

2. The restocked drug shall be used to fill the next prescription received for that product, *unless the restocked drug is used to fill automated counting devices and dispensers*. In the event that the drug is not dispensed prior to the new assigned expiration date, it shall be removed from working stock as expired, and disposed of in accordance with 18VAC110-20-210.

3. If there is no lot number on the label of a drug returned to stock or on the prescription records that can be cross-referenced from the prescription label, the drug shall be removed from stock upon any recall of that drug product and returned to the manufacturer or otherwise disposed of in accordance with 18VAC110-20-210.

Transmission of Prescriptions and Chart Orders

CVS Health, along with our subsidiary Omnicare, Inc commends the Board for the proposed changes eliminating the 5% pharmacy robotics systems daily random checks in 18VAC110-20-425 (5) and adding the first dose immediate drug supply allowance in 18VAC110-20-530(B)(1-2). We believe pharmacies providing first dose services to long-term care facilities through common ownership or written contract will enhance patient care by decreasing delays in therapy from the lag time between the patient's admission and the time it takes the pharmacy to receive new orders. Further, the Board's recommended changes dovetails nicely with the research and recent recommendations of the 2017 NABP task force on long-term care pharmacy rules.[14] CVS Health again commends the Board of years ago for addressing chart order provisions for long-term care pharmacies well before national recommendations were put forth. We believe permitting chart orders in long-term care facilities and correctional facilities streamlines patient care and aligns with the current NABP model rules and task force on long-term care rules recommendations.[6,14]

CVS Health supports the 18VAC110-20-420 unit dose dispensing systems rules as they provide patients necessary access to pharmacy services in long-term care facility settings. We believe 18VAC110-20-420(B) was written pursuant to federal law that has changed since the implementation of the Affordable Care Act (ACA). The ACA mandates caused Centers for Medicare and Medicaid Services (CMS) to promulgate regulations permitting pharmacies to dispense up to a 14-day cycle of medications.[15] Further, CMS regulations exclude antibiotics and drugs that must be dispensed in their original container as indicated in the Food and Drug Administration (FDA) Prescribing Information and drugs that are customarily dispensed in their original packaging to assist patients with compliance.

- We request the Board amend 18VAC110-20-240(C)(1) to align with the NABP model rules and task force on long-term care recomendations by permitting chart orders in correctional facilities.
- We request the Board amend 18VAC110-20-530(B)(1) to additionally align with the NABP model rules and task force on long-term care recomendations by allowing shared pharmacy services for immediate need between pharmacies with common ownership or written contract.
- We request the Board amend 18VAC110-20-420(B) to a maximum of 14-days pursuant to current CMS regulations.

Suggested Language:

18VAC110-20-240. Manner of maintaining records, prescriptions, inventory records.

C. Chart orders.

1. A chart order written for a patient in a hospital, *a correctional facility* or long-term care facility, a patient receiving home infusion services, or a hospice patient pursuant to § 54.1-3408.01 A of the

Code of Virginia shall be exempt from having to contain all required information of a written prescription provided:

Suggested Language:

18VAC110-20-530. Pharmacy's responsibilities to long-term care facilities.

B. The pharmacy providing services to the long term care facility may share a copy of a Schedule VI prescription or order with another pharmacy for the purpose of dispensing an immediate supply of drugs, not to exceed a seven-day supply, without transferring the prescription pursuant to 18VAC110-20-360 if the following conditions are satisfied:

1. The pharmacy providing services to the long term care facility has *common ownership or* a written contract with the other pharmacy outlining services to be provided, the recordkeeping associated with the dispensing, and the responsibilities of each pharmacy; and,

2. The pharmacy providing services to the long term care facility provides a valid oral or written prescription or order to the other pharmacy.

Suggested Language:

18VAC110-20-420. Unit dose dispensing system.

B. In providing unit dose systems to hospitals or long-term care facilities where only those persons licensed to administer are administering drugs, the pharmacy shall dispense not more than a ~~*seven*~~*fourteen*-day supply of a drug in a solid, oral dosage form at any one given time.

CVS Health appreciates and understands the ongoing effort since 2016 the Board has committed to in order to amend these rules and regulations to reflect the current and evolving practice of pharmacy. We are supportive of the allowance of patient drop boxes, pharmacist professional judgment decisions, removal of the 5% robotic pharmacy systems random checks, first dose for long-term care pharmacies, along with clarifying language that has been added throughout the rules. In order to continue to further the highest order of pharmacy practice, we have proposed suggested amendments to align the language with current trends across the nation which include but are not limited to allowance of pharmacy technician roles that enhance medication dispensing support, emergency temporary pharmacies, restock and resuse of medications, and chart orders in correctional facilties.

CVS Health appreciates the opportunity to submit comments for this periodic review of regulations in chapter 20 and 50. If you have any questions, please contact me directly at (401)601-1968.

Sincerely,

Mark Johnston, PharmD

Senior Director, Pharmacy Regulatory Affairs

CVS Health

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References:

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(Comments 2 of 2)

Commenter: Amy 2/22/19 12:48 pm

Changes in CE Requirements

Similarly to the opinions that were previously shared, I am personally opposed to the LIVE CE hour requirement. With different workloads and different work schedules, it may already be difficult for pharmacists to get CE hours in the specific topics that they would like to. Making a LIVE CE hour requirement will only push more people to use this as a check list to check off of instead of using CE credits to willingly and engagingly learn more.

Commenter: Wise Hospice Options 2/22/19 12:58 pm

Follow up

Thank you for the update. No comments at this time.

Commenter: Esther Pak 2/22/19 6:56 pm

Comment

I think sepearating the chapters allow the flow to be more organized. It is more clearer and less confusing since registration for pharmacy technicians is separate from the pharmacist registration. I cannot speak in favor or against live or interactive CE because I am only a technician.

Commenter: Judy L Humphreys 2/22/19 11:57 pm

Proposed Text/Agency Statement

I have been sick with 99.9 temp. and a dry,tickling cough for 3 months. I also have numerous other emergencies. I may have whooping cough. I read over the Agency Statement and Proposed Text up to chart orders. I skipped down and read over the fax section. I will have to finish the Proposed Text later. It is always good to review the laws. I am some worried about the 5 hr. live CE. I do 15hrs. live every other year, and 16hrs. with U.S. Pharmacist every other year. The live CE is $285 every other year. I only live off of $1115/month. I don't know how that I would pay for 5 hrs. live and a 10hr. mail CE every other year, and it would be hard to find CE's with those exact hrs. I don't think that this was enough time to read all of the Proposed Text especially if someone is sick with emergencies.

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Mid-Atlantic Permanente Medical Group, P.C.
Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc

Caroline Juran, RPh
Executive Director
Virginia Board of Pharmacy
9960 Mayland Drive
Suite 300
Richmond, VA 23233-1463

February 22, 2019

Re: Proposed Amendments 18VAC110-20. Regulations Governing the Practice of Pharmacy (amending 18VAC110-20-10, 18VAC110-20-20, 18VAC110-20-25, 18VAC110-20-110, 18VAC110-20-140, 18VAC110-20-150, 18VAC110-20-180, 18VAC110-20-200, 18VAC110-20-211, 18VAC110-20-220, 18VAC110-20-240, 18VAC110-20-270, 18VAC110-20-280, 18VAC110-20-290, 18VAC110-20-355, 18VAC110-20-390, 18VAC110-20-425, 18VAC110-20-470, 18VAC110-20-490, 18VAC110-20-530, 18VAC110-20-550, 18VAC110-20-580, 18VAC110-20-630, 18VAC110-20-680; adding 18VAC110-20-112; repealing 18VAC110-20-15, 18VAC110-20-21, 18VAC110-20-30 through 18VAC110-20-106).

18VAC110-21. Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians (adding 18VAC110-21-10 through 18VAC110-21-180).

18VAC110-50. Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers (amending 18VAC110-50-40, 18VAC11-50-60, 18VAC110-50-80).

Dear Ms. Juran,

Thank you for the opportunity to provide comment on proposed new regulations 18VAC110-20 *et seq.* Established in 1980, Kaiser Permanente is the trade name for the total health organization comprised of Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc., the Mid-Atlantic Permanente Medical Group, P.C., an independent medical group that features approximately 1,600 physicians who provide or arrange care for patients throughout the area, and Kaiser Foundation Hospitals, which contracts with community hospitals for the provision of hospital services to our patients. We provide and coordinate comprehensive health care services for approximately 780,000 members throughout the metropolitan area. Our organization operates thirteen pharmacies across ten medical facilities in the Commonwealth of Virginia with several more planned in the near future.

We request your consideration of the following amendments and comments, which we believe necessary to optimize safety and improve the well-being of the residents of the Commonwealth of Virginia:

(1) Proposed new item **18VAC110-20-140. (G) New Pharmacies, Acquisitions, and Changes to Existing Pharmacies** states:

"If the pharmacy is not operational within 90 days from the date the permit is issued, the board shall rescind the pharmacy permit unless an extension is granted for good cause shown."

COMMENT: We appreciate the Board's commitment to maintaining viable, safe pharmacies for residents of the Commonwealth by addressing the potential for fraudulent activity. Opening a new pharmacy involves a variety of factors such as construction, installation of equipment and security systems, ensuring staff members have appropriate professional licensure and procurement of hardware. Additionally, ordering medications in bulk requires establishing accounts with distributors often necessitating several levels of authentication. Although we acknowledge the potential to request an extension on an individual basis, much preparation occurs in anticipation of opening a new pharmacy and unpredictability may ensue as with any new business development, despite comprehensive preparatory efforts. As such, we suggest in the alternative that this proposed Section be amended to provide that:

"If the pharmacy is not operational within 120 days from the date the permit is issued, the board shall rescind the pharmacy permit unless an extension is granted for good cause shown."

(2) Proposed new item **18VAC110-20-425 (6) Robotic Pharmacy Systems** states:

"If the robot picks an incorrect medication, the pharmacy shall immediately institute a 100% check of all affected doses or compliance packages and perform a root cause analysis to investigate, identify, and correct the source of discrepancy or error in compliance with the pharmacy's policies and procedures prior to resuming full operations of the robot."

COMMENT: Our organization believes medication safety is essential for effective patient care, as errors can result in serious consequences. Formally, a root cause analysis (RCA) is a technique that attempts to identify the cause of the occurrence of a sentinel or unexpected event. The term RCA has been revised by the Institute for Healthcare Improvement to RCA^2 (Root Cause Analysis and Action or "RCA Squared") to indicate a more comprehensive, systematic analysis of an event. In short, an RCA^2 for robotic errors requires an interdisciplinary team comprised of pharmacists, technicians, practitioners, equipment manufacturer representatives and project coordinators to identify the source of clinically significant errors, recommend corrective action plans and determine continuous monitoring parameters. The formalized process can take days and, in some cases, up to weeks to properly complete. This time-intensive, multidisciplinary process is usually reserved for events that result in patient harm. There may be multiple contributing factors to errors. We have several verification steps beyond the selection of the incorrect medication that are effective in identifying the error prior to the prescription reaching the patient. Currently, quality assurance measures ensure reported medication errors are investigated and corresponding remedial actions occur in a timely manner. As such, we propose in the alternative that proposed Section (6) is amended to provide that:

"If it is identified that the robot selected an incorrect medication, the pharmacy shall identify and correct the source of discrepancy or error in compliance with the pharmacy's policies and procedures

prior to resuming full operations of the robot. An investigation of the cause of the event shall be completed and the outcome of the corrective action plan shall be summarized and documented in a readily retrievable format."

(3) Proposed new item **18VAC110-21-120(2) Requirements for Continuing Education** states:

"A maximum of one hour for serving as a preceptor for a pharmacy student or resident in an accredited school or program or for a foreign-trained student obtaining hours of practical experience."

COMMENT: We commend the Board for acknowledging the significance of experiential education to the profession of pharmacy and its ability to increase the quality of care available to the citizens of the Commonwealth. Evidence demonstrates that pharmacy residents and students add value to experiential sites by enhancing business growth potential, solving medication-related problems, and decreasing overall costs of healthcare while completing rotations. Preceptors use these opportunities to enhance practice settings with student pharmacists and/or supplement evidence of the positive impact of experiential education.[1] With growing diversity in the Commonwealth of Virginia, an invigorated healthcare workforce is necessary to broaden professional capabilities and such enthusiasm is often infused in practice environments via those gaining practical experience. Kaiser Permanente is in support of proposed new item 18VAC110-21-120(2) Requirements for Continuing Education.

Feel free to contact me at monet.stanford@kp.org or (301)816-7336, should any further inquiries arise. Thank you for your time and consideration.

Sincerely,

Monet M. Stanford

Monet Stanford, PharmD
Pharmacy Government Relations and Regulatory Affairs
Kaiser Foundation Health Plan of Mid-Atlantic States, Inc.
2101 East Jefferson Street
Rockville, Maryland 20852

[1] Chair KW, Aistrope DS, Ausili J, et al. The Report of the 2016-2017 Professional Affairs Standing Committee: Formally Embracing and Engaging Preceptors in the Academy - The Time Has Come. *Am J Pharm Educ*. 2017;81(9):S16.

Commonwealth of Virginia

Yeatts, Elaine <elaine.yeatts@dhp.virginia.gov>

Fwd: NACDS Comments Proposed Regulations Amending 18 VAC110-20 Regulations Governing the Practice of Pharmacy

1 message

Juran, Caroline <caroline.juran@dhp.virginia.gov> Fri, Feb 22, 2019 at 11:07 AM
To: Elaine Yeatts <elaine.yeatts@dhp.virginia.gov>

---------- Forwarded message ---------
From: **Jill McCormack** <JMcCormack@nacds.org>
Date: Fri, Feb 22, 2019 at 9:49 AM
Subject: NACDS Comments Proposed Regulations Amending 18 VAC110-20 Regulations Governing the Practice of Pharmacy
To: Juran, Caroline (DHP (Caroline.Juran@DHP.VIRGINIA.GOV) <Caroline.Juran@dhp.virginia.gov>

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

February 22, 2019

Ms. Caroline Juran

Executive Director

Virginia Board of Pharmacy

Submitted via email: caroline.juran@dhp.virginia.gov

RE: Proposed Regulations Amending 18 VAC110-20 Regulations Governing the Practice of Pharmacy

Dear Ms. Juran:

On behalf of the 1,171 chain pharmacies we jointly represent operating in the Commonwealth of Virginia, the National Association of Chain Drugs Stores (NACDS) and the Virginia Association of Chain Drug stores write to express our concerns with the Virginia Board of Pharmacy's proposed amendments to 18VAC110-20.

18VAC110-20-110- Pharmacist in Charge: Under the proposed rule, a licensed pharmacist would not be able to serve as PIC until they have obtained a minimum of two years of experience practicing pharmacy in Virginia or another state. We recognize and appreciate the important role of the PIC in the operation of pharmacies. Additionally, we understand the Board's intent for developing standards that serve to protect public health, safety, and welfare in the pharmacy setting. However, while the Board is willing to grant an exception to the minimum number of years of experience for good

cause, we believe that this requirement, as proposed, would be problematic for community pharmacies. This requirement would potentially unfairly disadvantage skilled pharmacists and pharmacies who would be forced to wait until the arbitrary timeline requirements are met. Additionally, it could potentially exacerbate staffing issues in rural areas of the Commonwealth where we already have challenges recruiting pharmacists.

We believe that the designation of a PIC should be made on a case-by-case basis and should be based on the level of knowledge and training that a pharmacist has without regard to the number of years in practice. Pharmacists who are appointed to this position are those who are motivated and dedicated to protecting patient safety while upholding the statutes and rules under which they practice. Careful consideration is made prior to appointing a PIC and we believe each institution should have the right to determine if a pharmacist can perform as their PIC. Many pharmacies proactively train their pharmacy residents and long-time technicians to be ready for management position upon graduation. Therefore, we request that the Board delete this provision in the proposed rule. If that is not acceptable, we would suggest amending to require one year of experience.

Additionally, we would also suggest extending the date for the application for a permit designation a new PIC and associated fee to be filled within 28 days instead of 14. This additional time will be useful in allowing the pharmacy to properly identify a new PIC.

18VAC110-20-112 Pharmacy Technicians Ratios: We believe that the pharmacist should determine the number of individuals he/she can safely supervise. This should be dependent on a multitude of factors including whether there are drugs being dispensed or if there is centralized support. A ratio of 4:1 assumes a typical or traditional dispensing model. There are now other models of pharmacy where the 4:1 ratio limits the quality of care that can be provided.

The current national trend is to eliminate this technician ratio. There are now 20 states plus the District of Columbia that have eliminated or do not have a technician ratio. Likewise, nearby states such as Delaware, Pennsylvania, and Rhode Island do not have ratios and there have been no viable quality issues that have arisen. We believe that the concept of a pharmacist to technician ratio is antiquated and no longer appropriate in today's pharmacy practice environment. Additionally, there is no other health professional that has limited the assistance they can utilize by the states professional governing body. Therefore, we would ask for pharmacists to be treated in the same manner as other healthcare professionals who are allowed to make appropriate decisions regarding how many individuals they can safely supervise.

We believe that setting arbitrary technician ratios prevent pharmacies from maximizing use of pharmacy technicians to provide a broader set of patient care services to the public. Many state boards of pharmacy - recognizing this to be true - have over the years relaxed or eliminated restrictive ratios to allow for optimal use of pharmacy technicians. Notably, the National Association of Boards of Pharmacy (NABP) believes that the pharmacist to technician ratio should be eliminated entirely.

Given the growing demand for pharmacist-provided patient care services in community pharmacies, there is a corresponding need to deploy pharmacy technicians for administrative and non-judgmental duties. Furthermore, elimination of technician to pharmacist ratios will enable pharmacists to focus more on counseling patients, performing MTM, providing disease management programs, engaging in other important patient care services, and collaborating with other health care professionals, thus integrating more fully in a patient's care. These services also help patients better adhere to their medication regimens and ultimately serve to improve patients' health and wellness and reduce our nation's health care costs.

18VAC110-20-360: Issuing a Copy of a Prescription That Can be Filled or Refilled: With respect to prescription transfers, NACDS supports policies that utilize an enhanced technician role to improve access to patient care services. By allowing pharmacy technicians to be involved in the prescription transfer process, Virginia will join other states that permit this activity for certified technicians. We believe that requiring a pharmacist to be involved in the transfer of prescriptions is unnecessary. The transfer of prescriptions is a non-judgmental task. Requiring pharmacists to be involved in the prescription transfer process creates distractions and increases the number of interruptions that interfere or prohibit pharmacists from performing their clinical duties. Every interruption or distraction increases the potential for a

prescription error. Allowing technicians and interns to alleviate some of these distractions may prevent errors and provide the pharmacist additional time to perform patient care services.

In addition, it is important to note that the National Association of Boards of Pharmacy (NABP) Model Act recommends certified technicians to transfer prescriptions (with no requirement for a pharmacist to be involved)[1]. Furthermore, intern-to-intern and technician-to-technician transfers has been demonstrated in other states and some for many years with no widespread concerns from these boards that patient safety was at risk. To that end, we would recommend allowing the pharmacist on duty the ability to delegate this task to appropriately trained/qualified individuals and therefore propose the following recommendation:

18VAC110-20-360(B)(1)(b) &(c)

b. Records on the reverse of the invalidated prescription the name, address, and, except for a prescription for a Schedule VI drug, the DEA number of the pharmacy to which it was transferred, and, for an oral transfer, the name of the ~~pharmacist~~ registrant receiving the prescription information;

c. Records the date of the transfer and, in the case of an oral transfer, the name of the ~~pharmacist~~ registrant transferring the information; and

18VAC110-20-360(B(2)(b)(6)

(6) Name of transferring pharmacist, pharmacy intern, or pharmacy technician if transferred orally.

NACDS strongly believes appropriately trained pharmacy technicians will be a vital resource to pharmacists as they strive to meet greater patient needs. In general, state laws and regulations do not delineate specific tasks pharmacy technicians may perform. Instead, they identify limitations for the duties performed by pharmacy technicians and allow pharmacists to determine what duties may be performed by technicians within those limitations. Current statistics reveal that pharmacists across practice settings are spending nearly 30% of their workday performing technician level duties.[2] NACDS strongly supports pharmacists practicing at the top of their license and correspondingly within their clinical ability, which in turn leads to optimal patient care and improved health outcomes.

In addition to the comments above, we also offer additional suggested changes to the proposed rules which can be found in amendment form in the attached document.

We appreciate the Board's consideration of our view and look forward continuing to work with you.

Sincerely,

Jill McCormack, Director

State Government Affairs

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Follow us on Twitter at www.twitter.com/NACDS and www.twitter.com/NACDSmeetings.

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[1] Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy Article I Title, Purpose, and Definitions. Section 105. Definitions.

(r) "Certified Pharmacy Technician" means personnel registered with the Board who have completed a certification program approved by the Board and may, under the supervision of a Pharmacist, perform certain activities involved in the Practice of Pharmacy, such as receiving new Prescription Drug Orders; prescription transfer; and Compounding but excluding Drug Regimen Review; clinical conflict resolution; prescriber contact concerning Prescription Drug Order clarification or therapy modification; Patient Counseling; and Dispensing process validation.

(ddddd) "Pharmacy Technician" means personnel registered with the Board who may, under the supervision of the pharmacist, assist in the pharmacy and perform such functions as assisting in the Dispensing process; processing of medical coverage claims; stocking of medications; cashiering but excluding Drug Regimen Review; clinical conflict resolution; prescriber contact concerning Prescription Drug Order clarification or therapy modification; Patient Counseling; Dispensing process validation; prescription transfer; and receipt of new Prescription Drug Orders.

[2] Midwest Pharmacy Workforce Research Consortium, *2014 National Pharmacist Workforce Survey*, pg. 62, April 8, 2015.

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Caroline D. Juran
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2 attachments

VA- 18VAC 110 Proposed Rules NACDS Comments 02-2019 final.docx
136K

VA- Proposed Rule -18 VAC110 NACDS Track Change Comments 02-2019.docx
299K

CHAPTER 15

REGULATIONS FOR DELEGATION TO AN AGENCY SUBORDINATE

18VAC110-15-10. Criteria for delegation of informal fact-finding proceeding to an agency subordinate.

A. Decision to delegate. In accordance with subdivision 10 of § 54.1-2400 of the Code of Virginia, the board may delegate an informal fact-finding proceeding to an agency subordinate upon determination that probable cause exists that a practitioner or an entity may be subject to a disciplinary action.

B. Criteria for delegation. Cases that may not be delegated to an agency subordinate, except as may be approved by a committee of the board, include those that involve:

1. Intentional or negligent conduct that causes or is likely to cause injury to a patient;

2. Drug diversion;

3. Impairment with an inability to practice with skill and safety;

4. Indiscriminate dispensing; and

5. Medication error in administration or dispensing.

C. Criteria for an agency subordinate.

1. An agency subordinate authorized by the board to conduct an informal fact-finding proceeding may include board members and professional staff or other persons deemed knowledgeable by virtue of their training and experience in administrative proceedings involving the regulation and discipline of health professionals.

2. The executive director shall maintain a list of appropriately qualified persons to whom an informal fact-finding proceeding may be delegated.

3. The board may delegate to the executive director the selection of the agency subordinate who is deemed appropriately qualified to conduct a proceeding based on the qualifications of the subordinate and the type of case being heard.

Part I

General Provisions

18VAC110-20-10. Definitions.

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

~~"ACPE" means the Accreditation Council for Pharmacy Education.~~

"Acquisition" of an existing entity permitted, registered, or licensed by the board means (i) the purchase or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor or change in partnership composition; (iii) the acquiring of 50% or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; or (iv) the merger of a corporation owning the entity, or of the parent corporation of a wholly owned subsidiary owning the entity, with another business or corporation.

"Actively reports" means reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error.

"Alternate delivery site" means a location authorized in 18VAC110-20-275 to receive dispensed prescriptions on behalf of and for further delivery or administration to a patient.

"Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.

"Authorized collector" means a narcotic treatment program, hospital, or clinic with an on-site pharmacy, or pharmacy that is authorized by the U.S. Drug Enforcement Administration to receive drugs ~~from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility~~ for the purpose of destruction.

"Beyond-use date" means the date beyond which the integrity of a compounded, repackaged, or dispensed drug can no longer be assured and as such is deemed to be adulterated or misbranded as defined in §§ 54.1-3461 and 54.1-3462 of the Code of Virginia.

"Board" means the Virginia Board of Pharmacy.

~~"CE" means continuing education as required for renewal of licensure by the Board of Pharmacy.~~

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

"Chart order" means a lawful order for a drug or device entered on the chart or in a medical record of a patient by a prescriber or ~~his~~the prescriber's designated agent.

"Compliance packaging" means packaging for dispensed drugs that is comprised of a series of containers for solid oral dosage forms and designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

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

"Correctional facility" means any prison, penitentiary, penal facility, jail, detention unit, or other facility in which persons are incarcerated by government officials.

"DEA" means the U.S. Drug Enforcement Administration.

"Dispensing error" means one or more of the following discovered after the final verification by the pharmacist, regardless of whether the patient received the drug:

1. Variation from the prescriber's prescription drug order, including ~~but not limited to~~:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form;

d. Incorrect patient; or

e. Inadequate or incorrect packaging, labeling, or directions.

2. Failure to exercise professional judgment in identifying and managing:

a. Known therapeutic duplication;

b. Known drug-disease contraindications;

c. Known drug-drug interactions;

d. Incorrect drug dosage or duration of drug treatment;

e. Known drug-allergy interactions;

f. A clinically significant, avoidable delay in therapy; or

g. Any other significant, actual, or potential problem with a patient's drug therapy.

3. Delivery of a drug to the incorrect patient.

4. Variation in bulk repackaging or filling of automated devices, including ~~but not limited to~~:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form; or

d. Inadequate or incorrect packaging or labeling.

"Drug donation site" means a permitted pharmacy that specifically registers with the board for the purpose of receiving or redispensing eligible donated prescription drugs pursuant to § 54.1-3411.1 of the Code of Virginia.

"Electronic prescription" means a written prescription that is generated on an electronic application and is transmitted to a pharmacy as an electronic data file; Schedules II through V prescriptions shall be transmitted in accordance with 21 CFR Part 1300 ~~and is transmitted to a pharmacy as an electronic data file~~.

"EMS" means emergency medical services.

"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

~~"Facsimile (FAX)~~"Faxed prescription" means a written prescription or order ~~which~~that is transmitted by an electronic device over telephone lines ~~which sends~~that send the exact image to the receiver (pharmacy) in a hard copy form ***or electronic image***.

Commented [NACDS1]: We would recommend the allowance of faxed prescriptions to be received by the pharmacy as an image n addition to hardcopy. Many pharmacy systems now receive faxes electronically.

"FDA" means the U.S. Food and Drug Administration.

"Floor stock" means a supply of drugs that have been distributed for the purpose of general administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

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

"Forgery" means a prescription that was falsely created, falsely signed, or altered.

~~"FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign Pharmacy Equivalency Examination and a credential review of foreign training to establish educational equivalency to board-approved schools of pharmacy, and has passed approved examinations establishing proficiency in English.~~

"Generic drug name" means the nonproprietary name listed in the United States Pharmacopeia-National Formulary (USP-NF) or in the United States Adopted Names (USAN) and the USP Dictionary of Drug Names.

"Hospital" or "nursing home" means those facilities as defined in Title 32.1 of the Code of Virginia or as defined in regulations by the Virginia Department of Health.

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

"Initials" means the first letters of a person's name or other unique personal identifier.

"Long-term care facility" means a nursing home, retirement care, mental care, or other facility or institution that provides extended health care to resident patients.

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

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

"On duty" means that a pharmacist is on the premises at the address of the permitted pharmacy and is available as needed.

"On-hold prescription" means a valid prescription that is received and maintained at the pharmacy for initial dispensing on a future date.

"Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 ~~(Pub. L.~~(P.L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality.

"Permitted physician" means a physician who is licensed pursuant to § 54.1-3304 of the Code of Virginia to dispense drugs to persons to whom or for whom pharmacy services are not reasonably available.

"Perpetual inventory" means an ongoing system for recording quantities of drugs received, dispensed, or otherwise distributed by a pharmacy.

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

Commented [NACDS2]: We suggest deleting the definition of "Personal Supervision." Virginia statute 54.1-3432 references personal supervision but does not give a specific definition. Virginia rules reference personal supervision for extemporaneous compounding in 18VAC110-20-112(B). Implementation of new audio-visual technology methods allow for a safe way for pharmacists to supervising compounding in community pharmacies. This definition, which is not statutorily required to be defined, prevents any new community pharmacy models of compounding practice from emerging.

"Pharmacy closing" means that the permitted pharmacy ceases pharmacy services or fails to provide for continuity of pharmacy services or lawful access to patient prescription records or other required patient records for the purpose of continued pharmacy services to patients.

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

"PIC" means the pharmacist-in-charge of a permitted pharmacy.

"Practice location" means any location in which a prescriber evaluates or treats a patient.

"Prescription department" means any contiguous or noncontiguous areas used for the compounding, dispensing, and storage of all ~~Schedule~~Schedules II through VI drugs and devices and any Schedule I investigational ~~drugs~~drug.

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

"Quality assurance plan" means a plan approved by the board for ongoing monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy function or system.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, ~~-~~but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Repackaged drug" means any drug removed from the manufacturer's original package and placed in different packaging.

"Robotic pharmacy system" means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, compounding, labeling, dispensing, or distribution of medications, ~~-~~and collects, controls, and maintains all transaction information.

"Safety closure container" means a container that meets the requirements of the federal Poison Prevention Packaging Act of 1970 (15 USC §§ 1471-1476), that is, in testing such containers, that 85% of a test group of 200 children of ages 41-52 months are unable to open the container in a five-minute period and that 80% fail in another five minutes after a demonstration of how to open it and that 90% of a test group of 100 adults must be able to open and close the container.

"Satellite pharmacy" means a pharmacy that is noncontiguous to the centrally permitted pharmacy of a hospital but at the location designated on the pharmacy permit.

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

"Special use permit" means a permit issued to conduct a pharmacy of a special scope of service that varies in any way from the provisions of any board regulation.

"Storage temperature" means those specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles shall be stored, where it is considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms:

1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is maintained thermostatically between -20° and -10°C (-4° and 14°F).

2. "Room temperature" means the temperature prevailing in a working area.

3. "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.

4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).

5. "Excessive heat" means any temperature above 40°C (104°F).

6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency,-or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.

7. "Cool" means any temperature between 8° and 15°C (46° and 59°F).

"Terminally ill" means a patient with a terminal condition as defined in § 54.1-2982 of the Code of Virginia.

"Ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household.

"Unit dose container" means a container that is a single-unit container, as defined in United States Pharmacopeia-National Formulary, for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

"Unit dose package" means a container that contains a particular dose ordered for a patient.

"Unit dose system" means a system in which multiple drugs in unit dose packaging are dispensed in a single container, such as a medication drawer or bin, labeled only with patient name and location. Directions for administration are not provided by the pharmacy on the drug packaging or container but are obtained by the person administering directly from a prescriber's order or medication administration record.

"USP-NF" means the United States Pharmacopeia-National Formulary.

"Well-closed container" means a container that protects the contents from extraneous solids and from loss of the drug under the ordinary or customary conditions of handling, shipment, storage, and distribution.

18VAC110-20-15. ~~Criteria for delegation of informal fact-finding proceedings to an agency subordinate.~~(Repealed.)

~~A. Decision to delegate. In accordance with § 54.1-2400 (10) of the Code of Virginia, the board may delegate an informal fact-finding proceeding to an agency subordinate upon determination that probable cause exists that a practitioner may be subject to a disciplinary action.~~

~~B. Criteria for delegation. Cases that may not be delegated to an agency subordinate, except as may be approved by a committee of the board, include those that involve:~~

~~1. Intentional or negligent conduct that causes or is likely to cause injury to a patient;~~

~~2. Drug diversion;~~

~~3. Impairment with an inability to practice with skill and safety;~~

~~4. Indiscriminate dispensing; and~~

~~5. Medication error in administration or dispensing.~~

~~C. Criteria for an agency subordinate.~~

~~1. An agency subordinate authorized by the board to conduct an informal fact-finding proceeding may include board members and professional staff or other persons deemed knowledgeable by virtue of their training and experience in administrative proceedings involving the regulation and discipline of health professionals.~~

~~2. The executive director shall maintain a list of appropriately qualified persons to whom an informal fact-finding proceeding may be delegated.~~

~~3. The board may delegate to the executive director the selection of the agency subordinate who is deemed appropriately qualified to conduct a proceeding based on the qualifications of the subordinate and the type of case being heard.~~

18VAC110-20-20. Fees.

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

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

C.B. Initial application fees.

~~1. Pharmacist license~~	~~$180~~
~~2. Pharmacy intern registration~~	~~$15~~
~~3. Pharmacy technician registration~~	~~$25~~
~~4.~~1. Pharmacy permit	$270
~~5.~~2. Permitted physician licensed to dispense drugs	$270
~~6.~~3. Medical equipment supplier permit	$180
~~7. Humane society permit~~	~~$20~~
~~8.~~4. Outsourcing facility permit	$270
~~9.~~5. Nonresident pharmacy registration	$270
~~10.~~6. Nonresident outsourcing facility registration	$270
~~11.~~7. Controlled substances registrations	$90

~~12.~~8. Innovative program approval.	$250
If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee.	
~~13. Approval of a pharmacy technician training program~~	~~$150~~
~~14. Approval of a continuing education program~~	~~$100~~
~~15.~~9. Approval of a repackaging training program	$50

D. C. Annual renewal fees.

~~1. Pharmacist active license - due no later than December 31~~	~~$90~~
~~2. Pharmacist inactive license - due no later than December 31~~	~~$45~~
~~3. Pharmacy technician registration - due no later than December 31~~	~~$25~~
~~4.~~1. Pharmacy permit - due no later than April 30	$270
~~5.~~2. Physician permit to practice pharmacy - due no later than February 28	$270
~~6.~~3. Medical equipment supplier permit - due no later than February 28	$180
~~7. Humane society permit - due no later than February 28~~	~~$20~~
~~8.~~4. Outsourcing facility permit - due no later than April 30	$270
~~9.~~5. Nonresident pharmacy registration - due no later than the date of initial registration	$270
~~10.~~6. Nonresident outsourcing facility registration - due no later than the date of initial registration	$270
~~11.~~7. Controlled substances registrations - due no later than February 28	$90
~~12.~~8. Innovative program continued approval based on board order not to exceed $200 per approval period.	
~~13. Approval of a pharmacy technician training program~~	~~$75 every two~~ years
~~14. Approval of a repackaging~~9. Repackaging training program	$30 every two years

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

~~1. Pharmacist license~~	~~$30~~
~~2. Pharmacist inactive license~~	~~$15~~
~~3. Pharmacy technician registration~~	~~$10~~
~~4.~~1. Pharmacy permit	$90
~~5.~~2. Physician permit to practice pharmacy	$90
~~6.~~3. Medical equipment supplier permit	$60
~~7. Humane society permit~~	~~$5~~
~~8.~~4. Outsourcing facility permit	$90
~~9.~~5. Nonresident pharmacy registration	$90
~~10.~~6. Nonresident outsourcing facility registration	$90
~~11.~~7. Controlled substances registrations	$30

~~12. Approval of a pharmacy technician training program~~	~~$15~~
~~13. Approval of a repackaging~~8. Repackaging training program	$10

F. E. Reinstatement fees.

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

~~1. Pharmacist license~~	~~$210~~
~~2. Pharmacist license after revocation or suspension~~	~~$500~~
~~3. Pharmacy technician registration~~	~~$35~~
~~4. Pharmacy technician registration after revocation or suspension~~	~~$125~~

~~5.~~2. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:

a. Pharmacy permit	$240
b. Physician permit to practice pharmacy	$240
c. Medical equipment supplier permit	$210
~~d. Humane society permit~~	~~$30~~
~~e.~~d. Outsourcing facility permit	$240
~~f.~~e. Nonresident pharmacy registration	$115
~~g.~~f. Nonresident outsourcing facility registration	$240
~~h.~~g. Controlled substances registration	$180
~~i. Approval of a pharmacy technician training program~~	~~$75~~
~~j. Approval of a repackaging~~h. Repackaging training program	$50

~~G.~~F. Application for change or inspection fees for facilities or other entities.

1. Change of pharmacist-in-charge	$50
2. Change of ownership for any facility	$50
3. Inspection for remodeling or change of location for any facility	$150
4. Reinspection of any facility	$150
5. Board-required inspection for a robotic pharmacy system	$150
6. Board-required inspection of an innovative program location	$150
7. Change of pharmacist responsible for an approved innovative program	$25

~~H.~~G. Miscellaneous fees.

~~1. Duplicate wall certificate~~	~~$25~~
~~2.~~1. Returned check	$35
~~3.~~2. Duplicate ~~license~~permit or registration	$10

~~4.~~3. Verification of ~~licensure~~permit or registration $25

18VAC110-20-21. ~~Public address.~~(Repealed.)

~~An individual licensed by or registered with the board who has provided the board with a public address that is different from the address of record shall notify the board in writing if there is a change in the address.~~

18VAC110-20-25. Unprofessional conduct.

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

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

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

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

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

~~5. Engaging or attempting to engage in a relationship with a patient that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a patient or his family, including but not limited to sexual misconduct with a patient or a member of his family or other conduct that results or could result in personal gain at the expense of the patient;~~

~~6.~~4. Failing to maintain adequate safeguards against diversion of controlled substances;

~~7.~~5. Failing to appropriately respond to a known dispensing error in a manner that protects the health and safety of the patient;

~~8.~~6. Delegating a task within the practice of pharmacy to a person who is not adequately trained to perform such a task;

~~9.~~7. Failing by the PIC to ensure that pharmacy interns and pharmacy technicians working in the pharmacy are registered and that such registration is current; ~~or~~

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

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

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

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

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

12. ~~Having a restriction of a license, permit, or registration to practice in another jurisdiction in the United States.~~

~~Part II~~

~~Licensure Requirements for Pharmacists~~ (Repealed).

Commented [NACDS3]: We recommend deleting this language. This rule addition would contribute to the ongoing trend of Boards of Pharmacy piling on piggyback discipline for chain pharmacies that have deficiencies in other states. There is no added patient safety benefit to these practices.

18VAC110-20-30. ~~Requirements for pharmacy practical experience.~~ (Repealed.)

~~A. Each applicant for licensure as a pharmacist shall have gained practical experience in the practice of pharmacy as set forth in this section and 18VAC110-20-40.~~

~~B. An applicant for licensure as a pharmacist shall attain a minimum of 1,500 hours of practical experience.~~

~~C. Practical experience that is gained within an ACPE-accredited school of pharmacy, that conforms to the current ACPE standards, and that allows the student to gain at least 1,500 hours of practical experience, shall meet the board's practical experience requirements for licensure as a pharmacist.~~

~~D. All practical experience credit gained outside of an ACPE-accredited school of pharmacy program shall only be gained after successful completion of the equivalent of at least two semesters in an ACPE-accredited school of pharmacy. Credit shall not be given for more than 50 hours in one week and not less than an average of 20 hours per week averaged over a month. The board may grant an exception to the minimum number of hours for good cause shown.~~

~~E. In accordance with § 54.1-3312 of the Code of Virginia, all practical experience required by this section shall be gained within the United States.~~

18VAC110-20-40. ~~Procedure for gaining practical experience.~~ (Repealed.)

~~A. Each person desiring to gain practical pharmacy experience in Virginia shall first register with the board as a pharmacy intern on a form provided by the board prior to becoming so engaged as a pharmacy intern. This requirement shall apply to any person gaining practical experience within the Commonwealth whether for licensure in Virginia or in another state.~~

~~B. In order to be eligible to register as a pharmacy intern, an applicant shall meet at least one of the following criteria:~~

~~1. The applicant shall be enrolled in and have started course work in a professional degree program of a board-approved school of pharmacy. Such registration is only valid while the student is enrolled in the school of pharmacy and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist. An expiration date shall be assigned to the registration to cover the estimated time period for the student to complete the school program and pass the required examinations. If the student is no longer enrolled in the school program, takes a voluntary break from the program, or is otherwise not actively participating in the school program, except for regularly scheduled school breaks, the registration is no longer valid and shall be returned to the board immediately;~~

~~2. The applicant is a graduate of a board-approved school of pharmacy or a graduate of a foreign school of pharmacy, has established educational equivalency and proficiency in English by obtaining the FPGEC certificate, and desires to gain required practical experience required for licensure as a pharmacist. Such applicant shall provide documentation on a board-approved form of current employment or an employment start date within 90 days in a pharmacy in Virginia with approval by the supervising pharmacist. An expiration date shall be assigned to cover the estimated time period needed to obtain the required practical experience hours and take the required examinations to become licensed as a pharmacist;~~

~~3. The applicant has already gained the required practical experience, but is an otherwise qualified applicant awaiting examination for licensure. A three-month expiration date shall be assigned to allow the applicant time to take required examinations; or~~

~~4. The applicant is an applicant for reactivation or reinstatement of a previously issued pharmacist license and is meeting board requirements for relicensure. An expiration date shall be assigned to reasonably cover the period of time necessary to meet the board requirements.~~

~~C. For documented, good cause shown, the executive director of the board may extend the expiration date of the intern registration upon submission of an application form approved by the board and payment of the initial application fee.~~

D. A pharmacy intern shall be supervised by a pharmacist who holds a current, unrestricted license and assumes full responsibility for the training, supervision and conduct of the intern.

E. The intern registration of a pharmacy student shall be valid only while the student is enrolled in a school of pharmacy. The registration card issued by the board shall be returned to the board upon failure to be enrolled.

F. Practical experience gained within any other state must be registered with and certified by the board of that state in order to be accepted or certified by this board. In the event that a state relies on the pharmacy school to certify the hours of experience, an affidavit from the pharmacy school certifying the hours of experience gained in the United States may be accepted in lieu of board certification.

G. All practical experience of the pharmacy intern shall be evidenced by an affidavit approved by the board, which shall be filed prior to or with the application for examination for licensure.

H. An applicant for licensure by endorsement may provide verification acceptable to the board of practical experience hours worked as a pharmacist in another state within the United States in lieu of prelicensure intern hours in order to meet the practical experience requirement.

I. A pharmacy intern shall notify the board in writing of any change in address of record within 14 days of such change.

18VAC110-20-50. Curriculum and approved schools of pharmacy.(Repealed.)

A. The following minimum educational requirements for the specified periods shall be recognized by the board for the purpose of licensure.

1. On and after June 1, 1936, but before June 1, 1964, the applicant for licensure shall have been graduated from a four-year course of study with a Bachelor of Science degree in pharmacy awarded.

2. On and after June 1, 1964, the applicant for licensure shall have been graduated from at least a five-year course of study with a Bachelor of Science degree in pharmacy or a Doctorate of Pharmacy degree awarded.

B. In order to be licensed as a pharmacist within this Commonwealth, the applicant shall have been granted the first professional degree from a program of a school of pharmacy which meets the requirements of § 54.1-3312 of the Code of Virginia.

18VAC110-20-60. Content of the examination and grades required; limitation on admittance to examination.(Repealed.)

A. Prior to admission to any examination required for licensure, the applicant shall have met all other requirements to include education and practical experience requirements, but in no case shall the applicant be admitted if grounds exist to deny licensure under § 54.1-3316 of the Code of Virginia.

B. The applicant shall achieve a passing score as determined by the board on the licensure examination which is approved by the board and which shall consist of an integrated examination of pharmacy practice, pharmacology, pharmacy mathematics, and such other subjects as are necessary to assure that the candidate possesses the necessary knowledge and skills to practice pharmacy.

C. When an applicant for licensure by examination fails to meet the passing requirements of the board-approved integrated pharmacy examination on three occasions, he shall not be readmitted to the examination until he has completed an additional 1,000 hours of practical experience as a pharmacy intern as set forth in 18VAC110-20-40.

D. The applicant shall also achieve a passing score as determined by the board on an examination that tests the candidate's knowledge of federal and state laws related to pharmacy practice.

E. When an applicant fails to pass the law examination, he shall not be allowed to retake it for a period of 30 days.

F. If an applicant requests a testing accommodation for either examination based on a physical or mental impairment that substantially limits one or more major life activities, subject to the Americans with Disabilities

Act, the board may approve a reasonable accommodation that does not compromise the security or integrity of the examination.

1.Supporting documentation shall be provided by the applicant to include the following to be considered for review:

a.A letter of request from the candidate that specifies the testing accommodation requested;

b. A written report of an evaluation (educational, psychological, or physical) within the preceding two years from a qualified professional that states a diagnosis of the disability, describes the disability, recommends specific accommodations, and provides justification that the accommodation is appropriate and necessary for the diagnosed disability. If the comprehensive evaluation was done more than two years ago and the condition is one that is not subject to change, the original evaluation report may be submitted along with a current letter from the qualified professional stating that there has been no change in the condition since the time of the evaluation; and

c.A written statement from the appropriate person at the applicant's school of pharmacy that describes any testing accommodations made while the student was enrolled, if applicable.

2.The applicant will be notified in writing of the decision. If the request for accommodation is granted, the approval information will be forwarded to the examination contractor and the form of the accommodation will be coordinated with the contractor.

18VAC110-20-70. Requirements for foreign-trained applicants.(Repealed.)

A.Applicants for licensure who were trained in foreign schools of pharmacy shall obtain the FPGEC certificate prior to being allowed to register as a pharmacy intern and gain required practical experience in Virginia.

B. After obtaining the FPGEC certificate, the applicant may apply for a pharmacy intern registration and shall fulfill the requirements for practical experience set forth in 18VAC110-20-30 and 18VAC110-20-40 before being admitted to examinations required by 18VAC110-20-60.

C.Applicants for licensure who were trained in foreign schools of pharmacy shall also complete and achieve passing scores on the examinations set forth in 18VAC110-20-60 before being licensed as a pharmacist.

18VAC110-20-75. Registration for voluntary practice by out-of-state licensees.(Repealed.)

Any pharmacist who seeks registration to practice on a voluntary basis pursuant to subdivision 12 of § 54.1-3301 of the Code of Virginia under the auspices of a publicly supported, all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people shall:

1.File a complete application for registration on a form provided by the board at least five business days prior to engaging in such practice;

2.Provide a complete list of each state in which he has held a pharmacist license and a copy of any current license;

3.Provide the name of the nonprofit organization and the dates and location of the voluntary provision of services;

4.Pay a registration fee of $10; and

5.Provide a notarized statement from a representative of the nonprofit organization attesting to its compliance with the provisions of subdivision 12 of § 54.1-3301 of the Code of Virginia.

18VAC110-20-80. Renewal and reinstatement of license.(Repealed.)

A.Pharmacist licenses expire on December 31 and shall be renewed annually prior to that date by the submission of a renewal fee, renewal form, and statement of compliance with continuing education requirements.

~~B. A pharmacist newly licensed on or after October 1 shall not be required to renew that license until December 31 of the following year.~~

~~C. A pharmacist who fails to renew his license by the expiration date may renew his license at any time within one year of its expiration by submission of the renewal fee and late fee, renewal form, and statement of compliance with continuing education requirements.~~

~~D. A pharmacist who fails to renew his license for more than one year following expiration and who wishes to reinstate such license shall submit an application for reinstatement, pay the current renewal fee and a reinstatement fee, and submit documentation showing compliance with continuing education requirements. Reinstatement is at the discretion of the board and may be granted by the executive director of the board provided no grounds exist to deny said reinstatement.~~

~~E. A pharmacist who has been registered as inactive for more than one year must apply for reinstatement, submit documentation showing compliance with continuing education requirements, and pay the current year active renewal fee in order to resume active licensure.~~

~~F. In order to reactivate or reinstate a license to active status, a pharmacist who holds an inactive license, who has allowed his license to lapse, or who has had his license suspended or revoked must submit evidence of completion of CEU's or hours equal to the requirements for the number of years in which his license has not been active, not to exceed a total of 60 hours of CE.~~

~~G. A pharmacist whose license has been lapsed, in inactive status, or suspended or revoked for more than five years shall, as a condition of reinstatement in addition to 60 hours CE, take and receive a passing score on the board-approved law examination and furnish acceptable documentation of one of the following:~~

~~1. Active pharmacy practice within the past five years as a properly licensed pharmacist in another state; or~~

~~2. Practical experience as a pharmacy intern registered with the board of at least 160 hours within six months immediately prior to being reinstated.~~

~~H. The practice of pharmacy without a current, active pharmacist license is unlawful and shall constitute grounds for disciplinary action by the board.~~

~~I. It shall be the duty and responsibility of each licensee to inform the board of his current address. A licensee shall notify the board within 14 days in writing or electronically of any change of an address of record. Properly updating address of record directly through the board's web-based application or other approved means shall constitute lawful notification. All notices required by law or by these rules and regulations are deemed to be legally given when mailed to the address of record and shall not relieve the licensee of the obligation to comply.~~

18VAC110-20-90. ~~Requirements for continuing education.~~ (Repealed.)

~~A. A pharmacist shall be required to have completed a minimum of 1.5 CEUs or 15 contact hours of continuing pharmacy education in an approved program for each annual renewal of licensure. CEUs or hours in excess of the number required for renewal may not be transferred or credited to another year.~~

~~B. A pharmacy education program approved for continuing pharmacy education is:~~

~~1. One that is approved by the Accreditation Council for Pharmacy Education (ACPE);~~

~~2. One that is approved as a Category I Continuing Medical Education (CME) course, the primary focus of which is pharmacy, pharmacology, or drug therapy; or~~

~~3. One that is approved by the board in accordance with the provisions of 18VAC110-20-100.~~

~~C. The board may grant an extension pursuant to § 54.1-3314.1 E of the Code of Virginia. Any subsequent extension shall be granted only for good cause shown.~~

~~D. Up to two hours of the 15 hours required for annual renewal may be satisfied through delivery of pharmacy services as a pharmacist, without compensation, to low-income individuals receiving health services through a~~

~~local health department or a free clinic organized in whole or primarily for the delivery of those services. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic.~~

~~E.Pharmacists are required to attest to compliance with CE requirements in a manner approved by the board at the time of their annual license renewal. Following each renewal period, the board may conduct an audit of the immediate past two years' CE documents to verify compliance with requirements. Pharmacists are required to maintain, for two years following renewal, the original certificates documenting successful completion of CE, showing date and title of the CE program or activity, the number of CEUs or contact hours awarded, and a certifying signature or other certification of the approved provider. Pharmacists selected for audit must provide these original documents to the board by the deadline date specified by the board in the audit notice.~~

18VAC110-20-100. ~~Approval of continuing education programs.~~(Repealed.)

~~A.The board will approve without application or further review any program offered by an ACPE-approved provider and will accept for credit certificates bearing the official ACPE logo and program number.~~

~~B. The board may approve an individual CE program under the following provisions:~~

~~1.An approved individual program is a course, activity, or lecture which includes subject matter related to the competency of the practice of pharmacy and which has been approved for CE credit by the board.~~

~~2.In order to receive approval for an individual program, the sponsor or provider must apply prior to the program offering on a form provided by the board. The information which must be provided shall include but not be limited to: name of provider, location, date and time of program, charges to participants, description of program content and objectives, credentials of speaker or author, method of delivery, evaluation procedure, evidence of a post assessment, credits requested, mechanism for recordkeeping, and any such information as the board deems necessary to assure quality and compliance.~~

~~3.The sponsor applying for board approval of an individual program must pay a fee as required in 18VAC110-20-20 C 12.~~

~~4.The board shall notify the provider or sponsor within 60 days following the receipt of a completed application of approval or disapproval of a program and the number of credits which may be awarded. The board shall also assign an expiration date for approval of the program not to exceed two years from the date of approval.~~

~~5.The provider of an approved program shall provide to each participant who completes the required hours and passes the post-test a certification with the name of the provider, name of the participant, description of course and method of delivery, number of hours credited, date of completion, and program identification number.~~

~~6.The provider of an approved program shall maintain all records on that program, its participants, and hours awarded for a period of five years and shall make those records available to the board upon request.~~

~~7.The board shall periodically review and monitor programs. The provider of a CE program shall waive registration fees for a representative of the board for that purpose.~~

~~8.Any changes in the information previously provided about an approved program or provider must be submitted or the board may withdraw its approval. If a provider wants to give a live program more than once, all program dates must either be submitted on the original application or provided to the board in subsequent correspondence at least five days prior to giving the program.~~

~~Part III~~

~~Requirements for Pharmacy Technician Registration~~ (Repealed)

18VAC110-20-101. ~~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. In order to be registered as a pharmacy technician, an applicant shall provide evidence of the following:~~

~~1.Satisfactory completion of an 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.~~

~~D. A pharmacy technician trainee may perform tasks restricted to pharmacy technicians for no more than nine months without becoming registered as a pharmacy technician.~~

18VAC110-20-102. ~~Criteria for approval for training programs.~~(Repealed.)

~~A.Any person wishing to apply for approval of a pharmacy technician training program shall submit the application fee 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 his 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 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 director, instructors, name of institution or business if applicable, address, program content, length of program, or location of records.~~

~~H.A pharmacy technician training program approval expires after two years, after which the program may apply for renewal. For continued approval, the program shall submit the renewal application, renewal fee, and a self-~~

evaluation report on a form provided by the board at the time of renewal notification. Renewal of a program's approval is at the discretion of the board, and the decision to renew shall be based on documentation of continued compliance with the criteria set forth in this section.

18VAC110-20-103. Examination.(Repealed.)

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

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

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

D. Any requests for testing accommodations under the Americans with Disabilities Act shall be in accordance with the provisions of 18VAC110-20-60 F.

18VAC110-20-104. Address of record; maintenance of certificate.(Repealed.)

A.It shall be the duty and responsibility of each pharmacy technician to inform the board of his current address. A pharmacy technician shall notify the board in writing or electronically of any change of an address of record within 14 days. Properly updating address of record directly through the board's web-based application or other approved means shall constitute lawful notification. All notices required by law or by these rules and regulations are deemed to be legally given when mailed to the address of record and shall not relieve the registrant of the obligation to comply.

B. A pharmacy technician shall maintain his current registration certificate at his principal place of practice available for inspection upon request. A pharmacy technician who does not have a principal place of practice may maintain it at any pharmacy in which he practices or his address of record.

18VAC110-20-105. Renewal and reinstatement of registration.(Repealed.)

A.Pharmacy technician registrations expire on December 31 and shall be renewed annually prior to that date by the submission of a renewal fee and renewal form. A pharmacy technician newly registered on or after July 1 shall not be required to renew that registration until December 31 of the following year. Failure to receive the application for renewal shall not relieve the pharmacy technician of the responsibility for renewing the registration by the expiration date.

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

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

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

18VAC110-20-106. Requirements for continued competency.(Repealed.)

A.A pharmacy technician shall be required to have completed a minimum of 0.5 CEUs or five contact hours of approved continuing education for each annual renewal of registration. Hours in excess of the number required for

~~renewal may not be transferred or credited to another year.~~

~~B. An approved continuing education program shall meet the requirements as set forth in subsection B of 18VAC110-20-90 or subsection B of 18VAC110-20-100.~~

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

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

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

Part ~~IV~~II

Pharmacies

18VAC110-20-110. Pharmacy permits generally.

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.

B. Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day and shall allow at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break.

C. The ~~pharmacist-in-charge (PIC)~~PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

D. A pharmacist shall not be eligible to serve as PIC until after having obtained a minimum of two years of experience practicing as a pharmacist in Virginia or another jurisdiction in the United States. The board may grant an exception to the minimum number of years of experience for good cause shown.

~~D.~~E. When the PIC ceases practice at a pharmacy or no longer wishes to be designated as PIC, he shall immediately return the pharmacy permit to the board indicating the effective date on which he ceased to be the PIC.

~~E.~~F. Although not required by law or regulation, an outgoing PIC shall have the opportunity to take a complete and accurate inventory of all ~~Schedule~~Schedules II through V controlled substances on hand on the date he ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

~~F.~~G. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. Pharmacists-in-charge having knowledge of upcoming absences for longer than 30 days shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC, which exceed 15 days with no known return date within the next 15 days, the owner shall immediately notify the board and shall obtain a new PIC.

~~G.~~H. An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. It shall be unlawful for a pharmacy to operate without a new permit past the 14-day deadline unless the board receives a request for an

extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

~~H.~~I. Only one pharmacy permit shall be issued to conduct a pharmacy occupying the same designated prescription department space. A pharmacy shall not engage in any other activity requiring a license or permit from the board, such as manufacturing or wholesale-distributing, out of the same designated prescription department space.

~~I.~~J. Before any permit is issued, the applicant shall attest to compliance with all federal, state, and local laws and ordinances. A pharmacy permit shall not be issued to any person to operate from a private dwelling or residence after September 2, 2009.

18VAC110-20-112. Supervision of pharmacy technicians.

A. A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time; ~~however, no pharmacist shall supervise more than four persons performing the duties of a pharmacy technician at one time.~~

B. ~~In addition to the acts restricted to a pharmacist in § 54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians.~~

18VAC110-20-140. New pharmacies, acquisitions, and changes to existing pharmacies.

A. Any person wishing to open a new pharmacy, engage in the acquisition of an existing pharmacy, change the location of an existing pharmacy, move the location or make structural changes to an existing prescription department, or make changes to a previously approved security system shall file an application with the board.

