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
June 21, 2018
9:00AM

TOPIC	PAGES

Call to Order of Public Hearing for Scheduling Certain Substances: Ryan Logan, Chairman
- Welcome & Introductions
- Reading of Emergency Evacuation Script

Public Hearing on Scheduling:
- Possible Scheduling of the Certain Chemicals in Schedule I of the Drug Control Act — 1-2
- Scheduling/De-scheduling to Conform to Federal Actions — 3

Adjournment of Public Hearing

Call to Order of Full Board Meeting: Ryan Logan, Chairman
- Approval of Agenda
- Approval of Previous Board Meeting Minutes:
  - March 28, 2018, Inspection Special Conference Committee — 4-7
  - March 29, 2018, Public Hearing for Scheduling Certain Chemicals — 8-9
  - March 29, 2018, Full Board Meeting — 10-17
  - March 29, 2018, Formal Hearings — 17A-B
  - April 18, 2018, Special Conference Committee — 18-23
  - April 24, 2018, Regulation Committee — 24-26
  - April 24, 2018, Formal Hearings — 27-28
  - May 17, 2018, Telephone Conference Call — 29-30
  - May 24, 2018, Special Conference Committee — 31-35
  - June 5, 2018, Special Conference Committee — Handout

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: Caroline D. Juran
- Regulatory Update
- Adoption of exempt regulation to add certain chemicals to Schedule I and scheduling/de-scheduling to conform to federal actions — 36
- Report from Regulation Committee Meeting and possible action: — 37-51
  - Review of Guidance Documents — 52-74
  - Petition for rulemaking from Lavino/CVS Health regarding 18VAC110-20-275 — 75-84
  - Adoption of revised emergency regulations for pharmaceutical processors — 85-144
- Adoption of emergency regulations related to delivery of Schedule VI devices — 145-158

- Adoption of exempt regulations for nonresident warehousers and nonresident third-party logistics providers — 159-180
- Adoption of fast-track regulation to rescind pharmacy permit if not operational
- Report from Ad Hoc Inspection Committee Meeting and possible action — 181-183 Handout

Old Business:

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

New Business:

- Presentation of 2017 Pharmacist and Pharmacy Technician Workforce Reports, Elizabeth A. Carter, PhD, Director, DHP Healthcare Workforce Data Center — Attachments I and II
- Consideration for a board retreat
- Elections for Chairman and Vice-Chairman

Reports:

- Chairman's Report – Ryan Logan
- Report on Board of Health Professions – Ryan Logan
- Report on Licensure Program – J. Samuel Johnson, Jr.
- Report on Disciplinary Program – Ellen B. Shinaberry — 184-196
- Executive Director's Report – Caroline D. Juran — 196-A 197-201

Consideration of consent orders & summary suspension or summary restrictions, if any

Adjourn

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

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 June 21, 2018** at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233. Public comment may also be submitted electronically or in writing prior to June 7, 2018 to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

The Virginia Department of Forensic Science (DFS) has identified eight (8) chemical compounds for recommended inclusion into the Code of Virginia. A brief description and chemical name for each compound is as follows:

The following compound is classified as a research chemical. Compounds of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

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.

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

2. **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.
3. **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.
4. **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.
5. **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.
6. **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.

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

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7. **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.

The following compound is classified as a benzodiazepine, which is a central nervous system depressant. Flualprazolam has no accepted medical use in the United States. Other compounds of this type have been placed in Schedule I (§ 54.1-3446(4)).

8. **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.

Notice of Public Hearing
Scheduling/De-scheduling to Conform to Federal Actions

Pursuant to subsection E of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider scheduling or de-scheduling certain drugs in the Virginia Drug Control Act. The public hearing will be conducted at **9:00 a.m. on June 21, 2018** at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233.

In order to conform the Drug Control Act to recent scheduling changes enacted by the Drug Enforcement Administration, the Board will:

1) Add MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine) to Schedule I;

2) Add Dronabinol [(-)-delta-9-*trans* tetrahydrocannabinol] in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration to Schedule II; and

3) Removes naldemedine from Schedule II.

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(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, March 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 09:30 a.m.
PRESIDING:	Sheila Elliott, Committee Chair
MEMBERS PRESENT:	Jody Allen, Committee Member
STAFF PRESENT:	J. Samuel Johnson , Deputy Executive Director Ellen B. Shinaberry, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
RADIOLOGY SERVICES OF VIRGINIA Permit No. 0201-004055	Sandra M. Geyser, Pharmacist-in-Charge, appeared on behalf of Radiology Services of Virginia to discuss allegations that Radiology Services of Virginia may have violated certain laws and regulations governing the conduct of pharmacy as stated in the February 28, 2018 Notice.
Closed Meeting:	Upon a motion by Ms. Allen, and duly seconded by Ms. Elliott, 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 Radiology Services of Virginia. Additionally, she moved that J. Samuel Johnson and Ellen B. Shinaberry attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:	Upon a motion by Ms. Allen and duly seconded Ms. Elliott, the Committee unanimously voted to enter an Order with terms to include the assessment of a monetary penalty.
WEGMANS FOOD MARKETS Permit No. 0201-004646	TJ Yantsides, Pharmacy Manager; and Mike Scozzaro, Director of Operations, appeared on behalf of Wegmans Food Markets to discuss allegations that Wegmans Food Markets may have violated certain laws and regulations governing the conduct of pharmacy as stated in the February 28, 2018 Notice.
Closed Meeting:	Upon a motion by Ms. Allen, and duly seconded by Ms. Elliott, 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 Wegmans Food Market. Additionally, she moved that J. Samuel Johnson and Ellen B. Shinaberry attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Allen and duly seconded Ms. Elliott, the Committee unanimously voted to enter an Order with terms and conditions.
WEGMANS FOOD MARKETS Permit No. 0201-004223	TJ Yantsides, Pharmacy Manager; and Mike Scozzaro, Director of Operations, appeared on behalf of Wegmans Food Markets to discuss allegations that Wegmans Food Markets may have violated certain laws and regulations governing the conduct of pharmacy as stated in the February 28, 2018 Notice.

Closed Meeting:	Upon a motion by Ms. Allen, and duly seconded by Ms. Elliott, 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 Wegmans Food Market. Additionally, she moved that J. Samuel Johnson and Ellen B. Shinaberry attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Allen and duly seconded Ms. Elliott, the Committee unanimously voted to enter an Order with terms to include the assessment of a monetary penalty.
JANET UNDERHILL License No. 0202-207242	Janet Underhill appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the February 28, 2018 Notice.
Closed Meeting:	Upon a motion by Ms. Allen, and duly seconded by Ms. Elliott, 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 Janet Underhill. Additionally, she moved that J. Samuel Johnson and Ellen B. Shinaberry attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:

Upon a motion by Ms. Allen, and duly seconded by Ms. Elliott, the Committee unanimously voted to issue an Order to reinstate Ms. Underhill's license to practice pharmacy after she obtains 15 additional hours of continuing education in the subject of medication errors and enroll in HPMP within 90 days of reinstatement.

ADJOURNED: 2:49 p.m.

Sheila Elliott, Chair

J. Samuel Johnson
Deputy Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
PUBLIC HEARING FOR SCHEDULING CERTAIN CHEMICALS

March 29, 2018
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The public hearing was called to order at 9:13 a.m.

PRESIDING: Ryan K. Logan, Chairman

MEMBERS PRESENT:
Jody Allen
Melvin L. Boone, Sr.
Freeda Cathcart
Sheila K. W. Elliott
Rafael Saenz
Rebecca Thornbury

MEMBERS ABSENT:
Michael I. Elliott
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
Barbara Allison-Bryan, Chief Deputy Director, DHP
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Sylvia Tamayo-Suijk, Executive Assistant

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

PUBLIC HEARING FOR SCHEDULING CERTAIN CHEMICALS: Pursuant to subsection D of §54.1-3443 of the Code, a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act was held. If approved by the Board of Pharmacy, the placement of these substances in Schedule I in the Virginia Drug Control Act 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.

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

Classified as research chemicals:

- 2-(ethylamino)-2-phenyl-cyclohexanone (other name: deschloro-N-ethyl-ketamine)
- 3,4-methylenedioxy-N-tert-butylcathinone
- 4-fluoro-N-ethylamphetamine
- beta-keto-4-bromo-2,5-dimethoxyphenethylamine (other name: bk-2C-B)

Classified as powerful synthetic opioids:

- N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-butenamide (other name: Crotonyl fentanyl)
- 2-(3,4-dichlorophenyl)-N-[2-(dimethylamino)cyclohexyl]-N-methylacetamide (other name: U-51754)
- N-phenyl-N-[4-phenyl-1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: 4-phenylfentanyl)

PUBLIC COMMENT: Public comment was provided by Scott Maye, Director of Chemistry Department, Virginia Department of Forensic Science. Mr. May requested that the Board schedule the four chemicals classified as research chemicals and the three chemicals classified as powerful synthetic opioids.

ADJOURN: The public hearing adjourned at 9:17 am.

Ryan K. Logan, Chairman	Caroline D. Juran, Executive Director
Date	Date

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

March 29, 2018
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:17AM

PRESIDING: Ryan K. Logan, Chairman

MEMBERS PRESENT:
Jody Allen
Melvin L. Boone, Sr.
Freeda Cathcart
Michael I. Elliott (arrived at 9:18)
Sheila K. W. Elliott
Rafael Saenz
Rebecca Thornbury

MEMBERS ABSENT: Cynthia Warriner

STAFF PRESENT:
Caroline D. Juran, Executive Director
James Samuel Johnson, Jr. Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Ellen B. Shinaberry, Deputy Executive Director
Barbara Allison-Bryan, Chief Deputy Director, DHP
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Sylvia Tamayo-Suijk, Executive Assistant

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

APPROVAL OF AGENDA: The agenda was amended to include:

- The minutes list was corrected to reflect that the December minutes were for 2017, not 2018.
- Amending Guidance Document 110-44 "Protocol for the Prescribing of Naloxone and Dispensing by Pharmacists and Distribution to Authorized Entities" , and
- Requesting guidance from the Board regarding whether certain tasks associated with medication synchronization were tasks restricted to a pharmacy technicians

The Board voted unanimously to approve the agenda as amended. (motion by Cathcart, second by Saenz)

APPROVAL OF MINUTES: The following minutes were considered for approval:

- December 4, 2017, Inspection Special Conference Committee
- December 7, 2017, Special Conference Committee
- December 11, 2017, Public Hearing for Scheduling Certain

Chemicals
- December 11, 2017, Full Board Meeting
- January 11, 2018, Telephone Conference Call
- January 17, 2018, Special Conference Committee
- February 14, 2018, Special Conference Committee
- February 27, 2018, Formal Hearings

MOTION: **The Board voted to adopt the minutes from December 4, 2017 through February 27, 2018 as presented. (motion by Allen, second by Boone; Thornbury abstained)**

PUBLIC COMMENTS: There was no public comment.

DIRECTOR'S REPORT: Dr. Allison-Bryan, Chief Deputy Director of the Department of Health Professions, delivered the report on behalf of Dr. Brown. Dr. Allison-Bryan introduced herself, shared that she has been a pediatrician for 20 years, and as a former member of the Board of Medicine, she convened two regulatory advisory panels relating to opioids. She further stated that Dr. Daniel Carey, formerly Chief Medical Officer of Centra, has been appointed as the new Secretary of Health and Human Resources and Marvin Figueroa is the new Assistant Deputy Secretary. Dr. Allison-Bryan confirmed that Dr. Brown was reappointed as Director of DHP and that Lisa Hahn, former Chief Deputy Director, is the new Chief Operations Officer. This position will provide continuity from one administration to another. Dr. Allison-Bryan mentioned that DHP has a new logo, that the agency has migrated from Outlook to Google email, and that the Business and IT Departments have relocated to the new office space on the first floor of the building.

LEGISLATIVE & REGULATORY ACTIONS:

- Legislative Update on 2018 General Assembly: Ms. Yeatts provided an overview of the summary of bills contained in the genda packet which were recently considered by the General Assembly. She highlighted several bills related to pharmacy:

- Regulatory Update: Ms. Yeatts reviewed the chart of regulatory actions provided in the agenda packet and gave updates on the status.

- Adoption of exempt regulation to add certain chemicals to Schedule I: There was a Public Hearing conducted a 9:13 a.m. this morning pursuant to the requirements of §54.1-3443 of the Drug Control Act.

MOTION: **The Board voted unanimously to adopt an exempt action amendment of Regulation 18VAC110-20-322 as presented which places the following chemicals into Schedule I:**
Classified as research chemicals:
- **2-(ethylamino)-2-phenyl-cyclohexanone (other name: deschloro-N-ethyl-ketamine)**

- **3,4-methylenedioxy-N-tert-butylcathinone**
- **4-fluoro-N-ethylamphetamine**
- **beta-keto-4-bromo-2,5-dimethoxyphenethylamine (other name: bk-2C-B)**

Classified as powerful synthetic opioids:

- **N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-butenamide (other name: Crotonyl fentanyl)**
- **2-(3,4-dichlorophenyl)-N-[2-(dimethylamino)cyclohexyl]-N-methylacetamide (other name: U-51754)**
- **N-phenyl-N-[4-phenyl-1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: 4-phenylfentanyl)**

(motion by Saenz, second by S. Elliott)

PETITION FOR RULEMAKING:

- Amend 18VAC110-20-240, *Manner of maintaining records, prescriptions, inventory records*

The Board reviewed a petition for rulemaking submitted by Judy Dietrick to amend Regulation 18VAC110-20-240 to extend the requirement for retention of records beyond two years, to include records of vaccine administration. The Board reviewed the comments regarding this petition and several questions arose. One was regarding the reporting to the VIIS system for immunizations. Ms. Allyson-Bryant informed the Board that reporting to the VIIS system is only required for EMS, although several physicians voluntarily register with VIIS for reporting even though it is not required. The request to maintain records of immunizations longer than the required 2 years was discussed and it was stated this may be overly burdensome based on volume of records. Ms. Allen noted that since there was already a system in place to report to the VIIS, possibly the Board should discuss requiring pharmacies to register and report to the system for immunizations. Ms. Yeatts stated this would be a legislative change to require such registration.

MOTION:

The Board voted unanimously to deny the petition for rulemaking and to refer the subject to the Regulation Committee for exploration of further options for immunization reporting and improvements to records retention. (motion by Allen, second by M. Elliott)

ADOPTION OF PROPOSED REGULATIONS FOR:

- Requirement for E-profile number on applications

Ms. Yeatts provided a handout of the suggested regulatory language to require pharmacists, pharmacy technicians, and pharmacy interns to provide an e-profile ID number upon application and renewal.

MOTION:

The Board voted unanimously to adopt proposed language to require pharmacists, pharmacy technicians, and pharmacy interns to provide an E-profile ID number upon application and renewal. (motion by Cathcart, second by Boone)

- Fee increase for all

Staff provided several handouts to the Board indicating the Board will

professions and facilities

experience a shortfall in the coming years if it does not increase its licensure fees. Charles Giles, DHP Budget Manager provided background information explaining the need for an increase in fees. The last fee increase was in 2002 and in those 16 years the following expenditure increases have occurred:

- 283% increase in the number of licensees
- 12 Full time employees at the Board vs. 6 in 2002
- 7 cost of living increases for staff
- 5% increase in salary due to mandatory retirement system contribution
- 84% increase in inspections and investigations
- 40% increase in Administrative Proceedings Division hours and number of cases
- 613% increase in mandated information technology costs

Ms. Yeatts and Ms. Juran provided additional comments for why this fee increase is necessary. Ms. Cathcart provided comment in opposition of raising fees for free clinic pharmacies.

MOTION:

The Board voted 7 to 1 to adopt the proposed fee increases for all Board of Pharmacy professions and facilities as presented. (motion by S. Elliott, second by Boone; Cathcart opposed)

- Amend Guidance Document 110-44, *Protocol for the Prescribing of Naloxone and Dispensing by Pharmacists and Distribution to Authorized Entities*

A handout was provided by staff. The Department of Behavioral Health and Developmental Services found the word "kit" and its specific contents to be confusing for licensees. Therefore, they requested that the language be removed from the guidance document.

MOTION:

The Board voted unanimously to amend Guidance Document 110-44, *Protocol for the Prescribing of Naloxone and Dispensing by Pharmacists and Distribution to Authorized Entities*, as presented. (motion by S. Elliott, second by Boone)

- Amend Guidance Document 110-45, *Protocol for the Prescribing of Naloxone and Dispensing by Trainers*

A handout was provided by staff. HB842 was recently passed which allows a Department of Behavioral Health and Developmental Services-approved REVIVE! trainer the ability to provide syringes and needles for the administration of naloxone in accordance with 54.1-3408(Y). Therefore, amendments of Guidance Document 110-45 are required to authorize the dispensing of injectable naloxone with syringes.

MOTION:

The Board voted unanimously to amend Guidance Document 110-45, *Protocol for the Prescribing of Naloxone and Dispensing by Trainers,* as presented in the handout. (motion by Saenz, second by Allen)

- Amend Guidance Document 110-5, *Theft*

Ms. Juran indicated the suggested language regarding theft or loss reporting had been twice reported in board e-newsletters, but that staff

or Loss of Drugs

recommends it be captured in a guidance document to increase access and awareness to the information.

MOTION:

The Board voted unanimously to amend Guidance Document 110-5, *Theft or Loss of Drugs,* to include the additional information as presented. (motion by Thornbury, second by S. Elliott)

- Amend Guidance Document 110-47, *Guidelines for Provision of Counseling and Information by Pharmacists regarding Proper Disposal of Unused Dispensed Drugs*

Ms. Juran stated that she was contacted by a VDH medical director requesting the board encourage pharmacies to provide drug deactivation or disposal pouches when dispensing opioids. It was determined that the Board may wish to include this disposal option in Guidance Document 110-47 in an effort to increase awareness of this option. There was discussion as to why Virginia differs from other states with respect to their drug take-back programs.

MOTION:

The Board voted unanimously to amend Guidance Document 110-47, *Guidelines for Provision of Counseling and Information by Pharmacists regarding Proper Disposal of Unused Dispensed Drugs,* to include the new language as presented. (motion by Cathcart, second by M. Elliott)

ACTION ITEM:

Board staff will research how the state could increase the number of drug collection boxes throughout Virginia and a means of reducing drug destruction-related costs. Staff will also research the possibility of NABP encouraging pharmacies to implement more collection boxes for drug destruction. Staff will report information back at a future meeting.

NEW BUSINESS:

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

Ernie Gates, President and CEO of Gates Healthcare Associates and Denise Frank, former MN Board member and former NABP inspector provided a presentation regarding the FDA 503B/cGMP Compliance services provided by Gates Healthcare Associates. Because facilities in Virginia are getting products from other states, and FDA inspections are not always timely, Gates Healthcare Associates can assist to ensure that out of state facilities are compliant. Ms. Juran stated that in the past, outside entities wishing to have their cGMP inspections for initial application of an outsourcing facility, accepted by the Board, were required to provide:

- A sample inspection report and the requirement of a written response to the inspection report within 15 days
- A willingness to testify at a hearing if needed
- Background on each of the inspectors

Mr. Johnson asked if the Gates Healthcare cGMP inspection report was being accepted for licensure of outsourcing facilities in other states. Mr. Gates indicated that it was not, however, Gates Healthcare will be visiting

several other states within the coming weeks to make a similar presentation. Mr. Gates and Ms. Frank indicated they would provide board staff with a copy of their inspection report for review and further consideration.

- Update on Pharmaceutical Processor Request for Application Process

Ms. Juran indicated the Request for Applications for the pharmaceutical processor permits would open in the near future and that registered users of Regulatory Town Hall would receive an electronic notification once it has been posted. She requested the Board delegate authority to the Chairman, in consultation with the Executive Director, to appoint persons to an ad hoc committee for reviewing the applications. The ad hoc committee would tentatively recommend to the full Board in September which applicants should be potentially awarded conditional approval. Once conditional approval is received, the applicant would have one year to operationalize the facility. An application for initial permit with fee would then be submitted, a final inspection would be performed, and if compliant, the pharmaceutical processor permit would be issued. The facility could then possess Cannabis seeds for cultivation and production of the CBD or THC-A oil.

Ms. Juran reminded staff and Board members that this is a competitive application process and to direct all inquiries to her. She informed the members that a procurement officer has advised that the names of the ad hoc committee members must remain confidential during the application review process. Mr. Rutkowski also provided the ethics rule in a procurement process that includes a prohibition of providing non-public information to a bidder and a prohibition on accepting gifts from a bidder.

MOTION:

The Board voted unanimously to delegate authority to the Board of Pharmacy Chairman, in consultation with the Executive Director, to appoint members to an ad hoc committee for reviewing pharmaceutical processor permit applications. (motion by Cathcart, second by Saenz)

- Medication Synchronization and Duties of a Pharmacy Technician

Ms. Juran indicated a pharmacist working for a pharmacy that offers medication synchronization as a service to patients wanted to know if a non-pharmacy technician could perform the following tasks:

- identify which patients would soon be in need of medications based on the last date of fill; and,
- Send a request for additional refills to the prescriber's office, if the patient required additional refills.

The pharmacist informed Ms. Juran that the non-pharmacy technician would not receive the response to the request for additional refills, but that the response would be transmitted directly from the prescriber's office to the pharmacist or pharmacy technician on-duty. Additionally, the non-pharmacy technician would not perform any data entry.

Mr. Saenz stated there should not be any harm with performing these tasks as described.

MOTION: **The Board voted unanimously that a person working in a pharmacy who is not registered as a pharmacy technician or pharmacist could identify patients for medication synchronization and transmit a refill authorization request to a prescriber's office but may not perform data entry of prescriptions or any subsequently authorized refills. (motion by Cathcart, second by Allen)**

ACTION ITEM: **Develop a Guidance Document of pharmacy technician exempt duties in the future and look at the pharmacist to pharmacy technician ratio.**

REPORTS:

- Chairman's Report: Mr. Logan stated that he had nothing to report at this time.
- Report on Board of Health Professions: Mr. Logan stated that he had nothing to report at this time.
- Report on Licensure Program: Mr. Johnson reported the Board currently licenses 32,502 individuals and facilities. The Board issued 957 licenses and registrations for the period of December 1, 2017 through February 28, 2018. Inspectors conducted 272 facility inspections including 232 routine inspections of pharmacies: 77 (33%) resulted in no deficiency, 77 (33%) with deficiencies and 78 (34%) with deficiencies and a consent order. Mr. Johnson reviewed the chart providing a graphic display of inspection deficiencies by quarter since September 2016 and reviewed the most frequently cited deficiencies for the reporting period.
- Report on Disciplinary Program: Ms. Shinaberry reported that DHP's goal is to maintain a 100% case clearance rate; in Q2 2018, the Board of Pharmacy's clearance rate was 121%. DHP's goal for pending caseload older than 250 days is no greater than 20%; in Q2 2018, the Board of Pharmacy's clearance rate was 9%. DPHs' goal for percent of cases closed within 250 business days is 90%; in Q2 2018, the Board of Pharmacy was at 84%. Ms Shinaberry reported that as of March 23, 2018, the Board had 281 open cases with 112 being patient care cases and 169 being non-patient care cases.
- Executive Director's Report: Ms. Juran reviewed her report with the board. She provided an update on three ongoing projects: implementation of oversight for pharmaceutical processors, amending the routine pharmacy inspection report to include USP Chapter<800>, and review of the current routine pharmacy inspection process. She discussed upcoming or recent meetings which she attended and indicated that she presented at the VACDS meeting in January and at VCU School of Pharmacy in February. At the May NABP Annual Meeting, Ms. Juran will moderate a Medical Marijuana presentation. Ms. Juran welcomed former board member, Ellen Shinaberry, who joined the Board in February 2018 as Deputy Executive

Director. Ms. Shinaberry will travel to the May NABP Annual Meeting to give a presentation on how PMP data is used in the regulatory environment. Ms. Juran indicated that there is a vacancy for Deputy Executive Director for Discipline and a vacancy for an Executive Assistant.

OTHER BUSINESS: Melody Morton introduced herself as the new Inspections Manager of Enforcement. She shared that in an effort to reduce the cost of inspections, the Enforcement division proposes to add a residency requirement for its inspectors to help reduce travel costs.

CONSIDERATION OF CONSENT ORDER

Closed Meeting: Upon a motion by Mr. Elliott, and duly seconded by Ms. Allen, the Board voted 8-0 to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of one Consent Order. Additionally, he moved that Ellen Shinaberry, Caroline D. Juran, Sammy Johnson, Jim Rutkowski and Sylvia Tamayo-Suijk attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations.

Reconvene: The Board voted unanimously that only public business matters lawfully exempt 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 meeting were heard, discussed or considered during the closed meeting.

MOTION: **Upon a motion by Ms. Allen and duly seconded by Mr. Boone, the Board voted 8-0 in favor of accepting the Consent Order as presented by Ms. Juran in the matter of Anthony J. Labashouskly, Pharmacist.**

ADJOURN: With all business concluded, the meeting adjourned at approximately 12:26 pm.

Ryan Logan, Chairman

Caroline D. Juran, Executive Director

DATE:

DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

Thursday, March 29, 2018
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 1:39 p.m.

PRESIDING: Ryan Logan, Chair

MEMBERS PRESENT:
Melvin Boone
Freeda Cathcart
Michael Elliott
Rafael Saenz
Rebecca Thornbury

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

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

ELIZABETH MULUGETA
Registration No. 0230-015307

A formal hearing was held in the matter of Elizabeth Mulugeta to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

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

Ms. Mulugeta was not present.

Rose DeMatteo, DHP Compliance Case Manager, testified in person on behalf of the Commonwealth.

CLOSED MEETING:	Upon a motion by Mr. Elliott, and duly seconded by Ms. Cathcart, the panel voted 5-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Elizabeth Mulugeta. 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 quorum re-convened an open meeting and announced the decision.
DECISION:	Upon a motion by Ms. Cathcart, and duly seconded by Mr. Boone, the panel voted 6-0 to accept the Findings and Fact and Conclusions of Law proposed by Mr. Egan and amended by the board. Upon a motion by Mr. Elliott, and duly seconded by Ms. Thornbury, the panel voted 6-0 to issue an Order to reprimand Ms. Mulugeta and that states she must complete 15 hours of continuing education not obtained prior to the year 2015 within 60 days of the Order being entered.
ADJOURNED:	With all business concluded, the meeting adjourned at 2:25 p.m.

Ryan Logan, Chair

Caroline D. Juran
Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, April 18, 2018
Commonwealth Conference Center
Second Floor
Board Room 1

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

PRESIDING:	Rafael Saenz, Committee Chair
MEMBERS PRESENT:	Melvin Boone, Committee Member
STAFF PRESENT:	Ellen B. Shinaberry, Deputy Executive Director Anne G. Joseph, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
Larita Alvarez License No. 0202-208936	Larita Alvarez did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the November 22, 2017 Notice. The Chair of the Committee chose to proceed with the informal conference as the Notice had been sent to Ms. Alvarez's legal address of record.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, 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 Larita Alvarez. Additionally, he moved that Ellen Shinaberry and Anne Joseph attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:	Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, the Committee unanimously voted to issue an Order to reprimand Ms. Alvarez.
Jodi V. Ettare License No. 0202-205862	Jodi Ettare appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the February 22, 2018.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, 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 Jodi Ettare. Additionally, he moved that Ellen Shinabery and Anne Joseph attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, the Committee unanimously voted to issue an Order for an unannounced inspection within the next six months and to impose a monetary penalty.
Edward R. Breslow License No. 0202-011951	Edward Breslow appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the February 22, 2018 Notice. Jamie Long, Pharmacy Technician, Rustburg Family Pharmacy, was present on his behalf.

Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, 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 Edward Breslow. Additionally, he moved that Ellen Shinaberry and Anne Joseph attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, the Committee unanimously voted to issue an Order to reprimand Mr. Breslow.
Hailu T. Wakjera License No. 0202-206385	Hailu Wakjera did appear to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the February 23, 2018 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, 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 Hailu Wakjera. Additionally, he moved that Ellen Shinaberry and Anne Joseph attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, the Committee unanimously voted to issue an Order to reprimand Mr. Wakjera.
Bassim W. Girgis License No. 0202-209688	Bassim Girgis appeared with Hunter Jamerson, his attorney to discuss allegations that he may have violated certain laws governing the practice of pharmacy as stated in the March 1, 2018 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, 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 Bassim Girgis. Additionally, he moved that Ellen Shinaberry and Anne Joseph attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, the Committee unanimously voted to issue an Order to impose a monetary penalty.

Akina Pharmacy Permit No. 0201-004538	Bassim Girgis, the PIC and Hunter Jamerson, it's attorney, appeared on behalf of Akina Pharmacy to discuss allegations that it may have violated certain laws and regulations governing the conduct of pharmacy as stated in the March 16, 2018 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, 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 Akina Pharmacy. Additionally, he moved that Ellen Shinaberry and Anne Joseph attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, the Committee unanimously voted to issue an Order to impose a monetary penalty.
Toni R. Waldron Registration No. 0230-010380	Toni Waldron did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the March 5, 2018 Notice. The Chair of the Committee chose to proceed with the informal conference as the Notice had been sent to Mr. Waldron's legal address of record.

Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, 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 Toni Waldron. Additionally, he moved that Ellen Shinaberry and Anne Joseph attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, the Committee unanimously voted to issue an Order to reprimand Mr. Waldron and to impose a monetary penalty.
ADJOURN:	With all business concluded, the meeting adjourned at 6:40 p.m.

Rafael Saenz, Chair

Ellen B. Shinaberry
Deputy Executive Director

Date

Date

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING

April 24, 2018
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:15am

PRESIDING: Michael I. Elliott, Committee Chairman

MEMBERS PRESENT: Rafael Saenz
Rebecca Thornbury
Ryan K. Logan
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
James Rutkowski, Board Counsel, Office of the Attorney General

APPROVAL OF AGENDA: Agenda presented for review included a regulatory update, consideration for adoption of revised emergency regulations for pharmaceutical processors, further consideration for petition for rulemaking regarding delivery of dispensed prescriptions, a review of legislation relating to delivery of schedule VI prescription devices and a periodic review of guidance documents.

MOTION: **The Committee voted unanimously to approve the agenda as presented for the Regulation Committee meeting (motion by Warriner, second by Logan)**

PUBLIC COMMENT: No public comment was offered to the Board.

AGENDA ITEMS:

Regulatory Update: Ms. Yeatts provided a brief overview of the regulatory actions that are pending for the Board of Pharmacy. The only recent change was the proposed action to increase fees has moved to the Office of the Attorney General for review.

Adoption of Revised Emergency Regulations for Pharmaceutical Processors of Cannabidiol Oil and THC-A Oil

Ms. Yeatts provided information regarding the 2018 General Assembly bills on this subject. Some of the legislative changes were as follows: expands the conditions for obtaining a written certification from intractable epilepsy to any diagnosed condition or disease, expands allowance for issuing a written certification to any physician registered by the Board of Pharmacy, changes the days' supply that may be dispensed from 30 to 90 days, requires the reporting of CBD oil and THC-A oil dispensing to the PMP, requires the practitioner to query the PMP prior to issuing a certification, requires the Board of Pharmacy to create a process for registering the products, and requires applicants for pharmaceutical processor permits to complete an criminal background check. The bills included an emergency clause. Staff advised that the Board should amend the emergency regulations based on the legislative amendments.

In addition to the agenda packet, a one-page handout with revisions of 18VAC110-60-310(A and B) was provided for their consideration. Staff provided a page-by-page walk through of the changes required in the emergency regulations. The committee discussed several points such as the possibility of requiring identification upon delivery of the dispensed drug and the number of plants required for a 90-day supply.

ACTION ITEM:

Prior to the board considering amendments to 18VAC110-60-240(A)(1), board staff will research the number of plants required to provide a 90-day supply of cannabidiol oil or THC-A oil to a patient.

MOTION:

The Committee voted unanimously to recommend to the full board that it revise the emergency regulations as indicated below or as otherwise presented, with the exception of 18VAC110-60-240(A)(1) that will be discussed at the June board meeting:

- **18 VAC 110-60-110(B)(3) change "owner or owners" to "applicant"**
- **18 VAC 110-60-285(B) strike "marijuana"**
- **18 VAC 110-60-310(A)(3), at the end of the sentence insert "and shall maintain a record in accordance with policy and procedures of the processor".**
- **18 VAC 110-60-310(C)(5) change from "20 oz" to "60 oz"**
- **18 VAC 110-60-310(G) change "intractable epilepsy" to "any diagnosed condition or disease". (motion by Saenz, second by Warriner)**

Further Consideration of Petition for Rulemaking from Lavino Regarding Delivery of Dispensed Prescriptions – 18 VAC 110-20-

The committee reviewed the petition from Joseph Lavino and the comments received from the petition. This petition was discussed at the December, 2017 full board meeting where the board voted to have the Regulation Committee further review and provide a decision on issuing a

275	NOIRA.
MOTION:	**The committee voted 3 to 2 to recommend to the Board to issue a NOIRA regarding the petition for rulemaking for the delivery of dispensed prescriptions. (motion by Saenz, second by Logan; opposed – Warriner and Thornbury)**
Review of Legislation Relating to the Delivery of Schedule VI Devices	Ms. Juran provided background information on the HB878 and SB413 passed during the 2018 General Assembly session that allows a permitted manufacturer, wholesale distributor, warehouse or nonresident warehouse, third-party logistics provider or nonresident third-party logistics provider or registered nonresident manufacturer or nonresident wholesale distributor to deliver a Schedule VI prescription device directly to an ultimate user or consumer. The bill directs the Board of Pharmacy to promulgate regulations within 280 days. The draft regulations for this law will be available for the full board's consideration at the June meeting.
ACTION ITEM:	**Board staff to provide draft regulations related to HB878 and SB413 to the board for its consideration at the June 2018 full board meeting.**
Periodic Review of Guidance Documents	The committee reviewed eight guidance documents that have not been revised in over seven years to determine if the board should keep, amend or repeal the guidance.
ACTION ITEM:	**Board members to send Ms. Juran possible amendments to Guidance Document 110-16 prior to June board meeting.**
MOTION:	**The committee voted unanimously to recommend to the full board re-adoption of Guidance Documents 110-10, 110-11, 110-19, 110-22, 110-24, and 110-25. (motion by Warriner, second by Thornbury)**
ADJOURN:	Next meeting TBD. With all business concluded, the meeting adjourned at 11:50A.M.

Michael I. Elliott, Chairman

Caroline D. Juran, Executive Director

DATE

DATE

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

April 24, 2018
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 1:35 p.m.
PRESIDING:	Ryan Logan, Chair
MEMBERS PRESENT:	Michael Elliott Sheila Elliott Rebecca Thornbury Cynthia Warriner
STAFF PRESENT:	Caroline D. Juran, Executive Director Ellen Shinaberry, Deputy Executive Director Kennia Butler, Disciplinary Program Specialist James Rutkowski, Assistant Attorney General Mykl Egan, DHP Adjudication Specialist
QUORUM:	With five (5) members of the Board present, a quorum was established.
CHARLOTTE M. LAWRENCE Registration No. 0230-002216	A formal hearing was held in the matter of Charlotte Lawrence to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia. Mykl D. Egan, DHP Adjudication Specialist, presented the case. Ms. Lawrence was not present. Rose DeMatteo, DHP Compliance Case Manager, testified in person on behalf of the Commonwealth.

CLOSED MEETING:	Upon a motion by Mr. Elliott, and duly seconded by Ms. Elliott, the panel voted 5-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Charlotte Lawrence. Additionally, he moved that Caroline Juran, Ellen Shinaberry, Kennia Butler 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. Thornbury, and duly seconded by Ms. Warriner, the panel voted 5-0 to accept the Findings and Fact and Conclusions of Law proposed by Mr. Egan and to issue an Order to indefinitely suspend Ms. Lawrence's pharmacy technician registration for no less than two years.
ADJOURNED:	With all business concluded, the meeting adjourned at 1:55 p.m.

Ryan Logan, Chair

Caroline D. Juran
Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Thursday, May 17, 2018

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

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

TIME & PURPOSE: Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on May 17, 2018, at 9:00 a.m., to consider the summary suspension of the registration of Maryann S. Hilton to practice as a pharmacy technician in the Commonwealth of Virginia.

PRESIDING: Ryan Logan, Chair

MEMBERS PRESENT:
Jody Allen
Melvin Boone
Sheila Elliott
Rafael Saenz
Rebecca Thornbury
Cynthia Warriner

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

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

With seven (7) members participating and one (1) member unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

MARYANN S. HILTON
Registration No. 0230-021989

James Schliessmann presented a summary of the evidence in this case.

DECISION:

Upon a motion by Ms. Allen and duly seconded by Ms. Warriner, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Maryann Hilton poses a substantial danger to the public; and therefore, the right to renew the registration of Ms. Hilton shall be summarily suspended.

Upon a motion by Ms. Warriner and duly seconded by Mr. Boone, with the Notice of Hearing, a Consent Order shall be offered to Ms. Hilton for the indefinite suspension of her registration for a period of not less than two years.

ADJOURN:

With all business concluded, the meeting adjourned at 9:21 a.m.

Ryan Logan, Chair

Ellen B. Shinaberry
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Thursday, May 24, 2018
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 09:32 a.m.
PRESIDING:	Cynthia Warriner, Committee Chair
MEMBERS PRESENT:	Melvin Boone, Committee Member
STAFF PRESENT:	Ellen B. Shinaberry, Deputy Executive Director Anne G. Joseph, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
TESSA JEAN-BAPTISTE License No. 0202-211993	Tessa Jean-Baptiste appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the March 8, 2018.
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 Tessa Jean Baptiste. Additionally, he moved that Ellen Shinaberry and Anne Joseph attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone, and duly seconded by Ms. Warriner, the Committee unanimously voted to issue an Order to dismiss this matter.

LORI L. RINGS License No. 0202-009812	Lori Rings did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the March 9, 2018 Notice. The Chair of the Committee chose to proceed with the informal conference as the Notice had been sent to Ms. Rings' legal address of record.
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 Lori Rings. Additionally, he moved that Ellen Shinabery and Anne Joseph attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone, and duly seconded by Ms. Warriner, the Committee unanimously voted to refer the matter to the full Board for a formal administrative hearing, and to offer Ms. Rings a Consent Order for the indefinite suspension of her license to practice as a pharmacist in lieu of a formal hearing.
ADAM C. JACQUES Registration No. 0230-023668	Adam Jacques did not appear to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the March 19, 2018 Notice. The Chair of the Committee chose to proceed with the informal conference as the Notice had been sent to Mr. Jacques' legal address of record.

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 Adam Jacques. Additionally, he moved that Ellen Shinaberry and Anne Joseph attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone, and duly seconded by Ms. Warriner, the Committee unanimously voted to refer the matter to the full Board for a formal administrative hearing, and to offer Mr. Jacques a Consent Order for the revocation of his right to renew his pharmacy technician registration in lieu of a formal hearing.
KRISTIN L. WILKERSON License No. 0202-205439	Kristin Wilkerson did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the March 27, 2018 Notice. The Chair of the Committee chose to proceed with the informal conference as the Notice had been sent to Ms. Wilkerson's legal address of record.
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 Kristin Wilkerson. Additionally, he moved that Ellen Shinaberry and Anne Joseph attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:	Upon a motion by Mr. Boone, and duly seconded by Ms. Warriner, the Committee unanimously voted to refer the matter to the full Board for a formal administrative hearing.
CVS PHARMACY #3508 Permit No. 0201-000707	Stacy Woody, the PIC, appeared on behalf of CVS Pharmacy #3508 to discuss allegations that it may have violated certain laws and regulations governing the conduct of pharmacy as stated in the March 28, 2018 Notice. Amanda M. Chiota, Divisional Professional Practice Lead, CVS Pharmacy, testified on its behalf.
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 CVS Pharmacy #3508. Additionally, he moved that Ellen Shinaberry and Anne Joseph attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone, and duly seconded by Ms. Warriner, the Committee unanimously voted to issue an Order to impose a monetary penalty.
MARIO E. LOPEZ Registration No. 0230-020425	Mario Lopez did not appear to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the April 11, 2018 Notice. The Chair of the Committee chose to proceed with the informal conference as the Notice had been sent to Mr. Lopez's legal address of record.

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 Mario Lopez. Additionally, he moved that Ellen Shinaberry and Anne Joseph attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone, and duly seconded by Ms. Warriner, the Committee unanimously voted to issue an Order to reprimand Mr. Lopez.
ADJOURN:	With all business concluded, the meeting adjourned at 2:50 p.m.

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

Agenda Item: Regulatory Actions - Chart of Regulatory Actions
As of June 1, 2018

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Brown bagging and white bagging [Action 4968] NOIRA - *At Governor's Office for 78 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Controlled substances registration for naloxone and teleprescribing [Action 4789] Proposed - *At Governor's Office for 23 days*
[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 - *At Governor's Office for 9 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Requirement for applicants and licensees to have an e-profile ID number [Action 4909] Proposed - *At Secretary's Office for 11 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Increase in fees [Action 4938] Proposed - *DPB Review in progress* [31 days]
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Final - *At Governor's Office for 9 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Response to petitions for rulemaking [Action 4694] Final - *At Governor's Office for 23 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	(E) Placement of chemicals in Schedule I [Action 5023] Final - *Register Date: 5/14/18* *Effective: 6/13/18*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	New regulations [Action 4695] Emergency/NOIRA - *Register Date: 8/7/17* *New Emergency regulations to be adopted: 6/21/18*

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

Scheduling Chemicals in Schedule I - Exempt action
Scheduling for conformity with DEA – Exempt action

Included in agenda package:

Copy of Notice of Public Hearing listing chemicals to be scheduled in Schedule I and scheduling/de-scheduling for conformity with DEA

Amendments to regulation: 18VAC110-20-322
Adoption of regulation: 18VAC110-20-323

Copy of § 54.1-3443 from the Code of Virginia

Staff Note:

A public hearing was conducted before the meeting this morning.

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

With the passage of HB1194, all chemicals currently scheduled in subsections A through D are placed in Schedule I in the Drug Control Act (effective 7/1/18) and can be deleted in regulation.

With the failure of passage of HB1440, the Board of Pharmacy must amend its regulations to schedule or de-schedule drugs to conform DCA to DEA schedules. Such action can subsequently be included in the Code of Virginia through a legislative action that will not necessitate a budget amendment.

Board action:

Adoption of final regulation in sections 322 and 323

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 June 21, 2018** at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233. Public comment may also be submitted electronically or in writing prior to June 7, 2018 to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

The Virginia Department of Forensic Science (DFS) has identified eight (8) chemical compounds for recommended inclusion into the Code of Virginia. A brief description and chemical name for each compound is as follows:

The following compound is classified as a research chemical. Compounds of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

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.

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

2. **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.
3. **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.
4. **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.
5. **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.
6. **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.

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

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7. **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.

The following compound is classified as a benzodiazepine, which is a central nervous system depressant. Flualprazolam has no accepted medical use in the United States. Other compounds of this type have been placed in Schedule I (§ 54.1-3446(4)).

8. **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.

Notice of Public Hearing
Scheduling/De-scheduling to Conform to Federal Actions

Pursuant to subsection E of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider scheduling or de-scheduling certain drugs in the Virginia Drug Control Act. The public hearing will be conducted at **9:00 a.m. on June 21, 2018** at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233.

In order to conform the Drug Control Act to recent scheduling changes enacted by the Drug Enforcement Administration, the Board will:

1) Add MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine) to Schedule I;

2) Add Dronabinol [(-)-delta-9-*trans* tetrahydrocannabinol] in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration to Schedule II; and

3) Removes naldemedine from Schedule II.