B. In the acquisition of an existing pharmacy, if prescription records are to be accessible to anyone for purposes other than for continuity of pharmacy services at substantially the same level offered by the previous owner or for the necessary transfer of prescription records, the owner of the pharmacy acquiring the records shall disclose such information in writing to each patient 14 days prior to the acquisition. Such release of prescription records shall be allowed only to the extent authorized by § 32.1-127.1:03 of the Code of Virginia.

C. Although a closing inventory is not required, a complete and accurate inventory shall be taken of all Schedules II through V controlled substances on hand in accordance with § 54.1-3404 of the Code of Virginia on the date the pharmacist first engages in business under the new ownership. Inventories associated with any change in PIC shall also be performed in accordance with 18VAC110-20-110.

~~C.~~D. The proposed location or structural changes shall be inspected by an authorized agent of the board prior to issuance of a permit.

1. Pharmacy permit applications ~~which~~that indicate a requested inspection date, ~~or~~ requests ~~which~~that are received after the application is filed, ~~shall~~ be honored provided a 14-day notice is allowed prior to the requested inspection date.

2. Requested inspection dates ~~which~~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.

3. At the time of the inspection, the dispensing area shall comply with 18VAC110-20-150, 18VAC110-20-160, 18VAC110-20-170, 18VAC110-20-180, and 18VAC110-20-190.

4. If an applicant substantially fails to meet the requirements for issuance of a 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 18VAC110-20-20 prior to a reinspection being conducted.

~~D.~~E. Drugs shall not be stocked within the proposed pharmacy or moved to a new location until approval is granted by the inspector or board staff.

Commented [NACDS4]: If there is a concern regarding creating potentially unsafe working environments by forcing pharmacists to use more technicians, they feel they can safely manage by their owners, we would recommend utilizing similar language found in Florida rules designed to address this:

"The determination of the appropriate pharmacist-technician supervision ratio shall be made by the Prescription Department Manager or Consultant Pharmacist of Record. No other person, permittee, or licensee shall interfere with the exercise of the Prescription Department Manager or Consultant Pharmacist of Record's independent professional judgment in setting the pharmacist to technician ratio(s)."

Commented [NACDS5]: See comment above regarding personal supervision.

E.F. Once the permit is issued, prescription drugs may not be stocked earlier than two weeks prior to the designated opening date. Once prescription drugs have been placed in the pharmacy, a pharmacist shall be present on a daily basis to ensure the safety and integrity of the drugs. If there is a change in the designated opening date, the pharmacy shall notify the board office, and a pharmacist shall continue to be on site on a daily basis.

G. If the pharmacy is not operational within 90 days from the date the permit is issued, the board shall rescind the pharmacy permit unless an extension is granted for good cause shown.

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

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

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

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

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

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

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

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

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

18VAC110-20-180. Security system.

A. A device for the detection of breaking shall be installed in each prescription department of each pharmacy. The installation and the device shall be based on accepted alarm industry standards, and shall be subject to the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.

2. The device shall have at least one hard-wired communication method, be monitored in accordance with accepted industry standards, maintained in operating order, have an auxiliary source of power, and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational.

3. The device shall fully protect the prescription department and shall be capable of detecting breaking by any means when activated.

4. Access to the alarm system for the prescription department area of the pharmacy shall be restricted to the pharmacists working at the pharmacy, except for access by other persons in accordance with 18VAC110-20-190 B

2, and the system shall be activated whenever the prescription department is closed for business.

5. The alarm system shall include a feature by which any breach in the alarm shall be communicated by the monitoring entity to the PIC or a pharmacist working at the pharmacy.

B. Exceptions to provisions in this section:

1. Alarm systems approved prior to November 4, 1993, will be deemed to meet the requirements of subdivisions A 1, A 2, and A 3 of this section, provided that no structural changes are made in the prescription department, that no changes are made in the security system, that the prescription department is not closed while the rest of the business remains open, and that a breaking and loss of drugs does not occur. If a breaking with a loss of drugs occurs, the pharmacy shall upgrade the alarm to meet the current standards and shall file an application with the board in accordance with 18VAC110-20-140 A within 14 days of the breaking.

2. If the prescription department was located in a business with extended hours prior to November 4, 1993, and had met the special security requirements by having a floor to ceiling enclosure, a separately activated alarm system shall not be required.

3. This section shall not apply to pharmacies ~~which~~that are open and staffed by pharmacists 24 hours a day. If the pharmacy changes its hours or if it must be closed for any reason, the PIC or owner must immediately notify the board, file an application in accordance with 18VAC110-20-140 A, and have installed prior to closing, ~~a~~ security system that meets the requirements of subdivisions A 1 through A 4 of this section.

18VAC110-20-200. Storage of drugs, devices, and controlled paraphernalia; expired drugs.

A. Prescriptions awaiting delivery. Prescriptions prepared for delivery to the patient may be placed in a secured area outside of the prescription department, not accessible to the public, where access to the prescriptions is restricted to individuals designated by the pharmacist. With the permission of the pharmacist, the prepared prescriptions may be transferred to the patient at a time when the pharmacist is not on duty. If a prescription is delivered at a time when the pharmacist is not on duty, written procedures shall be established and followed by the pharmacy ~~which~~that detail security of the dispensed prescriptions and a method of compliance with counseling requirements of § 54.1-3319 of the Code of Virginia. Additionally, a log shall be made and maintained of all prescriptions delivered to a patient when a pharmacist is not present to include the patient's name, prescription ~~number(s)~~number, date of delivery, and ~~the~~ signature of the person receiving the prescription. Such log shall be maintained for a period of one year.

B. Dispersion of Schedule II drugs. Schedule II drugs shall either be dispersed with other schedules of drugs or shall be maintained within a securely locked cabinet, drawer, or safe or maintained in a manner that combines the two methods for storage. The cabinet, drawer, or safe may remain unlocked during hours that the prescription department is open and a pharmacist is on duty.

C. Safeguards for controlled paraphernalia and Schedule VI medical devices. Controlled paraphernalia and Schedule VI medical devices shall not be placed in an area completely removed from the prescription department whereby patrons will have free access to such items or where the pharmacist cannot exercise reasonable supervision and control.

D. Expired, or otherwise adulterated or misbranded drugs; security. Any drug ~~which~~that has exceeded the expiration date, or is otherwise adulterated or misbranded, shall not be dispensed or sold; it shall be separated from the stock used for dispensing. Expired prescription drugs shall be maintained in a designated area within the prescription department until proper disposal.

18VAC110-20-211. Disposal of drugs by authorized collectors.

Any narcotic treatment program, hospital, or clinic with an on-site pharmacy, or pharmacy ~~wishing to accept for return~~that accepts a previously dispensed drug for the purpose of destruction shall first be authorized by the DEA as a collector. A collector so authorized may receive drugs from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user who

resides or has resided at that facility ~~shall first be authorized by the DEA as a collector~~. The process used to collect and destroy drugs, along with any required recordkeeping, shall comply with applicable federal and state law.

1. Prior to collecting drugs, an authorized collector shall submit in writing to the board:

a. The name, address, and license number, if applicable, of the facility;

b. The intended method or methods of collection (i.e., collection receptacle or mail-back program); and

c. Signature of PIC or medical director of a narcotic treatment program.

2. If an authorized collector chooses to cease acting as a collector, the PIC or medical director shall notify the board within 30 days.

3. A narcotic treatment program that does not have an in-house pharmacy shall obtain a controlled substance registration.

Part ~~V~~III

Nuclear Pharmacies

18VAC110-20-220. General requirements for pharmacies providing radiopharmaceutical services.

A. Nuclear pharmacies shall comply with standards and requirements of the Nuclear Regulatory Commission ~~(NRC)~~ and the Virginia Department of Health related to the staffing and operation of the facility.

B. Radiopharmaceuticals are to be dispensed only upon an order from a prescriber authorized to possess, use, and administer radiopharmaceuticals.

1. Orders shall originate at an institution or ~~healthcare~~health care facility licensed to receive and possess radiopharmaceuticals~~,~~ and must contain all necessary information relative to the radiopharmaceutical, activity, time of calibration, and any special preparation or delivery instructions.

2. Orders for radiopharmaceuticals may be transmitted orally, by ~~fax~~facsimile (fax), or by electronic transmission by an authorized agent of the prescriber. If the fax or electronic transmission of the authorized agent is pursuant to an oral order from the prescriber, the transmitted document need not include the prescriber's signature, ~~but~~ must include the name of the agent.

C. The immediate outside container of a radioactive drug to be dispensed shall also be labeled in accordance with requirements of § 54.1-3410.1 B of the Code of Virginia.

D. The immediate inner container shall be labeled with~~:~~ (i) the standard radiation symbol~~;~~, (ii) the words "Caution--Radioactive Material,"~~;~~ and (iii) the serial number assigned to the order.

E. Nuclear pharmacies may redistribute approved radioactive drugs if the pharmacy does not process the radioactive drugs in any manner nor violate the product packaging.

Part ~~VI~~IV

Drug Inventory and Records

18VAC110-20-240. Manner of maintaining records, prescriptions, inventory records.

A. Each pharmacy shall perform and maintain the inventories and records of drugs as follows:

1. Inventories and records of all drugs listed in Schedules I and II shall be maintained separately from all other records of the pharmacy. Inventories of drugs in Schedules I and II shall be performed by physically counting the drugs. Each pharmacy shall maintain a perpetual inventory of all Schedule II drugs received and dispensed, ~~with~~ that accurately indicates the physical count of each Schedule II drug "on-hand" at the time of performing the inventory. The perpetual inventory shall include a reconciliation of each Schedule II drug at least monthly with a written explanation for any difference between the physical count and the theoretical count. Electronic monitoring

at the pharmacy or by another entity that provides alerts for discrepancies between drugs received and drugs dispensed is acceptable provided such alerts are reviewed at least monthly.

2. Inventories and records of drugs listed in Schedules III, IV, and V may be maintained separately or with records of Schedule VI drugs but shall not be maintained with other records of the pharmacy. Inventories of drugs in Schedules III, IV, and V may be performed by estimating the count of drugs in Schedules III, IV, and V unless the container contains greater than 1,000 tablets or capsules or there has been a theft or any other unusual loss of drug and the exact kind and quantity of the drug loss is unknown.

3. All executed order forms, prescriptions, and inventories of ~~Schedule~~ Schedules II through V drugs shall be maintained at the same address as the stock of drugs to which the records pertain. If authorized by DEA, other records pertaining to ~~Schedule~~ Schedules II through V drugs, such as invoices, may be maintained in an off-site database or in secured storage. All records in off-site storage shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

4. All inventories required by § 54.1-3404 of the Code of Virginia shall be signed and dated by the person taking the inventory and shall indicate whether the inventory was taken prior to the opening of business or after close of business. A 24-hour pharmacy with no opening or closing of business shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.

5. Invoices or other records showing receipts of Schedule VI drugs shall be maintained ~~but~~ may be stored in an electronic database or record as an electronic image that provides an exact, clearly legible, ~~image~~ of the document or in secured storage either on site or off site. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

6. All records required by this section shall be filed chronologically and maintained for a period of not less than two years from the date of transaction.

B. Prescriptions.

1. A hard copy prescription shall be placed on file for every initial prescription dispensed and be maintained for two years from the date of last refill. All prescriptions shall be filed chronologically by date of initial dispensing or by date of initial entry into the automated data processing system in compliance with 18VAC110-20-250 if such a system is employed by the pharmacy.

2. Schedule II drugs. Prescriptions for Schedule II drugs shall be maintained in a separate prescription file.

3. ~~Schedule~~Schedules III ~~through~~, IV, and V drugs. Prescriptions for ~~Schedule~~Schedules III ~~through~~, IV, and V drugs shall be maintained either in a separate prescription file for drugs listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescriptions of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than one inch high and filed in the prescription file for drugs listed in the usual consecutively numbered prescription file for Schedule VI drugs. However, if a pharmacy employs an automated data processing system or other electronic recordkeeping system for prescriptions ~~which~~that permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

C. Chart orders.

1. A chart order written for a patient in a hospital or long-term care facility, a patient receiving home infusion services, or a hospice patient pursuant to § 54.1-3408.01 A of the Code of Virginia shall be exempt from having to contain all required information of a written prescription provided:

a. This information is contained in other readily retrievable records of the pharmacy; and

b. The pharmacy maintains and complies with a current policy and procedure manual that sets out where this information is maintained ~~and~~, how to retrieve it, and the minimum requirements for chart orders consistent with state and federal law and accepted standard of care.

2. A chart order may serve as the hard copy prescription for those patients listed in subdivision 1 of this subsection. When a chart order is intended for out-patient dispensing, it shall comply with requirements for a prescription in 18VAC110-20-286.

3. Requirements for filing of chart orders.

a. Chart orders shall be filed chronologically by date of initial dispensing with the following exception: If dispensing data can be produced showing a complete audit trail for any requested drug for a specified time period and each chart order is readily retrievable upon request, chart orders may be filed using another method. Such alternate method shall be clearly documented in a current policy and procedure manual.

b. If a single chart order contains both an order for a Schedule II drug and one or more orders for a drug in another schedule, where the Schedule II drug is not floor stocked, but is dispensed from the pharmacy pursuant to this order for the specific patient, the original order must be filed with records of dispensing of Schedule II drugs and a copy of the order placed in the file for other schedules.

Part ~~VII~~V

Prescription Order and Dispensing Standards

18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions~~; supervision of pharmacy technicians~~.

A. In addition to the ~~acts restricted to a pharmacist in § 54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians. B. A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time; however, no pharmacist shall supervise more than four persons acting as pharmacy technicians at one time~~ requirements in § 54.1-3408.01 of the Code of Virginia for an oral prescription or written prescription, including those transmitted via facsimile or electronically, a prescription shall include a quantity or duration of the order by which the pharmacist can calculate the authorized quantity using directions for use. Except for prescriptions transmitted electronically in compliance with 18VAC110-20-285, written prescriptions shall also include the prescriber's manual signature. ***In cases of failed electronic prescriptions, Schedule VI prescriptions transmitted electronically in compliance with 18VAC110-20-285 may utilize an electronic signature on faxes.***

Commented [NACDS6]: We have a concern with electronic prescriptions that fail. These failed electronic prescriptions usually default to fax. The fax sent usually has a mock physician signature and therefore doesn't have the actual physician's manual signature. We would recommend amending this section to permit fax prescriptions for Schedule VI medications being sent from a physician's software not required to have a manual signature.

~~C.~~B. After the prescription has been prepared and prior to the delivery of the order, a pharmacist shall inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction. If more than one pharmacist is involved in verifying the accuracy of the prescription product, a record shall be maintained identifying the date of dispensing, each pharmacist involved in the process, and the individual task for which ~~he~~ each pharmacist is responsible for verifying the accuracy. Such record showing verification of accuracy shall be maintained on a pharmacy record and, if necessary, an alternate record consistent with 18VAC110-20-255 for the required time period of two years, unless otherwise specified in regulation. If the dispensing involves central or remote processing, records of pharmacist verification shall be maintained in a manner consistent with 18VAC110-20-276 and 18VAC110-20-515.

~~D.~~C. If a pharmacist declines to fill a prescription for any reason other than the unavailability of the drug prescribed, he shall record on the back of the prescription the word "declined"; the name, address, and telephone number of the pharmacy; the date filling of the prescription was declined; and the signature of the pharmacist.

~~E.~~D. If a pharmacist determines from a prescriber or by other means, including the use of his professional judgment, that a prescription presented for dispensing is a forgery, the pharmacist ~~shall not~~ may refuse to return the forged prescription to the person presenting it. The forged prescription may be given to a law-enforcement official investigating the forgery, or it shall be retained for a minimum of 30 days before destroying

it, in the event it is needed for an investigative or other legitimate purpose.

~~F.~~E. An on-hold prescription shall be entered into the automated data processing system if such system is employed by the pharmacy, and the pharmacist on-duty shall verify the accuracy of the data entry at that time. The pharmacist subsequently dispensing the on-hold prescription on a future date shall, at a minimum, conduct a prospective drug review consistent with § 54.1-3319 A of the Code of Virginia. If an on-hold prescription is returned to a patient prior to the initial dispensing of the drug, the pharmacist shall delete the entry in the automated data processing system.

Commented [NACDS7]: We suggest the current language be amended to allow for the variety of two-step prescription verification processes used by pharmacies throughout the country. The current language restricts flexibility in these well-established processes for on-hold prescriptions.

F. A pharmacy may use a drop box for the collection of written prescriptions and refill requests. The drop box shall be located in a visible area within the permitted facility and shall be locked at all times with access to the items placed in the drop box restricted to pharmacists practicing at the pharmacy or an authorized pharmacy technician practicing at the pharmacy when a pharmacist is on duty. The drop box shall be constructed in a manner to prevent the theft or loss of a written prescription or confidential information and shall be bolted to the floor or a fixed structure. Pharmacists shall in some manner inform the public that containers left in a drop box for refill should not contain unused drugs.

18VAC110-20-280. Transmission of a prescription order by facsimile ~~machine~~ device.

A. Unless otherwise prohibited by federal law, prescription orders for ~~Schedule~~ Schedules III through VI drugs may be transmitted to pharmacies by facsimile (fax) device ~~(FAX)~~ upon the following conditions:

1. The prescription shall be faxed only to the pharmacy of the patient's choice.

2. A valid faxed prescription shall contain all required information for a prescription. A written prescription shall include the prescriber's signature.

3. An authorized agent, as defined in § 54.1-3408.01 C of the Code of Virginia, may transmit an oral prescription by facsimile and shall record on the faxed prescription the agent's full name and wording that clearly indicates that the prescription being transmitted is an oral prescription.

4. A faxed prescription shall be valid only if faxed from the prescriber's practice location, except in the following situations:

a. Forwarding a faxed chart order from a long-term care facility or from a hospice, including a home hospice;

b. Faxing an oral prescription by authorized agent under the conditions set forth in subdivision 3 of this subsection; or

c. Forwarding a written prescription by an authorized agent from a long-term care facility, provided the provider pharmacy maintains written procedures for such transactions, and provided the original prescription is obtained by the provider pharmacy within seven days of dispensing. The original prescription shall be attached to the faxed copy.

5. The following additional information shall be recorded on the faxed prescription:

a. The date that the prescription was faxed;

b. The printed name, address, phone number, and fax number of the authorized prescriber; and

c. The institution, if applicable, from which the prescription was faxed, including address, phone number, and fax number.

B. Prescription orders for Schedule II drugs may only be faxed for information purposes and may not serve as the original written prescription authorizing dispensing, except for orders to be administered to long-term care facility and home infusion patients in accordance with § 54.1-3408.01 B of the Code of Virginia and except for prescriptions written for a Schedule II narcotic substance for patients residing in a hospice certified by Medicare under Title XVIII or licensed by the state, which may include home hospice. The prescriber shall note on the prescription if the patient is a hospice patient, and the prescription shall meet all requirements for a written prescription, including the prescriber's manual signature.

C. If the faxed prescription is of such quality that the print will fade and not remain legible for the required retention period, the receiving pharmacist shall copy or transcribe the faxed prescription on paper of permanent quality.

D. Authorizations for refills may be faxed by the prescriber to the pharmacy provided the authorization includes patient name, address, drug name and strength, quantity, directions for use, prescriber's name, prescriber's manual signature or agent's name, and date of authorization.

18VAC110-20-290. Dispensing of Schedule II drugs.

A. A prescription for a Schedule II drug shall be dispensed in good faith but in no case shall it be dispensed more than six months after the date on which the prescription was issued.

B. A prescription for a Schedule II drug shall not be refilled except as authorized under the conditions for partial dispensing as set forth in 18VAC110-20-310.

C. In case of an emergency situation, a pharmacist may dispense a drug listed in Schedule II upon receiving oral authorization of a prescribing practitioner, provided that:

1. The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period;

2. The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in § 54.1-3410 of the Drug Control Act, except for the signature of the prescribing practitioner;

3. If the pharmacist does not know the practitioner, ~~he~~the pharmacist shall make a reasonable effort to determine that the oral authorization came from a practitioner using ~~his~~the practitioner's phone number as listed in the telephone directory or other good-faith efforts to ensure the practitioner's identity; and

4. Within seven days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of § 54.1-3410 of the Drug Control Act, the prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail postmarked within the seven-day period, ~~or~~ transmitted as an electronic prescription in accordance with federal law and regulation to include annotation of the electronic prescription with the original authorization and date of the oral order. Upon receipt, the dispensing pharmacist shall attach the paper prescription to the oral emergency prescription, which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Drug Enforcement Administration and the board if the prescribing practitioner fails to deliver a written prescription to ~~him~~the pharmacist. Failure of the pharmacist to do so shall void the authority conferred by this subdivision to dispense without a written prescription of a prescribing practitioner.

D. When presented a prescription written for a Schedule II controlled substance, a pharmacist may add or correct the patient's address upon verification, correct the patient's name upon verification, or add the prescriber's DEA registration number to the prescription. The pharmacist may add or change the dosage form, drug strength, directions for use, drug quantity, or issue date only after oral consultation directly with and agreement of the prescriber. Such consultations and corresponding changes shall be noted by the pharmacist on the prescription. The pharmacist shall not add or change the prescriber's signature or make changes to the controlled substance prescribed, except for dispensing therapeutically equivalent drugs as permitted by law.

18VAC110-20-355. Pharmacy repackaging of drug; records required; labeling requirements.

A. Pharmacies in which bulk reconstitution of injectable, bulk compounding, or the repackaging or prepackaging of drugs is performed shall maintain adequate control records for a period of one year or until the expiration, whichever is greater. The records shall show the name of the ~~drug(s)~~drugs used; strength, if any; date repackaged; quantity prepared; initials of the pharmacist verifying the process; the assigned lot or control number; the manufacturer's or distributor's name and lot or control number; and an expiration date.

B. The drug name; strength, if any; the assigned lot or control number or the manufacturer's or distributor's name and lot or control number; and an appropriate expiration date determined by the pharmacist in accordance with USP guidelines shall appear on any subsequently repackaged or reconstituted units.

C. Repackaging of drugs shall be performed in compliance with USP-NF standards.

~~C.~~D. Pharmacies using automated counting devices or dispensers in which drugs are removed from manufacturer's original packaging and placed in bulk bins shall comply with the following requirements:

1. A bin filling record shall be maintained~~,~~ manually or in a computerized record for a period of one year from date of filling from which information can be readily retrieved~~,~~ for each bin including:

a. The drug name and strength, if any;

b. The name of the manufacturer or distributor;

c. Manufacturer's control or lot ~~number(s)~~numbers and expiration date for all lots placed into the bin at the time of filling;

d. Any assigned lot number;

e. An expiration date determined according to USP guidelines for repackaging;

f. The date of filling; and

g. The pharmacist's initials verifying the accuracy of the process.

2. If more than one lot is added to a bin at the same time, the lot ~~which~~that expires first shall be used to determine the expiration date if shorter than a calculated date based on USP guidelines.

3. Each bin shall be labeled in such a manner as to cross-reference the information on the filling record with the correct expiration date.

4. If only one lot is added to a bin at one time, but a subsequent lot may be added before the first has cleared, the automated device shall be constructed to reasonably dispense the first lot before the second lot is dispensed, and the expiration date on the bin's label shall reflect the expiration date assigned to the earlier lot.

5. In the event of a drug recall involving one of multiple lots placed in a bin of an automated counting device in the last three months or if a recalled drug is known to remain in the bin, all drugs shall be removed from the bin and not used for patient care. The removal of drugs from the bin is not required if:

a. The technology of the automated counting device can ensure drugs in a particular lot have been cleared; or

b. The bin has been "run dry," with a record made of the "run dry" date, since the addition of the recalled lot number in which all drugs were completely removed prior to filling with a subsequent lot number.

6. An automated counting device shall be cleaned and maintained in accordance with recommended manufacturer guidelines and specifications.

~~D.~~E. A pharmacy may return a dispensed drug to stock for redispensing that has never left the pharmacy premises or the control of the pharmacy delivery agent pursuant to § 54.1-3411.1 A 3 of the Code of Virginia under the following conditions:

1. An expiration date shall be placed on the label prior to returning the drug to stock. In the absence of stability data to the contrary, the date on the label may not exceed the expiration date on the manufacturer's container or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier.

2. The restocked drug shall be used to fill the next prescription received for that product. In the event that the drug is not dispensed prior to the new assigned expiration date, it shall be removed from working stock as expired~~,~~ and disposed of in accordance with 18VAC110-20-210.

3. If there is no lot number on the label of a drug returned to stock or on the prescription records that can be cross-referenced from the prescription label, the drug shall be removed from stock upon any recall of that drug product and returned to the manufacturer or otherwise disposed of in accordance with 18VAC110-20-210.

18VAC110-20-390. Kickbacks, fee-splitting, interference with supplier.

A. A ~~pharmacist~~pharmacy shall not solicit or foster prescription practice with a prescriber of drugs or any other person providing for rebates, ~~"~~kickbacks,~~"~~ fee-splitting, or special charges in exchange for prescription orders ~~unless fully disclosed in writing to the patient and any third party payor~~.

B. A ~~pharmacist~~pharmacy shall not interfere with the patient's right to choose his supplier of medication or cooperate with any person ~~or persons~~ in denying a patient the opportunity to select his supplier of prescribed medications.

18VAC110-20-425. Robotic pharmacy systems.

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

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

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

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

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

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

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

c. Removing expired drugs;

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

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

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

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

~~g.~~h. Appropriately ~~investigating, identifying and correcting~~performing a root cause analysis to investigate, identify, and correct sources of discrepancies or errors associated with the robotic pharmacy system; and

~~h.~~i. Maintaining quality assurance reports.

~~5. Pharmacists shall perform a daily random check of medications or compliance packaging picked by the robot for 5.0% of all patients' bins and 5.0% of all first doses or cart updates. Documentation of this check shall include the pharmacist's initials for each medication checked and a description of all discrepancies found.~~

~~6.~~5. All manual picks shall be checked by pharmacists.

~~7.~~6. If the robot picks an incorrect medication, the pharmacy shall immediately institute a 100% check of all affected doses or compliance packages and ~~shall immediately report the error to the board. The 100% check procedure shall continue until such time as the pharmacy provides documentation to the board showing that the cause of the error has been determined and addressed and that the robot is no longer making errors, and the board allows the pharmacy to return to a reduction in checking~~perform a root cause analysis to investigate, identify, and correct the source of discrepancy or error in compliance with the pharmacy's policies and procedures prior to resuming full operations of the robot.

~~8.~~7. Quarterly quality assurance reports demonstrating the accuracy of the robot shall be maintained. At a minimum, these reports shall include~~: a. A~~a summary indicating the date and description of all discrepancies that include ~~but are not limited to~~ discrepancies involving the packaging, repackaging, and dispensing of drugs via the robotic pharmacy system found during that quarter plus a cumulative summary since initiation of the robotic pharmacy system.

~~b.The total number of doses packaged or compliance packages prepared for the robotic pharmacy system and total number of doses or compliance packages picked by the robot during the quarter.~~

~~c.The total number of doses or compliance packages picked by the robot that were checked in conducting the 5.0% checks.~~

~~d.Dates and time associated with any scheduled or unanticipated downtime with an explanation of the problem to include the time span of the downtime and the resolution.~~

~~9. All unanticipated downtime shall be immediately reported to the board.~~

~~10.~~8. All records required by this section shall be maintained at the address of the pharmacy for a minimum of two years. Records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

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

18VAC110-20-470. Emergency room.

All drugs in the emergency department shall be under the control and supervision of the PIC and shall be subject to the following additional requirements:

1. All drugs kept in the emergency room shall be in a secure place from which unauthorized personnel and the general public are excluded.

2. Oral orders for medications shall be reduced to writing and shall be signed by the ~~practitioner~~prescriber.

3. A medical practitioner may dispense drugs to his patients if in a bona fide medical emergency or when pharmaceutical services are not readily available and if permitted to do so by the hospital; the drug container and the labeling shall comply with the requirements of this chapter and the Drug Control Act.

4. A record shall be maintained of all drugs administered in the emergency room.

5. A separate record shall be maintained on all drugs, including drug samples, dispensed in the emergency room. The records shall be maintained for a period of two years showing:

a. Date and time dispensed;

b. Patient's name;

c. Prescriber's name;

d. Name of drug dispensed, strength, dosage form, quantity dispensed, and dose.

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

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

B. Policy and procedure manual; access codes.

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

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

C. Distribution of drugs from the pharmacy.

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

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

D. Distribution of drugs from the device.

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

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

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

F. Reviews and audits.

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

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

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

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

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

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

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

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

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

(2) Monitoring of overrides and unresolved discrepancies.

d. The report shall be used to identify suspicious activity, which includes~~, but is not limited to,~~ usage beyond three standard deviations in peer-to-peer comparisons. A focused audit of the suspicious activity and individuals associated with the activity shall be performed whenever suspicious activity is identified from the reports.

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

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

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

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

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

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

H. Records.

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

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

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

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

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

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

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

18VAC110-20-530. Pharmacy's responsibilities to long-term care facilities.

A. The pharmacy serving a long-term care facility shall:

1. Receive a valid order prior to the dispensing of any drug.

2. Ensure that personnel administering the drugs are trained in using the dispensing system provided by the pharmacy.

3. Ensure that the drugs for each patient are kept and stored in the originally received containers and that the medication of one patient shall not be transferred to another patient.

4. Ensure that each cabinet, cart, or other area utilized for the storage of drugs is locked and accessible only to authorized personnel.

5. Ensure that the storage area for patients' drugs is well lighted, of sufficient size to permit storage without crowding, and is maintained at appropriate temperature.

6. Ensure that poison and drugs for "external use only" are kept in a cabinet and separate from other medications.

7. Provide for the disposition of discontinued drugs under the following conditions:

a. Discontinued drugs may be returned to the pharmacy for resale or transferred to another pharmacy for redispensing to the indigent if authorized by § 54.1-3411.1 of the Code of Virginia and 18VAC110-20-400, or disposed of by appropriate means in compliance with 18VAC110-20-210 and with any applicable local, state, and federal laws and regulations.

b. Drug destruction at the pharmacy shall be witnessed by the PIC and by another pharmacy employee. The pharmacy may transfer the drugs for destruction to an entity appropriately licensed to accept returns for destruction. Drug destruction at the facility shall be witnessed by the director of nursing or, if there is no director, then by the facility administrator and by a pharmacist providing pharmacy services to the facility or by another employee authorized to administer medication.

c. A complete and accurate record of the drugs returned or destroyed or both shall be made. The original of the record of destruction shall be signed and dated by the persons witnessing the destruction and maintained at the long-term care facility for a period of two years. A copy of the destruction record shall be maintained at the provider pharmacy for a period of two years.

d. Long-term care facilities shall destroy discontinued or unused drugs or return them to the pharmacy within 30 days of the date the drug was discontinued.

8. Ensure that appropriate drug reference materials are available in the facility units.

9. Ensure that a monthly review of drug therapy by a pharmacist is conducted for each patient in long-term care facilities except those licensed under Title 63.2 of the Code of Virginia. Such review shall be used to determine any irregularities, which may include ~~but not be limited to~~ drug therapy, drug interactions, drug administration, or transcription errors. The pharmacist shall sign and date the notation of the review. All significant irregularities shall be brought to the attention of the attending practitioner or other party having authority to correct the potential problem.

B. The pharmacy providing services to the long-term care facility may share a copy of a Schedule VI prescription or order with another pharmacy for the purpose of dispensing an immediate supply of drugs, not to exceed a seven-day supply, without transferring the prescription pursuant to 18VAC110-20-360 if the following conditions are satisfied:

1. The pharmacy providing services to the long-term care facility has a written contract with the other pharmacy outlining services to be provided, the recordkeeping associated with the dispensing, and the responsibilities of each pharmacy; and

2. The pharmacy providing services to the long-term care facility provides a valid oral or written prescription or order to the other pharmacy.

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

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

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

a. The dispensing pharmacy must have a method of sealing such boxes so that once the seal is broken, it cannot be reasonably resealed without the breach being detected.

b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication or resealing, or both. The pharmacy shall maintain a record of the seal identifiers when placed on a box and maintain the record until such time as the seal is replaced.

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

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

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

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

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

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

b. The stat-drug box shall contain no more than 20 solid dosage units per schedule of Schedules II through V drugs except that one unit of liquid, not to exceed 30 ml, may be substituted for a solid dosage unit in each drug schedule. If the unit of a liquid that may contain more than one dose is removed from the stat-drug box pursuant to a patient order, the remainder shall be stored with that patient's other drugs, may be used for subsequent doses administered to that patient, and shall not be administered to any other patient.

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

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

18VAC110-20-580. ~~Humane societies and animal~~Animal shelters.

~~A humane society or~~An animal shelter, after having obtained the proper registrations pursuant to state and federal laws, may purchase, possess and administer controlled substances in accordance with provisions of § 54.1-3423 of the Code of Virginia provided that these procedures are followed:

1. Drugs ordered by a ~~humane society~~public or private animal shelter, as defined in § 3.2-6500 of the Code of Virginia, shall only be stored and administered at the address of the ~~humane society or~~ shelter.

2. A veterinarian shall provide general supervision for the facility and shall provide and certify training in accordance with guidelines set forth by the State Veterinarian to the ~~person(s)~~persons responsible for administration of the drugs. Certification of training signed by the veterinarian providing the training shall be maintained at the facility for each person administering drugs and must be retained for not less than two years after the person ceases administering.

3. The person in charge of administration of drugs for the facility shall obtain the required permit and controlled substances registration from the board and shall be responsible for maintaining proper security and required records of all controlled substances obtained and administered.

a. If that person ceases employment with the facility or relinquishes his position, he shall immediately return the registration to the board and shall take a complete and accurate inventory of all drugs in stock.

b. An application for a new registration shall be filed with the required fee within 14 days on a form provided by the board. At that time, the new responsible person shall take a complete and accurate inventory of all drugs in stock.

4. Drugs shall be stored in a secure, locked place and only the ~~person(s)~~person responsible for administering may have access to the drugs.

5. All invoices and order forms shall be maintained for a period of two years.

6. Complete and accurate records shall be maintained for two years on the administration of the drug. The record shall show the name and strength of the drug, date of administration, the species of the animal, the weight of animal, the amount of drug administered and the signature of the person administering the drug.

Part ~~XV~~XIII

Medical Equipment Suppliers

18VAC110-20-630. Issuance of a permit as a medical equipment supplier.

A. Any person or entity desiring to obtain a permit as a medical equipment supplier shall file an application with the board on a form approved by the board. An application shall be filed for a new permit or for acquisition of an existing medical equipment supplier. The application shall designate the hours of operation the location will be open to service the public and shall be signed by a person who works at the location address on the application and will act as a responsible party for that location.

B. Any change in the hours of operation expected to last for more than one week shall be reported to the board in writing and a notice posted, at least 14 days prior to the anticipated change, in a conspicuous place to the public.

1. Such notification of a change in hours of operation is not required when the change is necessitated by emergency circumstances beyond the control of the owner or responsible party or when the change will result in an expansion of the current hours of operation.

2. If the medical equipment supplier is unable to post the change in hours 14 days in advance, the responsible party or owner shall ensure the board is notified as soon as he knows of the change and disclose the emergency circumstances preventing the required notification.

C. Within 14 days of a change in the responsible party assigned to the permit, the outgoing responsible party shall inform the board, and a new application shall be submitted indicating the name of the new responsible party.

~~B.~~D. A permit holder proposing to change the location of an existing license or permit or make structural changes to an existing location shall file an application for approval of the changes following an inspection conducted by an authorized agent of the board.

~~C.~~E. A permit shall not be issued to any medical equipment supplier to operate from a private dwelling or residence or to operate without meeting the applicable facility requirements for proper storage and distribution of drugs or devices. Before any license or permit is issued, the applicant shall demonstrate compliance with all federal, state and local laws and ordinances.

18VAC110-20-680. Medical equipment suppliers.

A. A medical equipment supplier's location shall be inspected by the board prior to engaging in business. The location shall be clean and sanitary and shall have a system of temperature control to provide for specified storage conditions for any Schedule VI drug or device.

B. Hypodermic needles and syringes and Schedule VI drugs shall not be placed on open display or in an open area where patrons will have access to such items. No Schedule VI devices shall be placed in an area where responsible parties cannot exercise reasonable supervision and control.

C. A medical equipment supplier shall receive a valid order from a practitioner prior to dispensing and shall maintain this order on file on the premises for a period of two years from date of last dispensing. The original order may be kept at a centralized office as long as it is readily retrievable within 48 hours and a copy of the order is kept on the premises of the dispensing supplier. In lieu of a hard copy, an electronic image of an order may be maintained in an electronic database provided it preserves and provides an exact image of the order that is clearly legible and made available within 48 hours of a request by a person authorized by law to have access to prescription information.

D. Medical equipment suppliers shall make a record at the time of dispensing. This record shall be maintained on the premises for two years from date of dispensing and shall include:

1. Name and address of patient;

2. Item dispensed and quantity, if applicable; and

3. Date of dispensing.

E. A valid order authorizing the dispensing of drugs or devices may be transferred from one medical equipment supplier to another medical equipment supplier provided the order can be filled or refilled. The transfer shall be

communicated either orally by direct communication between an individual at the transferring medical equipment supplier and the receiving medical equipment supplier, by facsimile machine, or by electronic transmission.

1. The transferring medical equipment supplier shall:

a. Record the word "VOID" on the face of the invali - dated order;

b. Record on the reverse side of the invalidated order the name and address of the medical equipment supplier to which it was trans - ferred, the date of the transfer, and for an oral transfer, the name of the individual receiving the prescription information and the name of the individual transferring the information.

2. The receiving medical equipment supplier shall:

a. Write the word "TRANSFER" on the face of the trans - ferred pre - scription;

b. Provide all information required to be on a valid order to include:

(1) Date of issuance of original order;

(2) Original number of refills authorized on the original order;

(3) Date of original dispensing if applicable;

(4) Number of valid refills remaining and date of last dispensing;

(5) Medical equipment supplier name and address from which the order information was transferred; and

(6) Name of transferring individual if transferred orally.

3. Both the original and transferred order shall be main - tained for a period of two years from the date of last refill. In lieu of recording the required information on the hard copy of a valid order, a medical equipment supplier may record all required information in an automated data processing system used for the storage and retrieval of dispensing information.

~~E.~~F. A nonresident medical equipment supplier shall register and practice in accordance with § 54.1-3435.3:1 of the Code of Virginia.

CHAPTER 21

REGULATIONS GOVERNING THE LICENSURE OF PHARMACISTS AND REGISTRATION OF PHARMACY TECHNICIANS

Part I General

Provisions

18VAC110-21-10. Definitions.

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

"ACPE" means the Accreditation Council for Pharmacy Education.

"Board" means the Virginia Board of Pharmacy.

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

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

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

Commented [NACDS8]: We recommend striking the definition of PTCB and instead recommend adding a definition of "certification" to be defined as follows:

Certification: Any individual who has passed a certification exam administered by an organization accredited by the National Commission for Certifying Agencies (NCCA).

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

"FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign Pharmacy Equivalency Examination and a credential review of foreign training to establish educational equivalency to board approved schools of pharmacy and has passed approved examinations establishing proficiency in English.

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

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

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

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

18VAC110-21-20. Fees.

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

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

C. Initial application fees.

1. Pharmacist license	$180
2. Pharmacy intern registration	$15
3. Pharmacy technician registration	$25
4. Approval of a pharmacy technician training program	$150
5. Approval of a continuing education program	$100

D. Annual renewal fees.

1. Pharmacist active license - due no later than December 31	$90
2. Pharmacist inactive license - due no later than December 31	$45
3. Pharmacy technician registration - due no later than December 31	$25
4. Pharmacy technician training program	$75 every two years

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

1. Pharmacist license	$30
2. Pharmacist inactive license	$15
3. Pharmacy technician registration	$10
4. Pharmacy technician training program	$15

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

1.Pharmacist license	$210
2. Pharmacist license after revocation or suspension	$500
3. Pharmacy technician registration	$35
4. Pharmacy technician registration after revocation or suspension	$125
5. A pharmacy technician training program that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus a reinstatement fee of $75. A pharmacy technician training program that ceases operation and wishes to resume shall not be eligible for reinstatement but shall apply for a new registration.	

G.Miscellaneous fees.

1. Duplicate wall certificate	$25
2.Returned check	$35
3. Duplicate license or registration	$10
4. Verification of licensure or registration	$25

18VAC110-21-30. Current name and address.

A. It shall be the duty and responsibility of each licensee and registrant to inform the board of his current name and address. A licensee or registrant shall notify the board within 14 days in writing or electronically of a name change or a change of an address of record. Properly updating a name or an address of record directly through the board's web-based application or other approved means shall constitute lawful notification.

B. All notices required by law or by this chapter are deemed to be received by the licensee or registrant when sent to the address of record and shall not relieve the licensee or registrant of the obligation to comply.

C. An individual licensed by or registered with the board who has provided the board with a public address that is different from the address of record shall notify the board in writing if there is a change in the address.

18VAC110-21-40. Unprofessional conduct.

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

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

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

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

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

5. Engaging or attempting to engage in a relationship with a patient that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a patient or the patient's family, including sexual misconduct with a patient or a member of the patient's family or other conduct that results or could result in personal gain at the expense of the patient;

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

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

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

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

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

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

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

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

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

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

18VAC110-21-45. Kickbacks, fee-splitting, interference with supplier.

A. A pharmacist shall not solicit or foster prescription practice with a prescriber of drugs or any other person providing for rebates, kickbacks, fee-splitting, or special charges in exchange for prescription orders.

B. A pharmacist shall not interfere with the patient's right to choose his supplier of medication or cooperate with any person or persons in denying a patient the opportunity to select his supplier of prescribed medications.

Part II

Licensure Requirement for Pharmacists

18VAC110-21-50. Requirements for pharmacy practical experience.

A. Each applicant for licensure as a pharmacist shall have gained practical experience in the practice of pharmacy as set forth in this section and 18VAC110-21-60.

B. An applicant for licensure as a pharmacist shall attain a minimum of 1,500 hours of practical experience.

C. Practical experience that is gained within an ACPE-accredited school of pharmacy, that conforms to the current ACPE standards, and that allows the student to gain at least 1,500 hours of practical experience shall meet the board's practical experience requirements for licensure as a pharmacist.

D. All practical experience credit gained outside of an ACPE-accredited school of pharmacy program shall only be gained after successful completion of the equivalent of at least two semesters in an ACPE-accredited school of pharmacy. Credit shall not be given for more than 50 hours in one week and not less than an average of 20 hours per week averaged over a month. The board may grant an exception to the minimum number of hours for good cause shown.

E. In accordance with § 54.1-3312 of the Code of Virginia, all practical experience required by this section shall be gained within the United States.

18VAC110-21-60. Procedure for gaining practical experience.

A. Each person desiring to gain practical pharmacy experience in Virginia shall first register with the board as a pharmacy intern on a form provided by the board prior to becoming so engaged as a pharmacy intern. This requirement shall apply to any person gaining practical experience within the Commonwealth whether for licensure in Virginia or in another state.

B. In order to be eligible to register as a pharmacy intern, an applicant shall meet at least one of the following criteria:

1. The applicant shall be enrolled in and have started course work in a professional degree program of a board-approved school of pharmacy. Such registration is only valid while the student is enrolled in the school of pharmacy and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist. An expiration date shall be assigned to the registration to cover the estimated time period for the student to complete the school program and pass the required examinations. If the student is no longer enrolled in the school program, takes a voluntary break from the program, or is otherwise not actively participating in the school program, except for regularly scheduled school breaks, the registration is no longer valid and shall be returned to the board immediately;

2. The applicant is a graduate of a board-approved school of pharmacy or a graduate of a foreign school of pharmacy, has established educational equivalency and proficiency in English by obtaining the FPGEC certificate, and desires to gain required practical experience required for licensure as a pharmacist. Such applicant shall provide documentation on a board-approved form of current employment or an employment start date within 90 days in a pharmacy in Virginia with approval by the supervising pharmacist. An expiration date shall be assigned to cover the estimated time period needed to obtain the required practical experience hours and take the required examinations to become licensed as a pharmacist;

3. The applicant has already gained the required practical experience but is an otherwise qualified applicant awaiting examination for licensure. A three-month expiration date shall be assigned to allow the applicant time to take required examinations; or

4. The applicant is an applicant for reactivation or reinstatement of a previously issued pharmacist license and is meeting board requirements for relicensure. An expiration date shall be assigned to reasonably cover the period of time necessary to meet the board requirements.

C. For documented good cause shown, the executive director of the board may extend the expiration date of the intern registration upon submission of an application form approved by the board and payment of the initial application fee.

D. A pharmacy intern shall be supervised by a pharmacist who holds a current, unrestricted license and assumes full responsibility for the training, supervision, and conduct of the intern.

E. The intern registration of a pharmacy student shall be valid only while the student is enrolled in a school of pharmacy. The registration card issued by the board shall be returned to the board upon failure to be enrolled.

F. Practical experience gained within any other state must be registered with and certified by the board of that state in order to be accepted or certified by the board. In the event that a state relies on the pharmacy school to certify the hours of experience, an affidavit from the pharmacy school certifying the hours of experience gained in the United States may be accepted in lieu of board certification.

G. All practical experience of the pharmacy intern shall be evidenced by an affidavit approved by the board, which shall be filed prior to or with the application for examination for licensure.

H. An applicant for licensure by endorsement may provide verification acceptable to the board of practical experience hours worked as a pharmacist in another state within the United States in lieu of prelicensure intern

hours in order to meet the practical experience requirement.

I. A pharmacy intern shall notify the board in writing of any change in address of record within 14 days of such change.

18VAC110-21-70. Curriculum and approved schools of pharmacy.

A. The following minimum educational requirements for the specified periods shall be recognized by the board for the purpose of licensure.

1. On and after June 1, 1936, but before June 1, 1964, the applicant for licensure shall have been graduated from a four-year course of study with a Bachelor of Science degree in pharmacy awarded.

2. On and after June 1, 1964, the applicant for licensure shall have been graduated from at least a five-year course of study with a Bachelor of Science degree in pharmacy or a Doctorate of Pharmacy degree awarded.

B. In order to be licensed as a pharmacist within this Commonwealth, the applicant shall have been granted the first professional degree from a program of a school of pharmacy that meets the requirements of § 54.1-3312 of the Code of Virginia or shall satisfy the requirements of 18VAC110-21-90.

18VAC110-21-80. Content of the examination and grades required; limitation on admittance to examination.

A. Prior to admission to any examination required for licensure, the applicant shall have met all other requirements to include education and practical experience requirements, but in no case shall the applicant be admitted if grounds exist to deny licensure under § 54.1-3316 of the Code of Virginia.

B. The applicant shall achieve a passing score as determined by the board on the licensure examination that is approved by the board and that shall consist of an integrated examination of pharmacy practice, pharmacology, pharmacy mathematics, and such other subjects as are necessary to assure that the candidate possesses the necessary knowledge and skills to practice pharmacy.

C. When an applicant for licensure by examination fails to meet the passing requirements of the board-approved integrated pharmacy examination on three occasions, the applicant shall not be readmitted to the examination until he has completed an additional 1,000 hours of practical experience as a pharmacy intern as set forth in 18VAC110-21-60.

D. The applicant shall also achieve a passing score as determined by the board on an examination that tests the candidate's knowledge of federal and state laws related to pharmacy practice. If an applicant has not subsequently been issued a license by any jurisdiction in the United States within three years of achieving a passing score, the applicant shall retake the examination in order to be licensed in Virginia.

E. When an applicant fails to pass the law examination, the applicant shall not be allowed to retake it for a period of 30 days.

F. If an applicant requests a testing accommodation for either examination based on a physical or mental impairment that substantially limits one or more major life activities, subject to the Americans with Disabilities Act, the board may approve a reasonable accommodation that does not compromise the security or integrity of the examination.

1. Supporting documentation shall be provided by the applicant to include the following to be considered for review:

a. A letter of request from the candidate that specifies the testing accommodation requested;

b. A written report of an evaluation (educational, psychological, or physical) within the preceding two years from a qualified professional that states a diagnosis of the disability, describes the disability, recommends specific accommodations, and provides justification that the accommodation is appropriate and necessary for the diagnosed disability. If the comprehensive evaluation was done more than two years ago and the condition is one

that is not subject to change, the original evaluation report may be submitted along with a current letter from the qualified professional stating that there has been no change in the condition since the time of the evaluation; and

c. A written statement from the appropriate person at the applicant's school of pharmacy that describes any testing accommodations made while the student was enrolled, if applicable.

2. The applicant will be notified in writing of the decision. If the request for accommodation is granted, the approval information will be forwarded to the examination contractor and the form of the accommodation will be coordinated with the contractor.

18VAC110-21-90. Requirements for foreign-trained applicants.

A. Applicants for licensure who were trained in foreign schools of pharmacy shall obtain the FPGEC certificate prior to being allowed to register as a pharmacy intern and gain the required practical experience in Virginia.

B. After obtaining the FPGEC certificate, the applicant may apply for a pharmacy intern registration and shall fulfill the requirements for practical experience set forth in 18VAC110-21-50 and 18VAC110-21-60 before being admitted to examinations required by 18VAC110-21-80.

C. Applicants for licensure who were trained in foreign schools of pharmacy shall also complete and achieve passing scores on the examinations set forth in 18VAC110-21-80 before being licensed as a pharmacist.

D. Applicants for licensure who were trained in foreign schools of pharmacy, but who subsequently have been granted a professional degree from a program of a school of pharmacy that meets the requirements of § 54.1-3312 of the Code of Virginia, as specified in18VAC110-21-70, shall be exempt from the requirement for a FPGEC certificate but shall fulfill the requirements for practical experience set forth in 18VAC110-21-50 and 18VAC110-21-60 before being admitted to examinations required by 18VAC110-21-80.

18VAC110-21-100. Registration for voluntary practice by out-of-state licensees.

Any pharmacist who seeks registration to practice on a voluntary basis pursuant to subdivision 12 of § 54.1-3301 of the Code of Virginia under the auspices of a publicly supported, all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people shall:

1. File a complete application for registration on a form provided by the board at least five business days prior to engaging in such practice;

2. Provide a complete list of each state in which the pharmacist has held a pharmacist license and a copy of any current license;

3. Provide the name of the nonprofit organization and the dates and location of the voluntary provision of services;

4. Pay a registration fee of $10; and

5. Provide a notarized statement from a representative of the nonprofit organization attesting to its compliance with the provisions of subdivision 12 of § 54.1-3301 of the Code of Virginia.

Part III

Requirements for Renewal or Reinstatement of Licensure

18VAC110-21-110. Renewal and reinstatement of license.

A. Pharmacist licenses expire on December 31 and shall be renewed annually prior to that date by the submission of a renewal fee, renewal form, and statement of compliance with continuing education requirements.

B. A pharmacist newly licensed on or after October 1 shall not be required to renew that license until December 31 of the following year.

C. A pharmacist who fails to renew his license by the expiration date may renew his license at any time within one year of its expiration by submission of the renewal fee and late fee, renewal form, and statement of compliance with continuing education requirements.

D. A pharmacist who fails to renew his license for more than one year following expiration and who wishes to reinstate such license shall submit an application for reinstatement, pay the current renewal fee and a reinstatement fee, and submit documentation showing compliance with continuing education requirements. Reinstatement is at the discretion of the board and may be granted by the executive director of the board provided no grounds exist to deny said reinstatement.

E. A pharmacist who has been registered as inactive for more than one year must apply for reactivation, submit documentation showing compliance with continuing education requirements, and pay the difference between the inactive fee and the current year active renewal fee in order to resume active licensure.

F. In order to reactivate or reinstate a license to active status, a pharmacist who holds an inactive license, who has allowed his license to lapse, or who has had his license suspended or revoked must submit evidence of completion of CEUs or hours equal to the requirements for the number of years in which his license has not been active, not to exceed a total of 60 hours of CE.

G. A pharmacist whose license has been lapsed, is in inactive status, or has been suspended or revoked for more than five years shall, as a condition of reinstatement or reactivation in addition to 60 hours CE, take and receive a passing score on the board-approved law examination and furnish acceptable documentation of one of the following:

1. Active pharmacy practice within the past five years as a properly licensed pharmacist in another state; or

2. Practical experience as a pharmacy intern registered with the board of at least 160 hours within six months immediately prior to being reinstated or reactivated.

H. The practice of pharmacy without a current, active pharmacist license is unlawful and shall constitute grounds for disciplinary action by the board.

18VAC110-21-120. Requirements for continuing education.

A. A pharmacist shall be required to have completed a minimum of 1.5 CEUs or 15 contact hours of continuing pharmacy education in an approved program for each annual renewal of licensure. CEUs or hours in excess of the number required for renewal may not be transferred or credited to another year.

B. A pharmacy education program approved for continuing pharmacy education is:

1. One that is approved by the ACPE;

2. One that is approved as a Category I continuing medical education course, the primary focus of which is pharmacy, pharmacology, or drug therapy; or

3. One that is approved by the board in accordance with the provisions of 18VAC110-21-130.

C. Of the 15 contact hours required for annual renewal, at least five hours shall be obtained in courses or programs that are live or real-time interactive. Included in the five hours, the following may be credited:

1. A maximum of one hour for attendance at a board meeting or formal hearing; or

2. A maximum of one hour for serving as a preceptor for a pharmacy student or resident in an accredited school or program or for a foreign-trained student obtaining hours of practical experience.

D. The board may grant an extension pursuant to § 54.1-3314.1 E of the Code of Virginia. Any subsequent extension shall be granted only for good cause shown.

E. Pharmacists are required to attest to compliance with the CE requirements in a manner approved by the board at the time of their annual license renewal. Following each renewal period, the board may conduct an audit of the

immediate past two years CE documents to verify compli - ance with the requirements. Pharmacists are required to maintain for two years following renewal the original certificates documenting successful completion of CE, showing the date and title of the CE program or activity, the number of CEUs or contact hours awarded, and a certifying signature or other certification of the approved provider. Pharmacists selected for audit must provide these original documents to the board by the deadline date specified by the board in the audit notice.

18VAC110-21-130. Approval of continuing education programs.

A. The board will approve without application or further review any program offered by an ACPE-approved provider and will accept for credit certificates bearing the official ACPE logo and program number.

B. The board may approve an individual CE program under the following provisions:

1. An approved individual program is a course, activity, or lecture that includes subject matter related to the competency of the practice of pharmacy and that has been approved for CE credit by the board.

2. In order to receive approval for an individual program, the sponsor or provider must apply prior to offering the program on a form provided by the board. The information that must be provided shall include:

a. Name of provider;

b. Location;

c. Date and time of program;

d. Charges to participants;

e. Description of program content and objectives;

f. Credentials of speaker or author;

g. Method of delivery;

h. Evaluation procedure;

i. Evidence of a post assessment;

j. Credits requested;

k. Mechanism for recordkeeping; and

l. Any such information as the board deems necessary to assure quality and compliance.

3. The sponsor applying for board approval of an individual program shall pay a fee as required in 18VAC110-21-20 C 5.

4. The board shall notify the provider or sponsor within 60 days following the receipt of a completed application of approval or disapproval of a program and the number of credits that may be awarded. The board shall also assign an expiration date for approval of the program not to exceed two years from the date of approval.

5. The provider of an approved program shall provide to each participant who completes the required hours and passes the post-test a certification with the name of the provider, name of the participant, description of course and method of delivery, number of hours credited, date of completion, and program identification number.

6. The provider of an approved program shall maintain all records on that program, program participants, and hours awarded for a period of five years and shall make those records available to the board upon request.

7. The board shall periodically review and monitor programs. The provider of a CE program shall waive registration fees for a representative of the board for that purpose.

8. Any changes in the information previously provided about an approved program or provider shall be submitted, or the board may withdraw its approval. If a provider wants to give a live program more than once, all program

dates shall either be submitted on the original application or provided to the board in subsequent correspondence at least five days prior to giving the program.

Part IV

Requirements for Pharmacy Technician Registration

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

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~~ ***national certification.***

Commented [NACDS9]: Consistent with the comment above regarding PTCB:

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

18VAC110-21-150. Criteria for approval for training programs.

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

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

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

2. The preparation of prescription labels or patient information;

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

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

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

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

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

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

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

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

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

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

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

18VAC110-21-160. Examination.

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

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

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

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

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

A. Pharmacy technician registrations expire on December 31 and shall be renewed annually prior to that date by the submission of a renewal fee and renewal form. A pharmacy technician newly registered on or after July 1 shall not be required to renew that registration until December 31 of the following year. Failure to receive the application for renewal shall not relieve the pharmacy technician of the responsibility for renewing the registration by the expiration date.

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

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

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

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

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

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

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

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

CHAPTER 50

REGULATIONS GOVERNING WHOLESALE DISTRIBUTORS, MANUFACTURERS, THIRD-PARTY LOGISTICS PROVIDERS, AND WAREHOUSERS

18VAC110-50-40. Safeguards against diversion of drugs.

A. The holder of the license as a wholesale distributor or permit as a manufacturer, warehouser, or third-party logistics provider, or registration as a nonresident wholesale distributor or nonresident manufacturer shall restrict all areas in which prescription drugs are stored or kept for sale to only those persons specifically designated as necessary for the manufacture, receipt, storage, distribution, or quality control of the controlled substance inventory and shall provide reasonable security measures to include appropriate locking devices on all access doors to these areas and adequate lighting both inside and outside the facility to deter unauthorized entry and diversion.

B. The holder of the license, permit, or registration, except for those distributors of only medical gases other than nitrous oxide, shall install a device for the detection of breaking subject to the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.

2. ~~The~~One communication line installation shall be hardwired and both the installation and device shall be based on accepted burglar alarm industry standards to include wireless motion sensors.

3. The device shall be maintained in operating order ~~and~~, shall have an auxiliary source of power, and shall be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational.

4. The device shall fully protect all areas where prescription drugs are stored and shall be capable of detecting breaking by any means when activated.

5. Access to the alarm system shall be restricted to the person named on the application as the responsible party or to persons specifically designated in writing in a policy and procedure manual.

6. The system shall be activated whenever the drug storage areas are closed for business.

C. Distribution or delivery of prescription drugs shall be accomplished in a manner to prevent diversion or possession of drugs by unauthorized persons.

1. The holder of the license, permit, or registration shall only deliver prescription drugs to a person authorized to possess such drugs at a location where the person is authorized to possess such drugs, ~~and~~ only at a time when someone authorized to possess such drugs is in attendance.

2. The holder of the license, permit, or registration shall affirmatively verify that the person to whom prescription drugs are delivered is authorized by law to receive such drugs.

3. Prescription drugs may be transferred to an authorized agent of a person who may lawfully possess prescription drugs, provided the transfer occurs on the premises of the wholesale distributor, manufacturer, warehouser, third-party logistics provider, nonresident wholesale distributor, or nonresident manufacturer and provided the identity and authorization of the agent is verified, and such transfer is only used to meet the immediate needs of a patient ~~or patients~~.

Part II

Wholesale Distributors and Third-Party Logistics Providers

18VAC110-50-60. Special or limited-use licenses.

The board may issue a limited-use wholesale distributor license,~~;~~ limited-use nonresident wholesale distributor registration~~;~~; or limited-use manufacturer, limited-use nonresident manufacturer, or limited-use third-party logistics provider permit to entities that do not engage in the wholesale distribution of prescription drugs or in the acts of a third-party logistics provider except medical gases and may waive certain requirements of regulation based on the limited nature of such distribution. The issuance of such a license shall be subject to continuing compliance with the conditions set forth by the board.

18VAC110-50-80. Minimum qualifications, eligibility, and responsible party.

A. The board shall use the following factors in determining the eligibility for licensure of wholesale distributors, registration of nonresident wholesale distributors, and permitting of third-party logistics providers:

1. The existence of grounds to deny an application as set forth in § 54.1-3435.1 of the Code of Virginia;

2. The applicant's past experience in the manufacture or distribution of drugs or devices;

3. Compliance with the recordkeeping requirements;

4. Prior disciplinary action by a regulatory authority, prior criminal convictions, or ongoing investigations related to the manufacturing, distribution, prescribing, or dispensing of drugs by the responsible party or immediate family members of the responsible party, and owners, directors, or officers; and

5. The responsible party's credentials as set forth in subsection B of this section.

B. Requirements for the person named as the responsible party.

1. The responsible party shall be the primary contact person for the board as designated by the wholesale distributor, nonresident wholesale distributor, or third-party logistics provider, who shall be responsible for managing the wholesale distribution operations at that location;

2. The responsible party shall have a minimum of two years of verifiable experience in a pharmacy or wholesale distributor or third-party logistics provider licensed, registered, or permitted in Virginia or another state where the person's responsibilities included~~, but were not limited to,~~ managing or supervising the recordkeeping, storage, and shipment for drugs or devices;

3. A person may only serve as the responsible party for one wholesale distributor license, nonresident wholesale distributor registration, or third-party logistics provider permit at any one time;

4. The responsible party shall be employed full time in a managerial position and actively engaged in daily operations of the wholesale distributor, nonresident wholesale distributor, or third-party logistics provider;

5. The responsible party shall be present on a full-time basis at the location of the wholesale distributor, nonresident wholesale distributor, or third-party logistics provider during normal business hours, except for time periods when absent due to illness, family illness or death, vacation, or other authorized absence; and

6. The responsible party shall be aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale distributor, nonresident wholesale distributor, or third-party logistics provider and all applicable state and federal laws related to wholesale distribution of prescription drugs or the legal acts of a third-party logistics provider.

C. The person named as the responsible party on the application shall submit the following with the application:

1. A passport size and quality photograph taken within 30 days of submission of the application;

2. A resume listing employment, occupations, or offices held for the past seven years including names, addresses, and telephone numbers of the places listed;

3. An attestation disclosing whether the person has a criminal conviction or is the subject of any pending criminal charges within or outside the Commonwealth;

4. A federal criminal history record check ~~through the Central Criminal Records Exchange~~; and

5. A description of any involvement by the person with any business, including any investments, other than the ownership of stock in publicly traded company or mutual fund, during the past seven years, which manufactured, administered, prescribed, distributed, or stored drugs and devices and any lawsuits, regulatory actions, or criminal convictions related to drug laws or laws concerning third-party logistics providers or wholesale distribution of prescription drugs in which such businesses were named as a party.

D. Responsibilities of the responsible party.

1. Ensuring that any employee engaged in operations is adequately trained in the requirements for the lawful and appropriate wholesale distribution of prescription drugs or the legal acts of a third-party logistics provider;

2. Requiring any employee who has access to prescription drugs to attest that ~~he~~the employer has not been convicted of any federal or state drug law or any law relating to third-party logistics providers or to the manufacture, distribution, or dispensing of prescription drugs;

3. Maintaining current working knowledge of requirements for wholesale distributors or third-party logistics providers and assuring continued training for employees;

4. Maintaining proper security, storage, and shipping conditions for all prescription drugs; and

5. Maintaining all required records.

E. Each nonresident wholesale distributor shall designate a registered agent in Virginia for service of any notice or other legal document. Any nonresident wholesale distributor that does not so designate a registered agent shall be deemed to have designated the Secretary of the Commonwealth to be its true and lawful agent, upon ~~who~~whom may be served all legal process in any action or proceeding against such nonresident wholesale distributor. A copy of any such service of legal documents shall be mailed to the nonresident wholesale distributor by the board by certified mail at the address of record.

NOTICE: Forms used in administering the regulation have been filed by the agency. The forms are not being published; however, online users of this issue of the Virginia Register of Regulations may click on the name of a form with a hyperlink to access it. The forms are also available from the agency contact or may be viewed at the Office of the Registrar of Regulations, 900 East Main Street, 11th Floor, Richmond, Virginia 23219.

FORMS (18VAC110-50)

Application for a Permit as a Restricted Manufacturer (rev. ~~3/09).~~3/2009)

Application for a Permit as a Nonrestricted Manufacturer (rev. ~~3/09).~~3/2009)

Application for a Permit as a Warehouser (rev. ~~3/09).~~3/2009)

Application for a License as a Wholesale Distributor (rev. ~~3/09).~~3/2009)

Application for a Nonresident Wholesale Distributor Registration (rev. ~~9/08).~~9/2008)

Application for a License as a Wholesale Distributor - Limited Use for Distribution of Medical Gases Only (rev. 3/2010)~~.~~

Application for a Permit as a Third-Party Logistics Provider (eff. 9/2017)

Remedi SeniorCare®

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Virginia Board of Pharmacy
Department of Health Professions
9960 Mayland Drive, Suite 300
Henrico, VA 23233

Attn: Elaine Yeatts

February 14, 2019

RE: Public Comment - Periodic review result of Chapters 20 and 50; Promulgation of Chapters 16 and 25

To whom it may concern:

Remedi SeniorCare appreciates the Board of Pharmacy's action to amend 18VAC110-20 and 18VAC110-50. While the majority of these amendments will continue to expand the availability of pharmacy services within the Long Term Care industry allowing pharmacies to better serve the residents of Long Term Care Facilities within the Commonwealth, we have concerns specifically with the language proposed in 18VAC110-20-520. In addition we have concerns regarding the impact some amendments will have on the practice of pharmacy as outlined in subsequent sections.

We request the board take the following into consideration when revising the regulations:

1. **18VAC110-20-10. Definitions.**
   "Initials" means the first letters of a person's name or other unique personal identifier.

We would ask the board clarify what "first letters" is intended to suggest. Standard of practice would be to include at least the first letters of a person's first and last name to constitute initials.

2. **18VAC110-20-110. Pharmacy permits generally.**
   D. A pharmacist shall not be eligible to serve as PIC until after having obtained a minimum of two years of experience practicing as a pharmacist in Virginia or another jurisdiction in the United States. The board may grant an exception to the minimum number of years of experience for good cause shown.

We would ask the board to remove this mandate. There is not sufficient published evidence in the industry to suggest that prohibiting a newly licensed pharmacist from holding PIC positions prevents pharmacy deficiencies. Alternatively, one of the most egregious violations in the Commonwealth occurred in 2015 when the board took action against a Henrico pharmacy for multiple violations including loss of over 50,000 doses of controlled drugs and high-risk compounding violations. The PIC in this pharmacy had been licensed by the board for over 20 years. Further all pharmacists licensed regardless of their years of professional service, have passed the same competency law test within the commonwealth. The board has not quantified in the published documents the economic impact of how many pharmacists licensed for less than two years, currently holding PIC positions would be affected. The board has not provided any guidance on what "good cause shown" is intended to mean. We believe that this regulation could potentially discriminate against younger pharmacists who make up the majority of new graduates.

3. **18VAC110-20-520. Drugs in long-term care facilities.**
   9(B) 1. The pharmacy providing services to the long-term care facility has a written contract with the other pharmacy outlining services to be provided, the recordkeeping associated with the dispensing, and the responsibilities of each pharmacy; and

We ask the board to consider amending the language. Pharmacies servicing long term care facilities often provide services across large geographic regions working with multiple local pharmacies to ensure urgent new orders are available to long term care residents. In addition, multiple back-up pharmacies may have to be consulted to find the

medication needed for a specific resident. We believe the burden of record keeping and processes should lie upon the pharmacy providing services to the long-term care facility; rather than shared between the secondary pharmacy. Secondary pharmacies filling these orders should have no additional requirements other than the traditional regulatory requirements to filling an oral or written prescription as defined in regulation. ***Requiring long-term care pharmacies to enter into individual contracts with each pharmacy would pose significant legal expenses in order to contract with each pharmacy providing services. Further, many pharmacies may be unwilling to participate due to the additional requirements and legal expenses, limiting care to the geriatric population in the Commonwealth.*** The requirements of this subsection should not be more restrictive than issuing a copy of a prescription which does not require a written contract between the pharmacies as stated in 18VAC110-20-360.

We propose the following language for 9(B) 1: *Each pharmacy involved in the dispensing shall maintain records as outlined in 18VAC110-20-240. The pharmacy providing services to the long-term care facility shall conduct a prospective drug review consistent with § 54.1-3319 A of the Drug Control Act prior to sharing a copy of the prescription or order, and shall be responsible for documenting the pharmacy name, address and quantity to which the copy was shared.*

4. **18VAC110-20-25. Unprofessional conduct.**
   The following practices shall constitute unprofessional conduct within the meaning of § 54.1-3316 of the Code of Virginia:
   10. Violating any provision of this chapter, 18VAC110-20, or Chapter 33 (§ 54.1-3300 et seq.) or 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia;

We ask the board to consider the impact that the language in this subsection has on the practice of pharmacy within the commonwealth. With the implementation of this subsection, **ALL** pharmacists who make any error or violation would be considered to have engaged in "Unprofessional Conduct". To further clarify, a pharmacist who fails to write the word "TRANSFER" on a single prescription under 18VAC110-20-360, would be guilty of "Unprofessional Conduct" as outlined in the proposed regulation. While a violation of any aforementioned subsection **MAY** constitute "Unprofessional Conduct"; the boards use of **SHALL** removes any authority form the board to determine a minor infraction from an egregious or unethical behavior.

We propose the following language: The following practices **MAY** constitute unprofessional conduct within the meaning of § 54.1-3316 of the Code of Virginia:
-OR-
10. **Willful or grossly negligent failure to comply with** any provision of this chapter, 18VAC110-20, or Chapter 33 (§ 54.1-3300 et seq.) or 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia;

In closing, Remedi SeniorCare appreciates the Board of Pharmacy for their review of these important differences regarding the proposed revision to regulation. We look forward to improved care for the residents of Long Term Care Facilities and advancing the practice of pharmacy within the Commonwealth.

Respectfully,

R. Dale StClair, Jr, PharmD, RPh
Vice President, East Region
Remedi SeniorCare
Virginia Pharmacist: 0202208333

CVSHealth

Mark Johnston, PharmD | 200 Highland Corporate Drive | Woonsocket, RI 02895 | T: (401)601-1968

February 20, 2019

Caroline Juran, RPH
Executive Director
Virginia Board of Pharmacy
9960 Mayland Drive
Suite 300
Richmond, VA 23233-1463
Caroline.juran@dhp.virginia.gov

Re: CVS Health's comments on Virginia Board of Pharmacy periodic review of regulations in chapter 20 and 50.

Dear Executive Director Juran:

I am writing to you in my capacity as Senior Director of Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points of care to patients in the state of Virginia through our integrated offerings across the spectrum of pharmacy care. CVS Health appreciates the opportunity to submit comments on the Virginia Board of Pharmacy periodic review of regulations in chapter 20 and 50. Our suggested rule language changes are listed in red and *italicized* throughout this letter. We would also like to thank the Board for their vigilance to continuously improve the laws and regulations that guide pharmacists, pharmacy interns, and pharmacy technicians serving Virginia patients.

Supporting the Pharmacist

Community pharmacists provide high quality, accessible patient care services, including medication management, immunizations, preventive screenings, and chronic care management. Despite a growing need for increased access to patient care services, community pharmacists spend only 21% of their professional time performing patient care services that are not associated with dispensing prescriptions.[1] To further enhance and optimize patient care services delivered at community pharmacies, leveraging and expanding current roles of the pharmacy technician should be considered in community pharmacies. This means working towards a unified vision for pharmacy technician practice, which includes removing antiquated supervision requirements and expanding technician roles related to dispensing medications and supporting patient care services.[2] Increasing the scope of pharmacy technicians to include administrative and supportive tasks for pharmacist-provided patient care services will allow pharmacists to more effectively and efficiently provide for patients' medication-related needs.[3] Most importantly, some states have a patient safety track record of success with expanded pharmacy technicians roles that spans over four decades.[4]

- We request that the Board amend the definition of personal supervision in 18VAC110-20-10 to allow for emerging technology to safely assist pharmacists in the communication and observation of pharmacy technicians.[5]
- We request the that the Board follow the lead of the National Association of Boards of Pharmacy (NABP) Model Act and 21 other states to remove the ratio supervision requirements proposed in 18VAC110-20-112(A).[6]
- We request that the Board amend 18VAC110-20-360 to permit pharmacy technicians to transfer prescriptions.[4]

Suggested language:
18VAC110-20-10. Definitions.
"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act being performed. ~~*Neither prior nor future instructions shall be sufficient nor shall supervision rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.*~~ *or must be readily and immediately available through the use of real time, two-way technology communications between the pharmacist and technician(s).*

1. A pharmacist using technology as an adjunct to assist in the personal supervision of the pharmacy technician shall make certain all applicable state and federal laws, including, but not limited to confidentiality, are fully observed when employing technological means of communication and observation.
2. If technology is being used to provide personal supervision of pharmacy technician(s), such technology shall be sufficient to provide the personal assistance, direction and approval required to meet the standard of practice for the delegated tasks.

Suggested language:
18VAC110-20-112. Supervision of pharmacy technicians.
A. A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time. ~~; however, no pharmacist shall supervise more than four persons performing the duties of a pharmacy technician at one time.~~
B. In addition to the acts restricted to a pharmacist in §54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians.

Suggested language:
18VAC110-20-360. Issuing a copy of a prescription that can be filed or refilled.
A. Consistent with federal laws and regulations, a copy of a prescription shall be given upon request by one pharmacy to another pharmacy provided the drug can be filled or refilled pursuant to §§ 54.1-3410 and 54.1-3411 of the Code of Virginia and provided the patient has given permission for the transfer.
B. The transfer of original prescription information for a drug listed in Schedules III through VI for the purpose of dispensing is permissible between pharmacies if the transfer is communicated directly between the two pharmacies either orally by direct communication ~~between the transferring pharmacist and the receiving pharmacist~~, or by facsimile machine or by electronic transmission, provided:
1. The transferring pharmacy:
a. Records the word "VOID" on the face of the invalidated prescription;
b. Records on the reverse of the invalidated prescription the name, address, and, except for a prescription for a Schedule VI drug, the DEA number of the pharmacy to which it was transferred, and, for an oral transfer, the name of the *pharmacist or pharmacy technician* receiving the prescription information;
c. Records the date of the transfer and, in the case of an oral transfer, the name of the *pharmacist or pharmacy technician* transferring the information; and
2. The receiving pharmacy:
a. Writes the word "TRANSFER" on the face of the transferred prescription.
b. Provides all information required to be on a prescription to include:
(1) Date of issuance of original prescription;
(2) Original number of refills authorized on the original prescription;
(3) Date of original dispensing, if applicable;
(4) Number of valid refills remaining and date of last dispensing;
(5) Pharmacy name, address, DEA registry number, except for Schedule VI prescriptions, and original prescription number from which the prescription information was transferred; and
(6) Name of transferring pharmacist~~,~~ *or pharmacy technician* if transferred orally.
Both the original and transferred prescription shall be maintained for a period of two years from the date of last refill.
C. Nothing in this chapter shall prevent the giving of a prescription marked "For Information Only" to a patient.
D. In lieu of recording the required information in subsection B of this section on a hard copy prescription, a pharmacy may record all required information in an automated data processing system used for storage and retrieval of dispensing information in accordance with 18VAC110-20-250.
E. For prescriptions transferred between pharmacies using a common database, the pharmacy receiving the prescription shall not be required to maintain a hard copy pursuant to 18VAC110-20-240 B provided that the system used is capable of generating a hard copy of the transferred prescription upon request or except as required by federal law.

CVSHealth

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Supporting the Community

There are a variety of situations or natural disasters that can directly effect the temporary closing of community pharmacies across Virginia. In these events, patients can lose critical access to pharmacy services resulting in a fragmentation of their prescription medication management care. Mobile and temporary pharmacies have played a key role in other jursidictions in aiding patients to maintain or stabilize their health as they recover from the disaster's impact on other areas of their lives.[7-8]

- We request the Board amend 18VAC110-20-150(A) and (C) to permit pharmacies to aid Virginia communities with temporary pharmacy services during emergency situations.

Suggested Language:

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

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

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

C. The pharmacy shall be constructed of permanent and secure materials. Trailers or other moveable facilities or temporary construction shall ~~not only~~ be permitted *in a declared emergency pursuant to §54.1-3307.3 of the Code of Virginia*.

Dispensing of Prescriptions

CVS Health commends the Board for the proposed changes in in 18VAC110-20-270(D) and (F). We support all efforts that increase patient access to pharmacy services by allowing patients to utilize a drop box at their local pharmacy for the collection of written prescriptions and refill requests. We support the Board allowing pharmacists to use their professional judgment when determining whether or not to refuse to return forged prescriptions to patients. We believe the proposed changes align with the Drug Enforcement Admininstration (DEA) guidance publication to pharmacists on prescription fraud.[9] Empowering pharmacists to engage in all aspects of the prescription adaptation process can lead to improved medication management while promoting efficiencies between pharmacists and prescribers.[10-11] As the pharmacist's role in community pharmacies continues to transition to delivering a higher order of clinical care, it is vital to allow pharmacists the professional judgment to determine what practice models of the dispensing process best assist the needs of our patients.[1]

- We recommend the Board amend the title of 18VAC110-20-270 to remove supervision of pharmacy technicians, as the proposed supervision of pharmacy technician rule now rests in 18VAC110-20-112.
- We request the Board amend 18VAC110-20-270(B) for alignment with the DEA signature requirements for written prescriptions.[10]
- We request the Board amend proposed rule 18VAC110-20-270(E)(1-4) allowing adaptation of an existing prescription when, in the pharmacist professional judgment, the action is intended to optimize the therapeutic outcome of patient treatment.[11-12]
- We request the Board continue requiring both data entry verification and prospective drug utilization review as required by 18VAC110-20-270(F), but request that the Board amend the rule to allow for technical workflow efficiencies for on-hold prescriptions that increase pharmacists ability to spend time with patients.
- We request the Board strike 18VAC110-20-110(D) as is there is no published evidence that suggests a pharmacist graduating from an ACPE accredited college of pharmacy is not prepared and professionally capable to safely fulfill the duties of a PIC immediately upon passing the MPJE jurisprudence exam and licensure.

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Suggested Language:

18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions.~~; supervision of pharmacy technicians.~~

A. In addition to the ~~acts restricted to a pharmacist in § 54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians.~~

~~B. A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time; however, no pharmacist shall supervise more than four persons acting as pharmacy technicians at one time~~ requirements in §54.1-3408.01 of the Code of Virginia for an oral prescription or written prescription, including those transmitted via facsimile or electronically, a prescription shall include a quantity, or duration of the order by which the pharmacist can calculate the authorized quantity using directions for use. Except for prescriptions transmitted electronically in compliance with 18VAC110-20-285, written prescriptions *for controlled substances* shall also include the prescriber's manual signature.

~~C.~~B. After the prescription has been prepared and prior to the delivery of the order, a pharmacist shall inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction. If more than one pharmacist is involved in verifying the accuracy of the prescription product, a record shall be maintained identifying the date of dispensing, each pharmacist involved in the process, and the individual task for which he is responsible for verifying the accuracy. Such record showing verification of accuracy shall be maintained on a pharmacy record and, if necessary, an alternate record consistent with 18VAC110-20-255 for the required time period of two years, unless otherwise specified in regulation. If the dispensing involves central or remote processing, records of pharmacist verification shall be maintained in a manner consistent with 18VAC110-20-276 and 18VAC110-20-515.

~~D.~~C. If a pharmacist declines to fill a prescription for any reason other than the unavailability of the drug prescribed, he shall record on the back of the prescription the word "declined"; the name, address, and telephone number of the pharmacy; the date filling of the prescription was declined; and the signature of the pharmacist.

~~E.~~D. If a pharmacist determines from a prescriber or by other means, including the use of his professional judgment, that a prescription presented for dispensing is a forgery, the pharmacist shall not may refuse to return the forged prescription to the person presenting it. The forged prescription may be given to a law-enforcement official investigating the forgery; or it shall be retained for a minimum of 30 days before destroying it, in the event it is needed for an investigative or other legitimate purpose.

E. Upon patient consent, a pharmacist using professional judgement and acting in the best interest of patient care may adapt a prescription as specified in this rule, provided the drug is not for a controlled substance, and provided that the prescriber has not indicated by any means necessary that adaptation is not permitted.

1. A pharmacist may change the quantity, dosage, dosage form, or direction of medication dispensed if it meets the intent of the prescriber.

2. A pharmacist may complete missing information on a prescription if there is sufficient evidence to support the change.

3. A pharmacist may extend a maintenance drug for the limited quantity necessary to coordinate a patient's refills in medication synchronization program.

4. A pharmacist who adapts a prescription in accordance with these rules must document the adaptation in the patient's record.

~~F.~~E.*F.* An on-hold prescription shall be entered into the automated data processing system if such system is employed by the pharmacy, and the pharmacist ~~on duty~~ shall verify the accuracy of the data entry ~~at that time. The pharmacist subsequently dispensing the on-hold prescription on a future date shall, at a minimum,~~ *and* conduct a prospective drug review consistent with § 54.1-3319 A of the Code of Virginia. If an on-hold prescription is returned to a patient prior to the initial dispensing of the drug, the pharmacist shall delete the entry in the automated data processing system.

~~F.~~*G.* A pharmacy may utilize a drop box for the collection of written prescriptions and refill requests. The drop box shall be located in a visible area within the permitted facility and shall be locked at all times with access to the items placed in the drop box restricted to pharmacists practicing at the pharmacy or an authorized pharmacy technician practicing at the pharmacy when a pharmacist is on duty. The drop box shall be constructed in a manner to prevent the theft or loss of a written prescription or confidential information and shall be bolted to the floor or a fixed

structure. Pharmacists shall in some manner inform the public that containers left in a drop box for refill should not contain unused drugs.

18VAC110-20-110. Pharmacy permits generally.
A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.
B. Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day and shall allow at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break.
C. The pharmacist-in-charge (PIC) PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.
~~*D. A pharmacist shall not be eligible to serve as PIC until after having obtained a minimum of two years of experience practicing as a pharmacist in Virginia or another U.S. jurisdiction. The board may grant an exception to the minimum number of years of experience for good cause shown.*~~

Dispensing of Prescriptions (Continued)
In 2008, NABP convened the task force on Medication Collection Programs. Based on research conducted and task force recommendation, NABP developed a position statement and model rules for the safe return and resuse of prescription medications in community pharmacy settings.[6,13] CVS Health commends the Board of years ago for incorporating many of the recommendations set forth by NABP in 18VAC110-20-355(E) which are paramount for ensuring the integrity and stability of the medications are maintained. While it is not recommended in the NABP position statement and model rules, we acknowledge the best practices reasoning for 18VAC110-20-355(E)(2) and requiring restocked drugs to be dispensed as soon as possible. However, we believe the current rule does not account for automated counting device and dispensing processes which are stocked with medications that would qualify as fast-moving or high volume and therefore meet the intentions of current community pharmacy restock and reuse best practices.

- We request the Board amend 18VAC110-20-355(E)(2) to permit using returns of dispensed medication that never left the pharmacy or the control of the pharmacy delivery agent to be restocked for resuse in an automated counting device.

Suggested Language:
18VAC110-20-355. Pharmacy repackaging of drug; records required; labeling requirements.
~~D.~~E. A pharmacy may return a dispensed drug to stock for redispensing that has never left the pharmacy premises or the control of the pharmacy delivery agent pursuant to § 54.1-3411.1 A 3 of the Code of Virginia under the following conditions:
1. An expiration date shall be placed on the label prior to returning the drug to stock. In the absence of stability data to the contrary, the date on the label may not exceed the expiration date on the manufacturer's container or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier.
2. The restocked drug shall be used to fill the next prescription received for that product, *unless the restocked drug is used to fill automated counting devices and dispensers*. In the event that the drug is not dispensed prior to the new assigned expiration date, it shall be removed from working stock as expired, and disposed of in accordance with 18VAC110-20-210.
3. If there is no lot number on the label of a drug returned to stock or on the prescription records that can be cross-referenced from the prescription label, the drug shall be removed from stock upon any recall of that drug product and returned to the manufacturer or otherwise disposed of in accordance with 18VAC110-20-210.

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Transmission of Prescriptions and Chart Orders

CVS Health, along with our subsidiary Omnicare, Inc commends the Board for the proposed changes eliminating the 5% pharmacy robotics systems daily random checks in 18VAC110-20-425(5) and adding the first dose immediate drug supply allowance in 18VAC110-20-530(B)(1-2). We believe pharmacies providing first dose services to long-term care facilities through common ownership or written contract will enhance patient care by decreasing delays in therapy from the lag time between the patient's admission and the time it takes the pharmacy to receive new orders. Further, the Board's recommended changes dovetails nicely with the research and recent recommendations of the 2017 NABP task force on long-term care pharmacy rules.[14] CVS Health again commends the Board of years ago for addressing chart order provisions for long-term care pharmacies well before national recommendations were put forth. We believe permitting chart orders in long-term care facilities and correctional facilities streamlines patient care and aligns with the current NABP model rules and task force on long-term care rules recommendations.[6,14]

CVS Health supports the 18VAC110-20-420 unit dose dispensing systems rules as they provide patients necessary access to pharmacy services in long-term care facility settings. We believe 18VAC110-20-420(B) was written pursuant to federal law that has changed since the implementation of the Affordable Care Act (ACA). The ACA mandates caused Centers for Medicare and Medicaid Services (CMS) to promulgate regulations permitting pharmacies to dispense up to a 14-day cycle of medications.[15] Further, CMS regulations exclude antibiotics and drugs that must be dispensed in their original container as indicated in the Food and Drug Administration (FDA) Prescribing Information and drugs that are customarily dispensed in their original packaging to assist patients with compliance.

- We request the Board amend 18VAC110-20-240(C)(1) to align with the NABP model rules and task force on long-term care recomendations by permitting chart orders in correctional facilities.
- We request the Board amend 18VAC110-20-530(B)(1) to additionally align with the NABP model rules and task force on long-term care recomendations by allowing shared pharmacy services for immediate need between pharmacies with common ownership or written contract.
- We request the Board amend 18VAC110-20-420(B) to a maximum of 14-days pursuant to current CMS regulations.

Suggested Language:
18VAC110-20-240. Manner of maintaining records, prescriptions, inventory records.
C. Chart orders.
1. A chart order written for a patient in a hospital, *a correctional facility* or long-term care facility, a patient receiving home infusion services, or a hospice patient pursuant to § 54.1-3408.01 A of the Code of Virginia shall be exempt from having to contain all required information of a written prescription provided:

Suggested Language:
18VAC110-20-530. Pharmacy's responsibilities to long-term care facilities.
B. The pharmacy providing services to the long term care facility may share a copy of a Schedule VI prescription or order with another pharmacy for the purpose of dispensing an immediate supply of drugs, not to exceed a seven-day supply, without transferring the prescription pursuant to 18VAC110-20-360 if the following conditions are satisfied:
1. The pharmacy providing services to the long term care facility has *common ownership or* a written contract with the other pharmacy outlining services to be provided, the recordkeeping associated with the dispensing, and the responsibilities of each pharmacy; and,
2. The pharmacy providing services to the long term care facility provides a valid oral or written prescription or order to the other pharmacy.

Suggested Language:
18VAC110-20-420. Unit dose dispensing system.
B. In providing unit dose systems to hospitals or long-term care facilities where only those persons licensed to administer are administering drugs, the pharmacy shall dispense not more than a ~~seven~~*fourteen*-day supply of a drug in a solid, oral dosage form at any one given time.

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CVS Health appreciates and understands the ongoing effort since 2016 the Board has committed to in order to amend these rules and regulations to reflect the current and evolving practice of pharmacy. We are supportive of the allowance of patient drop boxes, pharmacist professional judgment decisions, removal of the 5% robotic pharmacy systems random checks, first dose for long-term care pharmacies, along with clarifying language that has been added throughout the rules. In order to continue to further the highest order of pharmacy practice, we have proposed suggested amendments to align the language with current trends across the nation which include but are not limited to allowance of pharmacy technician roles that enhance medication dispensing support, emergency temporary pharmacies, restock and resuse of medications, and chart orders in correctional facilties.

CVS Health appreciates the opportunity to submit comments for this periodic review of regulations in chapter 20 and 50. If you have any questions, please contact me directly at (401)601-1968.

Sincerely,

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Small Businesses:

Definition. Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million."

Costs and Other Effects. The proposed amendment does not create costs. In addition, it should not have other effects on small businesses as genetic counselors usually practice in large medical institutions/hospital systems.

Alternative Method that Minimizes Adverse Impact. The proposed amendment does not have adverse effects on small businesses.

Adverse Impacts:

Businesses. The proposed amendment should benefit large institutions/hospital systems by preventing a potential disruption in their employment of successful genetic counselor candidates.

Localities. The proposed amendment would not adversely affect localities.

Other Entities. The proposed amendment would not adversely affect other entities.

Agency's Response to Economic Impact Analysis: The Board of Medicine concurs with the analysis of the Department of Planning and Budget.

Summary:

The amendment clarifies that if an applicant fails the licensure examination for genetic counseling, the applicant's active candidate status is terminated and the applicant is no longer eligible for a temporary license. An applicant who passes the examination may continue to practice with a temporary license until a permanent license has been issued.

18VAC85-170-60. Licensure requirements.

A. An applicant for a license to practice as a genetic counselor shall provide documentation of (i) a master's degree from a genetic counseling training program that is accredited by the Accreditation Council of Genetic Counseling and (ii) a current, valid certificate issued by the ABGC or ABMG to practice genetic counseling.

B. Pursuant to § 54.1-2957.19 D of the Code of Virginia, applicants for licensure who do not meet the requirements of subsection A of this section may be issued a license provided they (i) apply for licensure before December 31, 2018; (ii) comply with the board's regulations relating to the NSGC Code of Ethics; (iii) have at least 20 years of documented work experience practicing genetic counseling; (iv) submit two letters of recommendation, one from a genetic counselor and another from a physician; and (v) have completed, within the last five years, 25 hours of continuing education approved by the NSGC or the ABGC. For the purpose of this subsection, the board deems the provisions of Part IV (18VAC85-170-110 et seq.) of this chapter to be consistent with the NSGC Code of Ethics.

C. An applicant for a temporary license shall provide documentation of having been granted the active candidate status by the ABGC. Such license shall expire 12 months from issuance or upon ~~expiration of active candidate status~~ failure of the ABGC certification examination, whichever comes first.

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BOARD OF PHARMACY

Proposed Regulation

Titles of Regulations: **18VAC110-15. Regulations for Delegation to an Agency Subordinate (adding 18VAC110-15-10).**

18VAC110-20. Regulations Governing the Practice of Pharmacy (amending 18VAC110-20-10, 18VAC110-20-20, 18VAC110-20-25, 18VAC110-20-110, 18VAC110-20-140, 18VAC110-20-150, 18VAC110-20-180, 18VAC110-20-200, 18VAC110-20-211, 18VAC110-20-220, 18VAC110-20-240, 18VAC110-20-270, 18VAC110-20-280, 18VAC110-20-290, 18VAC110-20-355, 18VAC110-20-390, 18VAC110-20-425, 18VAC110-20-470, 18VAC110-20-490, 18VAC110-20-530, 18VAC110-20-550, 18VAC110-20-580, 18VAC110-20-630, 18VAC110-20-680; adding 18VAC110-20-112; repealing 18VAC110-20-15, 18VAC110-20-21, 18VAC110-20-30 through 18VAC110-20-106).

18VAC110-21. Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians (adding 18VAC110-21-10 through 18VAC110-21-180).

18VAC110-50. Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers (amending 18VAC110-50-40, 18VAC110-50-60, 18VAC110-50-80).

Statutory Authority: §§ 54.1-2400 and 54.1-3307 of the Code of Virginia.

Public Hearing Information:

January 9, 2019 - 9:05 a.m. - Perimeter Center, Commonwealth Conference Center, 9960 Mayland Drive, Suite 201, Board Room 4, Henrico, VA 23233

Public Comment Deadline: February 22, 2019.

Agency Contact: Caroline Juran, RPh, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4456, FAX (804) 527-4472, or email caroline.juran@dhp.virginia.gov.

Basis: Chapter 24 (§ 54.1-2400 et seq.) of Title 54.1 of the Code of Virginia establishes the general powers and duties of health regulatory boards, including the responsibility to promulgate regulations and establish renewal schedules. The specific authority to control prescription drugs in the Commonwealth is found in Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia.

Purpose: Regulation of the practice of pharmacy is both complex and essential to public health and safety. The Board of Pharmacy takes seriously its statutory responsibility to ensure the safety, integrity, and efficacy of prescription drugs in the Commonwealth. At the same time, the practice of pharmacy is constantly changing as new technologies become available. To incorporate efficiency and cost-effectiveness, rules for pharmacy practice must be changed while balancing the assurances that controlled substances are dispensed in a manner that protects from medication error and diversion that is harmful to the patient and the community.

Substance: As part of the periodic review, the board determined that provisions in 18VAC110-20 relating to the licensure of pharmacists and registration of pharmacy technicians should be re-promulgated into a separate chapter, 18VAC110-21, to reduce the size and complexity of this chapter. Some of Part I, General Provisions, will be included in a new chapter, and all of Parts II and III will be repealed and restated. Additionally, 18VAC110-20-15, Criteria for delegation of informal fact-finding proceedings to an agency subordinate, will be moved into a separate chapter, 18VAC110-15, because it applies to all types of licensees, registrants, and permit holders regulated by the board.

Issues: The primary advantage to the public may be stronger provisions defining unprofessional conduct, such as "performing any act likely to deceive, defraud, or harm the public." While the board may currently be able to establish grounds for disciplinary action, additional specificity strengthens the ability of the board to take action if there is harm to the public. There are no disadvantages to the public. With exception of clearer rules for licensees, there are no advantages or disadvantages to the agency.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. As the result of a periodic review,[1] the Board of Pharmacy (Board) proposes to mainly update and reformat the regulation to improve clarity and readability. The proposed regulation also contains a number of changes to address issues identified in practice or to streamline enforcement.

Result of Analysis. The benefits likely exceed the costs.

Estimated Economic Impact. The majority of the changes in this action are intended to improve clarity and readability of the regulation without introducing any new requirements or altering existing ones. However, there are proposals that represent a change in practice. One such change is the proposed update of the practices that constitute unprofessional conduct. Based on situations encountered in disciplinary cases and/or included in other chapters enacted by other health regulatory boards, the Board proposes to update what constitutes unprofessional conduct. For example, obtaining money or property of a patient by fraud or misrepresentation, providing false information to the compliance inspector, performing acts to deceive, defraud, or harm the public are now listed in this section. This change does not directly affect any particular person or entity at this time but may be the basis of a disciplinary action for someone in the future.

In another change, the Board proposes to specify that if the pharmacy is not operational within 90 days from issuance of a new permit, the permit is rescinded unless an extension is granted. Normally, controlled substances should not be left in a facility that is not operational. This change was prompted by a questionable pharmacy operation that came to the Board's attention, but the Board could not take action due to lack of authority to rescind such a permit. Under the proposed rule, the Board will allow 90 days from the date the permit is issued for last minute preparations to occur. This change is not expected to have any direct impact on any regulated entity at this time because the questionable pharmacy operation has already been ceased but will likely strengthen the Board's enforcement authority if and when needed.

Similarly, one of the medical equipment suppliers has challenged the Board's authority to request hours of its operation. Medical equipment suppliers are sometimes open for limited hours, complicating enforcement. Without such information, the Board could not effectively schedule an unannounced inspection of the facility. Thus, the Board proposes to require that a medical equipment supplier must designate the hours of operation when it is open to the public and to require notification to the Board and to the public if those hours change. These requirements are similar to those for pharmacies. With the requested information, the Board will know the hours of operation, when the facility is open, and when an inspection can occur.

The Board is also concerned with the adequacy of the current requirements to become a pharmacist-in-charge. There is no minimum experience requirement to become a pharmacist-in-charge, yet the position requires broad knowledge of pharmacy operations and significant responsibilities for the inventory and security of the pharmacy. Thus, the Board proposes to require a minimum of two years of experience before becoming a pharmacist-in-charge. This change will narrow the pool of eligible pharmacists to become a pharmacist-in-charge but will likely improve public safety and protect the pharmacists who might be assigned the job of pharmacist-in-charge before he/she was ready to assume such a responsibility.

The Board proposes to require a temperature record for cold storage units and for maintenance of such record for two years. The facilities are already required to have proper refrigeration equipment to protect the integrity and safety of certain drugs such as vaccines. According to the Department of Health Professions (DHP), inexpensive tools are available to measure and record temperatures in a cold storage. This change will make sure that information to check compliance will be available for review by inspectors. Regulants may also benefit from proper refrigeration by reducing waste of valuable drugs due to exposing drugs to improper temperatures.

The Board proposes to add language that the policy and procedure manual must include provisions for granting and terminating user access in settings where automated devices dispense and administer drugs. According to the Board, it is vital that only appropriately qualified users have access to automated devices that dispense drugs to prevent diversion for personal use or for sale.

The Board proposes to require that five of the required 15 hours of continuing education for annual renewal be obtained in courses or programs that are live or interactive. The Board also proposes to allow two new activities that may be used to fulfill required live or interactive continuing education, including one hour for attendance at a board meeting or hearing and one hour for serving as a preceptor for someone gaining practical experience. The Board believes pharmacists benefit from some interaction in an educational environment, so a portion of continuing hours is proposed to be live or interactive. DHP notes that it would not be necessary for a pharmacist to attend a course in person; participation in an interactive, real-time course would suffice. To the extent live or interactive continuing education is more effective than other settings, this change should be beneficial.

The Board proposes to give a pharmacist who is presented with a forged prescription the option of returning it to the customer or keeping it for law enforcement. Current regulation prohibits the return of a forged prescription, but DHP notes that pharmacists sometimes feel threatened by refusing to return it. The regulation is being amended to give the pharmacist the option depending on the situation. This change will likely help pharmacists to safely get themselves out of a dangerous situation in the case of a criminal attempt to obtain drugs from them by forged prescriptions.

In response to a petition for rulemaking,[2] the Board proposes to allow sharing of prescriptions between a provider pharmacy for a long-term care facility and a back-up pharmacy for such a facility to dispense drugs up to a seven-day supply. Currently, the prescription must be transferred to the back-up facility to dispense any drugs. This change will facilitate coverage when the provider pharmacy experiences a temporary shortage in a medication that is needed at the facility.

Finally, the Board proposes to allow that a stat-drug box may include a substitution of liquid for solid dosage unit for each drug schedule. This change will provide more flexibility to the pharmacies that utilize stat-boxes.

Businesses and Entities Affected. There are 34,789 persons or entities that have been issued a license, registration, or permit by the Board. These entities include, but are not limited to, pharmacists, technicians, interns, pharmacies, manufacturers, wholesalers, warehouses, medical equipment suppliers, etc.

Localities Particularly Affected. The proposed regulation does not affect any particular locality more than others.

Projected Impact on Employment. No significant impact on employment is expected.

Effects on the Use and Value of Private Property. No significant impact on the use and value of private property is expected.

Real Estate Development Costs. No significant impact on real estate development costs is expected.

Small Businesses:

Definition. Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million."

Costs and Other Effects. There is no estimate of the number of small businesses. However, the majority of pharmacies are part of large national chains. The costs and other effects on any small business would be the same as discussed above.

Alternative Method that Minimizes Adverse Impact. The proposed changes are not likely to create a significant adverse impact on small businesses.

Adverse Impacts:

Businesses. The proposed changes are not likely to create a significant adverse impact on businesses.

Localities. The proposed regulation will not adversely affect localities.

Other Entities. The proposed regulation will not adversely affect other entities.

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[1]http://townhall.virginia.gov/l/ViewPReview.cfm?PRid=1466

[2]http://townhall.virginia.gov/L/ViewPetition.cfm?petitionId=233

Agency's Response to Economic Impact Analysis: The Board of Pharmacy concurs with the economic impact analysis of the Department of Planning and Budget.

Summary:

Pursuant to a periodic review, the Board of Pharmacy proposes to (i) move the provisions relating to the licensure of pharmacists and registration of pharmacy technicians from Regulations Governing the Practice of Pharmacy (18VAC110-20) into a new regulatory chapter, Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians (18VAC110-21); (ii) address current issues with practice, clarify requirements, and incorporate provisions currently found in guidance documents in 18VAC110-20 and Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers (18VAC-110-50); and (iii) move the provision regarding the delegation of informal fact-finding proceedings from 18VAC110-20 into a new chapter, Regulations for Delegation to an Agency Subordinate (18VAC110-15).

CHAPTER 15
REGULATIONS FOR DELEGATION TO AN AGENCY SUBORDINATE

18VAC110-15-10. Criteria for delegation of informal fact-finding proceeding to an agency subordinate.

A. Decision to delegate. In accordance with subdivision 10 of § 54.1-2400 of the Code of Virginia, the board may delegate an informal fact-finding proceeding to an agency subordinate upon determination that probable cause exists that a practitioner or an entity may be subject to a disciplinary action.

B. Criteria for delegation. Cases that may not be delegated to an agency subordinate, except as may be approved by a committee of the board, include those that involve:

1. Intentional or negligent conduct that causes or is likely to cause injury to a patient;

2. Drug diversion;

3. Impairment with an inability to practice with skill and safety;

4. Indiscriminate dispensing; and

5. Medication error in administration or dispensing.

C. Criteria for an agency subordinate.

1. An agency subordinate authorized by the board to conduct an informal fact-finding proceeding may include board members and professional staff or other persons deemed knowledgeable by virtue of their training and experience in administrative proceedings involving the regulation and discipline of health professionals.

2. The executive director shall maintain a list of appropriately qualified persons to whom an informal fact-finding proceeding may be delegated.

3. The board may delegate to the executive director the selection of the agency subordinate who is deemed appropriately qualified to conduct a proceeding based on the qualifications of the subordinate and the type of case being heard.

Part I
General Provisions

18VAC110-20-10. Definitions.

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

~~"ACPE" means the Accreditation Council for Pharmacy Education.~~

"Acquisition" of an existing entity permitted, registered, or licensed by the board means (i) the purchase or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor or change in partnership composition; (iii) the acquiring of 50% or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; or (iv) the merger of a corporation owning the entity, or of the parent corporation of a wholly owned subsidiary owning the entity, with another business or corporation.

"Actively reports" means reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error.

"Alternate delivery site" means a location authorized in 18VAC110-20-275 to receive dispensed prescriptions on behalf of and for further delivery or administration to a patient.

"Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.

"Authorized collector" means a narcotic treatment program, hospital, or clinic with an on-site pharmacy, or pharmacy that is authorized by the U.S. Drug Enforcement Administration to receive drugs ~~from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility~~ for the purpose of destruction.

"Beyond-use date" means the date beyond which the integrity of a compounded, repackaged, or dispensed drug can no longer be assured and as such is deemed to be adulterated or misbranded as defined in §§ 54.1-3461 and 54.1-3462 of the Code of Virginia.

"Board" means the Virginia Board of Pharmacy.

~~"CE" means continuing education as required for renewal of licensure by the Board of Pharmacy.~~

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

"Chart order" means a lawful order for a drug or device entered on the chart or in a medical record of a patient by a prescriber or ~~his~~ the prescriber's designated agent.

"Compliance packaging" means packaging for dispensed drugs that is comprised of a series of containers for solid oral dosage forms and designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

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

"Correctional facility" means any prison, penitentiary, penal facility, jail, detention unit, or other facility in which persons are incarcerated by government officials.

"DEA" means the U.S. Drug Enforcement Administration.

"Dispensing error" means one or more of the following discovered after the final verification by the pharmacist, regardless of whether the patient received the drug:

1. Variation from the prescriber's prescription drug order, including ~~but not limited to~~:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form;

d. Incorrect patient; or

e. Inadequate or incorrect packaging, labeling, or directions.

2. Failure to exercise professional judgment in identifying and managing:

a. Known therapeutic duplication;

b. Known drug-disease contraindications;

c. Known drug-drug interactions;

d. Incorrect drug dosage or duration of drug treatment;

e. Known drug-allergy interactions;

f. A clinically significant, avoidable delay in therapy; or

g. Any other significant, actual, or potential problem with a patient's drug therapy.

3. Delivery of a drug to the incorrect patient.

4. Variation in bulk repackaging or filling of automated devices, including ~~but not limited to~~:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form; or

d. Inadequate or incorrect packaging or labeling.

"Drug donation site" means a permitted pharmacy that specifically registers with the board for the purpose of receiving or redispensing eligible donated prescription drugs pursuant to § 54.1-3411.1 of the Code of Virginia.

"Electronic prescription" means a written prescription that is generated on an electronic application and is transmitted to a pharmacy as an electronic data file; Schedules II through V prescriptions shall be transmitted in accordance with 21 CFR Part 1300 ~~and is transmitted to a pharmacy as an electronic data file~~.

"EMS" means emergency medical services.

"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

~~"Facsimile (FAX)~~ "Faxed prescription" means a written prescription or order ~~which~~ that is transmitted by an electronic device over telephone lines ~~which sends~~ that send the exact image to the receiver (pharmacy) in a hard copy form.

"FDA" means the U.S. Food and Drug Administration.

"Floor stock" means a supply of drugs that have been distributed for the purpose of general administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

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

"Forgery" means a prescription that was falsely created, falsely signed, or altered.

~~"FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign Pharmacy Equivalency Examination and a credential review of foreign training to establish educational equivalency to board approved schools of pharmacy, and has~~

~~passed approved examinations establishing proficiency in English.~~

"Generic drug name" means the nonproprietary name listed in the United States Pharmacopeia-National Formulary (USP-NF) or in the United States Adopted Names (USAN) and the USP Dictionary of Drug Names.

"Hospital" or "nursing home" means those facilities as defined in Title 32.1 of the Code of Virginia or as defined in regulations by the Virginia Department of Health.

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

"Initials" means the first letters of a person's name or other unique personal identifier.

"Long-term care facility" means a nursing home, retirement care, mental care, or other facility or institution that provides extended health care to resident patients.

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

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

"On duty" means that a pharmacist is on the premises at the address of the permitted pharmacy and is available as needed.

"On-hold prescription" means a valid prescription that is received and maintained at the pharmacy for initial dispensing on a future date.

"Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 ~~(Pub. L.~~ (P.L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality.

"Permitted physician" means a physician who is licensed pursuant to § 54.1-3304 of the Code of Virginia to dispense drugs to persons to whom or for whom pharmacy services are not reasonably available.

"Perpetual inventory" means an ongoing system for recording quantities of drugs received, dispensed, or otherwise distributed by a pharmacy.

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

"Pharmacy closing" means that the permitted pharmacy ceases pharmacy services or fails to provide for continuity of pharmacy services or lawful access to patient prescription records or other required patient records for the purpose of continued pharmacy services to patients.

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

"PIC" means the pharmacist-in-charge of a permitted pharmacy.

"Practice location" means any location in which a prescriber evaluates or treats a patient.

"Prescription department" means any contiguous or noncontiguous areas used for the compounding, dispensing, and storage of all ~~Schedule~~ Schedules II through VI drugs and devices and any Schedule I investigational ~~drugs~~ drug.

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

"Quality assurance plan" means a plan approved by the board for ongoing monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy function or system.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance~~,~~ but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Repackaged drug" means any drug removed from the manufacturer's original package and placed in different packaging.

"Robotic pharmacy system" means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, compounding, labeling, dispensing, or distribution of medications~~,~~ and collects, controls, and maintains all transaction information.

"Safety closure container" means a container that meets the requirements of the federal Poison Prevention Packaging Act of 1970 (15 USC §§ 1471-1476), that is, in testing such containers, that 85% of a test group of 200 children of ages 41-52 months are unable to open the container in a five-minute period and that 80% fail in another five minutes after

a demonstration of how to open it and that 90% of a test group of 100 adults must be able to open and close the container.

"Satellite pharmacy" means a pharmacy that is noncontiguous to the centrally permitted pharmacy of a hospital but at the location designated on the pharmacy permit.

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

"Special use permit" means a permit issued to conduct a pharmacy of a special scope of service that varies in any way from the provisions of any board regulation.

"Storage temperature" means those specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles shall be stored, where it is considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms:

1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is maintained thermostatically between -20° and -10°C (-4° and 14°F).

2. "Room temperature" means the temperature prevailing in a working area.

3. "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.

4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).

5. "Excessive heat" means any temperature above 40°C (104°F).

6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.

7. "Cool" means any temperature between 8° and 15°C (46° and 59°F).

"Terminally ill" means a patient with a terminal condition as defined in § 54.1-2982 of the Code of Virginia.

"Ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household.

"Unit dose container" means a container that is a single-unit container, as defined in United States Pharmacopeia-National Formulary, for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

"Unit dose package" means a container that contains a particular dose ordered for a patient.

"Unit dose system" means a system in which multiple drugs in unit dose packaging are dispensed in a single container, such as a medication drawer or bin, labeled only with patient name and location. Directions for administration are not provided by the pharmacy on the drug packaging or container but are obtained by the person administering directly from a prescriber's order or medication administration record.

"USP-NF" means the United States Pharmacopeia-National Formulary.

"Well-closed container" means a container that protects the contents from extraneous solids and from loss of the drug under the ordinary or customary conditions of handling, shipment, storage, and distribution.

18VAC110-20-15. ~~Criteria for delegation of informal fact-finding proceedings to an agency subordinate.~~ (Repealed.)

~~A. Decision to delegate. In accordance with § 54.1-2400 (10) of the Code of Virginia, the board may delegate an informal fact-finding proceeding to an agency subordinate upon determination that probable cause exists that a practitioner may be subject to a disciplinary action.~~

~~B. Criteria for delegation. Cases that may not be delegated to an agency subordinate, except as may be approved by a committee of the board, include those that involve:~~

~~1. Intentional or negligent conduct that causes or is likely to cause injury to a patient;~~

~~2. Drug diversion;~~

~~3. Impairment with an inability to practice with skill and safety;~~

~~4. Indiscriminate dispensing; and~~

~~5. Medication error in administration or dispensing.~~

~~C. Criteria for an agency subordinate.~~

~~1. An agency subordinate authorized by the board to conduct an informal fact-finding proceeding may include board members and professional staff or other persons~~

~~deemed knowledgeable by virtue of their training and experience in administrative proceedings involving the regulation and discipline of health professionals.~~

~~2. The executive director shall maintain a list of appropriately qualified persons to whom an informal fact-finding proceeding may be delegated.~~

~~3. The board may delegate to the executive director the selection of the agency subordinate who is deemed appropriately qualified to conduct a proceeding based on the qualifications of the subordinate and the type of case being heard.~~

18VAC110-20-20. Fees.

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

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

~~C.~~ B. Initial application fees.

~~1. Pharmacist license~~	~~$180~~
~~2. Pharmacy intern registration~~	~~$15~~
~~3. Pharmacy technician registration~~	~~$25~~
~~4.~~ 1. Pharmacy permit	$270
~~5.~~ 2. Permitted physician licensed to dispense drugs	$270
~~6.~~ 3. Medical equipment supplier permit	$180
~~7. Humane society permit~~	~~$20~~
~~8.~~ 4. Outsourcing facility permit	$270
~~9.~~ 5. Nonresident pharmacy registration	$270
~~10.~~ 6. Nonresident outsourcing facility registration	$270
~~11.~~ 7. Controlled substances registrations	$90
~~12.~~ 8. Innovative program approval. If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee.	$250
~~13. Approval of a pharmacy technician training program~~	~~$150~~
~~14. Approval of a continuing education program~~	~~$100~~
~~15.~~ 9. Approval of a repackaging training program	$50

~~D.~~ C. Annual renewal fees.

~~1. Pharmacist active license – due no later than December 31~~	~~$90~~
~~2. Pharmacist inactive license – due no later than December 31~~	~~$45~~
~~3. Pharmacy technician registration – due no later than December 31~~	~~$25~~
~~4.~~ 1. Pharmacy permit – due no later than April 30	$270
~~5.~~ 2. Physician permit to practice pharmacy – due no later than February 28	$270
~~6.~~ 3. Medical equipment supplier permit – due no later than February 28	$180
~~7. Humane society permit – due no later than February 28~~	~~$20~~
~~8.~~ 4. Outsourcing facility permit – due no later than April 30	$270
~~9.~~ 5. Nonresident pharmacy registration – due no later than the date of initial registration	$270
~~10.~~ 6. Nonresident outsourcing facility registration – due no later than the date of initial registration	$270
~~11.~~ 7. Controlled substances registrations – due no later than February 28	$90
~~12.~~ 8. Innovative program continued approval based on board order not to exceed $200 per approval period.	
~~13. Approval of a pharmacy technician training program~~	~~$75 every two years~~
~~14. Approval of a repackaging~~ 9. Repackaging training program	$30 every two years

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

~~1. Pharmacist license~~	~~$30~~
~~2. Pharmacist inactive license~~	~~$15~~
~~3. Pharmacy technician registration~~	~~$10~~

~~4.~~ 1. Pharmacy permit	$90
~~5.~~ 2. Physician permit to practice pharmacy	$90
~~6.~~ 3. Medical equipment supplier permit	$60
~~7. Humane society permit~~	~~$5~~
~~8.~~ 4. Outsourcing facility permit	$90
~~9.~~ 5. Nonresident pharmacy registration	$90
~~10.~~ 6. Nonresident outsourcing facility registration	$90
~~11.~~ 7. Controlled substances registrations	$30
~~12. Approval of a pharmacy technician training program~~	~~$15~~
~~13. Approval of a repackaging~~ 8. Repackaging training program	$10

~~F.~~ E. Reinstatement fees.

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

~~1. Pharmacist license~~	~~$210~~
~~2. Pharmacist license after revocation or suspension~~	~~$500~~
~~3. Pharmacy technician registration~~	~~$35~~
~~4. Pharmacy technician registration after revocation or suspension~~	~~$125~~

~~5.~~ 2. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:

a. Pharmacy permit	$240
b. Physician permit to practice pharmacy	$240
c. Medical equipment supplier permit	$210
~~d. Humane society permit~~	~~$30~~
~~e.~~ d. Outsourcing facility permit	$240
~~f.~~ e. Nonresident pharmacy registration	$115
~~g.~~ f. Nonresident outsourcing facility registration	$240
~~h.~~ g. Controlled substances registration	$180
~~i. Approval of a pharmacy technician training program~~	~~$75~~
~~j. Approval of a repackaging~~ h. Repackaging training program	$50

~~G.~~ F. Application for change or inspection fees for facilities or other entities.

1. Change of pharmacist-in-charge	$50
2. Change of ownership for any facility	$50
3. Inspection for remodeling or change of location for any facility	$150
4. Reinspection of any facility	$150
5. Board-required inspection for a robotic pharmacy system	$150
6. Board-required inspection of an innovative program location	$150
7. Change of pharmacist responsible for an approved innovative program	$25

~~H.~~ G. Miscellaneous fees.