April 24, 2018

Code of Virginia
Title 54.1. Professions and Occupations
Chapter 34. Drug Control Act

§ 54.1-3443. Board to administer article

A. The Board shall administer this article and may add substances to or deschedule or reschedule all substances enumerated in the schedules in this article pursuant to the procedures of the Administrative Process Act (§ 2.2-4000 et seq.). In making a determination regarding a substance, the Board shall consider the following:

1. The actual or relative potential for abuse;

2. The scientific evidence of its pharmacological effect, if known;

3. The state of current scientific knowledge regarding the substance;

4. The history and current pattern of abuse;

5. The scope, duration, and significance of abuse;

6. The risk to the public health;

7. The potential of the substance to produce psychic or physical dependence; and

8. Whether the substance is an immediate precursor of a substance already controlled under this article.

B. After considering the factors enumerated in subsection A, the Board shall make findings and issue a regulation controlling the substance if it finds the substance has a potential for abuse.

C. If the Board designates a substance as an immediate precursor, substances which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.

D. If the Board, in consultation with the Department of Forensic Science, determines the substance shall be placed into Schedule I or II pursuant to § 54.1-3445 or 54.1-3447, the Board may amend its regulations pursuant to Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act. Prior to making such amendments, the Board shall conduct a public hearing. At least 30 days prior to conducting such hearing, it shall post notice of the hearing on the Virginia Regulatory Town Hall and shall send notice of the hearing to any persons requesting to be notified of a regulatory action. In the notice, the Board shall include a list of all substances it intends to schedule by regulation. The Board shall notify the House Courts of Justice and Senate Courts of Justice Committees of any new substance added to Schedule I or II pursuant to this subsection. Any substance added to Schedule I or II pursuant to this subsection shall remain on Schedule I or II for a period of 18 months. Upon expiration of such 18-month period, such substance shall be descheduled unless a general law is enacted adding such substance to Schedule I or II. Nothing in this subsection shall preclude the Board from adding substances to or descheduling or rescheduling all substances enumerated in the schedules pursuant to the provisions of subsections A, B, and E.

E. If any substance is designated, rescheduled, or descheduled as a controlled substance under

federal law and notice of such action is given to the Board, the Board may similarly control the substance under this chapter after the expiration of 30 days from publication in the Federal Register of a final or interim final order or rule designating a substance as a controlled substance or rescheduling or descheduling a substance by amending its regulations in accordance with the requirements of Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act. Prior to making such amendments, the Board shall post notice of the hearing on the Virginia Regulatory Town Hall and shall send notice of the hearing to any persons requesting to be notified of a regulatory action. The Board shall include a list of all substances it intends to schedule by regulation in such notice.

F. Authority to control under this section does not extend to distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 4.1.

G. The Board shall exempt any nonnarcotic substance from a schedule if such substance may, under the provisions of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.) or state law, be lawfully sold over the counter without a prescription.

1972, c. 798, § 54-524.84:1; 1976, c. 614; 1988, c. 765; 1993, c. 866; 1996, c. 408;2014, cc. 674, 719 ;2017, cc. 416, 432.

The chapters of the acts of assembly referenced in the historical citation at the end of this section may not constitute a comprehensive list of such chapters and may exclude chapters whose provisions have expired.

Project 5484 - none

BOARD OF PHARMACY

Scheduling 6-18

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. 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)-1-pentanone (other names: N,N-Dimethylpentylone, Dipentylone);~~

~~2. 4-chloro-alpha-Pyrrolidinovalerophenone (other name: 4-chloro-alpha-PVP);~~

~~3. 4-methyl-alpha-Pyrrolidinohexiophenone (other name: MPHP);~~

~~4. 4-fluoro-alpha-Pyrrolidinoheptiophenone (other name: 4-fluoro-PV8);~~

~~5. 1-(4-methoxyphenyl)-2-(pyrrolidin-1-yl)octan-1-one (other name: 4-methoxy-PV9);~~

~~6. 4-allyloxy-3,5-dimethoxyphenethylamine (other name: Allylescaline);~~

~~7. 4-methyl-alpha-ethylaminopentiophenone; and~~

~~8. N-(4-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: para-fluoroisobutyryl fentanyl).~~

~~The placement of drugs listed in this subsection shall remain in effect until August 22, 2018, 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. 6-ethyl-6-nor-lysergic acid diethylamide (other name: ETH-LAD), 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. 6-allyl-6-nor-lysergic acid diethylamide (other name: AL-LAD), 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. Synthetic opioids:~~

~~a. N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide (other name: beta-hydroxythiofentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation;~~

~~b. N-(2-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other names: 2-fluorofentanyl, ortho-fluorofentanyl), 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; and~~

~~c. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-propenamide (other name: Acryl 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;~~

~~4. Cannabimimetic agents:~~

a. 1-pentyl-N-(phenylmethyl)-1H-indole-3-carboxamide (other name: SDB-006), 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; and

b. Quinolin-8-yl 1-(4-fluorobenzyl)-1H-indole-3-carboxylate (other name: FUB-PB-22), 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; and

5. Benzodiazepine: flubromazepam, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until December 13, 2018, 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. 4-Bromo-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (25B-NBOH), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

2. Methyl N-[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]valinate (MMB-CHMICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide (Tetrahydrofuran 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.

~~The placement of drugs listed in this subsection shall remain in effect until February 18, 2019, 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. 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT), 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. 5-methoxy-N-ethyl-N-isopropyltryptamine (5-MeO-EIPT), 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. 4-hydroxy-N,N-diisopropyltryptamine (4-OH-DIPT), 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-methyl-aminopropyl)-2,3-dihydrobenzofuran (MAPDB), 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. 3,4-tetramethylene-alpha-pyrrolidinovalerophenone (TH-PVP), 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. 4-chloro-alpha-methylamino-valerophenone (4-chloropentedrone), 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. 2-methoxy-N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-acetamide (Methoxyacetyl fentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.~~

~~b. N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide (Cyclopropyl 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.~~

~~8. Cannabimimetic agent: N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamide (5-fluoro-ADB-PINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~The placement of drugs listed in this subsection shall remain in effect until June 12, 2019, 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. 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. 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 (18 months from the effective date of the regulation), unless enacted into law in the Drug Control Act.

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

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

1. Adds MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine) to Schedule I;

2. Adds Dronabinol [(-)-delta-9-*trans* tetrahydrocannabinol] in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration to Schedule II; and

3. Deletes naldemedine from Schedule II.

Agenda Item: Review of Guidance Documents

Included in your agenda package:

Current guidance documents for the Board that have not been reviewed, revised or readopted in the past four years

Board Action:

1. Re-adoption of guidance documents:
   110-10
   110-11
   110-19
   110-22
   110-24
   110-25
2. Deletion of:
   110-6
   110-13
   110-14
3. Revision of:
   110-16

BOARD OF PHARMACY

Copies of the following documents may be viewed during regular work days from 8:15 a.m. until 5 p.m. at the offices of the Department of Health Professions, 9960 Mayland Drive, Suite 300, Henrico, VA 23233. Copies may also be downloaded from the board's webpage at http://www.dhp.virginia.gov/Pharmacy or the Regulatory Town Hall at http://www.townhall.virginia.gov or requested by email at pharmbd@dhp.virginia.gov. Questions regarding interpretation or implementation of these documents or requests for copies may be directed to Caroline D. Juran, Executive Director of the Board, at the address above or by telephone at (804) 367-4456. Copies are free of charge.

Guidance Documents:

http://www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm

110-1, List of categories of facility licenses and a brief description of each, revised December 11, 2017

110-2, Instructions for applicants for pharmacist licensure, revised March 28, 2018

110-3, Guidance on alternative delivery of prescriptions, pharmacy to physician or pharmacy to controlled substance registration type of delivery, revised September 9, 2014

110-4, Continuing Education Guide for Pharmacists, revised December 11, 2017

110-5, Instructions and forms for reporting of thefts or losses of drugs, revised March 29, 2018

*110-6, Sanctions for non-compliance with reporting to the Prescription Monitoring Program, revised March 12, 2013

110-7, Practitioner/patient relationship and the prescribing of drugs for family or self, revised September 2015

110-8, Information on prescriptive authority in Virginia, revised January 15, 2016

110-9, Pharmacy Inspection Deficiency Monetary Penalty Guide, revised March 21, 2017

*110-10, Board guidance on dispensing of drugs from mobile vans, revised April 2006

*110-11, Board guidance on proof of identity for Schedule II drugs, revised July 1, 2011

110-12, Bylaws of the Board of Pharmacy, revised September 26, 2017

*110-13, Consent Order for the Board of Pharmacy v. CVS/pharmacy, case decision holding the corporate owner responsible for violations of pharmacy laws and regulations, October 9, 1997

*110-14, Consent Order for the Board of Pharmacy v. Eckerd Corporation, case decision holding the corporate owner responsible for violations of pharmacy laws and regulations, August 19, 1997

110-15, Delegation of authority in disciplinary matters, revised March 25, 2016

*110-16, Board guidance on performing inventories, adopted September 20, 2011

110-17, Instructions for graduates of foreign schools of pharmacy, revised October 12, 2016

110-18, Advance preparation of medications for administration, revised September 29, 2015

*110-19, Transferring valid orders between medical equipment providers, revised July 1, 2013

110-20, Practice as a pharmacy technician trainee, revised March 21, 2017

*110-21, Sanction Reference Points Manual, revised September, 2013

*110-22, Dispensing records; identification of pharmacist, revised December 12, 2013

110-23, Monetary penalties for inspection deficiencies for physicians selling controlled substances, adopted March 26, 2014

*110-24, Competency examination required and passing score, adopted June 2009

*110-25, Guidance for life of a prescription after a prescriber no longer in practice, September 3, 2008

110-27, Pharmacist-In-Charge responsibilities, revised December 1, 2015

*110-28, Guidance for free clinic pharmacy permit applicants, revised September 2009

110-29, Guidance for physician dispensing, revised June 2016

*110-30, Drugs within animal shelters and pounds, revised March 2011

110-31, Approved capture drugs and drug administering equipment, Directive from the State Veterinarian, revised September 2016

*110-32, Use of a drop-box for the collection of prescriptions, adopted December 12, 2007

*110-33, Pharmacy Interns as Pharmacy Technicians, Pharmacy Technician Ratio, revised September 2009

110-34, Manufacturer and wholesale distributor licensure, revised September 29, 2015

110-35, Requirements for Prescriptions, revised September 26, 2017

110-36, Compliance with USP Standards for Compounding, revised December 11, 2017

*110-37, Guidance for conducting informal fact-finding by an agency subordinate, revised June 8, 2011

110-38, Requirement for Non-resident Pharmacies to Submit Current Inspection Report, revised December 12, 2016

110-39, Hours of continuous work and taking breaks by pharmacists, adopted March 21, 2017

110-40, Storage of Schedule II drugs in a pharmacy, adopted June 2, 2014

*110-41, Changes a pharmacist may make to a Schedule II prescription, revised December 14, 2011

*110-42, Continuing education audit and recommended sanctions, adopted March 11, 2009

*110-43, Dispensing with an authorized generic, adopted December 12, 2012

110-44, Protocol for prescribing or dispensing naloxone, revised March 29, 2018

110-45, Protocol for prescribing and dispensing naloxone to trainers, revised March 29, 2018

110-46, Delivery of temperature-sensitive drugs, adopted December 11, 2017

110-47, Disposal of drugs, revised March 29, 2018

Adopted: March 8, 2006
Re-adopted: June 21, 2018

Virginia Board of Pharmacy
Mobile Units for Dispensing for the Indigent or Underserved Population

For good cause shown and pursuant to 54.1-3304, the Board of Pharmacy may grant a license to any physician licensed under the laws of Virginia authorizing such physician to dispense drugs to persons to whom a pharmaceutical service is not reasonably available. The Board has recently interpreted that the indigent and medically underserved may represent a population for which pharmacy services are not reasonably available. As such, a physician desiring to dispense drugs only to an indigent or underserved population from a mobile unit may apply for this license as a "permitted physician" which allows him to practice pharmacy pursuant to Board of Pharmacy regulations as set forth in 18VAC110-20-410. For purposes of this guidance document, "indigent" is defined as those persons whose income is not more than 200% above the federal poverty guidelines, and a medically underserved area or population is defined by criteria established by the Health Resources and Services Administration of the U.S. Department of Health and Human Resources.

Additionally, pursuant to 18 VAC 110-20-410 (B) and 18VAC110-20-120, the Board may issue a special or limited-use permit to a permitted physician, when the scope, degree or type of pharmacy practice or service to be provided is of a special, limited or unusual nature as compared to a regular pharmacy service. The Board has been made aware of at least two physicians who use mobile units traveling throughout a community to offer medical assistance to the indigent or underserved and who would like to include the dispensing of prescription drugs. Mobile units do not meet all physical requirements of 18VAC110-20-150 for security and appropriate storage conditions for drugs, and possibly do not meet the alarm requirements of 18VAC110-20-180. They also may not meet the traditional enclosure requirements of 18VAC110-20-190.

The Board recognizes that there is a growing need to be able to provide pharmacy services to this population. Therefore, if a physician applies for a permitted physician license for this purpose, he may request a waiver of sections A, B and C of 18VAC110-20-150, but must be able to meet the other requirements of this section including temperature control. The enclosure requirements in a mobile unit may, if approved after inspection, be met by a separate lockable room, compartment, or cabinet. In order for the Board to consider waiving these requirements for a mobile unit, the following criteria must be met in addition to all other legal requirements for a permitted physician:

- The mobile unit shall not stock any Schedule II-V controlled substances for dispensing.
- The mobile unit shall be parked daily during its off-hours at the same designated location as specified to the Board during the application process.
- When parked during the off-hours, the mobile unit shall be under camera surveillance or within a secure parking area with around-the-clock security staff, and in an area that is affiliated with the physician's practice location.
- The mobile unit shall at all times provide a controlled temperature environment pursuant to 18VAC110-20-150.
- The mobile unit shall have an alarm system that complies with the requirements of 18VAC110-20-180 and capable of alerting the alarm company or security staff to any breaking. It shall fully protect the drug storage area and shall only be controlled by the physician or designated personnel authorized to dispense medications. It shall be activated and operational at all times the mobile van is not in use to include any breaks during the day when it is not staffed.
- The mobile unit shall only be used to serve the indigent or underserved consistent with the permitted physician application.
- If the mobile unit is to be parked and not used for more than seven consecutive days, all drugs for dispensing must be removed from the unit and stored in a permanent location where access is restricted to the permitted physician.

An application for a limited-use pharmacy permit for a mobile unit for this same purpose would also have to meet the same requirements.

Virginia Board of Pharmacy

Proof of Identity when Dispensing Schedule II Drugs

Section 54.1-3420.1 of the Drug Control Act (see below) has always authorized a pharmacist to request proof of identity prior to dispensing or refilling prescriptions written for drugs in Schedules II through V.

Effective **July 1, 2011**, subsection B requires that a pharmacist *or his agent* obtain proof of identity at the time of delivery anytime the pharmacist or his agent does not know the patient or the person picking up or "seeking to take delivery" of the Schedule II dispensed drug prescribed for the patient. "Proof of identity" (hereafter referred to as "ID") is defined to mean a driver's license, government-issued identification card, or other photo identification along with documentation of the person's current address. Additionally, there is a requirement to either make a photocopy or electronic copy of the person's identification or record the full name and address whenever someone other than the patient for whom the drug was prescribed *is not known* to the pharmacist or his agent and is picking up or seeking to take delivery of the Schedule II dispensed prescription.

In summary:

- If any person picking up or "seeking to take delivery" of a Schedule II dispensed prescription is known to the pharmacist or his agent, then the pharmacist or his agent is not required to obtain ID.
- If the person picking up the Schedule II dispensed prescription is the patient for whom the prescription is written, and the pharmacist or his agent does not know that person, then the pharmacist or his agent must require ID.
- If anyone other than the patient for whom the prescription is written seeks to take delivery of the drug, and the pharmacist or his agent does not know the person, then the pharmacist or his agent must either make a photocopy or an electronic copy of such person's ID *or* record the full name and address of such person. The pharmacist must keep the record or copy of ID for at least one month.

Also, subsection C states that when a pharmacy delivers a Schedule II drug by mail, common carrier, or delivery service to a Virginia address, the method of delivery employed shall require the signature of the recipient as confirmation of receipt.

Code of Virginia:

§ 54.1-3420.1. Identification required for filling prescriptions.

A. Before dispensing any drug listed on Schedules III through V, a pharmacist may require proof of identity from any patient presenting a prescription or requesting a refill of a prescription.

B. A pharmacist, or his agent, shall require proof of identity at the time of delivery from any person seeking to take delivery of any drug listed on Schedule II pursuant to a valid prescription, unless such person is known to the pharmacist or to his agent. If the person seeking to take delivery of a drug listed on Schedule II pursuant to a valid prescription is not the patient for whom the drug is prescribed, and the person is not known to the pharmacist or his agent, the pharmacist or his agent either make a photocopy or electronic copy of such person's identification or record the full name and address of such person. The pharmacist shall keep records of the names and addresses or copies of proof of identity of persons taking delivery of drugs as required by this subsection for a period of at least one month. For the purposes of this subsection, "proof of identity" means a driver's license, government-issued identification card, or other photo identification along with documentation of the person's current address.

C. Whenever any pharmacist permitted to operate in the Commonwealth or nonresident pharmacist registered to conduct business in the Commonwealth delivers a prescription drug order for any drug listed on Schedule II by mail, common carrier, or delivery service to a Virginia address, the method of delivery employed shall require the signature of the recipient as confirmation of receipt.

Guidance Document: 110-19 Re-adopted: June 21, 2018

Virginia Board of Pharmacy

Transferring Valid Orders between Medical Equipment Suppliers

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 should be communicated either orally by direct communication between an individual at the transferring medical equipment supplier and the receiving medical equipment supplier, or by facsimile machine or by electronic transmission.

The transferring medical equipment supplier should:

a. Record the word "VOID" on the face of the invalidated order;

b. Record on the reverse 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; and,

The receiving medical equipment supplier should:

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.

Both the original and transferred order should 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 storage and retrieval of dispensing information.

Related statute and regulation:

§ 54.1-3435.2. Permit to act as medical equipment supplier; storage; limitation; regulations.

A. Unless otherwise authorized by this chapter or Chapter 33 (§ 54.1-3300 et seq.) of this title, it shall be unlawful for any person to act as a medical equipment supplier, as defined in § 54.1-3401, in this Commonwealth without a valid unrevoked permit issued by the Board. The applicant for a permit to act as a medical equipment supplier in this Commonwealth shall apply to the Board for a permit, using such form as the Board may furnish; renew such permit, if granted, annually on a date determined by the Board in regulation; and remit a fee as determined by the Board.

B. Prescription drugs received, stored, and distributed by authority of this section shall be limited to those Schedule VI controlled substances with no medicinal properties which are used for the operation and cleaning of medical equipment, solutions for peritoneal dialysis, and sterile water and saline for irrigation.

C. Distribution of any Schedule VI drug or device or of any hypodermic needle or syringe, or medicinal oxygen by authority of this section is limited to delivery to the ultimate user upon lawful order by a prescriber authorized to prescribe such drugs and devices.

D. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs, devices and controlled paraphernalia by medical equipment suppliers as it deems necessary to implement this section, to prevent diversion of prescription drugs and devices and controlled paraphernalia, and to protect the public.

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.

Virginia Board of Pharmacy

Use of Dispensing Records to Identify Pharmacist Responsible for Dispensing Error

To improve compliance with regulations and assist in determining which pharmacist to hold responsible for a dispensing error, the Board offers the following guidance on current dispensing practices and required recordkeeping when more than one pharmacist at the same location assumes responsibility for individual dispensing functions associated with dispensing one prescription product.

Dispensing Scenario #1

One pharmacist verifies the accuracy of the prescription product in all respects and assumes responsibility for the entire transaction. Per Regulation 18VAC110-20-270 C, he shall place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction. Such record showing verification of accuracy shall be maintained for the required time period of two years. Additionally, if the pharmacist makes use of an automated data processing system, he shall document the fact that the information entered into the computer is correct in compliance with Regulation 18VAC110-20-250.

Dispensing Scenario #2

More than one pharmacist at the same pharmacy location verifies the accuracy of individual tasks associated with the dispensing of a prescription product and assumes responsibility for these individual tasks, i.e., one pharmacist may verify accuracy of the data entry while another may verify accuracy of product selection. Per 18VAC110-20-270 C, 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. If the pharmacy's record of dispensing is non-compliant and inappropriately only captures one set of pharmacist initials on the record and this is the only record of dispensing maintained, then that pharmacist shall be responsible for the entire transaction and any resulting dispensing errors.

To identify more than one pharmacist responsible for individual tasks when the pharmacy's record of dispensing is incapable of capturing more than one set of pharmacist initials, an alternative record shall be used in compliance with Regulation 18VAC110-20-255. The alternative record shall indicate the date of dispensing and the identity of the other pharmacist(s) involved in the dispensing. An example of an alternative record could be a manual log. Such alternative record shall be maintained for a period of two years on premises. A pharmacy using such alternative record shall maintain a current policy and procedure manual documenting the procedures for using the record, how the record is integrated into the total dispensing record system, and how the data included in the record shall be interpreted, i.e., which set of pharmacist initials is associated with verifying the accuracy of which dispensing function. For example, the policy and procedure manual could indicate that the pharmacist whose initials are on the record of dispensing maintained in the computer is responsible for verifying the validity of the prescription, drug-therapy appropriateness, including, but not limited to, interactions, contraindications, adverse effects, incorrect dosage or duration of treatment, clinical misuse or abuse, noncompliance and duplication of therapy, and prospective drug review. Additionally, the manual could indicate that the pharmacist whose initials

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are captured on the manual log is responsible for product verification and ensuring that the correct quantity of the correct drug and strength has been placed in the properly labeled container.

Dispensing Scenario #3

More than one pharmacist at different pharmacy locations participate in central or remote processing pursuant to Regulation 18VAC110-20-276 or 18VAC110-20-515. The pharmacist and/or pharmacies must be properly licensed in compliance with regulations. Retrievable records shall be maintained at the participating pharmacies which show, for each prescription processed, each individual processing function and identity of the pharmacist or pharmacy technician who performed a processing function and the pharmacist who checked the processing function, if applicable. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board. The Virginia-licensed pharmacist identified on these records who assumed responsibility for checking an individual function which resulted in a dispensing error shall be held responsible for that dispensing error, i.e., if the dispensing error resulted from incorrect data entry, then the pharmacist identified on the record for checking the data entry shall be responsible for the error and if the dispensing error resulted from incorrect product selection, then the pharmacist identified on the record for checking the product selection shall be responsible for the error.

Note Regarding Partial Filling of a Prescription:** When a prescription is partially-filled, a record of each dispensing shall be maintained. The records shall indicate the date a partial quantity was dispensed, the quantity dispensed, and the initials of the pharmacist verifying the accuracy of the dispensing. If the pharmacy's record of dispensing is maintained in an automated dispensing system capable of capturing only the total quantity dispensed and not each partial dispensing, then the pharmacy's records are out of compliance. To improve compliance with recordkeeping requirements, the pharmacy shall maintain another record that is accurate from which dispensing information is retrievable and in which the original prescription and any information maintained in the data processing system concerning such prescription can be found. An example of an alternative record could be a manual log that indicates the date of dispensing for each partial quantity, the quantity dispensed, and the initials of the pharmacist verifying the accuracy of each dispensing. Pursuant to Regulation 18VAC110-20-255, a pharmacy using such alternative record shall maintain a current policy and procedure manual documenting the procedures for using the record, how the record is integrated into the total dispensing record system, and how the data included in the record shall be interpreted.

Relevant sections of law and regulation:

§ 54.1-3412. Date of dispensing; initials of pharmacist; automated data processing system.

Pursuant to regulations promulgated by the Board, the pharmacist dispensing any prescription shall record the date of dispensing and his initials on the prescription in (i) an automated data processing system used for the storage and retrieval of dispensing information for prescriptions or (ii) on another record that is accurate from which dispensing information is retrievable and in which the original prescription and any information maintained in such data processing system concerning such prescription can be found.

18VAC110-20-250. Automated data processing records of prescriptions.

A. An automated data processing system may be used for the storage and retrieval of original and refill dispensing information for prescriptions instead of manual record keeping requirements, subject to the following conditions:

1. A prescription shall be placed on file as set forth in 18VAC110-20-240 B with the following provisions:

a. In lieu of a hard copy file for Schedule VI prescriptions, an electronic image of a prescription may be maintained in an electronic database provided it preserves and provides an exact image of the prescription 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. Storing electronic images of prescriptions for Schedule II-V controlled substances instead of the hard copy shall only be authorized if such storage is allowed by federal law.

b. If the pharmacy system's automated data processing system fields are automatically populated by an electronic prescription, the automated record shall constitute the prescription and a hard copy or electronic image is not required.

c. For Schedule II-V controlled substances, electronic prescriptions shall be maintained in accordance with federal law and regulation.

2. Any computerized system shall provide retrieval (via computer monitor display or printout) of original prescription information for those prescriptions which are currently authorized for dispensing.

3. Any computerized system shall also provide retrieval via computer monitor display or printout of the dispensing history for prescriptions dispensed during the past two years.

4. Documentation of the fact that the information entered into the computer each time a pharmacist fills a prescription for a drug is correct shall be provided by the individual pharmacist who makes use of such system. If a printout is maintained of each day's prescription dispensing data, the printout shall be verified, dated and signed by the individual pharmacist who dispensed the prescription. The individual pharmacist shall verify that the data indicated is correct and then sign the document in the same manner as his name appears on his pharmacist license (e.g., J. H. Smith or John H. Smith).

If a bound log book, or separate file is maintained rather than a printout, each individual pharmacist involved in dispensing shall sign a statement each day in the log, in the manner previously described, attesting to the fact that the dispensing information entered into the computer that day has been reviewed by him and is correct as shown.

B. Printout of dispensing data requirements. Any computerized system shall have the capability of producing a printout of any dispensing data which the user pharmacy is responsible for maintaining under the Drug Control Act (§54.1-3400 et seq. of the Code of Virginia) and such printout shall be provided within 48 hours of a request of an authorized agent.

18VAC110-20-255. Other dispensing records.

Pursuant to §54.1-3412 of the Code of Virginia, any other record used to record the date of dispensing or the identity of the pharmacist dispensing shall be maintained for a period of two years on premises. A pharmacy using such an alternative record shall maintain a current policy and procedure manual documenting the procedures for using the record, how the record is integrated into the total dispensing record system, and how the data included in the record shall be interpreted.

18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians.

C. 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.

18VAC110-20-276. Central or remote processing.

A. Centralized or remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process:

1. Receiving, interpreting, analyzing, or clarifying prescriptions;
2. Entering prescription and patient data into a data processing system;
3. Transferring prescription information;
4. Performing a prospective drug review as set forth in § 54.1-3319 of the Code of Virginia;
5. Obtaining refill or substitution authorizations, or otherwise communicating with the prescriber concerning a patient's prescription;
6. Interpreting clinical data for prior authorization for dispensing;
7. Performing therapeutic interventions; or
8. Providing drug information or counseling concerning a patient's prescription to the patient or patient's agent.

B. A pharmacy may outsource certain prescription processing functions as described in subsection A to another pharmacy in Virginia or a registered non-resident pharmacy under the following conditions:

1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy;
2. Any central or remote pharmacy shall comply with Virginia law and regulation with respect to requirements for supervision of pharmacy technicians and the duties which are restricted to pharmacists and pharmacy technicians. Pharmacy technicians at the remote pharmacy shall either be registered in Virginia or possess credentials substantially equivalent to those required for a technician registered in Virginia;
3. A pharmacist licensed in Virginia, whether at the remote pharmacy or the dispensing pharmacy, shall perform a check for accuracy on all processing done by the remote processor; and
4. The pharmacies shall share a common electronic file or have technology which allows sufficient information necessary to process a non-dispensing function.

C. Any pharmacy that outsources prescription processing to another pharmacy shall provide notification of such to patients. A one-time written notification or a sign posted in the pharmacy in a location that is readily visible to the public will satisfy this notification requirement. The notice shall state the name of any contract pharmacy providing central or remote prescription processing. If the pharmacy uses a network of pharmacies under common ownership, this fact shall be disclosed in the notice.

D. A policy and procedure manual that relates to central or remote processing shall be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following:

1. The responsibilities of each pharmacy;
2. A list of the name, address, telephone numbers, and permit/registration numbers of all pharmacies involved in central or remote processing;
3. Procedures for protecting the confidentiality and integrity of patient information;
4. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;

5. Procedures for maintaining required records;
6. Procedures for complying with all applicable laws and regulations to include counseling;
7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and
8. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.

E. In addition to any other required records, pharmacies engaged in central or remote processing shall maintain retrievable records which show, for each prescription processed, each individual processing function and identity of the pharmacist or pharmacy technician who performs a processing function and the pharmacist who checked the processing function, if applicable.

1. The records may be maintained separately by each pharmacy, or in a common electronic file shared by both pharmacies provided the system can produce a record showing each processing task, the identity of the person performing each task, and the location where each task was performed.
2. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board.

F. Nothing in this section shall prohibit an individual employee licensed as a pharmacist in Virginia from accessing the employer pharmacy's database from a remote location for the purpose of performing certain prescription processing functions as described in subsection A, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

18VAC110-20-515. Remote prescription order processing for hospitals and long term care facilities.

A. Remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process:

1. Receiving, interpreting, analyzing, or clarifying prescriptions;
2. Entering prescription and patient data into a data processing system;
3. Transferring prescription information;
4. Performing a prospective drug review to include an evaluation of a prescription order and patient records for over- or under-utilization of medication, therapeutic duplication of medication, drug-disease contraindications, drug interactions, incorrect drug dosage or duration of drug treatment, or clinical abuse or misuse of medication;
5. Obtaining substitution authorizations, or otherwise communicating with the prescriber concerning a patient's order;
6. Interpreting or acting on clinical data;
7. Performing therapeutic interventions;
8. Providing drug information to the medical or nursing staff of the hospital or long term care facility; or
9. Authorizing the administration of the drug to the patient by appropriate hospital or long term care facility staff.

B. The primary pharmacy providing pharmacy services to a hospital or long term care facility may outsource certain order processing functions as described in subsection A to another pharmacy in Virginia or a registered non-resident pharmacy under the following conditions:

1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy;
2. Any central or remote pharmacy shall comply with Virginia law and regulation with respect to requirements for supervision of pharmacy technicians and the duties which are restricted to pharmacists and pharmacy technicians. Pharmacy technicians at the remote pharmacy shall either be registered in Virginia or possess credentials substantially equivalent to those required for a technician registered in Virginia;
3. Any pharmacist participating in remote prescription order processing shall be a Virginia licensed pharmacist; and

4. The pharmacies shall share a common electronic file or have technology which allows sufficient information necessary to process a prescription order.

C. A policy and procedure manual that relates to remote processing shall be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following:
1. The responsibilities of each pharmacy;
2. A list of the name, address, telephone numbers, and permit/registration numbers of all pharmacies involved in remote processing;
3. Procedures for protecting the confidentiality and integrity of patient information;
4. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;
5. Procedures for maintaining required records;
6. Procedures for complying with all applicable laws and regulations;
7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and
8. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.

D. A pharmacy involved in remote prescription order processing shall maintain a record that identifies each person who performed a processing function for every order.
1. The record shall be available by prescription order or by patient name.
2. The record may be maintained in a common electronic file if the record is maintained in such a manner that the data processing system can produce a printout which identifies every person who performed a task involved in processing a prescription order and the location where the task was processed.
3. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board.

E. Nothing in this section shall prohibit an individual employee licensed as a pharmacist in Virginia from accessing the employer pharmacy's database from a remote location for the purpose of performing certain prescription processing functions as described in subsection A, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

Virginia Board of Pharmacy

Competency Examination Required for Licensure as a Pharmacist NAPLEX Passing Score

In addition to other requirements of law or regulation, pharmacists applying for licensure by examination or endorsement must pass a competence assessment examination approved by the Board.

Pharmacists examined after June 1, 1979 must pass or have passed the National Association of Boards of Pharmacy Licensure Examination (NABPLEX) or its successor examination, the North American Pharmacist Licensure Examination (NAPLEX). The Board determines that the minimum acceptable passing score for the NAPLEX is 75 on the NAPLEX scale and adopts by reference the method for calculating the score as outlined in the current edition of the NAPLEX Registration Bulletin.

For pharmacists applying for licensure by endorsement, who were initially examined prior to June 1, 1979, the Board will accept the originating state's competence assessment examination and passing score as satisfactory evidence of meeting the same standard of competence required for licensure by examination in Virginia at that time.

Virginia Board of Pharmacy

Life of a Prescription When the Prescriber Is No Longer In Practice

Whenever a prescriber is no longer in practice due to death, extended illness, retirement, relocation, suspension or revocation of the license by the relevant licensing board, or other reason, pharmacists question whether they can fill or continue to refill prescriptions that were written prior to the cessation of practice. There will be prescriptions which have been filled, but for which there are still valid refills remaining. There will probably also be prescriptions written prior to the ceasing of practice, but not yet presented to a pharmacy for filling by the patient for any number of reasons. This could include Schedule II prescriptions written with "do not fill until *<future date>*" instructions.

While there is nothing in law that specifically addresses this issue, §54.1-3303 does state that no prescription shall be filled which does not result from a bona fide practitioner-patient-pharmacist relationship. At the point in time when the prescription was written and refills authorized, it is assumed that a bona fide relationship existed and that the prescriber envisioned that the patient could safely receive the authorized refills without further intervention on his part. However, while still in practice, the prescriber would be available for consultation should questions or problems arise. Once the prescriber retires, is suspended, moves from the area, etc. he is no longer available for consultation, and there is no longer a relationship if a problem occurs.

The Board believes that, in the absence of any specific instructions from the original prescriber or a subsequent practitioner assuming medical care of the patient, the decision to fill or refill these prescriptions should be left to the professional judgment of the pharmacist. Each prescription should be evaluated on an individual basis to determine which course of action would be in the best interest of the patient. At the same time, each patient should be encouraged to establish a relationship with a new medical practitioner as soon as possible and have that practitioner write new prescriptions for any required drugs. In cases where a license is denied, suspended, revoked, or restricted, in whole or part, because of illegal or inappropriate prescribing practices, the pharmacist must carefully evaluate the prescription and any remaining refills to determine if the prescription actually resulted from a bona fide practitioner-patient relationship at the time written, and if it was written for a legitimate medical purpose.

Virginia Board of Pharmacy

Failure to report to the Prescription Monitoring Program

The Board has determined standard procedures and sanctions for pharmacies who fail to submit timely required reports to the prescription monitoring program. A first letter will be sent concerning non-reporting and, if no response or an inadequate response if received, a certified letter would then be mailed.

Should the dispenser still not respond or give an inadequate response, the matter will be referred for disciplinary action to include, but not be limited to, the offering of a pre-hearing consent order requiring the immediate submission of the required data and a $500 fine for each unreported period.

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Virginia Board of Pharmacy

Performing Inventories

Various sections of law or regulation, to include §§ 54.1-3404 and 54.1-3434 of the Code of Virginia and 18 VAC 110-20-240 of the Regulations of the Board of Pharmacy, address requirements for performing an inventory of drugs in Schedules I-V. However, it is unclear whether certain individuals are required to perform a physical count of the drugs when performing the inventories. Recently, the Board concluded the following:

- Those persons required in law to perform an inventory of drugs shall physically count the drugs in Schedules I-V when a theft or any other unusual loss has occurred, and he is unable to determine the exact kind and quantity of the drug loss;

- Dispensers, researchers, and reverse distributors may otherwise perform the inventory in a manner consistent with federal allowances, as listed in 21 CFR 1304.11 (attached to this document), which require a physical count of drugs in Schedules I and II, but allow for an estimation of drugs in Schedules III-V unless the container contains greater than 1,000 tablets/capsules; and

- Nothing shall prohibit a person from choosing to perform a physical count of all drugs listed in Schedules I-V when performing an inventory.

Drugs that have been separated from the working stock that may be expired or earmarked for return or destruction must be included in an inventory of drugs in Schedules I-V.

Additionally, to comply with the requirement to perform a perpetual inventory of Schedule II drugs as stated in Regulation 18 VAC 110-20-240, the perpetual inventory record must accurately indicate the physical count of each Schedule II drug "on-hand" at the time of performing the inventory. Furthermore, to comply with the requirement to perform the required "reconciliation" of the perpetual inventory, an explanation for any difference between the physical count and the theoretical count must be noted.

from 21 CFR 1304.11

Section 1304.11 Inventory Requirements

(a)*General requirements.* Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

(b)*Initial inventory date.* Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.

(c) *Biennial inventory date.* After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

(d)*Inventory date for newly controlled substances.* On the effective date of a rule by the Administrator pursuant to §§1308.45, 1308.46, or 1308.47 of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance shall be included in each inventory made by the registrant pursuant to paragraph (c) of this section.

(e)*Inventories of manufacturers, distributors, dispensers, researchers, importers, exporters and chemical analysts.* Each person registered or authorized (by §1301.13 or §§1307.11–1307.13 of this chapter) to manufacture, distribute, dispense, import, export, conduct research or chemical analysis with controlled substances and required to keep records pursuant to §1304.03 shall include in the inventory the information listed below.

(1) *Inventories of manufacturers.* Each person registered or authorized to manufacture controlled substances shall include the following information in the inventory:

(i) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or non-controlled substances in finished form, the inventory shall include:

(A) The name of the substance and

(B) The total quantity of the substance to the nearest metric unit weight consistent with unit size.

(ii) For each controlled substance in the process of manufacture on the inventory date, the inventory shall include:

(A) The name of the substance;

(B) The quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number; and

(C) The physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number or volume thereof.

(iii)For each controlled substance in finished form the inventory shall include:

(A) The name of the substance;

(B) Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(C) The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and

(D) The number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).

(iv)For each controlled substance not included in paragraphs (e)(1)
(i), (ii) or (iii) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings) the inventories shall include:

(A) The name of the substance;

(B) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

(C) The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

(2) *Inventories of distributors.* Except for reverse distributors covered by paragraph (e)(3) of this section, each person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section.

(3) *Inventories of dispensers, researchers, and reverse distributors.* Each person registered or authorized to dispense, conduct research, or act as a reverse distributor with controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser, researcher, or reverse distributor shall do as follows:

(i) If the substance is listed in Schedule I or II, make an exact count or measure of the contents, or

(ii) If the substance is listed in Schedule III, IV or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.

(4)*Inventories of importers and exporters.* Each person registered or authorized to import or export controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section. Each such person who is also registered as a manufacturer or as a distributor shall include in his/her inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).

(5)*Inventories of chemical analysts.* Each person registered or authorized to conduct chemical analysis with controlled substances shall include in his inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section as to substances which have been manufactured, imported, or received by such person. If less than 1 kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I), or less than 20 grams of a hallucinogenic substance listed in Schedule I (other than lysergic acid diethylamide), or less than 0.5 gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory. Laboratories of the Administration may possess up to 150 grams of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances. No inventory is required of known or suspected controlled substances received as evidentiary materials for analysis.

Agenda Item: Petition for rulemaking:

Included in your package are:

Copy of petition from Joseph Lavino

Copy of Comments on the petition

Copy of applicable law and regulation

Staff note:

Lavino petition was discussed at the 12/11/7 Board meeting and motion made to refer it to the Regulation Committee for further review and decision on a Notice of Intended Regulatory Action (NOIRA).

At its meeting on April 24, 2018, the Regulation Committee voted to recommend issuance of a NOIRA to initiate rulemaking. The content of the amended regulation would be decided after the comment period closes.

Board action – Publication of a NOIRA or other decision on petitioner's request

COMMONWEALTH OF VIRGINIA
Board of Pharmacy

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

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

Petition for Rule-making

The Code of Virginia (§ 2.2-4007) and the Public Participation Guidelines of this board require a person who wishes to petition the board to develop a new regulation or amend an existing regulation to provide certain information. Within 14 days of receiving a valid petition, the board will notify the petitioner and send a notice to the Register of Regulations identifying the petitioner, the nature of the request and the plan for responding to the petition. Following publication of the petition in the Register, a 21-day comment period will begin to allow written comment on the petition. Within 90 days after the comment period, the board will issue a written decision on the petition.

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

Petitioner's full name (Last, First, Middle initial, Suffix,) Lavino, Joseph		
Street Address 1 CVS Drive, Mail Code 2325	Area Code and Telephone Number 401-369-0745	
City Woonsocket	State RI	Zip Code 01887
Email Address (optional) Joseph.Lavino@CVSHealth.com	Fax (optional)	

Respond to the following questions:

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

CVS Health is petitioning the Virginia Board of Pharmacy, to amend18 VAC 110-20-275(B)(2)(d), which pertains to the delivery of dispensed prescriptions.

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

18 VAC 110-20-275(B)(2)(d) requires that pharmacies, which fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup, maintain and comply with all procedures in a current policy and procedure manual that includes the procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription. While the regulation contemplates a model where a pharmacy is filling a prescription on behalf of a requesting pharmacy, which subsequently receives the prescription back for delivery, we do not believe the regulation contemplates situations where prescriptions are held for pick-up or further delivery at a pharmacy location, at a patient's request and without that pharmacy location's involvement in any part in the dispensing process other than delivery to the patient or the patient's agent ("Depot pharmacy").

Based on the current interpretation of the Virginia Board of pharmacy, in those cases where prescriptions are held for pick-up or further delivery at a depot pharmacy, the label on the prescription container would require the name and address of the pharmacy holding the prescription for pick-up or further delivery. This creates potential patient safety risks, confusion for patients and a redundancy.

As the Board is aware, the ability to craft a prescription label with adequate font size, white space, and highlighting of critical prescription elements is an essential component in driving patient adherence to medication as prescribed. The addition of a depot pharmacy name and address to a label may have the potential of encroaching on the essential elements of a label needed to drive adherence. Per the NABP Model State Pharmacy Act and Model Rules, the pharmacy name, while considered important information on a label, is not considered critical information for patients and should not supersede critical label information. Additionally, the Institute for Safe Medication Practices ("ISMP"), whose position is that the risk of medication error can occur when labels are poorly designed, made several recommendations on pharmacy label design based on an analysis of actual medication errors reported and a review of pharmacy-generated labels produced by a number of systems. Based on those recommendations, ISMP concluded that a pharmacy's information, if required at all, is not a critical element to reduce medication errors and may be placed at the bottom of the label. Of note, this recommendation contemplates the inclusion of information on a single pharmacy rather than multiple pharmacies, if required at all.

Secondly, the addition of a depot pharmacy name and address to a label may cause confusion to the patient. A pharmacy that did not participate in the filling and dispensing of a prescription, and serves solely to deliver the prescription to the patient or their agent, would not be best positioned to answer patient questions on the filling and dispensing processes of that prescription from a patient. The patient may be further confused as to which pharmacy(s) actually performed prescription processing or filling functions, mistaking the depot pharmacy as providing those functions.

Lastly, the addition of a depot pharmacy name and address to a label, for the sole purpose of providing the patient information on which pharmacy held the prescription for pick-up or further delivered it is a redundancy. The patient would likely be provided additional information or documentation (i.e. a leaflet or receipt) indicating the name and address of the pharmacy, which held the prescription for pick-up or further delivered the prescription to the patient. In the case of a patient or patient's agent physically presenting to a depot pharmacy, the patient or patient's agent would be physically present and have firsthand knowledge of which pharmacy delivered the prescription. Lastly, the patient or patient's agent would have knowledge of the name and address of the depot pharmacy because they would be in control of requesting the pharmacy location at which to pick-up the prescription.

Given these factors, CVS Health proposes the following amendments to 18 VAC 110-20-275(B)(2)(d):

d. The procedure for identifying on the prescription label a unique identifier for all pharmacies involved in filling and dispensing the prescription. This unique identifier is not required to identify a pharmacy solely involved in the holding of a prescription for pick-up or further delivery when that pharmacy has not shared in other filling or dispensing functions;

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

The general powers and duties of the Virginia Board of Pharmacy shall be to promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) which are reasonable and necessary to administer effectively the regulatory system.