~~1. Duplicate wall certificate~~	~~$25~~
~~2.~~ 1. Returned check	$35
~~3.~~ 2. Duplicate ~~license~~ permit or registration	$10
~~4.~~ 3. Verification of ~~licensure~~ permit or registration	$25

18VAC110-20-21. ~~Public address.~~ (Repealed.)

~~An individual licensed by or registered with the board who has provided the board with a public address that is different from the address of record shall notify the board in writing if there is a change in the address.~~

18VAC110-20-25. Unprofessional conduct.

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

1. Failing to comply with provisions of § 32.1-127.1:03 of the Code of Virginia related to the confidentiality and disclosure of patient records or related to provision of

patient records to another practitioner or to the patient or ~~his~~ the patient's personal representative;

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

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

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

~~5. Engaging or attempting to engage in a relationship with a patient that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a patient or his family, including but not limited to sexual misconduct with a patient or a member of his family or other conduct that results or could result in personal gain at the expense of the patient;~~

~~6.~~ 4. Failing to maintain adequate safeguards against diversion of controlled substances;

~~7.~~ 5. Failing to appropriately respond to a known dispensing error in a manner that protects the health and safety of the patient;

~~8.~~ 6. Delegating a task within the practice of pharmacy to a person who is not adequately trained to perform such a task;

~~9.~~ 7. Failing by the PIC to ensure that pharmacy interns and pharmacy technicians working in the pharmacy are registered and that such registration is current; ~~or~~

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

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

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

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

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

12. Having a restriction of a license, permit, or registration to practice in another jurisdiction in the United States.

~~Part II~~
~~Licensure Requirements for Pharmacists~~ (Repealed)

18VAC110-20-30. ~~Requirements for pharmacy practical experience.~~ (Repealed.)

~~A. Each applicant for licensure as a pharmacist shall have gained practical experience in the practice of pharmacy as set forth in this section and 18VAC110-20-40.~~

~~B. An applicant for licensure as a pharmacist shall attain a minimum of 1,500 hours of practical experience.~~

~~C. Practical experience that is gained within an ACPE accredited school of pharmacy, that conforms to the current ACPE standards, and that allows the student to gain at least 1,500 hours of practical experience, shall meet the board's practical experience requirements for licensure as a pharmacist.~~

~~D. All practical experience credit gained outside of an ACPE accredited school of pharmacy program shall only be gained after successful completion of the equivalent of at least two semesters in an ACPE accredited school of pharmacy. Credit shall not be given for more than 50 hours in one week and not less than an average of 20 hours per week averaged over a month. The board may grant an exception to the minimum number of hours for good cause shown.~~

~~E. In accordance with § 54.1-3312 of the Code of Virginia, all practical experience required by this section shall be gained within the United States.~~

18VAC110-20-40. ~~Procedure for gaining practical experience.~~ (Repealed.)

~~A. Each person desiring to gain practical pharmacy experience in Virginia shall first register with the board as a pharmacy intern on a form provided by the board prior to becoming so engaged as a pharmacy intern. This requirement shall apply to any person gaining practical experience within the Commonwealth whether for licensure in Virginia or in another state.~~

~~B. In order to be eligible to register as a pharmacy intern, an applicant shall meet at least one of the following criteria:~~

~~1. The applicant shall be enrolled in and have started course work in a professional degree program of a board approved school of pharmacy. Such registration is only valid while the student is enrolled in the school of pharmacy and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist. An expiration date shall be assigned to the registration to cover the estimated time period for the student to complete the school program and pass the required examinations. If the student is no longer enrolled in the school program, takes a voluntary break from the program, or is otherwise not actively participating in the school program, except for regularly scheduled school breaks, the registration is no~~

longer valid and shall be returned to the board immediately;

2. The applicant is a graduate of a board-approved school of pharmacy or a graduate of a foreign school of pharmacy, has established educational equivalency and proficiency in English by obtaining the FPGEC certificate, and desires to gain required practical experience required for licensure as a pharmacist. Such applicant shall provide documentation on a board-approved form of current employment or an employment start date within 90 days in a pharmacy in Virginia with approval by the supervising pharmacist. An expiration date shall be assigned to cover the estimated time period needed to obtain the required practical experience hours and take the required examinations to become licensed as a pharmacist;

3. The applicant has already gained the required practical experience, but is an otherwise qualified applicant awaiting examination for licensure. A three-month expiration date shall be assigned to allow the applicant time to take required examinations; or

4. The applicant is an applicant for reactivation or reinstatement of a previously issued pharmacist license and is meeting board requirements for relicensure. An expiration date shall be assigned to reasonably cover the period of time necessary to meet the board requirements.

C. For documented, good cause shown, the executive director of the board may extend the expiration date of the intern registration upon submission of an application form approved by the board and payment of the initial application fee.

D. A pharmacy intern shall be supervised by a pharmacist who holds a current, unrestricted license and assumes full responsibility for the training, supervision and conduct of the intern.

E. The intern registration of a pharmacy student shall be valid only while the student is enrolled in a school of pharmacy. The registration card issued by the board shall be returned to the board upon failure to be enrolled.

F. Practical experience gained within any other state must be registered with and certified by the board of that state in order to be accepted or certified by this board. In the event that a state relies on the pharmacy school to certify the hours of experience, an affidavit from the pharmacy school certifying the hours of experience gained in the United States may be accepted in lieu of board certification.

G. All practical experience of the pharmacy intern shall be evidenced by an affidavit approved by the board, which shall be filed prior to or with the application for examination for licensure.

H. An applicant for licensure by endorsement may provide verification acceptable to the board of practical experience hours worked as a pharmacist in another state within the United States in lieu of prelicensure intern hours in order to meet the practical experience requirement.

I. A pharmacy intern shall notify the board in writing of any change in address of record within 14 days of such change.

18VAC110-20-50. Curriculum and approved schools of pharmacy. (Repealed.)

A. The following minimum educational requirements for the specified periods shall be recognized by the board for the purpose of licensure.

1. On and after June 1, 1936, but before June 1, 1964, the applicant for licensure shall have been graduated from a four-year course of study with a Bachelor of Science degree in pharmacy awarded.

2. On and after June 1, 1964, the applicant for licensure shall have been graduated from at least a five-year course of study with a Bachelor of Science degree in pharmacy or a Doctorate of Pharmacy degree awarded.

B. In order to be licensed as a pharmacist within this Commonwealth, the applicant shall have been granted the first professional degree from a program of a school of pharmacy which meets the requirements of § 54.1-3312 of the Code of Virginia.

18VAC110-20-60. Content of the examination and grades required; limitation on admittance to examination. (Repealed.)

A. Prior to admission to any examination required for licensure, the applicant shall have met all other requirements to include education and practical experience requirements, but in no case shall the applicant be admitted if grounds exist to deny licensure under § 54.1-3316 of the Code of Virginia.

B. The applicant shall achieve a passing score as determined by the board on the licensure examination which is approved by the board and which shall consist of an integrated examination of pharmacy practice, pharmacology, pharmacy mathematics, and such other subjects as are necessary to assure that the candidate possesses the necessary knowledge and skills to practice pharmacy.

C. When an applicant for licensure by examination fails to meet the passing requirements of the board-approved integrated pharmacy examination on three occasions, he shall not be readmitted to the examination until he has completed an additional 1,000 hours of practical experience as a pharmacy intern as set forth in 18VAC110-20-40.

D. The applicant shall also achieve a passing score as determined by the board on an examination that tests the candidate's knowledge of federal and state laws related to pharmacy practice.

E. When an applicant fails to pass the law examination, he shall not be allowed to retake it for a period of 30 days.

F. If an applicant requests a testing accommodation for either examination based on a physical or mental impairment that substantially limits one or more major life activities, subject to the Americans with Disabilities Act, the board may approve a reasonable accommodation that does not compromise the security or integrity of the examination.

1. Supporting documentation shall be provided by the applicant to include the following to be considered for review:

a. A letter of request from the candidate that specifies the testing accommodation requested;

b. A written report of an evaluation (educational, psychological, or physical) within the preceding two years from a qualified professional that states a diagnosis of the disability, describes the disability, recommends specific accommodations, and provides justification that the accommodation is appropriate and necessary for the diagnosed disability. If the comprehensive evaluation was done more than two years ago and the condition is one that is not subject to change, the original evaluation report may be submitted along with a current letter from the qualified professional stating that there has been no change in the condition since the time of the evaluation; and

c. A written statement from the appropriate person at the applicant's school of pharmacy that describes any testing accommodations made while the student was enrolled, if applicable.

2. The applicant will be notified in writing of the decision. If the request for accommodation is granted, the approval information will be forwarded to the examination contractor and the form of the accommodation will be coordinated with the contractor.

18VAC110-20-70. Requirements for foreign-trained applicants. (Repealed.)

A. Applicants for licensure who were trained in foreign schools of pharmacy shall obtain the FPGEC certificate prior to being allowed to register as a pharmacy intern and gain required practical experience in Virginia.

B. After obtaining the FPGEC certificate, the applicant may apply for a pharmacy intern registration and shall fulfill the requirements for practical experience set forth in 18VAC110-20-30 and 18VAC110-20-40 before being admitted to examinations required by 18VAC110-20-60.

C. Applicants for licensure who were trained in foreign schools of pharmacy shall also complete and achieve passing scores on the examinations set forth in 18VAC110-20-60 before being licensed as a pharmacist.

18VAC110-20-75. Registration for voluntary practice by out-of-state licensees. (Repealed.)

Any pharmacist who seeks registration to practice on a voluntary basis pursuant to subdivision 12 of § 54.1-3301 of the Code of Virginia under the auspices of a publicly supported, all-volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people shall:

1. File a complete application for registration on a form provided by the board at least five business days prior to engaging in such practice;

2. Provide a complete list of each state in which he has held a pharmacist license and a copy of any current license;

3. Provide the name of the nonprofit organization and the dates and location of the voluntary provision of services;

4. Pay a registration fee of $10; and

5. Provide a notarized statement from a representative of the nonprofit organization attesting to its compliance with the provisions of subdivision 12 of § 54.1-3301 of the Code of Virginia.

18VAC110-20-80. Renewal and reinstatement of license. (Repealed.)

A. Pharmacist licenses expire on December 31 and shall be renewed annually prior to that date by the submission of a renewal fee, renewal form, and statement of compliance with continuing education requirements.

B. A pharmacist newly licensed on or after October 1 shall not be required to renew that license until December 31 of the following year.

C. A pharmacist who fails to renew his license by the expiration date may renew his license at any time within one year of its expiration by submission of the renewal fee and late fee, renewal form, and statement of compliance with continuing education requirements.

D. A pharmacist who fails to renew his license for more than one year following expiration and who wishes to reinstate such license shall submit an application for reinstatement, pay the current renewal fee and a reinstatement fee, and submit documentation showing compliance with continuing education requirements. Reinstatement is at the discretion of the board and may be granted by the executive director of the board provided no grounds exist to deny said reinstatement.

E. A pharmacist who has been registered as inactive for more than one year must apply for reinstatement, submit documentation showing compliance with continuing education requirements, and pay the current year active renewal fee in order to resume active licensure.

F. In order to reactivate or reinstate a license to active status, a pharmacist who holds an inactive license, who has allowed

his license to lapse, or who has had his license suspended or revoked must submit evidence of completion of CEU's or hours equal to the requirements for the number of years in which his license has not been active, not to exceed a total of 60 hours of CE.

G. A pharmacist whose license has been lapsed, in inactive status, or suspended or revoked for more than five years shall, as a condition of reinstatement in addition to 60 hours CE, take and receive a passing score on the board-approved law examination and furnish acceptable documentation of one of the following:

1. Active pharmacy practice within the past five years as a properly licensed pharmacist in another state; or

2. Practical experience as a pharmacy intern registered with the board of at least 160 hours within six months immediately prior to being reinstated.

H. The practice of pharmacy without a current, active pharmacist license is unlawful and shall constitute grounds for disciplinary action by the board.

I. It shall be the duty and responsibility of each licensee to inform the board of his current address. A licensee shall notify the board within 14 days in writing or electronically of any change of an address of record. Properly updating address of record directly through the board's web-based application or other approved means shall constitute lawful notification. All notices required by law or by these rules and regulations are deemed to be legally given when mailed to the address of record and shall not relieve the licensee of the obligation to comply.

18VAC110-20-90. ~~Requirements for continuing education.~~ (Repealed.)

A. A pharmacist shall be required to have completed a minimum of 1.5 CEUs or 15 contact hours of continuing pharmacy education in an approved program for each annual renewal of licensure. CEUs or hours in excess of the number required for renewal may not be transferred or credited to another year.

B. A pharmacy education program approved for continuing pharmacy education is:

1. One that is approved by the Accreditation Council for Pharmacy Education (ACPE);

2. One that is approved as a Category I Continuing Medical Education (CME) course, the primary focus of which is pharmacy, pharmacology, or drug therapy; or

3. One that is approved by the board in accordance with the provisions of 18VAC110-20-100.

C. The board may grant an extension pursuant to § 54.1-3314.1 E of the Code of Virginia. Any subsequent extension shall be granted only for good cause shown.

D. Up to two hours of the 15 hours required for annual renewal may be satisfied through delivery of pharmacy services as a pharmacist, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those services. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic.

E. Pharmacists are required to attest to compliance with CE requirements in a manner approved by the board at the time of their annual license renewal. Following each renewal period, the board may conduct an audit of the immediate past two years' CE documents to verify compliance with requirements. Pharmacists are required to maintain, for two years following renewal, the original certificates documenting successful completion of CE, showing date and title of the CE program or activity, the number of CEUs or contact hours awarded, and a certifying signature or other certification of the approved provider. Pharmacists selected for audit must provide these original documents to the board by the deadline date specified by the board in the audit notice.

18VAC110-20-100. ~~Approval of continuing education programs.~~ (Repealed.)

A. The board will approve without application or further review any program offered by an ACPE-approved provider and will accept for credit certificates bearing the official ACPE logo and program number.

B. The board may approve an individual CE program under the following provisions:

1. An approved individual program is a course, activity, or lecture which includes subject matter related to the competency of the practice of pharmacy and which has been approved for CE credit by the board.

2. In order to receive approval for an individual program, the sponsor or provider must apply prior to the program offering on a form provided by the board. The information which must be provided shall include but not be limited to: name of provider, location, date and time of program, charges to participants, description of program content and objectives, credentials of speaker or author, method of delivery, evaluation procedure, evidence of a post assessment, credits requested, mechanism for recordkeeping, and any such information as the board deems necessary to assure quality and compliance.

3. The sponsor applying for board approval of an individual program must pay a fee as required in 18VAC110-20-20 C 12.

4. The board shall notify the provider or sponsor within 60 days following the receipt of a completed application of approval or disapproval of a program and the number of

~~credits which may be awarded. The board shall also assign an expiration date for approval of the program not to exceed two years from the date of approval.~~

~~5. The provider of an approved program shall provide to each participant who completes the required hours and passes the post-test a certification with the name of the provider, name of the participant, description of course and method of delivery, number of hours credited, date of completion, and program identification number.~~

~~6. The provider of an approved program shall maintain all records on that program, its participants, and hours awarded for a period of five years and shall make those records available to the board upon request.~~

~~7. The board shall periodically review and monitor programs. The provider of a CE program shall waive registration fees for a representative of the board for that purpose.~~

~~8. Any changes in the information previously provided about an approved program or provider must be submitted or the board may withdraw its approval. If a provider wants to give a live program more than once, all program dates must either be submitted on the original application or provided to the board in subsequent correspondence at least five days prior to giving the program.~~

~~Part III~~
~~Requirements for Pharmacy Technician Registration~~
(Repealed)

18VAC110-20-101. ~~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. In order to be registered as a pharmacy technician, an applicant shall provide evidence of the following:~~

~~1. Satisfactory completion of an 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.~~

~~D. A pharmacy technician trainee may perform tasks restricted to pharmacy technicians for no more than nine months without becoming registered as a pharmacy technician.~~

18VAC110-20-102. ~~Criteria for approval for training programs.~~ (Repealed.)

~~A. Any person wishing to apply for approval of a pharmacy technician training program shall submit the application fee 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 his 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 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 director, instructors, name of institution or business if applicable, address, program content, length of program, or location of records.~~

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

18VAC110-20-103. ~~Examination.~~ (Repealed.)

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

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

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

~~D. Any requests for testing accommodations under the Americans with Disabilities Act shall be in accordance with the provisions of 18VAC110-20-60 F.~~

18VAC110-20-104. ~~Address of record; maintenance of certificate.~~ (Repealed.)

~~A. It shall be the duty and responsibility of each pharmacy technician to inform the board of his current address. A pharmacy technician shall notify the board in writing or electronically of any change of an address of record within 14 days. Properly updating address of record directly through the board's web-based application or other approved means shall constitute lawful notification. All notices required by law or by these rules and regulations are deemed to be legally given when mailed to the address of record and shall not relieve the registrant of the obligation to comply.~~

~~B. A pharmacy technician shall maintain his current registration certificate at his principal place of practice available for inspection upon request. A pharmacy technician who does not have a principal place of practice may maintain it at any pharmacy in which he practices or his address of record.~~

18VAC110-20-105. ~~Renewal and reinstatement of registration.~~ (Repealed.)

~~A. Pharmacy technician registrations expire on December 31 and shall be renewed annually prior to that date by the submission of a renewal fee and renewal form. A pharmacy technician newly registered on or after July 1 shall not be required to renew that registration until December 31 of the following year. Failure to receive the application for renewal shall not relieve the pharmacy technician of the responsibility for renewing the registration by the expiration date.~~

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

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

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

18VAC110-20-106. ~~Requirements for continued competency.~~ (Repealed.)

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

~~B. An approved continuing education program shall meet the requirements as set forth in subsection B of 18VAC110-20-90 or subsection B of 18VAC110-20-100.~~

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

~~D. Up to one hour of the five hours required for annual renewal may be satisfied through delivery of pharmacy services as a pharmacy technician, without compensation, to~~

~~low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those services. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic.~~

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

Part ~~IV~~ II
Pharmacies

18VAC110-20-110. Pharmacy permits generally.

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.

B. Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day and shall allow at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break.

C. The ~~pharmacist-in-charge (PIC)~~ PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

D. A pharmacist shall not be eligible to serve as PIC until after having obtained a minimum of two years of experience practicing as a pharmacist in Virginia or another jurisdiction in the United States. The board may grant an exception to the minimum number of years of experience for good cause shown.

~~D.~~ E. When the PIC ceases practice at a pharmacy or no longer wishes to be designated as PIC, he shall immediately return the pharmacy permit to the board indicating the effective date on which he ceased to be the PIC.

~~E.~~ F. Although not required by law or regulation, an outgoing PIC shall have the opportunity to take a complete and accurate inventory of all ~~Schedule~~ Schedules II through V controlled substances on hand on the date he ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

~~F.~~ G. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. Pharmacists-in-charge having knowledge of upcoming absences for longer than 30 days shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC, which exceed 15 days with no known return date within the next 15 days, the owner shall immediately notify the board and shall obtain a new PIC.

~~G.~~ H. An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. It shall be unlawful for a pharmacy to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

~~H.~~ I. Only one pharmacy permit shall be issued to conduct a pharmacy occupying the same designated prescription department space. A pharmacy shall not engage in any other activity requiring a license or permit from the board, such as manufacturing or wholesale-distributing, out of the same designated prescription department space.

~~I.~~ J. Before any permit is issued, the applicant shall attest to compliance with all federal, state, and local laws and ordinances. A pharmacy permit shall not be issued to any person to operate from a private dwelling or residence after September 2, 2009.

18VAC110-20-112. Supervision of pharmacy technicians.

A. A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time; however, no pharmacist shall supervise more than four persons performing the duties of a pharmacy technician at one time.

B. In addition to the acts restricted to a pharmacist in § 54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians.

18VAC110-20-140. New pharmacies, acquisitions, and changes to existing pharmacies.

A. Any person wishing to open a new pharmacy, engage in the acquisition of an existing pharmacy, change the location of an existing pharmacy, move the location or make structural changes to an existing prescription department, or make changes to a previously approved security system shall file an application with the board.

B. In the acquisition of an existing pharmacy, if prescription records are to be accessible to anyone for purposes other than for continuity of pharmacy services at substantially the same level offered by the previous owner or for the necessary transfer of prescription records, the owner of the pharmacy acquiring the records shall disclose such information in writing to each patient 14 days prior to the acquisition. Such

release of prescription records shall be allowed only to the extent authorized by § 32.1-127.1:03 of the Code of Virginia.

C. Although a closing inventory is not required, a complete and accurate inventory shall be taken of all Schedules II through V controlled substances on hand in accordance with § 54.1-3404 of the Code of Virginia on the date the pharmacist first engages in business under the new ownership. Inventories associated with any change in PIC shall also be performed in accordance with 18VAC110-20-110.

~~C.~~ D. The proposed location or structural changes shall be inspected by an authorized agent of the board prior to issuance of a permit.

1. Pharmacy permit applications ~~which~~ that indicate a requested inspection date~~,~~ or requests ~~which~~ that are received after the application is filed~~,~~ shall be honored provided a 14-day notice is allowed prior to the requested inspection date.

2. Requested inspection dates ~~which~~ 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.

3. At the time of the inspection, the dispensing area shall comply with 18VAC110-20-150, 18VAC110-20-160, 18VAC110-20-170, 18VAC110-20-180, and 18VAC110-20-190.

4. If an applicant substantially fails to meet the requirements for issuance of a 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 18VAC110-20-20 prior to a reinspection being conducted.

~~D.~~ E. Drugs shall not be stocked within the proposed pharmacy or moved to a new location until approval is granted by the inspector or board staff.

~~E.~~ F. Once the permit is issued, prescription drugs may not be stocked earlier than two weeks prior to the designated opening date. Once prescription drugs have been placed in the pharmacy, a pharmacist shall be present on a daily basis to ensure the safety and integrity of the drugs. If there is a change in the designated opening date, the pharmacy shall notify the board office, and a pharmacist shall continue to be on site on a daily basis.

G. If the pharmacy is not operational within 90 days from the date the permit is issued, the board shall rescind the pharmacy permit unless an extension is granted for good cause shown.

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

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

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

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

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

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

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

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

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

18VAC110-20-180. Security system.

A. A device for the detection of breaking shall be installed in each prescription department of each pharmacy. The installation and the device shall be based on accepted alarm industry standards~~,~~ and shall be subject to the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.

2. The device shall have at least one hard-wired communication method, be monitored in accordance with accepted industry standards, maintained in operating order, have an auxiliary source of power, and be capable of

sending an alarm signal to the monitoring entity when breached if the communication line is not operational.

3. The device shall fully protect the prescription department and shall be capable of detecting breaking by any means when activated.

4. Access to the alarm system for the prescription department area of the pharmacy shall be restricted to the pharmacists working at the pharmacy, except for access by other persons in accordance with 18VAC110-20-190 B 2, and the system shall be activated whenever the prescription department is closed for business.

5. The alarm system shall include a feature by which any breach in the alarm shall be communicated by the monitoring entity to the PIC or a pharmacist working at the pharmacy.

B. Exceptions to provisions in this section:

1. Alarm systems approved prior to November 4, 1993, will be deemed to meet the requirements of subdivisions A 1, A 2, and A 3 of this section, provided that no structural changes are made in the prescription department, that no changes are made in the security system, that the prescription department is not closed while the rest of the business remains open, and that a breaking and loss of drugs does not occur. If a breaking with a loss of drugs occurs, the pharmacy shall upgrade the alarm to meet the current standards and shall file an application with the board in accordance with 18VAC110-20-140 A within 14 days of the breaking.

2. If the prescription department was located in a business with extended hours prior to November 4, 1993, and had met the special security requirements by having a floor to ceiling enclosure, a separately activated alarm system shall not be required.

3. This section shall not apply to pharmacies ~~which~~ that are open and staffed by pharmacists 24 hours a day. If the pharmacy changes its hours or if it must be closed for any reason, the PIC or owner must immediately notify the board, file an application in accordance with 18VAC110-20-140 A, and have installed prior to closing, a security system that meets the requirements of subdivisions A 1 through A 4 of this section.

18VAC110-20-200. Storage of drugs, devices, and controlled paraphernalia; expired drugs.

A. Prescriptions awaiting delivery. Prescriptions prepared for delivery to the patient may be placed in a secured area outside of the prescription department, not accessible to the public, where access to the prescriptions is restricted to individuals designated by the pharmacist. With the permission of the pharmacist, the prepared prescriptions may be transferred to the patient at a time when the pharmacist is not on duty. If a prescription is delivered at a time when the pharmacist is not on duty, written procedures shall be established and followed by the pharmacy ~~which~~ that detail security of the dispensed prescriptions and a method of compliance with counseling requirements of § 54.1-3319 of the Code of Virginia. Additionally, a log shall be made and maintained of all prescriptions delivered to a patient when a pharmacist is not present to include the patient's name, prescription ~~number(s)~~ number, date of delivery, and ~~the~~ signature of the person receiving the prescription. Such log shall be maintained for a period of one year.

B. Dispersion of Schedule II drugs. Schedule II drugs shall either be dispersed with other schedules of drugs or shall be maintained within a securely locked cabinet, drawer, or safe or maintained in a manner that combines the two methods for storage. The cabinet, drawer, or safe may remain unlocked during hours that the prescription department is open and a pharmacist is on duty.

C. Safeguards for controlled paraphernalia and Schedule VI medical devices. Controlled paraphernalia and Schedule VI medical devices shall not be placed in an area completely removed from the prescription department whereby patrons will have free access to such items or where the pharmacist cannot exercise reasonable supervision and control.

D. Expired, or otherwise adulterated or misbranded drugs; security. Any drug ~~which~~ that has exceeded the expiration date, or is otherwise adulterated or misbranded, shall not be dispensed or sold; it shall be separated from the stock used for dispensing. Expired prescription drugs shall be maintained in a designated area within the prescription department until proper disposal.

18VAC110-20-211. Disposal of drugs by authorized collectors.

Any narcotic treatment program, hospital, or clinic with an on-site pharmacy, or pharmacy ~~wishing to accept for return~~ that accepts a previously dispensed drug for the purpose of destruction shall first be authorized by the DEA as a collector. A collector so authorized may receive drugs from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility ~~shall first be authorized by the DEA as a collector~~. The process used to collect and destroy drugs, along with any required recordkeeping, shall comply with applicable federal and state law.

1. Prior to collecting drugs, an authorized collector shall submit in writing to the board:

a. The name, address, and license number, if applicable, of the facility;

b. The intended method or methods of collection (i.e., collection receptacle or mail-back program); and

c. Signature of PIC or medical director of a narcotic treatment program.

2. If an authorized collector chooses to cease acting as a collector, the PIC or medical director shall notify the board within 30 days.

3. A narcotic treatment program that does not have an in-house pharmacy shall obtain a controlled substance registration.

Part ~~V~~ III
Nuclear Pharmacies

18VAC110-20-220. General requirements for pharmacies providing radiopharmaceutical services.

A. Nuclear pharmacies shall comply with standards and requirements of the Nuclear Regulatory Commission ~~(NRC)~~ and the Virginia Department of Health related to the staffing and operation of the facility.

B. Radiopharmaceuticals are to be dispensed only upon an order from a prescriber authorized to possess, use, and administer radiopharmaceuticals.

1. Orders shall originate at an institution or ~~healthcare~~ health care facility licensed to receive and possess radiopharmaceuticals~~,~~ and must contain all necessary information relative to the radiopharmaceutical, activity, time of calibration, and any special preparation or delivery instructions.

2. Orders for radiopharmaceuticals may be transmitted orally, by ~~fax~~ facsimile (fax), or by electronic transmission by an authorized agent of the prescriber. If the fax or electronic transmission of the authorized agent is pursuant to an oral order from the prescriber, the transmitted document need not include the prescriber's signature~~,~~ but must include the name of the agent.

C. The immediate outside container of a radioactive drug to be dispensed shall also be labeled in accordance with requirements of § 54.1-3410.1 B of the Code of Virginia.

D. The immediate inner container shall be labeled with~~:~~ (i) the standard radiation symbol~~;~~, (ii) the words "Caution--Radioactive Material,"~~;~~ and (iii) the serial number assigned to the order.

E. Nuclear pharmacies may redistribute approved radioactive drugs if the pharmacy does not process the radioactive drugs in any manner nor violate the product packaging.

Part ~~VI~~ IV
Drug Inventory and Records

18VAC110-20-240. Manner of maintaining records, prescriptions, inventory records.

A. Each pharmacy shall perform and maintain the inventories and records of drugs as follows:

1. Inventories and records of all drugs listed in Schedules I and II shall be maintained separately from all other records of the pharmacy. Inventories of drugs in Schedules I and II shall be performed by physically counting the drugs. Each pharmacy shall maintain a perpetual inventory of all Schedule II drugs received and dispensed~~, with~~ that accurately indicates the physical count of each Schedule II drug "on-hand" at the time of performing the inventory. The perpetual inventory shall include a reconciliation of each Schedule II drug at least monthly with a written explanation for any difference between the physical count and the theoretical count. Electronic monitoring at the pharmacy or by another entity that provides alerts for discrepancies between drugs received and drugs dispensed is acceptable provided such alerts are reviewed at least monthly.

2. Inventories and records of drugs listed in Schedules III, IV, and V may be maintained separately or with records of Schedule VI drugs but shall not be maintained with other records of the pharmacy. Inventories of drugs in Schedules III, IV, and V may be performed by estimating the count of drugs in Schedules III, IV, and V unless the container contains greater than 1,000 tablets or capsules or there has been a theft or any other unusual loss of drug and the exact kind and quantity of the drug loss is unknown.

3. All executed order forms, prescriptions, and inventories of ~~Schedule~~ Schedules II through V drugs shall be maintained at the same address as the stock of drugs to which the records pertain. If authorized by DEA, other records pertaining to ~~Schedule~~ Schedules II through V drugs, such as invoices, may be maintained in an off-site database or in secured storage. All records in off-site storage shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

4. All inventories required by § 54.1-3404 of the Code of Virginia shall be signed and dated by the person taking the inventory and shall indicate whether the inventory was taken prior to the opening of business or after close of business. A 24-hour pharmacy with no opening or closing of business shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.

5. Invoices or other records showing receipts of Schedule VI drugs shall be maintained~~,~~ but may be stored in an electronic database or record as an electronic image that

provides an exact, clearly legible, image of the document or in secured storage either on site or off site. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

6. All records required by this section shall be filed chronologically and maintained for a period of not less than two years from the date of transaction.

B. Prescriptions.

1. A hard copy prescription shall be placed on file for every initial prescription dispensed and be maintained for two years from the date of last refill. All prescriptions shall be filed chronologically by date of initial dispensing or by date of initial entry into the automated data processing system in compliance with 18VAC110-20-250 if such a system is employed by the pharmacy.

2. Schedule II drugs. Prescriptions for Schedule II drugs shall be maintained in a separate prescription file.

3. ~~Schedule~~ Schedules III ~~through~~, IV, and V drugs. Prescriptions for ~~Schedule~~ Schedules III ~~through~~, IV, and V drugs shall be maintained either in a separate prescription file for drugs listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescriptions of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than one inch high and filed in the prescription file for drugs listed in the usual consecutively numbered prescription file for Schedule VI drugs. However, if a pharmacy employs an automated data processing system or other electronic recordkeeping system for prescriptions ~~which~~ that permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

C. Chart orders.

1. A chart order written for a patient in a hospital or long-term care facility, a patient receiving home infusion services, or a hospice patient pursuant to § 54.1-3408.01 A of the Code of Virginia shall be exempt from having to contain all required information of a written prescription provided:

a. This information is contained in other readily retrievable records of the pharmacy; and

b. The pharmacy maintains and complies with a current policy and procedure manual that sets out where this information is maintained ~~and~~, how to retrieve it, and the minimum requirements for chart orders consistent with state and federal law and accepted standard of care.

2. A chart order may serve as the hard copy prescription for those patients listed in subdivision 1 of this subsection. When a chart order is intended for out-patient dispensing, it shall comply with requirements for a prescription in 18VAC110-20-286.

3. Requirements for filing of chart orders.

a. Chart orders shall be filed chronologically by date of initial dispensing with the following exception: If dispensing data can be produced showing a complete audit trail for any requested drug for a specified time period and each chart order is readily retrievable upon request, chart orders may be filed using another method. Such alternate method shall be clearly documented in a current policy and procedure manual.

b. If a single chart order contains both an order for a Schedule II drug and one or more orders for a drug in another schedule, where the Schedule II drug is not floor stocked, but is dispensed from the pharmacy pursuant to this order for the specific patient, the original order must be filed with records of dispensing of Schedule II drugs and a copy of the order placed in the file for other schedules.

Part ~~VII~~ V

Prescription Order and Dispensing Standards

18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions; ~~supervision of pharmacy technicians.~~

A. In addition to the ~~acts restricted to a pharmacist in § 54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians. B. A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time; however, no pharmacist shall supervise more than four persons acting as pharmacy technicians at one time~~ requirements in § 54.1-3408.01 of the Code of Virginia for an oral prescription or written prescription, including those transmitted via facsimile or electronically, a prescription shall include a quantity or duration of the order by which the pharmacist can calculate the authorized quantity using directions for use. Except for prescriptions transmitted electronically in compliance with 18VAC110-20-285, written prescriptions shall also include the prescriber's manual signature.

~~C.~~ B. After the prescription has been prepared and prior to the delivery of the order, a pharmacist shall inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction. If more than one pharmacist is involved in verifying the accuracy of the prescription product, a record shall be maintained identifying the date of dispensing, each

pharmacist involved in the process, and the individual task for which ~~he~~ each pharmacist is responsible for verifying the accuracy. Such record showing verification of accuracy shall be maintained on a pharmacy record and, if necessary, an alternate record consistent with 18VAC110-20-255 for the required time period of two years~~,~~ unless otherwise specified in regulation. If the dispensing involves central or remote processing, records of pharmacist verification shall be maintained in a manner consistent with 18VAC110-20-276 and 18VAC110-20-515.

~~D.~~ C. If a pharmacist declines to fill a prescription for any reason other than the unavailability of the drug prescribed, he shall record on the back of the prescription the word "declined"; the name, address, and telephone number of the pharmacy; the date filling of the prescription was declined; and the signature of the pharmacist.

~~E.~~ D. If a pharmacist determines from a prescriber or by other means, including the use of his professional judgment, that a prescription presented for dispensing is a forgery, the pharmacist ~~shall not~~ may refuse to return the forged prescription to the person presenting it. The forged prescription may be given to a law-enforcement official investigating the forgery~~;~~, or it shall be retained for a minimum of 30 days before destroying it~~,~~ in the event it is needed for an investigative or other legitimate purpose.

~~F.~~ E. An on-hold prescription shall be entered into the automated data processing system if such system is employed by the pharmacy, and the pharmacist on-duty shall verify the accuracy of the data entry at that time. The pharmacist subsequently dispensing the on-hold prescription on a future date shall, at a minimum, conduct a prospective drug review consistent with § 54.1-3319 A of the Code of Virginia. If an on-hold prescription is returned to a patient prior to the initial dispensing of the drug, the pharmacist shall delete the entry in the automated data processing system.

F. A pharmacy may use a drop box for the collection of written prescriptions and refill requests. The drop box shall be located in a visible area within the permitted facility and shall be locked at all times with access to the items placed in the drop box restricted to pharmacists practicing at the pharmacy or an authorized pharmacy technician practicing at the pharmacy when a pharmacist is on duty. The drop box shall be constructed in a manner to prevent the theft or loss of a written prescription or confidential information and shall be bolted to the floor or a fixed structure. Pharmacists shall in some manner inform the public that containers left in a drop box for refill should not contain unused drugs.

18VAC110-20-280. Transmission of a prescription order by facsimile ~~machine~~ device.

A. Unless otherwise prohibited by federal law, prescription orders for ~~Schedule~~ Schedules III through VI drugs may be transmitted to pharmacies by facsimile (fax) device ~~(FAX)~~ upon the following conditions:

1. The prescription shall be faxed only to the pharmacy of the patient's choice.

2. A valid faxed prescription shall contain all required information for a prescription. A written prescription shall include the prescriber's signature.

3. An authorized agent, as defined in § 54.1-3408.01 C of the Code of Virginia, may transmit an oral prescription by facsimile and shall record on the faxed prescription the agent's full name and wording that clearly indicates that the prescription being transmitted is an oral prescription.

4. A faxed prescription shall be valid only if faxed from the prescriber's practice location, except in the following situations:

a. Forwarding a faxed chart order from a long-term care facility or from a hospice, including a home hospice;

b. Faxing an oral prescription by authorized agent under the conditions set forth in subdivision 3 of this subsection; or

c. Forwarding a written prescription by an authorized agent from a long-term care facility, provided the provider pharmacy maintains written procedures for such transactions~~,~~ and provided the original prescription is obtained by the provider pharmacy within seven days of dispensing. The original prescription shall be attached to the faxed copy.

5. The following additional information shall be recorded on the faxed prescription:

a. The date that the prescription was faxed;

b. The printed name, address, phone number, and fax number of the authorized prescriber; and

c. The institution, if applicable, from which the prescription was faxed, including address, phone number~~,~~ and fax number.

B. Prescription orders for Schedule II drugs may only be faxed for information purposes and may not serve as the original written prescription authorizing dispensing, except for orders to be administered to long-term care facility and home infusion patients in accordance with § 54.1-3408.01 B of the Code of Virginia and except for prescriptions written for a Schedule II narcotic substance for patients residing in a hospice certified by Medicare under Title XVIII or licensed by the state, which may include home hospice. The prescriber shall note on the prescription if the patient is a hospice patient, and the prescription shall meet all requirements for a written prescription, including the prescriber's manual signature.

C. If the faxed prescription is of such quality that the print will fade and not remain legible for the required retention period, the receiving pharmacist shall copy or transcribe the faxed prescription on paper of permanent quality.

D. Authorizations for refills may be faxed by the prescriber to the pharmacy provided the authorization includes patient name, address, drug name and strength, quantity, directions for use, prescriber's name, prescriber's manual signature or agent's name, and date of authorization.

18VAC110-20-290. Dispensing of Schedule II drugs.

A. A prescription for a Schedule II drug shall be dispensed in good faith but in no case shall it be dispensed more than six months after the date on which the prescription was issued.

B. A prescription for a Schedule II drug shall not be refilled except as authorized under the conditions for partial dispensing as set forth in 18VAC110-20-310.

C. In case of an emergency situation, a pharmacist may dispense a drug listed in Schedule II upon receiving oral authorization of a prescribing practitioner, provided that:

1. The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period;

2. The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in § 54.1-3410 of the Drug Control Act, except for the signature of the prescribing practitioner;

3. If the pharmacist does not know the practitioner, ~~he~~ the pharmacist shall make a reasonable effort to determine that the oral authorization came from a practitioner using ~~his~~ the practitioner's phone number as listed in the telephone directory or other good-faith efforts to ensure the practitioner's identity; and

4. Within seven days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of § 54.1-3410 of the Drug Control Act, the prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail postmarked within the seven-day period, or transmitted as an electronic prescription in accordance with federal law and regulation to include annotation of the electronic prescription with the original authorization and date of the oral order. Upon receipt, the dispensing pharmacist shall attach the paper prescription to the oral emergency prescription, which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Drug Enforcement Administration and the board if the prescribing practitioner fails to deliver a written prescription to ~~him~~ the pharmacist. Failure of the pharmacist to do so shall void the authority conferred by this subdivision to dispense without a written prescription of a prescribing practitioner.

D. When presented a prescription written for a Schedule II controlled substance, a pharmacist may add or correct the patient's address upon verification, correct the patient's name upon verification, or add the prescriber's DEA registration number to the prescription. The pharmacist may add or change the dosage form, drug strength, directions for use, drug quantity, or issue date only after oral consultation directly with and agreement of the prescriber. Such consultations and corresponding changes shall be noted by the pharmacist on the prescription. The pharmacist shall not add or change the prescriber's signature or make changes to the controlled substance prescribed, except for dispensing therapeutically equivalent drugs as permitted by law.

18VAC110-20-355. Pharmacy repackaging of drug; records required; labeling requirements.

A. Pharmacies in which bulk reconstitution of injectable, bulk compounding, or the repackaging or prepackaging of drugs is performed shall maintain adequate control records for a period of one year or until the expiration, whichever is greater. The records shall show the name of the ~~drug(s)~~ drugs used; strength, if any; date repackaged; quantity prepared; initials of the pharmacist verifying the process; the assigned lot or control number; the manufacturer's or distributor's name and lot or control number; and an expiration date.

B. The drug name; strength, if any; the assigned lot or control number or the manufacturer's or distributor's name and lot or control number; and an appropriate expiration date determined by the pharmacist in accordance with USP guidelines shall appear on any subsequently repackaged or reconstituted units.

C. Repackaging of drugs shall be performed in compliance with USP-NF standards.

~~C.~~ D. Pharmacies using automated counting devices or dispensers in which drugs are removed from manufacturer's original packaging and placed in bulk bins shall comply with the following requirements:

1. A bin filling record shall be maintained, manually or in a computerized record for a period of one year from date of filling from which information can be readily retrieved, for each bin including:

a. The drug name and strength, if any;

b. The name of the manufacturer or distributor;

c. Manufacturer's control or lot ~~number(s)~~ numbers and expiration date for all lots placed into the bin at the time of filling;

d. Any assigned lot number;

e. An expiration date determined according to USP guidelines for repackaging;

f. The date of filling; and

g. The pharmacist's initials verifying the accuracy of the process.

2. If more than one lot is added to a bin at the same time, the lot ~~which~~ that expires first shall be used to determine the expiration date if shorter than a calculated date based on USP guidelines.

3. Each bin shall be labeled in such a manner as to cross-reference the information on the filling record with the correct expiration date.

4. If only one lot is added to a bin at one time, but a subsequent lot may be added before the first has cleared, the automated device shall be constructed to reasonably dispense the first lot before the second lot is dispensed, and the expiration date on the bin's label shall reflect the expiration date assigned to the earlier lot.

5. In the event of a drug recall involving one of multiple lots placed in a bin of an automated counting device in the last three months or if a recalled drug is known to remain in the bin, all drugs shall be removed from the bin and not used for patient care. The removal of drugs from the bin is not required if:

a. The technology of the automated counting device can ensure drugs in a particular lot have been cleared; or

b. The bin has been "run dry," with a record made of the "run dry" date, since the addition of the recalled lot number in which all drugs were completely removed prior to filling with a subsequent lot number.

6. An automated counting device shall be cleaned and maintained in accordance with recommended manufacturer guidelines and specifications.

~~D.~~ E. A pharmacy may return a dispensed drug to stock for redispensing that has never left the pharmacy premises or the control of the pharmacy delivery agent pursuant to § 54.1-3411.1 A 3 of the Code of Virginia under the following conditions:

1. An expiration date shall be placed on the label prior to returning the drug to stock. In the absence of stability data to the contrary, the date on the label may not exceed the expiration date on the manufacturer's container or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier.

2. The restocked drug shall be used to fill the next prescription received for that product. In the event that the drug is not dispensed prior to the new assigned expiration date, it shall be removed from working stock as expired, and disposed of in accordance with 18VAC110-20-210.

3. If there is no lot number on the label of a drug returned to stock or on the prescription records that can be cross-referenced from the prescription label, the drug shall be removed from stock upon any recall of that drug product and returned to the manufacturer or otherwise disposed of in accordance with 18VAC110-20-210.

18VAC110-20-390. Kickbacks, fee-splitting, interference with supplier.

A. A ~~pharmacist~~ pharmacy shall not solicit or foster prescription practice with a prescriber of drugs or any other person providing for rebates, "kickbacks," fee-splitting, or special charges in exchange for prescription orders ~~unless fully disclosed in writing to the patient and any third party payor~~.

B. A ~~pharmacist~~ pharmacy shall not interfere with the patient's right to choose his supplier of medication or cooperate with any person ~~or persons~~ in denying a patient the opportunity to select his supplier of prescribed medications.

18VAC110-20-425. Robotic pharmacy systems.

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

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

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

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

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

a. Accurate packaging and repackaging of all drugs for use in the robotic pharmacy system, to include properly labeled barcodes, and method for ensuring pharmacist

verification of all packaged and repacked drugs compliant with this chapter and assigned barcodes;

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

c. Removing expired drugs;

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

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

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

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

~~g.~~ h. Appropriately ~~investigating, identifying and correcting~~ performing a root cause analysis to investigate, identify, and correct sources of discrepancies or errors associated with the robotic pharmacy system; and

~~h.~~ i. Maintaining quality assurance reports.

~~5. Pharmacists shall perform a daily random check of medications or compliance packaging picked by the robot for 5.0% of all patients' bins and 5.0% of all first doses or cart updates. Documentation of this check shall include the pharmacist's initials for each medication checked and a description of all discrepancies found.~~

~~6.~~ 5. All manual picks shall be checked by pharmacists.

~~7.~~ 6. If the robot picks an incorrect medication, the pharmacy shall immediately institute a 100% check of all affected doses or compliance packages and ~~shall immediately report the error to the board. The 100% check procedure shall continue until such time as the pharmacy provides documentation to the board showing that the cause of the error has been determined and addressed and that the robot is no longer making errors, and the board allows the pharmacy to return to a reduction in checking~~ perform a root cause analysis to investigate, identify, and correct the source of discrepancy or error in compliance with the pharmacy's policies and procedures prior to resuming full operations of the robot.

~~8.~~ 7. Quarterly quality assurance reports demonstrating the accuracy of the robot shall be maintained. At a minimum, these reports shall include~~: a. A~~ a summary indicating the date and description of all discrepancies that include ~~but are not limited to~~ discrepancies involving the packaging, repackaging, and dispensing of drugs via the robotic pharmacy system found during that quarter plus a cumulative summary since initiation of the robotic pharmacy system.

~~b. The total number of doses packaged or compliance packages prepared for the robotic pharmacy system and total number of doses or compliance packages picked by the robot during the quarter.~~

~~c. The total number of doses or compliance packages picked by the robot that were checked in conducting the 5.0% checks.~~

~~d. Dates and time associated with any scheduled or unanticipated downtime with an explanation of the problem to include the time span of the downtime and the resolution.~~

~~9. All unanticipated downtime shall be immediately reported to the board.~~

~~10.~~ 8. All records required by this section shall be maintained at the address of the pharmacy for a minimum of two years. Records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

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

18VAC110-20-470. Emergency room.

All drugs in the emergency department shall be under the control and supervision of the PIC and shall be subject to the following additional requirements:

1. All drugs kept in the emergency room shall be in a secure place from which unauthorized personnel and the general public are excluded.

2. Oral orders for medications shall be reduced to writing and shall be signed by the ~~practitioner~~ prescriber.

3. A medical practitioner may dispense drugs to his patients if in a bona fide medical emergency or when pharmaceutical services are not readily available and if permitted to do so by the hospital; the drug container and the labeling shall comply with the requirements of this chapter and the Drug Control Act.

4. A record shall be maintained of all drugs administered in the emergency room.

5. A separate record shall be maintained on all drugs, including drug samples, dispensed in the emergency room.

The records shall be maintained for a period of two years showing:

a. Date and time dispensed;

b. Patient's name;

c. Prescriber's name;

d. Name of drug dispensed, strength, dosage form, quantity dispensed, and dose.

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

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

B. Policy and procedure manual; access codes.

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

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

C. Distribution of drugs from the pharmacy.

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

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

D. Distribution of drugs from the device.

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

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

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

F. Reviews and audits.

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

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

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

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

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

a. The audit shall include a review of administration records ~~from~~ for each device per month for possible

diversion by fraudulent charting. The review shall include all ~~Schedule~~ Schedules II through V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

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

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

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

(2) Monitoring of overrides and unresolved discrepancies.

d. The report shall be used to identify suspicious activity, which includes~~, but is not limited to,~~ usage beyond three standard deviations in peer-to-peer comparisons. A focused audit of the suspicious activity and individuals associated with the activity shall be performed whenever suspicious activity is identified from the reports.

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

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

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

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

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

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

H. Records.

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

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

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

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

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

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

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

18VAC110-20-530. Pharmacy's responsibilities to long-term care facilities.

A. The pharmacy serving a long-term care facility shall:

1. Receive a valid order prior to the dispensing of any drug.

2. Ensure that personnel administering the drugs are trained in using the dispensing system provided by the pharmacy.

3. Ensure that the drugs for each patient are kept and stored in the originally received containers and that the medication of one patient shall not be transferred to another patient.

4. Ensure that each cabinet, cart, or other area utilized for the storage of drugs is locked and accessible only to authorized personnel.

5. Ensure that the storage area for patients' drugs is well lighted, of sufficient size to permit storage without crowding, and is maintained at appropriate temperature.

6. Ensure that poison and drugs for "external use only" are kept in a cabinet and separate from other medications.

7. Provide for the disposition of discontinued drugs under the following conditions:

a. Discontinued drugs may be returned to the pharmacy for resale or transferred to another pharmacy for redispensing to the indigent if authorized by § 54.1-3411.1 of the Code of Virginia and 18VAC110-20-400, or disposed of by appropriate means in compliance with 18VAC110-20-210 and with any applicable local, state, and federal laws and regulations.

b. Drug destruction at the pharmacy shall be witnessed by the PIC and by another pharmacy employee. The pharmacy may transfer the drugs for destruction to an entity appropriately licensed to accept returns for destruction. Drug destruction at the facility shall be witnessed by the director of nursing or, if there is no director, then by the facility administrator and by a pharmacist providing pharmacy services to the facility or by another employee authorized to administer medication.

c. A complete and accurate record of the drugs returned or destroyed or both shall be made. The original of the record of destruction shall be signed and dated by the persons witnessing the destruction and maintained at the long-term care facility for a period of two years. A copy of the destruction record shall be maintained at the provider pharmacy for a period of two years.

d. Long-term care facilities shall destroy discontinued or unused drugs or return them to the pharmacy within 30 days of the date the drug was discontinued.

8. Ensure that appropriate drug reference materials are available in the facility units.

9. Ensure that a monthly review of drug therapy by a pharmacist is conducted for each patient in long-term care facilities except those licensed under Title 63.2 of the Code of Virginia. Such review shall be used to determine any irregularities, which may include ~~but not be limited to~~ drug therapy, drug interactions, drug administration, or transcription errors. The pharmacist shall sign and date the notation of the review. All significant irregularities shall be brought to the attention of the attending practitioner or other party having authority to correct the potential problem.

B. The pharmacy providing services to the long-term care facility may share a copy of a Schedule VI prescription or order with another pharmacy for the purpose of dispensing an immediate supply of drugs, not to exceed a seven-day supply, without transferring the prescription pursuant to 18VAC110-20-360 if the following conditions are satisfied:

1. The pharmacy providing services to the long-term care facility has a written contract with the other pharmacy outlining services to be provided, the recordkeeping associated with the dispensing, and the responsibilities of each pharmacy; and

2. The pharmacy providing services to the long-term care facility provides a valid oral or written prescription or order to the other pharmacy.

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

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

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

a. The dispensing pharmacy must have a method of sealing such boxes so that once the seal is broken, it cannot be reasonably resealed without the breach being detected.

b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication or resealing, or both. The pharmacy shall maintain a record of the seal identifiers when placed on a box and maintain the record until such time as the seal is replaced.

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

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

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

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

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

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

b. The stat-drug box shall contain no more than 20 solid dosage units per schedule of Schedules II through V drugs except that one unit of liquid, not to exceed 30 ml, may be substituted for a solid dosage unit in each drug schedule. If the unit of a liquid that may contain more than one dose is removed from the stat-drug box pursuant to a patient order, the remainder shall be stored with that patient's other drugs, may be used for subsequent doses administered to that patient, and shall not be administered to any other patient.

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

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

18VAC110-20-580. ~~Humane societies and animal~~ Animal shelters.

~~A humane society or~~ An animal shelter, after having obtained the proper registrations pursuant to state and federal laws, may purchase, possess and administer controlled substances in accordance with provisions of § 54.1-3423 of the Code of Virginia provided that these procedures are followed:

1. Drugs ordered by a ~~humane society~~ public or private animal shelter, as defined in § 3.2-6500 of the Code of Virginia, shall only be stored and administered at the address of the ~~humane society or~~ shelter.

2. A veterinarian shall provide general supervision for the facility and shall provide and certify training in accordance with guidelines set forth by the State Veterinarian to the ~~person(s)~~ persons responsible for administration of the drugs. Certification of training signed by the veterinarian providing the training shall be maintained at the facility for each person administering drugs and must be retained for not less than two years after the person ceases administering.

3. The person in charge of administration of drugs for the facility shall obtain the required permit and controlled substances registration from the board and shall be responsible for maintaining proper security and required records of all controlled substances obtained and administered.

a. If that person ceases employment with the facility or relinquishes his position, he shall immediately return the registration to the board and shall take a complete and accurate inventory of all drugs in stock.

b. An application for a new registration shall be filed with the required fee within 14 days on a form provided by the board. At that time, the new responsible person shall take a complete and accurate inventory of all drugs in stock.

4. Drugs shall be stored in a secure, locked place and only the ~~person(s)~~ person responsible for administering may have access to the drugs.

5. All invoices and order forms shall be maintained for a period of two years.

6. Complete and accurate records shall be maintained for two years on the administration of the drug. The record shall show the name and strength of the drug, date of administration, the species of the animal, the weight of animal, the amount of drug administered and the signature of the person administering the drug.

Part ~~XV~~ XIII
Medical Equipment Suppliers

18VAC110-20-630. Issuance of a permit as a medical equipment supplier.

A. Any person or entity desiring to obtain a permit as a medical equipment supplier shall file an application with the board on a form approved by the board. An application shall be filed for a new permit or for acquisition of an existing medical equipment supplier. The application shall designate the hours of operation the location will be open to service the public and shall be signed by a person who works at the location address on the application and will act as a responsible party for that location.

B. Any change in the hours of operation expected to last for more than one week shall be reported to the board in writing and a notice posted, at least 14 days prior to the anticipated change, in a conspicuous place to the public.

1. Such notification of a change in hours of operation is not required when the change is necessitated by emergency circumstances beyond the control of the owner or responsible party or when the change will result in an expansion of the current hours of operation.

2. If the medical equipment supplier is unable to post the change in hours 14 days in advance, the responsible party or owner shall ensure the board is notified as soon as he knows of the change and disclose the emergency circumstances preventing the required notification.

C. Within 14 days of a change in the responsible party assigned to the permit, the outgoing responsible party shall inform the board, and a new application shall be submitted indicating the name of the new responsible party.

~~B.~~ D. A permit holder proposing to change the location of an existing license or permit or make structural changes to an existing location shall file an application for approval of the changes following an inspection conducted by an authorized agent of the board.

~~C.~~ E. A permit shall not be issued to any medical equipment supplier to operate from a private dwelling or residence or to operate without meeting the applicable facility requirements for proper storage and distribution of drugs or devices. Before any license or permit is issued, the applicant shall demonstrate compliance with all federal, state and local laws and ordinances.

18VAC110-20-680. Medical equipment suppliers.

A. A medical equipment supplier's location shall be inspected by the board prior to engaging in business. The location shall be clean and sanitary and shall have a system of temperature control to provide for specified storage conditions for any Schedule VI drug or device.

B. Hypodermic needles and syringes and Schedule VI drugs shall not be placed on open display or in an open area where patrons will have access to such items. No Schedule VI devices shall be placed in an area where responsible parties cannot exercise reasonable supervision and control.

C. A medical equipment supplier shall receive a valid order from a practitioner prior to dispensing and shall maintain this order on file on the premises for a period of two years from date of last dispensing. The original order may be kept at a centralized office as long as it is readily retrievable within 48 hours and a copy of the order is kept on the premises of the dispensing supplier. In lieu of a hard copy, an electronic image of an order may be maintained in an electronic database provided it preserves and provides an exact image of the order that is clearly legible and made available within 48 hours of a request by a person authorized by law to have access to prescription information.

D. Medical equipment suppliers shall make a record at the time of dispensing. This record shall be maintained on the premises for two years from date of dispensing and shall include:

1. Name and address of patient;

2. Item dispensed and quantity, if applicable; and

3. Date of dispensing.

E. A valid order authorizing the dispensing of drugs or devices may be transferred from one medical equipment supplier to another medical equipment supplier provided the order can be filled or refilled. The transfer shall be communicated either orally by direct communication between an individual at the transferring medical equipment supplier and the receiving medical equipment supplier, by facsimile machine, or by electronic transmission.

1. The transferring medical equipment supplier shall:

a. Record the word "VOID" on the face of the invalidated order;

b. Record on the reverse side of the invalidated order the name and address of the medical equipment supplier to which it was transferred, the date of the transfer, and for an oral transfer, the name of the individual receiving the prescription information and the name of the individual transferring the information.

2. The receiving medical equipment supplier shall:

a. Write the word "TRANSFER" on the face of the transferred prescription;

b. Provide all information required to be on a valid order to include:

(1) Date of issuance of original order;

(2) Original number of refills authorized on the original order;

(3) Date of original dispensing if applicable;

(4) Number of valid refills remaining and date of last dispensing;

(5) Medical equipment supplier name and address from which the order information was transferred; and

(6) Name of transferring individual if transferred orally.