Virginia.gov Agencies | Governor

Logged in as
Elaine J. Yeatts

Department of Health Professions

Board **Board of Pharmacy**

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

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

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Commenter: Keith Richardson 11/6/17 9:04 am

Reply

I am okay with removing the unique identifer as suggested by the petition for rulemaking

However to the best of my knowledge

National Council for Prescription Drug Programs (NCPDP) maintains NPI
(National Provider Identifier)

All licensed pharmacies are assigned a seven digit number known as the **NCPDP** Provider **ID**.

National Provider Identifier (NPI) is a ten digit number

A npi is searchable and accessible online

A npi is synonymous to an individual

If the unique identifer is to be removed

Other than payor sheets

By which means does anyone have the ability to reference a pharamacy?

Is there a way to find a pharmacy?

Commenter: Rx Partnership 11/17/17 2:57 pm

Rx Partnership favors amendment

Rx Partnership, a nonprofit organization working statewide to increase medication access, supports this amendment as proposed in the petition. The change would increase efficiency and ease related to providing prescriptions for individuals who need a convenient location for pick-up that may not necessarily be where the prescription was filled.

We believe this amendment will help encourage more pharmacies to be involved in helping patients receive medications at a preferred location. Many of the low income and uninsured patients Rx Partnership supports experience transportation challenges and being able to receive medication(s) at a preferred pharmacy would greatly improve medication adherence and health outcomes.

CVSHealth

Lauren Berton, PharmD | 200 Highland Corporate Drive | Woonsocket, RI 02895 | T: 540-604-3661

November 20, 2017

Caroline Juran, RPH
Executive Director
Virginia Board of Pharmacy
9960 Mayland Drive
Suite 300
Richmond, VA 23233-1463
Caroline.juran@dhp.virginia.gov

Re: Proposed amendment to 18VAC110-20-275. Delivery of dispensed prescriptions.

Dear Executive Director Juran:

I am writing to you in my capacity as 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 to 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 proposed amendment to 18VAC110-20-275 Delivery of Dispensed Prescriptions. 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.

CVS Health appreciates the Board's acceptance of Petition for Rule-making to amend 18VAC 110-20-275 which changes the policy and procedure requirements for delivery to another pharmacy allowing for a unique identifier to be used in identifying all pharmacies used in filling and dispensing the prescription. Amendments also include the allowance for the unique identifier to not be placed on the label if the pharmacy solely holds the prescription for further pick up and delivery without being involved in the filling and dispensing. The Institute for Safe Medication Practices provided industry guidelines for medication labels for community and mail order pharmacies. They suggest maximixing the use of white space on a label to improve medication adherence and reduce inadvertent medication errors. These changes would assist in achieving maximum white space, while still providing an audit trail for the tracking of the prescription as required.

CVS Health appreciates the opportunity to submit comments for this proposed rule amendment. If you have any questions, please contact me directly at 540-604-3661.

Sincerely,

Lauren Berton, PharmD

Lauren Berton, PharmD.
Director, Pharmacy Regulatory Affairs
CVS Health

§ 54.1-3420.2. Delivery of prescription drug order.

A. Whenever any pharmacy permitted to operate in this Commonwealth or nonresident pharmacy registered to conduct business in the Commonwealth delivers a prescription drug order by mail, common carrier, or delivery service, when the drug order is not personally hand delivered directly, to the patient or his agent at the person's residence or other designated location, the following conditions shall be required:

1. Written notice shall be placed in each shipment alerting the consumer that under certain circumstances chemical degradation of drugs may occur; and

2. Written notice shall be placed in each shipment providing a toll-free or local consumer access telephone number which is designed to respond to consumer questions pertaining to chemical degradation of drugs.

B. If a prescription drug order for a Schedule VI controlled substance is not personally hand delivered directly to the patient or the patient's agent, or if the prescription drug order is not delivered to the residence of the patient, the delivery location shall hold a current permit, license, or registration with the Board that authorizes the possession of controlled substances at that location. The Board shall promulgate regulations related to the security, access, required records, accountability, storage, and accuracy of delivery of such drug delivery systems. Schedule II through Schedule V controlled substances shall be delivered to an alternate delivery location only if such delivery is authorized by federal law and regulations of the Board.

C. Prescription drug orders dispensed to a patient and delivered to a community services board or behavioral health authority facility licensed by the Department of Behavioral Health and Developmental Services upon the signed written request of the patient or the patient's legally authorized representative may be stored, retained, and repackaged at the facility on behalf of the patient for subsequent delivery or administration. The repackaging of a dispensed prescription drug order retained by a community services board or behavioral health authority facility for the purpose of assisting a client with self-administration pursuant to this subsection shall only be performed by a pharmacist, pharmacy technician, nurse, or other person who has successfully completed a Board-approved training program for repackaging of prescription drug orders as authorized by this subsection. The Board shall promulgate regulations relating to training, packaging, labeling, and recordkeeping for such repackaging.

D. Prescription drug orders dispensed to a patient and delivered to a Virginia Department of Health or local health department clinic upon the signed written request of a patient, a patient's legally authorized representative, or a Virginia Department of Health district director or his designee may be stored and retained at the clinic on behalf of the patient for subsequent delivery or administration.

E. Prescription drug orders dispensed to a patient and delivered to a program of all-inclusive care for the elderly (PACE) site licensed by the Department of Social Services pursuant to § 63.2-1701 and overseen by the Department of Medical Assistance Services in accordance with § 32.1-330.3 upon the signed written request of the patient or the patient's legally authorized representative may be stored, retained, and repackaged at the site on behalf of the patient for subsequent delivery or administration. The repackaging of a dispensed prescription drug order

retained by the PACE site for the purpose of assisting a client with self-administration pursuant to this subsection shall only be performed by a pharmacist, pharmacy technician, nurse, or other person who has successfully completed a Board-approved training program for repackaging of prescription drug orders as authorized by this subsection. The Board shall promulgate regulations relating to training, packaging, labeling, and recordkeeping for such repackaging.

1998, c. 597; 2002, c. 411; 2010, c. 28; 2015, c. 505.

18VAC110-20-275. Delivery of dispensed prescriptions.

A. Pursuant to § 54.1-3420.2 B of the Code of Virginia, in addition to direct hand delivery to a patient or patient's agent or delivery to a patient's residence, a pharmacy may deliver a dispensed prescription drug order for Schedule VI controlled substances to another pharmacy, to a practitioner of the healing arts licensed to practice pharmacy or to sell controlled substances, or to an authorized person or entity holding a controlled substances registration issued for this purpose in compliance with this section and any other applicable state or federal law. Prescription drug orders for Schedule II through Schedule V controlled substances may not be delivered to an alternate delivery location unless such delivery is authorized by federal law and regulations of the board.

B. Delivery to another pharmacy.

1. One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup or direct delivery to the patient provided the two pharmacies have the same owner, or have a written contract or agreement specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with all applicable federal and state law.

2. Each pharmacy using such a drug delivery system shall maintain and comply with all procedures in a current policy and procedure manual that includes the following information:

a. A description of how each pharmacy will comply with all applicable federal and state law;

b. The procedure for maintaining required, retrievable dispensing records to include which pharmacy maintains the hard-copy prescription, which pharmacy maintains the active prescription record for refilling purposes, how each pharmacy will access prescription information necessary to carry out its assigned responsibilities, method of recordkeeping for identifying the pharmacist or pharmacists responsible for dispensing the prescription and counseling the patient, and how and where this information can be accessed upon request by the board;

c. The procedure for tracking the prescription during each stage of the filling, dispensing, and delivery process;

d. The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription;

e. The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information;

f. The policy and procedure for ensuring accuracy and accountability in the delivery process;

g. The procedure and recordkeeping for returning to the initiating pharmacy any prescriptions that are not delivered to the patient; and

h. The procedure for informing the patient and obtaining consent for using such a dispensing and delivery process.

3. Drugs waiting to be picked up at or delivered from the second pharmacy shall be stored in accordance with subsection A of 18VAC110-20-200.

C. Delivery to a practitioner of the healing arts licensed by the board to practice pharmacy or to sell controlled substances or other authorized person or entity holding a controlled substances registration authorized for this purpose.

1. A prescription may be delivered by a pharmacy to the office of such a practitioner or other authorized person provided there is a written contract or agreement between the two parties describing the procedures for such a delivery system and the responsibilities of each party.

2. Each pharmacy using this delivery system shall maintain a policy and procedure manual that includes the following information:

a. Procedure for tracking and assuring security, accountability, integrity, and accuracy of delivery for the dispensed prescription from the time it leaves the pharmacy until it is handed to the patient or agent of the patient;

b. Procedure for providing counseling;

c. Procedure and recordkeeping for return of any prescription medications not delivered to the patient;

d. The procedure for assuring confidentiality of patient information; and

e. The procedure for informing the patient and obtaining consent for using such a delivery process.

3. Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in a lockable room or lockable cabinet, cart, or other device which cannot be easily moved and which shall be locked at all times when not in use. Access shall be restricted to the licensed practitioner

of the healing arts or the responsible party listed on the application for the controlled substances registration, or either person's designee.

D. The contracts or agreements and the policy and procedure manuals required by this section for alternate delivery shall be maintained both at the originating pharmacy as well as the alternate delivery site.

E. A controlled substances registration as an alternate delivery site shall only be issued to an entity without a prescriber or pharmacist present at all times the site is open if there is a valid patient health or safety reason not to deliver dispensed prescriptions directly to the patient and if compliance with all requirements for security, policies, and procedures can be reasonably assured.

Agenda Item: Adoption of Revised Emergency Regulations for Pharmaceutical Processors of Cannabidioil and THC-A oil

Included in your agenda package are:

Copies of the 2018 legislation mandating adoption of emergency regulations to implement provisions of the Acts (HB1251 and SB330)

A copy of the revised emergency regulations as recommended by the Regulation Committee

Board action:

Adoption of revised emergency regulations - (must in effect by12/14/18)

CHAPTER 246

An Act to amend and reenact §§ 18.2-250.1, 54.1-3408.3, 54.1-3442.5, and 54.1-3442.7 of the Code of Virginia, relating to certification for use of cannabidiol oil or THC-A oil.

[H 1251]

Approved March 9, 2018

Be it enacted by the General Assembly of Virginia:

1. That §§ 18.2-250.1, 54.1-3408.3, 54.1-3442.5, and 54.1-3442.7 of the Code of Virginia are amended and reenacted as follows:

§ 18.2-250.1. Possession of marijuana unlawful.

A. It is unlawful for any person knowingly or intentionally to possess marijuana unless the substance was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of his professional practice, or except as otherwise authorized by the Drug Control Act (§ 54.1-3400 et seq.).

Upon the prosecution of a person for violation of this section, ownership or occupancy of the premises or vehicle upon or in which marijuana was found shall not create a presumption that such person either knowingly or intentionally possessed such marijuana.

Any person who violates this section is guilty of a misdemeanor and shall be confined in jail not more than 30 days and fined not more than $500, either or both; any person, upon a second or subsequent conviction of a violation of this section, is guilty of a Class 1 misdemeanor.

B. The provisions of this section shall not apply to members of state, federal, county, city, or town law-enforcement agencies, jail officers, or correctional officers, as defined in § 53.1-1, certified as handlers of dogs trained in the detection of controlled substances when possession of marijuana is necessary for the performance of their duties.

C. In any prosecution under this section involving marijuana in the form of cannabidiol oil or THC-A oil as those terms are defined in § 54.1-3408.3, it shall be an affirmative defense that the individual possessed such oil pursuant to a valid written certification issued by a practitioner in the course of his professional practice pursuant to § 54.1-3408.3 for treatment or to alleviate the symptoms of (i) the individual's ~~intractable epilepsy~~ *diagnosed condition or disease* or (ii) if such individual is the parent or legal guardian of a minor or of an incapacitated adult as defined in § 18.2-369, such minor's or incapacitated adult's ~~intractable epilepsy~~ *diagnosed condition or disease*. If the individual files the valid written certification with the court at least 10 days prior to trial and causes a copy of such written certification to be delivered to the attorney for the Commonwealth, such written certification shall be prima facie evidence that such oil was possessed pursuant to a valid written certification.

§ 54.1-3408.3. Certification for use of cannabidiol oil or THC-A oil for treatment.

A. As used in this section:

"Cannabidiol oil" means a processed Cannabis plant extract that contains at least 15 percent cannabidiol but no more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least ~~50~~ *five* milligrams of cannabidiol per milliliter but not more than five percent tetrahydrocannabinol.

"Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine ~~who is a neurologist or who specializes in the treatment of epilepsy~~.

"THC-A oil" means a processed Cannabis plant extract that contains at least 15 percent tetrahydrocannabinol acid but not more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least ~~50~~ *five* milligrams of tetrahydrocannabinol acid per milliliter but not more than five percent tetrahydrocannabinol.

B. A practitioner in the course of his professional practice may issue a written certification for the use of cannabidiol oil or THC-A oil for treatment or to alleviate the symptoms of ~~a patient's intractable epilepsy~~ *any diagnosed condition or disease determined by the practitioner to benefit from such use*.

C. The written certification shall be on a form provided by the Office of the Executive Secretary of the Supreme Court developed in consultation with the Board of Medicine. Such written certification shall contain the name, address, and telephone number of the practitioner, the name and address of the patient issued the written certification, the date on which the written certification was made, and the signature of the practitioner. Such written certification issued pursuant to subsection B shall expire no later than one year after its issuance unless the practitioner provides in such written certification an earlier expiration.

D. No practitioner shall be prosecuted under § 18.2-248 or 18.2-248.1 for dispensing or distributing cannabidiol oil or THC-A oil for the treatment or to alleviate the symptoms of a patient's ~~intractable epilepsy~~ *diagnosed condition or disease* pursuant to a written certification issued pursuant to subsection

B. Nothing in this section shall preclude the Board of Medicine from sanctioning a practitioner for failing to properly evaluate or treat a patient's medical condition or otherwise violating the applicable standard of care for evaluating or treating medical conditions.

E. A practitioner who issues a written certification to a patient pursuant to this section shall register with the Board. The Board shall, in consultation with the Board of Medicine, set a limit on the number of patients to whom a practitioner may issue a written certification.

F. A patient who has been issued a written certification shall register with the Board or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, a patient's parent or legal guardian shall register and shall register such patient with the Board.

G. The Board shall promulgate regulations to implement the registration process. Such regulations shall include (i) a mechanism for sufficiently identifying the practitioner issuing the written certification, the patient being treated by the practitioner, and, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian; (ii) a process for ensuring that any changes in the information are reported in an appropriate timeframe; and (iii) a prohibition for the patient to be issued a written certification by more than one practitioner during any given time period.

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

§ 54.1-3442.5. Definitions.

As used in this article:

"Cannabidiol oil" has the same meaning as specified in § 54.1-3408.3.

"Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant to § 54.1-3408.3 and (ii) cultivates Cannabis plants intended only for the production of cannabidiol oil or THC-A oil, produces cannabidiol oil or THC-A oil, and dispenses cannabidiol oil or THC-A oil to a registered patient or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian ~~for the treatment of intractable epilepsy~~.

"Practitioner" has the same meaning as specified in § 54.1-3408.3.

"THC-A oil" has the same meaning as specified in § 54.1-3408.3.

§ 54.1-3442.7. Dispensing cannabidiol oil and THC-A oil; report.

A. A pharmaceutical processor shall dispense or deliver cannabidiol oil or THC-A oil only in person to (i) a patient who is a Virginia resident, has been issued a valid written certification, and is registered with the Board pursuant to § 54.1-3408.3 or (ii) if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian who is a Virginia resident and is registered with the Board pursuant to § 54.1-3408.3. Prior to dispensing, the pharmaceutical processor shall verify that the practitioner issuing the written certification, the patient, and, if such patient is a minor or an incapacitated adult, the patient's parent or legal guardian are registered with the Board. No pharmaceutical processor shall dispense more than a ~~30-day~~ *90-day*supply for any patient during any ~~30-day~~ *90-day* period. The Board shall establish in regulation an amount of cannabidiol oil or THC-A oil that constitutes a ~~30-day~~ *90-day* supply to treat or alleviate the symptoms of a patient's ~~intractable epilepsy~~ *diagnosed condition or disease*.

B. A pharmaceutical processor shall dispense only cannabidiol oil and THC-A oil that has been cultivated and produced on the premises of such pharmaceutical processor.

C. The Board shall report annually by December 1 to the Chairmen of the House and Senate Committees for Courts of Justice on the operation of pharmaceutical processors issued a permit by the Board, including the number of practitioners, patients, and parents or legal guardians of patients who have registered with the Board and the number of written certifications issued pursuant to § 54.1-3408.3.

2. That an emergency exists and this act is in force from its passage.

CHAPTER 567

An Act to amend and reenact §§ 54.1-2519, 54.1-2521, 54.1-2522.1, as it is currently effective and as it shall become effective, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia, relating to dispensing of THC-A oil; tetrahydrocannabinol levels and stability testing.

[S 330]

Approved March 30, 2018

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-2519, 54.1-2521, 54.1-2522.1, as it is currently effective and as it shall become effective, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-2519. Definitions.

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

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by (i) a practitioner or, under the practitioner's direction, his authorized agent or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"Bureau" means the Virginia Department of State Police, Bureau of Criminal Investigation, Drug Diversion Unit.

"Controlled substance" means a drug, substance or immediate precursor in Schedules I through VI of the Drug Control Act, Chapter 34 (§ 54.1-3400 et seq.) of this title.

"Covered substance" means all controlled substances included in Schedules II, III, and IV and all drugs of concern that are required to be reported to the Prescription Monitoring Program, pursuant to this chapter. *"Covered substance" also includes cannabidiol oil or THC-A oil dispensed by a pharmaceutical processor in Virginia.*

"Department" means the Virginia Department of Health Professions.

"Director" means the Director of the Virginia Department of Health Professions.

"Dispense" means to deliver a controlled substance 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 that delivery.

"Dispenser" means a person or entity that (i) is authorized by law to dispense a covered substance or to maintain a stock of covered substances for the purpose of dispensing, and (ii) dispenses the covered substance to a citizen of the Commonwealth regardless of the location of the dispenser, or who dispenses such covered substance from a location in Virginia regardless of the location of the recipient.

"Drug of concern" means any drug or substance, including any controlled substance or other drug or substance, where there has been or there is the potential for abuse and that has been identified by the Board of Pharmacy pursuant to § 54.1-3456.1.

"Prescriber" means a practitioner licensed in the Commonwealth who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance or a practitioner licensed in another state to so issue a prescription for a covered substance.

"Recipient" means a person who receives a covered substance from a dispenser.

"Relevant health regulatory board" means any such board that licenses persons or entities with the authority to prescribe or dispense covered substances, including, but not limited to, the Board of Dentistry, the Board of Medicine, and the Board of Pharmacy.

§ 54.1-2521. Reporting requirements.

A. The failure by any person subject to the reporting requirements set forth in this section and the Department's regulations to report the dispensing of covered substances shall constitute grounds for disciplinary action by the relevant health regulatory board.

B. Upon dispensing a covered substance, a dispenser of such covered substance shall report the following information:

1. The recipient's name and address.
2. The recipient's date of birth.
3. The covered substance that was dispensed to the recipient.
4. The quantity of the covered substance that was dispensed.
5. The date of the dispensing.
6. The prescriber's identifier number *and, in cases in which the covered substance is cannabidiol oil or THC-A oil, the expiration date of the written certification.*
7. The dispenser's identifier number.
8. The method of payment for the prescription.

9. Any other non-clinical information that is designated by the Director as necessary for the implementation of this chapter in accordance with the Department's regulations.

10. Any other information specified in regulations promulgated by the Director as required in order for the Prescription Monitoring Program to be eligible to receive federal funds.

C. The reports required herein shall be made to the Department or its agent within 24 hours or the dispenser's next business day, whichever comes later, and shall be made and transmitted in such manner and format and according to the standards and schedule established in the Department's regulations.

§ 54.1-2522.1. (Effective until July 1, 2022) Requirements of practitioners.

A. Any prescriber who is licensed in the Commonwealth to treat human patients and is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance shall be registered with the Prescription Monitoring Program by the Department of Health Professions.

B. A prescriber registered with the Prescription Monitoring Program or a person to whom he has delegated authority to access information in the possession of the Prescription Monitoring Program pursuant to § 54.1-2523.2 shall, at the time of initiating a new course of treatment to a human patient that includes the prescribing of opioids anticipated at the onset of treatment to last more than seven consecutive days, request information from the Director for the purpose of determining what, if any, other covered substances are currently prescribed to the patient. In addition, any prescriber who holds a special identification number from the Drug Enforcement Administration authorizing the prescribing of controlled substances approved for use in opioid addiction therapy shall, prior to or as a part of execution of a treatment agreement with the patient, request information from the Director for the purpose of determining what, if any, other covered substances the patient is currently being prescribed. Nothing in this section shall prohibit prescribers from making additional periodic requests for information from the Director as may be required by routine prescribing practices.

C. A prescriber shall not be required to meet the provisions of subsection B if:

1. The opioid is prescribed to a patient currently receiving hospice or palliative care;

2. The opioid is prescribed to a patient as part of treatment for a surgical or invasive procedure and such prescription is for no more than 14 consecutive days;

3. The opioid is prescribed to a patient during an inpatient hospital admission or at discharge;

4. The opioid is prescribed to a patient in a nursing home or a patient in an assisted living facility that uses a sole source pharmacy;

5. The Prescription Monitoring Program is not operational or available due to temporary technological or electrical failure or natural disaster; or

6. The prescriber is unable to access the Prescription Monitoring Program due to emergency or disaster and documents such circumstances in the patient's medical record.

D. Prior to issuing a written certification for the use of cannabidiol oil or THC-A oil in accordance with § 54.1-3408.3, a practitioner shall request information from the Director for the purpose of determining what, if any, other covered substances have been dispensed to the patient.

§ 54.1-2522.1. (Effective July 1, 2022) Requirements of practitioners.

A. Any prescriber who is licensed in the Commonwealth to treat human patients and is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance shall be registered with the Prescription Monitoring Program by the Department of Health Professions.

B. Prescribers registered with the Prescription Monitoring Program shall, at the time of initiating a new course of treatment to a human patient that includes the prescribing of benzodiazepine or an opiate anticipated at the onset of treatment to last more than 90 consecutive days, request information from the Director for the purpose of determining what, if any, other covered substances are currently prescribed to the patient. In addition, any prescriber who holds a special identification number from the Drug Enforcement Administration authorizing the prescribing of controlled substances approved for use in opioid addiction therapy shall, prior to or as a part of execution of a treatment agreement with the patient, request information from the Director for the purpose of determining what, if any, other covered substances the patient is currently being prescribed. Nothing in this section shall prohibit prescribers from making additional periodic requests for information from the Director as may be required by routine prescribing practices.

C. The Secretary of Health and Human Resources may identify and publish a list of benzodiazepines or opiates that have a low potential for abuse by human patients. Prescribers who prescribe such identified benzodiazepines or opiates shall not be required to meet the provisions of subsection B. In addition, a prescriber shall not be required to meet the provisions of subsection B if the course of treatment arises from pain management relating to dialysis or cancer treatments.

D. Prior to issuing a written certification for the use of cannabidiol oil or THC-A oil in accordance with § 54.1-3408.3, a practitioner shall request information from the Director for the purpose of determining what, if any, other covered substances have been dispensed to the patient.

§ 54.1-3442.6. Permit to operate pharmaceutical processor.

A. No person shall operate a pharmaceutical processor without first obtaining a permit from the Board. The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the pharmaceutical processor. The Board shall

establish an application fee and other general requirements for such application.

B. Each permit shall expire annually on a date determined by the Board in regulation. The number of permits that the Board may issue or renew in any year is limited to one for each health service area established by the Board of Health. Permits shall be displayed in a conspicuous place on the premises of the pharmaceutical processor.

C. The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors. Such regulations shall include requirements for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum equipment and resources; (v) recordkeeping; (vi) labeling and packaging; (vii) quarterly inspections; (viii) processes for safely and securely cultivating Cannabis plants intended for producing cannabidiol oil and THC-A oil, producing cannabidiol oil and THC-A oil, and dispensing and delivering in person cannabidiol oil and THC-A oil to a registered patient or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian; (ix) a maximum number of marijuana plants a pharmaceutical processor may possess at any one time; ~~and~~ (x) the secure disposal of plant remains*; and (xi) a process for registering a cannabidiol oil and THC-A oil product.*

D. Every pharmaceutical processor shall be under the personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor.

E. *The Board shall require an applicant for a pharmaceutical processor permit to submit to fingerprinting and provide personal descriptive information to be forwarded along with his fingerprints through the Central Criminal Records Exchange to the Federal Bureau of Investigation for the purpose of obtaining criminal history record information regarding the applicant. The cost of fingerprinting and the criminal history record search shall be paid by the applicant. The Central Criminal Records Exchange shall forward the results of the criminal history background check to the Board or its designee, which shall be a governmental entity.*

F. No person who has been convicted of a felony or of any offense in violation of Article 1 (§ 18.2-247 et seq.) or Article 1.1 (§ 18.2-265.1 et seq.) of Chapter 7 of Title 18.2 shall be employed by or act as an agent of a pharmaceutical processor.

§ 54.1-3442.7. Dispensing cannabidiol oil and THC-A oil; report.

A. A pharmaceutical processor shall dispense or deliver cannabidiol oil or THC-A oil only in person to (i) a patient who is a Virginia resident, has been issued a valid written certification, and is registered with the Board pursuant to § 54.1-3408.3 or (ii) if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian who is a Virginia resident and is registered with the Board pursuant to § 54.1-3408.3. Prior to *the initial* dispensing *of each written certification*, the *pharmacist or pharmacy technician at the location of the* pharmaceutical processor shall ~~verify that the practitioner issuing the written certification, the patient, and, if such patient is a minor or an incapacitated adult, the patient's parent or legal guardian are registered with the Board~~ *make and maintain for two years a paper or electronic copy of the written certification that provides an exact image of the document that is clearly legible; shall view a current photo identification of the patient, parent, or legal guardian; and shall verify current board registration of the practitioner and the corresponding patient, parent, or legal guardian. Prior to any subsequent dispensing of each written certification, the pharmacist, pharmacy technician, or delivery agent shall view the current written certification; a current photo identification of the patient, parent, or legal guardian; and the current board registration issued to the patient, parent, or legal guardian.* No pharmaceutical processor shall dispense more than a 30-day supply for any patient during any 30-day period. The Board shall establish in regulation an amount of cannabidiol oil or THC-A oil that constitutes a 30-day supply to treat or alleviate the symptoms of a patient's intractable epilepsy.

B. A pharmaceutical processor shall dispense only cannabidiol oil and THC-A oil that has been cultivated and produced on the premises of such pharmaceutical processor.

C. The Board shall report annually by December 1 to the Chairmen of the House and Senate Committees for Courts of Justice on the operation of pharmaceutical processors issued a permit by the Board, including the number of practitioners, patients, and parents or legal guardians of patients who have registered with the Board and the number of written certifications issued pursuant to § 54.1-3408.3.

D. A pharmaceutical processor shall ensure that the concentration of tetrahydrocannabinol in any THC-A oil on site is within 10 percent of the level of tetrahydrocannabinol measured for labeling and shall establish a stability testing schedule of THC-A oil.

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 an emergency exists and this act is in force from its passage.

Project 4878 - Emergency/NOIRA

BOARD OF PHARMACY

New regulations

CHAPTER 60

REGULATIONS GOVERNING PHARMACEUTICAL PROCESSORS

Part I

General Provisions

18VAC110-60-10. Definitions.

In addition to words and terms defined in §§ 54.1-3408.3 and 54.1-3442.5 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:

"Board" means the Board of Pharmacy.

"Certification" means a written statement, consistent with requirements of § 54.1-3408.3 of the Code of Virginia, issued by a practitioner for the use of cannabidiol oil or THC-A oil for treatment or to alleviate the symptoms of [~~a patient's intractable epilepsy~~ any diagnosed condition or disease determined by the practitioner to benefit from such use] .

"Code" means the Code of Virginia.

"Dispensing error" means an act or omission relating to the dispensing of cannabidiol oil or THC-A oil that results in, or may reasonably be expected to result in, injury to or death of a registered patient or results in any detrimental change to the medical treatment for the patient.

"Electronic tracking system" means an electronic radio-frequency identification (RFID) seed-to-sale tracking system that tracks the Cannabis from either the seed or immature plant stage

until the cannabidiol oil and THC-A oil are sold to a registered patient, parent, or legal guardian or until the Cannabis, including the seeds, parts of plants, and extracts, are destroyed. The electronic tracking system shall include, at a minimum, a central inventory management system and standard and ad hoc reporting functions as required by the board and shall be capable of otherwise satisfying required recordkeeping.

[~~"Intractable epilepsy" means drug-resistant epilepsy (DRE), which is defined as failure of adequate trials of two tolerated, appropriately chosen and used antiepileptic drug schedules (whether as monotherapies or in combination) to achieve sustained seizure freedom.~~

"Ninety-day supply" means the amount of cannabidiol oil or THC-A oil reasonably necessary to ensure an uninterrupted availability of supply for a 90-day period for registered patients, which cannot exceed 60 fluid ounces.]

"On duty" means that a pharmacist is on the premises at the address of the permitted pharmaceutical processor and is available as needed.

[~~"One-month supply" means the amount of cannabidiol oil or THC-A oil reasonably necessary to ensure an uninterrupted availability of supply for a 30-day period for registered patients, which cannot exceed 20 fluid ounces.~~]

"PIC" means the pharmacist-in-charge.

"Production" or "produce" means the manufacture, planting, preparation, cultivation, growing, harvesting, propagation, conversion, or processing of marijuana, either directly or indirectly by extraction from substances of natural origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container.

"Resident" means a person whose principal place of residence is within the Commonwealth as evidenced by a federal or state income tax return or a current Virginia driver's license. If a

person is a minor, residency may be established by evidence of Virginia residency by a parent or legal guardian.

"Qualifying patient" means a Virginia resident who has received [from a practitioner, as defined in § 54.1-3408.3 of the Code,] a written certification for the use of cannabidiol oil or THC-A oil for treatment of [~~intractable epilepsy~~ or to alleviate the symptoms of any diagnosed condition or disease ~~from a practitioner, as defined in § 54.1-3408.3 of the Code~~] .

"Registered patient" means a qualifying patient who has been issued a registration by the board for the dispensing of cannabidiol oil or THC-A oil.

"Registration" means an identification card or other document issued by the board that identifies a person as a practitioner or a qualifying patient, parent, or legal guardian.

"Temperature and humidity" means temperature and humidity maintained in the following ranges:

Room or Phase	Temperature	Humidity
Mother room	65 - 75°	50% - 60%
Nursery phase	77 - 85° F	65% - 75%
Vegetation phase	77 - 85° F	55% - 65%
Flower/harvest phase	77 - 85° F	55% - 60%
Drying/extraction rooms	< 75° F	55% - 60%

18VAC110-60-20. Fees.

A. Fees are required by the board as specified in this section. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Registration of practitioner.

1. Initial registration	$50
2. Annual renewal of registration	$50
3. Replacement of registration for a qualifying practitioner whose information has changed or	$50

whose original registration certificate has been lost, stolen, or destroyed	

C. Registration by a qualifying patient or by a parent or legal guardian.

1. Initial registration	$50
2. Annual renewal of registration	$50
3. Replacement of registration for a qualifying patient or parent or legal guardian whose information has changed or whose original registration certificate has been lost, stolen, or destroyed	$50

D. Pharmaceutical processor permit.

1. Application	$10,000
2. Initial permit	$60,000
3. Annual renewal of permit	$10,000
4. Change of name of processor	$100
5. Change of PIC or any other information provided on the permit application	$100
6. Any acquisition, expansion, remodel, or change of location requiring an inspection	$1,000
7. Reinspection fee	$1,000
[8. Registration of each cannabidiol oil or THC-A oil product	$25]

Part II

Requirements for Practitioners and Patients

18VAC110-60-30. Requirements for practitioner issuing a certification.

A. Prior to issuing a certification for cannabidiol oil or THC-A oil for [~~the treatment or to alleviate symptoms of intractable epilepsy~~ any diagnosed condition or disease] , the practitioner shall meet the requirements of § 54.1-3408.3 of the Code, shall submit an application and fee as prescribed in 18VAC110-60-20, and shall be registered with the board.

B. A practitioner issuing a certification shall:

1. Conduct an assessment and evaluation of the patient in order to develop a treatment plan for the patient, which shall include an examination of the patient and the patient's medical history, prescription history, and current medical condition, including an in-person physical examination;

2. Diagnose the patient [~~as having intractable epilepsy~~] ;

3. Be of the opinion that the potential benefits of cannabidiol oil or THC-A oil would likely outweigh the health risks of such use to the qualifying patient;

4. Explain proper administration and the potential risks and benefits of the cannabidiol oil or THC-A oil to the qualifying patient and, if the qualifying patient lacks legal capacity, to a parent or legal guardian prior to issuing the written certification;

5. Be available or ensure that another practitioner, as defined in § 54.1-3408.3 of the Code, is available to provide follow-up care and treatment to the qualifying patient, including physical examinations, to determine the efficacy of cannabidiol oil or THC-A oil for treating the [~~intractable epilepsy~~ diagnosed condition or disease] ;

7. Comply with generally accepted standards of medical practice, except to the extent such standards would counsel against certifying a qualifying patient for cannabidiol oil or THC-A oil;

8. Maintain medical records for all patients for whom the practitioner has issued a certification in accordance with 18VAC85-20-26; and

9. [~~Be registered with and able to access~~ Access or direct his delegate to access the Virginia Prescription Monitoring Program for the purpose of determining which, if any, covered substances have been dispensed to the patient] .

C. Patient care and evaluation shall not occur by telemedicine for at least the first year of certification. Thereafter, the practitioner shall use his professional judgment to determine the manner and frequency of patient care and evaluation.

D. A practitioner shall not delegate the responsibility of diagnosing a patient or determining whether a patient should be issued a certification. Employees under the direct supervision of the practitioner may assist with preparing a certification, so long as the final certification is approved and signed by the practitioner before it is issued to the patient.

E. The practitioner shall provide instructions for the use of cannabidiol oil or THC-A oil to the patient, or parent or guardian, as applicable, and shall also securely transmit such instructions to the permitted pharmaceutical processor.

F. A practitioner shall not issue certifications for cannabidiol oil or THC-A oil to more than 600 patients at any given time. However, the practitioner may petition the Board of Pharmacy and Board of Medicine for an increased number of patients for whom certifications may be issued, upon submission of evidence that the limitation represents potential patient harm.

G. Upon request, a practitioner shall make a copy of medical records available to an agent of the Board of Medicine or Board of Pharmacy for the purpose of enabling the board to ensure compliance with the law and regulations or to investigate a possible violation.

18VAC110-60-40. Prohibited practices for practitioners.

A. A practitioner who issues certifications shall not:

1. Directly or indirectly accept, solicit, or receive anything of value from any person associated with a pharmaceutical processor or provider of paraphernalia;

2. Offer a discount or any other thing of value to a qualifying patient, parent, or guardian based on the patient's agreement or decision to use a particular pharmaceutical processor or cannabidiol oil or THC-A oil product;

3. Examine a qualifying patient for purposes of diagnosing [~~intractable epilepsy~~ the condition or disease] at a location where cannabidiol oil or THC-A oil is dispensed or produced; or

4. Directly or indirectly benefit from a patient obtaining a certification. Such prohibition shall not prohibit a practitioner from charging an appropriate fee for the patient visit.

B. A practitioner who issues certifications, and such practitioner's coworker, employee, spouse, parent, or child, shall not have a direct or indirect financial interest in a pharmaceutical processor or any other entity that may benefit from a qualifying patient's acquisition, purchase, or use of cannabidiol oil or THC-A oil, including any formal or informal agreement whereby a pharmaceutical processor or other person provides compensation if the practitioner issues a certification for a qualifying patient or steers a qualifying patient to a specific pharmaceutical processor or cannabidiol oil or THC-A oil product.

C. A practitioner shall not issue a certification for himself or for family members, employees, or coworkers.

D. A practitioner shall not provide product samples containing cannabidiol oil or THC-A oil other than those approved by the U.S. Food and Drug Administration.

18VAC110-60-50. Registration of a patient, parent, or legal guardian.

A. A qualifying patient for whom a practitioner has issued a certification, and, if such patient is a minor or an incapacitated adult, the qualifying patient's parent or legal guardian shall register with the board in accordance with this section. For a registration application to be considered complete, the following items shall be submitted:

1. A copy of the certification issued by a registered practitioner;

2. Proof of residency of the qualifying patient and proof of residency of a parent or legal guardian, if applicable, such as a government-issued identification card or tax receipt;

3. Proof of identity of the qualifying patient and, if the patient is a minor, proof of identity of the parent or legal guardian in the form of a government-issued identification card;

4. Proof of the qualifying patient's age in the form of a birth certificate or other government-issued identification;

5. Payment of the appropriate fees; and

6. Such other information as the board may require to determine the applicant's suitability for registration or to protect public health and safety.

B. A qualifying patient shall not be issued a written certification by more than one practitioner during a given time period.

C. Patients, parents, and legal guardians issued a registration shall carry their registration with them whenever they are in possession of cannabidiol oil or THC-A oil.

18VAC110-60-60. Denial of a qualifying patient, parent, or legal guardian registration application.

A. The board may deny an application or renewal of the registration of a qualifying patient, parent, or legal guardian if the applicant:

1. Does not meet the requirements set forth in law or regulation or fails to provide complete information on the application form;

2. Does not provide acceptable proof of identity, residency, or age of the patient to the board;

3. Provides false, misleading, or incorrect information to the board;

4. Has had a qualifying registration of a qualifying patient, parent, or legal guardian denied, suspended, or revoked by the board in the previous six months;

5. Has a certification issued by a practitioner who is not authorized to certify patients for cannabidiol oil or THC-A oil; or

6. Has a prior conviction of a violation of any law pertaining to controlled substances.

B. If the board denies an application or renewal of a qualifying patient applicant or parent or legal guardian applicant, the board shall provide the applicant with notice of the grounds for the denial and shall inform the applicant of the right to request a hearing pursuant to § 2.2-4019 of the Code.

18VAC110-60-70. Reporting requirements for practitioners, patients, parents, or legal guardians.

A. A practitioner shall report to the board, on a form prescribed by the board, the death of a registered patient or a change in status involving a registered patient for whom the practitioner has issued a certification if such change affects the patient's continued eligibility to use cannabidiol oil or THC-A oil, or the practitioner's inability to continue treating the patient. A practitioner shall report such death, change of status, or inability to continue treatment not more than 15 days after the practitioner becomes aware of such fact.

B. A patient, parent, or legal guardian who has been issued a registration shall notify the board of any change in the information provided to the board not later than 15 days after such change. The patient, parent, or legal guardian shall report changes that include a change in name, address, contact information, medical status of the patient, or change of the certifying practitioner. The patient, parent, or legal guardian shall report such changes on a form prescribed by the board.

C. If a patient, parent, or legal guardian notifies the board of any change that results in information on the patient, parent, or legal guardian's registration being inaccurate, the patient, parent, or legal guardian shall submit the fee for a replacement registration. Upon receipt of a

new registration, the qualifying patient, parent, or legal guardian shall destroy in a nonrecoverable manner the registration that was replaced.

D. If a patient, parent, or legal guardian becomes aware of the loss, theft, or destruction of the registration of such patient, parent, or legal guardian, the patient, parent, or legal guardian shall notify the board not later than five business days after becoming aware of the loss, theft, or destruction, and submit the fee for a replacement registration. The board shall inactivate the initial registration upon receiving such notice and issue a replacement registration upon receiving the applicable fee, provided the applicant continues to satisfy the requirements of law and regulation.

18VAC110-60-80. Proper storage and disposal of cannabidiol oil or THC-A oil by patients, parents, or legal guardians.

A. A registered patient, parent, or legal guardian shall exercise reasonable caution to store cannabidiol oil or THC-A oil in a manner to prevent theft, loss, or access by unauthorized persons.

B. A registered patient, parent, or legal guardian shall dispose of all usable cannabidiol oil or THC-A oil in the registered patient, parent, or legal guardian's possession no later than 10 calendar days after the expiration of the patient's registration if such registration is not renewed, or sooner should the patient no longer wish to possess cannabidiol oil or THC-A oil. A registered patient, parent, or legal guardian shall complete such disposal by one of the following methods:

1. By removing the oil from the original container and mixing it with an undesirable substance such as used coffee grounds, dirt, or kitty litter. The mixture shall be placed in a sealable bag, empty can, or other container to prevent the drug from leaking or breaking out of a garbage bag.

2. By transferring it to law enforcement via a medication drop-box or drug take-back event, if permissible under state and federal law.

18VAC110-60-90. Revocation or suspension of a qualifying patient, parent, or legal guardian registration.

The board may revoke or suspend the registration of a patient, a parent, or a legal guardian under the following circumstances:

1. The patient's practitioner notifies the board that the practitioner is withdrawing the written certification submitted on behalf of the patient, and 30 days after the practitioner's withdrawal of the written certification, the patient has not obtained a valid written certification from a different practitioner;

2. The patient, parent, or legal guardian provided false, misleading, or incorrect information to the board;

3. The patient, parent, or legal guardian is no longer a resident of Virginia;

4. The patient, parent, or legal guardian obtained more than a [~~one-month~~ 90-day] supply of cannabidiol oil or THC-A oil in a [~~one-month~~ 90-day] period;

5. The patient, parent, or legal guardian provided or sold cannabidiol oil or THC-A oil to any person, including another registered patient, parent, or legal guardian;

6. The patient, parent, or legal guardian permitted another person to use the patient, parent, or legal guardian's registration;

7. The patient, parent, or legal guardian tampered, falsified, altered, modified, or allowed another person to tamper, falsify, alter, or modify the patient, parent, or legal guardian's registration;

8. The patient, parent, or legal guardian's registration was lost, stolen, or destroyed, and the patient, parent, or legal guardian failed to notify the board or notified the board of such

incident more than five business days after becoming aware that the registration was lost, stolen, or destroyed;

9. The patient, parent, or legal guardian failed to notify the board of a change in registration information or notified the board of such change more than 14 days after the change; or

10. The patient, parent, or legal guardian violated any federal or state law or regulation.

Part III

Application and Approval Process for Pharmaceutical Processors

18VAC110-60-100. Publication of notice for submission of applications.

A. The board shall publish a notice of open applications for pharmaceutical processor permits. Such notice shall include information on how to obtain and complete an application, the required fees, the criteria for issuance of a permit, and the deadline for receipt of applications.

B. The board shall have the right to amend the notice of open applications prior to the deadline for submitting an application. Such amended notice shall be published in the same manner as the original notice of open applications.

C. The board shall have the right to cancel a notice of open applications prior to the award of a pharmaceutical processor permit.

18VAC110-60-110. Application process for pharmaceutical processor permits.

A. The application process for permits shall occur in three stages: submission of initial application, awarding of conditional approval, and granting of a pharmaceutical processor permit.

B. Submission of initial application.

1. A pharmaceutical processor permit applicant shall submit the required application fee and form with the following information and documentation:

a. The name and address of the applicant and the applicant's owners;

b. The location within the health service area established by the State Board of Health for the pharmaceutical processor that is to be operated under such permit;

c. Detailed information regarding the applicant's financial position, indicating all assets, liabilities, income, and net worth, to demonstrate the financial capacity of the applicant to build and operate a facility to cultivate Cannabis plants intended only for the production and dispensing of cannabidiol oil and THC-A oil pursuant to §§ 54.1-3442.6 and 54.1-3442.7 of the Code of Virginia, which may include evidence of an escrow account, letter of credit, or performance surety bond;

d. Details regarding the applicant's plans for security to maintain adequate control against the diversion, theft, or loss of the Cannabis plants and the cannabidiol oil or THC-A oil;

e. Documents sufficient to establish that the applicant is authorized to conduct business in Virginia and that all applicable state and local building, fire, and zoning requirements and local ordinances are met or will be met prior to issuance of a permit;

f. Information necessary for the board to conduct a criminal background check on [~~owners and any other person who is employed by or acts as an agent of the proposed pharmaceutical processor~~ applicants] ;

g. Information about any previous or current involvement in the medical cannabidiol oil or THC-A oil industry;

h. Whether the person has ever applied for a permit or registration related to medical cannabidiol oil or THC-A oil in any state and, if so, the status of that application, permit, or registration, to include any disciplinary action taken by any state on the permit, the registration, or an associated license;

i. Any business and marketing plans related to the operation of the pharmaceutical processor or the sale of cannabidiol oil or THC-A oil;

j. Text and graphic materials showing the exterior appearance of the proposed pharmaceutical processor;

k. A blueprint of the proposed pharmaceutical processor, which shall show and identify the square footage of each area of the facility, to include the location of all safes or vaults used to store the Cannabis plants and oils and the location of all areas that may contain Cannabis plants, cannabidiol oil, or THC-A oil, showing the placement of walls, partitions, counters, and all areas of ingress and egress;

l. Documents related to any compassionate need program the pharmaceutical processor intends to offer;

m. Information about the applicant's expertise in agriculture and other production techniques required to produce cannabidiol oil or THC-A oil and to safely dispense such products; and

n. Such other documents and information required by the board to determine the applicant's suitability for permitting or to protect public health and safety.

2. In the event any information contained in the application or accompanying documents changes after being submitted to the board, the applicant shall immediately notify the board in writing and provide corrected information in a timely manner so as not to disrupt the permit selection process.

3. The board shall conduct criminal background checks on [~~the owner or owners~~ applicants] and may verify information contained in each application and accompanying documentation in order to assess the applicant's ability to operate a pharmaceutical processor.

C. In the event the board determines that there are no qualified applicants to award conditional approval for a pharmaceutical processor permit in a health service area, the board may republish, in accordance with 18VAC110-60-100, a notice of open applications for pharmaceutical processor permits.

D. No person who has been convicted of a felony or of any offense in violation of Article 1 (§ 18.2-247 et seq.) or Article 1.1 (§ 18.2-265.1 et seq.) of Chapter 7 of Title 18.2 of the Code of Virginia shall have any form of ownership, be employed by, or act as an agent of a pharmaceutical processor.

18VAC110-60-120. Conditional approval.

A. Following the deadline for receipt of applications, the board shall evaluate each complete and timely submitted application and may grant conditional approval on a competitive basis based on compliance with requirements set forth in 18VAC110-60-110.

B. The board shall consider, but is not limited to, the following criteria in evaluating pharmaceutical processor permit applications:

1. The results of the criminal background checks required in 18VAC110-60-110 B 3 or any history of disciplinary action imposed by a state or federal regulatory agency;

2. The location for the proposed pharmaceutical processor, which shall not be within 1,000 feet of a school or daycare;

3. The applicant's ability to maintain adequate control against the diversion, theft, and loss of the Cannabis, to include the seeds, any parts or extracts of the Cannabis plants, the cannabidiol oil, or THC-A oil;

4. The applicant's ability to maintain the knowledge, understanding, judgment, procedures, security controls, and ethics to ensure optimal safety and accuracy in the dispensing and sale of cannabidiol oil or THC-A oil;

5. The extent to which the applicant or any of the applicant's pharmaceutical processor owners have a financial interest in another license, permit, registrant, or applicant; and

6. Any other reason provided by state or federal statute or state or federal regulation that is not inconsistent with the law and regulations regarding pharmaceutical processors.

B. The board may disqualify any applicant who:

1. Submits an incomplete, false, inaccurate, or misleading application;

2. Fails to submit an application by the published deadline;

3. Fails to pay all applicable fees; or

4. Fails to comply with all requirements for a pharmaceutical processor.

C. Following review, the board shall notify applicants of denial or conditional approval. The decision of the board not to grant conditional approval to an applicant shall be final.

D. If granted conditional approval, an applicant shall have one year from date of notification to complete all requirements for issuance of a permit to include employment of a PIC and other personnel necessary for operation of a pharmaceutical processor, the construction or remodeling of a facility, installation of equipment, and securing local zoning approval.

18VAC110-60-130. Granting of a pharmaceutical processor permit.

A. The board may issue a pharmaceutical processor permit when all requirements of the board have been met to include:

1. Designation of a PIC;

2. Evidence of criminal background checks for all employees and agents of the processor to ensure compliance with § 54.1-3442.6 of the Code;

3. Evidence of utilization of an electronic tracking system; and

4. A satisfactory inspection of the facility conducted by the board or its agents.

B. The permit shall not be awarded until any deficiencies identified by inspectors have been corrected and the facility has been satisfactorily reinspected, if warranted.

C. Before any permit is issued, the applicant shall attest to compliance with all state and local laws and ordinances. A pharmaceutical processor permit shall not be issued to any person to operate from a private dwelling or residence.

D. If an applicant has been awarded a pharmaceutical processor permit and has not commenced operation of such facility within 180 days of being notified of the issuance of a pharmaceutical processor permit, the board may rescind such permit, unless such delay was caused by circumstances beyond the control of the permit holder.

E. A pharmaceutical processor shall be deemed to have commenced operation if Cannabis plants are under cultivation by the processor in accordance with the approved application.

F. In the event a permit is rescinded pursuant to this subsection, the board may award a pharmaceutical processor permit by selecting among the qualified applicants who applied for the pharmaceutical processor permit subject to rescission. If no other qualified applicant applied for such pharmaceutical processor permit satisfied the criteria for awarding a permit, the board shall publish, in accordance with this section, a notice of open applications for a pharmaceutical processor permit.

G. Once the permit is issued, Cannabis may not be grown or held in the pharmaceutical processor earlier than two weeks prior to the opening date designated on the application. Once Cannabis has been placed in the pharmaceutical processor, a pharmacist shall be present during hours of operation to ensure the safety, security, and integrity of the Cannabis. If there is a change in the designated opening date, the pharmaceutical processor shall notify the board office, and a pharmacist shall continue to be on site on a daily basis.

18VAC110-60-140. Notification of changes by pharmaceutical processor.

A. Unless otherwise provided in law or regulation, the PIC designated on the application to be in full and actual charge of the pharmaceutical processor shall provide any notification or information that is required from a pharmaceutical processor.

B. Prior to making any change to the pharmaceutical processor name, the pharmaceutical processor shall submit an application for such change to the board and pay the fee.

C. Any person wishing to engage in the acquisition of an existing pharmaceutical processor, change the location of an existing pharmaceutical processor, make structural changes to an existing pharmaceutical processor, or make changes to a previously approved security system shall submit an application to the board and pay the required fee.

1. The proposed location or structural changes shall be inspected by an authorized agent of the board prior to issuance of a permit.

2. Cannabis shall not be moved to a new location until approval is granted by the inspector or board staff.

18VAC110-60-150. Pharmaceutical processor closings; going out of business; change of ownership.

A. At least 30 days prior to the date a pharmaceutical processor closes, either temporarily or permanently, the owner shall:

1. Notify the board;

2. Send written notification to patients with current certification; and

3. Post a notice on the window or door of the pharmaceutical processor.

B. The proposed disposition of all Cannabis, dispensing records, patient information records, and other required records shall be reported to the board. If the Cannabis and records are to be

transferred to another processor located in Virginia, the owner shall inform the board and the patients and include on the public notice the name and address of the processor to whom the Cannabis and records are being transferred and the date of transfer.

C. Exceptions to the public notice shall be approved by the board and may include sudden closing due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances. If the pharmaceutical processor is not able to meet the notification requirements, the owner shall ensure that the board and public are properly notified as soon as he knows of the closure and shall disclose the emergency circumstances preventing the notification within the required deadlines.

D. In the event of an exception to the notice, the PIC or owner shall provide notice as far in advance of closing as allowed by the circumstances.

E. At least 14 days prior to any change in ownership of an existing pharmaceutical processor, the owner shall notify the board of the pending change.

1. Upon any change in ownership of an existing pharmaceutical processor, the dispensing records for the two years immediately preceding the date of change of ownership and other required patient information shall be provided to the new owners on the date of change of ownership in substantially the same format as previously used immediately prior to the transfer to provide continuity of services.

2. The previous owner shall be held responsible for assuring the proper and lawful transfer of records on the date of the transfer.

18VAC110-60-160. Grounds for action against a pharmaceutical processor permit.

In addition to the bases enumerated in § 54.1-3316 of the Code of Virginia, the board may suspend, revoke, or refuse to grant or renew a permit issued, or place such permit on probation,

place conditions on such permit, or take other actions permitted by statute or regulation on the following grounds:

1. Any criminal conviction under federal or state statutes or regulations or local ordinances, unless the conviction was based on a federal statute or regulation related to the possession, purchase, or sale of cannabidiol oil or THC-A oil that is authorized under state law and regulations;

2. Any civil action under any federal or state statute or regulation or local ordinance (i) relating to the applicant's, licensee's, permit holder's, or registrant's profession or (ii) involving drugs, medical devices, or fraudulent practices, including fraudulent billing practices;

3. Failure to maintain effective controls against diversion, theft, or loss of Cannabis, cannabidiol oil or THC-A oil, or other controlled substances;

4. Intentionally, or through negligence, obscuring, damaging, or defacing a permit or registration card;

5. Permitting another person to use the permit of a permit holder or registration of a qualifying patient, parent, or legal guardian;

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

7. Discontinuance of business for more than 60 days, unless the board approves an extension of such period for good cause shown, upon a written request from a pharmaceutical processor. Good cause includes exigent circumstances that necessitate the closing of the facility. Good cause shall not include a voluntary closing of the pharmaceutical processor or production facility.

Part IV

Requirements for Pharmaceutical Processor Personnel

18VAC110-60-170. Pharmaceutical processor employee licenses and registrations.

A. A pharmacist with a current, unrestricted license issued by the board, practicing at the location of the address on the pharmaceutical processor application shall be in full and actual charge of a pharmaceutical processor and serve as the pharmacist-in-charge.

B. A pharmacist with a current, unrestricted license issued by the board shall provide personal supervision on the premises of the pharmaceutical processor at all times during hours of operation or whenever the processor is being accessed.

C. No person shall perform the following duties under pharmacist supervision without maintaining a current, unrestricted registration as a pharmacy technician pursuant to § 54.1-3321 of the Code of Virginia and having been registered with the board or registered or certified by the board of another United States jurisdiction as a pharmacy technician for the previous two years:

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

2. The preparation of labels for dispensing the oils or patient information;

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

4. The measuring of the oil to be dispensed;

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

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

7. The selling of the oil to the registered patient, parent, or legal guardian;

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

D. A pharmacist with a current, unrestricted license or a pharmacy technician with a current, unrestricted registration issued by the board may perform duties associated with the cultivation, extraction, and dispensing of the oils, as authorized by the PIC or as otherwise authorized in law.

E. Persons who do not maintain licensure as a pharmacist or registration as a pharmacy technician but have received a degree in horticulture or have at least two years of experience cultivating plants may perform duties associated with the cultivation of Cannabis, as authorized by the PIC.

F. Persons who do not maintain licensure as a pharmacist or registration as a pharmacy technician, but have received a degree in chemistry or pharmacology or have at least two years of experience extracting chemicals from plants may perform duties associated with the extraction of cannabidiol oil and THC-A oil, as authorized by the PIC.

G. A pharmacist on duty shall directly supervise the activities in all areas designated for cultivation, extraction, and dispensing or have a process in place, approved by the board, that provides adequate supervision to protect the security of the Cannabis, seeds, extracts, cannabidiol oil, and THC-A oil and ensure quality of the dispensed oils.

H. At no time shall a pharmaceutical processor operate or be accessed without a pharmacist on duty.

I. No person shall be employed by or serve as an agent of a pharmaceutical processor without being at least 18 years of age.

J. No person who has had a license or registration suspended or revoked or been denied issuance of such license or registration shall serve as an employee or agent of the pharmaceutical processor.

18VAC110-60-180. Employee training.

A. All employees of a pharmaceutical processor shall complete training, prior to the employee commencing work at the pharmaceutical processor, at a minimum, in the following:

1. The proper use of security measures and controls that have been adopted for the prevention of diversion, theft, or loss of Cannabis, to include the seeds, any parts or extracts of the Cannabis plants, cannabidiol oil, and THC-A oil;

2. Procedures and instructions for responding to an emergency;

3. Professional conduct, ethics, and state and federal statutes and regulations regarding patient confidentiality; and

4. Developments in the field of the medical use of cannabidiol oil or THC-A oil.

B. Prior to regular performance of assigned tasks, the employee shall also receive on-the-job training and other related education, which shall be commensurate with the tasks assigned to the employee.

C. The PIC shall assure the continued competency of all employees through continuing in-service training designed to supplement initial training, which shall include any guidance specified by the board.

D. The PIC shall be responsible for maintaining a written record documenting the initial and continuing training of all employees, which shall contain:

1. The name of the person receiving the training;

2. The dates of the training;

3. A general description of the topics covered;

4. The name of the person supervising the training; and

5. The signatures of the person receiving the training and the PIC.

E. When a change of pharmaceutical processor PIC occurs, the new PIC shall review the training record and sign it, indicating that the new PIC understands its contents.

F. A pharmaceutical processor shall maintain the record documenting the employee training and make it available in accordance with regulations.

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

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

B. The pharmacist providing direct supervision of pharmacy technicians may be held responsible for the pharmacy technicians' actions. Any violations relating to the dispensing of cannabidiol oil or THC-A oil resulting from the actions of a pharmacy technician shall constitute grounds for action against the license of the pharmacist and the registration of the pharmacy technician. As used in this subsection, "direct supervision" means a supervising pharmacist who:

1. Is on duty where the pharmacy technician is performing routine cannabidiol oil or THC-A oil production or dispensing functions; and

2. Conducts in-process and final checks on the pharmacy technician's performance.

C. Pharmacy technicians shall not:

1. Counsel a registered patient or the patient's parent or legal guardian regarding cannabidiol oil, THC-A oil, or other drugs, either before or after cannabidiol oil or THC-A oil has been dispensed, or regarding any medical information contained in a patient medication record;

2. Consult with the practitioner who certified the qualifying patient, or the practitioner's agent, regarding a patient or any medical information pertaining to the patient's cannabidiol oil or THC-A oil or any other drug the patient may be taking;

3. Interpret the patient's clinical data or provide medical advice;

4. Determine whether a different formulation of cannabidiol oil or THC-A oil should be substituted for the cannabidiol oil or THC-A oil product or formulation recommended by the practitioner or requested by the registered patient or parent or legal guardian; or

5. Communicate with a practitioner who certified a registered patient, or the practitioner's agent, to obtain a clarification on a qualifying patient's written certification or instructions.

18VAC110-60-200. Responsibilities of the PIC.

A. No person shall be PIC for more than one pharmaceutical processor at any time. A processor shall employ the PIC at the pharmaceutical processor for at least 35 hours per week, except as otherwise authorized by the board.

B. The PIC or the pharmacist on duty shall control all aspects of the practice of the pharmaceutical processor. Any decision overriding such control of the PIC or other pharmacist on duty may be grounds for disciplinary action against the pharmaceutical processor permit.

C. The pharmaceutical processor PIC shall be responsible for ensuring that:

1. Pharmacy technicians are registered and all employees are properly trained;

2. All record retention requirements are met;

3. All requirements for the physical security of the Cannabis, to include the seeds, any parts or extracts of the Cannabis plants, the cannabidiol oil, and THC-A oil are met;

4. The pharmaceutical processor has appropriate pharmaceutical reference materials to ensure that cannabidiol oil or THC-A oil can be properly dispensed;

5. The following items are conspicuously posted in the pharmaceutical processor in a location and in a manner so as to be clearly and readily identifiable to registered patients, parents, or legal guardians:

a. Pharmaceutical processor permit;

b. Licenses for all pharmacists practicing at the pharmaceutical processor; and

c. The price of all cannabidiol oil or THC-A oil products offered by the pharmaceutical processor; and

6. Any other required filings or notifications are made on behalf of the processor as set forth in regulation.

D. When the PIC ceases practice at a pharmaceutical processor or no longer wishes to be designated as PIC, he shall immediately return the pharmaceutical processor permit to the board indicating the effective date on which he ceased to be the PIC.

E. An outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Cannabis, to include plants, extracts, cannabidiol oil, or THC-A oil 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. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. If the PIC knows of an upcoming absence of longer than 30 days, he 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 permit holder shall immediately notify the board and shall obtain a new PIC.

G. An application for a permit designating the new PIC shall be filed with the required fee within 15 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 pharmaceutical processor to operate without a new permit

past the 15-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.

Part V

Operation of a Pharmaceutical Processor

18VAC110-60-210. General provisions.

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

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

C. The PIC or pharmacist on duty shall restrict access to the pharmaceutical processor to:

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

2. Such person who is a registered patient, parent, or legal guardian, in which case such person shall not be permitted behind the service counter or in other areas where Cannabis plants, extracts, cannabidiol oil, or THC-A oil is stored.

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

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

F. A pharmaceutical processor shall be open for registered patients, parents, or legal guardians to purchase cannabidiol oil or THC-A oil products for a minimum of 35 hours a week, except as otherwise authorized by the board.

G. A pharmaceutical processor that closes during its normal hours of operation shall implement procedures to notify registered patients, parents, and legal guardians of when the pharmaceutical processor will resume normal hours of operation. Such procedures may include telephone system messages and conspicuously posted signs. If the pharmaceutical processor is, or will be, closed during its normal hours of operation for longer than two business days, the pharmaceutical processor shall immediately notify the board.

H. A pharmacist shall counsel registered patients, parents, and legal guardians regarding the use of cannabidiol oil or THC-A oil. Such counseling shall include information related to safe techniques for proper use and storage of cannabidiol oil or THC-A oil;

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

18VAC110-60-220. Pharmaceutical processor prohibitions.

A. No pharmaceutical processor shall:

1. Cultivate Cannabis plants, produce, or dispense cannabidiol oil or THC-A oil in any place except the approved facility at the address of record on the application for the pharmaceutical processor permit;

2. Sell, deliver, transport, or distribute Cannabis, including cannabidiol oil or THC-A oil, to any other facility;

3. Produce or manufacture cannabidiol oil or THC-A oil for use outside of Virginia; or

4. Provide cannabidiol oil or THC-A oil samples.

B. No pharmaceutical processor shall be open or in operation, and no person shall be in the pharmaceutical processor, unless a pharmacist is on the premises and directly supervising the activity within the pharmaceutical processor. At all other times, the pharmaceutical processor shall be closed and properly secured.

C. No pharmaceutical processor shall sell anything other than cannabidiol oil or THC-A oil products from the pharmaceutical processor.

D. A pharmaceutical processor shall not [~~market or~~] advertise cannabidiol oil or THC-A oil products, except it may post the following information on websites:

1. Name and location of the processor;

2. Contact information for the processor;

3. Hours and days the pharmaceutical processor is open for dispensing cannabidiol oil or THC-A oil products;

4. Laboratory results; and

5. Directions to the processor facility.

E. No cannabidiol oil or THC-A oil shall be consumed on the premises of a pharmaceutical processor, except for emergency administration to a registered patient.

F. No person except a pharmaceutical processor employee or a registered patient, parent, or legal guardian shall be allowed on the premises of a processor with the following exceptions: laboratory staff may enter a processor for the sole purpose of identifying and collecting Cannabis,

cannabidiol oil, or THC-A oil samples for purposes of conducting laboratory tests; the board or the board's authorized representative may waive the prohibition upon prior written request.

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

1. An employee shall escort and monitor such a visitor at all times the visitor is in the pharmaceutical processor.

2. A visitor shall visibly display the visitor identification badge at all times the visitor is in the pharmaceutical processor and shall return the visitor identification badge to a pharmaceutical processor employee upon exiting the pharmaceutical processor.

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

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

H. No cannabidiol oil or THC-A oil shall be sold, dispensed, or distributed via a delivery service or any other manner outside of a pharmaceutical processor, except that a registered parent or legal guardian may deliver cannabidiol oil or THC-A oil to the registered patient [or in accordance with subsection A of 18VAC110-60-310] .

I. Notwithstanding the requirements of subsection [~~E~~ F] of this section, an agent of the board, local law enforcement or other federal, state, or local government officials may enter any area of a pharmaceutical processor if necessary to perform their governmental duties.

18VAC110-60-230. Inventory requirements.

A. Each pharmaceutical processor, prior to commencing business, shall:

1. Conduct an initial comprehensive inventory of all Cannabis plants, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil at the facility. The inventory shall include, at a minimum, the date of the inventory, a summary of the inventory findings, and the name, signature, and title of the pharmacist or pharmacy technician who conducted the inventory. If a facility commences business with no Cannabis on hand, the pharmacist shall record this fact as the initial inventory; and

2. Establish ongoing inventory controls and procedures for the conduct of inventory reviews and comprehensive inventories of all Cannabis plants, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, which shall enable the facility to detect any diversion, theft, or loss in a timely manner.

B. Upon commencing business, each pharmaceutical processor and production facility shall conduct a weekly inventory of all Cannabis plants, including the seeds, parts of plants, cannabidiol oil, and THC-A oil in stock, which shall include, at a minimum, the date of the inventory, a summary of the inventory findings, and the name, signature, and title of the pharmacist or pharmacy technician who conducted the inventory. The record of all cannabidiol oil and THC-A oil sold, dispensed, or otherwise disposed of shall show the date of sale, the name of the pharmaceutical processor, registered patient, parent, or legal guardian to whom the cannabidiol oil or THC-A oil was sold, the address of such person, and the kind and quantity of cannabidiol oil or THC-A oil sold.

C. A complete and accurate record of all Cannabis plants, including the seeds, parts of plants, cannabidiol oil, and THC-A oil on hand shall be prepared annually on the anniversary of the initial inventory or such other date that the PIC may choose, so long as it is not more than one year following the prior year's inventory.

D. All inventories, procedures, and other documents required by this section shall be maintained on the premises and made available to the board or its agent.

E. Inventory records shall be maintained for three years from the date the inventory was taken.

F. Whenever any sample or record is removed by a person authorized to enforce state or federal law for the purpose of investigation or as evidence, such person shall tender a receipt in lieu thereof and the receipt shall be kept for a period of at least three years.

18VAC110-60-240. Security requirements.

A. A pharmaceutical processor shall initially cultivate only the number of Cannabis plants necessary to produce cannabidiol oil or THC-A oil for the number of patients anticipated within the first [~~three~~ nine] months of operation. Thereafter, the processor shall:

1. Not maintain more than [~~four~~ 12] Cannabis plants per patient at any given time based on dispensing data from the previous [~~30~~ 90] days;

2. Not maintain cannabidiol oil or THC-A oil in excess of the quantity required for normal, efficient operation;

3. Maintain all Cannabis plants, seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil in a secure area or location accessible only by the minimum number of authorized employees essential for efficient operation;

4. Store all cut parts of Cannabis plants, extracts, cannabidiol oil, or THC-A oil in an approved safe or approved vault within the pharmaceutical processor and shall not sell cannabidiol oil or THC-A oil products when the pharmaceutical processor is closed;

5. Keep all approved safes, approved vaults, or any other approved equipment or areas used for the production, cultivation, harvesting, processing, manufacturing, or storage of cannabidiol oil or THC-A oil securely locked or protected from entry, except for the actual time required to remove or replace the Cannabis, seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil;

6. Keep all locks and security equipment in good working order;

7. Restrict access to keys or codes to all safes, approved vaults, or other approved equipment or areas to pharmacists practicing at the pharmaceutical processor; and

8. Not allow keys to be left in the locks or accessible to nonpharmacists.

B. The pharmaceutical processor shall have an adequate security system to prevent and detect diversion, theft, or loss of Cannabis seeds, plants, extracts, cannabidiol oil, or THC-A oil. A device for the detection of breaking and a back-up alarm system with an ability to remain operational during a power outage shall be installed in each pharmaceutical processor. 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 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 entire processor facility and shall be capable of detecting breaking by any means when activated;

4. The device shall include a duress alarm, a panic alarm, and automatic voice dialer; and

5. Access to the alarm system for the pharmaceutical processor shall be restricted to the pharmacists working at the pharmaceutical processor and the system shall be activated whenever the pharmaceutical processor is closed for business.

C. A pharmaceutical processor shall keep the outside perimeter of the premises well-lit. A processor shall have video cameras in all areas that may contain Cannabis plants, seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance.

1. The processor shall direct cameras at all approved safes, approved vaults, dispensing areas, cannabidiol oil, or THC-A oil sales areas and any other area where Cannabis plants, seeds, extracts, cannabidiol oil, or THC-A oil are being produced, harvested, manufactured, stored, or handled. At entry and exit points, the processor shall angle cameras so as to allow for the capture of clear and certain identification of any person entering or exiting the facility;

2. The video system shall have:

a. A failure notification system that provides an audible, text, or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the processor within five minutes of the failure, either by telephone, email, or text message;

b. The ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera image (live or recorded);

c. A date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture; and

d. The ability to remain operational during a power outage;

3. All video recording shall allow for the exporting of still images in an industry standard image format. Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system. A pharmaceutical processor shall erase all recordings prior to disposal or sale of the facility; and

4. The processor shall make 24-hour recordings from all video cameras available for immediate viewing by the board or the board's agent upon request and shall retain the recordings for at least 30 days. If a processor is aware of a pending criminal, civil, or administrative investigation or legal proceeding for which a recording may contain relevant information, it shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the pharmaceutical processor PIC that it is not necessary to retain the recording.

D. The processor shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction, or alterations. All security equipment shall be maintained in good working order and shall be tested no less than two times per year.

E. A pharmaceutical processor shall limit access to surveillance areas to persons who are essential to surveillance operations, law-enforcement agencies, security system service employees, the board or the board's agent, and others when approved by the board. A processor shall make available a current list of authorized employees and security system service

employees who have access to the surveillance room to the processor. The pharmaceutical processor shall keep all onsite surveillance rooms locked and shall not use such rooms for any other function.

F. If diversion, theft, or loss of Cannabis plants, seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil has occurred from a pharmaceutical processor, the board may require additional safeguards to ensure the security of the products.

18VAC110-60-250. Requirements for the storage and handling of Cannabis, cannabidiol oil, or THC-A oil.

A. A pharmaceutical processor shall:

1. Have storage areas that provide adequate lighting, ventilation, sanitation, temperature, and humidity as defined in 18VAC110-60-10 and space, equipment, and security conditions for the cultivation of Cannabis, and the production and dispensing of cannabidiol oil or THC-A oil;

2. Separate for storage in a quarantined area Cannabis plants, seeds, parts of plants, extracts, including cannabidiol oil or THC-A oil, that is outdated, damaged, deteriorated, misbranded, or adulterated, or whose containers or packaging have been opened or breached, until such Cannabis plants, seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil is destroyed;

3. Be maintained in a clean, sanitary, and orderly condition; and

4. Be free from infestation by insects, rodents, birds, or vermin of any kind.

B. A processor shall compartmentalize all areas in the facility based on function and shall restrict access between compartments. The processor shall establish, maintain, and comply with written policies and procedures regarding best practices for the secure and proper cultivation of

Cannabis and production of cannabidiol oil or THC-A oil. These shall include policies and procedures that:

1. Restrict movement between compartments;

2. Provide for different colored identification cards for facility employees based on the compartment to which they are assigned at a given time so as to ensure that only employees necessary for a particular function have access to that compartment of the facility;

3. Require pocketless clothing for all production facility employees working in an area containing Cannabis plants, seeds, and extracts, including cannabidiol oil or THC-A oil; and

4. Document the chain of custody of all Cannabis plants, parts of plants, seeds, extracts, cannabidiol oil, and THC-A oil products.

C. The PIC shall establish, maintain, and comply with written policies and procedures for the cultivation, production, security, storage, and inventory of Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil. Such policies and procedures shall include methods for identifying, recording, and reporting diversion, theft, or loss, and for correcting all errors and inaccuracies in inventories. Pharmaceutical processors shall include in their written policies and procedures, a process for the following:

1. Handling mandatory and voluntary recalls of cannabidiol oil or THC-A oil. Such process shall be adequate to deal with recalls due to any action initiated at the request of the board and any voluntary action by the pharmaceutical processor to remove defective or potentially defective cannabidiol oil or THC-A oil from the market or any action undertaken to promote public health and safety by replacing existing cannabidiol oil or THC-A oil with improved products or packaging;

2. Preparing for, protecting against, and handling any crises that affect the security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;

3. Ensuring that any outdated, damaged, deteriorated, misbranded, or adulterated Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, is segregated from all other Cannabis, seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil and destroyed. This procedure shall provide for written documentation of the Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil disposition; and

4. Ensuring the oldest stock of Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil product is used first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

D. The processor shall store all Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, in the process of production, transfer, or analysis in such a manner as to prevent diversion, theft, or loss; shall make Cannabis, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil accessible only to the minimum number of specifically authorized employees essential for efficient operation; and shall return the aforementioned items to their secure location immediately after completion of the production, transfer, or analysis process or at the end of the scheduled business day. If a production process cannot be completed at the end of a working day, the pharmacist shall securely lock the processing area or tanks, vessels, bins, or bulk containers containing Cannabis, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, inside an area or building that affords adequate security.

18VAC110-60-260. Recordkeeping requirements.

A. If a pharmaceutical processor uses an electronic system for the storage and retrieval of patient information or other records related to cultivating, producing, and dispensing cannabidiol oil or THC-A oil, the pharmaceutical processor shall use a system that:

1. Guarantees the confidentiality of the information contained therein;

2. Is capable of providing safeguards against erasures and unauthorized changes in data after the information has been entered and verified by the pharmacist; and

3. Is capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of the data bank.

B. All records relating to the inventory, laboratory results, and dispensing shall be maintained for a period of three years and shall be made available to the board upon request.

18VAC110-60-270. Reportable events; security.

A. Upon becoming aware of diversion, theft, loss, discrepancies identified during inventory, or unauthorized destruction of any cannabidiol oil or THC-A oil or of any loss or unauthorized alteration of records related to cannabidiol oil or THC-A oil or qualifying patients, a pharmacist or pharmaceutical processor shall immediately notify appropriate law-enforcement authorities and the board.

B. A pharmacist or processor shall provide the notice required by subsection A of this section to the board by way of a signed statement that details the circumstances of the event, including an accurate inventory of the quantity and brand names of cannabidiol oil or THC-A oil diverted, stolen, lost, destroyed, or damaged and confirmation that the local law-enforcement authorities were notified. A pharmacist or processor shall make such notice no later than 24 hours after discovery of the event.

C. A pharmacist or pharmaceutical processor shall notify the board no later than the next business day, followed by written notification no later than 10 business days, of any of the following:

1. An alarm activation or other event that requires a response by public safety personnel;

2. A breach of security;

3. The failure of the security alarm system due to a loss of electrical support or mechanical malfunction that is expected to last longer than eight hours; and

4. Corrective measures taken, if any.

Part VI

Cultivation, Production, and Dispensing of Cannabidiol Oil or THC-A Oil

18VAC110-60-280. Cultivation and production of cannabidiol oil or THC-A oil.

A. No cannabidiol oil or THC-A oil shall have had pesticide chemicals or petroleum-based solvents used during the cultivation, extraction, production, or manufacturing process, except that the board may authorize the use of pesticide chemicals for purposes of addressing an infestation that could result in a catastrophic loss of Cannabis crops.

B. Cultivation methods for Cannabis plants and extraction methods used to produce the cannabidiol oil and THC-A shall be performed in a manner deemed safe and effective based on current standards or scientific literature.

C. Any Cannabis plant, seed, parts of plant, extract, cannabidiol oil, or THC-A oil not in compliance with this section shall be deemed adulterated.

[18VAC110-60-285. Registration of products.

A. A pharmaceutical processor shall assign a brand name to each product of cannabidiol oil or THC-A oil. The pharmaceutical processor shall register each brand name with the board, on

a form prescribed by the board, prior to any dispensing and shall associate each brand name with a specific laboratory test that includes a terpenes profile and a list of all active ingredients, including:

1. Tetrahydrocannabinol (THC);

2. Tetrahydrocannabinol acid (THCA);

3. Cannabidiols (CBD);

4. Cannabidiolic acid (CBDA); and

5. Any other active ingredient that constitutes at least 1% of the batch used in the product.

B. A pharmaceutical processor shall not label two products with the same brand name unless the laboratory test results for each product indicate that they contain the same level of each active ingredient listed within subsection A of this section within a range of 97% to 103%.

C. The board shall not register any brand name that:

1. Is identical to, or confusingly similar to, the name of an existing commercially available product;

2. Is identical to, or confusingly similar to, the name of an unlawful product or substance;

3. Is confusingly similar to the name of a previously approved cannabidiol oil or THC-A oil product brand name;

4. Is obscene or indecent;

5. May encourage the use of marijuana, cannabidiol oil, or THC-A oil for recreational purposes;

6. May encourage the use of cannabidiol oil or THC-A oil for a disease or condition other than the disease or condition for which the practitioner intended to treat;

7. Is customarily associated with persons under the age of 18; or

8. Is related to the benefits, safety or efficacy of the cannabidiol oil or THC-A oil product unless supported by substantial evidence or substantial clinical data.]

18VAC110-60-290. Labeling of batch of cannabidiol oil or THC-A oil products.

[~~A.~~] Cannabidiol oil or THC-A oil produced [~~for dispensing~~ as a batch] shall not be adulterated and shall be:

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

2. Labeled with [~~the results of an active ingredient analysis, a microbiological contaminants analysis, a mycotoxin analysis, a heavy metal analysis, and a pesticide chemical residue analysis that have been completed on a batch basis by a laboratory.~~ :

a. The name and address of the pharmaceutical processor;

b. The brand name of the cannabidiol oil or THC-A oil product that was registered with the board pursuant to 18VAC110-20-285;

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

d. The date of final testing and packaging;

e. The expiration date;

f. The quantity of cannabidiol oil or THC-A oil contained therein;

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

i. tetrahydrocannabinol (THC);

ii. tetrahydrocannabinol acid (THCA);

iii. cannabidiol (CBD);

iv. cannabidiolic acid (CBDA); and

v. any other active ingredient that constitute at least 1% of the batch used in the product.

h. A pass or fail rating based on the laboratory's microbiological, mycotoxins, and heavy metals and chemical residue analysis.

~~B. The pharmaceutical processor shall assign a name to each cannabidiol oil or THC-A oil product and associate each name with a specific laboratory test that includes a terpenes profile and a list of all active ingredients, including:~~

~~1. Tetrahydrocannabinol (THC);~~

~~2. Tetrahydrocannabinol acid (THC-A); and~~

~~3. Cannabidiol (CBD).~~

~~C. The pharmaceutical processor shall not label two cannabidiol oil or THC-A oil products with the same name unless the laboratory test results for each product indicate that they contain the same level of each active ingredient listed in subsection A of this section within a range of 97% to 103%.~~

~~D. The pharmaceutical processor shall not name a batched product that:~~

~~1. Is identical to, or confusingly similar to, the name of an existing noncannabidiol oil or THC-A oil product;~~

~~2. Is identical to, or confusingly similar to, the name of an unlawful product or substance;~~

~~3. Is confusingly similar to the name of another cannabidiol oil or THC-A oil product name;~~

~~4. Is obscene or indecent;~~

~~5. May encourage the use of cannabidiol oil or THC-A oil for recreational purposes;~~

~~6. May encourage the use of cannabidiol oil or THC-A oil for a condition other than intractable epilepsy;~~

~~7. Is customarily associated with persons younger than the age of 18 years; or~~

~~8. Is related to the benefits, safety, or efficacy of the cannabidiol oil or THC-A oil product unless supported by substantial evidence or substantial clinical data.~~

~~E. A pharmaceutical processor shall label each cannabidiol oil or THC-A oil product prior to dispensing by a pharmacist and shall securely affix to the package a label that states in legible English:~~

~~1. The name of the cannabidiol oil or THC-A oil;~~

~~2. A unique serial number that will match the product with a pharmaceutical processor batch and lot number so as to facilitate any warnings or recalls the board or pharmaceutical processor deem appropriate;~~

~~3. The date of final testing and packaging;~~

~~4. An appropriate expiration date, not to exceed six months;~~

~~5. The quantity of cannabidiol oil or THC-A oil contained therein;~~

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

~~a. Tetrahydrocannabinol (THC);~~

~~b. Tetrahydrocannabinol acid (THC-A); and~~

~~c. Cannabidiol (CBD); and~~

~~7. A pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, and chemical residue analysis.~~

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

[18VAC110-60-295. Labeling of dispensed cannabidiol oil or THC-A oil.

A. A pharmaceutical processor shall label each cannabidiol oil or THC-A oil product prior to dispensing by a pharmacist and shall securely affix to the package a label that states in legible English:

1. The brand name of the cannabidiol oil or THC-A oil that was registered with the board pursuant to 18VAC110-20-285;

2. A serial number as assigned by the pharmaceutical processor;

3. The date of dispensing the cannabidiol oil or THC-A oil;

4. An appropriate expiration date, not to exceed six months;

5. The quantity of cannabidiol oil or THC-A oil contained therein;

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

a. Tetrahydrocannabinol (THC);

b. Tetrahydrocannabinol acid (THC-A); and

c. Cannabidiol (CBD);

7. A pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, and chemical residue analysis;

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

9. The name of the certifying practitioner;

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

11. Name and address of the pharmaceutical processor; and

12. Any cautionary statement as may be required by statute or regulation.

B. No person except a pharmacist or pharmacist technician under the direct supervision of a pharmacist at the pharmaceutical processor shall alter, deface, or remove any label so affixed.

C. A pharmaceutical processor shall not label cannabidiol oil or THC-A oil products as "organic" unless the Cannabis plants have been organically grown and the cannabidiol oil or THC-A oil products have been produced, processed, manufactured, and certified to be consistent with organic standards in compliance with 7 CFR Part 205.]

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

A. No pharmaceutical processor shall utilize a laboratory to handle, test, or analyze cannabidiol oil or THC-A oil unless such laboratory:

1. Is independent from all other persons involved in the cannabidiol oil or THC-A oil industry in Virginia, which shall mean that no person with a direct or indirect interest in the laboratory shall have a direct or indirect financial interest in a pharmacist, pharmaceutical processor, certifying practitioner, or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase, or use of cannabidiol oil or THC-A oil; and

2. Has employed at least one person to oversee and be responsible for the laboratory testing who has earned, from a college or university accredited by a national or regional certifying authority, at least a master's level degree in chemical or biological sciences and a minimum of two years of post-degree laboratory experience or a bachelor's degree in biological sciences and a minimum of four years of post-degree laboratory experience.

B. Immediately prior to producing any cannabidiol oil or THC-A oil product, a pharmaceutical processor shall segregate all harvested Cannabis into homogenized batches. A pharmaceutical processor shall make a sample available from each batch for a laboratory to test for microbiological contaminants, mycotoxins, heavy metals, and pesticide chemical residue, and for purposes of conducting an active ingredient analysis.

C. From the time that a batch of Cannabis has been homogenized for sample testing and eventual packaging, until the laboratory provides the results from its tests and analysis, the pharmaceutical processor shall segregate and withhold from use the entire batch of Cannabis, except the samples that have been removed by the laboratory for testing. During this period of segregation, the pharmaceutical processor shall maintain the Cannabis in a secure, cool, and dry location so as to prevent the Cannabis from becoming contaminated or losing its efficacy.

D. Under no circumstances shall a pharmaceutical processor include Cannabis in a cannabidiol oil or THC-A oil product or sell it prior to the time that the laboratory has completed its testing and analysis and provided those results, in writing, to the pharmaceutical processor or other designated facility employee.

E. The processor shall require the laboratory to immediately return or properly dispose of any Cannabis upon the completion of any testing, use, or research.

F. If a sample of Cannabis does not pass the microbiological, mycotoxin, heavy metal, or pesticide chemical residue test based on the standards set forth in this subsection, the pharmaceutical processor shall dispose of the entire batch from which the sample was taken.

1. For purposes of the microbiological test, a cannabidiol oil or THC-A oil sample shall be deemed to have passed if it satisfies the standards set forth in Section 1111 of the United States Pharmacopeia.

2. For purposes of the mycotoxin test, a Cannabis sample shall be deemed to have passed if it meets the following standards:

Test Specification	
Aflatoxin B1	<20 uG/KG of Substance
Aflatoxin B2	<20 uG/KG of Substance
Aflatoxin O1	<20 uG/KG of Substance
Aflatoxin O2	<20 uG/KG of Substance
Ochratoxin A	<20 uG/KG of Substance

3. For purposes of the heavy metal test, a Cannabis sample shall be deemed to have passed if it meets the following standards:

Metal	Natural Health Products Acceptable Limits uG/KG BW/Day
Arsenic	<0.14
Cadmium	<0.09
Lead	<0.29
Mercury	<0.29

4. For purposes of the pesticide chemical residue test, a Cannabis sample shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the federal Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 CFR Part 180.

G. If a sample of Cannabis passes the microbiological, mycotoxin, heavy metal, and pesticide chemical residue test, the entire batch may be utilized by the processor for immediate manufacturing, packaging and labeling for sale.

H. The processor shall require the laboratory to file with the board an electronic copy of each laboratory test result for any batch that does not pass the microbiological, mycotoxin, heavy metal, or pesticide chemical residue test at the same time that it transmits those results to the pharmaceutical processor. In addition, the laboratory shall maintain the laboratory test results and make them available to the board or an agent of the board.

I. Each pharmaceutical processor shall have such laboratory results available upon request to registered patients, parents, or legal guardians and registered practitioners who have certified qualifying patients.

18VAC110-60-310. Dispensing of cannabidiol oil or THC-A oil.

A. A pharmacist, in good faith, may dispense cannabidiol oil or THC-A oil to any registered patient, parent, or legal guardian as indicated on the written certification.

[1. ~~A pharmacist or pharmacy technician shall require the presentation of a current registration for the patient and parent or legal guardian, if applicable, current written certification and current valid photographic identification issued to a registered patient, parent, or legal guardian, prior to selling oil to such registered patient, parent, or legal guardian.~~ Prior to the initial dispensing of oil pursuant to each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor shall view a current photo identification of the patient, parent, or legal guardian.] The pharmacist or pharmacy technician shall verify in the prescription monitoring program or other program recognized by the board that the registrations are current, the written

certification has not expired, and the date and quantity of the last dispensing of cannabidiol oil or THC-A oil to the registered patient.

[2. The pharmacist or pharmacy technician shall make and maintain for two years a paper or electronic copy of the current written certification that provides an exact image of the document that is clearly legible.

3. Prior to any subsequent dispensing, the pharmacist, pharmacy technician, or delivery agent shall view the current written certification and a current photo identification and current registration of the patient, parent, or legal guardian and shall maintain record of such viewing in accordance with policies and procedures of the processor.]

B. A pharmacist may dispense a portion of a registered patient's [~~one-month~~ 90-day] supply of cannabidiol oil or THC-A oil. The pharmacist may dispense the remaining portion of the [~~one-month~~ 90-day] supply of cannabidiol oil or THC-A oil at any time except that no registered patient, parent, or legal guardian shall receive more than a [~~one-month~~ 90-day] supply of cannabidiol oil or THC-A oil in a [~~one-month~~ 90-day] period from any pharmaceutical processor.

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

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

2. The name or kind of cannabidiol oil or THC-A oil and its strength;

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

4. The date of dispensing the cannabidiol oil or THC-A oil;

5. The quantity of cannabidiol oil or THC-A oil dispensed, which cannot exceed [~~29~~ 60] fluid ounces;

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

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

8. Such directions for use as may be included in the practitioner's written certification or otherwise provided by the practitioner;

9. The name or initials of the dispensing pharmacist;

10. Name, address, and telephone number of the pharmaceutical processor;

11. Any cautionary statement as may be necessary; and

12. A prominently printed expiration date based on the pharmaceutical processor's recommended conditions of use and storage that can be read and understood by the ordinary individual.