3. Both the original and transferred order shall be maintained for a period of two years from the date of last refill. In lieu of recording the required information on the hard copy of a valid order, a medical equipment supplier may record all required information in an automated data processing system used for the storage and retrieval of dispensing information.

~~E.~~ F. A nonresident medical equipment supplier shall register and practice in accordance with § 54.1-3435.3:1 of the Code of Virginia.

CHAPTER 21
REGULATIONS GOVERNING THE LICENSURE OF PHARMACISTS AND REGISTRATION OF PHARMACY TECHNICIANS

Part I General Provisions

18VAC110-21-10. Definitions.

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

"ACPE" means the Accreditation Council for Pharmacy Education.

"Board" means the Virginia Board of Pharmacy.

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

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

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

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

"FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign Pharmacy Equivalency Examination and a credential review of foreign training to establish educational equivalency to board approved schools of pharmacy and has passed approved examinations establishing proficiency in English.

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

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

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

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

18VAC110-21-20. Fees.

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

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

C. Initial application fees.

1. Pharmacist license	$180
2. Pharmacy intern registration	$15
3. Pharmacy technician registration	$25
4. Approval of a pharmacy technician training program	$150
5. Approval of a continuing education program	$100

D. Annual renewal fees.

1. Pharmacist active license – due no later than December 31	$90
2. Pharmacist inactive license – due no later than December 31	$45
3. Pharmacy technician registration – due no later than December 31	$25
4. Pharmacy technician training program	$75 every two years

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

1. Pharmacist license	$30
2. Pharmacist inactive license	$15
3. Pharmacy technician registration	$10
4. Pharmacy technician training program	$15

F. Reinstatement fees. Any person or entity attempting to renew a license or registration more than one year after the expiration date, or more than two years after the expiration date in the case of a pharmacy technician training program, shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board

and, except for reinstatement following revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

1. Pharmacist license	$210
2. Pharmacist license after revocation or suspension	$500
3. Pharmacy technician registration	$35
4. Pharmacy technician registration after revocation or suspension	$125
5. A pharmacy technician training program that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus a reinstatement fee of $75. A pharmacy technician training program that ceases operation and wishes to resume shall not be eligible for reinstatement but shall apply for a new registration.	

G. Miscellaneous fees.

1. Duplicate wall certificate	$25
2. Returned check	$35
3. Duplicate license or registration	$10
4. Verification of licensure or registration	$25

18VAC110-21-30. Current name and address.

A. It shall be the duty and responsibility of each licensee and registrant to inform the board of his current name and address. A licensee or registrant shall notify the board within 14 days in writing or electronically of a name change or a change of an address of record. Properly updating a name or an address of record directly through the board's web-based application or other approved means shall constitute lawful notification.

B. All notices required by law or by this chapter are deemed to be received by the licensee or registrant when sent to the address of record and shall not relieve the licensee or registrant of the obligation to comply.

C. An individual licensed by or registered with the board who has provided the board with a public address that is different from the address of record shall notify the board in writing if there is a change in the address.

18VAC110-21-40. Unprofessional conduct.

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

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

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

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

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

5. Engaging or attempting to engage in a relationship with a patient that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a patient or the patient's family, including sexual misconduct with a patient or a member of the patient's family or other conduct that results or could result in personal gain at the expense of the patient;

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

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

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

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

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

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

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

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

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

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

18VAC110-21-45. Kickbacks, fee-splitting, interference with supplier.

A. A pharmacist shall not solicit or foster prescription practice with a prescriber of drugs or any other person providing for rebates, kickbacks, fee-splitting, or special charges in exchange for prescription orders.

B. A pharmacist shall not interfere with the patient's right to choose his supplier of medication or cooperate with any person or persons in denying a patient the opportunity to select his supplier of prescribed medications.

Part II
Licensure Requirement for Pharmacists

18VAC110-21-50. Requirements for pharmacy practical experience.

A. Each applicant for licensure as a pharmacist shall have gained practical experience in the practice of pharmacy as set forth in this section and 18VAC110-21-60.

B. An applicant for licensure as a pharmacist shall attain a minimum of 1,500 hours of practical experience.

C. Practical experience that is gained within an ACPE-accredited school of pharmacy, that conforms to the current ACPE standards, and that allows the student to gain at least 1,500 hours of practical experience shall meet the board's practical experience requirements for licensure as a pharmacist.

D. All practical experience credit gained outside of an ACPE-accredited school of pharmacy program shall only be gained after successful completion of the equivalent of at least two semesters in an ACPE-accredited school of pharmacy. Credit shall not be given for more than 50 hours in one week and not less than an average of 20 hours per week averaged over a month. The board may grant an exception to the minimum number of hours for good cause shown.

E. In accordance with § 54.1-3312 of the Code of Virginia, all practical experience required by this section shall be gained within the United States.

18VAC110-21-60. Procedure for gaining practical experience.

A. Each person desiring to gain practical pharmacy experience in Virginia shall first register with the board as a pharmacy intern on a form provided by the board prior to becoming so engaged as a pharmacy intern. This requirement shall apply to any person gaining practical experience within the Commonwealth whether for licensure in Virginia or in another state.

B. In order to be eligible to register as a pharmacy intern, an applicant shall meet at least one of the following criteria:

1. The applicant shall be enrolled in and have started course work in a professional degree program of a board-approved school of pharmacy. Such registration is only valid while the student is enrolled in the school of pharmacy and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist. An expiration date shall be assigned to the registration to cover the estimated time period for the student to complete the school program and pass the required examinations. If the student is no longer enrolled in the school program, takes a voluntary break from the program, or is otherwise not actively participating in the school program, except for regularly scheduled school breaks, the registration is no longer valid and shall be returned to the board immediately;

2. The applicant is a graduate of a board-approved school of pharmacy or a graduate of a foreign school of pharmacy, has established educational equivalency and proficiency in English by obtaining the FPGEC certificate, and desires to gain required practical experience required for licensure as a pharmacist. Such applicant shall provide documentation on a board-approved form of current employment or an employment start date within 90 days in a pharmacy in Virginia with approval by the supervising pharmacist. An expiration date shall be assigned to cover the estimated time period needed to obtain the required practical experience hours and take the required examinations to become licensed as a pharmacist;

3. The applicant has already gained the required practical experience but is an otherwise qualified applicant awaiting examination for licensure. A three-month expiration date shall be assigned to allow the applicant time to take required examinations; or

4. The applicant is an applicant for reactivation or reinstatement of a previously issued pharmacist license and is meeting board requirements for relicensure. An expiration date shall be assigned to reasonably cover the period of time necessary to meet the board requirements.

C. For documented good cause shown, the executive director of the board may extend the expiration date of the intern registration upon submission of an application form approved by the board and payment of the initial application fee.

D. A pharmacy intern shall be supervised by a pharmacist who holds a current, unrestricted license and assumes full

responsibility for the training, supervision, and conduct of the intern.

E. The intern registration of a pharmacy student shall be valid only while the student is enrolled in a school of pharmacy. The registration card issued by the board shall be returned to the board upon failure to be enrolled.

F. Practical experience gained within any other state must be registered with and certified by the board of that state in order to be accepted or certified by the board. In the event that a state relies on the pharmacy school to certify the hours of experience, an affidavit from the pharmacy school certifying the hours of experience gained in the United States may be accepted in lieu of board certification.

G. All practical experience of the pharmacy intern shall be evidenced by an affidavit approved by the board, which shall be filed prior to or with the application for examination for licensure.

H. An applicant for licensure by endorsement may provide verification acceptable to the board of practical experience hours worked as a pharmacist in another state within the United States in lieu of prelicensure intern hours in order to meet the practical experience requirement.

I. A pharmacy intern shall notify the board in writing of any change in address of record within 14 days of such change.

18VAC110-21-70. Curriculum and approved schools of pharmacy.

A. The following minimum educational requirements for the specified periods shall be recognized by the board for the purpose of licensure.

1. On and after June 1, 1936, but before June 1, 1964, the applicant for licensure shall have been graduated from a four-year course of study with a Bachelor of Science degree in pharmacy awarded.

2. On and after June 1, 1964, the applicant for licensure shall have been graduated from at least a five-year course of study with a Bachelor of Science degree in pharmacy or a Doctorate of Pharmacy degree awarded.

B. In order to be licensed as a pharmacist within this Commonwealth, the applicant shall have been granted the first professional degree from a program of a school of pharmacy that meets the requirements of § 54.1-3312 of the Code of Virginia or shall satisfy the requirements of 18VAC110-21-90.

18VAC110-21-80. Content of the examination and grades required; limitation on admittance to examination.

A. Prior to admission to any examination required for licensure, the applicant shall have met all other requirements to include education and practical experience requirements, but in no case shall the applicant be admitted if grounds exist to deny licensure under § 54.1-3316 of the Code of Virginia.

B. The applicant shall achieve a passing score as determined by the board on the licensure examination that is approved by the board and that shall consist of an integrated examination of pharmacy practice, pharmacology, pharmacy mathematics, and such other subjects as are necessary to assure that the candidate possesses the necessary knowledge and skills to practice pharmacy.

C. When an applicant for licensure by examination fails to meet the passing requirements of the board-approved integrated pharmacy examination on three occasions, the applicant shall not be readmitted to the examination until he has completed an additional 1,000 hours of practical experience as a pharmacy intern as set forth in 18VAC110-21-60.

D. The applicant shall also achieve a passing score as determined by the board on an examination that tests the candidate's knowledge of federal and state laws related to pharmacy practice. If an applicant has not subsequently been issued a license by any jurisdiction in the United States within three years of achieving a passing score, the applicant shall retake the examination in order to be licensed in Virginia.

E. When an applicant fails to pass the law examination, the applicant shall not be allowed to retake it for a period of 30 days.

F. If an applicant requests a testing accommodation for either examination based on a physical or mental impairment that substantially limits one or more major life activities, subject to the Americans with Disabilities Act, the board may approve a reasonable accommodation that does not compromise the security or integrity of the examination.

1. Supporting documentation shall be provided by the applicant to include the following to be considered for review:

a. A letter of request from the candidate that specifies the testing accommodation requested;

b. A written report of an evaluation (educational, psychological, or physical) within the preceding two years from a qualified professional that states a diagnosis of the disability, describes the disability, recommends specific accommodations, and provides justification that the accommodation is appropriate and necessary for the diagnosed disability. If the comprehensive evaluation was done more than two years ago and the condition is one that is not subject to change, the original evaluation report may be submitted along with a current letter from the qualified professional stating that there has been no change in the condition since the time of the evaluation; and

c. A written statement from the appropriate person at the applicant's school of pharmacy that describes any testing accommodations made while the student was enrolled, if applicable.

2. The applicant will be notified in writing of the decision. If the request for accommodation is granted, the approval information will be forwarded to the examination contractor and the form of the accommodation will be coordinated with the contractor.

18VAC110-21-90. Requirements for foreign-trained applicants.

A. Applicants for licensure who were trained in foreign schools of pharmacy shall obtain the FPGEC certificate prior to being allowed to register as a pharmacy intern and gain the required practical experience in Virginia.

B. After obtaining the FPGEC certificate, the applicant may apply for a pharmacy intern registration and shall fulfill the requirements for practical experience set forth in 18VAC110-21-50 and 18VAC110-21-60 before being admitted to examinations required by 18VAC110-21-80.

C. Applicants for licensure who were trained in foreign schools of pharmacy shall also complete and achieve passing scores on the examinations set forth in 18VAC110-21-80 before being licensed as a pharmacist.

D. Applicants for licensure who were trained in foreign schools of pharmacy, but who subsequently have been granted a professional degree from a program of a school of pharmacy that meets the requirements of § 54.1-3312 of the Code of Virginia, as specified in18VAC110-21-70, shall be exempt from the requirement for a FPGEC certificate but shall fulfill the requirements for practical experience set forth in 18VAC110-21-50 and 18VAC110-21-60 before being admitted to examinations required by 18VAC110-21-80.

18VAC110-21-100. Registration for voluntary practice by out-of-state licensees.

Any pharmacist who seeks registration to practice on a voluntary basis pursuant to subdivision 12 of § 54.1-3301 of the Code of Virginia under the auspices of a publicly supported, all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people shall:

1. File a complete application for registration on a form provided by the board at least five business days prior to engaging in such practice;

2. Provide a complete list of each state in which the pharmacist has held a pharmacist license and a copy of any current license;

3. Provide the name of the nonprofit organization and the dates and location of the voluntary provision of services;

4. Pay a registration fee of $10; and

5. Provide a notarized statement from a representative of the nonprofit organization attesting to its compliance with the provisions of subdivision 12 of § 54.1-3301 of the Code of Virginia.

Part III
Requirements for Renewal or Reinstatement of Licensure

18VAC110-21-110. Renewal and reinstatement of license.

A. Pharmacist licenses expire on December 31 and shall be renewed annually prior to that date by the submission of a renewal fee, renewal form, and statement of compliance with continuing education requirements.

B. A pharmacist newly licensed on or after October 1 shall not be required to renew that license until December 31 of the following year.

C. A pharmacist who fails to renew his license by the expiration date may renew his license at any time within one year of its expiration by submission of the renewal fee and late fee, renewal form, and statement of compliance with continuing education requirements.

D. A pharmacist who fails to renew his license for more than one year following expiration and who wishes to reinstate such license shall submit an application for reinstatement, pay the current renewal fee and a reinstatement fee, and submit documentation showing compliance with continuing education requirements. Reinstatement is at the discretion of the board and may be granted by the executive director of the board provided no grounds exist to deny said reinstatement.

E. A pharmacist who has been registered as inactive for more than one year must apply for reactivation, submit documentation showing compliance with continuing education requirements, and pay the difference between the inactive fee and the current year active renewal fee in order to resume active licensure.

F. In order to reactivate or reinstate a license to active status, a pharmacist who holds an inactive license, who has allowed his license to lapse, or who has had his license suspended or revoked must submit evidence of completion of CEUs or hours equal to the requirements for the number of years in which his license has not been active, not to exceed a total of 60 hours of CE.

G. A pharmacist whose license has been lapsed, is in inactive status, or has been suspended or revoked for more than five years shall, as a condition of reinstatement or reactivation in addition to 60 hours CE, take and receive a passing score on the board-approved law examination and furnish acceptable documentation of one of the following:

1. Active pharmacy practice within the past five years as a properly licensed pharmacist in another state; or

2. Practical experience as a pharmacy intern registered with the board of at least 160 hours within six months immediately prior to being reinstated or reactivated.

H. The practice of pharmacy without a current, active pharmacist license is unlawful and shall constitute grounds for disciplinary action by the board.

18VAC110-21-120. Requirements for continuing education.

A. A pharmacist shall be required to have completed a minimum of 1.5 CEUs or 15 contact hours of continuing pharmacy education in an approved program for each annual renewal of licensure. CEUs or hours in excess of the number required for renewal may not be transferred or credited to another year.

B. A pharmacy education program approved for continuing pharmacy education is:

1. One that is approved by the ACPE;

2. One that is approved as a Category I continuing medical education course, the primary focus of which is pharmacy, pharmacology, or drug therapy; or

3. One that is approved by the board in accordance with the provisions of 18VAC110-21-130.

C. Of the 15 contact hours required for annual renewal, at least five hours shall be obtained in courses or programs that are live or real-time interactive. Included in the five hours, the following may be credited:

1. A maximum of one hour for attendance at a board meeting or formal hearing; or

2. A maximum of one hour for serving as a preceptor for a pharmacy student or resident in an accredited school or program or for a foreign-trained student obtaining hours of practical experience.

D. The board may grant an extension pursuant to § 54.1-3314.1 E of the Code of Virginia. Any subsequent extension shall be granted only for good cause shown.

E. Pharmacists are required to attest to compliance with the CE requirements in a manner approved by the board at the time of their annual license renewal. Following each renewal period, the board may conduct an audit of the immediate past two years CE documents to verify compliance with the requirements. Pharmacists are required to maintain for two years following renewal the original certificates documenting successful completion of CE, showing the date and title of the CE program or activity, the number of CEUs or contact hours awarded, and a certifying signature or other certification of the approved provider. Pharmacists selected for audit must provide these original documents to the board by the deadline date specified by the board in the audit notice.

18VAC110-21-130. Approval of continuing education programs.

A. The board will approve without application or further review any program offered by an ACPE-approved provider and will accept for credit certificates bearing the official ACPE logo and program number.

B. The board may approve an individual CE program under the following provisions:

1. An approved individual program is a course, activity, or lecture that includes subject matter related to the competency of the practice of pharmacy and that has been approved for CE credit by the board.

2. In order to receive approval for an individual program, the sponsor or provider must apply prior to offering the program on a form provided by the board. The information that must be provided shall include:

a. Name of provider;

b. Location;

c. Date and time of program;

d. Charges to participants;

e. Description of program content and objectives;

f. Credentials of speaker or author;

g. Method of delivery;

h. Evaluation procedure;

i. Evidence of a post assessment;

j. Credits requested;

k. Mechanism for recordkeeping; and

l. Any such information as the board deems necessary to assure quality and compliance.

3. The sponsor applying for board approval of an individual program shall pay a fee as required in 18VAC110-21-20 C 5.

4. The board shall notify the provider or sponsor within 60 days following the receipt of a completed application of approval or disapproval of a program and the number of credits that may be awarded. The board shall also assign an expiration date for approval of the program not to exceed two years from the date of approval.

5. The provider of an approved program shall provide to each participant who completes the required hours and passes the post-test a certification with the name of the provider, name of the participant, description of course and method of delivery, number of hours credited, date of completion, and program identification number.

6. The provider of an approved program shall maintain all records on that program, program participants, and hours awarded for a period of five years and shall make those records available to the board upon request.

7. The board shall periodically review and monitor programs. The provider of a CE program shall waive registration fees for a representative of the board for that purpose.

8. Any changes in the information previously provided about an approved program or provider shall be submitted, or the board may withdraw its approval. If a provider wants to give a live program more than once, all program dates shall either be submitted on the original application or provided to the board in subsequent correspondence at least five days prior to giving the program.

Part IV
Requirements for Pharmacy Technician Registration

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

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.

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

18VAC110-21-150. Criteria for approval for training programs.

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

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

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

2. The preparation of prescription labels or patient information;

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

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

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

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

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

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

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

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

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

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

H. A pharmacy technician training program approval expires after two years, after which the program may apply for renewal. For continued approval, the program shall submit the renewal application, renewal fee, and a self-evaluation

report on a form provided by the board at the time of renewal notification. Renewal of a program's approval is at the discretion of the board, and the decision to renew shall be based on documentation of continued compliance with the criteria set forth in this section.

18VAC110-21-160. Examination.

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

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

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

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

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

A. Pharmacy technician registrations expire on December 31 and shall be renewed annually prior to that date by the submission of a renewal fee and renewal form. A pharmacy technician newly registered on or after July 1 shall not be required to renew that registration until December 31 of the following year. Failure to receive the application for renewal shall not relieve the pharmacy technician of the responsibility for renewing the registration by the expiration date.

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

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

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

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

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

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

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

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

CHAPTER 50
REGULATIONS GOVERNING WHOLESALE DISTRIBUTORS, MANUFACTURERS, THIRD-PARTY LOGISTICS PROVIDERS, AND WAREHOUSERS

18VAC110-50-40. Safeguards against diversion of drugs.

A. The holder of the license as a wholesale distributor or permit as a manufacturer, warehouser, or third-party logistics provider, or registration as a nonresident wholesale distributor or nonresident manufacturer shall restrict all areas in which prescription drugs are stored or kept for sale to only those persons specifically designated as necessary for the manufacture, receipt, storage, distribution, or quality control of the controlled substance inventory and shall provide reasonable security measures to include appropriate locking devices on all access doors to these areas and adequate lighting both inside and outside the facility to deter unauthorized entry and diversion.

B. The holder of the license, permit, or registration, except for those distributors of only medical gases other than nitrous oxide, shall install a device for the detection of breaking subject to the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.

2. ~~The~~ One communication line installation shall be hardwired and both the installation and device shall be based on accepted burglar alarm industry standards to include wireless motion sensors.

3. The device shall be maintained in operating order ~~and~~, shall have an auxiliary source of power, and shall be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational.

4. The device shall fully protect all areas where prescription drugs are stored and shall be capable of detecting breaking by any means when activated.

5. Access to the alarm system shall be restricted to the person named on the application as the responsible party or to persons specifically designated in writing in a policy and procedure manual.

6. The system shall be activated whenever the drug storage areas are closed for business.

C. Distribution or delivery of prescription drugs shall be accomplished in a manner to prevent diversion or possession of drugs by unauthorized persons.

1. The holder of the license, permit, or registration shall only deliver prescription drugs to a person authorized to possess such drugs at a location where the person is authorized to possess such drugs~~,~~ and only at a time when someone authorized to possess such drugs is in attendance.

2. The holder of the license, permit, or registration shall affirmatively verify that the person to whom prescription drugs are delivered is authorized by law to receive such drugs.

3. Prescription drugs may be transferred to an authorized agent of a person who may lawfully possess prescription drugs, provided the transfer occurs on the premises of the wholesale distributor, manufacturer, warehouser, third-party logistics provider, nonresident wholesale distributor, or nonresident manufacturer and provided the identity and authorization of the agent is verified, and such transfer is only used to meet the immediate needs of a patient ~~or patients~~.

Part II
Wholesale Distributors and Third-Party Logistics Providers

18VAC110-50-60. Special or limited-use licenses.

The board may issue a limited-use wholesale distributor license~~,~~; limited-use nonresident wholesale distributor registration~~,~~; or limited-use manufacturer, limited-use nonresident manufacturer, or limited-use third-party logistics provider permit to entities that do not engage in the wholesale distribution of prescription drugs or in the acts of a third-party logistics provider except medical gases and may waive certain requirements of regulation based on the limited nature of such distribution. The issuance of such a license shall be subject to continuing compliance with the conditions set forth by the board.

18VAC110-50-80. Minimum qualifications, eligibility, and responsible party.

A. The board shall use the following factors in determining the eligibility for licensure of wholesale distributors, registration of nonresident wholesale distributors, and permitting of third-party logistics providers:

1. The existence of grounds to deny an application as set forth in § 54.1-3435.1 of the Code of Virginia;

2. The applicant's past experience in the manufacture or distribution of drugs or devices;

3. Compliance with the recordkeeping requirements;

4. Prior disciplinary action by a regulatory authority, prior criminal convictions, or ongoing investigations related to the manufacturing, distribution, prescribing, or dispensing of drugs by the responsible party or immediate family members of the responsible party, and owners, directors, or officers; and

5. The responsible party's credentials as set forth in subsection B of this section.

B. Requirements for the person named as the responsible party.

1. The responsible party shall be the primary contact person for the board as designated by the wholesale distributor, nonresident wholesale distributor, or third-party logistics provider, who shall be responsible for managing the wholesale distribution operations at that location;

2. The responsible party shall have a minimum of two years of verifiable experience in a pharmacy or wholesale distributor or third-party logistics provider licensed, registered, or permitted in Virginia or another state where the person's responsibilities included~~, but were not limited to,~~ managing or supervising the recordkeeping, storage, and shipment for drugs or devices;

3. A person may only serve as the responsible party for one wholesale distributor license, nonresident wholesale distributor registration, or third-party logistics provider permit at any one time;

4. The responsible party shall be employed full time in a managerial position and actively engaged in daily operations of the wholesale distributor, nonresident wholesale distributor, or third-party logistics provider;

5. The responsible party shall be present on a full-time basis at the location of the wholesale distributor, nonresident wholesale distributor, or third-party logistics provider during normal business hours, except for time

periods when absent due to illness, family illness or death, vacation, or other authorized absence; and

6. The responsible party shall be aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale distributor, nonresident wholesale distributor, or third-party logistics provider and all applicable state and federal laws related to wholesale distribution of prescription drugs or the legal acts of a third-party logistics provider.

C. The person named as the responsible party on the application shall submit the following with the application:

1. A passport size and quality photograph taken within 30 days of submission of the application;

2. A resume listing employment, occupations, or offices held for the past seven years including names, addresses, and telephone numbers of the places listed;

3. An attestation disclosing whether the person has a criminal conviction or is the subject of any pending criminal charges within or outside the Commonwealth;

4. A federal criminal history record check ~~through the Central Criminal Records Exchange~~; and

5. A description of any involvement by the person with any business, including any investments, other than the ownership of stock in publicly traded company or mutual fund, during the past seven years, which manufactured, administered, prescribed, distributed, or stored drugs and devices and any lawsuits, regulatory actions, or criminal convictions related to drug laws or laws concerning third-party logistics providers or wholesale distribution of prescription drugs in which such businesses were named as a party.

D. Responsibilities of the responsible party.

1. Ensuring that any employee engaged in operations is adequately trained in the requirements for the lawful and appropriate wholesale distribution of prescription drugs or the legal acts of a third-party logistics provider;

2. Requiring any employee who has access to prescription drugs to attest that ~~he~~ the employer has not been convicted of any federal or state drug law or any law relating to third-party logistics providers or to the manufacture, distribution, or dispensing of prescription drugs;

3. Maintaining current working knowledge of requirements for wholesale distributors or third-party logistics providers and assuring continued training for employees;

4. Maintaining proper security, storage, and shipping conditions for all prescription drugs; and

5. Maintaining all required records.

E. Each nonresident wholesale distributor shall designate a registered agent in Virginia for service of any notice or other legal document. Any nonresident wholesale distributor that does not so designate a registered agent shall be deemed to have designated the Secretary of the Commonwealth to be its true and lawful agent, upon ~~who~~ whom may be served all legal process in any action or proceeding against such nonresident wholesale distributor. A copy of any such service of legal documents shall be mailed to the nonresident wholesale distributor by the board by certified mail at the address of record.

NOTICE: Forms used in administering the regulation have been filed by the agency. The forms are not being published; however, online users of this issue of the Virginia Register of Regulations may click on the name of a form with a hyperlink to access it. The forms are also available from the agency contact or may be viewed at the Office of the Registrar of Regulations, 900 East Main Street, 11th Floor, Richmond, Virginia 23219.

FORMS (18VAC110-50)

Application for a Permit as a Restricted Manufacturer (rev. ~~3/09).~~ 3/2009)

Application for a Permit as a Nonrestricted Manufacturer (rev. ~~3/09).~~ 3/2009)

Application for a Permit as a Warehouser (rev. ~~3/09).~~ 3/2009)

Application for a License as a Wholesale Distributor (rev. ~~3/09).~~ 3/2009)

Application for a Nonresident Wholesale Distributor Registration (rev. ~~9/08).~~ 9/2008)

Application for a License as a Wholesale Distributor - Limited Use for Distribution of Medical Gases Only (rev. 3/2010).

Application for a Permit as a Third-Party Logistics Provider (eff. 9/2017)

VA.R. Doc. No. R16-4673; Filed November 27, 2018, 8:49 a.m.

Final Regulation

Title of Regulation: **18VAC110-20. Regulations Governing the Practice of Pharmacy (amending 18VAC110-20-690, 18VAC110-20-700, 18VAC110-20-710; adding 18VAC110-20-735).**

Statutory Authority: § 54.1-2400 of the Code of Virginia.

Effective Date: January 23, 2019.

Agency Contact: Caroline Juran, RPh, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4456, FAX (804) 527-4472, or email caroline.juran@dhp.virginia.gov.

Board of Pharmacy

2019 Session of the General Assembly

A BILL to amend the *Code of Virginia* by amending §§ 54.1-3300 and 54.1-3321, relating to registration as a pharmacy technician.

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3303, and 54.1-3321 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 practice 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 for completing an accredited pharmacy technician training program in accordance with § 54.1-3321 D of the Code of Virginia.

"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 the proper and safe storage and distribution of drugs; the maintenance of proper records; the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; and the management of patient care under the terms of a collaborative agreement as defined in this section.

"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.

§ 54.1-3321. Registration of pharmacy technicians.

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

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

2. The preparation of prescription labels or patient information;

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

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

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

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

7. The acceptance of refill authorization from a prescriber or his authorized agency, so long as there is no change to the original prescription; and

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

B. To be registered as a pharmacy technician trainee, a person shall submit application to the Board and fee established in regulation.

C. To be registered as a pharmacy technician, a person shall: (i) submit to the Board an application and fee established in regulation to obtain a pharmacy technician registration; (ii) satisfactory evidence that he ~~is of good moral character and~~ has ~~satisfactorily~~ successfully completed a training program accredited by the Association of Health-Systems Pharmacists and Accreditation Council for Pharmacy Education and (iii) successfully passed a national certification examination administered by the Pharmacy Technician Certification Board or National Healthcare Association ~~that meet the criteria approved by the Board in regulation or that he holds current certification from the Pharmacy Technician Certification Board~~.

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

~~D.~~E. In addition, a ~~person~~ a pharmacy technician trainee enrolled in an ~~approved~~ accredited training program for pharmacy technicians may engage in the acts set forth in subsection A for the purpose of obtaining practical experience required for ~~registration as a pharmacy technician~~ completion of the training program, so long as such activities are directly monitored by a supervising pharmacist.

~~E.~~F. The Board shall promulgate regulations establishing requirements for evidence of continued competency as a condition of renewal of a registration as a pharmacy technician.

~~F.~~G. The Board shall waive the initial registration fee ~~and the first examination fee for the Board-approved examination~~ for a pharmacy technician applicant who works as a pharmacy technician exclusively in a free clinic pharmacy. If such applicant fails the examination, he shall be responsible for any subsequent fees to retake the examination. A person registered pursuant to this subsection shall be issued a limited-use registration. A pharmacy technician with a limited-use registration shall not perform pharmacy technician tasks in any setting other than a free clinic pharmacy. The Board shall also waive renewal fees for such limited-use registrations. A pharmacy technician with a limited-use registration may convert to an unlimited registration by paying the current renewal fee.

2. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment.

3. That the amendments to subsection C of this section shall not become effective until July 1, 2021.

Draft 2020 Legislative Proposal

§ 54.1-3410.2. Compounding; pharmacists' authority to compound under certain conditions; labeling and record maintenance requirements.

A. A pharmacist may engage in compounding of drug products when the dispensing of such compounded products is (i) pursuant to valid prescriptions for specific patients and (ii) consistent with the provisions of § **54.1-3303** relating to the issuance of prescriptions and the dispensing of drugs.

Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription in accordance with this chapter and the Board's regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

B. A pharmacist may also engage in compounding of drug products in anticipation of receipt of prescriptions based on a routine, regularly observed prescribing pattern.

Pharmacists shall label all products compounded prior to dispensing with (i) the name and strength of the compounded medication or a list of the active ingredients and strengths; (ii) the pharmacy's assigned control number that corresponds with the compounding record; (iii) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (iv) the quantity.

C. In accordance with the conditions set forth in subsections A and B, pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place; however, a pharmacist may distribute to a veterinarian in accordance with federal law.

Compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed by a pharmacy to a veterinarian for further distribution or sale to his own patients shall be limited to drugs necessary to treat an emergent condition when timely access to a compounding pharmacy is not available as determined by the prescribing veterinarian.

A pharmacist may, however, deliver compounded products dispensed pursuant to valid prescriptions to alternate delivery locations pursuant to § **54.1-3420.2**.

A pharmacist may provide a reasonable amount of compounded products to practitioners of medicine, osteopathy, podiatry, or dentistry to administer to their patients, either personally or under their direct and immediate supervision, if there is a critical need to treat an emergency condition, or as allowed by federal law or regulations. A pharmacist may also provide compounded products to practitioners of veterinary medicine for office-based administration to their patients.

Pharmacists who provide compounded products for office-based administration for treatment of an emergency condition or as allowed by federal law or regulations shall label all compounded products distributed to practitioners other than veterinarians for administration to their patients with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the facility's control number; (iv) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (v) the name and address of the pharmacy; and (vi) the quantity.

Pharmacists shall label all compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed to a veterinarian for either further distribution or sale to his own patient or administration to his own patient with (a) the name and strength of the compounded medication or list of the active ingredients and strengths; (b) the facility's control number; (c) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (d) the name and address of the pharmacy; and (e) the quantity.

D. Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.

E. Pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding.

F. Pharmacists may use bulk drug substances in compounding when such bulk drug substances:

1. Comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if such monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; or are drug substances that are components of drugs approved by the FDA for use in the United States; or are otherwise approved by the FDA; or are manufactured by an establishment that is registered by the FDA; and

2. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, or are distributed by a supplier otherwise approved by the Board and the FDA to distribute bulk drug substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.

G. Pharmacists may compound using ingredients that are not considered drug products in accordance with the USP-NF standards and guidance on pharmacy compounding.

H. Pharmacists shall not engage in the following:

1. The compounding for human use of a drug product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe. However, this prohibition shall be limited to the scope of the FDA withdrawal;

2. The regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. However, this prohibition shall not include (i) the compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient, (ii) the compounding of a commercially manufactured drug only during times when the product is not available from the manufacturer or supplier, (iii) the compounding of a commercially manufactured drug whose manufacturer has notified the FDA that the drug is unavailable due to a current drug shortage, (iv) the compounding of a commercially manufactured drug when the prescriber has indicated in the oral or written prescription for an individual patient that there is an emergent need for a drug that is not readily available within the time medically necessary, ~~or (v) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product;~~ or

3. The compounding of inordinate amounts of any preparation in cases in which there is no observed historical pattern of prescriptions and dispensing to support an expectation of receiving a valid prescription for the preparation. The compounding of an inordinate amount of a preparation in such cases shall constitute manufacturing of drugs.

I. Pharmacists shall maintain records of all compounded drug products as part of the prescription, formula record, formula book, or other log or record. Records may be maintained electronically, manually, in a combination of both, or by any other readily retrievable method.

1. In addition to other requirements for prescription records, records for products compounded pursuant to a prescription order for a single patient where only manufacturers' finished products are used as components shall include the name and quantity of all components, the date of compounding and dispensing, the prescription number or other identifier of the prescription order, the total quantity of finished product, the signature or initials of the pharmacist or pharmacy technician performing the compounding, and the signature or initials of the pharmacist responsible for supervising the pharmacy technician and verifying the accuracy and integrity of compounded products.

2. In addition to the requirements of subdivision I 1, records for products compounded in bulk or batch in advance of dispensing or when bulk drug substances are used shall include: the generic name and the name of the manufacturer of each component or the brand name of each component; the manufacturer's lot number and expiration date for each component or when the original manufacturer's lot number and expiration date are unknown, the source of acquisition of the component; the assigned lot number if subdivided, the unit or package size and the number of units or packages prepared; and the beyond-use date. The criteria for establishing the beyond-use date shall be available for inspection by the Board.

3. A complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail shall be maintained where such instructions are necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product.

4. A formal written quality assurance plan shall be maintained that describes specific monitoring and evaluation of compounding activities in accordance with USP-NF standards. Records shall be maintained showing compliance with monitoring and evaluation requirements of the plan to include training and initial and periodic competence assessment of personnel involved in compounding, monitoring of environmental controls and equipment calibration, and any end-product testing, if applicable.

J. Practitioners who may lawfully compound drugs for administering or dispensing to their own patients pursuant to §§ **54.1-3301**, **54.1-3304**, and **54.1-3304.1** shall comply with all provisions of this section and the relevant Board regulations.

K. Every pharmacist-in-charge or owner of a permitted pharmacy or a registered nonresident pharmacy engaging in sterile compounding shall notify the Board of its intention to dispense or otherwise deliver a sterile compounded drug product into the Commonwealth. Upon renewal of its permit or registration, a pharmacy or nonresident pharmacy shall notify the Board of its intention to continue dispensing or otherwise delivering sterile compounded drug products into the Commonwealth. Failure to provide notification to the Board shall constitute a violation of Chapter 33 (§ **54.1-3300** et seq.) or Chapter 34 (§ **54.1-3400** et seq.). The Board shall maintain this information in a manner that will allow the production of a list identifying all such sterile compounding pharmacies.

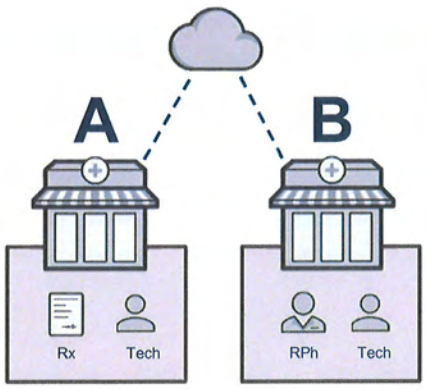
A Quick Look at Telepharmacy

Jessica Adams, PharmD

March 2019

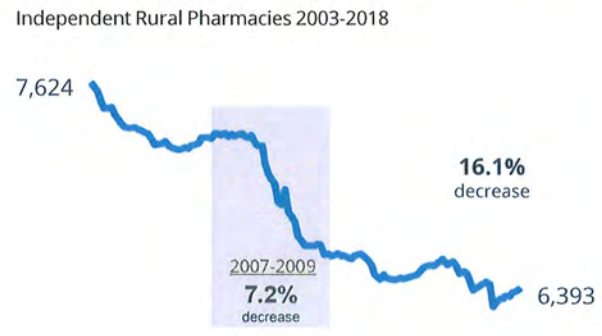
TelePharm
A Cardinal Health company

Telepharmacy workflow



1. New prescription arrives at **Pharmacy A**
2. **Technician A** fills, taking images of the process
3. **Pharmacist B** reviews images to verify fill is accurate
4. Patient picks up Rx at **Pharmacy A** and **Pharmacist B** counsels

Need for alternative delivery



1,231
independent rural pharmacies closed

630
rural communities lost their only pharmacy

Source: Update: Independently Owned Pharmacy Closures in Rural America, 2003-2018; RUPRI Center for Rural Health Policy Analysis, Rural Policy Brief July 2018; Abiodun Salako, MPH; Fred Ullrich, BA; Keith J. Mueller, PhD

North Dakota telepharmacy case study

Study conducted from 2002 - 2008

Medication dispensing error rate for telepharmacies

1.3%

Compared to a national average of: **~1.7%**

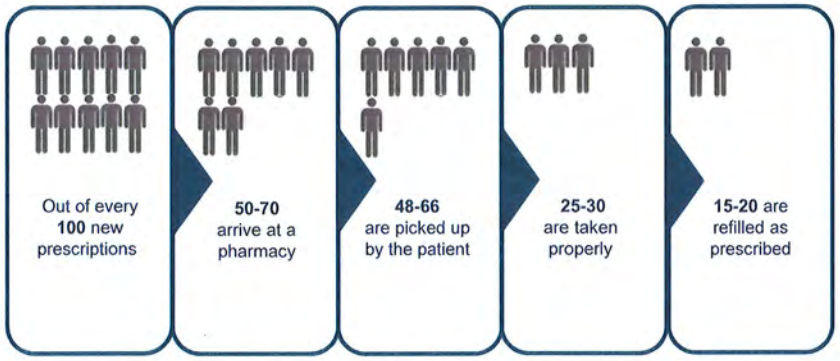
Information of the North Dakota Telepharmacy Program provided by North Dakota State University School of Pharmacy

Result: Positive outcomes, mechanisms could be improved

Source: The North Dakota Experience: Achieving High-Performance Health Care Through Rural Innovation And Cooperation. May 2008

"The Leaky Bucket"

According to IMS Health:



Source: IMS Health Data, March 2011

Medically underserved areas

Areas with lack of access to healthcare services

- Rural
- Urban

***medically underserved areas marked in purple**

Source: https://bhw.hrsa.gov/shortage-designation/muap

Rural is becoming more rural

64M

people live
in rural areas

77%

rural counties considered
health professional shortage areas

Source: The Crisis in Rural Primary Care. WWAMI Rural Health Research Center. Policy Brief April 2009
2010 Census Urban and Rural Classification and Urban Area Criteria. https://www.census.gov/geo/reference/ua/urban-rural-2010.html

Access challenges in urban areas

University of Illinois Chicago did a study looking at "pharmacy deserts" in Chicago:

Source: Source: 'Pharmacy Deserts' Are Prevalent In Chicago's Predominantly Minority Communities, Raising Medication Access Concerns. Dima M. Qato, Martha L. Daviglus, Jocelyn Wilder, Todd Lee, Danya Qato and Bruce Lambert.

Rural telepharmacy next to a health clinic

Interior of a rural telepharmacy

Telepharmacy in a community health center

Economics of telepharmacy

NORTH DAKOTA

Results of the 6-year study with 81 locations:

$26.5 million
in economic development

80-100
new jobs created

ILLINOIS

Estimate for one pharmacy based on financial data:

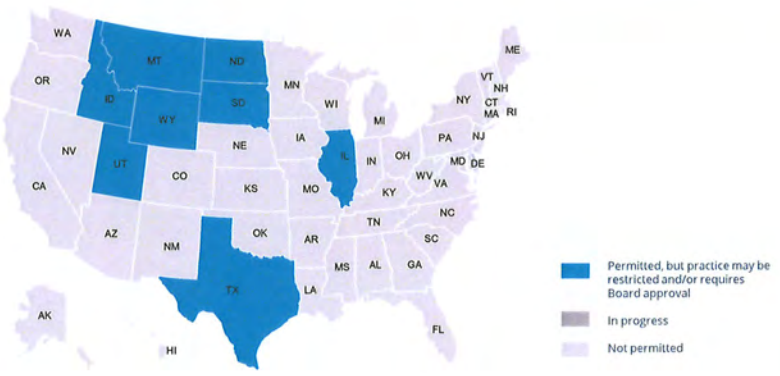
$640,000
annual economic impact

Source: North Dakota Telepharmacy Project https://www.ndsu.edu/telepharmacy/. Rural Economic Technical Assistance Center (RETAC) in Macomb, IL; Economic Impacts of a pharmacy for Delterich, Illinois, June 2015

FAQ

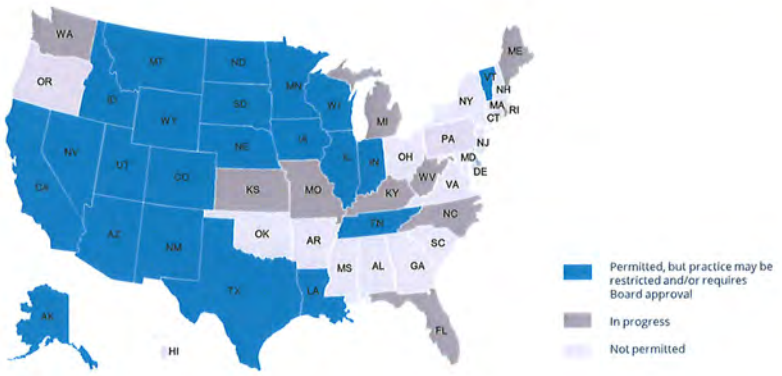
- Fill Accuracy
- Safety (staff & location)
- Diversion
- Internet outage

Telepharmacy regulations, 2008



Source: Telepharmacy project expands across country, 9/12/2008; Dave Kolpack, Associated Press

Telepharmacy regulations, 2018



Virginia Statistics

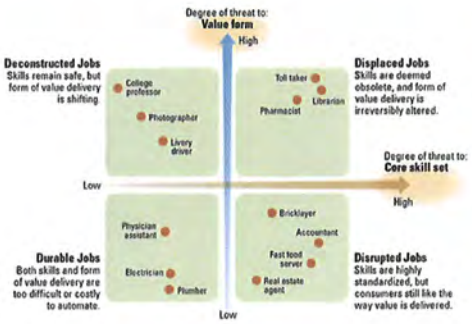
- **Over 20,200** residents in pharmacy deserts
- **14** pharmacy deserts
- **31** at-risk communities
- **194** HPSAs
  - 83 mental health
  - 111 primary care

*145 cities without a pharmacy

Virginia Legislative & Regulatory

- Statutes and regulations do not address the operations of telepharmacy
- Requires statutory changes
- Supervision
  - Va. Code Ann. § 54.1-3300: direction and control by a rph of the activities of a pharmacy intern or a pharmacy technician whereby the supervising pharmacist is **physically present** in the pharmacy

Potential Threats to Pharmacy Services



- **Push for Physician Dispensing**
  - Already occurring in some states
- **Amazon/PillPack + Walgreens/FedEx**
  - AZ board meeting
- **Mail Order**
  - More money leaving the state
- **Get ahead of legislators**
  - Industry should make their own rules

Telepharmacy as an Opportunity

- Greater, convenient access to pharmacy and pharmacist
- Safe & effective
- More one-on-one time with RPh for counseling
- Less delays in treatment
- Pharmacy services restored or established
- Positive economic impact in local rural communities
- *Scope of practice has not changed*

TelePharm
A Cardinal Health company

Questions?

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(512)426.6868

For updates and more information, visit **telepharm.com/learn**

Virginia Board of Pharmacy
Inspection Report
March 26, 2019

Licenses Issued

	9/1/17-11/30/17	12/1/17-2/28/18	3/1/18-5/31/18	6/1/18-8/31/18	9/1/18-11/30/18	12/1/18-2/28/19	License Count 3/1/2019
Business CSR	40	81	86	50	59	41	959
CE Courses	1	0	1	0	2	0	9
Limited Use Pharmacy Technician	1	0	0	0	1	0	11
Medical Equipment Supplier	3	2	5	4	1	2	206
Nonresident Manufacturer	13	92	20	4	7	24	143
Nonresident Medical Equipment Supplier	19	12	12	12	9	10	239
Non-resident Outsourcing Facility	3	1	9	1	2	0	34
Non-resident Pharmacy	38	32	35	33	27	24	772
Non-resident Wholesale Distributor	8	13	22	16	12	13	592
Non-restricted Manufacturer	0	1	0	0	1	1	27
Outsourcing Facility	0	0	0	0	0	0	0
Permitted Physician	0	0	0	0	0	0	0
Pharmacist	251	142	157	439	250	157	14,850
Pharmacist Volunteer Registration	1	0	0	2	0	0	0
Pharmacy	17	3	15	18	21	13	1,817
Pharmacy Intern	204	148	115	140	189	122	1,672
Pharmacy Technician	387	357	363	420	378	388	12,690
Pharmacy Technician Training Program	5	5	3	2	4	3	141
Physician Selling Controlled Substances	30	22	55	25	42	44	614
Physician Selling Drugs Location	5	1	10	10	4	8	165
Pilot Programs	0	2	0	1	0	0	13
Registered Physician For CBD/THC-A Oil				118	83	40	239
Repackaging Training Program	0	0	0	0	0	0	2
Restricted Manufacturer	1	0	0	0	0	1	50
Third Party Logistics Provider	2	3	1	0	1	0	4
Warehouser	0	39	3	10	7	9	104
Wholesale Distributor	5	1	0	3	0	0	61
Total	**1,034**	**957**	**912**	**1,308**	**1,100**	**900**	**35,414**

Virginia Board of Pharmacy
Inspection Report
March 26, 2019

Inspections Completed

	9/1/17-11/30/17		12/1/17-2/28/18		3/1/18-5/31/18		6/1/18-8/31/18		9/1/18-11/30/18		12/1/18-2/28/19	
License Type												
Controlled Substances Registration	131		163		182		120		174		164	
Medical Equipment Supplier	32		22		22		25		19		10	
Non-restricted Manufacturer	1		1		0		0		3		3	
Permitted Physician	0		0		0		0		0		0	
Physician Selling Drugs Location	39		23		22		31		38		30	
Restricted Manufacturer	3		0		2		0		0		1	
Third Party Logistics Provider	2		1		1		0		2		1	
Warehouse	6		11		11		14		12		10	
Wholesale Distributor	13		6		3		7		7		9	
Pharmacy	293		272		291		328		306		227	
Pilot	1		0		1		0		1		0	
Total	**521**		**499**		**535**		**525**		**562**		**455**	
Pharmacy (0201) Inspections												
Change of Location	3		4		5		9		7		0	
New	13		3		15		19		18		12	
Reinspection	14		2		8		6		13		14	
Remodel	55		31		43		31		42		40	
Routine	206		232		218		242		222		159	
Focus	0		0		2		1		4		0	
Federal Agency	0		0		0		18		0		0	
Compliance	2		0		0		2		0		2	
Pilot	0		0		0		0		0		0	
Total	**293**		**272**		**291**		**328**		**306**		**227**	
Pharmacy Routine Inspections												
No Deficiency	43	21%	77	33%	66	30%	93	38%	109	49%	57	36.0%
Deficiency	66	32%	77	33%	80	37%	75	31%	64	29%	55	34.0%
Deficiency & IPHCO	97	47%	78	34%	72	33%	74	31%	49	22%	47	30.0%
Total	**206**		**232**		**218**		**242**		**222**		**159**	

Virginia Board of Pharmacy
March 26, 2019
Frequently Cited Deficiencies
September 2017 - February 2019

Deficiencies Numbered Less 1-100 (Formerly Major Deficiency)	Cumulative Total
15. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on-hand at time of performing inventory or not noting explanation for any difference between "physical count" and "theoretical count"; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required	137
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 (12/12/13 Cite Minor 13 if only expired drugs not included)	52
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	50
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	35
12. Storage of prescription drugs not in the prescription department	34
18. Records of dispensing not maintained as required	34
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	33
7. Change of location or remodel of pharmacy without submitting application or Board approval	32
20. Pharmacist not checking and documenting repackaging or bulk packaging	30
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounding of sterile preparations.	27
Deficiencies Numbered Greater Than 100 (Formerly Minor Deficiency)	**Cumulative Total**
109. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs 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)	186
113. 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.	171
127. Repackaging records and labeling not kept as required or in compliance	139
130a. Compounded products not properly labeled	97
142. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization, to include any zero reports. Record maintained and available for 12 months from date of analysis of dispensing error, to include any zero reports, but is not in compliance	93
108. Emergency access alarm code/key not maintained in compliance	82
124. Labels do not include all required information	80
122. Engaging in alternate delivery not in compliance	78
123. Engaging in remote processing not in compliance	45
130. Required compounding/dispensing/distribution records not complete and properly maintained	42

Virginia Board of Pharmacy
Inspection Report
March 26, 2019

Deficiencies 1 - 100
(Formerly Major Deficiency)

	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	Total	12/18-2/19	Cumulative
Routine Inspections Completed	**206**	**232**	**218**	**242**	**222**	**159**	**1279**	**Repeat**	**Repeat**
Total Deficiencies	**158**	**127**	**115**	**123**	**83**	**60**	**666**	**2**	**208**
Average Deficiencies per Inspection	**0.8**	**0.5**	**0.5**	**0.5**	**0.4**	**0.4**	**0.5**		
1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location	3	2	2	2	0	1	10		
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	0	5	3	9	12	6	35		2
3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months from the initial enrollment date in a Board-approved pharmacy technician training program	2	4	2	2	7	2	19		
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	0	1	2	0	0	0	3		
5. Pharmacy technicians, pharmacy interns performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists	1	2	1	1	1	0	6		1
6. Exceeds pharmacist to pharmacy technician ratio (12/12/13 New Minor 43 for first offense)	0	0	0	0	1	0	1		1
7. Change of location or remodel of pharmacy without submitting application or Board approval	10	4	6	7	3	2	32		1
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.	2	1	0	1	1	1	6		1
9. Alarm not operational or not being set	3	0	1	1	0	0	5		
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. (12/12/13 New Minor 44 if no drug loss)	2	1	0	1	1	0	5		1

Virginia Board of Pharmacy
Inspection Report
March 26, 2019

Deficiencies 1 - 100
(Formerly Major Deficiency)

	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	Total	12/18-2/19	Cumulative
10. Unauthorized access to alarm or locking device to the prescription department	7	1	2	2	1	0	13		1
11. Insufficient enclosures or locking devices (12/12/13 New Minor 45 if no drug loss)	0	0	0	1	1	1	3		
12. Storage of prescription drugs not in the prescription department	7	12	8	5	1	1	34		9
12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe. (12/12/13 New Minor 46 if no drug loss)	1	0	1	5	0	0	7		3
13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V (12/12/13 Cite Minor 13 if only expired drugs not included)	6	0	5	2	0	2	15		2
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 (12/12/13 Cite Minor 13 if only expired drugs not included)	8	6	5	16	9	8	52		8
15. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on-hand at time of performing inventory or not noting explanation for any difference between "physical count" and "theoretical count"; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required	29	31	17	24	20	16	137	2	97
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	9	6	7	6	2	3	33		3
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)	2	0	2	2	0	2	8		
18. Records of dispensing not maintained as required	15	7	3	4	2	3	34		

Virginia Board of Pharmacy
Inspection Report
March 26, 2019

Deficiencies 1 - 100
(Formerly Major Deficiency)

	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	Total	12/18-2/19	Cumulative
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	7	2	0	1	0	1	11		1
20. Pharmacist not checking and documenting repackaging or bulk packaging	10	5	7	4	4	0	30		15
20a. Pharmacist not documenting final verification of non-sterile compounding	7	6	5	3	3	1	25		3
20b. Pharmacist not documenting final verification of sterile compounding	4	6	2	5	3	1	21		10
21. No clean room	1	0	0	0	0	0	1		
21a. Performing sterile compounding outside of a clean room (Added 12/12/13)	0	0	0	0	0	0	0		
22. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 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	0	0	1	0	0	0	1		
23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.	1	0	1	1	0	2	5		1
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	0	2	1	0	0	0	3		
25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level compounded sterile preparations or high risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	2	0	0	1	0	0	3		2
25a. No documentation of initial and semi-annual (6 months) media-fill testing for persons performing high-risk level compounding of sterile preparations.	0	0	0	0	0	0	0		1

Virginia Board of Pharmacy
Inspection Report
March 26, 2019

Deficiencies 1 - 100
(Formerly Major Deficiency)

	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	Total	12/18-2/19	Cumulative
25b. . High-risk compounded sterile preparations intended for use are improperly stored	0	0	0	0	0	0	0		
25c. Documentation that a person who failed a media-fill 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 test	0	0	0	0	0	0	0		
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounding of sterile preparations.	2	6	8	5	4	2	27		28
26a. Documentation that a person who failed a media-fill test has performed low or medium risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test	2	0	1	1	0	0	4		
27. Compounding using ingredients in violation of 54.1-3410.2.	0	0	0	0	0	0	0		1
28. Compounding copies of commercially available products	2	3	2	3	0	0	10		
29. Unlawful compounding for further distribution by other entities	0	3	3	3	0	1	10		
30. Security of after-hours stock not in compliance	0	0	0	0	0	0	0		
31. Drugs removed and administered to a patient from an automated dispensing device in a nursing home prior to review of the order and authorization by a pharmacist.	0	0	0	0	0	0	0		
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	12	10	14	4	6	4	50		14
33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	1	0	0	0	0	0	1		1
34. Combined with Minor 42 – 12/2013.	0	0	0	0	0	0	0		
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-compliant manner	0	1	3	1	1	0	6		1

Virginia Board of Pharmacy
Inspection Report
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Deficiencies Above 100
(Formerly Minor Deficiency)

	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	Total	12/18-2/19	Cumulative
Routine Inspections Completed	**206**	**232**	**218**	**242**	**222**	**159**	**1279**	**Repeat**	**Repeat**
Total Deficiencies	**338**	**302**	**259**	**228**	**160**	**160**	**1287**	**13**	**269**
Average Deficiencies per Inspection	**1.6**	**1.3**	**1.2**	**0.9**	**0.7**	**1.0**	**1.0**		
101. Repealed 6/2011	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
102. Special/limited-use scope being exceeded without approval	0	0	0	0	0	0	0		
103. Repealed 12/12/2013 - Decreased hours of operation without public/Board notice	0	0	0	0	0	0	0		
104. Sink with hot and cold running water not available within the prescription department.	4	7	6	4	1	7	29	1	7
105. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit	5	4	5	3	1	1	19		7
106. Prescription department substantially not clean and sanitary and in good repair	2	1	0	0	1	2	6		2
107. Current dispensing reference not maintained	6	4	1	3	1	6	21		10
108. Emergency access alarm code/key not maintained in compliance	16	18	17	15	8	8	82	1	17
109. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs 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)	33	27	38	38	24	26	186	5	33
110. Storage of paraphernalia/Rx devices not in compliance	0	0	0	0	1	0	1		
111. Storage of prescriptions awaiting delivery outside of the prescription department not in compliance	1	2	1	1	0	1	6		1
112. Biennial taken late but within 30 days	2	1	3	1	3	2	12		
113. 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.	25	40	28	32	26	20	171	1	52

Virginia Board of Pharmacy
Inspection Report
March 26, 2019

Deficiencies Above 100
(Formerly Minor Deficiency)

	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	Total	12/18-2/19	Cumulative
114. Records of receipt (e.g. invoices) not on site or retrievable	9	10	4	7	2	0	32		
115. Other records of distributions not maintained as required	3	0	2	1	0	0	6		
116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	4	4	4	4	2	4	22		0
117. Minor 17 combined with Minor 16 – 6/2011	0	0	0	0	0	0	0		
118. Schedule II emergency oral prescriptions not dispensed in compliance	0	1	0	0	0	0	1		
119. Not properly documenting partial filling of prescriptions	6	10	8	4	4	5	37		24
120. Offer to counsel not made as required	2	2	0	0	0	0	4		
121. Prospective drug review not performed as required	1	0	0	0	1	2	4		
122. Engaging in alternate delivery not in compliance	18	14	15	16	9	6	78		6
123. Engaging in remote processing not in compliance	5	9	12	7	4	8	45		2
124. Labels do not include all required information	15	15	17	16	10	7	80		13
125. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages	8	5	5	3	0	8	29	2	7
126. Special packaging not used or no documentation of request for non-special packaging	1	0	2	1	0	0	4		4
Repackaging, specialty dispensing, compounding:									
127. Repackaging records and labeling not kept as required or in compliance	41	33	21	18	17	9	139	1	22
128. Unit dose procedures or records not in compliance	0	0	0	0	2	0	2		
129. Robotic pharmacy systems not in compliance	0	0	0	2	0	0	2		
130. Required compounding/dispensing/distribution records not complete and properly maintained	10	5	8	9	6	4	42		12
130a. Compounded products not properly labeled	42	18	9	10	9	9	97	1	9

Virginia Board of Pharmacy
Inspection Report
March 26, 2019

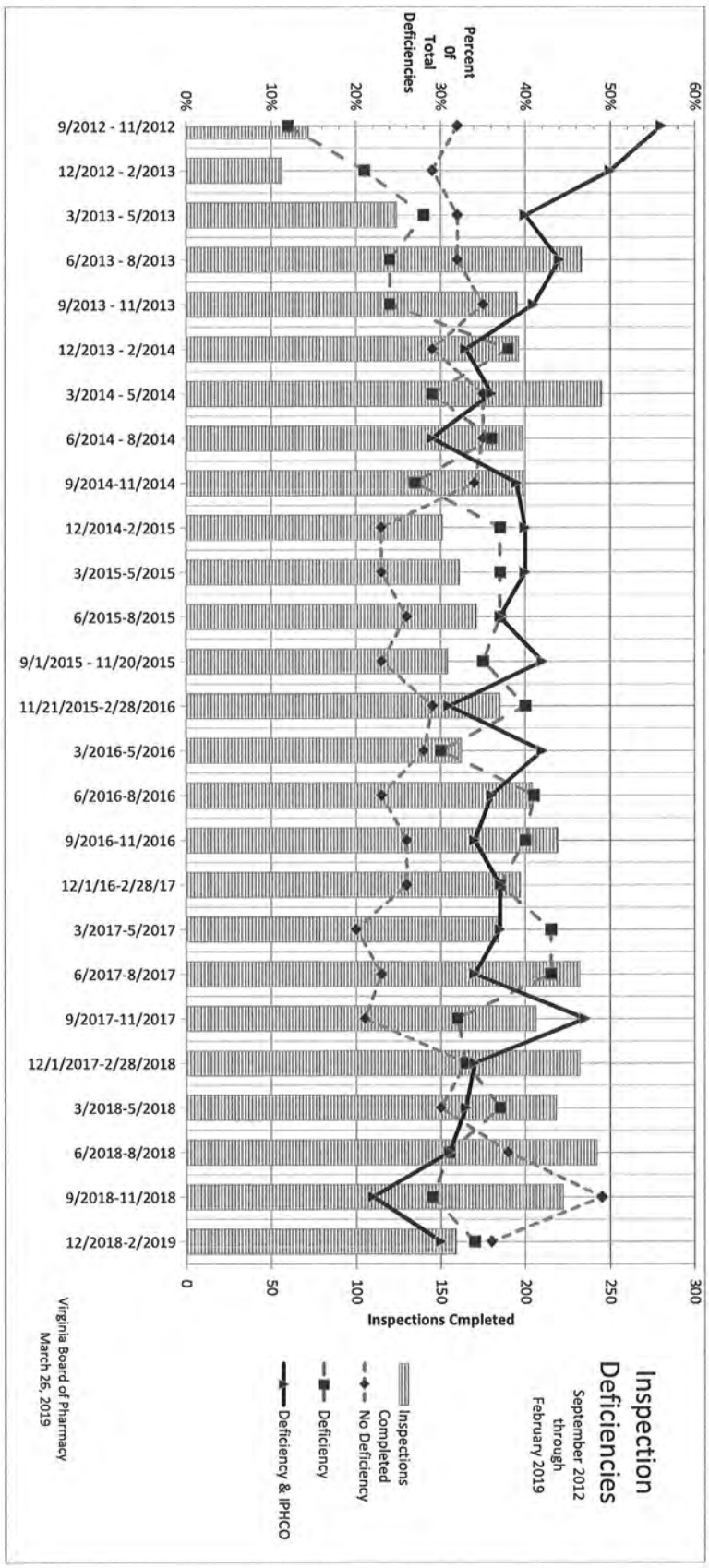
Deficiencies Above 100
(Formerly Minor Deficiency)

	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	Total	12/18-2/19	Cumulative
131. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	6	0	1	5	3	3	18		
132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	14	8	7	6	4	3	42		1
133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2	3	0	0	0	0	0	3		
Hospital specific or long-term care specific:							0		
134. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	0	0	0	0	0	0	0		
135. Policies and procedures for drug therapy reviews not maintained or followed	0	0	0	0	0	0	0		
136. After hours access to a supply of drugs or records not in compliance	0	0	0	0	0	0	0		
137. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	0	1	2	1	1	0	5		1
138. Automated dispensing device loading, records, and monitoring/reconciliation not in compliance	0	1	0	1	4	1	7		
139. Emergency medical services procedures or records not in compliance	3	3	2	0	2	0	10		5
140. Emergency kit or stat-drug box procedures or records not in compliance	3	3	4	0	1	0	11		6
141. Maintaining floor stock in a long-term care facility when not authorized	0	0	0	0	0	0	0		
142. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization, to include any zero reports. Record maintained and available for 12 months from date of analysis of dispensing error, to include any zero reports, but is not in compliance	24	17	16	16	10	10	93	1	10
143. Exceeds pharmacist to pharmacy technician ratio (Added 12/12/13)	0	0	1	1	0	0	2		

Virginia Board of Pharmacy
Inspection Report
March 26, 2019

Deficiencies Above 100
(Formerly Minor Deficiency)

	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	Total	12/18-2/19	Cumulative
144. 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. (Added 12/12/13)	14	9	9	1	0	0	33		6
145. Insufficient enclosures or locking devices (Added 12/12/13)	2	0	5	0	0	0	7		4
146. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe. (Added 12/12/13)	9	14	4	0	0	0	27		2
147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions. (Added 12/12/13)	1	16	2	1	0	1	21		3
148. Theft/unusual loss of drugs reported to board but report not maintained by pharmacy (Added 6/21/18)				1	3	7	11		3


Inspection Deficiencies
September 2012 through February 2019
Inspections Completed
No Deficiency
Deficiency
Deficiency & IPHCO
Virginia Board of Pharmacy
March 26, 2019
Inspections Cmpleted
Percent Of Total Deficiencies
0%
10%
20%
30%
40%
50%
60%
0
50
100
150
200
250
300
9/2012 - 11/2012
12/2012 - 2/2013
3/2013 - 5/2013
6/2013 - 8/2013
9/2013 - 11/2013
12/2013 - 2/2014
3/2014 - 5/2014
6/2014 - 8/2014
9/2014-11/2014
12/2014-2/2015
3/2015-5/2015
6/2015-8/2015
9/1/2015 - 11/20/2015
11/21/2015-2/28/2016
3/2016-5/2016
6/2016-8/2016
9/2016-11/2016
12/1/16-2/28/17
3/2017-5/2017
6/2017-8/2017
9/2017-11/2017
12/1/2017-2/28/2018
3/2018-5/2018
6/2018-8/2018
9/2018-11/2018
12/2018-2/2019

Discipline Program Report

Staffing:
Ileita Redd has recently been hired as the Board's Discipline Program Specialist. Interviews for the Discipline Case Manager position were conducted last week.