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

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

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

G. A pharmacist shall document a registered patient's self-assessment of the effects of cannabidiol oil or THC-A oil in treating the registered patient's [~~intractable epilepsy~~ diagnosed condition or disease] or the symptoms thereof. A pharmaceutical processor shall maintain such documentation in writing or electronically for two years from the date of dispensing and such documentation shall be made available in accordance with regulation.

H. A pharmacist shall exercise professional judgment to determine whether to dispense cannabidiol oil or THC-A oil to a registered patient, parent, or legal guardian if the pharmacist suspects that dispensing cannabidiol oil or THC-A oil to the registered patient, parent, or legal guardian may have negative health or safety consequences for the registered patient or the public.

18VAC110-60-320. Dispensing error review and reporting; quality assurance program.

A. A pharmaceutical processor shall implement and comply with a quality assurance program that describes, in writing, policies and procedures to detect, identify, and prevent dispensing errors. A pharmaceutical processor shall distribute it to all pharmaceutical processor employees and shall make it readily available on the premises of the pharmaceutical processor. Such policies and procedures shall include:

1. Directions for communicating the details of a dispensing error to the practitioner who certified a qualifying patient and to the qualifying patient, the patient's parent or legal guardian or appropriate family member if the patient is deceased or is unable to fully comprehend the communication. Such communication shall describe methods of correcting the dispensing error or reducing the negative impact of the error on the qualifying patient; and

2. A process to document and assess dispensing errors to determine the cause of the error and an appropriate response.

B. A pharmaceutical processor shall use the findings of its quality assurance program to develop systems and workflow processes designed to prevent dispensing errors. A pharmaceutical processor PIC shall:

1. Inform pharmaceutical processor employees of changes to policy, procedure, systems, or processes made as a result of recommendations generated by the quality assurance program;

2. Notify all processor employees that the discovery or reporting of a dispensing error shall be relayed immediately to a pharmacist on duty;

3. Ensure that a pharmacist performs a quality assurance review for each dispensing error. A pharmacist shall commence such review as soon as is reasonably possible, but no later than two business days from the date the dispensing error is discovered; and

4. Create a record of every quality assurance review. This record shall contain at least the following:

a. The date or dates of the quality assurance review and the names and titles of the persons performing the review;

b. The pertinent data and other information relating to the dispensing error reviewed;

c. Documentation of contact with the registered patient, parent, or legal guardian where applicable, and the practitioner who certified the patient;

d. The findings and determinations generated by the quality assurance review; and

e. Recommended changes to pharmaceutical processor policy, procedure, systems, or processes, if any.

C. A pharmaceutical processor shall maintain for three years a copy of the pharmaceutical processor's quality assurance program and records of all reported dispensing errors and quality assurance reviews in an orderly manner and filed by date.

18VAC110-60-330. Disposal of cannabidiol oil or THC-A oil.

A. To mitigate the risk of diversion, a pharmaceutical processor, an agent of the board, or the board's agent shall routinely and promptly dispose of undesired, excess, unauthorized, obsolete, adulterated, misbranded, or deteriorated Cannabis plants, including seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil by disposal in the presence of an agent of the board in such a manner as to render the cannabidiol oil or THC-A oil nonrecoverable.

B. The person disposing of the cannabidiol oil or THC-A oil shall maintain and make available a separate record of each such disposal indicating:

1. The date and time of disposal;

2. The manner of disposal;

3. The name and quantity of cannabidiol oil or THC-A oil disposed of; and

4. The signatures of the persons disposing of the cannabidiol oil or THC-A oil, the agent of the board, and any other persons present during the disposal.

C. The record of disposal shall be maintained at the pharmaceutical processor for three years from the date of disposal.

Agenda Item: Adoption of emergency regulations relating to delivery of Schedule VI prescription devices

Included in package:

Copy of HB878 (SB413 was identical)

Copy of draft amendments to regulation

Staff note:

The 2nd enactment on HB878 requires the Board to promulgate regulations to be effective within 280 days of its enactment (day the Governor signed the bill). The legislation becomes effective on July 1, 2018, so the Board will need to have regulations in effect by December 14, 2018.

Board action:

Adoption of emergency regulations as drafted or as amended
Approval of a Notice of Intended Regulatory Action to replace emergency regulations

CHAPTER 241

An Act to amend and reenact § 54.1-3401, as it is currently effective and as it shall become effective, and to amend the Code of Virginia by adding a section numbered 54.1-3415.1, relating to delivery of Schedule VI prescription devices.

[H 878]

Approved March 9, 2018

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3401, as it is currently effective and as it shall become effective, of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding a section numbered 54.1-3415.1 as follows:

§ 54.1-3401. (Effective until July 1, 2020) Definitions.

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

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by (i) a practitioner or by his authorized agent and under his direction or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs or devices.

"Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

"Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone.

"Animal" means any nonhuman animate being endowed with the power of voluntary action.

"Automated drug dispensing system" means a mechanical or electronic system that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for such drugs.

"Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or any derivative of arsphenamine or any other trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human beings.

"Biosimilar" means a biological product that is highly similar to a specific reference biological product, notwithstanding minor differences in clinically inactive compounds, such that there are no clinically meaningful differences between the reference biological product and the biological product that has been licensed as a biosimilar pursuant to 42 U.S.C. § 262(k) in terms of safety, purity, and potency of the product.

"Board" means the Board of Pharmacy.

"Bulk drug substance" means any substance that is represented for use, and that, when used in the compounding, manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug; however, "bulk drug substance" shall not include intermediates that are used in the synthesis of such substances.

"Change of ownership" of an existing entity permitted, registered, or licensed by the Board means (i) the sale 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, the dissolution of a partnership, or change in partnership composition; (iii) the acquisition or disposal of 50 percent 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; (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; or (v) the expiration or forfeiture of a corporation's charter.

"Co-licensed partner" means a person who, with at least one other person, has the right to engage in the manufacturing or marketing of a prescription drug, consistent with state and federal law.

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by

a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in expectation of receiving a valid prescription based on observed historical patterns of prescribing and dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a manufacturer's product drugs for the purpose of administration to a patient, when performed by a practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person supervised by such practitioner pursuant to subdivision A 6 or 19 of § 54.1-2901, or a person supervised by such practitioner or a licensed nurse practitioner or physician assistant pursuant to subdivision A 4 of § 54.1-2901 shall not be considered compounding.

"Controlled substance" means a drug, substance, or immediate precursor in Schedules I through VI of this chapter. The term shall not include distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 3.2 or Title 4.1. The term "controlled substance" includes a controlled substance analog that has been placed into Schedule I or II by the Board pursuant to the regulatory authority in subsection D of § 54.1-3443.

"Controlled substance analog" means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance in Schedule I or II and either (i) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II or (ii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II. "Controlled substance analog" does not include (a) any substance for which there is an approved new drug application as defined under § 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) or that is generally recognized as safe and effective pursuant to §§ 501, 502, and 503 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 351, 352, and 353) and 21 C.F.R. Part 330; (b) with respect to a particular person, any substance for which an exemption is in effect for investigational use for that person under § 505 of the federal Food, Drug, and Cosmetic Act to the extent that the conduct with respect to that substance is pursuant to such exemption; or (c) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

"DEA" means the Drug Enforcement Administration, U.S. Department of Justice, or its successor agency.

"Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated by this chapter, whether or not there exists an agency relationship, *including delivery of a Schedule VI prescription device to an ultimate user or consumer on behalf of a medical equipment supplier by a manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider at the direction of a medical equipment supplier in accordance with § 54.1-3415.1.*

"Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals or to affect the structure or any function of the body of man or animals.

"Dialysis care technician" or "dialysis patient care technician" means an individual who is certified by an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.) and who, under the supervision of a licensed physician, nurse practitioner, physician assistant, or a registered nurse, assists in the care of patients undergoing renal dialysis treatments in a Medicare-certified renal dialysis facility.

"Dialysis solution" means either the commercially available, unopened, sterile solutions whose purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal dialysis, or commercially available solutions whose purpose is to be used in the performance of hemodialysis not to include any solutions administered to the patient intravenously.

"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 that delivery. However, dispensing shall not include the transportation of drugs mixed, diluted, or reconstituted in accordance with this chapter to other sites operated by such practitioner or that practitioner's medical practice for the purpose of administration of such drugs to patients of the practitioner or that practitioner's medical practice at such other sites. For practitioners of medicine or osteopathy, "dispense" shall only include the provision of drugs by a practitioner to patients to take with them away from the practitioner's place of practice.

"Dispenser" means a practitioner who dispenses.

"Distribute" means to deliver other than by administering or dispensing a controlled substance.

"Distributor" means a person who distributes.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of man or animals; (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii), or (iii); or (v) a biological product. "Drug" does not include devices or their components, parts, or accessories.

"Drug product" means a specific drug in dosage form from a known source of manufacture, whether by brand or therapeutically equivalent drug product name.

"Electronic transmission prescription" means any prescription, other than an oral or written prescription or a prescription transmitted by facsimile machine, that is electronically transmitted directly to a pharmacy without interception or intervention from a third party from a practitioner authorized to prescribe or from one pharmacy to another pharmacy.

"Facsimile (FAX) prescription" means a written prescription or order that is transmitted by an electronic device over telephone lines that sends the exact image to the receiving pharmacy in hard copy form.

"FDA" means the U.S. Food and Drug Administration.

"Hashish oil" means any oily extract containing one or more cannabinoids, but shall not include any such extract with a tetrahydrocannabinol content of less than 12 percent by weight.

"Immediate precursor" means a substance which the Board of Pharmacy has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

"Interchangeable" means a biosimilar that meets safety standards for determining interchangeability pursuant to 42 U.S.C. § 262(k)(4).

"Label" means a display of written, printed, or graphic matter upon the immediate container of any article. A requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such article or is easily legible through the outside container or wrapper.

"Labeling" means all labels and other written, printed, or graphic matter on an article or any of its containers or wrappers, or accompanying such article.

"Manufacture" means the production, preparation, propagation, conversion, or processing of any item regulated by this chapter, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. This term does not include compounding.

"Manufacturer" means every person who manufactures, a manufacturer's co-licensed partner, or a repackager.

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana include the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis. Marijuana shall not include industrial hemp as defined in § 3.2-4112 that is possessed, cultivated, or manufactured by a grower licensed pursuant to § 3.2-4115.

"Medical equipment supplier" means any person, as defined in § 1-230, engaged in the delivery to the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment, solutions for peritoneal dialysis, and sterile water or saline for irrigation.

"Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative, or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (i), but not including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (iv) coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain cocaine or ecgonine.

"New drug" means (i) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug is not generally recognized, among

experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use, or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

"Nuclear medicine technologist" means an individual who holds a current certification with the American Registry of Radiological Technologists or the Nuclear Medicine Technology Certification Board.

"Official compendium" means the official United States Pharmacopoeia National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them.

"Official written order" means an order written on a form provided for that purpose by the U.S. Drug Enforcement Administration, under any laws of the United States making provision therefor, if such order forms are authorized and required by federal law, and if no such order form is provided then on an official form provided for that purpose by the Board of Pharmacy.

"Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under Article 4 (§ 54.1-3437 et seq.), the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

"Opium poppy" means the plant of the species Papaver somniferum L., except the seeds thereof.

"Original package" means the unbroken container or wrapping in which any drug or medicine is enclosed together with label and labeling, put up by or for the manufacturer, wholesaler, or distributor for use in the delivery or display of such article.

"Outsourcing facility" means a facility that is engaged in the compounding of sterile drugs and is currently registered as an outsourcing facility with the U.S. Secretary of Health and Human Services and that complies with all applicable requirements of federal and state law, including the Federal Food, Drug, and Cosmetic Act.

"Person" means both the plural and singular, as the case demands, and includes an individual, partnership, corporation, association, governmental agency, trust, or other institution or entity.

"Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the application for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in a manner complying with the laws and regulations for the practice of pharmacy and the sale and dispensing of controlled substances; the "pharmacist-in-charge" shall personally supervise the pharmacy and the pharmacy's personnel as required by § 54.1-3432.

"Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

"Practitioner" means a physician, dentist, licensed nurse practitioner pursuant to § 54.1-2957.01, licensed physician assistant pursuant to § 54.1-2952.1, pharmacist pursuant to § 54.1-3300, TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to a controlled substance in the course of professional practice or research in the Commonwealth.

"Prescriber" means a practitioner who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription.

"Prescription" means an order for drugs or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph, or other means of communication to a pharmacist by a duly licensed physician, dentist, veterinarian, or other practitioner authorized by law to prescribe and administer such drugs or medical supplies.

"Prescription drug" means any drug required by federal law or regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353(b)).

"Production" or "produce" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance or marijuana.

"Proprietary medicine" means a completely compounded nonprescription drug in its unbroken, original package which does not contain any controlled substance or marijuana as defined in this chapter and is not in itself poisonous, and which is sold, offered, promoted, or advertised directly to the general public by or under the authority of the manufacturer or primary distributor, under a trademark, trade name, or other trade symbol privately owned, and the labeling of which conforms to the requirements of this chapter and applicable federal law. However, this definition shall not include a drug that is only advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic,

a drug that may be dispensed only upon prescription or the label of which bears substantially the statement "Warning — may be habit-forming," or a drug intended for injection.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any non-radioactive 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.

"Reference biological product" means the single biological product licensed pursuant to 42 U.S.C. § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food and Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to 42 U.S.C. § 262(k).

"Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as an individual, proprietor, agent, servant, or employee.

"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."

"Third-party logistics provider" means a person that provides or coordinates warehousing of or other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device but does not take ownership of the product or have responsibility for directing the sale or disposition of the product.

"USP-NF" means the current edition of the United States Pharmacopeia-National Formulary.

"Warehouser" means any person, other than a wholesale distributor, manufacturer, or third-party logistics provider, engaged in the business of *(i)* selling or otherwise distributing prescription drugs or devices to any person who is not the ultimate user or consumer *and (ii) delivering Schedule VI prescription devices to the ultimate user or consumer pursuant to § 54.1-3415.1.* No person shall be subject to any state or local tax by reason of this definition.

"Wholesale distribution" means *(i)* distribution of prescription drugs to persons other than consumers or patients *and (ii) delivery of Schedule VI prescription devices to the ultimate user or consumer pursuant to § 54.1-3415.1,* subject to the exemptions set forth in the federal Drug Supply Chain Security Act.

"Wholesale distributor" means any person other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager that engages in wholesale distribution.

The words "drugs" and "devices" as used in Chapter 33 (§ 54.1-3300 et seq.) and in this chapter shall not include surgical or dental instruments, physical therapy equipment, X-ray apparatus, or glasses or lenses for the eyes.

The terms "pharmacist," "pharmacy," and "practice of pharmacy" as used in this chapter shall be defined as provided in Chapter 33 (§ 54.1-3300 et seq.) unless the context requires a different meaning.

§ 54.1-3401. (Effective July 1, 2020) Definitions.

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

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by (i) a practitioner or by his authorized agent and under his direction or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs or devices.

"Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

"Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone.

"Animal" means any nonhuman animate being endowed with the power of voluntary action.

"Automated drug dispensing system" means a mechanical or electronic system that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for such drugs.

"Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or any derivative of arsphenamine or any other trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human

beings.

"Biosimilar" means a biological product that is highly similar to a specific reference biological product, notwithstanding minor differences in clinically inactive compounds, such that there are no clinically meaningful differences between the reference biological product and the biological product that has been licensed as a biosimilar pursuant to 42 U.S.C. § 262(k) in terms of safety, purity, and potency of the product.

"Board" means the Board of Pharmacy.

"Bulk drug substance" means any substance that is represented for use, and that, when used in the compounding, manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug; however, "bulk drug substance" shall not include intermediates that are used in the synthesis of such substances.

"Change of ownership" of an existing entity permitted, registered, or licensed by the Board means (i) the sale 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, the dissolution of a partnership, or change in partnership composition; (iii) the acquisition or disposal of 50 percent 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; (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; or (v) the expiration or forfeiture of a corporation's charter.

"Co-licensed partner" means a person who, with at least one other person, has the right to engage in the manufacturing or marketing of a prescription drug, consistent with state and federal law.

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in expectation of receiving a valid prescription based on observed historical patterns of prescribing and dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a manufacturer's product drugs for the purpose of administration to a patient, when performed by a practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person supervised by such practitioner pursuant to subdivision A 6 or 19 of § 54.1-2901, or a person supervised by such practitioner or a licensed nurse practitioner or physician assistant pursuant to subdivision A 4 of § 54.1-2901 shall not be considered compounding.

"Controlled substance" means a drug, substance, or immediate precursor in Schedules I through VI of this chapter. The term shall not include distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 3.2 or Title 4.1. The term "controlled substance" includes a controlled substance analog that has been placed into Schedule I or II by the Board pursuant to the regulatory authority in subsection D of § 54.1-3443.

"Controlled substance analog" means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance in Schedule I or II and either (i) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II or (ii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II. "Controlled substance analog" does not include (a) any substance for which there is an approved new drug application as defined under § 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) or that is generally recognized as safe and effective pursuant to §§ 501, 502, and 503 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 351, 352, and 353) and 21 C.F.R. Part 330; (b) with respect to a particular person, any substance for which an exemption is in effect for investigational use for that person under § 505 of the federal Food, Drug, and Cosmetic Act to the extent that the conduct with respect to that substance is pursuant to such exemption; or (c) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

"DEA" means the Drug Enforcement Administration, U.S. Department of Justice, or its successor agency.

"Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated by this chapter, whether or not there exists an agency relationship, *including delivery of a Schedule VI prescription device to an ultimate user or consumer on behalf of a medical equipment supplier by a manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor,*

warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider at the direction of a medical equipment supplier in accordance with § 54.1-3415.1.

"Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals or to affect the structure or any function of the body of man or animals.

"Dialysis care technician" or "dialysis patient care technician" means an individual who is certified by an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.) and who, under the supervision of a licensed physician, nurse practitioner, physician assistant, or a registered nurse, assists in the care of patients undergoing renal dialysis treatments in a Medicare-certified renal dialysis facility.

"Dialysis solution" means either the commercially available, unopened, sterile solutions whose purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal dialysis, or commercially available solutions whose purpose is to be used in the performance of hemodialysis not to include any solutions administered to the patient intravenously.

"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 that delivery. However, dispensing shall not include the transportation of drugs mixed, diluted, or reconstituted in accordance with this chapter to other sites operated by such practitioner or that practitioner's medical practice for the purpose of administration of such drugs to patients of the practitioner or that practitioner's medical practice at such other sites. For practitioners of medicine or osteopathy, "dispense" shall only include the provision of drugs by a practitioner to patients to take with them away from the practitioner's place of practice.

"Dispenser" means a practitioner who dispenses.

"Distribute" means to deliver other than by administering or dispensing a controlled substance.

"Distributor" means a person who distributes.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of man or animals; (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii), or (iii); or (v) a biological product. "Drug" does not include devices or their components, parts, or accessories.

"Drug product" means a specific drug in dosage form from a known source of manufacture, whether by brand or therapeutically equivalent drug product name.

"Electronic prescription" means a written prescription that is generated on an electronic application and is transmitted to a pharmacy as an electronic data file; Schedule II through V prescriptions shall be transmitted in accordance with 21 C.F.R. Part 1300.

"Facsimile (FAX) prescription" means a written prescription or order that is transmitted by an electronic device over telephone lines that sends the exact image to the receiving pharmacy in hard copy form.

"FDA" means the U.S. Food and Drug Administration.

"Hashish oil" means any oily extract containing one or more cannabinoids, but shall not include any such extract with a tetrahydrocannabinol content of less than 12 percent by weight.

"Immediate precursor" means a substance which the Board of Pharmacy has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

"Interchangeable" means a biosimilar that meets safety standards for determining interchangeability pursuant to 42 U.S.C. § 262(k)(4).

"Label" means a display of written, printed, or graphic matter upon the immediate container of any article. A requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such article or is easily legible through the outside container or wrapper.

"Labeling" means all labels and other written, printed, or graphic matter on an article or any of its containers or wrappers, or accompanying such article.

"Manufacture" means the production, preparation, propagation, conversion, or processing of any item regulated by this chapter, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. This term does not include compounding.

"Manufacturer" means every person who manufactures, a manufacturer's co-licensed partner, or a repackager.

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or

its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana include the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis. Marijuana shall not include industrial hemp as defined in § 3.2-4112 that is possessed, cultivated, or manufactured by a grower licensed pursuant to § 3.2-4115.

"Medical equipment supplier" means any person, as defined in § 1-230, engaged in the delivery to the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment, solutions for peritoneal dialysis, and sterile water or saline for irrigation.

"Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative, or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (i), but not including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (iv) coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain cocaine or ecgonine.

"New drug" means (i) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use, or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

"Nuclear medicine technologist" means an individual who holds a current certification with the American Registry of Radiological Technologists or the Nuclear Medicine Technology Certification Board.

"Official compendium" means the official United States Pharmacopoeia National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them.

"Official written order" means an order written on a form provided for that purpose by the U.S. Drug Enforcement Administration, under any laws of the United States making provision therefor, if such order forms are authorized and required by federal law, and if no such order form is provided then on an official form provided for that purpose by the Board of Pharmacy.

"Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under Article 4 (§ 54.1-3437 et seq.), the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

"Opium poppy" means the plant of the species Papaver somniferum L., except the seeds thereof.

"Original package" means the unbroken container or wrapping in which any drug or medicine is enclosed together with label and labeling, put up by or for the manufacturer, wholesaler, or distributor for use in the delivery or display of such article.

"Outsourcing facility" means a facility that is engaged in the compounding of sterile drugs and is currently registered as an outsourcing facility with the U.S. Secretary of Health and Human Services and that complies with all applicable requirements of federal and state law, including the Federal Food, Drug, and Cosmetic Act.

"Person" means both the plural and singular, as the case demands, and includes an individual, partnership, corporation, association, governmental agency, trust, or other institution or entity.

"Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the application for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in a manner complying with the laws and regulations for the practice of pharmacy and the sale and dispensing of controlled substances; the "pharmacist-in-charge" shall personally supervise the pharmacy and the pharmacy's personnel as required by § 54.1-3432.

"Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

"Practitioner" means a physician, dentist, licensed nurse practitioner pursuant to § 54.1-2957.01, licensed physician assistant pursuant to § 54.1-2952.1, pharmacist pursuant to § 54.1-3300, TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to a controlled substance in the course of professional practice or research in the Commonwealth.

"Prescriber" means a practitioner who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription.

"Prescription" means an order for drugs or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph, or other means of communication to a pharmacist by a duly licensed physician, dentist, veterinarian, or other practitioner authorized by law to prescribe and administer such drugs or medical supplies.

"Prescription drug" means any drug required by federal law or regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353(b)).

"Production" or "produce" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance or marijuana.

"Proprietary medicine" means a completely compounded nonprescription drug in its unbroken, original package which does not contain any controlled substance or marijuana as defined in this chapter and is not in itself poisonous, and which is sold, offered, promoted, or advertised directly to the general public by or under the authority of the manufacturer or primary distributor, under a trademark, trade name, or other trade symbol privately owned, and the labeling of which conforms to the requirements of this chapter and applicable federal law. However, this definition shall not include a drug that is only advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic, a drug that may be dispensed only upon prescription or the label of which bears substantially the statement "Warning — may be habit-forming," or a drug intended for injection.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any non-radioactive 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.

"Reference biological product" means the single biological product licensed pursuant to 42 U.S.C. § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food and Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to 42 U.S.C. § 262(k).

"Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as an individual, proprietor, agent, servant, or employee.

"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."

"Third-party logistics provider" means a person that provides or coordinates warehousing of or other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device but does not take ownership of the product or have responsibility for directing the sale or disposition of the product.

"USP-NF" means the current edition of the United States Pharmacopeia-National Formulary.

"Warehouser" means any person, other than a wholesale distributor, manufacturer, or third-party logistics provider, engaged in the business of *(i)* selling or otherwise distributing prescription drugs or devices to any person who is not the ultimate user or consumer *and (ii) delivering Schedule VI prescription devices to the ultimate user or consumer pursuant to § 54.1-3415.1.* No person shall be subject to any state or local tax by reason of this definition.

"Wholesale distribution" means *(i)* distribution of prescription drugs to persons other than consumers or patients *and (ii) delivery of Schedule VI prescription devices to the ultimate user or consumer pursuant to § 54.1-3415.1,* subject to the exemptions set forth in the federal Drug Supply Chain Security Act.

"Wholesale distributor" means any person other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager that engages in wholesale distribution.

The words "drugs" and "devices" as used in Chapter 33 (§ 54.1-3300 et seq.) and in this chapter shall not include surgical or dental instruments, physical therapy equipment, X-ray apparatus, or glasses or lenses for the eyes.

The terms "pharmacist," "pharmacy," and "practice of pharmacy" as used in this chapter shall be

defined as provided in Chapter 33 (§ 54.1-3300 et seq.) unless the context requires a different meaning.

§ 54.1-3415.1. Delivery of medical devices on behalf of a medical equipment supplier.

A. A permitted manufacturer, wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider, or registered nonresident manufacturer or nonresident wholesale distributor may deliver Schedule VI prescription devices directly to an ultimate user or consumer on behalf of a medical equipment supplier provided that (i) such delivery occurs at the direction of a medical equipment supplier that has received a valid order from a prescriber authorizing the dispensing of such prescription device to the ultimate user or consumer and (ii) the manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider has entered into an agreement with the medical equipment supplier for such delivery.

B. A permitted manufacturer, wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider, or registered nonresident manufacturer or nonresident wholesale distributor 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.

2. That the Board of Pharmacy (the Board) shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment. Such regulations shall include provisions governing agreements between a manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider and a medical equipment supplier, home health agency, hospice, pharmacy, nursing home, or assisted living facility for delivery of Schedule VI prescription devices directly to an ultimate user or consumer and such other provisions as the Board may deem appropriate.

Project 5526 - none

BOARD OF PHARMACY

Delivery of Schedule VI devices

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

A. In accordance with provisions of subsection A of § 54.1-3415.1 of the Code of Virginia, a manufacturer, nonresident manufacturer, wholesale distributor, non-resident wholesaler distributor, third party logistics provider, non-resident third party logistics provider, warehouser, or non-resident 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 subsection A of this section 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 patients receiving services from the medical equipment supplier who require delivery of Schedule VI devices.

3. The medical equipment supplier 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 valid order from a prescriber for the delivery of a Schedule VI prescription device to patient or ultimate 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 provisions of subsection B of § 54.1-3415.1 of the Code of Virginia, a manufacturer, nonresident manufacturer, wholesale distributor, non-resident wholesaler distributor, third party logistics provider, non-resident third party logistics provider, warehouser, or non-resident warehouser permitted, licensed, or registered in Virginia may deliver Schedule VI prescription devices directly to an ultimate user 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 subsection B of this section 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 patients of the home health agency, nursing home, assisted living facility, or hospice who require delivery of Schedule VI 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 patient or ultimate 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 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 Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Agenda Item: Adoption of Exempt Regulations for Registration of nonresident warehousers and nonresident third-party-logistics providers

Included in package:

- Copy of HB520
- Draft amendments to regulations

Board action:

- Motion to amend sections of 18VAC110-50-10 et seq., as presented in the agenda package

CHAPTER 96

An Act to amend and reenact § 54.1-3435.1 of the Code of Virginia and to amend the Code of Virginia by adding sections numbered 54.1-3435.4:01 and 54.1-3435.4:2, relating to the Board of Pharmacy; nonresident warehousers and nonresident third-party logistics providers; registration and regulation.

[H 520]

Approved March 2, 2018

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3435.1 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding sections numbered 54.1-3435.4:01 and 54.1-3435.4:2 as follows:

§ 54.1-3435.1. Denial, revocation, and suspension of license, permit, or registration of certain entities.

A. The Board may deny, revoke, suspend, or take other disciplinary actions against a wholesale distributor license, nonresident wholesale distributor registration, third-party logistics provider permit, *nonresident third-party logistics provider registration,* manufacturer permit, ~~or~~ nonresident manufacturer permit, *or nonresident warehouser registration* as provided for in § 54.1-3316 or the following:

1. Any conviction of the applicant, licensee, or registrant under federal or state laws relating to controlled substances, including, but not limited to, drug samples and wholesale or retail prescription drug distribution;

2. Violations of licensing requirements under previously held licenses;

3. Failure to maintain and make available to the Board or to federal regulatory officials those records required to be maintained by wholesale distributors of prescription drugs; or

4. Violations of the minimum requirements for qualifications, personnel, storage, and handling of prescription drugs and maintenance of prescription drug records as set forth in the federal Drug Supply Chain Security Act of 2013, Title II of P. L. 113-54, and the requirements of Chapter 21 of the Code of Federal Regulations.

B. Wholesale drug distributors, nonresident wholesale drug distributors, third-party logistics providers, *nonresident third-party logistics providers,* manufacturers, ~~and~~ nonresident manufacturers, *and nonresident warehousers* shall allow the Board or its authorized agents to enter and inspect, at reasonable times and in a reasonable manner, their premises and delivery vehicles, and to audit their records and written operating procedures. Such agents shall be required to show appropriate identification prior to being permitted access to wholesale drug distributors' premises and delivery vehicles.

§ 54.1-3435.4:01. Registration to act as a nonresident warehouser; regulations.

A. Any warehouser located outside the Commonwealth that ships prescription drugs or devices into the Commonwealth shall be registered with the Board. Such nonresident warehouser shall renew such registration annually on a date determined by the Board and shall notify the Board within 30 days of any substantive change in the information previously submitted.

B. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs and devices by nonresident warehousers as it deems necessary to implement this section, to prevent diversion of prescription drugs and devices, and to protect the public.

C. The nonresident warehouser shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located that authorizes the possession and distribution of such prescription drugs and devices and shall furnish proof of such upon application and at each renewal.

D. Records of prescription drugs and devices distributed into the Commonwealth shall be maintained in such a manner that they are readily retrievable from records of distributions into other jurisdictions and shall be provided to the Board, its authorized agent, or any agent designated by the Superintendent of State Police upon request within seven days of receipt of such request.

§ 54.1-3435.4:2. Registration of nonresident third-party logistics provider; renewal.

A. Any third-party logistics provider located outside the Commonwealth that ships prescription drugs or devices into the Commonwealth shall be registered with the Board. Such nonresident third-party logistics provider shall renew such registration annually on a date determined by the Board and shall notify the Board within 30 days of any substantive change in the information previously submitted.

B. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs and devices by nonresident third-party logistics providers as it deems necessary to implement this section, to prevent diversion of prescription drugs and devices, and to protect the public.

C. The nonresident third-party logistics provider shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located or current licensure as a third-party logistics provider with the FDA and shall furnish proof of such upon application and at each renewal.

D. Records of prescription drugs and devices distributed into the Commonwealth shall be maintained in such a manner that they are readily retrievable from records of distributions into other jurisdictions and shall be provided to the Board, its authorized agent, or any agent designated by the Superintendent of State Police upon request within seven days of receipt of such request.

Project 5525 - none

BOARD OF PHARMACY

Registration of non-residents

CHAPTER 50

REGULATIONS GOVERNING WHOLESALE DISTRIBUTORS, MANUFACTURERS, ~~AND~~ WAREHOUSERS, AND THIRD-PARTY LOGISTICS PROVIDERS

18VAC110-50-20. Fees.

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

B. Initial application fees.

1. Nonrestricted manufacturer permit	$270
2. Restricted manufacturer permit	$180
3. Wholesale distributor license	$270
4. Warehouser permit	$270
5. Nonresident wholesale distributor registration	$270
6. Controlled substances registration	$90
7. Third-party logistics provider permit	$270
8. Nonresident manufacturer registration	$270
9. Nonresident warehouser registration	$270
10. Nonresident third-party logistics provider registration	$270

C. Annual renewal fees shall be due on February 28 of each year.

1. Nonrestricted manufacturer permit	$270
2. Restricted manufacturer permit	$180
3. Wholesale distributor license	$270
4. Warehouser permit	$270
5. Nonresident wholesale distributor registration	$270
6. Controlled substances registration	$90
	$270

7. Third-party logistics provider permit	$270
8. Nonresident manufacturer registration	$270
9. Nonresident warehouser registration	$270
10. Nonresident third-party logistics provider registration	$270

D. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date. 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. Nonrestricted manufacturer permit	$90
2. Restricted manufacturer permit	$60
3. Wholesale distributor license	$90
4. Warehouser permit	$90
5. Nonresident wholesale distributor registration	$90
6. Controlled substances registration	$30
7. Third-party logistics provider permit	$90
8. Nonresident manufacturer registration	$90
9. Nonresident warehouser registration	$90
10. Nonresident third-party logistics provider registration	$90

E. Reinstatement fees.

1. Any entity attempting to renew a license, permit, or registration more than one year after the expiration date 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.

2. 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. 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.

3. 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. Nonrestricted manufacturer permit	$240
b. Restricted manufacturer permit	$210
c. Wholesale distributor license	$240
d. Warehouser permit	$240
e. Nonresident wholesale distributor registration	$240
f. Controlled substances registration	$180
g. Third-party logistics provider permit	$240
h. Nonresident manufacturer registration	$240
i. Nonresident warehouser registration	$240
j. Nonresident third-party logistics provider registration	$240

F. Application for change or inspection fees.

1. Reinspection fee	$150
2. Inspection fee for change of location, structural changes, or security system changes	$150
3. Change of ownership fee	$50
4. Change of responsible party	$50

G. The fee for a returned check shall be $35.

H. The fee for verification of license, permit, or registration shall be $25.

18VAC110-50-30. Application; location of business; inspection required.

A. Any person or entity desiring to obtain a license as a wholesale distributor, registration as a nonresident wholesale distributor ~~or~~ ,nonresident manufacturer, nonresident warehouser, or nonresident third-party logistics provider, or permit as a manufacturer, warehouser, or third-party logistics provider shall file an application with the board on a form approved by the board. An application shall be filed for a new license, registration, or permit, or for acquisition of an existing

wholesale distributor, manufacturer, warehouser, nonresident wholesale distributor, nonresident manufacturer, or third-party logistics provider.

B. A licensee or permit holder proposing to change the location of an existing license or permit, or make structural or security system 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. A license, permit, or registration shall not be issued to any wholesale distributor, manufacturer, warehouser, nonresident warehouser, nonresident wholesale distributor, nonresident manufacturer, ~~or~~ third-party logistics provider, or nonresident third-party logistics provider 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, permit, or registration is issued, the applicant shall demonstrate compliance with all federal, state and local laws and ordinances.

D. If a wholesale distributor, manufacturer, warehouser, or third-party logistics provider engages in receiving, possessing, storing, using, manufacturing, distributing, or otherwise disposing of any Schedules II through V controlled substances, it shall also obtain a controlled substances registration from the board in accordance with § 54.1-3422 of the Code of Virginia, and shall also be duly registered with DEA and in compliance with all applicable laws and rules for the storage, distribution, shipping, handling, and transporting of controlled substances.

E. The proposed location, structural changes, or security system changes shall be inspected by an authorized agent of the board prior to issuance of a license or permit.

1. Applications that indicate a requested inspection date, or requests 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 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 proposed prescription drug storage area shall comply with 18VAC110-50-40 and 18VAC110-50-50, and wholesale distributors shall meet the requirements of 18VAC110-50-90.

4. If an applicant substantially fails to meet the requirements for issuance of a permit or license 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 18VAC110-50-20 prior to a reinspection being conducted.

F. Prescription drugs shall not be stocked within the proposed location or moved to a new location until approval is granted by the inspector or board staff.

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, nonresident warehouser, nonresident third-party logistics provider 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 installation shall be hardwired and both the installation and device shall be based on accepted burglar alarm industry standards.

3. The device shall be maintained in operating order and shall have an auxiliary source of power.

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 third-party logistics provider permit, or limited-use nonresident third-party logistics provider registration 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.

18VAC110-50-70. Minimum required information.

A. The application form for a new license, registration as a nonresident wholesale distributor or a nonresident third-party logistics provider, or permit as a third-party logistics provider or any change of ownership shall include at least the following information:

1. The name, full business address, and telephone number of the applicant or licensee, registrant, or permit holder and name and telephone number of a designated contact person;

2. All trade or business names used by the applicant or licensee, registrant, or permit holder;

3. The federal employer identification number of the applicant or licensee, registrant, or permit holder;

4. The type of ownership and name of the owner of the entity, including:

a. If an individual, the name, address, and social security number or control number;

b. If a partnership, the name, address, and social security number or control number of each partner who is specifically responsible for the operations of the facility, and the name of the partnership and federal employer identification number;

c. If a corporation:

(1) The name and address of the corporation, federal employer identification number, state of incorporation, and the name and address of the resident agent of the corporation;

(2) The name, address, social security number or control number, and title of each corporate officer and director who is specifically responsible for the operations of the facility;

(3) For nonpublicly held corporations, the name and address of each shareholder that owns 10% or more of the outstanding stock of the corporation;

(4) The name, federal employer identification number, and state of incorporation of the parent company;

d. If a sole proprietorship, the full name, address, and social security number or control number of the sole proprietor and the name and federal employer identification number of the business entity;

e. If a limited liability company, the name and address of each member, the name and address of each manager, the name of the limited liability company and federal employer identification number, the name and address of the resident agent of the

limited liability company, and the name of the state in which the limited liability company was organized;

5. Name, business address and telephone number, and social security number or control number, and documentation of required qualifications as stated in 18VAC110-50-80 of the person who will serve as the responsible party;

6. A list of all states in which the entity is licensed, registered, or permitted to purchase, possess and distribute prescription drugs, and into which it ships prescription drugs;

7. A list of all disciplinary actions imposed against the entity by state or federal regulatory bodies, including any such actions against the responsible party, principals, owners, directors, or officers over the last seven years;

8. A full description, for nonresident wholesale distributors, including the address, square footage, security and alarm system description, temperature and humidity control, and other relevant information of the facility or warehouse space used for prescription drug storage and distribution; and

9. An attestation providing a complete disclosure of any past criminal convictions and violations of the state and federal laws regarding drugs or devices or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts. Such attestation shall include the responsible party, principals, owners, directors, or officers.

B. An applicant or licensee, registrant, or permit holder shall notify the board of any changes to the information required in this section within 30 days of such change.

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 or nonresident third-party logistics providers, 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, or nonresident 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, or nonresident third-party logistics provider registration 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 , or nonresident 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, or nonresident 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, or nonresident 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 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 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 or nonresident third-party logistics provider shall designate a registered agent in Virginia for service of any notice or other legal document. Any nonresident wholesale distributor or nonresident third-party logistics provider 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 may be served all legal process in any

action or proceeding against such nonresident wholesale distributor or nonresident third-party logistics provider. A copy of any such service of legal documents shall be mailed to the nonresident wholesale distributor or nonresident third-party logistics provider by the board by certified mail at the address of record.

18VAC110-50-100. Examination of drug shipments and accompanying documents.

A. Upon receipt, each shipping container shall be visually examined for identity to determine if it may contain contaminated, contraband, counterfeit, suspected of being counterfeit, or damaged drugs, or drugs or devices that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination, adulteration, misbranding, counterfeiting, suspected counterfeiting, or other damage to the contents.

B. Upon receipt of drugs, a wholesale distributor, nonresident wholesale distributor, ~~or~~ third-party logistics provider, or nonresident third-party logistics provider must review records for accuracy, completeness, and the integrity of the drugs considering the total facts and circumstances surrounding the transactions and the wholesale distributors, nonresident wholesale distributor, ~~or~~ third-party logistics provider, or nonresident third-party logistics provider involved.

C. Each outgoing shipment shall be carefully inspected for identity of the drugs and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

18VAC110-50-110. Returned, damaged and counterfeit drugs; investigations.

A. Any drug or device returned to a manufacturer, another wholesale distributor, or a third-party logistics provider shall be kept under the proper conditions and documentation showing that

proper conditions were maintained shall be provided to the manufacturer, wholesale distributor, or third-party logistics provider to which the drugs are returned.

B. Any drug or device that, or any drug whose immediate or sealed outer or secondary container or labeling, is outdated, damaged, deteriorated, misbranded, adulterated, counterfeited, suspected of being counterfeited or adulterated, or otherwise deemed unfit for human consumption shall be quarantined and physically separated from other drugs and devices until its appropriate disposition.

C. When a drug or device is adulterated, misbranded, counterfeited or suspected of being counterfeit, or when the immediate or sealed outer or secondary container or labeling of any drug or device is adulterated, misbranded other than misbranding identified by the manufacturer through a recall or withdrawal, counterfeited, or suspected of being counterfeit, the wholesale distributor, nonresident wholesale distributor, ~~or~~ third-party logistics provider, or nonresident third-party logistics provider shall:

1. Provide notice to the board and the manufacturer, wholesale distributor, or third-party logistics provider from which such drug or device was acquired within three business days of that determination.

2. Maintain any such drug or device, its containers and labeling, and its accompanying documentation or any evidence of criminal activity until its disposition by the appropriate state and federal government authorities.

D. The wholesale distributor, nonresident wholesale distributor, ~~or~~ third-party logistics provider, or nonresident third-party logistics provider shall fully cooperate with authorities conducting any investigation of counterfeiting or suspected counterfeiting to include the provision of any records related to receipt or distribution of the suspect drug or device.

18VAC110-50-120. Policies and procedures.

All wholesale distributors, nonresident wholesale distributors, ~~or~~ third-party logistics providers, or nonresident third-party logistics provider shall establish, maintain, and adhere to written policies and procedures for the proper receipt, security, storage, inventory, and distribution of prescription drugs. Wholesale distributors, nonresident wholesale distributors, ~~or~~ third-party logistics providers, or nonresident third-party logistics provider shall include in their policies and procedures at least the following:

1. A procedure for reporting thefts or losses of prescription drugs to the board and other appropriate authorities;

2. A procedure whereby the oldest approved stock of a prescription drug is distributed first. The procedure may permit deviation from this process provided the deviation is temporary and appropriate for the distribution;

3. A procedure for handling recalls and withdrawals of prescription drugs and devices;

4. Procedures for preparing for, protecting against, and handling emergency situations that affect the security and integrity of drugs or the operations of the wholesale distributor, nonresident wholesale distributor, ~~or~~ third-party logistics provider, or nonresident third-party logistics provider;

5. A procedure to ensure that outdated drugs are segregated from other drugs to include the disposition of such drugs;

6. A procedure to ensure initial and ongoing training of all employees;

7. A procedure for ensuring, both initially and on an ongoing basis, that persons with access to prescription drugs have not been convicted of a drug law or any law related to wholesale distribution of prescription drugs or that of a third-party logistics provider; and

8. A procedure for reporting counterfeit or suspected counterfeit prescription drugs or counterfeiting or suspected counterfeiting activities to the board and other appropriate law enforcement or regulatory agencies.

18VAC110-50-130. Recordkeeping.

A. All records and documentation required in this subsection shall be maintained and made available for inspection and photocopying upon request by an authorized agent of the board for a period of three years following the date the record was created or received by the wholesale distributor, nonresident wholesale distributor, ~~or~~ third-party logistics provider, or nonresident third-party logistics provider. If records are not maintained on premises at the address of record, they shall be made available within 48 hours of such request. A wholesale distributor, nonresident wholesale distributor, or third-party logistics provider shall establish and maintain the following:

1. Unless otherwise indicated in federal law, inventories and records of all transactions, including the dates of receipt and distribution or other disposition or provision, and records related to the federal requirements for an electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed;

2. Records documenting monitoring of environmental conditions to ensure compliance with the storage requirements as required in 18VAC110-50-50;

3. Documentation of visual inspection of drugs and accompanying documents required in 18VAC110-50-100, including the date of such inspection and the identity of the person conducting the inspection;

4. Documentation of quarantine of any product and steps taken for the proper reporting and disposition of the product shall be maintained, including the handling and disposition of all outdated, damaged, deteriorated, misbranded, or adulterated drugs;

5. An ongoing list of persons or entities from whom it receives prescription drugs and persons or entities to whom it distributes prescription drugs or provides prescription drugs as a third-party logistics provider; and

6. Copies of the mandated report of thefts or unusual losses of Schedules II through V controlled substances in compliance with the requirements of § 54.1-3404 of the Code of Virginia.