Open Cases as of 3/7/19:

Patient Care Cases	PC	APD	Investigation	FH	IFC	Pending Closure	TOTALS
	32	9	79	2	12	0	134
Non-Patient Care Cases	73	6	24	0	16	10	129
							263

Notes:

1) Patient care cases:
   - We have thirty-two (32) patient care cases at Probable Cause as compared to thirty-four (34) that were reported in December 2018. Fourteen (14) of these cases are pending an IFC or FH.
   - Only three (3) patient care cases at Probable Cause exceed 250 work days compared to seven (7) reported in December 2018. (Note: This remains substantially below our 10% threshold for open cases).
   - We have a significantly higher number of cases at investigation.
2) Non-patient care cases (inspection cases or compliance related cases)
   - We are continuing to see a decrease in the number of inspection-related cases resulting in a PHCO.
   - All of the cases from the 2018 CE audit have been adjudicated.

Upcoming Disciplinary Proceedings:

March 26, 2019	Formal Hearing
March 28, 2019	SCC-A Rafael Saenz and Melvin Boone (sub)
April 17, 2019	SCC-C Cindy Warriner and Melvin Boone
April 18, 2019	Formal Hearings
April 23, 2019	Pilot SCC Rafael Saenz and Ryan Logan
May 3, 2019	Regulation Committee/Formal Hearings
May 14, 2019	SCC-B Ryan Logan and Kris Ratliff
June 21, 2019	Full Board Meeting/Formal Hearings

Executive Director's Report – March 26, 2019

Recent Presentations/Meetings:

- January 31, 2019, NABP Executive Committee Meeting
- March 13-15, 2019, NABP MPJE Item Writing – Johnson/Shinaberry
- March 15, 2019, VSHP Spring Seminar
- March 16, 2019, VCU Health

Upcoming Meetings:

- April 16, 2019, Board Retreat, VCU Rice Rivers Center
- April 17, 2019, Special Conference Committee
- April 18, 2019, Formal Hearing
- April 22-25, 2019 Rx Drug Abuse & Heroin Summit, Atlanta
- May 3, 2019, Regulation Committee
- May 14, 2019, Special Conference Committee
- May 16-18, 2019, NABP Annual Meeting, Minneapolis, MN
- May 23, 2019, Presentation at Virginia Alcohol Safety Action Program
- June, 2019, Rescheduling of board meeting

Staffing:

- Kiara Christian began employment as Executive Assistant
- Ileita Redd transitioned to Disciplinary Office Specialist
- Recruiting for Disciplinary Case Manager, Records Administrative Assistant, Deputy Executive Director supervising pharmaceutical processor program

Attachment 1

DRAFT

Virginia's Pharmacist Workforce: 2018

Healthcare Workforce Data Center

February 2019

Virginia Department of Health Professions
Healthcare Workforce Data Center
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233
804-367-2115, 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: ***https://www.dhp.virginia.gov/hwdc/findings.htm***

13,962 Pharmacists 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 your ongoing cooperation.*

Thank You!

Virginia Department of Health Professions

David E. Brown, DC
Director

Barbara Allison-Bryan, MD
Chief Deputy Director

Healthcare Workforce Data Center Staff:

Elizabeth Carter, PhD
Director

Yetty Shobo, PhD
Deputy Director

Laura Jackson, MSHSA
Operations Manager

Christopher Coyle
Research Assistant

The Board of Pharmacy

Chair

Rafael Saenz
Crozet

Vice-Chair

Cynthia Warriner
Chester

Members

Glenn Bolyard
Glen Allen

Melvin L. Boone, Sr.
Chesapeake

James L. Jenkins, Jr.
Mechanicsville

Ryan K. Logan
Fairfax

Cheryl H. Nelson
Richmond

Kristopher S. Ratliff
Marion

Patricia Lynn Richards-Spruill
Suffolk

Rebecca Thornbury
Grundy

Executive Director

Caroline D. Juran
Richmond

Contents

The Pharmacist Workforce: At a Glance:

The Workforce

Licensees:	15,424
Virginia's Workforce:	8,620
FTEs:	6,943

Survey Response Rate

All Licensees:	91%
Renewing Practitioners:	96%

Demographics

Female:	65%
Diversity Index:	51%
Median Age:	44

Background

Rural Childhood:	32%
HS Degree in VA:	48%
Prof. Degree in VA:	49%

Education

Baccalaureate:	36%
Pharm.D./Professional:	64%

Finances

Median Inc.:	$120k-$130k
Health Benefits:	70%
Under 40 w/ Ed debt:	74%

Current Employment

Employed in Prof.:	91%
Hold 1 Full-time Job:	72%
Satisfied?:	87%

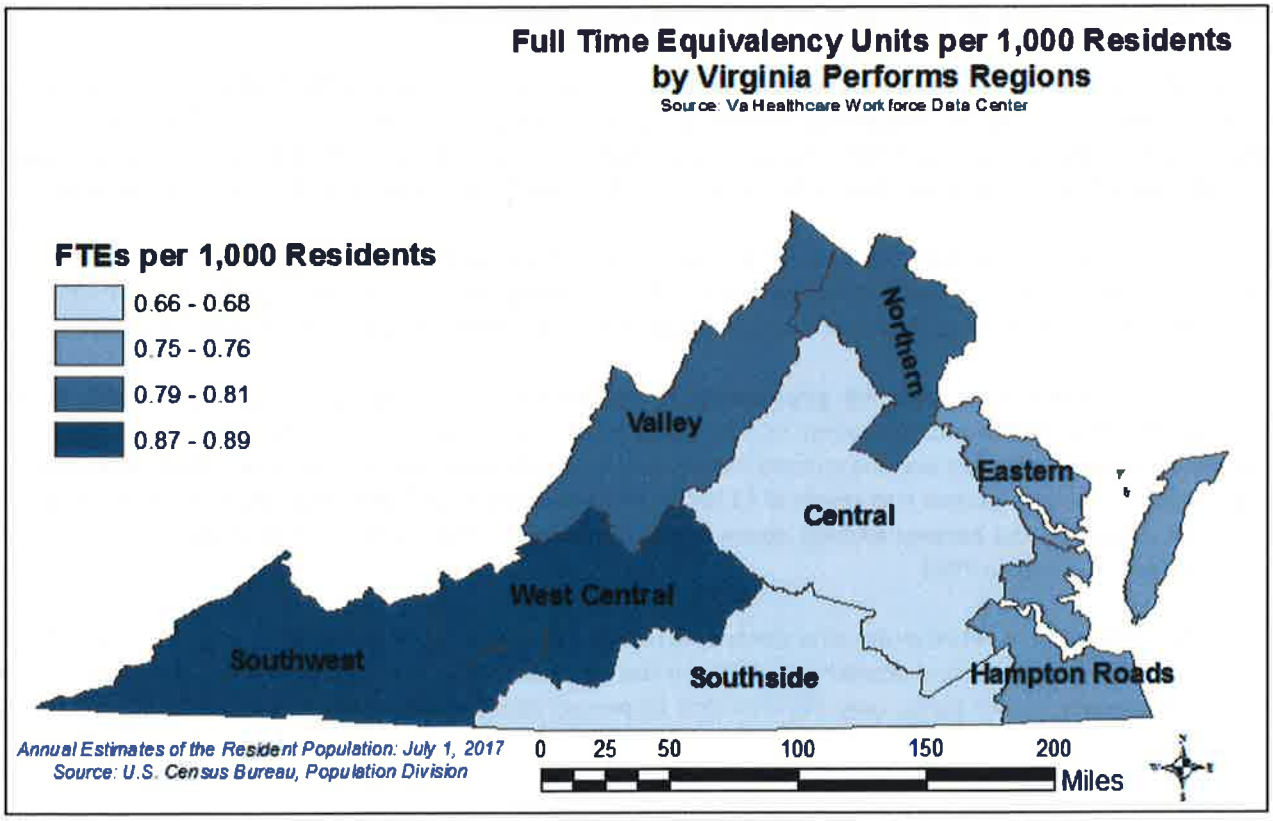
Job Turnover

Switched Jobs in 2018:	5%
Employed over 2 yrs:	62%

Primary Roles

Patient Care:	74%
Administration:	7%
Education:	1%

Source: Va. Healthcare Workforce Data Center



Results in Brief

A total of 13,962 pharmacists voluntarily took part in the 2018 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 91% of the 15,424 pharmacists who are licensed in the state and 96% of renewing practitioners. The HWDC estimates that 8,620 pharmacists participated in Virginia's workforce during the survey period and they provided 6,943 full-time equivalency units (FTE).

The majority of Virginia's pharmacists are female, and the median age among those in the workforce is 44. About one-third of pharmacists grew up in a rural area, and nearly 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. Around 64% of Virginia's pharmacist workforce have earned a doctoral or other professional degree as their highest educational attainment. About 42% of pharmacists currently carry educational debt, including about three-quarters of those under the age of 40. The median debt for those pharmacists with educational debt is between $110,000 and $120,000.

Nine out of every ten pharmacists are currently employed in the profession, with 72% holding one full-time position. Over the past year, 3% of pharmacists have been involuntarily unemployed, while another 3% have been underemployed. The typical pharmacist earned between $120,000 and $130,000 in 2018. Around 87% of all pharmacists are satisfied with their current employment situation, including 47% who indicated that they are "very satisfied".

About 90% of all pharmacists work in the private sector, including 66% who work at a for-profit organization. Large community pharmacies (i.e. pharmacies with more than 10 locations) were the most common working establishment type for Virginia's pharmacist workforce, employing 28% of all professionals. Hospital systems and smaller pharmacies were also common employers. About 4 in 10 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 2043.

Summary of Trends

The total number of licensed pharmacists has grown by 21% since 2013. Of these, the number working in the state workforce has also increased but the increase of 9% is more modest by comparison. Further, the 1.4% increase in FTE provided by pharmacists over the same period is an even more modest increase.

The race/ethnicity diversity index of Virginia's pharmacists has increased from 47% in 2013 to 51% in 2018. The percentage of pharmacist who are female has inched up by about one percent every year from 62% in 2013 to 65% in the current report. Median age has been relatively stable between 44 to 45 years in the past six surveys. Even the percent under age 40, which increased from 37% in 2013 to 40% in 2016, has stayed at 40% in the past two years.

Educational attainment continues to increase among the pharmacist workforce. In 2013, only 51% had a pharmacy doctorate compared to 64% in 2018. Although the percent reporting educational debt declined from 41% to 40% between 2017 and 2018, the amount of debt increased from a median of $90K-$100K in 2013 to $110K-$120K in 2018.

The labor market was a bit slack for pharmacists in the past year; 3% reported being involuntarily employed compared to the 1% involuntary employment rate in nearly all pre-2017 surveys. However, around 91% still reported being employed in the profession and the current involuntary unemployment rate in December 2018, when the survey took place, was 2%. Median income was stable at $120K to $130K between 2016 and 2018 after increasing from $110K-$120K in 2013. However, the percent earning above $140,000 increased from 17% in 2016 to 20% in 2018; only 12% earned in that income range in 2013.

Pharmacists intending to retire in the next decade increased from 22% in the pre-2017 surveys to 23% in 2017 and stayed at 23% in 2018. The percent planning to retire in the next two years has increased from 6% in 2013 to 7% in recent years. Regarding future plans, only 9% intended to pursue additional education in 2018 compared to 13% in 2013.

A Closer Look:

Licensee Counts		
License Status	#	%
Renewing Practitioners	13,765	89%
New Licensees	944	6%
Non-Renewals	715	5%
All Licensees	**15,424**	**100%**

Source: Va. Healthcare Workforce Data Center

HWDC surveys tend to achieve very high response rates. 96% of renewing pharmacists submitted a survey. These represent 91% of pharmacists who held a license at some point in 2018.

Response Rates			
Statistic	**Non Respondents**	**Respondent**	**Response Rate**
By Age			
Under 30	144	903	86%
30 to 34	204	2,269	92%
35 to 39	179	2,101	92%
40 to 44	149	1,786	92%
45 to 49	149	1,733	92%
50 to 54	143	1,508	91%
55 to 59	93	1,304	93%
60 and Over	401	2,358	86%
Total	**1,462**	**13,962**	**91%**
New Licenses			
Issued in 2018	303	641	68%
Metro Status			
Non-Metro	118	1,022	90%
Metro	571	7,760	93%
Not in Virginia	772	5,179	87%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Licensed Pharmacists

Number:	15,424
New:	6%
Not Renewed:	5%

Survey Response Rates

All Licensees:	91%
Renewing Practitioners:	96%

Source: Va. Healthcare Workforce Data Center

Response Rates	
Completed Surveys	13,962
Response Rate, all licensees	91%
Response Rate, Renewals	96%

Source: Va. Healthcare Workforce Data Center

Definitions

1. **The Survey Period:** The survey was conducted in December 2018.
2. **Target Population:** All pharmacists who held a Virginia license at some point in 2018.
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 2018.

At a Glance:

Workforce

Pharmacist Workforce:	8,620
FTEs:	6,943

Utilization Ratios

Licensees in VA Workforce:	56%
Licensees per FTE:	2.22
Workers per FTE:	1.24

Source: Va. Healthcare Workforce Data Center

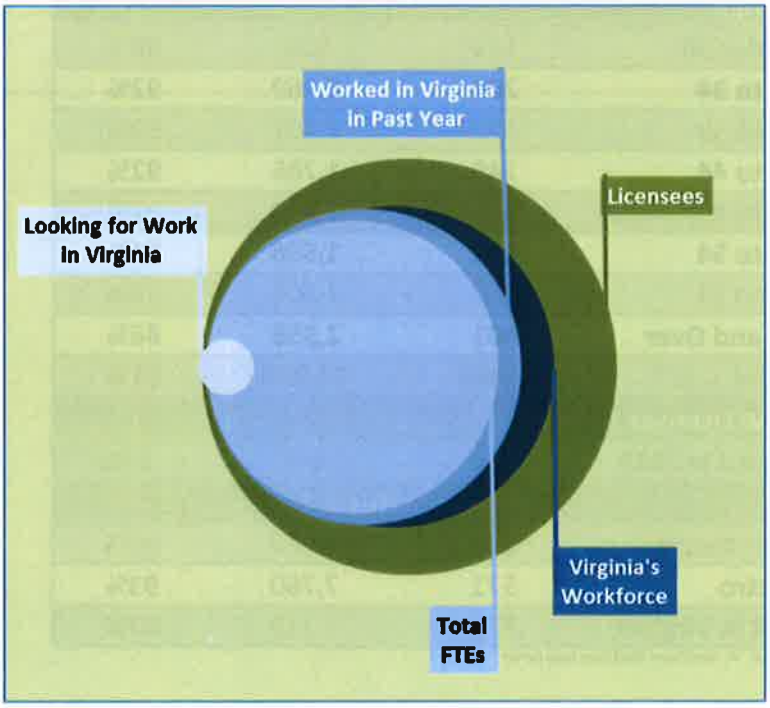
Definitions

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.

Virginia's Pharmacist Workforce		
Status	**#**	**%**
Worked in Virginia in Past Year	8,355	97%
Looking for Work in Virginia	265	3%
Virginia's Workforce	**8,620**	**100%**
Total FTEs	**6,943**	
Licensees	**15,424**	

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



Source: Va. Healthcare Workforce Data Center

A Closer Look:

Age & Gender						
Age	Male		Female		Total	
	#	% Male	#	% Female	#	% in Age Group
Under 30	190	29%	470	71%	660	9%
30 to 34	380	32%	806	68%	1,186	17%
35 to 39	272	27%	732	73%	1,004	14%
40 to 44	246	29%	594	71%	841	12%
45 to 49	228	27%	632	74%	861	12%
50 to 54	243	32%	516	68%	759	11%
55 to 59	222	36%	391	64%	613	9%
60 +	722	58%	522	42%	1,244	17%
Total	**2,503**	**35%**	**4,663**	**65%**	**7,167**	**100%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Gender

% Female:	65%
% Under 40 Female:	70%

Age

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

Diversity

Diversity Index:	51%
Under 40 Div. Index:	57%

Source: Va. Healthcare Workforce Data Center

Race & Ethnicity					
Race/ Ethnicity	Virginia*	Pharmacists		Pharmacists Under 40	
	%	#	%	#	%
White	62%	4,765	67%	1,717	60%
Black	19%	785	11%	364	13%
Asian	6%	1,247	17%	592	21%
Other Race	0%	108	2%	32	1%
Two or more races	3%	120	2%	86	3%
Hispanic	9%	108	2%	52	2%
Total	**100%**	**7,133**	**100%**	**2,843**	**100%**

** Population data in this chart is from the US Census, Annual Estimates of the Resident Population by Sex, Race, and Hispanic Origin for the United States, States, and Counties: July 1, 2017. *Source: Va. Healthcare Workforce Data Center*

In a chance encounter between two pharmacists, there is a 51% 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 56%.

40% of pharmacists are under the age of 40, and 70% of these professionals are female. In addition, pharmacists who are under the age of 40 are slightly more diverse than Virginia's overall population.

Source: Va. Healthcare Workforce Data Center

At a Glance:

Childhood

Urban Childhood:	17%
Rural Childhood:	32%

Virginia Background

HS in Virginia:	48%
Prof. Education in VA:	49%
HS/Prof. Educ. in VA:	56%

Location Choice

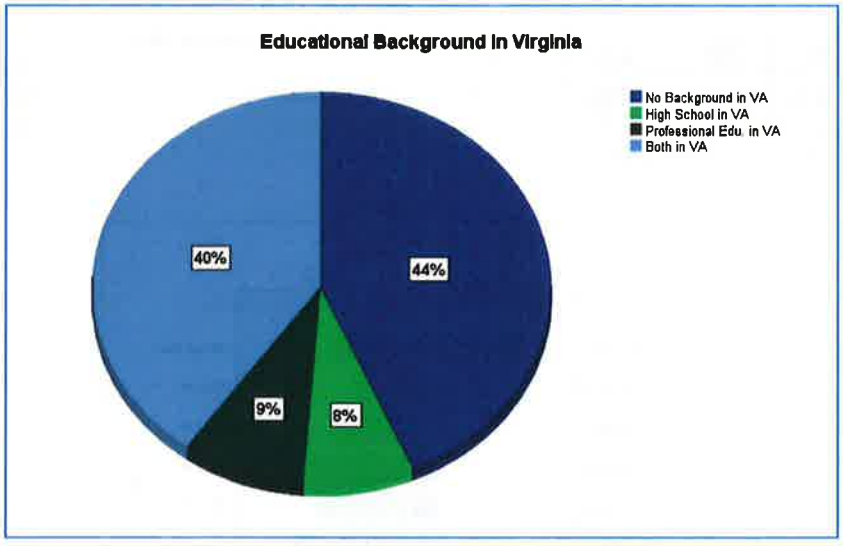
% Rural to Non-Metro:	23%
% Urban/Suburban to Non-Metro:	5%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Primary Location: USDA Rural Urban Continuum		Rural Status of Childhood Location		
Code	Description	Rural	Suburban	Urban
	Metro Counties			
1	Metro, 1 million+	22%	57%	21%
2	Metro, 250,000 to 1 million	50%	40%	10%
3	Metro, 250,000 or less	40%	46%	14%
	Non-Metro Counties			
4	Urban pop 20,000+, metro adjacent	50%	39%	11%
6	Urban pop, 2,500-19,999, metro adjacent	66%	28%	6%
7	Urban pop, 2,500-19,999, non adjacent	87%	8%	6%
8	Rural, metro adjacent	58%	31%	11%
9	Rural, non adjacent	63%	27%	10%
	Overall	**32%**	**51%**	**17%**

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

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

Top Ten States for Pharmacy Recruitment

Rank	All Pharmacists			
	High School	#	Professional School	#
1	Virginia	3,376	Virginia	3,402
2	Outside U.S./Canada	799	Pennsylvania	496
3	Pennsylvania	450	North Carolina	302
4	New York	362	New York	291
5	West Virginia	204	Outside U.S./Canada	287
6	Maryland	203	Maryland	217
7	North Carolina	195	West Virginia	198
8	New Jersey	139	Massachusetts	193
9	Ohio	138	Washington, D.C.	190
10	Florida	101	Ohio	134

Source: Va. Healthcare Workforce Data Center

48% of Virginia's pharmacists received their high school degree in Virginia, and 49% received their initial professional degree in the state.

Among pharmacists who have been licensed in the past five years, 42% received their high school degree in Virginia, and 45% received their initial professional degree in the state.

Rank	Licensed in the Past 5 Years			
	High School	#	Professional School	#
1	Virginia	788	Virginia	824
2	Outside U.S./Canada	202	Pennsylvania	132
3	Pennsylvania	132	New York	96
4	New York	115	North Carolina	96
5	North Carolina	75	Maryland	86
6	Maryland	73	Tennessee	62
7	West Virginia	39	West Virginia	57
8	New Jersey	37	Outside U.S./Canada	52
9	Florida	35	Massachusetts	46
10	Ohio	33	Florida	45

Source: Va. Healthcare Workforce Data Center

44% of Virginia's licensed pharmacists did not participate in Virginia's workforce in 2018. 91% of these professionals worked at some point in the past year, including 83% who currently work as pharmacists.

At a Glance:

Not in VA Workforce

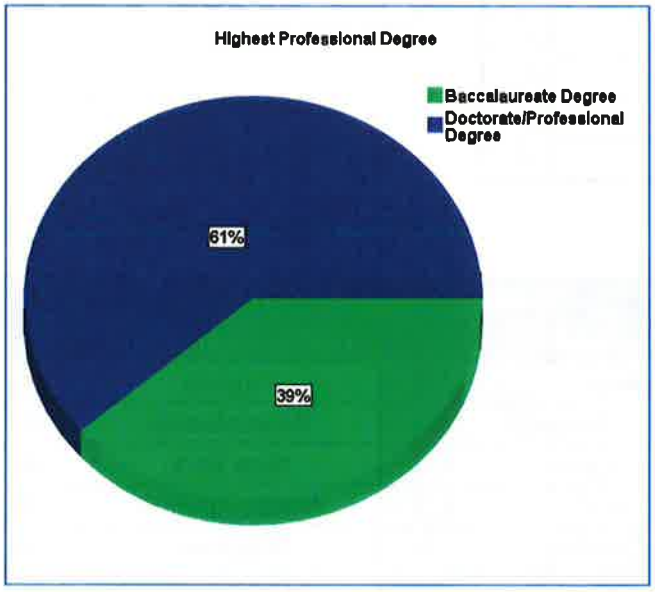
Total:	6,802
% of Licensees:	44%
Federal/Military:	7%
VA Border State/DC:	19%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Highest Professional Degree		
Degree	#	%
B.S. Pharmacy	2,494	36%
Pharm.D.	4,400	64%
Total	**6,894**	**100%**

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

42% of pharmacists currently have educational debt, including 74% of those under the age of 40. For those with educational debt, the median debt is between $110,000 and $120,000. Among those under the age of 40 with debt, median is $130,000 to $140,000.

At a Glance:

Education

B.S. Pharmacy: 36%
Pharm.D.: 64%

Educational Debt

Carry debt: 42%
Under age 40 w/ debt: 74%
Median debt: $110k-$120k

Source: Va. Healthcare Workforce Data Center

64% 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				
Amount Carried	All Pharmacists		Pharmacists Under 40	
	#	%	#	%
None	3,456	58%	598	26%
$20,000 or less	178	3%	89	4%
$20,001-$40,000	192	3%	96	4%
$40,001-$60,000	249	4%	124	5%
$60,001-$80,000	219	4%	121	5%
$80,001-100,000	228	4%	143	6%
$100,001-$120,000	225	4%	161	7%
$120,001-$140,000	172	3%	128	5%
$140,001-$160,000	159	3%	136	6%
$160,001-$180,000	142	2%	117	5%
$180,001-$200,000	127	2%	106	5%
Over $200,000	579	10%	509	22%
Total	**5,926**	**100%**	**2,328**	**100%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Top Specialties

Immunization:	17%
Community Pharmacy:	8%
Ambulatory Care:	4%

Top Board Certifications

BPS - Pharmacotherapy:	5%
BPS - Ambulatory Care:	1%
BCGP - Geriatrics:	1%

Top Residencies (PGY1)

Pharmacy Practice (Post 1993):	10%
Community Pharmacy:	5%
Pharmacy Practice (Pre 1993):	4%

Source: Va. Healthcare Workforce Data Center

PGY1		
Residency	#	%
Pharmacy Practice (Post 1993)	875	10%
Community Pharmacy	440	5%
Pharmacy Practice (Pre 1993)	347	4%
Managed Care Pharmacy	38	0%
Other	0	0%
Total	**1,700**	**20%**
PGY2		
Ambulatory Care	102	16%
Critical Care	56	9%
Drug Information	49	8%
Internal Medicine/Cardiology	47	8%
Health-system Pharmacy Administration	32	5%
Infectious Disease	26	4%
Psychiatry	26	4%
Geriatrics	25	4%
Pediatrics	24	4%
Oncology	22	4%
Pharmacotherapy	20	3%
Managed Care Pharmacy Systems	13	2%
Emergency Medicine	11	2%
Other	169	27%
At Least One	**622**	**7%**

Source: Va. Healthcare Workforce Data Center

Board Certifications		
Certification	#	%
BPS-Pharmacotherapy	468	5%
BPS-Ambulatory Care	95	1%
BCGP-Geriatrics	89	1%
BPS-Oncology	36	0%
BPS- Psychiatric	24	0%
BPS- Nutrition	12	0%
BPS-Nuclear Pharmacy	10	0%
ABAT-Applied Toxicology	1	0%
Other Board Certification	179	2%
At Least One Certification	**825**	**10%**

Source: Va. Healthcare Workforce Data Center

10% of pharmacists hold a board certification, including 5% who hold a certification in Pharmacotherapy. 34% also have a self-designated specialty area, including 17% who have a specialization in immunization.

At a Glance:

Top Services

Immunization:	33%
Medication Management:	30%
Compounding:	27%

Disease Management

Anticoagulation:	16%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Services Provided

Services	Primary		Secondary	
	#	%	#	%
Immunization	2,837	33%	2,837	33%
Medication Therapy Management	2,566	30%	287	3%
Compounding	2,350	27%	240	3%
Central Filling	1,135	13%	144	2%
Remote Order Processing	810	9%	82	1%
Collaborative Practice Agreement	531	6%	64	1%
Remote Consulting/ Telepharmacy	0	0%	0	0%
At Least One Service	**4,702**	**55%**	**3,112**	**36%**

Source: Va. Healthcare Workforce Data Center

Disease Management in Collaborative Practice

	#	%
Anticoagulation	85	16%
Hypertension, Hypercholesterolemia, Asthma, Tobacco cessation, Travel medications, Anticoagulation, Diabetes	32	6%
Hypertension, Hypercholesterolemia, Asthma Tobacco cessation, Anticoagulation, Diabetes	23	4%
Hypertension, Hypercholesterolemia, Asthma, Diabetes	13	2%
Hypertension, Hypercholesterolemia, Anticoagulation, Diabetes	12	2%
Diabetes	12	2%
Anticoagulation, Diabetes	12	2%
Hypertension, Hypercholesterolemia, Asthma, Tobacco cessation, Diabetes	10	2%
Hypertension	7	1%
Hypertension, Hypercholesterolemia, Asthma, Diabetes	5	1%
Hypertension, Diabetes	4	1%
Hypertension, Hypercholesterolemia, Anticoagulation	3	1%
Hypertension, Hypercholesterolemia	2	0%
Hypertension, Anticoagulation, Diabetes	2	0%
Hypertension, Hypercholesterolemia, Asthma, Tobacco cessation, Travel medications, Diabetes	2	0%
Asthma, Anticoagulation, Diabetes	2	0%
Hypertension, Asthma, Anticoagulation	1	0%
Hypercholesterolemia, Tobacco cessation, Travel medications, Diabetes	1	0%
Hypertension, Hypercholesterolemia, Asthma, Anticoagulation	1	0%
Hypertension, Asthma, Diabetes	1	0%
Hypercholesterolemia	1	0%
Hypertension, Anticoagulation	1	0%
Other	296	56%
Total	**528**	**100%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Employment

Employed in Profession: 91%
Involuntarily Unemployed: 2%

Positions Held

1 Full-time: 72%
2 or More Positions: 8%

Weekly Hours:

40 to 49: 50%
60 or more: 4%
Less than 30: 13%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Current Work Status		
Status	#	%
Employed, capacity unknown	7	0%
Employed in a pharmacy-related capacity	6,345	91%
Employed, NOT in a pharmacy-related capacity	209	3%
Not working, reason unknown	0	0%
Involuntarily unemployed	108	2%
Voluntarily unemployed	169	2%
Retired	138	2%
Total	**6,976**	**100%**

Source: Va. Healthcare Workforce Data Center

91% of Virginia's pharmacists are currently employed in the profession, and 2% of all pharmacy professionals are involuntarily unemployed at the moment. 72% of the state's pharmacist workforce have one full-time job, while 8% of pharmacists have multiple positions. 50% of pharmacists work between 40 and 49 hours per week, while 4% of pharmacy professionals work at least 60 hours per week.

Current Positions		
Positions	#	%
No Positions	415	6%
One Part-Time Position	933	14%
Two Part-Time Positions	143	2%
One Full-Time Position	4,945	72%
One Full-Time Position & One Part-Time Position	364	5%
Two Full-Time Positions	4	0%
More than Two Positions	34	0%
Total	**6,838**	**100%**

Source: Va. Healthcare Workforce Data Center

Current Weekly Hours		
Hours	#	%
0 hours	415	6%
1 to 9 hours	171	3%
10 to 19 hours	233	3%
20 to 29 hours	454	7%
30 to 39 hours	1,351	20%
40 to 49 hours	3,410	50%
50 to 59 hours	496	7%
60 to 69 hours	153	2%
70 to 79 hours	69	1%
80 or more hours	54	1%
Total	**6,806**	**100%**

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Income		
Annual Income	#	%
Volunteer Work Only	67	1%
$50,000 or less	473	9%
$50,001-$60,000	104	2%
$60,001-$70,000	111	2%
$70,001-$80,000	143	3%
$80,001-$90,000	147	3%
$90,001-$100,000	222	4%
$100,001-$110,000	553	10%
$110,001-$120,000	669	13%
$120,001-$130,000	916	17%
$130,001-$140,000	794	15%
$140,001-$150,000	482	9%
More than $150,000	595	11%
Total	5,276	100%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Annual Income
Median Income: $120k-130k

Benefits
Employer Health Insrnce: 70%
Employer Retirement: 72%

Satisfaction
Satisfied: 87%
Very Satisfied: 47%

Source: Va. Healthcare Workforce Data Center

Job Satisfaction		
Level	#	%
Very Satisfied	3,150	47%
Somewhat Satisfied	2,680	40%
Somewhat Dissatisfied	601	9%
Very Dissatisfied	300	5%
Total	6,731	100%

Source: Va. Healthcare Workforce Data Center

The typical pharmacist earned between $120,000 and $130,000 in 2018. Among pharmacists who received either an hourly wage or a salary as compensation at their primary work location, 70% received health insurance and 72% also had access to a retirement plan.

Employer-Sponsored Benefits			
Benefit	#	%	% of Wage/Salary Employees
Paid Vacation Leave	4,858	77%	80%
Retirement	4,390	69%	72%
Health Insurance	4,284	68%	70%
Dental Insurance	4,118	65%	68%
Paid Sick Leave	3,750	59%	62%
Group Life Insurance	3,144	50%	52%
Signing/Retention Bonus	409	6%	7%
Received At Least One Benefit	5,140	81%	84%

*From any employer at time of survey.
Source: Va. Healthcare Workforce Data Center

A Closer Look:

Underemployment in Past Year		
In the past year did you . . .?	#	%
Experience Involuntary Unemployment?	220	3%
Experience Voluntary Unemployment?	261	3%
Work Part-time or temporary positions, but would have preferred a full-time/permanent position?	292	3%
Work two or more positions at the same time?	673	8%
Switch employers or practices?	396	5%
Experienced at least 1	1,512	18%

Source: Va. Healthcare Workforce Data Center

3% of Virginia's pharmacists were involuntary unemployed at some point in 2018. For comparison, Virginia's average monthly unemployment rate was 3.0%.[1]

Location Tenure				
Tenure	Primary		Secondary	
	#	%	#	%
Not Currently Working at this Location	166	3%	71	8%
Less than 6 Months	620	10%	106	12%
6 Months to 1 Year	507	8%	96	11%
1 to 2 Years	1,198	18%	166	19%
3 to 5 Years	1,448	22%	174	20%
6 to 10 Years	942	15%	127	14%
More than 10 Years	1,603	25%	136	16%
Subtotal	6,485	100%	876	100%
Did not have location	311		7,706	
Item Missing	1,824		39	
Total	8,620		8,620	

Source: Va. Healthcare Workforce Data Center

Half of all pharmacists receive a salary or commission at their primary work location, while 43% receive an hourly wage.

At a Glance:

Unemployment Experience

Involuntarily Unemployed: 3%
Underemployed: 3%

Stability

Switched: 5%
New Location: 20%
Over 2 years: 62%
Over 2 yrs, 2nd location: 50%

Employment Type

Salary or Wage: 93%

Source: Va. Healthcare Workforce Data Center

62% 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	2,945	50%
Hourly Wage	2,538	43%
By Contract	81	1%
Business/ Practice Income	295	5%
Unpaid	47	1%
Subtotal	5,906	100%

Source: Va. Healthcare Workforce Data Center

[1] As reported by the US Bureau of Labor Statistics, the non-seasonally adjusted monthly unemployment rate fell from 3.7% in January 2018 to 2.6% in December 2018. December 2018 unemployment rate from was preliminary at the time of publication.

At a Glance:

Concentration

Top Region:	26%
Top 3 Regions:	71%
Lowest Region:	2%

Locations

2 or more (2018):	11%
2 or more (Now*):	12%

Source: Va. Healthcare Workforce Data Center

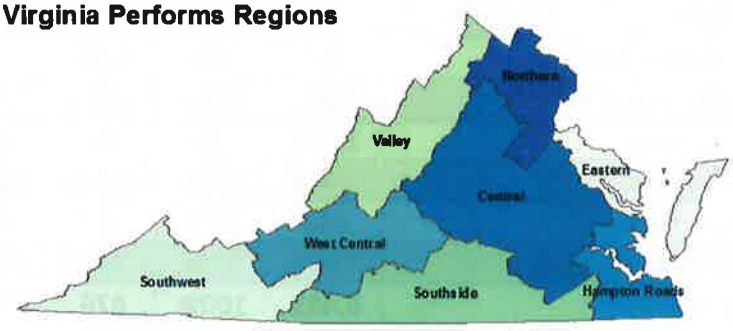
Over half of all pharmacists in the state work in either Northern Virginia or Central Virginia.

A Closer Look:

Regional Distribution of Work Locations				
Virginia Performs Region	Primary Location		Secondary Location	
	#	%	#	%
Central	1,679	26%	170	19%
Eastern	105	2%	18	2%
Hampton Roads	1,233	19%	157	18%
Northern	1,645	26%	209	24%
Southside	227	4%	26	3%
Southwest	360	6%	71	8%
Valley	381	6%	62	7%
West Central	736	11%	97	11%
Virginia Border State/DC	32	0%	31	3%
Other US State	51	1%	44	5%
Outside of the US	1	0%	3	0%
Total	6,450	100%	888	100%
Item Missing	1,859		28	

Source: Va. Healthcare Workforce Data Center

Virginia Performs Regions



Number of Work Locations				
Locations	Work Locations in 2018		Work Locations Now*	
	#	%	#	%
0	308	4%	395	6%
1	7,398	86%	5,515	82%
2	475	6%	449	7%
3	291	3%	255	4%
4	34	0%	23	0%
5	17	0%	13	0%
6 or More	99	1%	76	1%
Total	8,620	100%	6,726	100%

*At the time of survey completion, December 2018.

Source: Va. Healthcare Workforce Data Center

Over the past year, 11% of Virginia's pharmacists worked at multiple locations.

Establishment Type

A Closer Look:

Location Sector				
Sector	Primary Location		Secondary Location	
	#	%	#	%
For-Profit	3,992	66%	583	70%
Non-Profit	1,459	24%	189	23%
State/Local Government	260	4%	31	4%
Veterans Administration	126	2%	8	1%
U.S. Military	132	2%	17	2%
Other Federal Gov't	71	1%	2	0%
Total	**6,040**	**100%**	**830**	**100%**
Did not have location	311		7,706	
Item Missing	2,269		85	

Source: Va. Healthcare Workforce Data Center

At a Glance:
(Primary Locations)

Sector

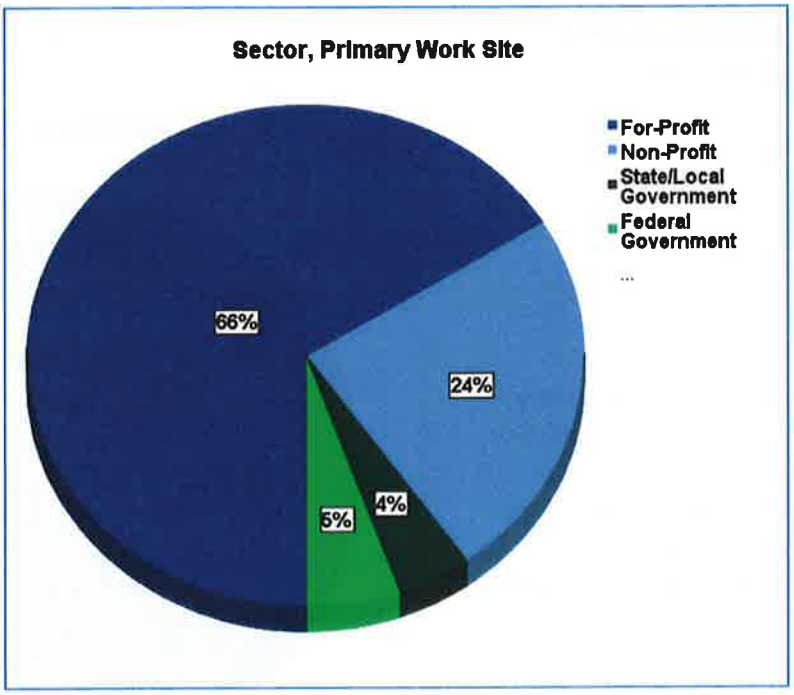
For Profit: 66%
Federal: 5%

Top Establishments

Large Chain Pharmacy (11+ Stores): 28%
Hospital/Health System (Inpatient): 24%
Independent Pharmacy (1-4 Stores): 10%

Source: Va. Healthcare Workforce Data Center

90% of all pharmacists work in the private sector, including 66% who work at a for-profit company. Another 5% of pharmacists work for the federal government, while 4% work for a state or local government.



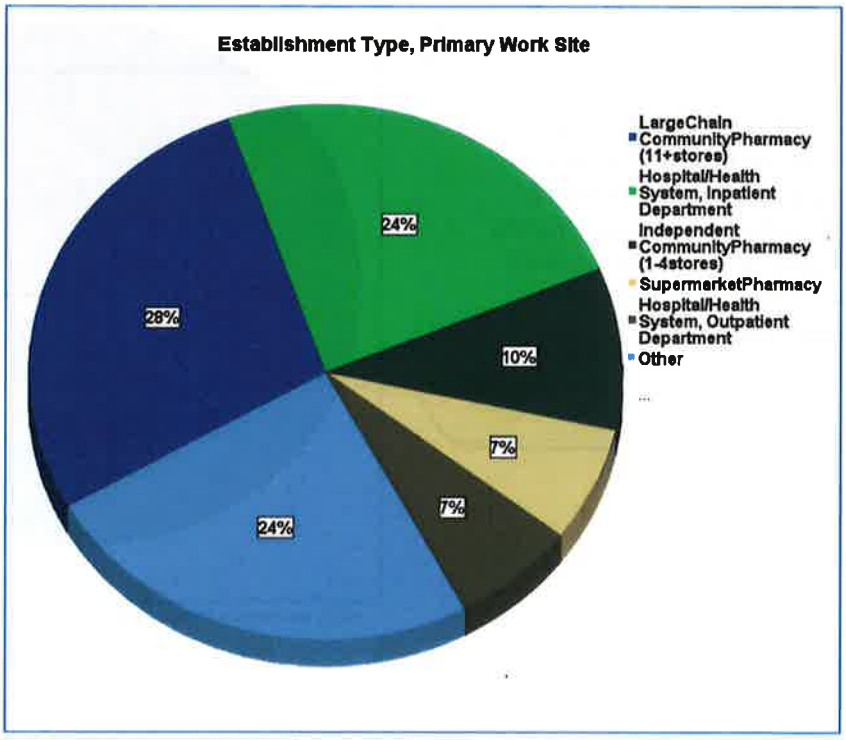
Source: Va. Healthcare Workforce Data Center

Top Location Types				
Establishment Type	Primary Location		Secondary Location	
	#	%	#	%
Large Chain Community Pharmacy	1,653	28%	190	23%
Hospital/Health System, Inpatient Department	1,415	24%	134	16%
Independent Community Pharmacy	575	10%	141	17%
Supermarket Pharmacy	411	7%	42	5%
Hospital/Health System, Outpatient Department	401	7%	40	5%
Mass Merchandiser (i.e. Big Box Store)	258	4%	33	4%
Clinic-Based Pharmacy	199	3%	71	9%
Nursing Home/Long-Term Care	184	3%	32	4%
Benefit Administration	152	3%	4	0%
Academic Institution	112	2%	36	4%
Home Health/Infusion	70	1%	3	0%
Manufacturer	52	1%	0	0%
Mail Service Pharmacy	41	1%	8	1%
Small Chain Community Pharmacy	27	0%	8	1%
Wholesale Distributor	7	0%	0	0%
Other	343	6%	77	9%
Total	5,900	100%	819	100%
Did Not Have a Location	311		7,706	

Source: Va. Healthcare Workforce Data Center

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

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



Source: Va. Healthcare Workforce Data Center

At a Glance:
(Primary Locations)

Typical Time Allocation

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

Roles

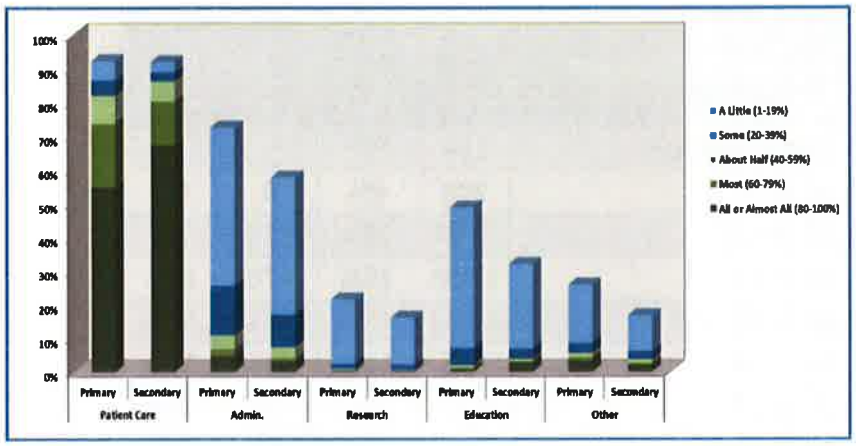
Patient Care:	74%
Administration:	7%
Education:	1%

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, nearly three-quarters of pharmacists fill a patient care role, defined as spending at least 60% of her time in that activity.

Time Allocation										
Time Spent	Patient Care		Admin.		Research		Education		Other	
	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%	4%	3%	0%	0%	1%	3%	3%	2%
Most (60-79%)	19%	13%	2%	1%	0%	0%	0%	0%	1%	0%
About Half (40-59%)	8%	6%	4%	3%	0%	0%	1%	1%	1%	1%
Some (20-39%)	4%	3%	15%	10%	1%	1%	5%	3%	3%	2%
A Little (1-20%)	6%	3%	47%	41%	19%	14%	42%	25%	17%	11%
None (0%)	8%	8%	27%	42%	78%	84%	51%	68%	74%	83%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Retirement Expectations				
Expected Retirement Age	All		Over 50	
	#	%	#	%
Under age 50	154	3%	-	-
50 to 54	208	4%	0	0%
55 to 59	539	10%	110	5%
60 to 64	1,396	25%	478	23%
65 to 69	2,047	37%	861	42%
70 to 74	636	11%	346	17%
75 to 79	176	3%	95	5%
80 or over	86	2%	48	2%
I do not intend to retire	310	6%	131	6%
Total	5,551	100%	2,069	100%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Retirement Expectations

All Pharmacists

Under 65:	41%
Under 60:	16%

Pharmacists 50 and over

Under 65:	28%
Under 60:	5%

Time until Retirement

Within 2 years:	7%
Within 10 years:	23%
Half the workforce:	By 2043

Source: Va. Healthcare Workforce Data Center

41% of Virginia's pharmacists expect to retire before the age of 65, while 22% plan on working until at least age 70. Among pharmacists who are age 50 and over, 28% still plan on retiring by age 65, while close to one-third expect to work until at least age 70.

Within the next two years, 1% of Virginia's pharmacists plan on leaving the profession and 3% expect to leave the state. Meanwhile, 9% of pharmacists expect to pursue additional educational opportunities, and 8% also plan on increasing the number of hours that they devote to patients.

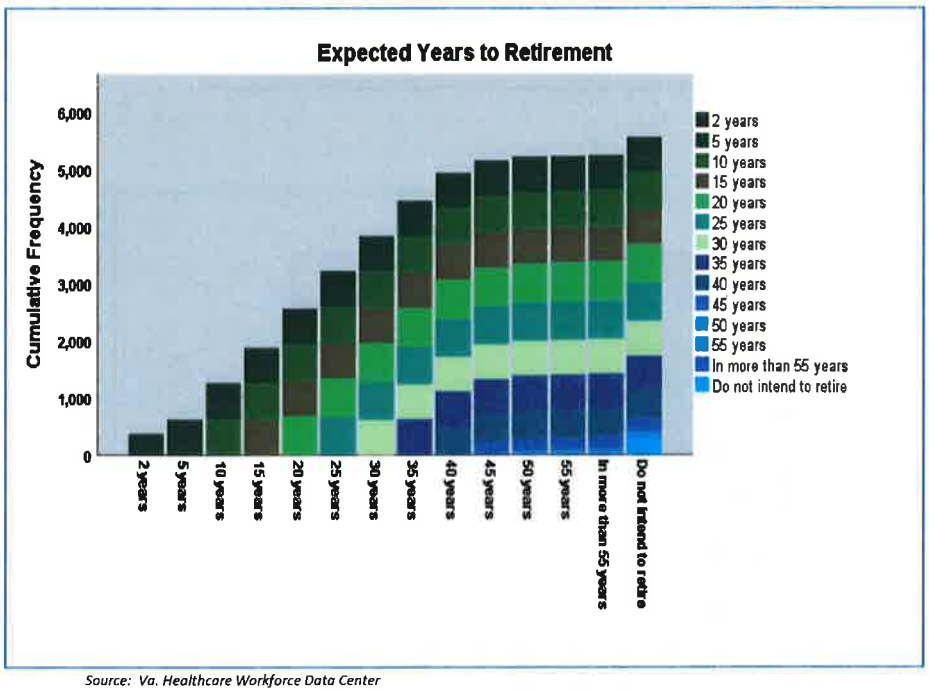
Future Plans		
2 Year Plans:	#	%
Decrease Participation		
Leave Profession	114	1%
Leave Virginia	256	3%
Decrease Patient Care Hours	236	3%
Decrease Teaching Hours	30	0%
Increase Participation		
Increase Patient Care Hours	689	8%
Increase Teaching Hours	446	5%
Pursue Additional Education	806	9%
Return to Virginia's Workforce	120	1%

Source: Va. Healthcare Workforce Data Center

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 23% plan on retiring in the next ten years. Half of the current pharmacist workforce expect to retire by 2043.

Time to Retirement			
Expect to retire within. . .	#	%	Cumulative %
2 years	371	7%	7%
5 years	242	4%	11%
10 years	641	12%	23%
15 years	613	11%	34%
20 years	684	12%	46%
25 years	659	12%	58%
30 years	611	11%	69%
35 years	623	11%	80%
40 years	482	9%	89%
45 years	216	4%	93%
50 years	64	1%	94%
55 years	16	0%	94%
In more than 55 years	20	0%	94%
Do not intend to retire	310	6%	100%
Total	**5,551**	**100%**	

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

Using these estimates, retirement will begin to reach 10% of the current workforce starting in 2028. Retirement will peak at 12% of the current workforce at that time before declining to under 10% of the current workforce again around 2058.

Full-Time Equivalency Units

At a Glance:

FTEs

Total:	6,943
FTEs/1,000 Residents[2]:	0.825
Average:	0.84

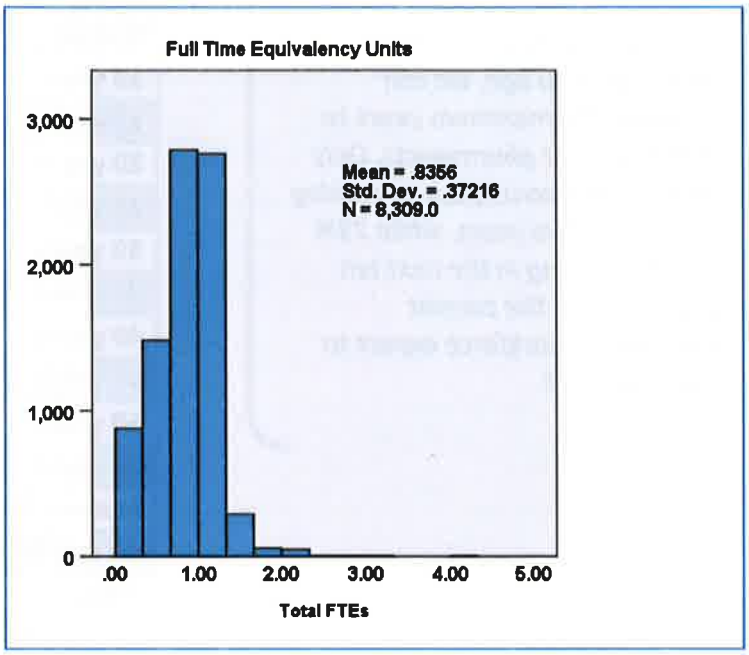
Age & Gender Effect

Age, Partial Eta[3]:	Small
Gender, Partial Eta[3]:	Negligible

Partial Eta[3] Explained:
Partial Eta[3] is a statistical measure of effect size.