B. Records shall either (i) be kept at the inspection site or immediately retrievable by computer or other electronic means and made readily available at the time of inspection or (ii) if kept at a central location and not electronically retrievable at the inspection site, be made available for inspection within 48 hours of a request by an authorized agent of the board.

C. All facilities shall have adequate backup systems to protect against the inadvertent loss or deliberate destruction of data.

18VAC110-50-140. Due diligence.

A. Prior to the initial purchase of prescription drugs from another wholesale distributor or third-party logistics provider not residing and licensed in Virginia, a wholesale distributor or third-party logistics provider shall obtain, and update annually, the following information from the selling wholesale distributor or third-party logistics provider:

1. A copy of the license to wholesale distribute or act as a third-party logistics provider from the resident state. If the resident state does not require licensure as a third-party logistics provider, documentation confirming active registration with the U.S. Food and Drug Administration is acceptable;

2. The most recent facility inspection report, if available;

3. A list of other names under which the wholesale distributor or third-party logistics provider is doing business, or was formerly known as;

4. A list of principals, directors, officers, or any shareholder who owns 10% or more of outstanding stock in any nonpublicly held corporation;

5. A list of all disciplinary actions by state and federal agencies;

6. A description, including the address, dimensions, and other relevant information, of each facility or warehouse used for drug storage and distribution or for the legal acts of a third-party logistics provider; and

7. A listing of any manufacturers for whom the wholesale distributor or third-party logistics provider is an authorized distributor of record.

B. If the selling wholesale distributor's or third-party logistics provider's facility has not been inspected by the resident board or the board's agent within three years of the contemplated purchase, the purchasing wholesale distributor or third-party logistics provider may conduct an inspection of the wholesale distributor's or third-party logistics provider's facility prior to the first purchase of drugs or devices from another wholesale distributor or third-party logistics provider to ensure compliance with applicable laws and regulations relating to the storage and handling of drugs or devices. A third party may be engaged to conduct the site inspection on behalf of the purchasing wholesale distributor or third-party logistics provider.

C. Prior to the first purchase of drugs from another wholesale distributor or third-party logistics provider not residing in and licensed in Virginia, the purchasing wholesale distributor or third-party logistics provider shall secure a national criminal background check of all of the wholesale distributor's or third-party logistics provider's owners, corporate officers, and the person named as the responsible party with the resident board or licensing agency.

Part III

Manufacturers

18VAC110-50-150. Good manufacturing practices.

A. The Good Manufacturing Practice for Finished Pharmaceuticals regulations set forth in 21 CFR Part 211 are adopted by reference.

B. Each manufacturer or nonresident manufacturer of drugs shall comply with the requirements set forth in the federal regulations referred to in subsection A of this section.

Agenda Item: Adoption of Fast-track Regulations – Pharmacy permit recension

Staff note:

This regulatory action is included in the periodic review currently in Executive branch review. However, Board staff is concerned that there have been several incidences in recent months of entities acquiring pharmacy permits and then not becoming operational. Therefore, a fast-track action is recommended.

Included in your agenda package are:

A copy of the proposed regulations

Board action:

Adoption of amendment to section 140 to authorize the Board to rescind a permit if the pharmacy is not operational 90 days after issuance.

Project 5528 - none

BOARD OF PHARMACY

Rescension of permit

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. 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 indicate a requested inspection date, or requests which 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 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. 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. 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.

F. If the pharmacy is not fully operational within 90 days of issuance of a permit, the board may rescind such permit. For good cause shown, such as circumstances beyond the control of the permit holder, the board may grant an extension.

Virginia Board of Pharmacy
Inspection Report
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Licenses Issued

	12/1/16-2/28/17	3/1/17-5/31/17	6/1/17-8/31/17	9/1/17-11/30/17	12/1/17-2/28/18	3/1/18-5/31/18	License Count 6/1/2018
Business CSR	16	38	34	40	81	86	1,329
CE Courses	0	1	0	1	0	1	10
Limited Use Pharmacy Technician	0	0	0	1	0	0	17
Medical Equipment Supplier	2	9	3	3	2	6	226
Nonresident Manufacturer				13	92	20	124
Nonresident Medical Equipment Supplier				19	12	12	305
Non-resident Outsourcing Facility	279	40	17	3	1	9	31
Non-resident Pharmacy	25	9	4	38	32	35	758
Non-resident Wholesale Distributor	14	40	42	8	13	22	654
Non-restricted Manufacturer	1	18	10	0	1	0	28
Outsourcing Facility	0	0	0	0	0	0	0
Permitted Physician	0	0	0	0	0	0	1
Pharmacist	130	166	438	251	142	157	14,633
Pharmacist Volunteer Registration	0	0	4	1	0	0	0
Pharmacy	15	18	24	17	3	15	1,830
Pharmacy Intern	148	107	140	204	148	115	1,852
Pharmacy Technician	475	513	621	387	357	363	13,626
Pharmacy Technician Training Program	1	5	4	5	5	3	137
Physician Selling Controlled Substances	30	26	44	30	22	55	700
Physician Selling Drugs Location	3	5	5	5	1	10	151
Pilot Programs	0	0	2	0	2	0	11
Repackaging Training Program	0	0	0	0	0	0	2
Restricted Manufacturer	0	0	0	1	0	0	55
Third Party Logistics Provider				2	3	1	5
Warehouser	0	1	1	0	39	3	84
Wholesale Distributor	1	2	3	5	1	0	79
Total	**1,140**	**998**	**1,396**	**1,034**	**957**	**912**	**36,648**

Virginia Board of Pharmacy
Inspection Report
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Inspections Completed

	12/1/16-2/28/17		3/1/17-5/31/17		6/1/17-8/31/17		9/1/17-11/30/17		12/1/17-2/28/18		3/1/18-5/31/18	
License Type												
Controlled Substances Registration	109		149		133		131		163		182	
Medical Equipment Supplier	16		25		18		32		22		22	
Non-restricted Manufacturer	1		2		1		1		1		0	
Permitted Physician	0		0		0		0		0		0	
Physician Selling Drugs Location	17		18		32		39		23		22	
Restricted Manufacturer	0		1		1		3		0		2	
Third Party Logistics Provider							2		1		1	
Warehouse	1		5		3		6		11		11	
Wholesale Distributor	12		12		20		13		6		3	
Pharmacy	262		281		313		293		272		291	
Pilot	2		1		2		1		0		1	
Total	**420**		**494**		**523**		**521**		**499**		**535**	
Pharmacy (0201) Inspections												
Change of Location	3		4		3		3		4		5	
New	14		17		21		13		3		15	
Reinspection	15		9		8		14		2		8	
Remodel	30		48		45		55		31		43	
Routine	197		184		232		206		232		218	
Focus	3		3		4		0		0		2	
Federal Agency	0		15		0		0		0		0	
Compliance	0		1		0		2		0		0	
Pilot	0		0		0		0		0		0	
Total	**262**		**281**		**313**		**293**		**272**		**291**	
Pharmacy Routine Inspections												
No Deficiency	50	25%	37	20%	52	23%	43	21%	77	33%	66	30%
Deficiency	74	38%	79	43%	100	43%	66	32%	77	33%	80	37%
Deficiency & IPHCO	73	37%	68	37%	80	34%	97	47%	78	34%	72	33%
Total	**197**		**184**		**232**	*	**206**		**232**		**218**	

* Corrected 12/11/17

Virginia Board of Pharmacy
June 21, 2018
Frequently Cited Deficiencies
December 2016 - May 2018

Deficiencies Numbered Less Than 100	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 requirec	149
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	69
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)	54
20a. Pharmacist not documenting final verification of non-sterile compounding	43
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	39
20. Pharmacist not checking and documenting repackaging or bulk packaging	39
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounding of sterile preparations.	38
12. Storage of prescription drugs not in the prescription department	35
18. Records of dispensing not maintained as required	34
7. Change of location or remodel of pharmacy without submitting application or Board approval	33

Virginia Board of Pharmacy
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Frequently Cited Deficiencies
December 2016 - May 2018

Deficiencies Numbered Greater Than 100	Cumulative Total
130a. Compounded products not properly labeled	196
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)	194
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.	186
127. Repackaging records and labeling not kept as required or in compliance	150
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	134
124. Labels do not include all required information	92
108. Emergency access alarm code/key not maintained in compliance	88
122. Engaging in alternate delivery not in compliance	81
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)	66
132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	60

Virginia Board of Pharmacy
Inspection Report
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Deficiencies

	12/16-2/17	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	Total	3/18-5/18	Cumulative
Routine Inspections Completed	**197**	**184**	**232**	**206**	**232**	**218**	**1269**	**Repeat**	**Repeat**
Total Deficiencies	**112**	**117**	**131**	**158**	**127**	**115**	**760**	**20**	**192**
Average Deficiencies per Inspection	**0.6**	**0.6**	**0.6**	**0.8**	**0.5**	**0.5**	**0.6**		
1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location	3	0	2	3	2	2	12		
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	4	2	2	0	5	3	16	1	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	6	0	2	2	4	2	16		
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	1	0	0	0	1	2	4		
5. Pharmacy technicians, pharmacy interns performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists	2	3	1	1	2	1	10	1	1
6. Exceeds pharmacist to pharmacy technician ratio (12/12/13 New Minor 43 for first offense)	0	0	0	0	0	0	0		1
7. Change of location or remodel of pharmacy without submitting application or Board approval	5	3	5	10	4	6	33		1
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.	3	2	0	2	1	0	8		1
9. Alarm not operational or not being set	2	1	5	3	0	1	12		
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)	0	0	1	2	1	0	4		1

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Deficiencies

	12/16-2/17	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	Total	3/18-5/18	Cumulative
10. Unauthorized access to alarm or locking device to the prescription department	2	1	8	7	1	2	21	1	1
11. Insufficient enclosures or locking devices (12/12/13 New Minor 45 if no drug loss)	0	1	1	0	0	0	2		
12. Storage of prescription drugs not in the prescription department	0	3	5	7	12	8	35	1	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)	0	4	0	1	0	1	6		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)	3	3	2	6	0	5	19		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)	10	10	15	8	6	5	54		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	19	28	25	29	31	17	149	6	93
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	4	6	7	9	6	7	39	1	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)	0	0	0	2	0	2	4		
18. Records of dispensing not maintained as required	2	1	6	15	7	3	34		

Virginia Board of Pharmacy
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Deficiencies

	12/16-2/17	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	Total	3/18-5/18	Cumulative
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	0	1	2	7	2	0	12		1
20. Pharmacist not checking and documenting repackaging or bulk packaging	4	4	9	10	5	7	39	1	15
20a. Pharmacist not documenting final verification of non-sterile compounding	10	7	8	7	6	5	43		3
20b. Pharmacist not documenting final verification of sterile compounding	8	5	5	4	6	2	30	1	7
21. No clean room	0	0	0	1	0	0	1		
21a. Performing sterile compounding outside of a clean room (Added 12/12/13)	1	3	0	0	0	0	4		
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	1	2		
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.	0	1	1	1	0	1	4		1
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	0	0	0	0	2	1	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)	0	0	0	2	0	0	2		1
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
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June 21, 2018

Deficiencies

	12/16-2/17	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	Total	3/18-5/18	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.	9	7	6	2	6	8	38	3	26
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	2	0	2	0	1	7		
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	0	1	1	2	3	2	9		
29. Unlawful compounding for further distribution by other entities	0	1	2	0	3	3	9		
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	11	14	8	12	10	14	69	4	8
33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	0	1	1	1	0	0	3		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	1	2	0	0	1	3	7		1

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Deficiencies

	12/16-2/17	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	Total	3/18-5/18	Cumulative
Routine Inspections Completed	197	184	232	206	232	218	1269	Repeat	Repeat
Total Deficiencies	265	275	317	338	302	259	1497	28	232
Average Deficiencies per Inspection	1.3	1.5	1.4	1.6	1.3	1.2	1.2		
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	1	0	0	0	0	1		
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.	9	4	3	4	7	6	33		5
105. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit	5	9	1	5	4	5	29		7
106. Prescription department substantially not clean and sanitary and in good repair	3	2	0	2	1	0	8		2
107. Current dispensing reference not maintained	2	6	1	6	4	1	20	1	9
108. Emergency access alarm code/key not maintained in compliance	16	8	13	16	18	17	88	2	14
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)	28	35	33	33	27	38	194	3	27
110. Storage of paraphernalia/Rx devices not in compliance	0	0	2	0	0	0	2		
111. Storage of prescriptions awaiting delivery outside of the prescription department not in compliance	0	1	5	1	2	1	10		1
112. Biennial taken late but within 30 days	7	0	1	2	1	3	14		
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.	30	26	37	25	40	28	186	5	43

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Deficiencies

	12/16-2/17	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	Total	3/18-5/18	Cumulative
114. Records of receipt (e.g. invoices) not on site or retrievable	0	3	5	9	10	4	31		
115. Other records of distributions not maintained as required	0	3	3	3	0	2	11		
116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	0	5	3	4	4	4	20		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	0	1	0	1	0	2		
119. Not properly documenting partial filling of prescriptions	6	5	5	6	10	8	40	1	24
120. Offer to counsel not made as required	0	7	7	2	2	0	18		
121. Prospective drug review not performed as required	0	1	0	1	0	0	2		
122. Engaging in alternate delivery not in compliance	6	9	19	18	14	15	81		4
123. Engaging in remote processing not in compliance	0	10	3	5	9	12	39	2	2
124. Labels do not include all required information	14	16	15	15	15	17	92	1	11
125. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages	7	4	6	8	5	5	35	1	5
126. Special packaging not used or no documentation of request for non-special packaging	0	2	0	1	0	2	5	1	4
Repackaging, specialty dispensing, compounding:									
127. Repackaging records and labeling not kept as required or in compliance	11	18	26	41	33	21	150	2	20
128. Unit dose procedures or records not in compliance	0	0	0	0	0	0	0		
129. Robotic pharmacy systems not in compliance	1	0	1	0	0	0	2		
130. Required compounding/dispensing/distribution records not complete and properly maintained	10	6	9	10	5	8	48	2	11
130a. Compounded products not properly labeled	37	30	60	42	18	9	196		8

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Deficiencies

	12/16-2/17	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	Total	3/18-5/18	Cumulative
131. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	0	3	3	6	0	1	13		
132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	7	15	9	14	8	7	60		1
133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2	0	0	3	3	0	0	6		
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	0	1	0	1	2	4		
138. Automated dispensing device loading, records, and monitoring/reconciliation not in compliance	2	2	0	0	1	0	5		
139. Emergency medical services procedures or records not in compliance	1	3	1	3	3	2	13		4
140. Emergency kit or stat-drug box procedures or records not in compliance	3	0	0	3	3	4	13		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	40	22	15	24	17	16	134	5	9
143. Exceeds pharmacist to pharmacy technician ratio (Added 12/12/13)	2	1	1	0	0	1	5		

Virginia Board of Pharmacy
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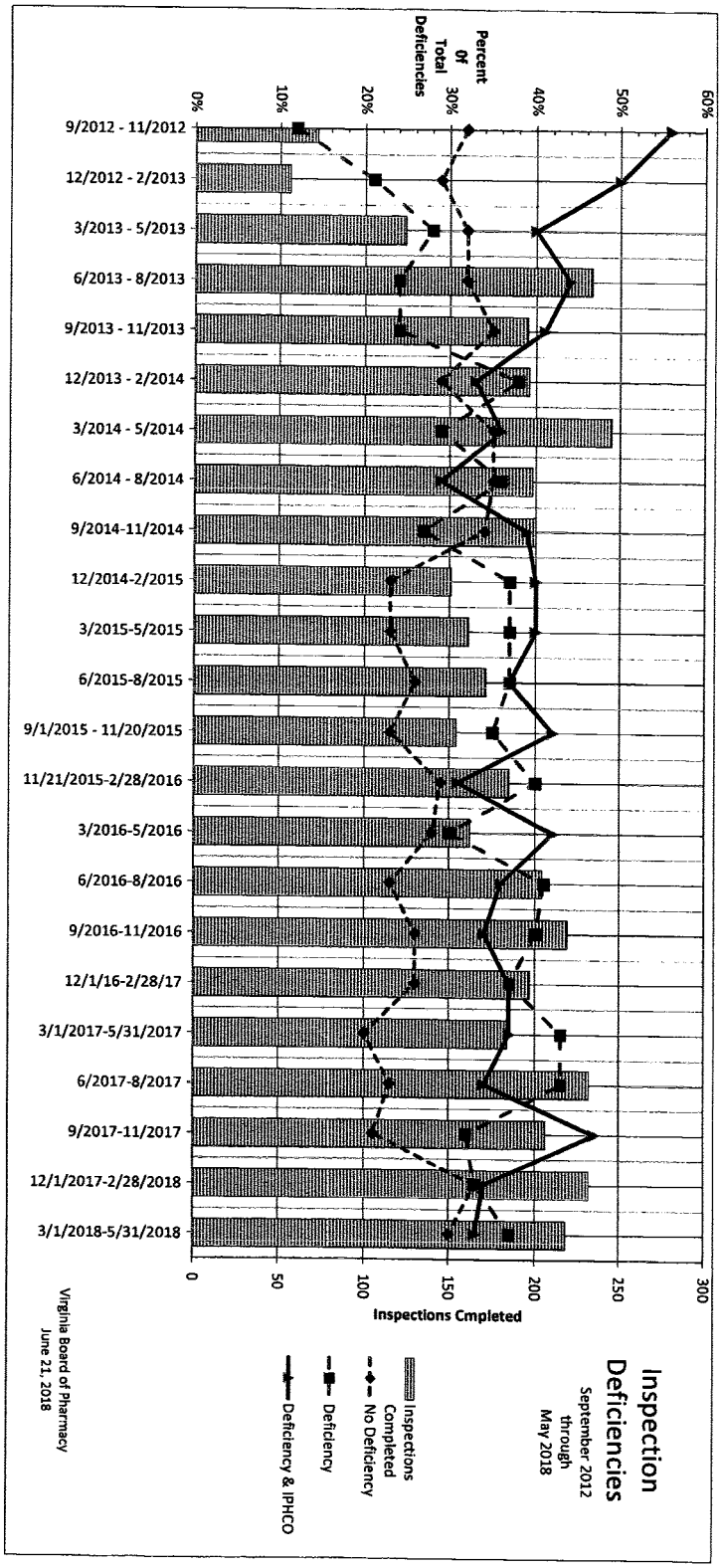
Deficiencies

	12/16-2/17	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	Total	3/18-5/18	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)	13	6	15	14	9	9	66		6
145. Insufficient enclosures or locking devices (Added 12/12/13)	2	0	3	2	0	5	12	1	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)	2	4	4	9	14	4	37	1	2
147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions. (Added 12/12/13)	1	8	3	1	16	2	31		3


Inspection Deficiencies
September 2012 through May 2018
Inspections Completed
No Deficiency
Deficiency
Deficiency & IPHCO
Percent Of Total Deficiencies
0%
10%
20%
30%
40%
50%
60%
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
3/1/2017-5/31/2017
6/2017-8/2017
9/2017-11/2017
12/1/2017-2/28/2018
3/1/2018-5/31/2018
0
50
100
150
200
250
300
Inspections Cmpleted
Virginia Board of Pharmacy
June 21, 2018

Open Cases as of 6/7/18:

Patient Care	PC	APD	Investigation	FH	IFC	Pending Closure	TOTALS
	16	40	66	0	3	0	125
Non-Patient Care	94	16	32	0	10	19	171
							296

- There has been an increase in the number of non-patient care cases since the last Board meeting, primarily due to the CE Audit and cases opened for non-compliance.
- The Board currently has six possible summary suspension/restriction cases.
- We have eleven patient care cases greater than 250 work days. All but one are either at investigation or APD.

Executive Director's Report – June 21, 2018

- Board Member Terms, Appointments
  - ❖ Melvin L. Boone, Sr. (citizen) – 1st term expires June 30, 2018
  - ❖ Michael I. Elliott – 1st term expires June 30, 2018
  - ❖ Sheila K. W. Elliott - 1st term expires June 30, 2018
  - ❖ Jody H. Allen – 2nd term expires June 30, 2018
  - ❖ James L. Jenkins, Jr., unexpired term ends June 30, 2019
- New Board Member Orientation – Summer
- Board Retreat - Fall
- Recent or Ongoing Projects:
  - ❖ Status Update on Pharmaceutical Processors
  - ❖ Online License Verifications
  - ❖ Paperless License Initiative
  - ❖ CBD Workgroup
  - ❖ Board E-newsletter published June 2018
  - ❖ Revision of Routine Pharmacy Inspection Report
  - ❖ Efficiencies in Disciplinary Case Management
- Upcoming Meetings:
  - ❖ 7/19/18 – Special Conference Committee
  - ❖ 7/25/18 – Formal Hearings
  - ❖ 8/01/18 – Innovative Pilot Program Special Conference Committee
  - ❖ 8/14/18 – Meeting to Award Pharmaceutical Processor Conditional Approvals in morning and Formal Hearings in afternoon
  - ❖ 8/15/18 - Special Conference Committee
  - ❖ 9/13/18 – Special Conference Committee
  - ❖ 9/24/18 – Inspection Special Conference Committee
  - ❖ 9/25/18 – Full Board Meeting with Formal Hearings
  - ❖ E-prescribing Workgroup – TBD, possibly August (HB2165)

Recent Presentations/Meetings:

- ❖ VSHP – April 2018
- ❖ Howard University – April 2018 (Beth O'Halloran)
- ❖ NABP Annual Meeting – May 2018
- ❖ DHP Staff Training – May 2018
- ❖ Community Coalitions of Virginia – June 2018

Staffing:

- Vacancies – deputy executive director (discipline), executive assistant

Elections at 114th NABP Annual Meeting and Executive Committee Composition

Chairperson: Jeanne D. Waggener (Texas)
President: Susan Ksiazek (New York)
President-elect: Jack W. "Jay" Campbell IV (North Carolina)
Treasurer: Timothy D. Fensky (Massachusetts)
Executive Committee Member, District 1: Bradley S. Hamilton (Maine)
Executive Committee Member, District 2: Caroline D. Juran (Virginia)
Executive Committee Member, District 3: Reginald B. "Reggie" Dilliard (Tennessee)
Executive Committee Member, District 4: Philip P. Burgess (Illinois)
Executive Committee Member, District 5: Gary W. Dewhirst (North Dakota)
Executive Committee Member, District 6: Lenora Newsome (Arkansas)
Executive Committee Member, District 7: Nicole L. Chopski (Idaho)
Executive Committee Member, District 8: Richard B. Mazzoni (New Mexico)

Resolutions Passed at 114th NABP Annual Meeting

RESOLUTION NO: 114-1-18

TITLE: Implementation and Regulation of Technology in Pharmacy Practice
ACTION: PASS
WHEREAS, technology is a critical component in the provision of pharmacy and patient care services; and
WHEREAS, state boards of pharmacy regulate the practice of pharmacy, and consequently the use of technology in practice; and
WHEREAS, challenges exist to effectively regulate the use of technology due to its evolving nature and rapid development that often outpace the development and adoption of governing state laws and rules; and
WHEREAS, the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* includes broad and effective language addressing the implementation and regulation of the use of technology in pharmacy practice;
THEREFORE BE IT RESOLVED that NABP, in collaboration with state boards of pharmacy, communicate, where applicable, to state legislative and regulatory authorities the NABP *Model Act* language pertaining to the implementation and regulation of technology to allow for the appropriate use, innovation, and safeguards that address security and patient safety.

RESOLUTION NO: 114-2-18

TITLE: Safety Standards for the Compounding and Dispensing of Compounded Drug Products
ACTION: PASS
WHEREAS, the compounding of drug products for patients may include materials that are deemed hazardous by the appropriate state or federal agency or active pharmaceutical ingredients (APIs) that require black box warnings in their labeling; and
WHEREAS, the handling of those types of materials or APIs in the preparation of such compounded drug products or the dispensing of those drug products to the patient or caregiver

could endanger the health of the pharmacist or technician who compounded the drug product, and the patient or caregiver who received the compounded drug product;
THEREFORE BE IT RESOLVED that NABP encourage United States Pharmacopeial Convention (USP) and/or other stakeholders to develop educational information concerning USP Chapter <800> and the appropriate handling of these types of materials to be provided to the patient or caregiver.

RESOLUTION NO: 114-3-18
TITLE: Electronic Transmission of Prescriptions
ACTION: PASS
WHEREAS, the electronic transmission of prescriptions from prescribers to pharmacists is a more effective means of transmission compared to a handwritten prescription or verbal order; and
WHEREAS, there is evidence that mandating the electronic transmission of prescriptions provides multiple advantages;
THEREFORE BE IT RESOLVED that NABP collaborate with appropriate stakeholders including, but not limited to, Drug Enforcement Administration, Centers for Medicare & Medicaid Services, and electronic prescribing experts, to examine the feasibility of mandating that all prescriptions be transmitted electronically.

RESOLUTION NO: 114-4-18
TITLE: Task Force to Develop Regulations Based on Standards of Care
ACTION: PASS
WHEREAS, the practice of pharmacy continues to evolve toward direct patient care; and
WHEREAS, in some settings, pharmacists are currently prescribing drugs and devices, ordering and interpreting drug therapy-related tests, and administering drugs; and
WHEREAS, technology continues to develop and lead to advancements within the pharmacy profession; and
WHEREAS, medical and nursing regulations include standards of care that have allowed flexibility in their professional scope of practice while preserving the ability of their respective regulatory boards to maintain patient safety;
THEREFORE BE IT RESOLVED that NABP convene an interdisciplinary task force to explore considerations for transitioning from strictly prescriptive rule-based regulations to a model that includes a standard of care process, and discuss the necessary tools (eg, peer review committees, enforcement approaches) for boards of pharmacy to make this transition.

RESOLUTION NO: 114-5-18
TITLE: Cooperative Interstate Registration System
ACTION: PASS
WHEREAS, state boards of pharmacy are charged with protecting the public health as it relates to patient safety, patient health, and patient services provided by pharmacies and pharmacists; and
WHEREAS, the practice of pharmacy has expanded to include dispensing models wherein a single dispensing transaction may extend across state boundaries; and

WHEREAS, states do not always require individual pharmacists who participate in interstate dispensing models to obtain a pharmacist license in each state into which the pharmacist participates in dispensing medications; and

WHEREAS, errors may occur in such interstate transactions where the pharmacist who committed the error is beyond the jurisdiction of the state in which the patient is harmed or potentially harmed; and

WHEREAS, the board of pharmacy in the patient's resident state is unable to meet its charge to protect the public because it lacks jurisdiction to pursue a remedial action and/or discipline against the offending pharmacist;

THEREFORE BE IT RESOLVED that NABP explore developing an interstate registration system to provide for pharmacists' participation in interstate dispensing models while maintaining boards of pharmacy jurisdiction to initiate possible administrative proceedings to protect the public health.

RESOLUTION NO: 114-6-18

TITLE: Recognition Resolution

ACTION: PASS

WHEREAS, the individuals listed here have made significant contributions to NABP, the protection of the public health, and the practice of pharmacy:

W. Franklin Gilmore (MS)
Joseph Victor Greco (LA)
Lester Hardy (LA)
Martin Fleming "Buddy" McDonough, Jr (TN)
Jimmy E. Wilson (TN)

WHEREAS, NABP and its member boards of pharmacy are saddened by the death of these individuals;

THEREFORE BE IT RESOLVED that NABP and its members formally acknowledge the leadership and contributions made by these individuals; and

BE IT FURTHER RESOLVED that NABP and the boards of pharmacy extend their sincere sympathies to the family and friends of these members.

RESOLUTION NO: 114-1-18

TITLE: Implementation and Regulation of Technology in Pharmacy Practice

ACTION: PASS

WHEREAS, technology is a critical component in the provision of pharmacy and patient care services; and

WHEREAS, state boards of pharmacy regulate the practice of pharmacy, and consequently the use of technology in practice; and

WHEREAS, challenges exist to effectively regulate the use of technology due to its evolving nature and rapid development that often outpace the development and adoption of governing state laws and rules; and

WHEREAS, the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* includes broad and effective language addressing the implementation and regulation of the use of technology in pharmacy practice;

THEREFORE BE IT RESOLVED that NABP, in collaboration with state boards of pharmacy, communicate, where applicable, to state legislative and regulatory authorities the NABP *Model Act* language pertaining to the implementation and regulation of technology to allow for the appropriate use, innovation, and safeguards that address security and patient safety.

Attachment I

Virginia's Pharmacist Workforce: 2017

Healthcare Workforce Data Center

February 2018

Virginia Department of Health Professions
Healthcare Workforce Data Center
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, VA 23233
804-367-2115, 804-527-4466(fax)
E-mail: *HWDC@dhp.virginia.gov*

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

13,604 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

Lisa R. Hahn, MPA
Chief Deputy Director

Healthcare Workforce Data Center Staff:

Dr. Elizabeth Carter, PhD	Yetty Shobo, PhD	Laura Jackson	Christopher Coyle
Executive Director	*Deputy Director*	*Operations Manager*	*Research Assistant*

The Board of Pharmacy

Chair

Ryan K. Logan
Fairfax

Vice-Chair
Michael I. Elliott
Forest

Members

Jody H. Allen
Midlothian

Melvin L. Boone, Sr.
Chesapeake

Freda Cathcart
Roanoke

Sheila K. W. Elliott
Hampton

Rafael Saenz
Crozet

Ellen B. Shinaberry
Harrisonburg

Rebecca Thornbury
Grundy

Cynthia Warriner
Chester

Executive Director

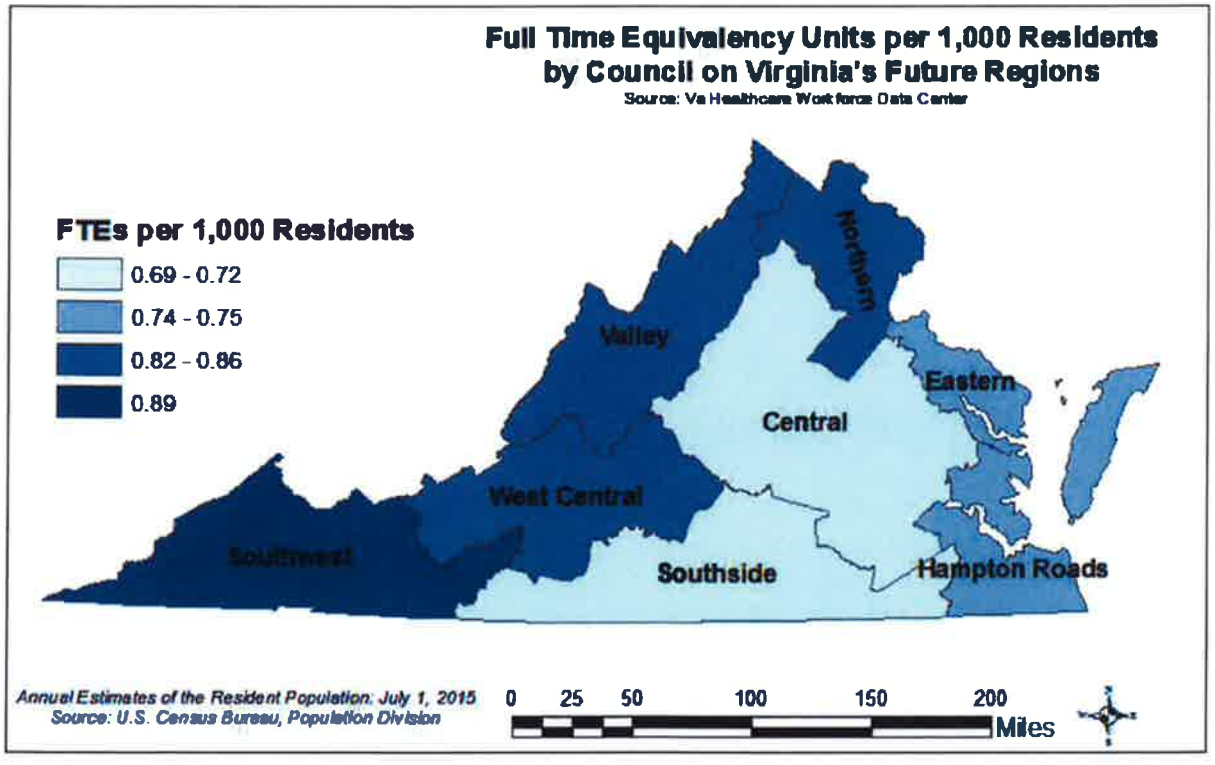
Caroline D. Juran
Richmond

Contents

The Pharmacist Workforce: At a Glance:

The Workforce		Background		Current Employment	
Licensees:	14,953	Rural Childhood:	33%	Employed in Prof.:	92%
Virginia's Workforce:	8,599	HS Degree in VA:	47%	Hold 1 Full-time Job:	72%
FTEs:	7,139	Prof. Degree in VA:	49%	Satisfied?:	89%
Survey Response Rate		**Education**		**Job Turnover**	
All Licensees:	91%	Baccalaureate:	39%	Switched Jobs in 2017:	5%
Renewing Practitioners:	96%	Pharm.D./Professional:	61%	Employed over 2 yrs:	62%
Demographics		**Finances**		**Primary Roles**	
Female:	64%	Median Inc.:	$120k-$130k	Patient Care:	74%
Diversity Index:	50%	Health Benefits:	70%	Administration:	8%
Median Age:	44	Under 40 w/ Ed debt:	76%	Education:	1%

Source: Va Healthcare Workforce Data Center



Results in Brief

13,604 pharmacists voluntarily took part in the 2017 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 14,953 pharmacists who are licensed in the state and 96% of renewing practitioners.

The HWDC estimates that 8,599 pharmacists 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 as a pharmacist at some point in the future. During 2017, Virginia's pharmacists provided 7,139 "full-time equivalency units", which the HWDC defines simply as working 2,000 hours a year (or 40 hours per week for 50 weeks with 2 weeks off).

Majority of Virginia's pharmacists are female, and the median age among those in the workforce is 44. In a random encounter between two pharmacists, there is a one-in-two chance that they would be of different races or ethnicities, a measure known as the diversity index. This makes Virginia's pharmacists slightly less diverse than the state's overall population, where there is a 56% chance that two randomly chosen people would be of different races or ethnicities.

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. Meanwhile, 47% of Virginia's pharmacists graduated from high school in Virginia, and 49% of pharmacists earned their initial professional degree in the state. In total, 56% of Virginia's pharmacists have some educational background in the state.

A slight majority of Virginia's pharmacist workforce has earned a doctoral or other professional degree as their highest level of educational attainment. 41% of pharmacists currently carry educational debt, including more than three-quarters of those under the age of 40. The median debt burden for those pharmacists with educational debt is between $100,000 and $110,000.

92% of pharmacists are currently employed in the profession. 72% of all pharmacists hold one full-time position, and more than half of all professionals work between 40 and 49 hours per week. Over the past year, only 2% of pharmacists have been involuntarily unemployed, while another 3% have been underemployed.

The typical pharmacist earned between $120,000 and $130,000 last year. In addition, 84% of pharmacists who receive an hourly wage or salary at their primary work location also received at least one employer-sponsored benefit, including 70% who received health insurance. 89% of all pharmacists are satisfied with their current employment situation, including 48% who indicated they are "very satisfied".

More than 90% of all pharmacists work in the private sector, including 68% 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 nearly one-third of all professionals. Hospital systems and smaller pharmacies were also common employers of Virginia's pharmacist workforce.

A typical pharmacist spends most of her time treating patients. About three quarters of all pharmacists served a patient care role, meaning that at least 60% of their time is spent in patient care activities. Meanwhile, another 8% of pharmacists served an administrative role at their primary work location.

About 4 in 10 pharmacists expect to retire by the age of 65. Just 7% of the current workforce expect to retire in the next two years, while half of the current workforce expects to retire by 2042. Over the next two years, only 1% of Virginia's current pharmacist workforce expect to leave the profession, while 3% expect to leave the state entirely. Meanwhile, 8% of pharmacists plan on increasing patient care activities over the next two years, and 10% expect to pursue additional educational opportunities.

Summary of Trends

There were over 700 more survey respondents obtained in the 2017 survey compared to the previous years. The number of licensed pharmacists, the state workforce, and the full time equivalency (FTE) units provided by the state pharmacists have all increased slightly over time. For example, there were 12,732 licensees in the 2013 survey compared to 13,998 in 2015 and 14,953 in 2017. Similarly, there were 6,846 FTEs in 2013, compared to 6,932, 6,976, and 7,139 in 2015, 2016, and 2017 respectively. Survey response rate also continues its increase over the years; 96% of renewing licensees completed a survey this year compared to 87% who did in 2013.

The racial, ethnic, gender, and age diversity of the pharmacist workforce was stable in the last year; the diversity index increased from 47% in 2013 to 50% in 2016. There was no change in the index between 2016 and 2017. For those under age 40, the index increased from 57% in 2013 to 58% in 2016 but is now back to 57%. Further, there was no change in the gender diversity of the workforce. The percent female inched up by a percent every year from 62% in 2013 to 64% in 2016 but stayed at 64% in 2017. Median age has also been relatively stable between 44 to 45 years of age in the past five surveys. Even the percent under age 40, which increased from 37% in 2013 to 40% in 2016, stayed at 40% in 2017.

Educational attainment continues to increase among the pharmacist workforce. In 2013, only 51% had a pharmacy doctorate compared to 61% in 2017. This increase may also be the reason why a higher proportion of pharmacists reported educational debt. Thirty-six had educational debt in 2013 compared to 41% in 2016 and 2017. The amount of debt also increased from a median of $90K-$100K in 2013 to $100K-$110K in 2016 and 2017. Meanwhile, the percent reporting residency or specialization has declined slightly. Twenty-four percent reported at least one residency in 2013 compared to 20% in 2017; 25% also had an immunization specialty in 2013 compared to 18% in 2017.

The labor market was a little bit worse for pharmacists in the past year; 2% reported being involuntarily employed compared to the 1% involuntary employment rate in nearly all the previous surveys. However, around 92% still reported being employed in the profession and current involuntary unemployment rate in December 2017, when the survey took place, was 1%. Median income was stable at $120K to $130K between 2016 and 2017 after increasing from $110K-$120K in 2013. However, the percent earning above $140,000 increased from 17% in 2016 to 19% in 2017; only 12% earned in that income range in 2013.

The percent of wage and salaried employees receiving at least one employer sponsored benefit, which had increased from 83% in 2013 to 86% in 2016, declined to 84% in 2017. Specifically, those receiving health insurance declined from 72% in 2016 to 70% in 2017. Additionally, there was a slight decline in pharmacists' job satisfaction as 89% now reported being satisfied with their current job situation compared to 90% in 2016. Most of the decline occurred among those who were very satisfied with their work situation; 50% were very satisfied in 2016 compared to 48% who were very satisfied in 2017.

The geographical distribution of the pharmacist workforce has held constant, with at least a quarter working in Central and Northern locations of the state. However, 12% report working at two or more work locations in 2017 compared to 17% in 2013. The same 11% also reported working in non-metro areas in both the 2016 and 2017 surveys. There has been some change over the years in the types of establishment where pharmacists work. Compared to 2013 when 71% worked at for profit organizations and 21% worked at non-profit establishments, 68% and 23%, respectively, now do so.

Pharmacists who plan to retire in the next decade increased from 22% in all past surveys to 23% in 2017. Those under age 50 who plan to retire by age 65 also increased from 25% in 2013 to 28% in the past two surveys. Further, those planning to leave the profession in the next two years increased from 1% in 2016 to 2% in 2017. Further, only 8% and 5% plan to increase patient hours and teaching hours, respectively, in the next two years compared to 9% and 6% who reported the same plans in 2016.

A Closer Look:

Licensee Counts		
License Status	#	%
Renewing Practitioners	13,348	89%
New Licensees	976	7%
Non-Renewals	629	4%
All Licensees	**14,953**	**100%**

Source: Va. Healthcare Workforce Data Center

HWDC surveys tend to achieve very high response rates. 98% of renewing pharmacists submitted a survey. These represent 89% of pharmacists who held a license at some point in 2017.

Response Rates			
Statistic	Non Respondents	Respondent	Response Rate
By Age			
Under 30	114	953	89%
30 to 34	188	2,203	92%
35 to 39	168	1,968	92%
40 to 44	151	1,705	92%
45 to 49	154	1,709	92%
50 to 54	107	1,453	93%
55 to 59	96	1,268	93%
60 and Over	371	2,345	86%
Total	**1,349**	**13,604**	**91%**
New Licenses			
Issued in 2017	265	711	73%
Metro Status			
Non-Metro	112	997	90%
Metro	570	7,636	93%
Not in Virginia	667	4,971	88%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Licensed Pharmacists

Number:	14,953
New:	7%
Not Renewed:	4%

Survey Response Rates

All Licensees:	91%
Renewing Practitioners:	96%

Source: Va. Healthcare Workforce Data Center

Response Rates	
Completed Surveys	**13,604**
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 2017.
2. **Target Population:** All pharmacists who held a Virginia license at some point in 2017.
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 2017.

At a Glance:

Workforce

Pharmacist Workforce:	8,599
FTEs:	7,139

Utilization Ratios

Licensees in VA Workforce:	58%
Licensees per FTE:	2.09
Workers per FTE:	1.20

Source: Va. Healthcare Workforce Data Center

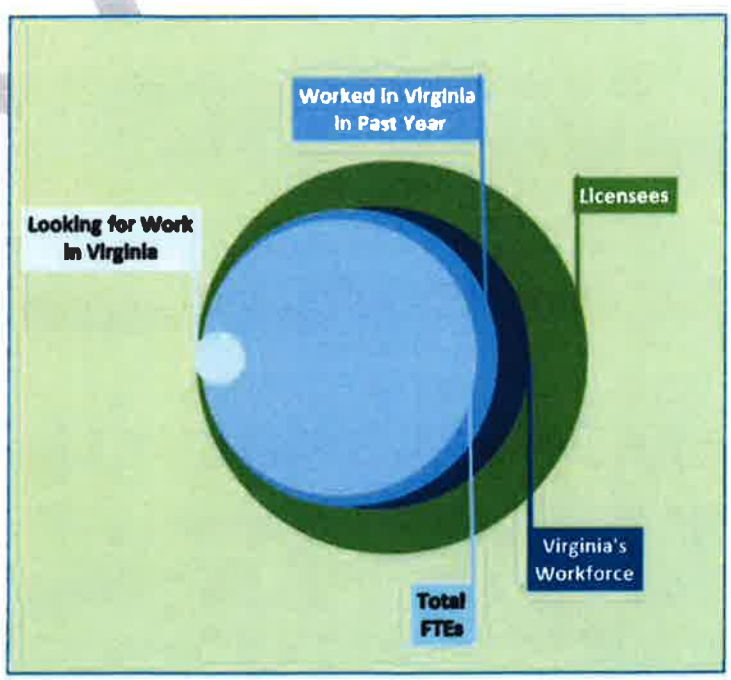
Definitions

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 Pharmacist Workforce		
Status	#	%
Worked in Virginia In Past Year	8,352	97%
Looking for Work in Virginia	247	3%
Virginia's Workforce	8,599	100%
Total FTEs	7,139	
Licensees	14,953	

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	**187**	**27%**	**510**	**73%**	**697**	**9%**
30 to 34	401	32%	837	68%	1,238	17%
35 to 39	**284**	**28%**	**722**	**72%**	**1,005**	**14%**
40 to 44	237	29%	587	71%	824	11%
45 to 49	**235**	**27%**	**630**	**73%**	**864**	**12%**
50 to 54	255	33%	520	67%	775	11%
55 to 59	**240**	**37%**	**416**	**63%**	**656**	**9%**
60 +	799	61%	501	39%	1,301	18%
Total	**2,637**	**36%**	**4,724**	**64%**	**7,361**	**100%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Gender

% Female:	64%
% Under 40 Female:	70%

Age

Median Age:	44
% Under 40:	40%
% 55+:	27%

Diversity

Diversity Index:	50%
Under 40 Div. Index:	57%

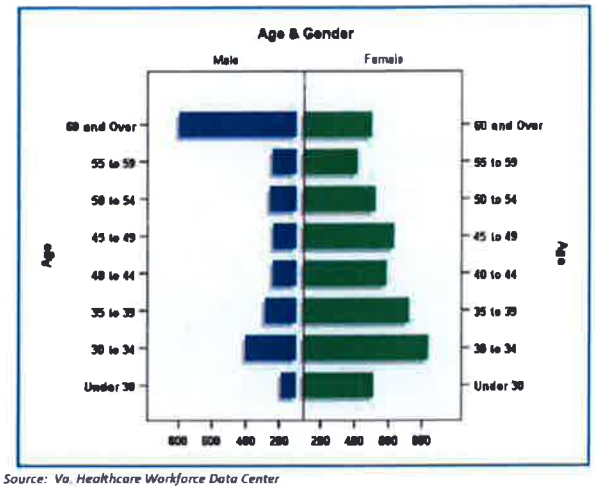
Source: Va. Healthcare Workforce Data Center

Race & Ethnicity					
Race/ Ethnicity	Virginia*	Pharmacists		Pharmacists Under 40	
	%	#	%	#	%
White	**63%**	**4,985**	**68%**	**1,799**	**61%**
Black	**19%**	**773**	**11%**	**371**	**13%**
Asian	**6%**	**1,231**	**17%**	**592**	**20%**
Other Race	**0%**	**110**	**2%**	**41**	**1%**
Two or more races	**3%**	**139**	**2%**	**80**	**3%**
Hispanic	**9%**	**107**	**1%**	**49**	**2%**
Total	**100%**	**7,346**	**100%**	**2,933**	**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, 2015 Source: Va. Healthcare Workforce Data Center

In a chance encounter between two pharmacists, there is a 50% 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:	33%

Virginia Background

HS in Virginia:	47%
Prof. Education in VA:	49%
HS/Prof. Educ. in VA:	56%

Location Choice

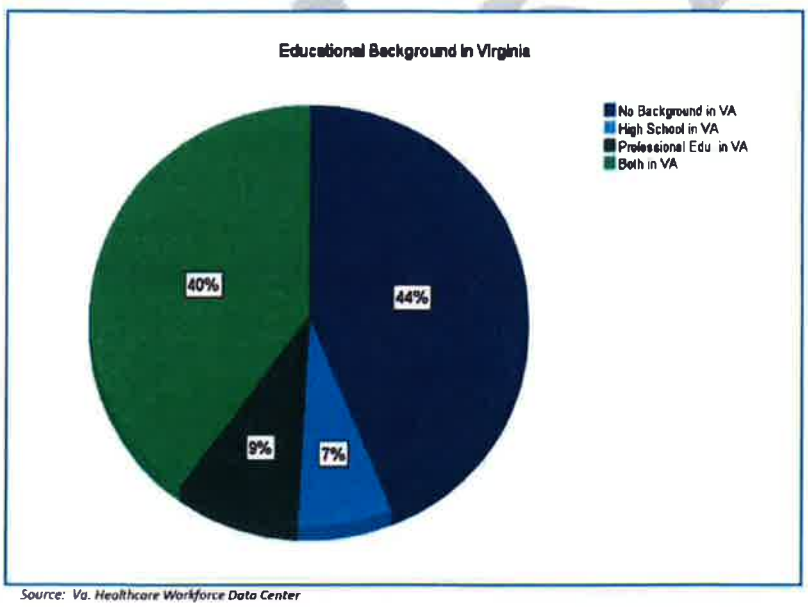
% Rural to Non-Metro:	23%
% Urban/Suburban to Non-Metro:	6%

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+**	**23%**	**56%**	**21%**
2	Metro, 250,000 to 1 million	49%	43%	8%
3	**Metro, 250,000 or less**	**42%**	**44%**	**14%**
	Non-Metro Counties			
4	**Urban pop 20,000+, Metro adj**	**49%**	**35%**	**16%**
6	Urban pop, 2,500-19,999, Metro adj	61%	29%	10%
7	**Urban pop, 2,500-19,999, nonadj**	**88%**	**9%**	**3%**
8	Rural, Metro adj	60%	30%	10%
9	**Rural, nonadj**	**59%**	**30%**	**11%**
	Overall	**33%**	**50%**	**17%**

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

33% 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	3,442	Virginia	3,525
2	Outside U.S./Canada	827	Pennsylvania	505
3	Pennsylvania	460	Outside U.S./Canada	306
4	New York	372	New York	280
5	West Virginia	216	North Carolina	276
6	Maryland	206	Massachusetts	214
7	North Carolina	183	Maryland	213
8	New Jersey	150	West Virginia	204
9	Ohio	148	Washington, D.C.	194
10	Florida	103	Ohio	145

Source: Va. Healthcare Workforce Data Center

47% 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	804	Virginia	855
2	Outside U.S./Canada	197	Pennsylvania	143
3	Pennsylvania	142	New York	94
4	New York	132	Maryland	86
5	Maryland	76	North Carolina	82
6	North Carolina	61	Tennessee	63
7	New Jersey	41	Massachusetts	57
8	West Virginia	39	West Virginia	53
9	Florida	38	Outside U.S./Canada	48
10	Illinois	37	Florida	40

Source: Va. Healthcare Workforce Data Center

Nearly 42% of Virginia's licensed pharmacists did not participate in Virginia's workforce in 2017. 90% 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

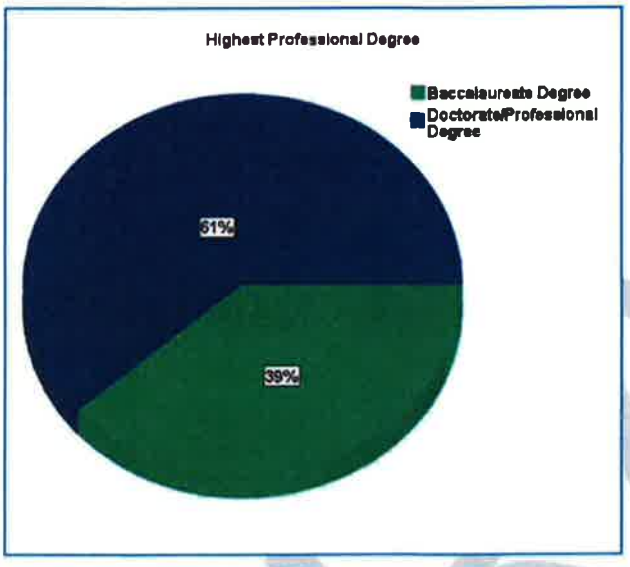
Total:	6,353
% of Licensees:	42%
Federal/Military:	8%
VA Border State/DC:	17%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Highest Professional Degree		
Degree	#	%
B.S. Pharmacy	2,740	39%
Pharm.D.	4,361	61%
Total	7,101	100%

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

At a Glance:

Education

B.S. Pharmacy: 39%
Pharm.D.: 61%

Educational Debt

Carry debt: 41%
Under age 40 w/ debt: 76%
Median debt: $100k-$110k

Source: Va. Healthcare Workforce Data Center

61% of pharmacists hold a Doctorate in Pharmacy as their highest professional degree, while all remaining professionals have earned a Bachelor's degree in Pharmacy.

41% of pharmacists currently have educational debt, including 76% of those under the age of 40. For those with educational debt, the median debt load is between $100,000 and $110,000. Among those under the age of 40 with debt, median is $120,000 to $130,000.

Educational Debt				
Amount Carried	All Pharmacists		Pharmacists Under 40	
	#	%	#	%
None	**3,564**	**59%**	**576**	**24%**
$20,000 or less	178	3%	94	4%
$20,001-$40,000	**209**	**3%**	**113**	**5%**
$40,001-$60,000	262	4%	159	7%
$60,001-$80,000	**229**	**4%**	**137**	**6%**
$80,001-100,000	241	4%	172	7%
$100,001-$120,000	**227**	**4%**	**167**	**7%**
$120,001-$140,000	206	3%	170	7%
$140,001-$160,000	**154**	**3%**	**131**	**5%**
$160,001-$180,000	149	2%	128	5%
$180,001-$200,000	**147**	**2%**	**127**	**5%**
Over $200,000	505	8%	452	19%
Total	**6,071**	**100%**	**2,427**	**100%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Top Specialties

Immunization:	18%
Community Pharmacy:	9%
Ambulatory Care:	4%

Top Board Certifications

BPS - Pharmacotherapy:	5%
BCGP - Geriatrics:	1%
BPS - Ambulatory Care:	1%

Top Residencies (PGY1)

Pharmacy Practice (Post 1993):	10%
Community Pharmacy:	5%
Pharmacy Practice (Pre 1993):	4%

Source: Va. Healthcare Workforce Data Center

Board Certifications		
Certification	#	%
BPS-Pharmacotherapy	427	5%
BCGP-Geriatrics	80	1%
BPS-Ambulatory Care	78	1%
BPS-Oncology	36	0%
BPS- Psychiatric	24	0%
BPS- Nutrition	12	0%
BPS-Nuclear Pharmacy	8	0%
ABAT-Applied Toxicology	3	0%
Other Board Certification	173	2%
At Least One Certification	772	9%

Source: Va. Healthcare Workforce Data Center

PGY1		
Residency	#	%
Pharmacy Practice (Post 1993)	852	10%
Community Pharmacy	420	5%
Pharmacy Practice (Pre 1993)	380	4%
Managed Care Pharmacy	32	0%
Other	0	0%
Total	1,684	20%
PGY2		
Ambulatory Care	120	1%
Critical Care	56	1%
Internal Medicine/Cardiology	49	1%
Drug Information	38	0%
Health-system Pharmacy Administration	37	0%
Pharmacotherapy	28	0%
Psychiatry Infectious Disease	26	0%
Pediatrics	24	0%
Oncology	24	0%
Geriatrics	22	0%
Managed Care Pharmacy Systems	18	0%
Informatics	15	0%
Nuclear	12	0%
Other	190	2%
Total	659	8%

Source: Va. Healthcare Workforce Data Center

9% of pharmacists hold a board certification, including 5% who hold a certification in Pharmacotherapy. 35% also have a self-designated specialty area, including 18% who have a specialization in immunization.

At a Glance:

Top Services

Immunization:	35%
Medication Management:	34%
Compounding:	28%

Disease Management

Any Disease Management:	61%
Anticoagulation:	18%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Services Provided

Services	Primary		Secondary	
	#	%	#	%
Immunization	3,019	35%	3,019	35%
Medication Therapy Management	2,885	34%	333	4%
Compounding	2,450	28%	292	3%
Central Filling	1,143	13%	164	2%
Remote Order Processing	821	10%	79	1%
Collaborative Practice Agreement	495	6%	73	1%
Remote Consulting/ Telepharmacy	0	0%	0	0%
At Least One Service	4,948	58%	3,300	38%

Source: Va. Healthcare Workforce Data Center

Disease Management in Collaborative Practice

	#	%
Anticoagulation	88	18%
Hypertension, Hypercholesterolemia, Asthma, Tobacco cessation, Travel medications, Anticoagulation, Diabetes	23	5%
Hypertension, Hypercholesterolemia, Asthma Tobacco cessation, Anticoagulation, Diabetes	22	5%
Hypertension, Hypercholesterolemia, Anticoagulation, Diabetes	14	3%
Anticoagulation, Diabetes	10	2%
Diabetes	10	2%
Hypertension, Hypercholesterolemia, Asthma, Diabetes	7	1%
Hypertension, Hypercholesterolemia, Asthma, Tobacco cessation, Diabetes	6	1%
Hypertension, Hypercholesterolemia, Asthma, Anticoagulation, Diabetes	5	1%
Hypertension, Diabetes	2	0%
Hypertension, Hypercholesterolemia	2	0%
Hypertension, Asthma, Anticoagulation, Diabetes	2	0%
Hypercholesterolemia, Diabetes	1	0%
Hypertension, Asthma, Tobacco cessation, Diabetes	1	0%
Hypercholesterolemia	1	0%
Hypertension, Asthma, Diabetes	1	0%
Hypertension, Anticoagulation, Diabetes	1	0%
Hypertension, Asthma, Tobacco cessation, Travel medications, Diabetes	1	0%
Hypertension, Asthma, Travel medications, Anticoagulation, Diabetes	1	0%
Hypertension, Asthma, Anticoagulation	1	0%
Hypertension, Hypercholesterolemia, Anticoagulation	1	0%
Hypercholesterolemia, Travel medications, Diabetes	1	0%
Hypertension, Hypercholesterolemia, Asthma, Tobacco cessation	1	0%
Other	100	20%
Total	304	61%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Employment

Employed in Profession: 92%
Involuntarily Unemployed: 1%

Positions Held

1 Full-time: 72%
2 or More Positions: 8%

Weekly Hours:

40 to 49: 52%
60 or more: 4%
Less than 30: 12%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Current Work Status		
Status	#	%
Employed, capacity unknown	**4**	**<1%**
Employed in a pharmacy-related capacity	**6,567**	**92%**
Employed, NOT in a pharmacy-related capacity	**196**	**3%**
Not working, reason unknown	**0**	**0%**
Involuntarily unemployed	**87**	**1%**
Voluntarily unemployed	**170**	**2%**
Retired	**140**	**2%**
Total	**7,164**	**100%**

Source: Va. Healthcare Workforce Data Center

92% of Virginia's pharmacists are currently employed in the profession, and only 1% of all pharmacy professionals are involuntarily unemployed at the moment. 72% of the state's pharmacist workforce has one full-time job, while just 8% of pharmacists have multiple positions. 52% 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	**397**	**6%**
One Part-Time Position	**947**	**13%**
Two Part-Time Positions	**156**	**2%**
One Full-Time Position	**5,084**	**72%**
One Full-Time Position & One Part-Time Position	**391**	**6%**
Two Full-Time Positions	**10**	**0%**
More than Two Positions	**35**	**0%**
Total	**7,019**	**100%**

Source: Va. Healthcare Workforce Data Center

Current Weekly Hours		
Hours	#	%
0 hours	**397**	**6%**
1 to 9 hours	**180**	**3%**
10 to 19 hours	**255**	**4%**
20 to 29 hours	**430**	**6%**
30 to 39 hours	**1,328**	**19%**
40 to 49 hours	**3,641**	**52%**
50 to 59 hours	**467**	**7%**
60 to 69 hours	**177**	**3%**
70 to 79 hours	**77**	**1%**
80 or more hours	**48**	**1%**
Total	**7,000**	**100%**

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Income		
Annual Income	#	%
Volunteer Work Only	64	1%
$50,000 or less	412	8%
$50,001-$60,000	111	2%
$60,001-$70,000	118	2%
$70,001-$80,000	150	3%
$80,001-$90,000	142	3%
$90,001-$100,000	235	4%
$100,001-$110,000	561	10%
$110,001-$120,000	754	14%
$120,001-$130,000	1,073	20%
$130,001-$140,000	799	15%
$140,001-$150,000	471	9%
More than $150,000	567	10%
Total	5,457	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: 89%
Very Satisfied: 48%

Source: Va. Healthcare Workforce Data Center

Job Satisfaction		
Level	#	%
Very Satisfied	3,322	48%
Somewhat Satisfied	2,789	40%
Somewhat Dissatisfied	545	8%
Very Dissatisfied	249	4%
Total	6,904	100%

Source: Va. Healthcare Workforce Data Center

The typical pharmacist earned between $120,000 and $130,000 in 2017. 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	465	7%	7%
Retirement	4,285	65%	68%
Health Insurance	4,447	68%	70%
Dental Insurance	3,336	51%	53%
Paid Sick Leave	4,527	69%	72%
Group Life Insurance	3,915	60%	62%
Signing/Retention Bonus	5,077	77%	80%
Received At Least One Benefit	5,371	82%	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?	159	2%
Experience Voluntary Unemployment?	282	3%
Work Part-time or temporary positions, but would have preferred a full-time/permanent position?	256	3%
Work two or more positions at the same time?	728	8%
Switch employers or practices?	398	5%
Experienced at least 1	**1,509**	**18%**

Source: Va. Healthcare Workforce Data Center

Only 2% of Virginia's pharmacists were involuntary unemployed at some point in 2017. For comparison, Virginia's average monthly unemployment rate was 3.8%.[1]

At a Glance:

Unemployment Experience

Involuntarily Unemployed: 2%
Underemployed: 3%

Stability

Switched: 5%
New Location: 21%
Over 2 years: 62%
Over 2 yrs, 2nd location: 52%

Employment Type

Salary or Wage 94%

Source: Va. Healthcare Workforce Data Center

Location Tenure				
Tenure	Primary		Secondary	
	#	%	#	%
Not Currently Working at this Location	165	2%	76	8%
Less than 6 Months	618	9%	132	14%
6 Months to 1 Year	523	8%	105	11%
1 to 2 Years	1,250	19%	157	16%
3 to 5 Years	1,445	22%	209	21%
6 to 10 Years	1,010	15%	117	12%
More than 10 Years	1,687	25%	178	18%
Subtotal	6,699	100%	975	100%
Did not have location	298		7,587	
Item Missing	1,602		37	
Total	8,599		8,599	

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.

Half of all pharmacists receive a salary or commission at their primary work location, while 42% receive an hourly wage.

Employment Type		
Primary Work Site	#	%
Salary/ Commission	3,189	52%
Hourly Wage	2,551	42%
By Contract	57	1%
Business/ Practice Income	299	5%
Unpaid	42	1%
Subtotal	6,138	100%

Source: Va. Healthcare Workforce Data Center

[1] As reported by the US Bureau of Labor Statistics. The non-seasonally adjusted monthly unemployment rate ranged from 3.4% in December to 4.2% in January 2017. At the time of this publication, results from December were preliminary.

At a Glance:

Concentration

Top Region:	26%
Top 3 Regions:	70%
Lowest Region:	2%

Locations

2 or more (2017):	12%
2 or more (Now*):	13%

Source: Va. Healthcare Workforce Data Center

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

A Closer Look:

Regional Distribution of Work Locations				
COVF Region[2]	Primary Location		Secondary Location	
	#	%	#	%
Central	**1,663**	**25%**	**176**	**18%**
Eastern	113	2%	15	2%
Hampton Roads	**1,256**	**19%**	**173**	**18%**
Northern	**1,715**	**26%**	**231**	**24%**
Southside	**243**	**4%**	**34**	**4%**
Southwest	382	6%	95	10%
Valley	**429**	**6%**	**54**	**6%**
West Central	747	11%	109	11%
Virginia Border State/DC	**39**	**1%**	**30**	**3%**
Other US State	65	1%	46	5%
Outside of the US	**1**	**0%**	**6**	**1%**
Total	**6,653**	**100%**	**969**	**100%**
Item Missing	**1,649**		**42**	

Source: Va. Healthcare Workforce Data Center

Council On Virginia's Future Regions

Number of Work Locations				
Locations	Work Locations in 2017		Work Locations Now*	
	#	%	#	%
0	**297**	**4%**	**380**	**6%**
1	**7,291**	**85%**	**5,636**	**81%**
2	**513**	**6%**	**500**	**7%**
3	**328**	**4%**	**285**	**4%**
4	**42**	**1%**	**26**	**0%**
5	21	0%	14	0%
6 or More	**107**	**1%**	**87**	**1%**
Total	**8,599**	**100%**	**6,927**	**100%**

*At the time of survey completion, December 2017.

Source: Va. Healthcare Workforce Data Center

Over the past year, 12% of Virginia's pharmacists have worked at multiple locations.

[2] These are now referred to as VA Perform's regions: http://vaperforms.virginia.gov/Regions/regionalScorecards.php

A Closer Look:

Location Sector				
Sector	Primary Location		Secondary Location	
	#	%	#	%
For-Profit	**4,239**	**68%**	**630**	**70%**
Non-Profit	1,457	23%	213	24%
State/Local Government	**239**	**4%**	**29**	**3%**
Veterans Administration	114	2%	6	1%
U.S. Military	**133**	**2%**	**17**	**2%**
Other Federal Gov't	76	1%	11	1%
Total	**6,258**	**100%**	**906**	**100%**
Did not have location	298		7,587	
Item Missing	**2,045**		**104**	

Source: Va. Healthcare Workforce Data Center

At a Glance:
(Primary Locations)

Sector

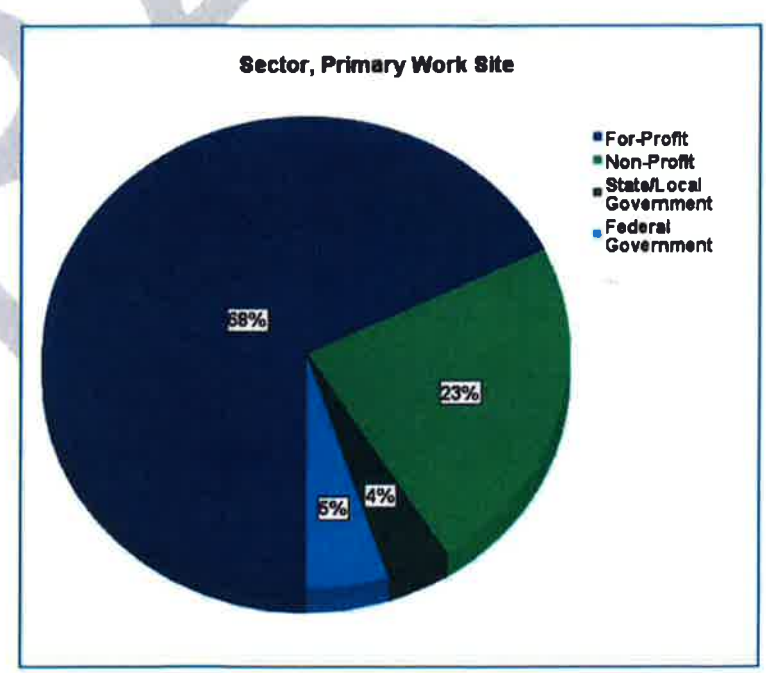
For Profit: 68%
Federal: 5%

Top Establishments

Large Chain Pharmacy (11+ Stores): 30%
Hospital/Health System (Inpatient): 23%
Independent Pharmacy (1-4 Stores): 9%

Source: Va. Healthcare Workforce Data Center

More than 90% of all pharmacists work in the private sector, including 68% 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.



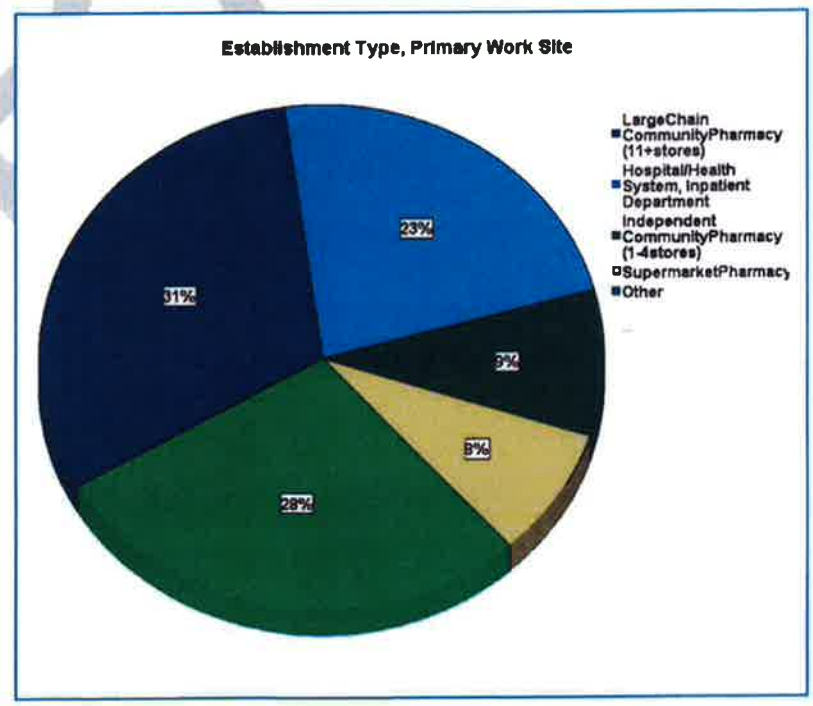
Source: Va. Healthcare Workforce Data Center

Top Location Types				
Establishment Type	Primary Location		Secondary Location	
	#	%	#	%
Large Chain Community Pharmacy	**1,810**	**30%**	**202**	**23%**
Hospital/Health System, Inpatient Department	1,423	23%	155	17%
Independent Community Pharmacy	**576**	**9%**	**151**	**17%**
Supermarket Pharmacy	501	8%	46	5%
Hospital/Health System, Outpatient Department	**338**	**6%**	**44**	**5%**
Mass Merchandiser (i.e. Big Box Store)	275	4%	29	3%
Nursing Home/Long-Term Care	**203**	**3%**	**41**	**5%**
Clinic-Based Pharmacy	196	3%	79	9%
Benefit Administration	**144**	**2%**	**12**	**1%**
Academic Institution	104	2%	25	3%
Home Health/Infusion	**71**	**1%**	**8**	**1%**
Manufacturer	53	1%	2	0%
Mail Service Pharmacy	**40**	**1%**	**4**	**0%**
Small Chain Community Pharmacy	27	0%	12	1%
Wholesale Distributor	**6**	**0%**	**1**	**0%**
Other	351	6%	78	9%
Total	**6,118**	**100%**	**889**	**100%**
Did Not Have a Location	298		7,587	

Source: Va. Healthcare Workforce Data Center

Large chain community pharmacies of more than 10 stores are the most common establishment type in Virginia, employing nearly one-third 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%
Education:	0%

Roles

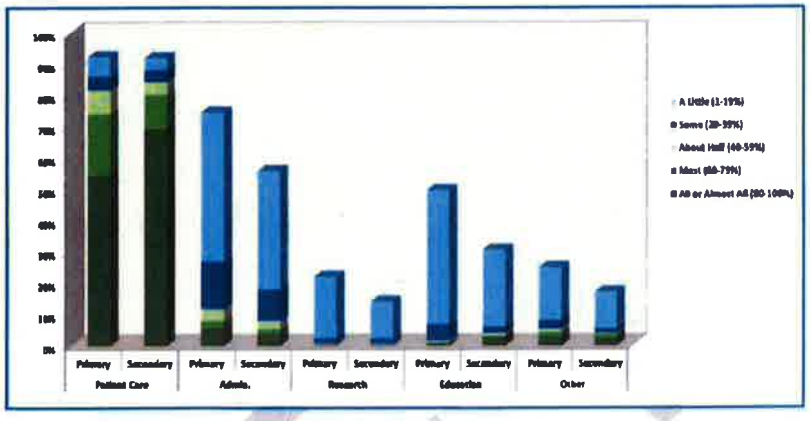
Patient Care:	74%
Administration:	8%
Education:	1%

Patient Care Pharmacists

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

Source: Va. Healthcare Workforce Data Center

A Closer Look:



Source: Va. Healthcare Workforce Data Center

A typical pharmacist spends most of her time in patient care activities. In fact, 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%)	**54%**	**69%**	**6%**	**4%**	**0%**	**0%**	**1%**	**3%**	**3%**	**2%**
Most (60-79%)	20%	11%	2%	2%	0%	0%	0%	0%	1%	1%
About Half (40-59%)	**8%**	**4%**	**4%**	**3%**	**0%**	**0%**	**1%**	**1%**	**1%**	**0%**
Some (20-39%)	4%	4%	15%	10%	2%	2%	5%	2%	3%	1%
A Little (1-20%)	**6%**	**4%**	**48%**	**38%**	**20%**	**12%**	**43%**	**25%**	**17%**	**12%**
None (0%)	8%	8%	26%	44%	78%	86%	50%	69%	75%	83%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Retirement Expectations				
Expected Retirement Age	All		Over 50	
	#	%	#	%
Under age 50	**146**	**3%**	**-**	**-**
50 to 54	203	4%	0	0%
55 to 59	**552**	**10%**	**112**	**5%**
60 to 64	1,415	25%	497	23%
65 to 69	**2,177**	**38%**	**912**	**42%**
70 to 74	690	12%	353	16%
75 to 79	**184**	**3%**	**89**	**4%**
80 or over	89	2%	55	3%
I do not intend to retire	**310**	**5%**	**134**	**6%**
Total	**5,766**	**100%**	**2,151**	**100%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Retirement Expectations

All Pharmacists

Under 65:	40%
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 2042

Source: Va. Healthcare Workforce Data Center

*40% of Virginia's pharmacists expect to retire before the age of **65, while 23% 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, 2% of Virginia's pharmacists plan on leaving the profession and 3% expect to leave the state. Meanwhile, 10% of pharmacists expect to pursue additional educational opportunities, and 8% also plan on increasing the number of hours that they devote to patients.

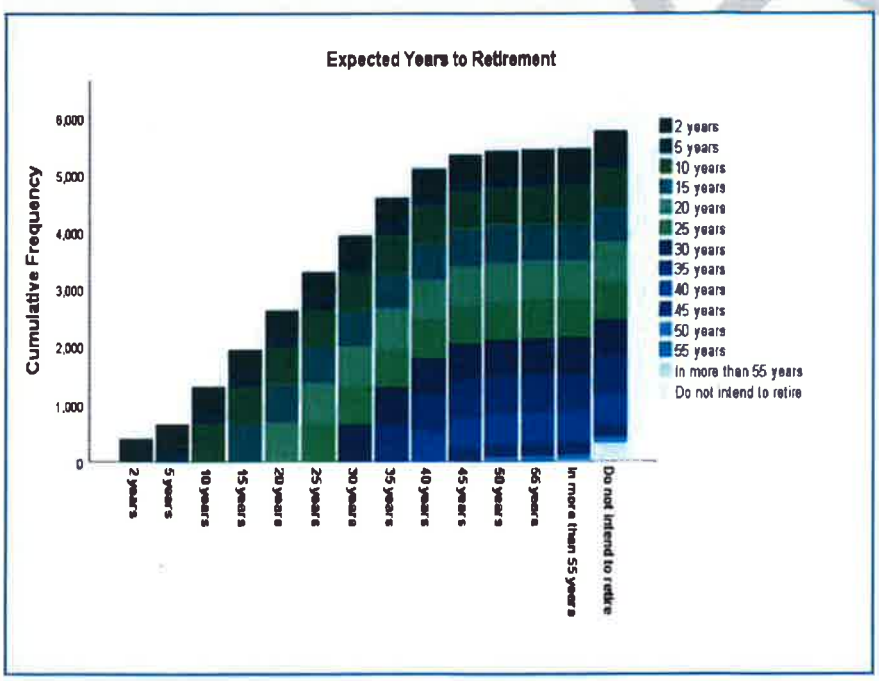
Future Plans		
2 Year Plans:	#	%
Decrease Participation		
Leave Profession	**146**	**2%**
Leave Virginia	217	3%
Decrease Patient Care Hours	**209**	**2%**
Decrease Teaching Hours	35	0%
Increase Participation		
Increase Patient Care Hours	**714**	**8%**
Increase Teaching Hours	469	5%
Pursue Additional Education	**840**	**10%**
Return to Virginia's Workforce	111	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 expects to be retired by 2042.

Time to Retirement			
Expect to retire within. . .	#	%	Cumulative %
2 years	395	7%	7%
5 years	246	4%	11%
10 years	657	11%	23%
15 years	645	11%	34%
20 years	685	12%	46%
25 years	673	12%	57%
30 years	639	11%	68%
35 years	654	11%	80%
40 years	503	9%	88%
45 years	251	4%	93%
50 years	64	1%	94%
55 years	25	0%	94%
In more than 55 years	17	0%	95%
Do not intend to retire	310	5%	100%
Total	5,766	100%	

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

Using these estimates, retirements will begin to reach 10% of the current workforce starting in 2027. Retirements will peak at 12% of the current workforce around 2037 before declining to under 10% of the current workforce again around 2057.

At a Glance:

FTEs

Total:	7,139
FTEs/1,000 Residents:	0.852
Average:	0.86

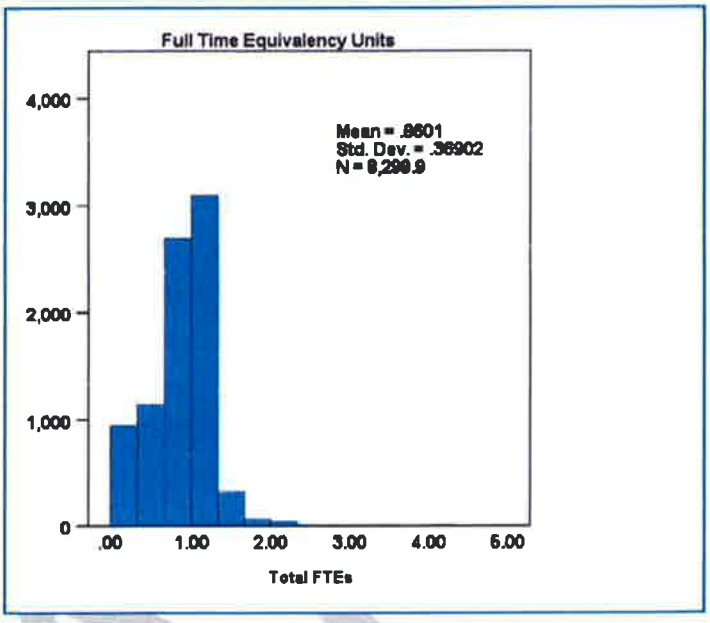
Age & Gender Effect

Age, Partial Eta^2:	Small
Gender, Partial Eta^2:	Negligible

Partial Eta^2 Explained:
Partial Eta^2 is a statistical measure of effect size.

Source: Va. Healthcare Workforce Data Center

A Closer Look:

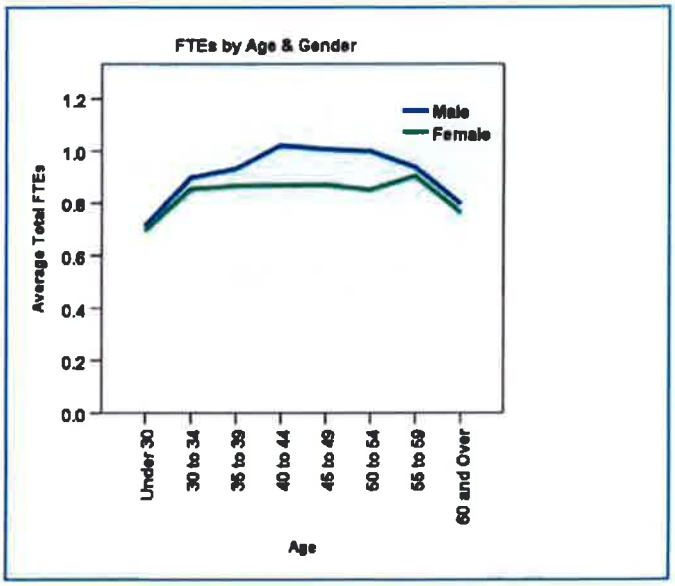


Source: Va. Healthcare Workforce Data Center

The typical pharmacist provided 0.96 FTEs in 2017, 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	0.71	0.83
30 to 34	0.86	0.91
35 to 39	0.85	0.91
40 to 44	0.93	0.99
45 to 49	0.93	1.03
50 to 54	0.92	1.01
55 to 59	0.91	0.93
60 and Over	0.79	0.81
Gender		
Male	0.89	1.01
Female	0.84	0.94

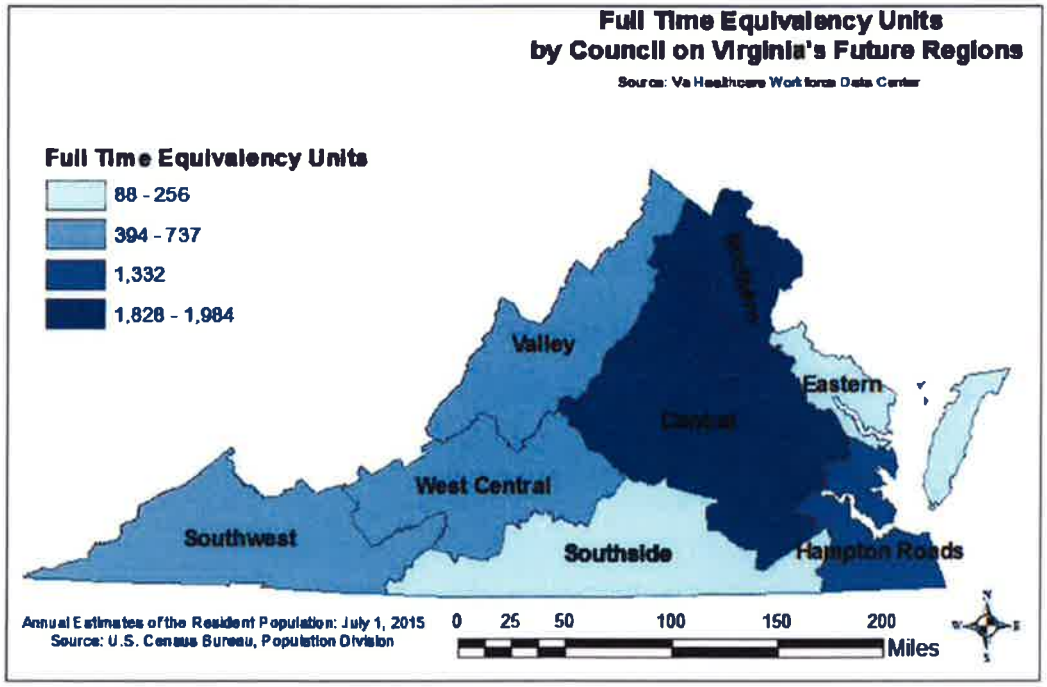
Source: Va. Healthcare Workforce Data Center

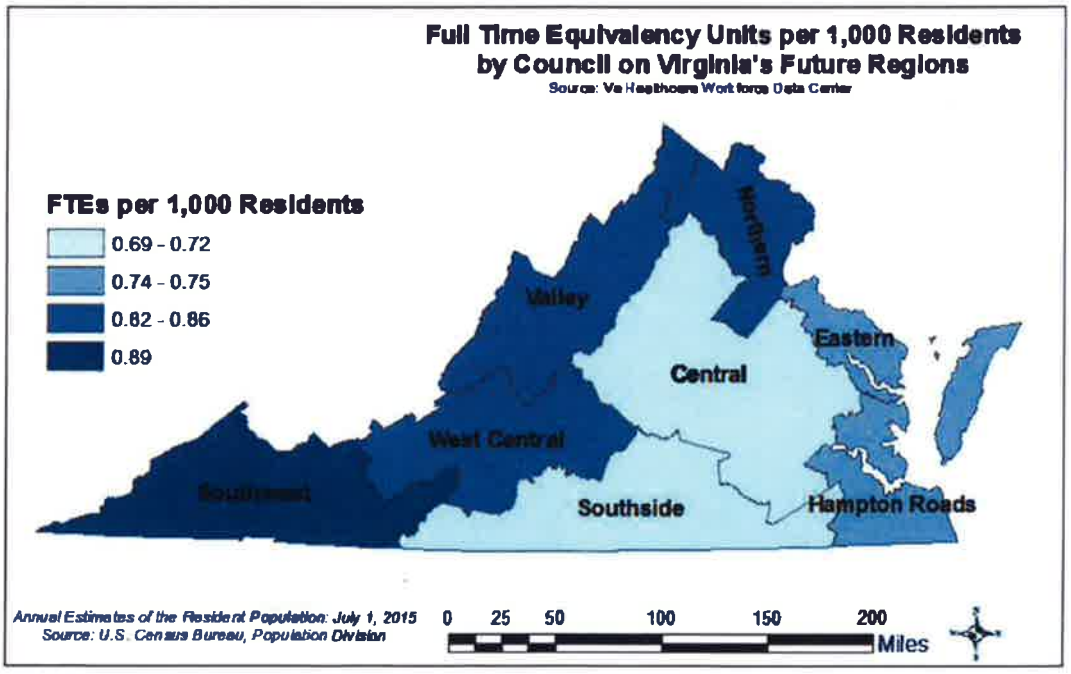


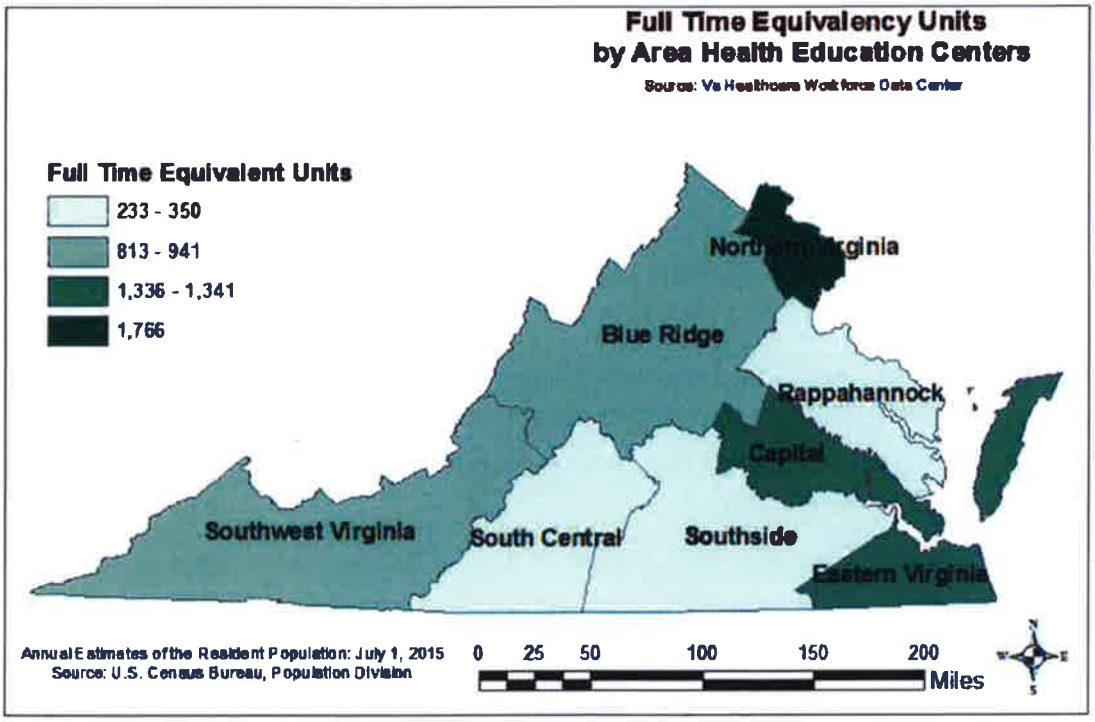
Source: Va. Healthcare Workforce Data Center

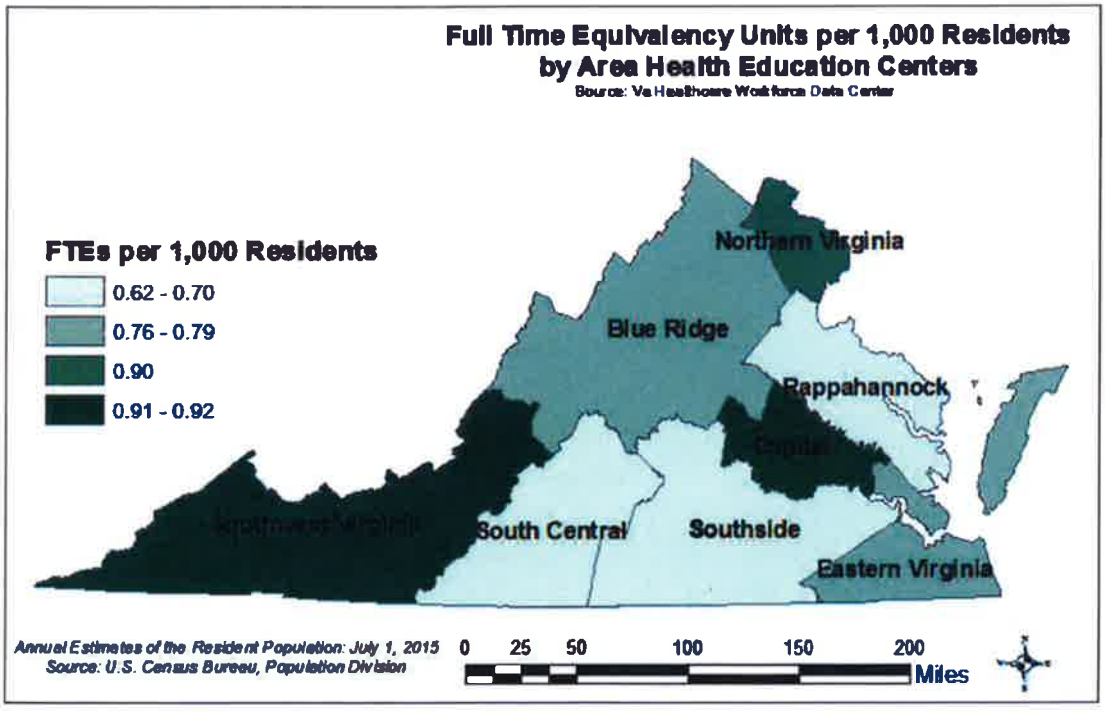
[3] Due to assumption violations in Mixed between-within ANOVA (Levene's Test & Interaction effect are significant).