Source: Va. Healthcare Workforce Data Center

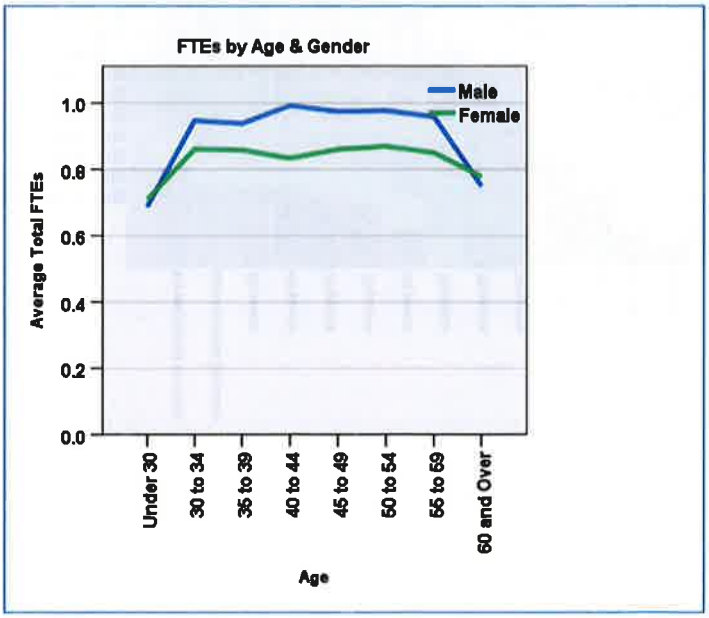
A Closer Look:



The typical pharmacist provided 0.92 FTEs in 2018, or about 37 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		
	Average	Median
Age		
Under 30	0.69	0.64
30 to 34	0.89	0.92
35 to 39	0.83	0.90
40 to 44	0.78	0.91
45 to 49	0.91	0.97
50 to 54	0.95	1.05
55 to 59	0.86	0.85
60 and Over	0.76	0.72
Gender		
Male	0.88	0.97
Female	0.83	0.93

Source: Va. Healthcare Workforce Data Center

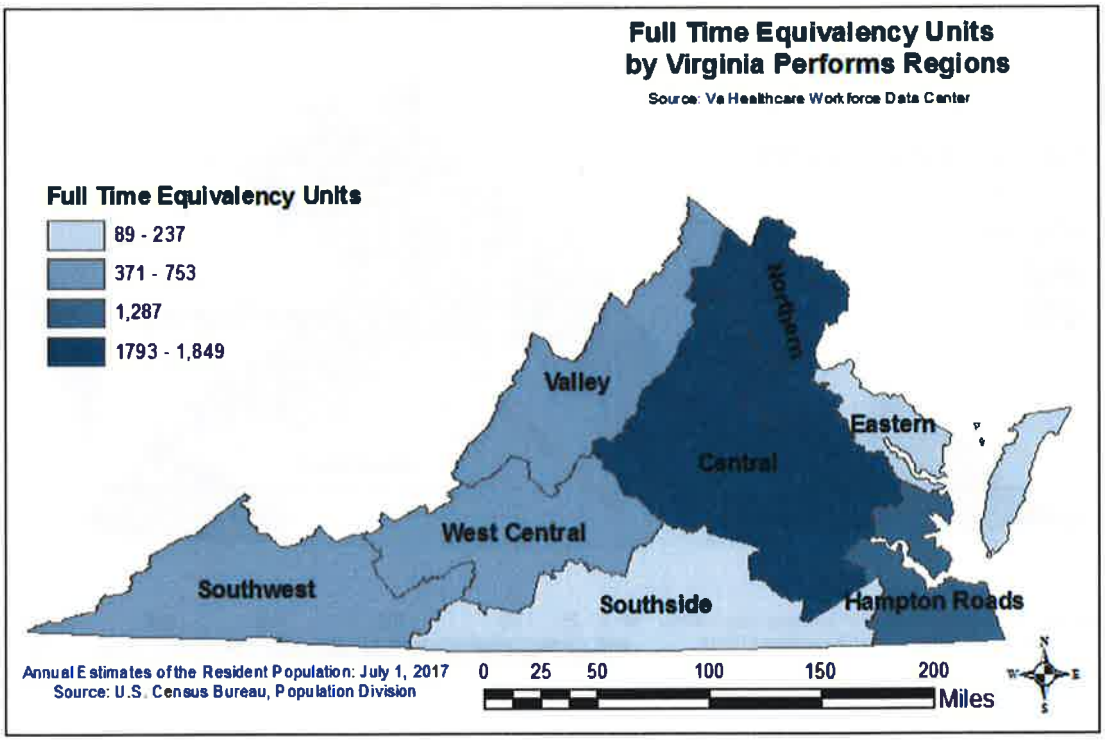


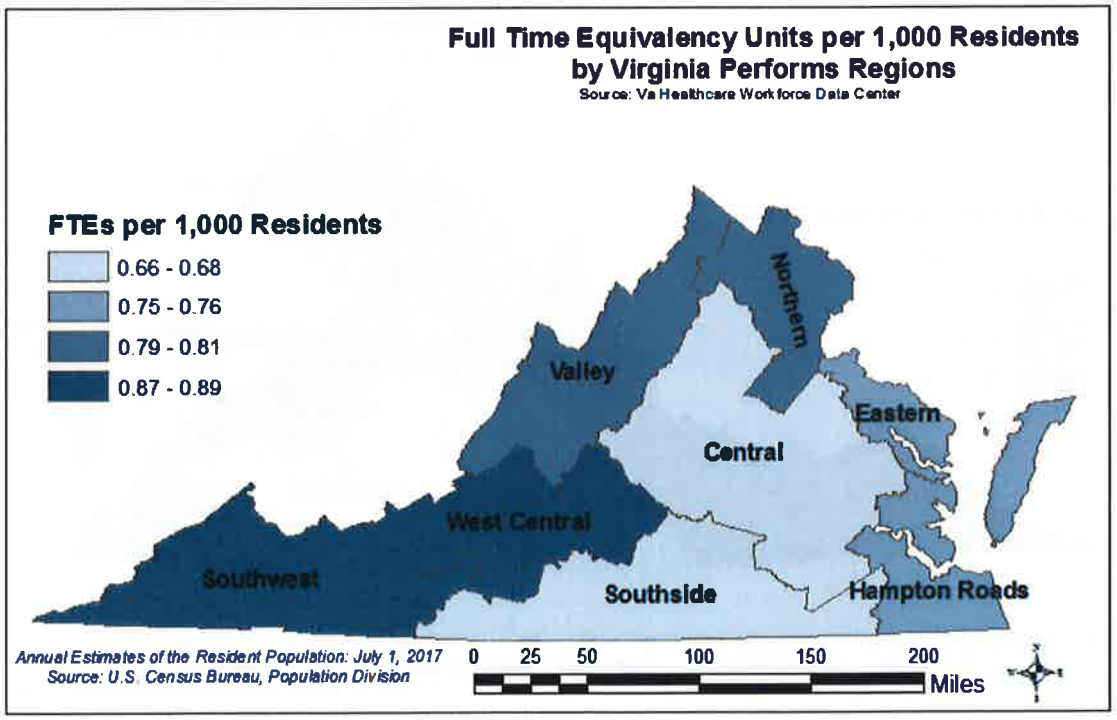
[2] Number of residents in 2017 was used as the denominator. Source: Va. Healthcare Workforce Data Center

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

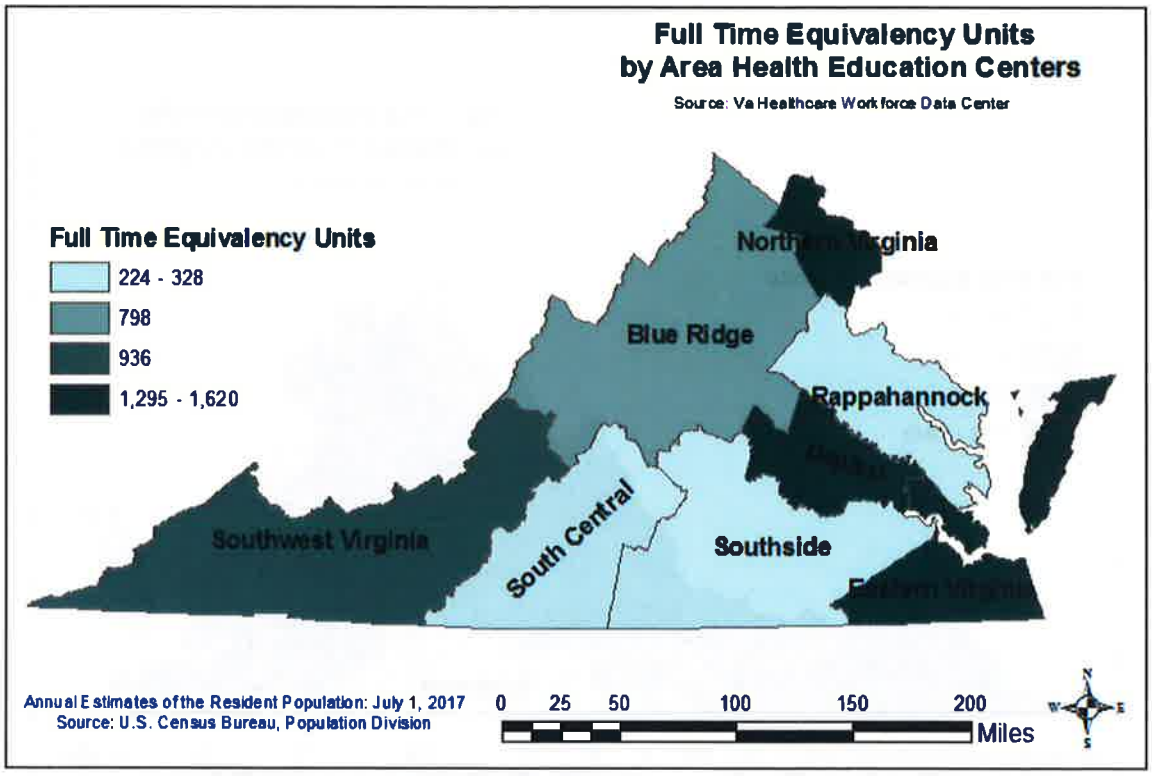
Maps

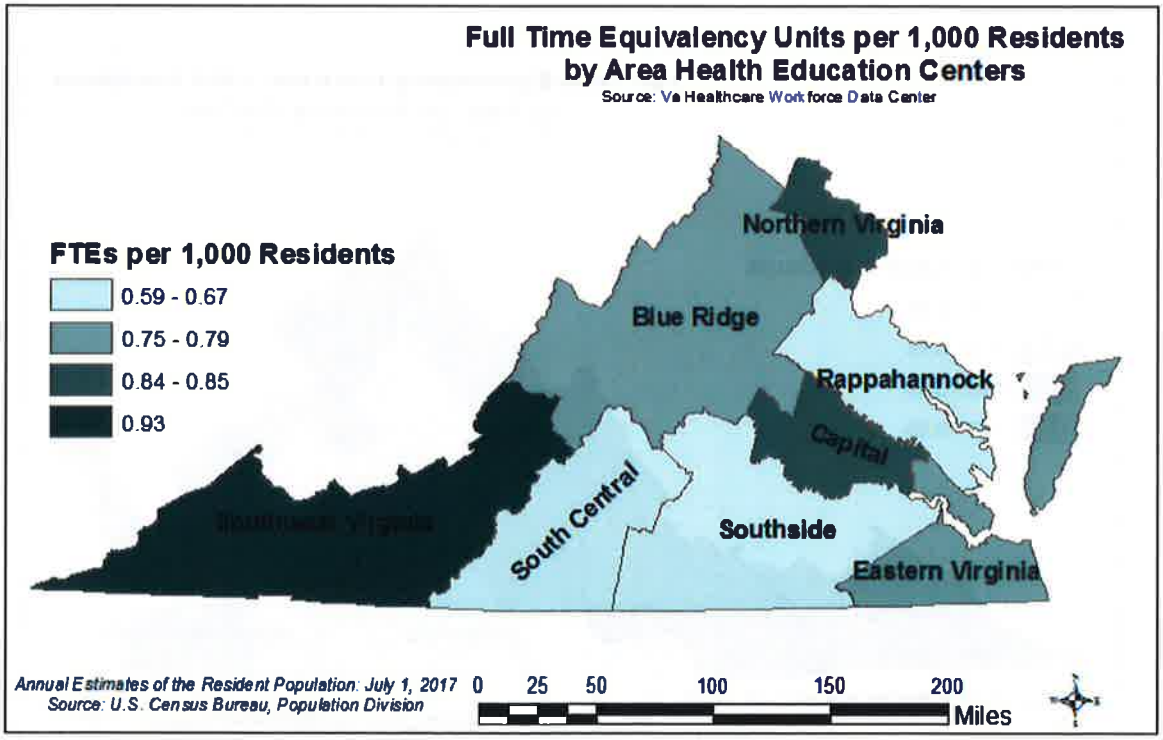
Virginia Performs Regions



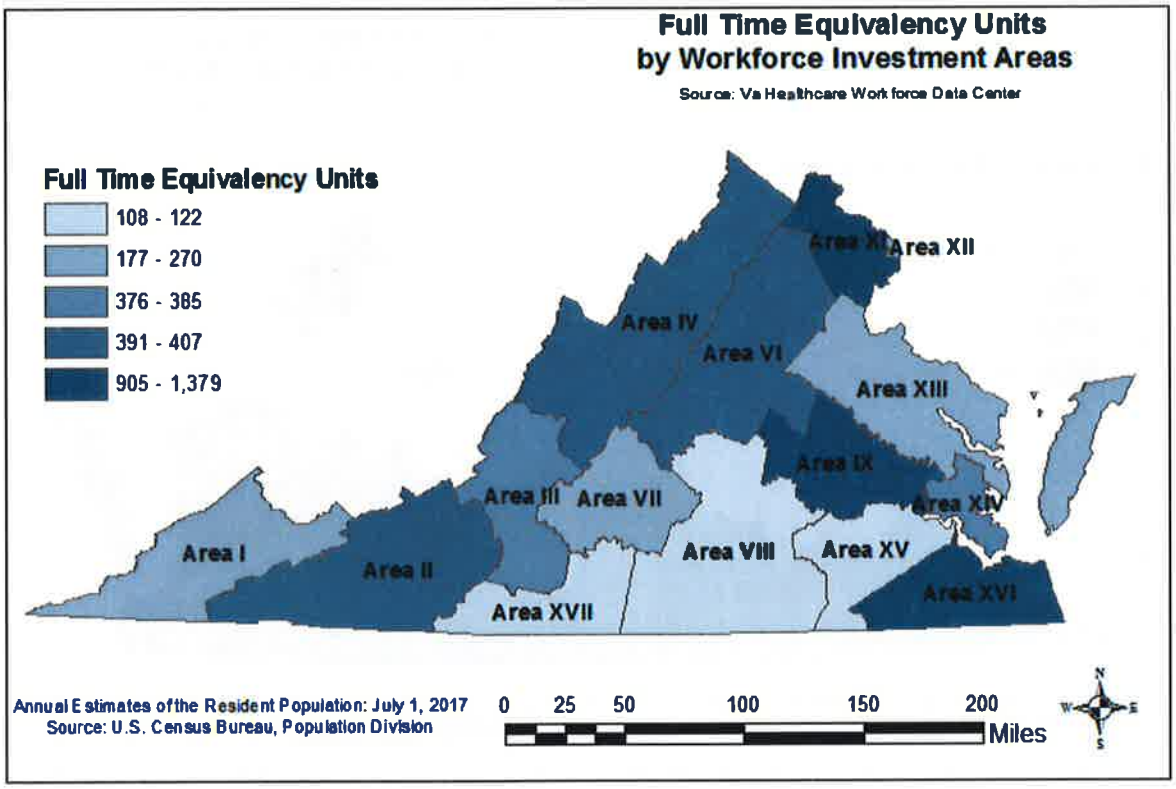


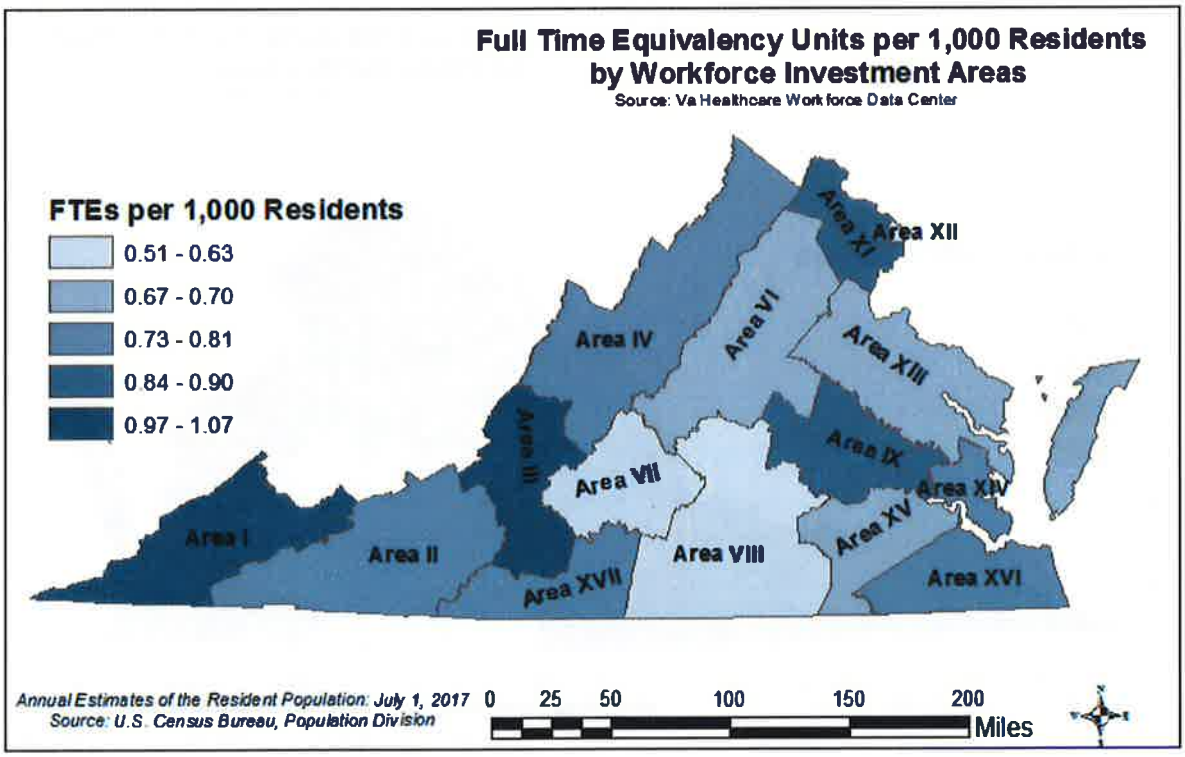
Area Health Education Center Regions



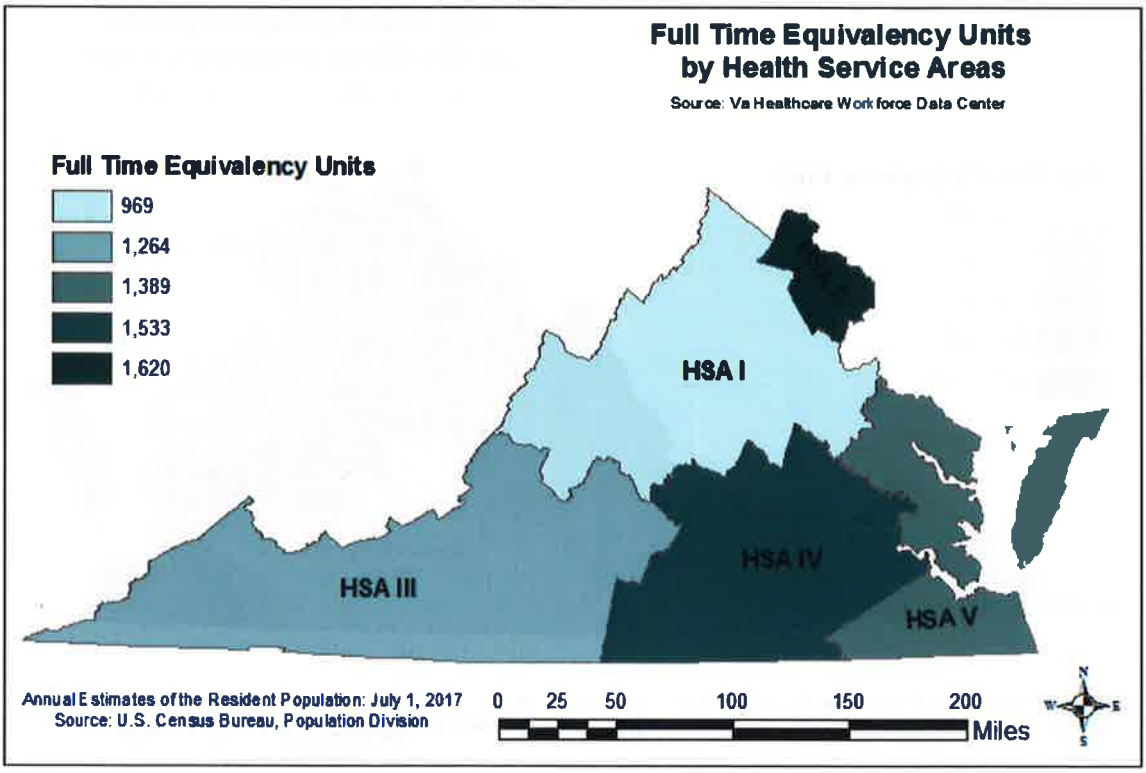


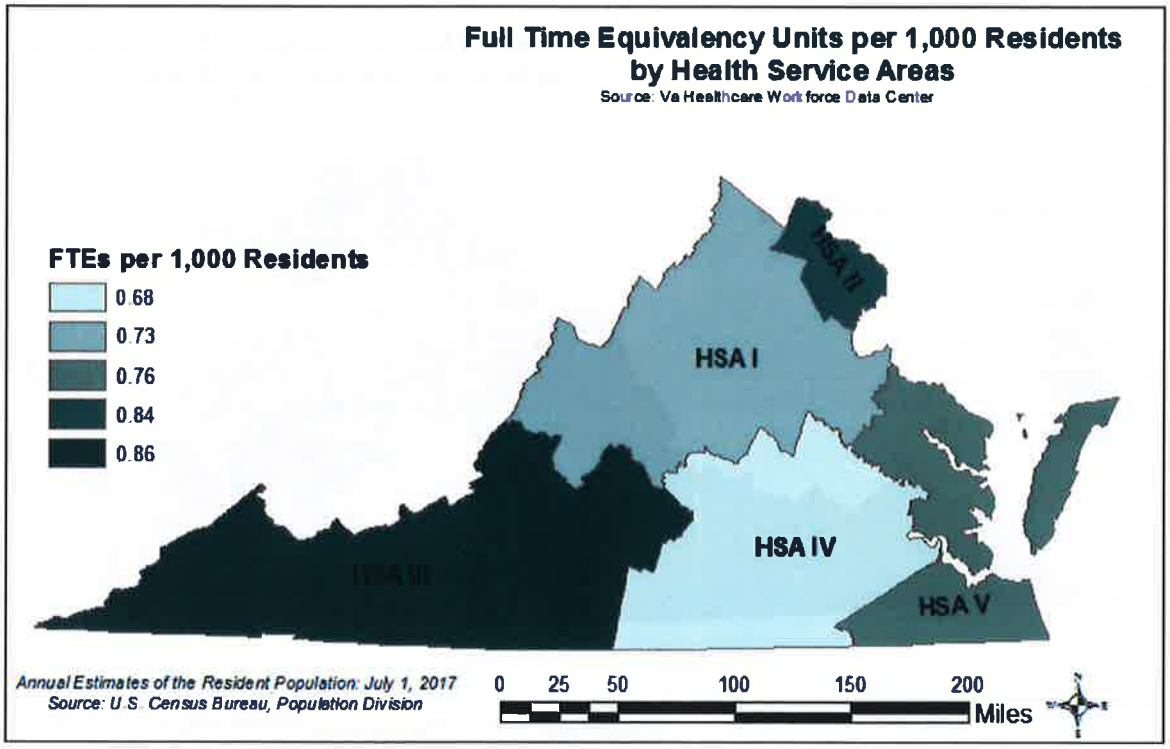
Workforce Investment Areas

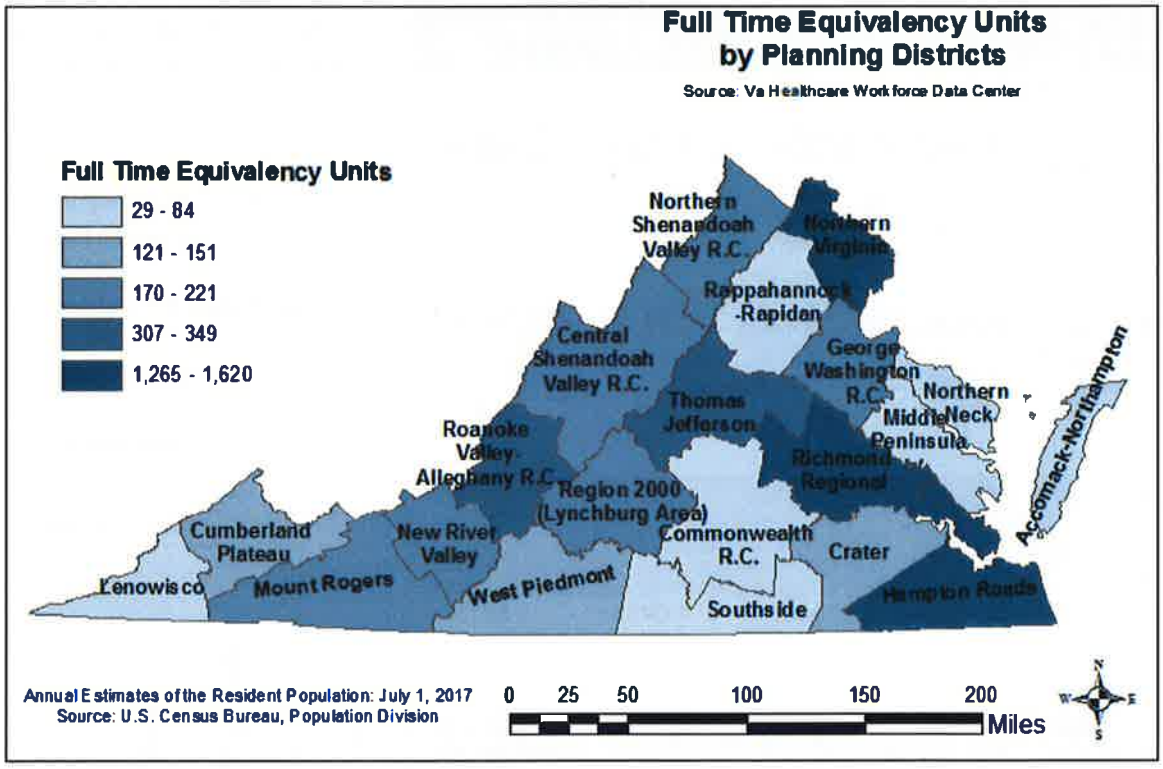


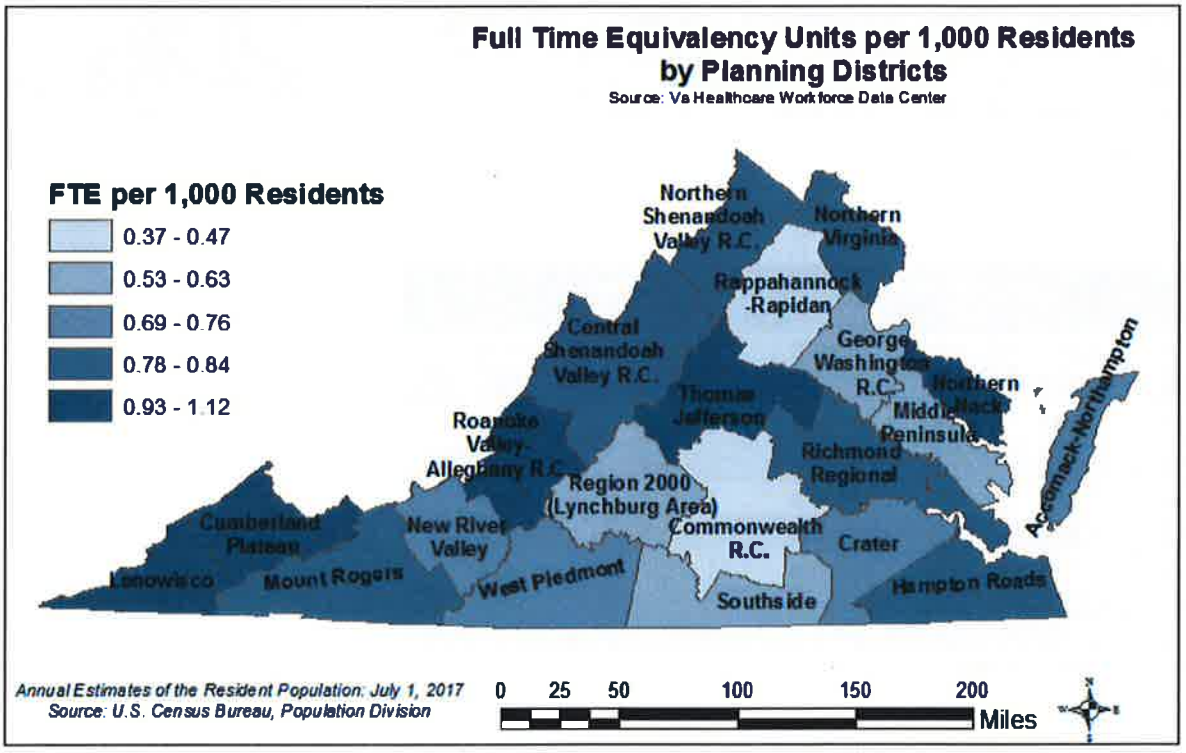


Health Services Areas






Full Time Equivalency Units
by Planning Districts
Source: Va Healthcare Workforce Data Center
Full Time Equivalency Units
29 - 84
121 - 151
170 - 221
307 - 349
1,265 - 1,620
Northern Shenandoah Valley R.C.
Northern Virginia
Rappahannock -Rapidan
Central Shenandoah Valley R.C.
George Washington R.C.
Thomas Jefferson
Northern Middle Neck Peninsula
Accomack-Northampton
Roanoke Valley-Alleghany R.C.
Richmond Regional
Region 2000 (Lynchburg Area)
Commonwealth R.C.
Crater
Cumberland Plateau
New River Valley
Lenowisco
Mount Rogers
West Piedmont
Southside
Hampton Roads
Annual Estimates of the Resident Population: July 1, 2017
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles


Full Time Equivalency Units per 1,000 Residents
by Planning Districts
Source: Va Healthcare Workforce Data Center
FTE per 1,000 Residents
0.37 - 0.47
0.53 - 0.63
0.69 - 0.76
0.78 - 0.84
0.93 - 1.12
Northern Shenandoah Valley R.C.
Northern Virginia
Rappahannock -Rapidan
Central Shenandoah Valley R.C.
George Washington R.C.
Thomas Jefferson
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Southside
Hampton Roads
Annual Estimates of the Resident Population: July 1, 2017
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles

Appendix

Weights

Rural Status	Location Weight			Total Weight	
	#	Rate	Weight	Min	Max
Metro, 1 million+	6,392	93.21%	1.072843	1.0404	1.13630
Metro, 250,000 to 1 million	909	93.29%	1.071934	1.0395	1.13534
Metro, 250,000 or less	1,030	92.62%	1.079665	1.0470	1.14353
Urban pop 20,000+, Metro adj	122	92.62%	1.079646	1.0470	1.14351
Urban pop 20,000+, nonadj	0	NA	NA	NA	NA
Urban pop, 2,500-19,999, Metro adj	377	88.33%	1.132132	1.0979	1.19910
Urban pop, 2,500-19,999, nonadj	290	92.76%	1.078067	1.0455	1.14184
Rural, Metro adj	227	84.14%	1.188482	1.1526	1.25878
Rural, nonadj	124	93.55%	1.068966	1.0367	1.13220
Virginia border state/DC	2,610	88.85%	1.125485	1.0915	1.19206
Other US State	3,341	85.60%	1.168182	1.1329	1.23728

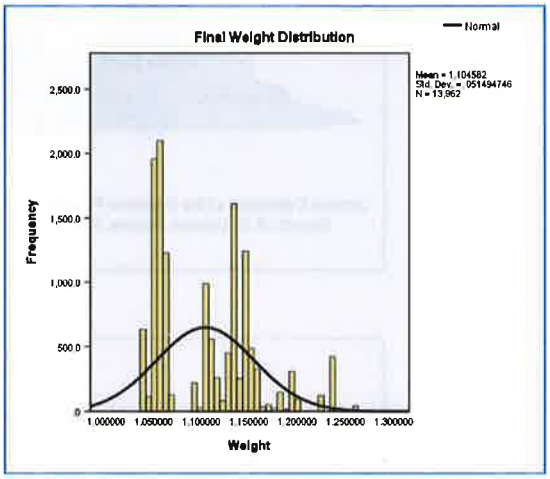
Source: Va. Healthcare Workforce Data Center

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: 0.74362



Source: Va. Healthcare Workforce Data Center

Age	Age Weight			Total Weight	
	#	Rate	Weight	Min	Max
Under 30	1,047	86.25%	1.159468	1.1219	1.2474
30 to 34	2,473	91.75%	1.089907	1.0546	1.1726
35 to 39	2,280	92.15%	1.085198	1.0501	1.1675
40 to 44	1,935	92.30%	1.083427	1.0484	1.1656
45 to 49	1,882	92.08%	1.085978	1.0508	1.1683
50 to 54	1,651	91.34%	1.094828	1.0594	1.1778
55 to 59	1,397	93.34%	1.071319	1.0367	1.1526
60 and Over	2,759	85.47%	1.170059	1.1322	1.2588

Source: Va. Healthcare Workforce Data Center

Attachment 2

DRAFT

Virginia's Pharmacy Technician Workforce: 2018

Healthcare Workforce Data Center

January 2019

Virginia Department of Health Professions
Healthcare Workforce Data Center
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233
804-367-2115, 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: ***https://www.dhp.virginia.gov/hwdc/findings.htm***

More than 11,000 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 your ongoing cooperation.*

Thank You!

Virginia Department of Health Professions

David E. Brown, DC
Director

Barbara Allison-Bryan, MD
Chief Deputy Director

Healthcare Workforce Data Center Staff:

Elizabeth Carter, PhD	Yetty Shobo, PhD	Laura Jackson, MSHSA	Christopher Coyle
Executive Director	*Deputy Director*	*Operations Manager*	*Research Assistant*

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Executive Director

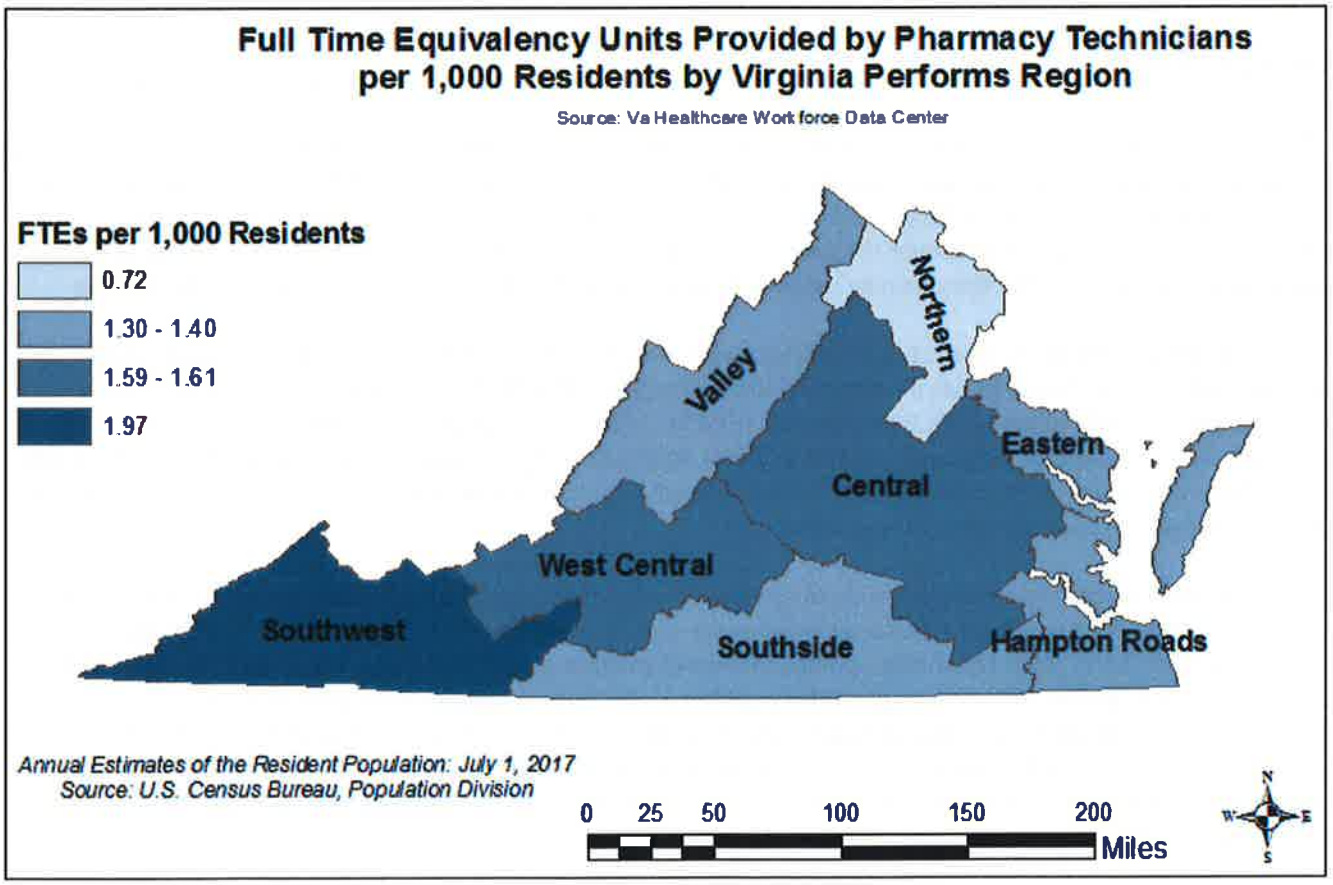
Caroline D. Juran
Richmond

Contents

The Pharmacy Technician Workforce: At a Glance:

The Workforce		Background		Current Employment	
Licensees:	14,623	Rural Childhood:	41%	Employed in Prof.:	80%
Virginia's Workforce:	13,678	HS Degree in VA:	75%	Hold 1 Full-time Job:	65%
FTEs:	10,441	% Work Non-Metro:	14%	Satisfied?:	90%
Survey Response Rate		**Education**		**Job Turnover**	
All Licensees:	76%	High School/GED:	58%	Switched Jobs in 2018:	4%
Renewing Practitioners:	98%	Associate Degree:	21%	Employed over 2 yrs:	53%
Demographics		**Finances**		**Primary Roles**	
Female:	84%	Median Inc.:	$25k-$30k	Medication Disp.:	60%
Diversity Index:	59%	Health Benefits:	62%	Administration:	5%
Median Age:	34	Under 40 w/ Ed debt:	50%	Supervision:	2%

Source: Va. Healthcare Workforce Data Center



Results in Brief

More than 11,000 pharmacy technicians voluntarily took part in the 2018 Pharmacy Technician 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 pharmacy technicians. These survey respondents represent 76% of the 14,623 pharmacy technicians who are licensed in the state and 98% of renewing practitioners.

The HWDC estimates that 13,678 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 10,441 "full-time equivalency units" during the survey time period, which the HWDC defines simply as working 2,000 hours a year.

More than four out of every five pharmacy technicians are female, and nearly two-thirds are under the age of 40. In a random encounter between two pharmacy technicians, there is a 59% chance that they would be of different races or ethnicities, a measure known as the diversity index. This makes the pharmacy technician workforce slightly less diverse than the state's overall population, which has a diversity index of 56%. More than 40% of all pharmacy technicians grew up in a rural area, and 27% of these professionals currently work in non-metro areas of Virginia. In total, 14% of Virginia's pharmacy technician workforce work in non-metro areas of the state.

Four-fifths of all pharmacy technicians are currently employed in the profession, and nearly two-thirds have one full-time job. Nearly three-fourths of all pharmacy technicians work in the for-profit sector. In addition, more than one out of every three professionals work in large chain community pharmacies, the most of any establishment type in the state. Only 1% of pharmacy technicians have been involuntarily unemployed over the past year and another 4% have been underemployed. The median annual income for Virginia's pharmacy technician workforce is between $25,000 and $30,000. In addition, 79% receive at least one employer-sponsored benefit, including 62% who receive health insurance from their employer.

Summary of Trends

Since 2013, the total number of pharmacy technicians licensed in the state has increased by 3% (14,623 vs. 14,262). The response rate among these professionals has also increased (76% vs. 70%). Meanwhile, the size of the pharmacy technician workforce has grown by 2% (13,678 vs. 13,404). However, the number of FTEs provided by these professionals has actually decreased over the past six years (10,441 vs 10,703). With respect to the demographics of Virginia's pharmacy technicians, the diversity index of these professionals has increased since 2013 (59% vs 57%).

Although the percentage of pharmacy technicians who carry education debt has increased only slightly (39% vs 38%), the median size of this debt has increased considerably ($16,000-$18,000 vs. $10,000-$12,000). Pharmacy technicians are less likely to hold a PTCB certification (64% vs. 72%), but employers are more likely to require a certification as a condition for employment (49% vs. 39%). At the same time, employers are more likely to offer a pay raise for those who have a certification (43% vs. 30%). Regardless, pharmacy technicians are less likely to plan to pursue additional educational opportunities (21% vs. 26%).

Pharmacy technicians are more likely to hold one full-time job (65% vs 61%) and work between 40 and 49 hours per week (44% vs. 39%). Meanwhile, pharmacy technicians are slightly less likely to be involuntarily unemployed (1% vs. 2%) or underemployed (4% vs. 5%). The median annual income of pharmacy technicians has increased ($25,000-$30,000 vs. $20,000-$22,500) as well as the percentage of this workforce who receive additional benefits (79% vs. 74%). Although there was no change in the typical time allocation of a pharmacy technician, they were less likely to fulfill a medication dispensation role (60% vs. 64%) and more likely to serve an administrative role (5% vs. 3%). In addition, pharmacy technicians were less likely to work at a for-profit institution (74% vs. 76%) and more likely to work in the non-profit sector (16% vs. 13%).

A Closer Look:

Licensee Counts		
License Status	**#**	**%**
Renewing Practitioners	10,849	74%
New Licensees	1,405	10%
Non-Renewals	2,369	16%
All Licensees	**14,623**	**100%**

Source: Va. Healthcare Workforce Data Center

HWDC surveys tend to achieve very high response rates. Nearly all renewing pharmacy technicians submitted a survey. These represent 76% of all pharmacy technicians who held a license at some point in 2018.

Response Rates			
Statistic	**Non Respondents**	**Respondent**	**Response Rate**
By Age			
Under 30	1,666	3,353	67%
30 to 34	524	1,798	77%
35 to 39	364	1,433	80%
40 to 44	234	1,064	82%
45 to 49	185	1,053	85%
50 to 54	154	852	85%
55 to 59	141	725	84%
60 and Over	226	851	79%
Total	**3,494**	**11,129**	**76%**
New Licenses			
Issued in 2018	967	438	31%
Metro Status			
Non-Metro	419	1,663	80%
Metro	2,688	8,879	77%
Not in Virginia	387	587	60%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Licensed Pharmacy Tech.

Number:	14,623
New:	10%
Not Renewed:	16%

Survey Response Rates

All Licensees:	76%
Renewing Practitioners:	98%

Source: Va. Healthcare Workforce Data Center

Response Rates	
Completed Surveys	11,129
Response Rate, All Licensees	76%
Response Rate, Renewals	98%

Source: Va. Healthcare Workforce Data Center

Definitions

1. **The Survey Period:** The survey was conducted in December 2018.
2. **Target Population:** All professionals who held a Virginia license at some point in 2018.
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 professionals newly licensed in 2018.

At a Glance:

Workforce

2018 Pharm. Tech. Workforce: 13,678
FTEs: 10,441

Utilization Ratios

Licensees in VA Workforce: 94%
Licensees per FTE: 1.40
Workers per FTE: 1.31

Source: Va. Healthcare Workforce Data Center

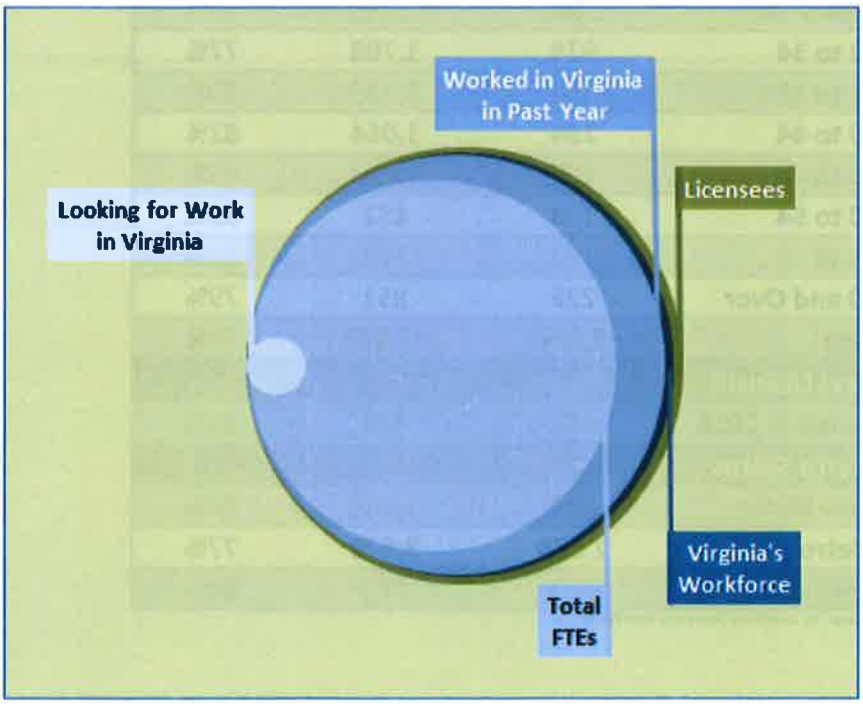
Definitions

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 (40 hours for 50 weeks) 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.

Virginia's Pharm. Tech. Workforce		
Status	**#**	**%**
Worked in Virginia in Past Year	13,429	98%
Looking for Work in Virginia	249	2%
Virginia's Workforce	**13,678**	**100%**
Total FTEs	**10,441**	
Licensees	**14,623**	

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



Source: Va. Healthcare Workforce Data Center

A Closer Look:

Age & Gender						
Age	Male		Female		Total	
	#	% Male	#	% Female	#	% in Age Group
Under 30	809	19%	3,421	81%	4,231	36%
30 to 34	270	15%	1,593	86%	1,863	16%
35 to 39	188	14%	1,196	86%	1,384	12%
40 to 44	164	16%	851	84%	1,015	9%
45 to 49	107	11%	840	89%	946	8%
50 to 54	104	13%	691	87%	795	7%
55 to 59	83	12%	594	88%	677	6%
60 +	108	13%	707	87%	815	7%
Total	**1,833**	**16%**	**9,894**	**84%**	**11,727**	**100%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Gender

% Female:	84%
% Under 40 Female:	83%

Age

Median Age:	34
% Under 40:	64%
% 55+:	13%

Diversity

Diversity Index:	59%
Under 40 Div. Index:	63%

Source: Va. Healthcare Workforce Data Center

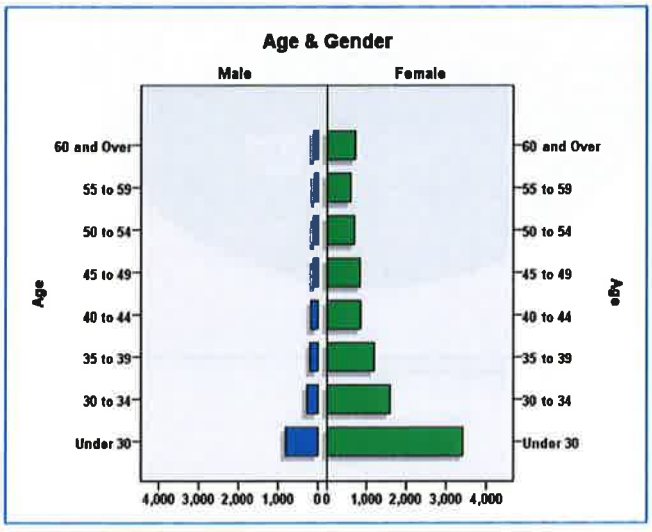
Race & Ethnicity					
Race/ Ethnicity	Virginia*	Pharmacy Tech.		Pharm. Tech. Under 40	
	%	#	%	#	%
White	63%	6,890	59%	4,077	54%
Black	19%	2,643	22%	1,818	24%
Asian	6%	1,038	9%	678	9%
Other Race	0%	149	1%	105	1%
Two or More Races	3%	413	4%	326	4%
Hispanic	9%	635	5%	484	6%
Total	**100%**	**11,768**	**100%**	**7,488**	**100%**

* Population data in this chart is from the US Census, Annual Estimates of the Resident Population by Sex, Race, and Hispanic Origin for the United States, States, and Counties: July 1, 2017.

Source: Va. Healthcare Workforce Data Center

In a chance encounter between two professionals, there is a 59% 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 56%.

Among pharmacy technicians who are under the age of 40, 83% are female. In addition, the diversity index among those professionals who are under the age of 40 is 63%.



Source: Va. Healthcare Workforce Data Center

At a Glance:

Childhood

Urban Childhood:	20%
Rural Childhood:	41%

Virginia Background

HS in Virginia:	75%
HS in Va., Past 5 Years:	74%

Location Choice

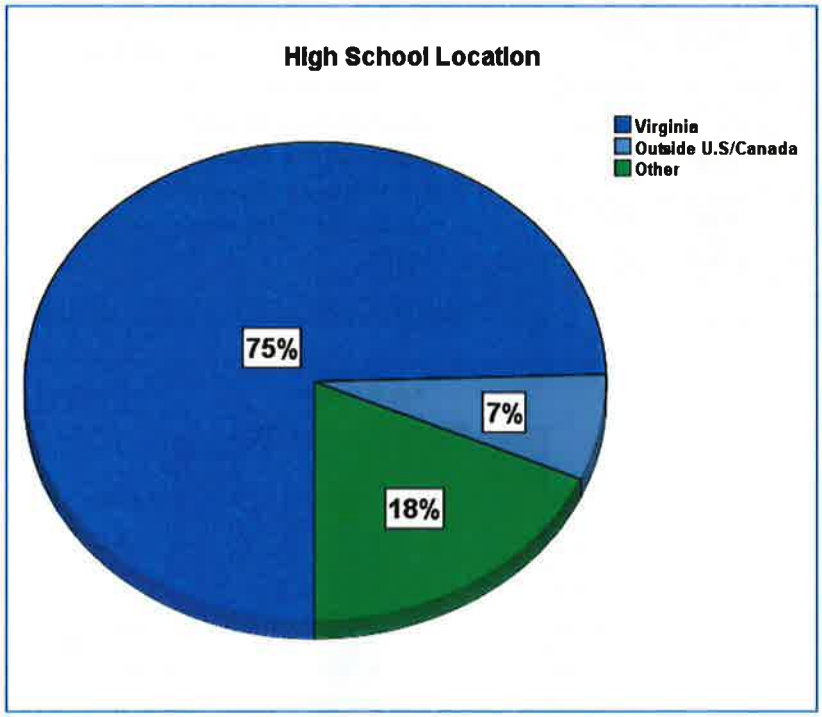
% Work Non-Metro:	14%
% Rural to Non-Metro:	27%
% Urban/Suburban to Non-Metro:	5%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Primary Location: USDA Rural Urban Continuum		Rural Status of Childhood Location		
Code	Description	Rural	Suburban	Urban
	Metro Counties			
1	Metro, 1 Million+	25%	49%	26%
2	Metro, 250,000 to 1 Million	59%	31%	10%
3	Metro, 250,000 or Less	62%	29%	9%
	Non-Metro Counties			
4	Urban Pop 20,000+, Metro Adjacent	64%	21%	15%
6	Urban pop, 2,500-19,999, Metro Adjacent	80%	13%	7%
7	Urban pop, 2,500-19,999, Non-Adjacent	90%	6%	4%
8	Rural, Metro Adjacent	77%	16%	8%
9	Rural, Non-Adjacent	73%	22%	5%
	Overall	**41%**	**40%**	**20%**

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

More than two out of every five pharmacy technicians grew up in self-described rural areas, and 27% of these professionals currently work in non-metro counties. Overall, 14% of Virginia's pharmacy technician workforce is employed in non-metro areas of the state.

Top Ten States for Pharmacy Technician Recruitment

Rank	High School Location: All Pharmacy Technicians		High School Location: Licensed in Past 5 Years	
	State	#	State	#
1	Virginia	8,651	Virginia	3,641
2	Outside U.S./Canada	833	Outside U.S./Canada	318
3	New York	202	North Carolina	89
4	North Carolina	185	Maryland	86
5	Maryland	161	New York	82
6	West Virginia	146	Pennsylvania	64
7	Florida	142	Florida	62
8	Pennsylvania	141	West Virginia	59
9	New Jersey	121	New Jersey	52
10	California	109	California	47

Source: Va. Healthcare Workforce Data Center

Three-fourths of Virginia's pharmacy technician workforce received their high school diploma in Virginia. Among those pharmacy technicians who received their initial license in the past five years, 74% also received their high school degree in the state.

Among all Virginia's licensed pharmacy technicians, only 6% did not participate in the state's workforce in 2018. However, 82% of these professionals worked at some point in the past year, including 61% who currently work as pharmacy technicians.

At a Glance:

Not in VA Workforce

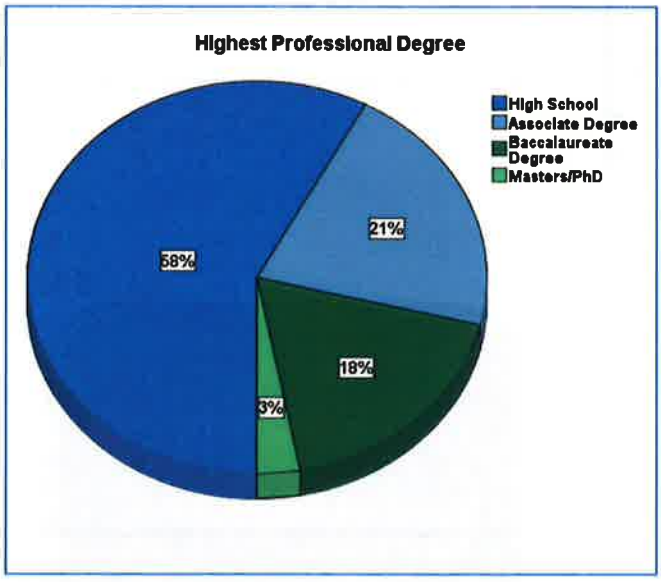
Total:	942
% of Licensees:	6%
Federal/Military:	4%
VA Border State/DC:	38%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Highest Professional Degree		
Degree	**#**	**%**
High School/GED	6,650	58%
Associate	2,422	21%
Baccalaureate	2,079	18%
Masters	320	3%
PhD	31	0%
Total	**11,503**	**100%**

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

Nearly 40% of all pharmacy technicians currently carry education debt, including one-half of those under the age of 40. For those with education debt, the median amount is between $16,000 and $18,000.

At a Glance:

Education

High School/GED: 58%
Associate Degree: 21%

Educational Debt

Carry Debt: 39%
Under Age 40 w/ Debt: 50%
Median Debt: $16k-$18k

Source: Va. Healthcare Workforce Data Center

Nearly three out of every five pharmacy technicians hold either a high school degree or a GED as their highest professional degree.

Educational Debt				
Amount Carried	**All Pharm. Tech.**		**Pharm. Tech. Under 40**	
	#	**%**	**#**	**%**
None	5,669	61%	2,946	50%
Less Than $10,000	1,205	13%	986	17%
$10,000-$19,999	797	9%	674	11%
$20,000-$29,999	611	7%	501	8%
$30,000 or More	1,046	11%	836	14%
Total	**9,328**	**100%**	**5,943**	**100%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Top Certifications

PTCB:	64%
ExCPT:	9%
Total w/ Cert.:	73%

Nat'l Certifications

Required:	49%
Pay Raise w/ Cert.:	43%

Source: Va. Healthcare Workforce Data Center

Professional Certifications		
Certification	**#**	**% of Workforce**
Pharmacy Technician Certification (PTCB)	8,799	64%
Exam for Certification of Pharmacy Technicians (ExCPT)	1,200	9%
Total	**9,999**	**73%**

Source: Va. Healthcare Workforce Data Center

Nearly three-quarters of Virginia's pharmacy technician workforce hold a professional certification, including 64% who have a Pharmacy Technician Certification (PTCB).

Nearly half of all pharmacy technicians work for an employer that requires a national certification as a condition of employment. In addition, 43% of employers offer a pay raise for those pharmacy technicians that have earned a national certification.

National Certifications		
Required for Employment?	**#**	**%**
Yes	5,578	49%
No	5,719	51%
Pay Raise with Certification?	**#**	**%**
Yes	4,198	43%
No	4,536	47%
No Certification Held	1,010	10%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Employment

Employed in Profession: 80%
Involuntarily Unemployed: 1%

Positions Held

1 Full-time: 65%
2 or More Positions: 9%

Weekly Hours:

40 to 49: 44%
60 or more: 3%
Less than 30: 17%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Current Work Status		
Status	**#**	**%**
Employed, Capacity Unknown	16	< 1%
Employed in a Pharmacy Technician-Related Capacity	9,206	80%
Employed, NOT in a Pharmacy Technician-Related Capacity	1,785	16%
Not Working, Reason Unknown	0	0%
Involuntarily Unemployed	107	1%
Voluntarily Unemployed	302	3%
Retired	63	1%
Total	**11,479**	**100%**

Source: Va. Healthcare Workforce Data Center

Four-fifths of Virginia's pharmacy technicians are currently employed in the profession, while only 1% are involuntarily unemployed at the moment. In addition, 65% of all pharmacy technicians currently hold one full-time job, and 44% work between 40 and 49 hours per week.

Current Positions		
Positions	**#**	**%**
No Positions	472	4%
One Part-Time Position	2,368	21%
Two Part-Time Positions	209	2%
One Full-Time Position	7,383	65%
One Full-Time Position & One Part-Time Position	789	7%
Two Full-Time Positions	30	0%
More than Two Positions	39	0%
Total	**11,290**	**100%**

Source: Va. Healthcare Workforce Data Center

Current Weekly Hours		
Hours	**#**	**%**
0 hours	472	4%
1 to 9 Hours	362	3%
10 to 19 Hours	582	5%
20 to 29 Hours	936	9%
30 to 39 Hours	3,012	27%
40 to 49 Hours	4,878	44%
50 to 59 Hours	396	4%
60 to 69 Hours	159	1%
70 to 79 Hours	82	1%
80 or More Hours	127	1%
Total	**11,006**	**100%**

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Income		
Annual Income	#	%
Volunteer Work Only	127	2%
Less than $10,000	580	11%
$10,000-$14,999	386	7%
$15,000-$19,999	396	8%
$20,000-$24,999	731	14%
$25,000-$29,999	704	14%
$30,000-$34,999	837	16%
$35,000-$39,999	539	10%
$40,000-$44,999	390	8%
$45,000-$49,999	251	5%
$50,000 or more	288	6%
Total	**5,227**	**100%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Annual Income
Median Income: $25k-30k

Benefits
Employer Health Ins.: 62%
Employer Retirement: 55%

Satisfaction
Satisfied: 90%
Very Satisfied: 49%

Source: Va. Healthcare Workforce Data Center

Job Satisfaction		
Level	#	%
Very Satisfied	5,483	49%
Somewhat Satisfied	4,657	41%
Somewhat Dissatisfied	786	7%
Very Dissatisfied	328	3%
Total	**11,254**	**100%**

Source: Va. Healthcare Workforce Data Center

The typical pharmacy technician earns between $25,000 and $30,000 per year. Among pharmacy technicians who receive either an hourly wage or a salary as compensation at their primary work location, 56% receive health insurance and 50% have access to a retirement plan.

Employer-Sponsored Benefits			
Benefit	#	%	% of Wage/Salary Employees
Paid Leave	5,794	63%	56%
Health Insurance	5,704	62%	56%
Dental Insurance	5,461	59%	53%
Retirement	5,106	55%	50%
Group Life Insurance	3,216	35%	32%
Signing/Retention Bonus	329	4%	3%
Received At Least One Benefit	**7,284**	**79%**	**71%**

*From any employer at time of survey.

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Underemployment in Past Year		
In The Past Year Did You . . .?	#	%
Experience Involuntary Unemployment?	168	1%
Experience Voluntary Unemployment?	401	3%
Work Part-time or Temporary Positions, but Would Have Preferred a Full-Time/Permanent Position?	544	4%
Work Two or More Positions at the Same Time?	1,466	11%
Switch Employers or Practices?	602	4%
Experienced At Least One	2,626	19%

Source: Va. Healthcare Workforce Data Center

Only 1% of pharmacy technicians were involuntarily unemployed at some point in the past year. For comparison, Virginia's average monthly unemployment rate was 3.0%.[1]

Location Tenure				
Tenure	Primary		Secondary	
	#	%	#	%
Not Currently Working at this Location	300	3%	241	11%
Less than 6 Months	975	9%	295	14%
6 Months to 1 Year	1,085	10%	263	13%
1 to 2 Years	2,628	25%	408	19%
3 to 5 Years	2,508	24%	404	19%
6 to 10 Years	1,269	12%	231	11%
More than 10 Years	1,829	17%	254	12%
Subtotal	10,593	100%	2,096	100%
Did Not Have Location	657		11,298	
Item Missing	2,428		285	
Total	13,678		13,678	

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 2018

Involuntarily Unemployed: 1%
Underemployed: 4%

Turnover & Tenure

Switched: 4%
New Location: 25%
Over 2 years: 53%
Over 2 yrs, 2nd location: 42%

Employment Type

Hourly Wage: 91%

Source: Va. Healthcare Workforce Data Center

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

Employment Type		
Primary Work Site	#	%
Hourly Wage	9,177	91%
Salary/ Commission	730	7%
By Contract/Per Diem	59	1%
Unpaid	55	1%
Business/ Practice Income	19	0%
Subtotal	10,041	100%

Source: Va. Healthcare Workforce Data Center

[1] As reported by the US Bureau of Labor Statistics. The non-seasonally adjusted monthly unemployment rate fell from 3.7% in January 2018 to 2.6% in December 2018. The unemployment rate from December 2018 was still preliminary at the time of publication.

At a Glance:

Concentration

Top Region:	25%
Top 3 Regions:	67%
Lowest Region:	2%

Locations

2 or more (Past Year):	22%
2 or more (Now*):	18%

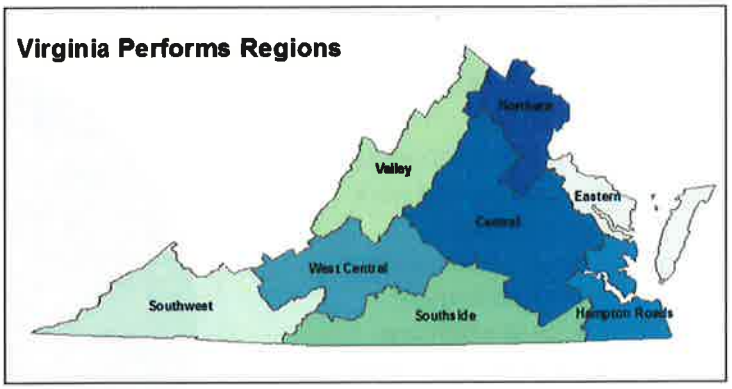
Source: Va. Healthcare Workforce Data Center

Two-thirds of all pharmacy technicians work in either Central Virginia, Hampton Roads, or Northern Virginia.

A Closer Look:

Regional Distribution of Work Locations				
Virginia Performs Region	Primary Location		Secondary Location	
	#	%	#	%
Central	2,618	25%	540	24%
Eastern	223	2%	44	2%
Hampton Roads	2,259	22%	536	24%
Northern	2,155	21%	474	21%
Southside	457	4%	91	4%
Southwest	764	7%	121	5%
Valley	705	7%	131	6%
West Central	1,248	12%	226	10%
Virginia Border State/DC	34	0%	39	2%
Other US State	26	0%	31	1%
Outside of the US	3	0%	9	0%
Total	10,492	100%	2,242	100%
Item Missing	2,530		139	

Source: Va. Healthcare Workforce Data Center



Number of Work Locations				
Locations	Work Locations in Past Year		Work Locations Now*	
	#	%	#	%
0	246	2%	463	4%
1	8,201	76%	8,439	78%
2	1,432	13%	1,171	11%
3	750	7%	649	6%
4	63	1%	36	0%
5	35	0%	19	0%
6 or More	69	1%	19	0%
Total	10,796	100%	10,796	100%

*At the time of survey completion, December 2018.

Source: Va. Healthcare Workforce Data Center

Nearly one in five pharmacy technicians currently have multiple work locations, while 22% have had multiple work locations at some point over the past year.

A Closer Look:

Location Sector				
Sector	Primary Location		Secondary Location	
	#	%	#	%
For-Profit	7,350	74%	1,404	73%
Non-Profit	1,543	16%	280	15%
State/Local Government	689	7%	172	9%
Veterans Administration	55	1%	5	0%
U.S. Military	182	2%	34	2%
Other Federal Gov't	132	1%	36	2%
Total	9,951	100%	1,931	100%
Did Not Have Location	657		11,298	
Item Missing	3,070		450	

Source: Va. Healthcare Workforce Data Center

At a Glance:
(Primary Locations)

Sector

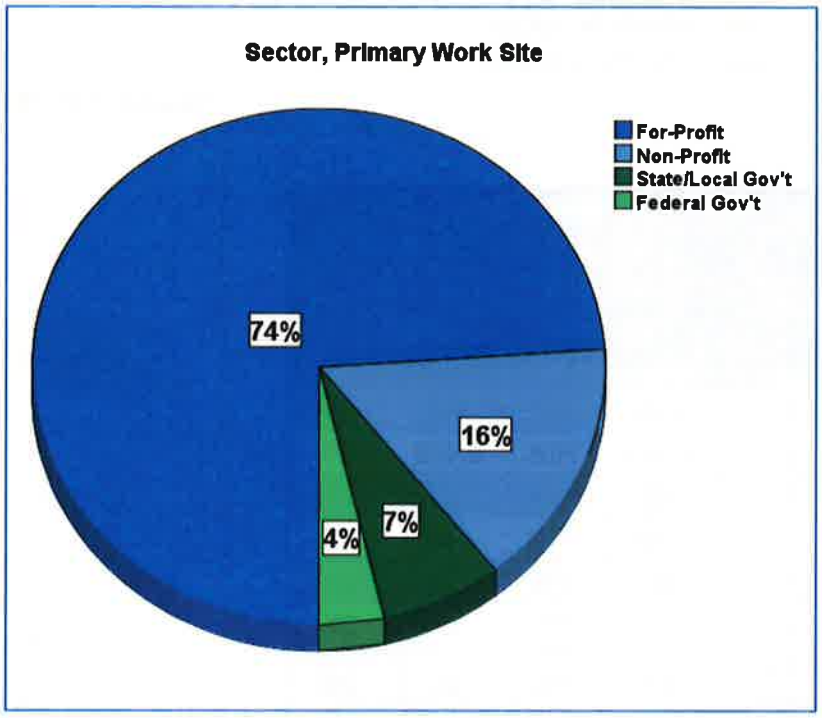
For Profit: 74%
Federal: 4%

Top Establishments

Large Chain Pharmacy (11+ Stores): 34%
Hospital/Health System (Inpatient): 15%
Independent Pharmacy (1-4 Stores): 11%

Source: Va. Healthcare Workforce Data Center

Nearly 90% of Virginia's pharmacy technicians work in the private sector, including 74% who work in a for-profit establishment. Another 7% of pharmacy technicians work for a state or local government.



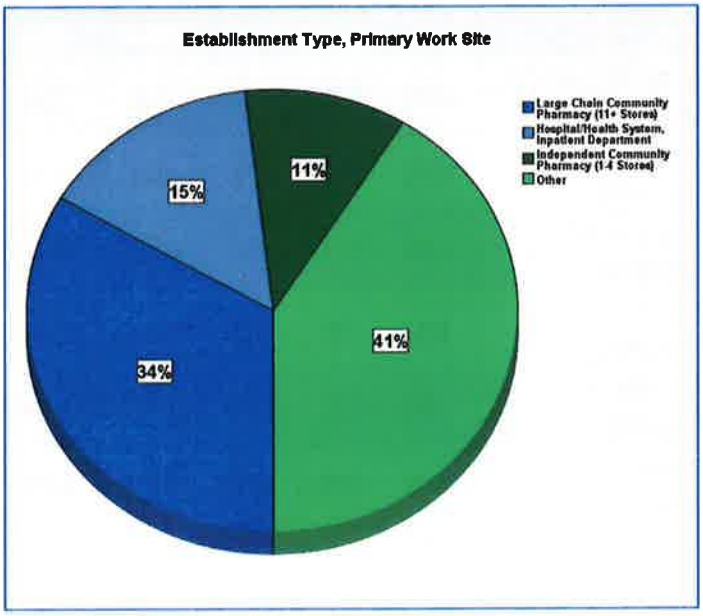
Source: Va. Healthcare Workforce Data Center

Top 10 Location Type				
Establishment Type	Primary Location		Secondary Location	
	#	%	#	%
Large Chain Community Pharmacy (11+ Stores)	3,293	34%	639	34%
Hospital/Health System, Inpatient Department	1,439	15%	223	12%
Independent Community Pharmacy (1-4 Stores)	1,046	11%	166	9%
Supermarket Pharmacy	775	8%	118	6%
Hospital/Health System, Outpatient Department	568	6%	78	4%
Nursing Home/Long-Term Care	458	5%	62	3%
Mass Merchandiser (i.e. Big Box Store)	411	4%	87	5%
Clinic-Based Pharmacy	268	3%	62	3%
Pharmacy Benefit Administration (e.g. PBM, Managed Care)	229	2%	26	1%
Home Health/Infusion	142	1%	30	2%
Mail Service Pharmacy	94	1%	23	1%
Small Chain Community Pharmacy (5-10 Stores)	94	1%	22	1%
Academic Institution	71	1%	49	3%
Wholesale Distributor	37	0%	14	1%
Manufacturer	35	0%	7	0%
Other	860	9%	287	15%
Total	**9,820**	**100%**	**1,893**	**100%**
Did Not Have Location	657		11,298	

Source: Va. Healthcare Workforce Data Center

More than one-third of all pharmacy technicians in Virginia work in a large chain community pharmacy, the most of any establishment type in the state.

For pharmacy technicians who also have a secondary work location, 34% are employed by large chain community pharmacies.



Source: Va. Healthcare Workforce Data Center

At a Glance:
(Primary Locations)

Typical Time Allocation

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

Roles

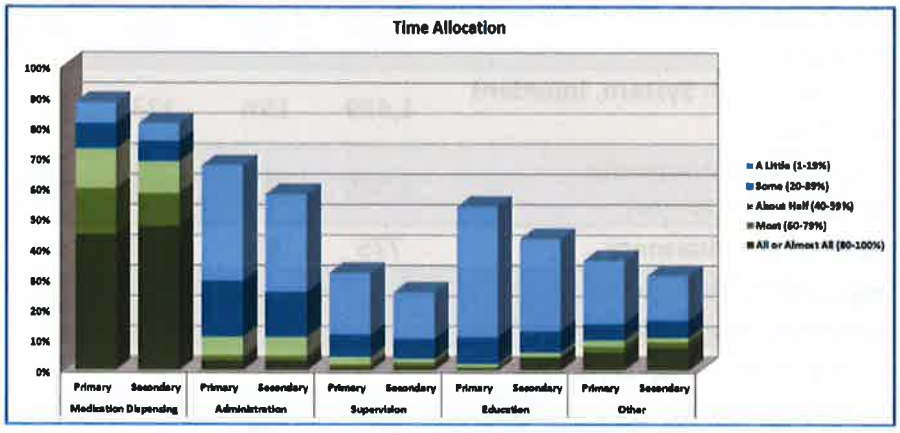
Medication Disp.:	60%
Administration:	5%
Supervision:	2%
Education:	1%

Patient Care Pharm. Techs.

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

Three out of every five pharmacy technicians fill a medication dispensing & customer service role, defined as spending 60% or more of their time in that activity.

Time Allocation										
Time Spent	Medication Disp.		Admin.		Supervision		Education		Other	
	Prim. Site	Sec. Site	Prim. Site	Sec. Site	Prim. Site	Sec. Site	Prim. Site	Sec. Site	Prim. Site	Sec. Site
All or Almost All (80-100%)	45%	47%	3%	3%	1%	1%	1%	4%	6%	7%
Most (60-79%)	15%	11%	2%	2%	1%	1%	0%	0%	2%	2%
About Half (40-59%)	13%	11%	6%	6%	3%	1%	1%	1%	2%	2%
Some (20-39%)	8%	7%	18%	15%	7%	6%	9%	7%	5%	6%
A Little (1-19%)	7%	6%	38%	32%	20%	15%	43%	30%	21%	15%
None (0%)	12%	19%	33%	42%	68%	74%	46%	57%	64%	69%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Retirement Expectations				
Expected Retirement Age	All		Over 50	
	#	%	#	%
Under Age 50	2,187	24%	-	-
50 to 54	408	5%	20	1%
55 to 59	582	7%	107	6%
60 to 64	1,387	16%	413	23%
65 to 69	2,199	25%	761	43%
70 to 74	592	7%	230	13%
75 to 79	164	2%	41	2%
80 or over	120	1%	29	2%
I Do Not Intend to Retire	1,306	15%	188	11%
Total	8,946	100%	1,789	100%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Retirement Expectations

All Pharmacy Technicians

Under 65:	51%
Under 60:	36%

Pharm. Tech. 50 and Over

Under 65:	30%
Under 60:	7%

Time Until Retirement

Within 2 Years:	4%
Within 10 Years:	13%
Half the Workforce:	By 2048

Source: Va. Healthcare Workforce Data Center

More than half of all pharmacy technicians expect to retire by the age of 65. Among pharmacy technicians who are age 50 and over, 30% still expect to retire by the age of 65.

Within the next two years, 21% of all pharmacy technicians expect to pursue additional educational opportunities, and 7% want to increase their patient care hours.

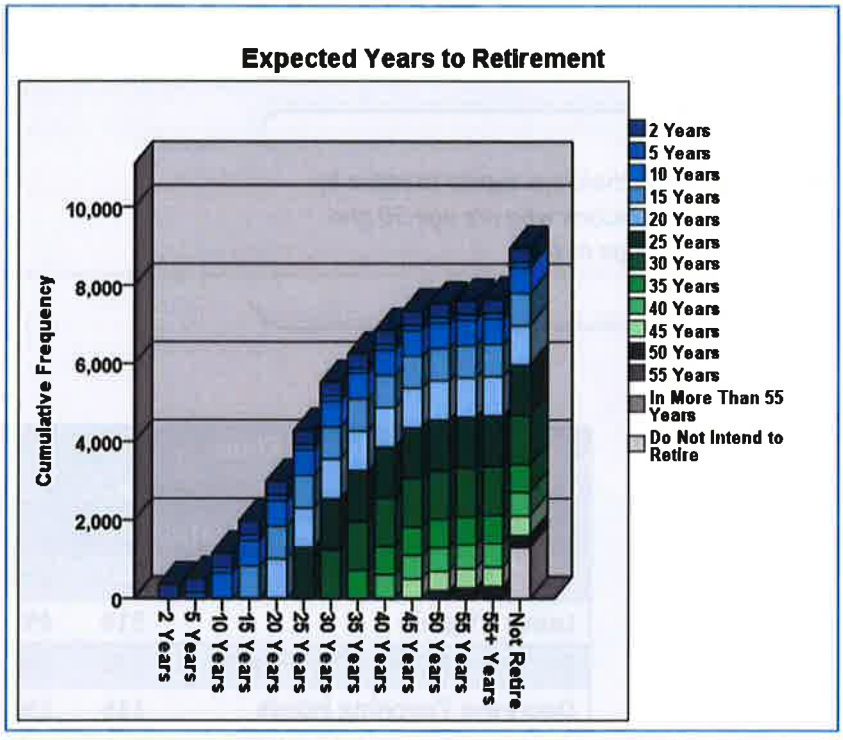
Future Plans		
2 Year Plans:	#	%
Decrease Participation		
Leave Profession	1,114	8%
Leave Virginia	514	4%
Decrease Patient Care Hours	186	1%
Decrease Teaching Hours	116	1%
Increase Participation		
Increase Patient Care Hours	959	7%
Increase Teaching Hours	702	5%
Pursue Additional Education	2,835	21%
Return to Virginia's Workforce	139	1%

Source: Va. Healthcare Workforce Data Center

By comparing retirement expectation to age, we can estimate the maximum years to retirement for pharmacy technicians. Only 4% of pharmacy technicians plan to retire in the next two years, while 13% plan to retire within the next ten years. Half of the current workforce expect to retire by 2048.

Time to Retirement			
Expect to Retire Within. . .	#	%	Cumulative %
2 Years	356	4%	4%
5 Years	148	2%	6%
10 Years	645	7%	13%
15 Years	825	9%	22%
20 Years	1,013	11%	33%
25 Years	1,295	14%	48%
30 Years	1,242	14%	62%
35 Years	715	8%	70%
40 Years	603	7%	76%
45 Years	498	6%	82%
50 Years	191	2%	84%
55 Years	71	1%	85%
In More Than 55 Years	39	0%	85%
Do Not Intend to Retire	1,306	15%	100%
Total	8,946	100%	

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

Using these estimates, retirement will begin to reach 10% of the current workforce starting in 2038. Retirement will peak at 14% of the current workforce between 2043 and 2048 before declining to below 10% of the current workforce again around 2053.

At a Glance:

FTEs

Total:	10,441
FTEs/1,000 Residents[2]:	1.233
Average:	0.80

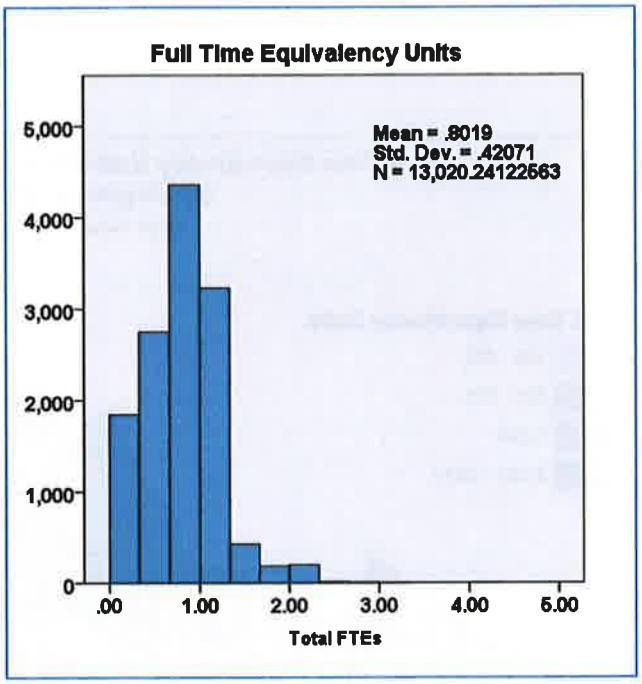
Age & Gender Effect

Age, Partial Eta[3]:	Small
Gender, Partial Eta[3]:	None

Partial Eta[3] Explained:
Partial Eta[3] is a statistical measure of effect size.

Source: Va. Healthcare Workforce Data Center

A Closer Look:

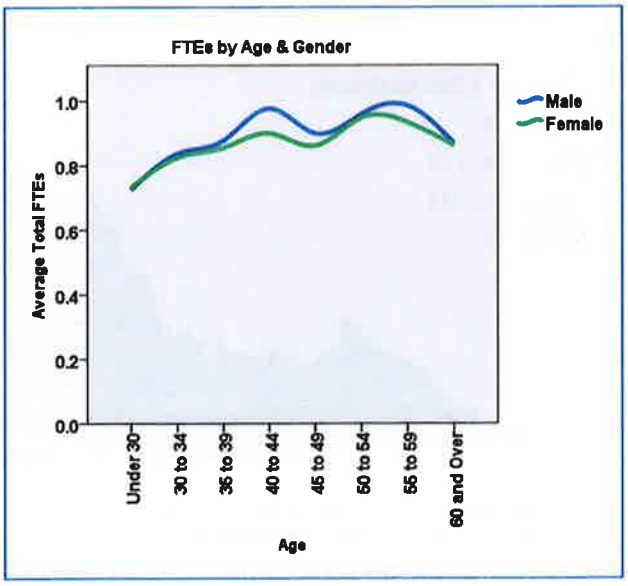


Source: Va. Healthcare Workforce Data Center

The typical pharmacy technician provided 0.83 FTEs in 2018, or approximately 33 hours per week for 50 weeks. Although FTEs appear to vary by age, statistical tests did not verify that a difference exists.[3]

Full-Time Equivalency Units		
	Average	Median
Age		
Under 30	0.72	0.68
30 to 34	0.80	0.81
35 to 39	0.84	0.83
40 to 44	0.88	0.90
45 to 49	0.78	0.83
50 to 54	0.93	0.93
55 to 59	0.91	0.90
60 and Over	0.86	0.85
Gender		
Male	0.82	0.92
Female	0.82	0.89

Source: Va. Healthcare Workforce Data Center

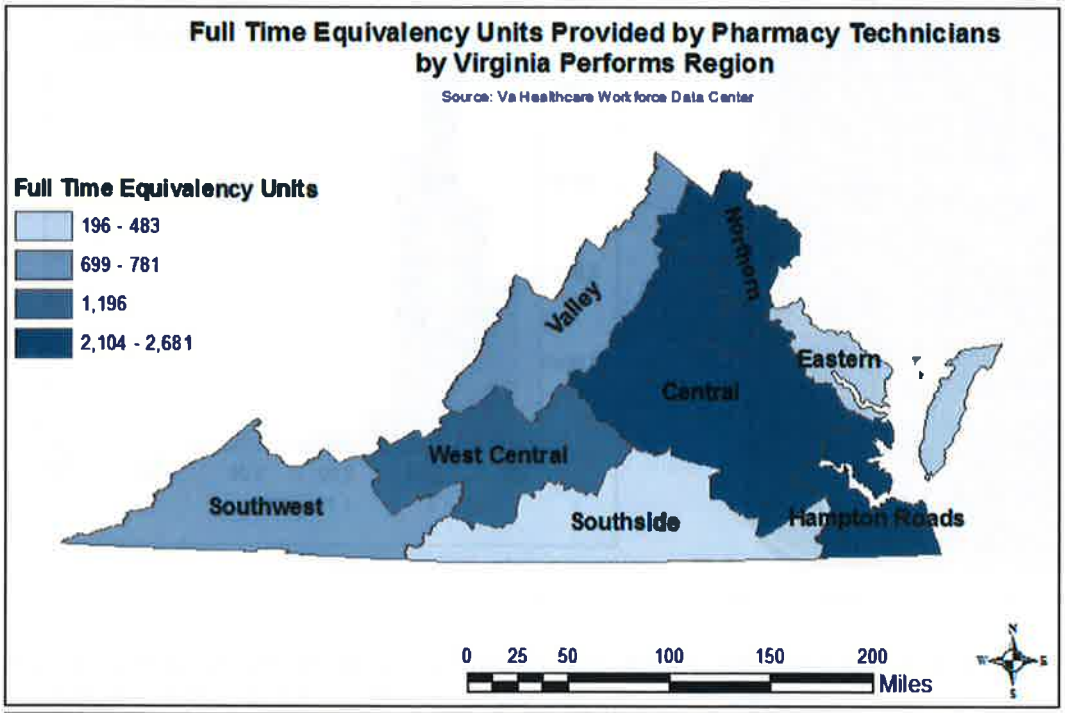


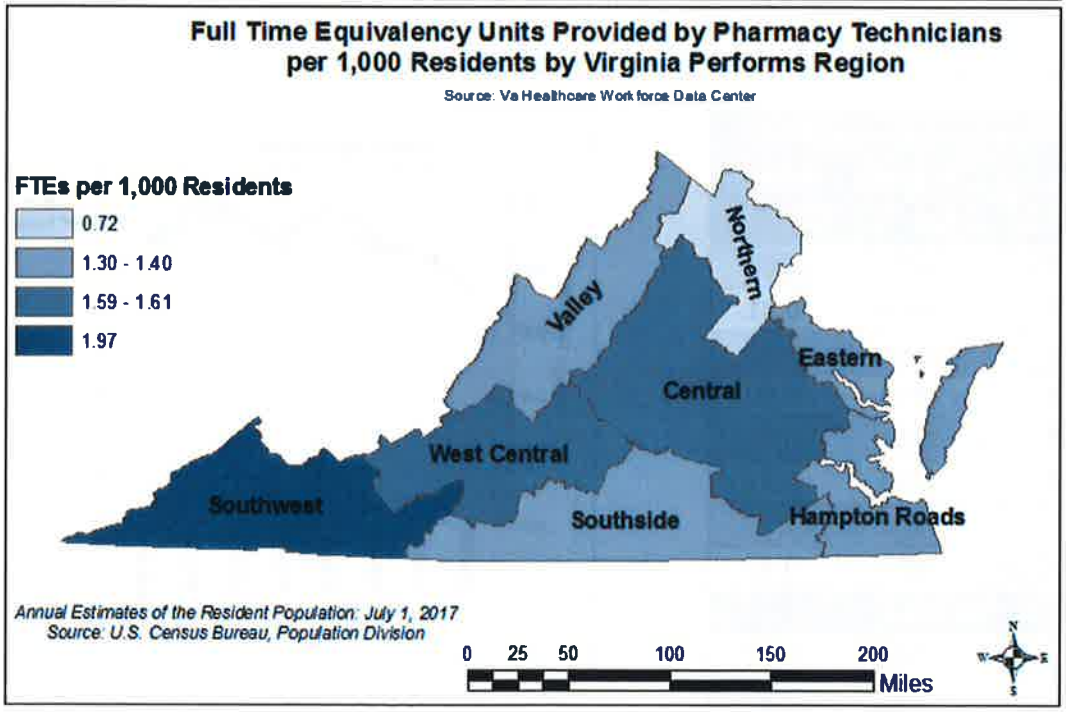
Source: Va. Healthcare Workforce Data Center

[2] Number of residents in 2017 was used as the denominator.
[3] Due to assumption violations in Mixed between-within ANOVA (Levene's Test was significant).

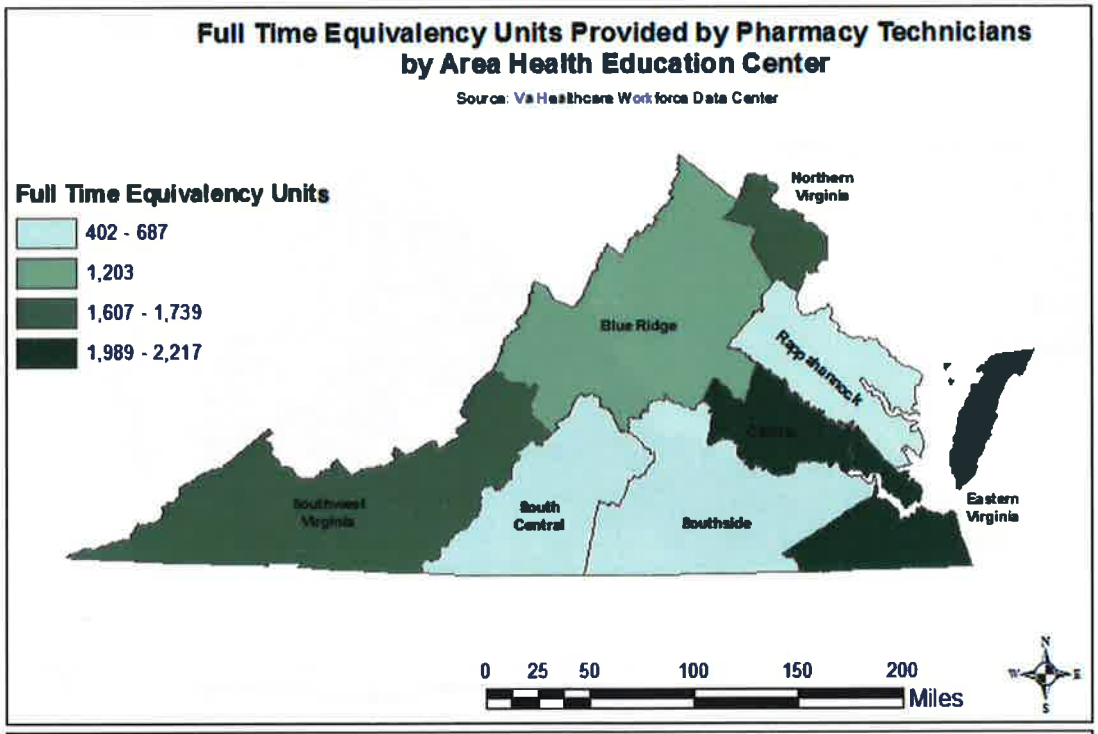
Maps

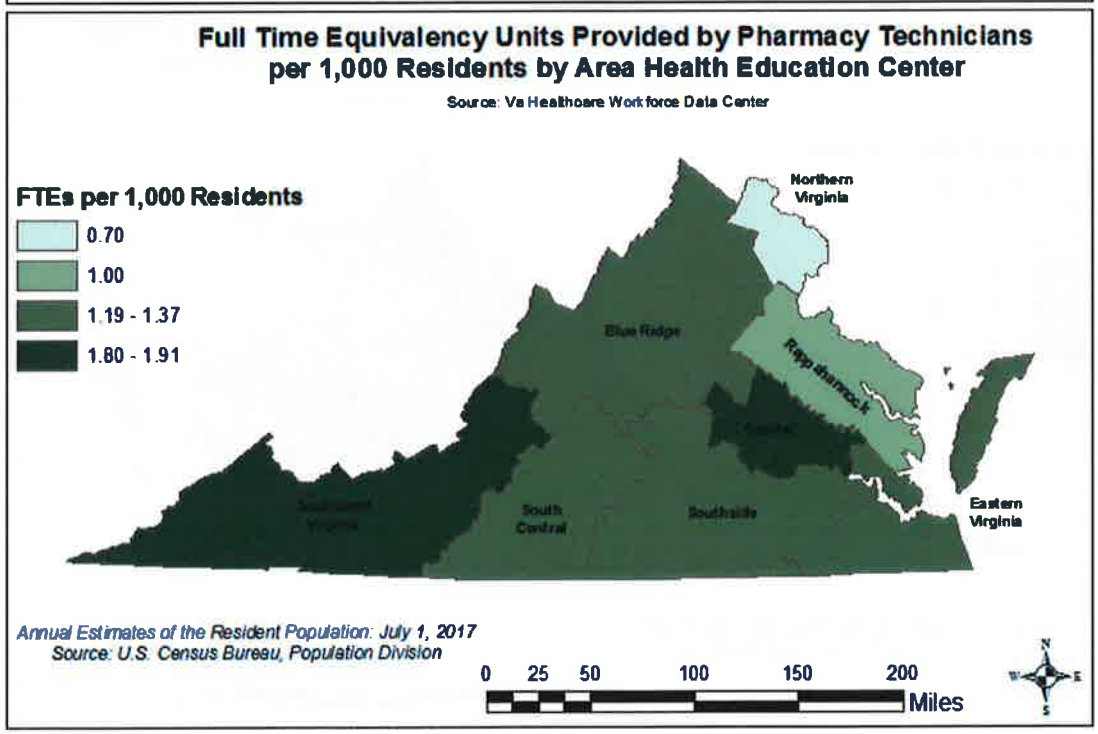
Virginia Performs Regions

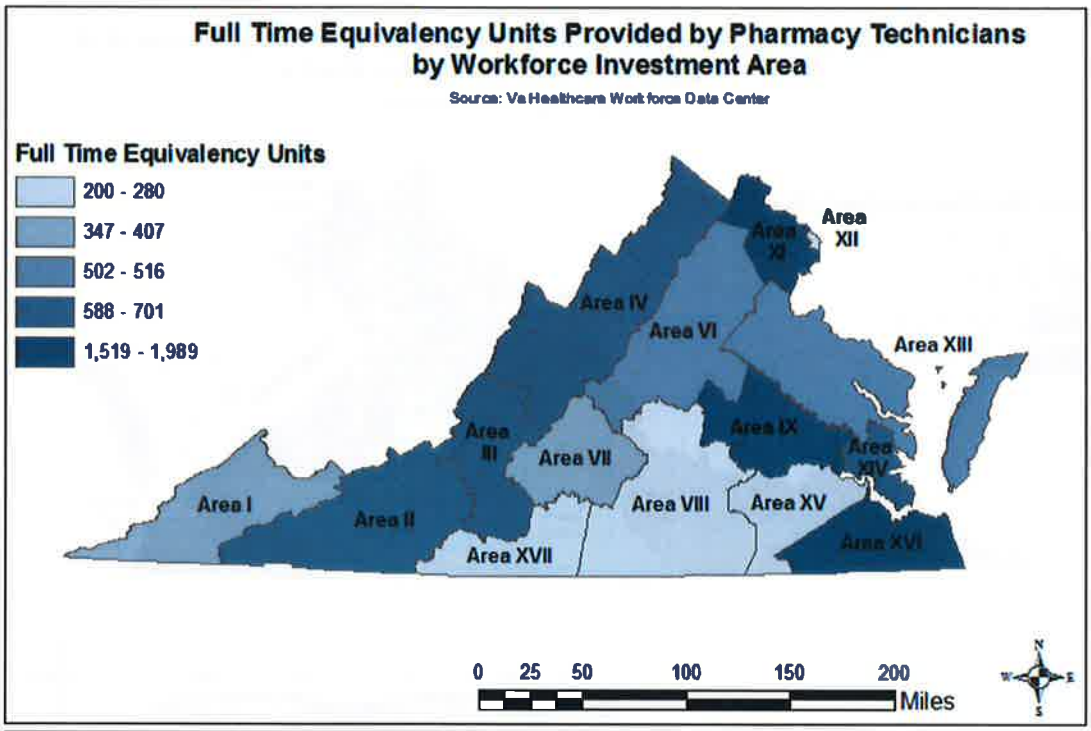


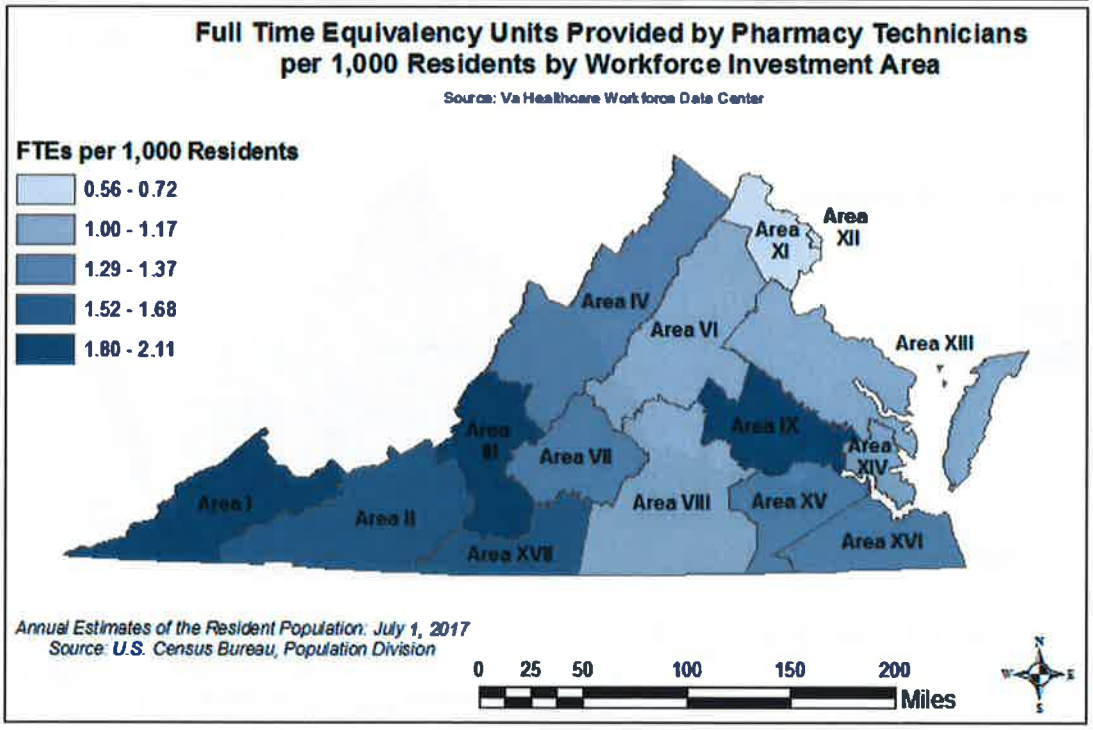


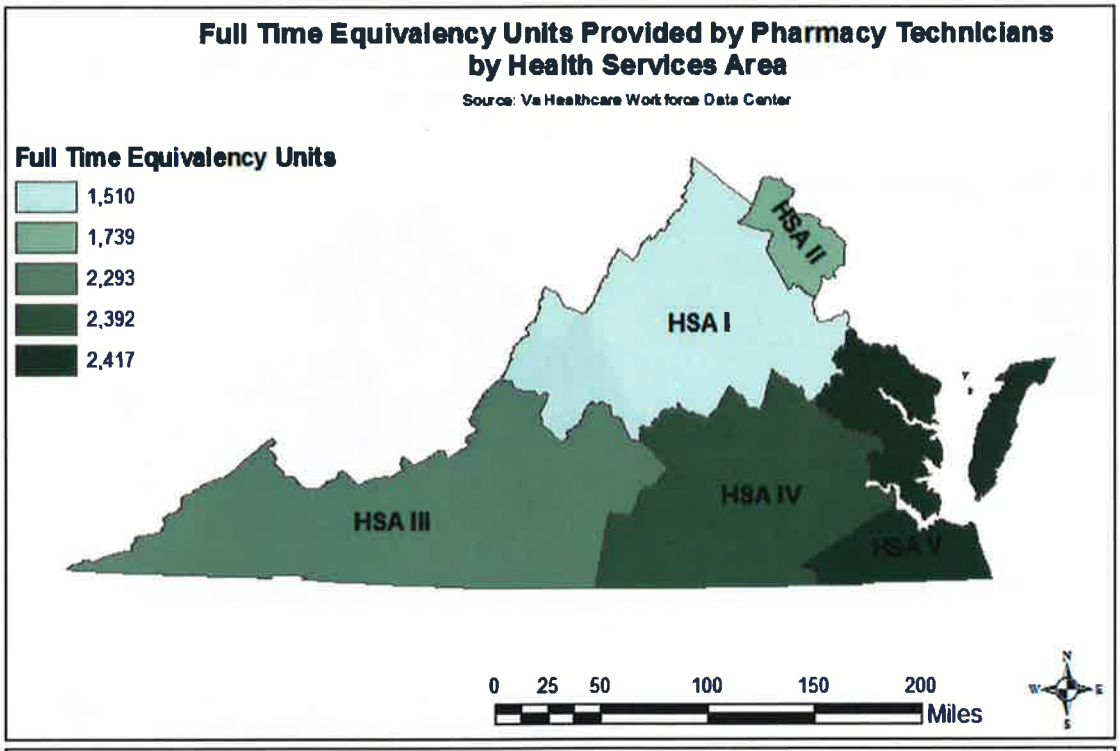
Area Health Education Center Regions

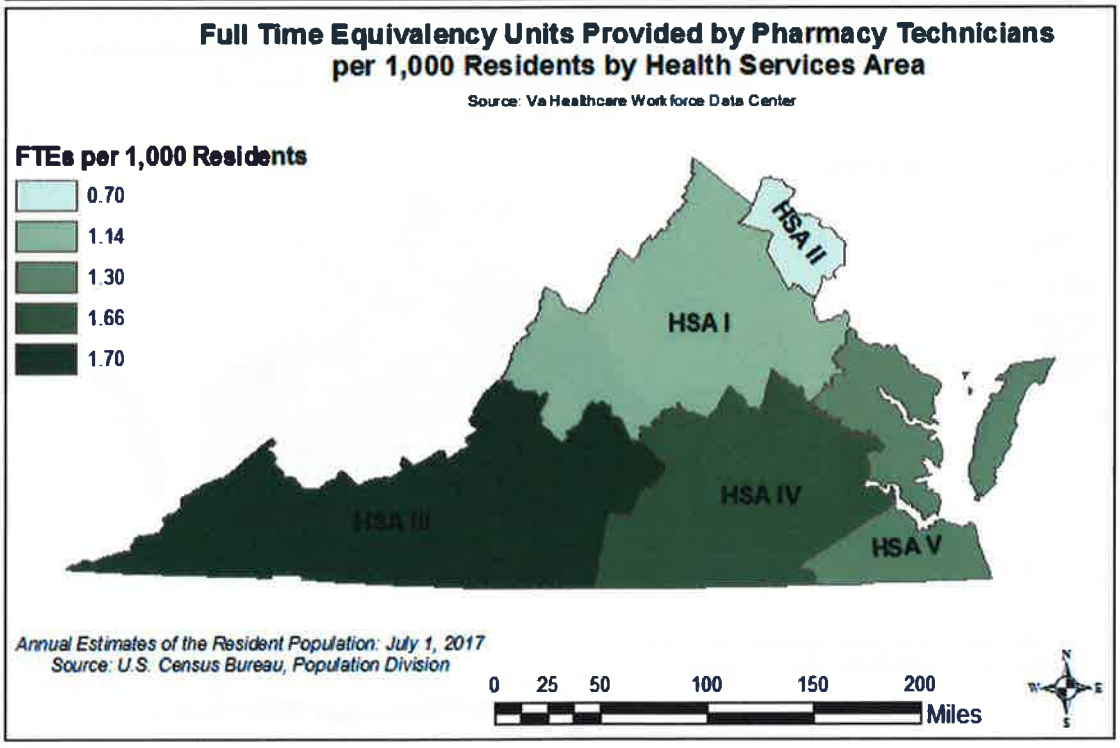


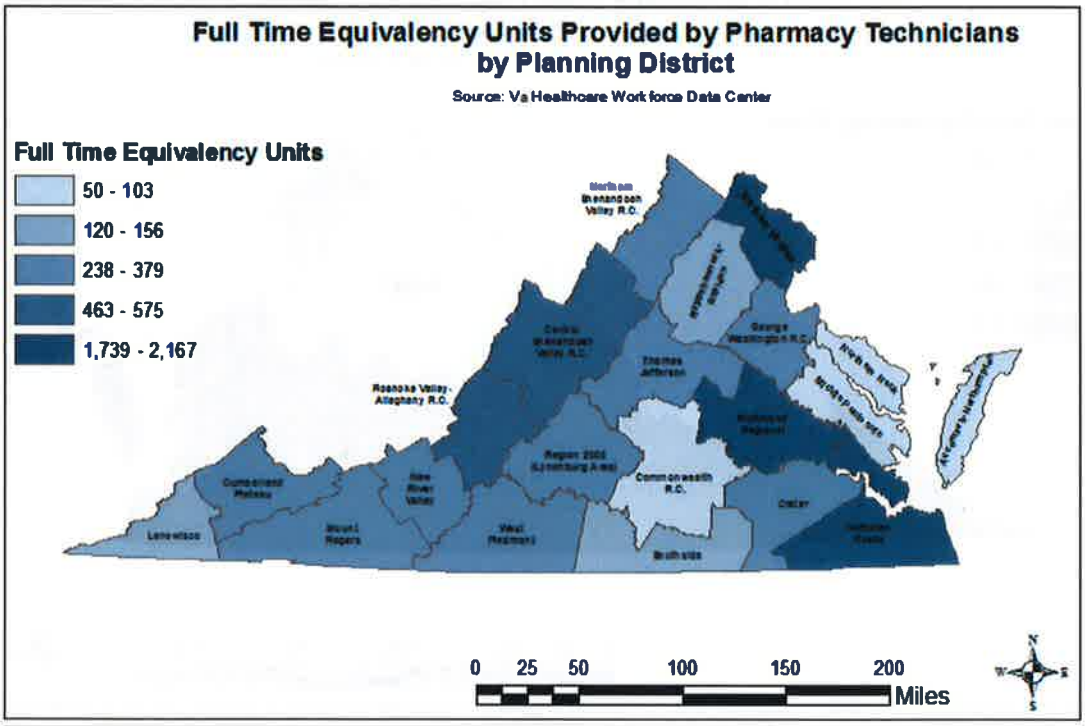


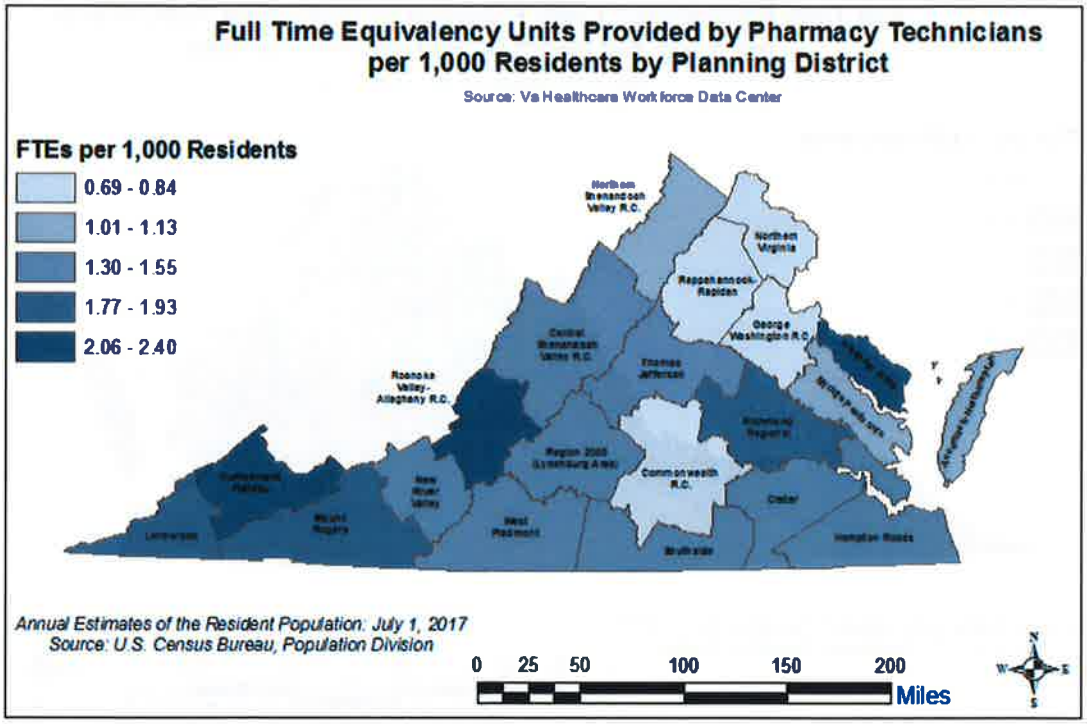

Full Time Equivalency Units Provided by Pharmacy Technicians
by Workforce Investment Area
Source: Va Healthcare Workforce Data Center
Full Time Equivalency Units
200 - 280
347 - 407
502 - 516
588 - 701
1,519 - 1,989
Area XII
Area XI
Area IV
Area VI
Area XIII
Area IX
Area III
Area VII
Area XIV
Area I
Area II
Area VIII
Area XV
Area XVII
Area XVI
0 25 50 100 150 200
Miles


Full Time Equivalency Units Provided by Pharmacy Technicians
per 1,000 Residents by Workforce Investment Area
Source: Va Healthcare Workforce Data Center
FTEs per 1,000 Residents
0.56 - 0.72
1.00 - 1.17
1.29 - 1.37
1.52 - 1.68
1.80 - 2.11
Area XII
Area XI
Area IV
Area VI
Area XIII
Area IX
Area III
Area VII
Area XIV
Area I
Area II
Area VIII
Area XV
Area XVII
Area XVI
Annual Estimates of the Resident Population: July 1, 2017
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles


Full Time Equivalency Units Provided by Pharmacy Technicians by Health Services Area
Source: Va Healthcare Workforce Data Center
Full Time Equivalency Units
1,510
1,739
2,293
2,392
2,417
HSA I
HSA II
HSA III
HSA IV
HSA V
0 25 50 100 150 200
Miles


Full Time Equivalency Units Provided by Pharmacy Technicians per 1,000 Residents by Health Services Area
Source: Va Healthcare Workforce Data Center
FTEs per 1,000 Residents
0.70
1.14
1.30
1.66
1.70
HSA I
HSA II
HSA III
HSA IV
HSA V
Annual Estimates of the Resident Population: July 1, 2017
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles


Full Time Equivalency Units Provided by Pharmacy Technicians by Planning District
Source: Va Healthcare Workforce Data Center
Full Time Equivalency Units
50 - 103
120 - 156
238 - 379
463 - 575
1,739 - 2,167
Northern Shenandoah Valley R.C.
Northern Virginia
Rappahannock-Rapidan
George Washington R.C.
Thomas Jefferson
Roanoke Valley-Alleghany R.C.
Region 2000 (Lynchburg Area)
Commonwealth R.C.
Crater
Cumberland Plateau
New River Valley
Mount Rogers
West Piedmont
Southside
Hampton Roads
0 25 50 100 150 200
Miles
N
W
E
S


Full Time Equivalency Units Provided by Pharmacy Technicians per 1,000 Residents by Planning District
Source: Va Healthcare Workforce Data Center
FTEs per 1,000 Residents
0.69 - 0.84
1.01 - 1.13
1.30 - 1.55
1.77 - 1.93
2.06 - 2.40
Northern Shenandoah Valley R.C.
Northern Virginia
Rappahannock-Rapidan
George Washington R.C.
Thomas Jefferson
Roanoke Valley-Alleghany R.C.
Region 2000 (Lynchburg Area)
Commonwealth R.C.
Crater
New River Valley
West Piedmont
Southside
Hampton Roads
Annual Estimates of the Resident Population: July 1, 2017
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles
N
W
E
S

Appendix

Weights

Rural Status	Location Weight			Total Weight	
	#	Rate	Weight	Min	Max
Metro, 1 Million+	8,872	75.95%	1.316711	1.178155	1.500009
Metro, 250,000 to 1 Million	1,359	79.62%	1.256007	1.123839	1.430855
Metro, 250,000 or Less	1,336	79.27%	1.261568	1.128814	1.437189
Urban Pop 20,000+, Metro Adj	316	80.06%	1.249012	1.11758	1.422885
Urban Pop 20,000+, Non-Adj	0	NA	NA	NA	NA
Urban Pop, 2,500-19,999, Metro Adj	703	82.79%	1.207904	1.080797	1.376055
Urban Pop, 2,500-19,999, Non-Adj	534	75.47%	1.325062	1.185627	1.509522
Rural, Metro Adj	298	80.54%	1.241667	1.111007	1.414518
Rural, Non-Adj	231	80.09%	1.248649	1.117255	1.422471
Virginia Border State/DC	673	63.15%	1.583529	1.416896	1.803971
Other US State	301	53.82%	1.858025	1.662507	2.116678

Source: Va. Healthcare Workforce Data Center

Age	Age Weight			Total Weight	
	#	Rate	Weight	Min	Max
Under 30	5,019	66.81%	1.496868	1.376055	2.116678
30 to 34	2,322	77.43%	1.291435	1.187202	1.82618
35 to 39	1,797	79.74%	1.254013	1.1528	1.773263
40 to 44	1,298	81.97%	1.219925	1.121463	1.72506
45 to 49	1,238	85.06%	1.175689	1.080797	1.662507
50 to 54	1,006	84.69%	1.180751	1.085451	1.669666
55 to 59	866	83.72%	1.194483	1.098075	1.689083
60 and Over	1,077	79.02%	1.26557	1.163424	1.789605

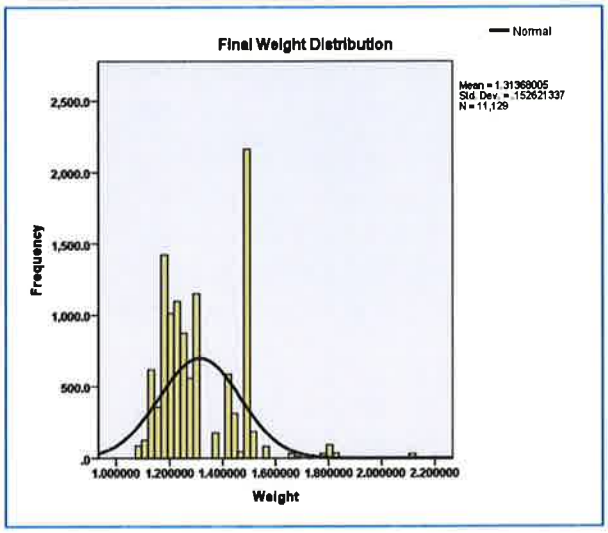
Source: Va. Healthcare Workforce Data Center

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: 0.761061



Source: Va. Healthcare Workforce Data Center