Council on Virginia's Future Regions

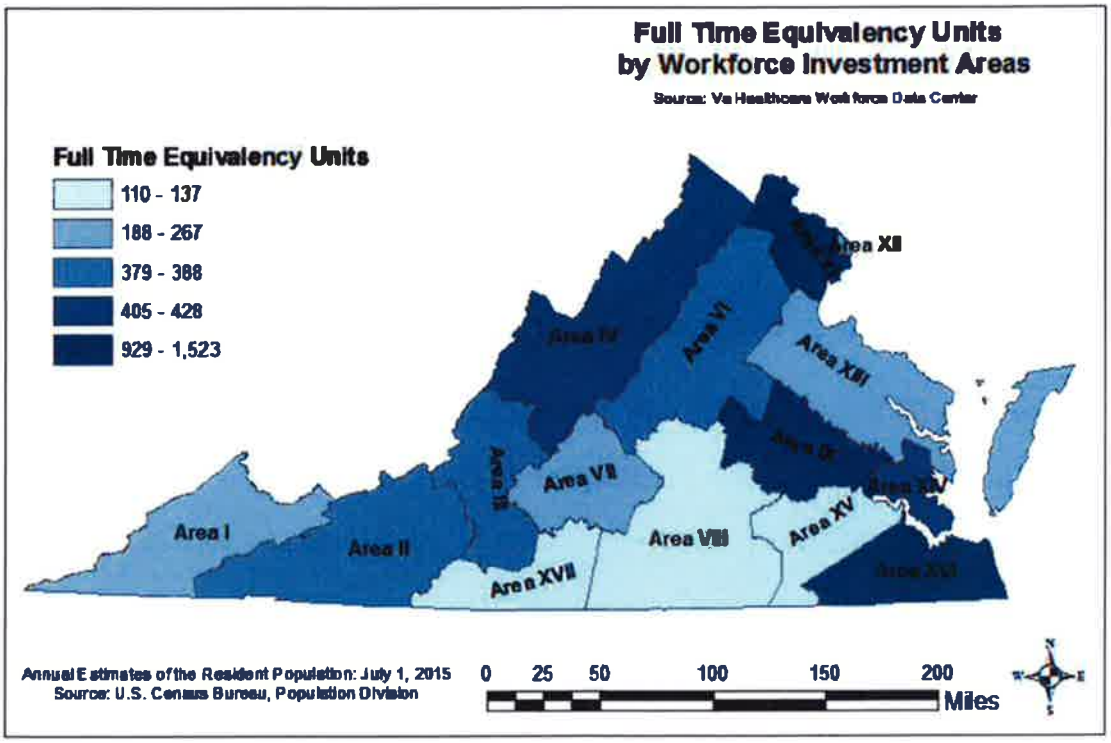


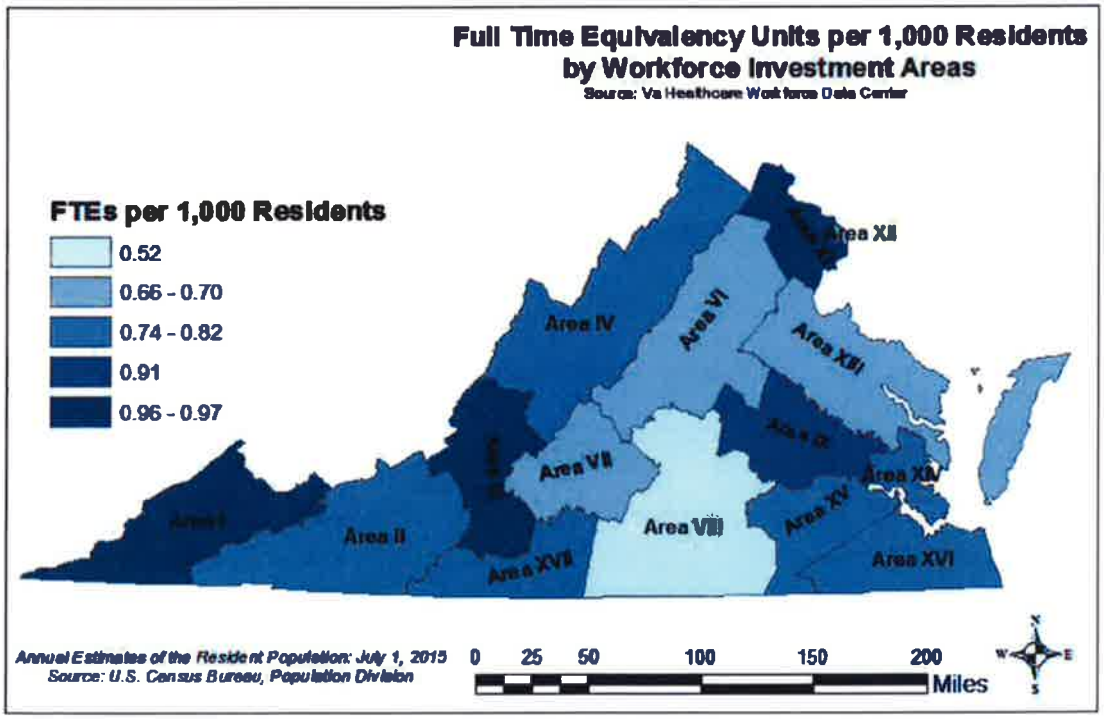



Full Time Equivalency Units
by Area Health Education Centers
Source: Va Healthcare Workforce Data Center
Full Time Equivalent Units
233 - 350
813 - 941
1,336 - 1,341
1,766
Blue Ridge
Rappahannock
Capital
Southwest Virginia
South Central
Southside
Eastern Virginia
Annual Estimates of the Resident Population: July 1, 2015
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles


Full Time Equivalency Units per 1,000 Residents
by Area Health Education Centers
Source: Va Healthcare Workforce Data Center
FTEs per 1,000 Residents
0.62 - 0.70
0.76 - 0.79
0.90
0.91 - 0.92
Blue Ridge
Rappahannock
South Central
Southside
Eastern Virginia
Annual Estimates of the Resident Population: July 1, 2015
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles

Workforce Investment Areas





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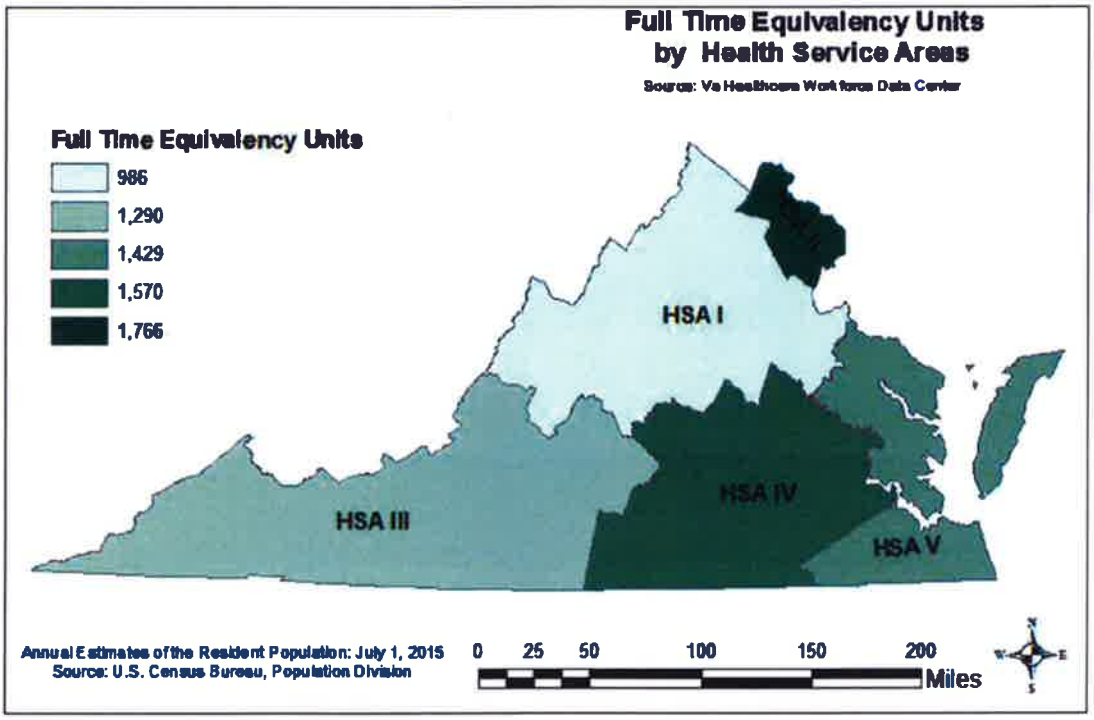
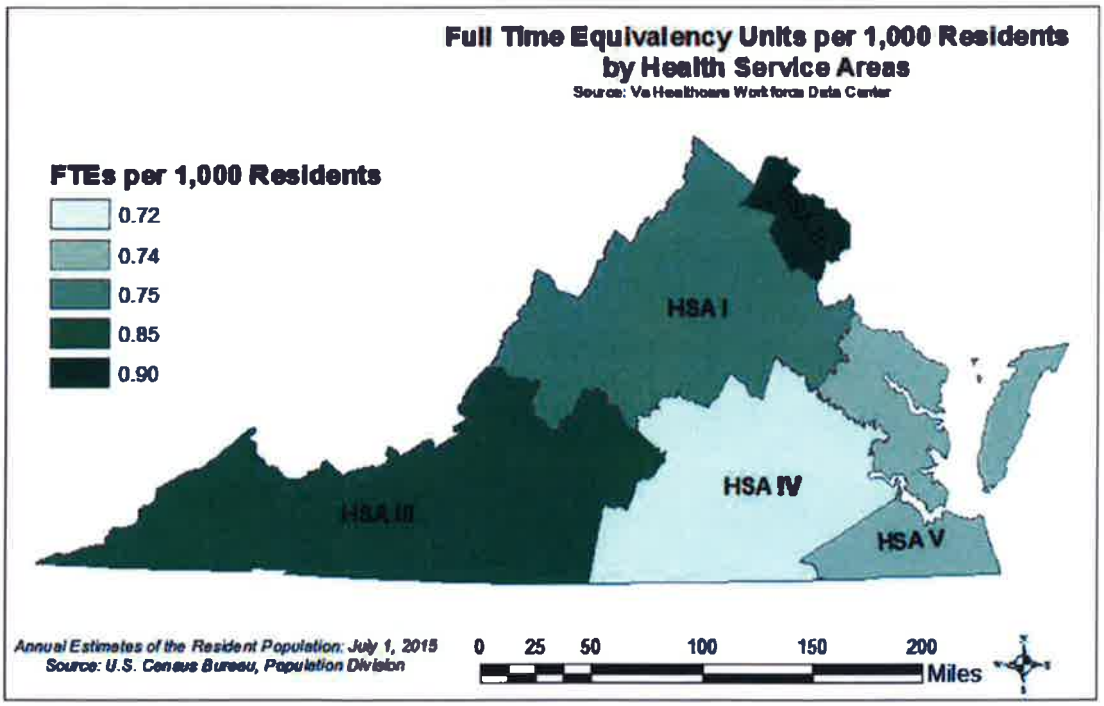
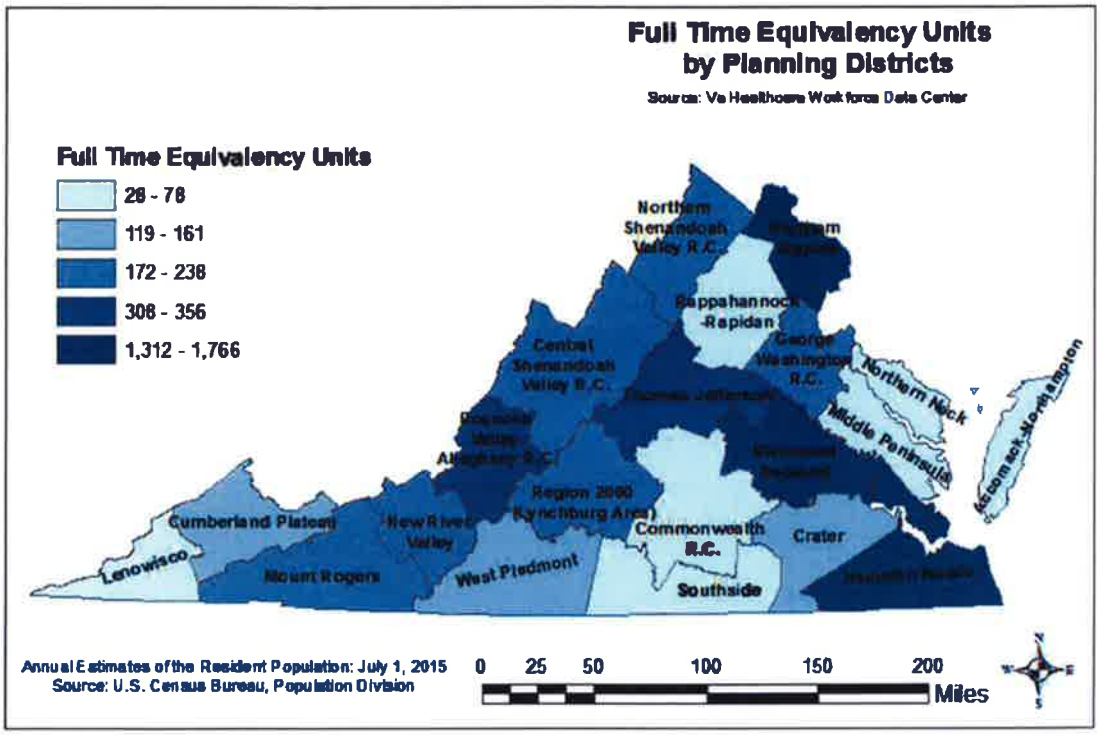
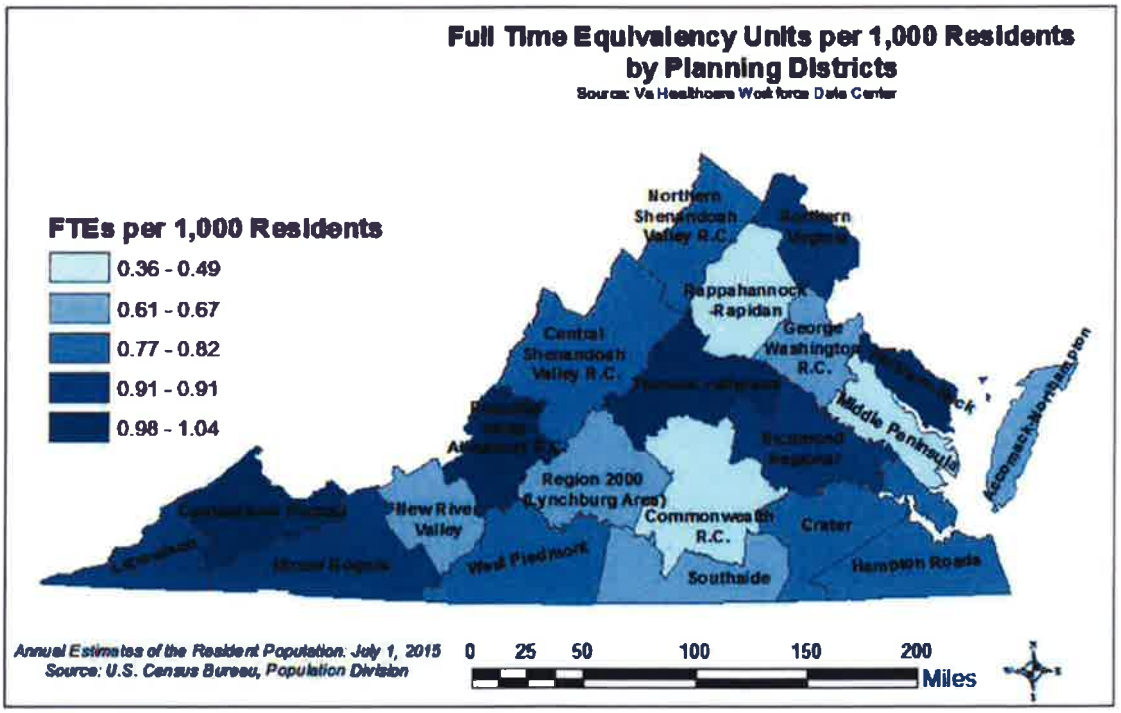

Full Time Equivalency Units
by Health Service Areas
Source: Va Healthcare Workforce Data Center
Full Time Equivalency Units
986
1,290
1,429
1,570
1,766
HSA I
HSA III
HSA IV
HSA V
Annual Estimates of the Resident Population: July 1, 2015
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles


Full Time Equivalency Units per 1,000 Residents
by Health Service Areas
Source: Va Healthcare Workforce Data Center
FTEs per 1,000 Residents
0.72
0.74
0.75
0.85
0.90
HSA I
HSA III
HSA IV
HSA V
Annual Estimates of the Resident Population: July 1, 2015
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles


Full Time Equivalency Units
by Planning Districts
Source: Va Healthcare Workforce Data Center
Full Time Equivalency Units
28 - 78
119 - 161
172 - 238
308 - 356
1,312 - 1,766
Northern Shenandoah Valley R.C.
Rappahannock-Rapidan
George Washington R.C.
Central Shenandoah Valley R.C.
Northern Neck
Middle Peninsula
Accomack-Northampton
Region 2000 (Lynchburg Area)
Commonwealth R.C.
Crater
Cumberland Plateau
New River Valley
Lenowisco
Mount Rogers
West Piedmont
Southside
Annual Estimates of the Resident Population: July 1, 2015
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
FTEs per 1,000 Residents
0.36 - 0.49
0.61 - 0.67
0.77 - 0.82
0.91 - 0.91
0.98 - 1.04
Northern Shenandoah Valley R.C.
Rappahannock-Rapidan
George Washington R.C.
Central Shenandoah Valley R.C.
Middle Peninsula
Accomack-Northampton
Region 2000 (Lynchburg Area)
Commonwealth R.C.
Crater
New River Valley
West Piedmont
Southside
Hampton Roads
Annual Estimates of the Resident Population: July 1, 2015
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles

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Appendix

Weights

Rural Status	Location Weight			Total Weight	
	#	Rate	Weight	Min	Max
Metro, 1 million+	6,286	92.94%	1.076001369	1.051017865	1.133804125
Metro, 250,000 to 1 million	937	93.17%	1.073310424	1.0483894	1.130968622
Metro, 250,000 or less	983	93.69%	1.067318132	1.042536243	1.124654424
Urban pop 20,000+, Metro adj	119	93.28%	1.072072072	1.047179801	1.129663746
Urban pop 20,000+, nonadj	0	NA	NA	NA	NA
Urban pop, 2,500-19,999, Metro adj	385	90.39%	1.106321839	1.080634328	1.165753409
Urban pop, 2,500-19,999, nonadj	264	91.67%	1.090909091	1.065579446	1.149512688
Rural, Metro adj	231	84.42%	1.184615385	1.157109988	1.248252881
Rural, nonadj	110	91.82%	1.089108911	1.063821064	1.147615803
Virginia border state/DC	2,458	89.79%	1.113729044	1.087869546	1.173558528
Other US State	3,180	86.92%	1.150506512	1.123793085	1.212311681

Source: Va. Healthcare Workforce Data Center

Age	Age Weight			Total Weight	
	#	Rate	Weight	Min	Max
Under 30	1,067	89.32%	1.119622246	1.087185612	1.206666282
30 to 34	2,391	92.14%	1.085338175	1.053894788	1.169716827
35 to 39	2,136	92.13%	1.085365854	1.053921664	1.169746657
40 to 44	1,856	91.86%	1.08856305	1.057026234	1.173192416
45 to 49	1,863	91.73%	1.090111176	1.05852951	1.1748609
50 to 54	1,560	93.14%	1.073640743	1.042536243	1.157109988
55 to 59	1,364	92.96%	1.075709779	1.044545336	1.15933988
60 and Over	2,716	86.34%	1.158208955	1.124654424	1.248252881

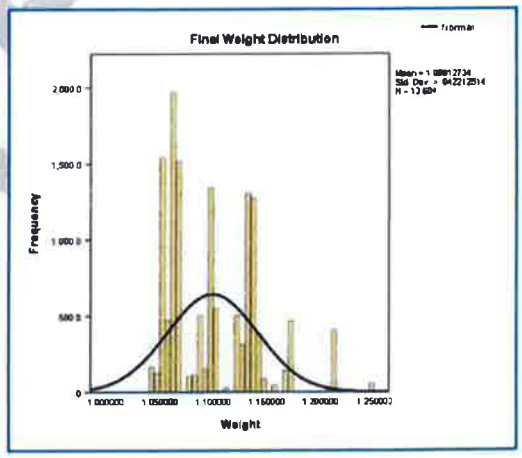
Source: Va. Healthcare Workforce Data Center

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: 0.90978



Source: Va. Healthcare Workforce Data Center

Attachment II

Virginia's Pharmacy Technician Workforce: 2017

Healthcare Workforce Data Center

January 2018

Virginia Department of Health Professions
Healthcare Workforce Data Center
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, VA 23233
804-367-2115, 804-527-4466(fax)
E-mail: *HWDC@dhp.virginia.gov*

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

11,494 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

Lisa R. Hahn, MPA
Chief Deputy Director

Healthcare Workforce Data Center Staff:

Dr. Elizabeth Carter, PhD	Yetty Shobo, PhD	Laura Jackson	Christopher Coyle
Executive Director	*Deputy Director*	*Operations Manager*	*Research Assistant*

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Rafael Saenz
Crozet

Cynthia Warriner
Chester

Executive Director

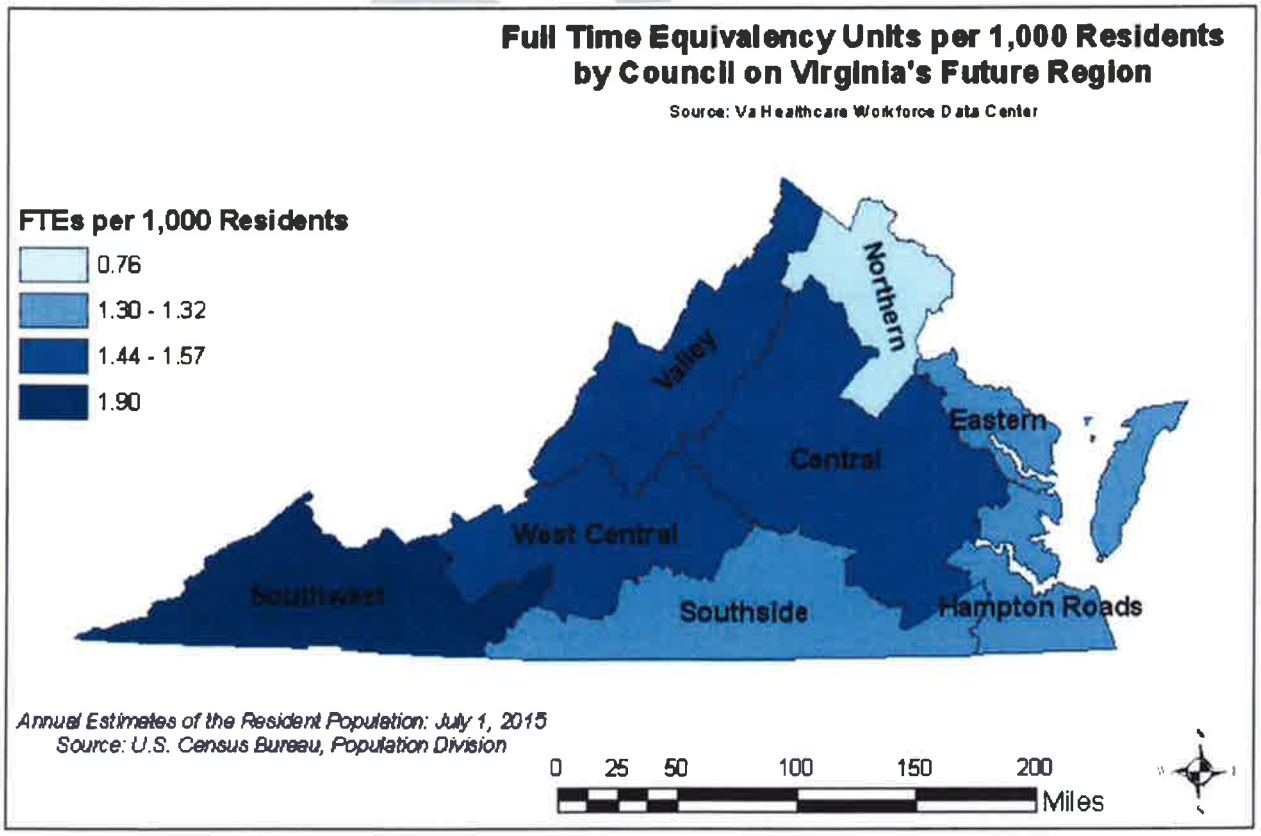
Caroline D. Juran
Richmond

Contents

The Pharmacy Technician Workforce: At a Glance:

The Workforce		Background		Current Employment	
Licensees:	14,941	Rural Childhood:	41%	Employed in Prof.:	79%
Virginia's Workforce:	13,967	HS Degree in VA:	74%	Hold 1 Full-time Job:	64%
FTEs:	10,390	% Work Non-Metro:	14%	Satisfied?:	90%
Survey Response Rate		**Education**		**Job Turnover**	
All Licensees:	77%	High School/GED:	59%	Switched Jobs in 2017:	5%
Renewing Practitioners:	98%	Associate Degree:	20%	Employed over 2 yrs:	51%
Demographics		**Finances**		**Primary Roles**	
Female:	84%	Median Inc.:	$25k-$30k	Medication Disp.:	60%
Diversity Index:	59%	Health Benefits:	61%	Administration:	4%
Median Age:	35	Under 40 w/ Ed debt:	51%	Supervision:	2%

Source: Va Healthcare Workforce Data Center



Results in Brief

11,494 pharmacy technicians voluntarily took part in the 2017 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 77% of the 14,941 pharmacy technicians who are licensed in the state and 98% of renewing practitioners.

The HWDC estimates that 13,967 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 10,390 "full-time equivalency units" during the survey time period, which the HWDC defines simply as working 2,000 hours a year (or 40 hours per week for 50 weeks with 2 weeks off).

84% of all pharmacy technicians are female, including 83% of those pharmacy technicians who are under the age of 40. In total, 63% of all pharmacy technicians are under the age of 40. In addition, Virginia's pharmacy technician workforce is more diverse than the state's overall population. In a random encounter between two pharmacy technicians, there is a 59% chance that they would be of a different race or ethnicity, a measure known as the diversity index. This diversity index increases to 63% for those pharmacy technicians who are under the age of 40. The overall diversity index for the state's total population is 56%.

41% of all pharmacy technicians grew up in a rural area, and 27% of these professionals currently work in non-Metro areas of the state. Overall, 14% of pharmacy technicians currently work in non-Metro areas of the state. 74% of pharmacy technicians earned their high school degree in the state, and this percentage does not change for those who graduated high school in the past five years.

59% of all pharmacy technicians earned a high school degree or GED as their highest professional degree, while another 20% have gone on to earn an Associate degree. In addition, 18% of all pharmacy technicians have also earned a baccalaureate degree as their highest professional degree. 40% of pharmacy technicians currently carry educational debt, including 51% of those who are under the age of 40. The median debt burden for those with educational debt is between $16,000 and $18,000.

79% of pharmacy technicians are currently employed in the profession, and only 1% of the pharmacy technician workforce is involuntarily unemployed at the moment. 51% of pharmacy technicians have been at their primary work location for at least two years, while 5% have switched jobs at some point in the past year. In addition, 74% of all pharmacy technicians work in the for-profit sector, while 4% work in the federal government. Large Chain Community Pharmacies (i.e. pharmacies with more than 10 locations) are the most common establishment type in the state, employing 34% of Virginia's pharmacy technician workforce.

92% of all pharmacy technicians receive an hourly wage at their primary work location. In total, the median annual income for a pharmacy technician in the state is between $25,000 and $30,000. In addition, 79% of Virginia's pharmacy technician workforce receive at least one employee-sponsored benefit, including 61% who receive health insurance. 90% of pharmacy technicians indicate they are satisfied with their current employment situation, including 49% who indicate they are "very satisfied".

A typical pharmacy technician spends approximately three-quarters of her time dispensing medication. In fact, 60% of all pharmacy technicians serve a medication dispensing role, meaning that at least 60% of their time is spent in such activities.

51% of pharmacy technicians expect to retire by the age of 65. 14% of the current workforce expect to retire in the next decade, while half of the current workforce expect to retire by 2042. Over the next two years, 22% of Virginia's pharmacy technician workforce expect to pursue additional educational opportunities, and 7% plan to increase their patient care activities.

Summary of Trends

In 2012, there were 13,610 licensed pharmacy technicians in Virginia. 9,597 of these pharmacy technicians voluntarily took part in the 2012 Pharmacy Technician Workforce Survey. Thus, 71% of all licensees and 88% of renewing practitioners took part in the 2012 survey. Five years later, the number of licensed pharmacy technicians in the state has increased to 14,941. In addition, 11,494 of these licensees voluntarily participated in the 2017 Pharmacy Technician Workforce Survey. Therefore, 77% of Virginia's licensed pharmacy technicians and 98% of all renewing practitioners responded to the 2017 survey.

Similarly, Virginia's pharmacy technician workforce has increased although the number of FTEs produced by these professionals actually decreased during this period. In 2012, 12,843 pharmacy technicians provided 10,568 FTEs. By contrast, 13,967 pharmacy technicians provided only 10,390 FTEs in 2017.

Virginia's pharmacy technicians also experienced small changes with respect to its gender and age distribution as well as its overall diversity. Although the percentage of female pharmacy technicians has stayed at 84% since 2012, the percentage of female pharmacy technicians who are under the age of 40 has increased slightly from 82% to 83%. Meanwhile, the median age of Virginia's pharmacy technician workforce has also increased slightly from 34 to 35 years old. Finally, the state's pharmacy technicians have become more diverse over the past five years. In 2012, the diversity index of Virginia's pharmacy technicians was 56%, a figure that increased to 60% among those pharmacy technicians who were under the age of 40. In 2017, these percentages increased to 59% and 63%, respectively.

There have also been small changes in the background of the state's pharmacy technician workforce. In particular, Virginia's pharmacy technicians are now slightly less likely to come from and work in rural areas of the state. In 2012, 42% of all pharmacy technicians had a rural childhood, and 28% of these professions worked in non-metro areas of the state. However, these percentages have fallen to 41% and 27%, respectively, in 2017. In addition, the percentage of pharmacy technicians who work in rural areas of the state has decreased from 15% to 14% over the past five years.

The state's pharmacy technicians have also experienced changes to their financial situation since 2012. Five years ago, 37% of all pharmacy technicians, including 49% of those who were under the age of 40, carried education debt. In addition, the median education debt among those who carried it was between $10,000 and $12,000. In 2017, 40% of all pharmacy technicians, including 51% of those who are under the age of 40, carry education debt. Among those professionals in Virginia's 2017 pharmacy technician workforce who carry education debt, the median amount was between $16,000 and $18,000.

Over the past five years, the overall employment situation of Virginia's pharmacy technician workforce has generally improved. For example, 62% of Virginia's pharmacy technician workforce held one full-time job in 2017, but this percentage increased to 64% in 2017. In addition, the percentage of pharmacy technicians who work less than 30 hours per week has fallen from 25% in 2012 to just 18% in 2017. Meanwhile, the percentage of pharmacy technicians who are involuntarily unemployed over the course of the prior year has fallen from 3% to 1%, and the percentage underemployed has decreased from 7% to 4%.

With respect to establishment types, Virginia's pharmacy technician workforce was somewhat less likely to work in the for-profit sector. 76% of all pharmacy technicians worked at a for-profit establishment in 2012, but only 74% did so in 2017. On the other hand, the percentage of pharmacy technicians who work at a non-profit establishment has increased over the past five years from 12% to 15%. Large chain pharmacies of 11 or more stores continue to be the largest employer of Virginia's pharmacy technician workforce. However, the percentage of pharmacy technicians employed at large chain pharmacies has fallen from 36% to 34% over the past five years.

A Closer Look:

Licensee Counts		
License Status	#	%
Renewing Practitioners	10,871	73%
New Licensees	1,907	13%
Non-Renewals	2,163	14%
All Licensees	**14,941**	**100%**

Source: Va. Healthcare Workforce Data Center

HWDC surveys tend to achieve very high response rates. 98% of renewing pharmacy technicians submitted a survey. These represent 77% of pharmacy technicians who held a license at some point in 2017.

At a Glance:

Licensed Pharmacy Tech.

Number:	14,941
New:	13%
Not Renewed:	14%

Survey Response Rates

All Licensees:	77%
Renewing Practitioners:	98%

Source: Va. Healthcare Workforce Data Center

Response Rates	
Completed Surveys	**11,494**
Response Rate, all licensees	**77%**
Response Rate, Renewals	**98%**

Source: Va. Healthcare Workforce Data Center

Response Rates			
Statistic	Non Respondents	Respondent	Response Rate
By Age			
Under 30	1,621	3,309	**67%**
30 to 34	553	1,869	**77%**
35 to 39	349	1,508	**81%**
40 to 44	226	1,096	83%
45 to 49	205	1,068	**84%**
50 to 54	153	895	85%
55 to 59	136	771	**85%**
60 and Over	204	978	83%
Total	**3,447**	**11,494**	**77%**
New Licenses			
Issued in 2017	1,138	769	**40%**
Metro Status			
Non-Metro	408	1,712	**81%**
Metro	2,698	9,232	77%
Not in Virginia	341	550	**62%**

Source: Va. Healthcare Workforce Data Center

Definitions

1. **The Survey Period:** The survey was conducted in December 2017.
2. **Target Population:** All professionals who held a Virginia license at some point in 2017.
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 2017.

At a Glance:

Workforce

2017 Pharm. Tech. Workforce:	13,967
FTEs:	10,390

Utilization Ratios

Licensees in VA Workforce:	93%
Licensees per FTE:	1.44
Workers per FTE:	1.34

Source: Va. Healthcare Workforce Data Center

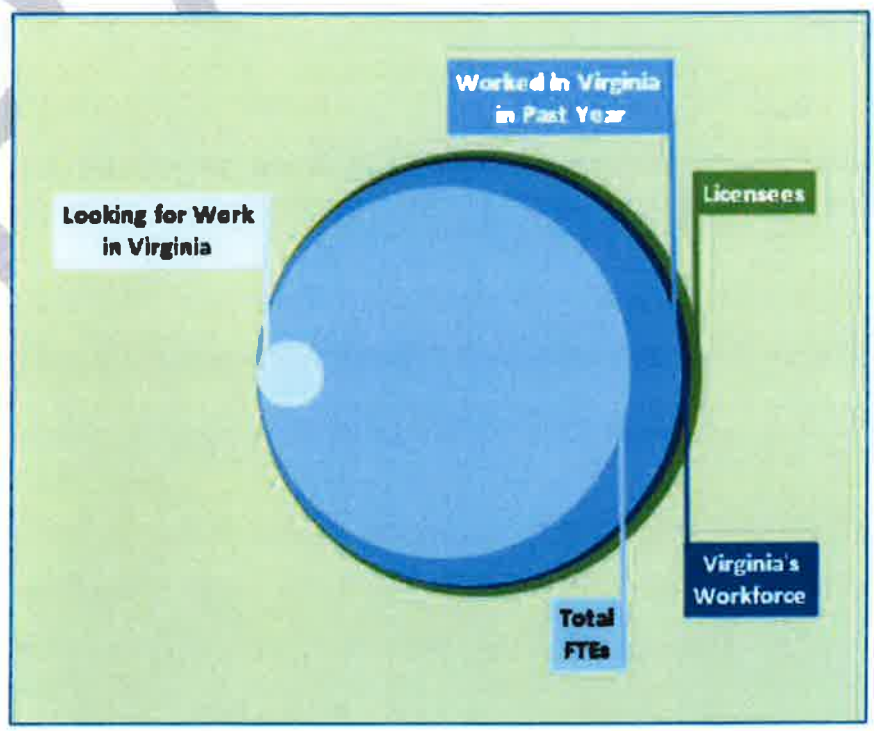
Definitions

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	13,641	98%
Looking for Work in Virginia	327	2%
Virginia's Workforce	13,967	100%
Total FTEs	10,390	
Licensees	14,941	

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	**792**	**19%**	**3,501**	**82%**	**4,294**	**35%**
30 to 34	315	16%	1,714	85%	2,029	16%
35 to 39	**218**	**14%**	**1,299**	**86%**	**1,517**	**12%**
40 to 44	175	17%	875	83%	1,050	8%
45 to 49	**123**	**12%**	**918**	**88%**	**1,041**	**8%**
50 to 54	120	14%	722	86%	842	7%
55 to 59	**92**	**12%**	**656**	**88%**	**747**	**6%**
60 +	120	13%	803	87%	923	7%
Total	**1,956**	**16%**	**10,486**	**84%**	**12,442**	**100%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Gender

% Female:	84%
% Under 40 Female:	83%

Age

Median Age:	35
% Under 40:	63%
% 55+:	13%

Diversity

Diversity Index:	59%
Under 40 Div. Index:	63%

Source: Va. Healthcare Workforce Data Center

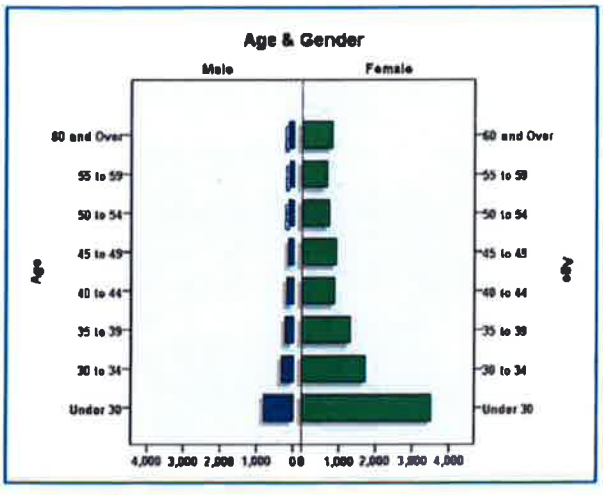
Race & Ethnicity					
Race/ Ethnicity	Virginia*	Pharmacy Tech.		Pharm. Tech. Under 40	
	%	#	%	#	%
White	63%	7,321	59%	4,277	54%
Black	19%	2,823	23%	1,923	24%
Asian	6%	1,101	9%	721	9%
Other Race	0%	192	2%	125	2%
Two or more races	3%	429	3%	339	4%
Hispanic	9%	604	5%	469	6%
Total	100%	12,470	100%	7,854	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, 2015.

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%.

63% of all pharmacy technicians are under the age of 40, and 83% of these professionals 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:	74%
HS in Va., Past 5 Years:	74%

Location Choice

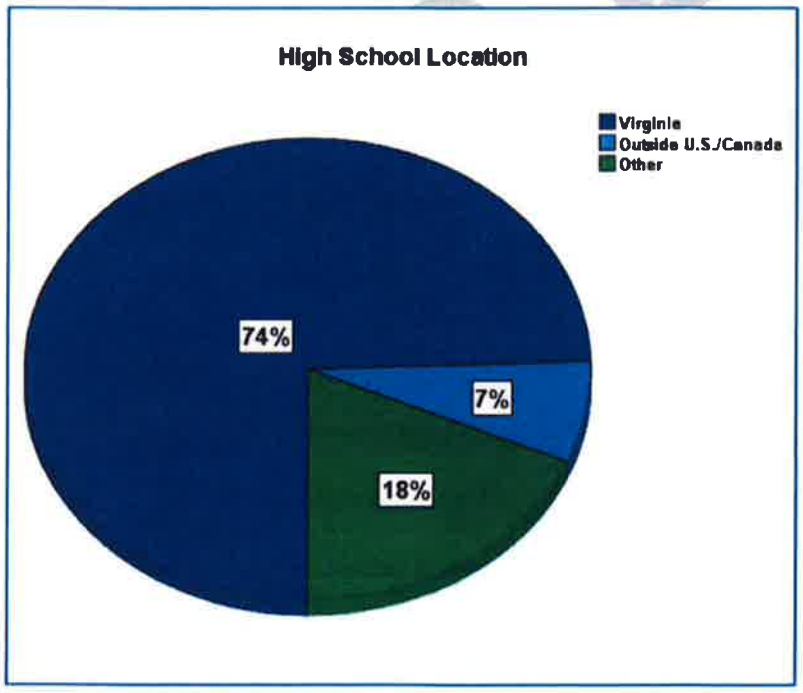
% Work Non-Metro:	14%
% Rural to Non-Metro:	27%
% Urban/Suburban to Non-Metro:	5%

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	58%	29%	13%
3	**Metro, 250,000 or less**	**65%**	**26%**	**9%**
	Non-Metro Counties			
4	**Urban pop 20,000+, Metro adj**	**67%**	**20%**	**12%**
6	Urban pop, 2,500-19,999, Metro adj	79%	13%	8%
7	**Urban pop, 2,500-19,999, nonadj**	**92%**	**5%**	**3%**
8	Rural, Metro adj	82%	11%	6%
9	**Rural, nonadj**	**69%**	**22%**	**9%**
	Overall	**41%**	**40%**	**20%**

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

41% of 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		Licensed in Past 5 Years	
	State	#	State	#
1	Virginia	9,164	Virginia	4,179
2	Outside U.S./Canada	881	Outside U.S./Canada	371
3	New York	243	New York	111
4	North Carolina	204	North Carolina	104
5	Maryland	167	Maryland	98
6	West Virginia	155	Florida	72
7	Pennsylvania	153	Pennsylvania	63
8	Florida	149	West Virginia	59
9	New Jersey	110	California	52
10	California	110	New Jersey	52

Source: Va. Healthcare Workforce Data Center

74% 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% have also received their high school degree in the state.

7% of Virginia's licensed pharmacy technicians did not participate in the state's workforce in 2017. 79% of these professionals worked at some point in the past year, including 56% who currently work as pharmacy technicians.

At a Glance:

Not in VA Workforce

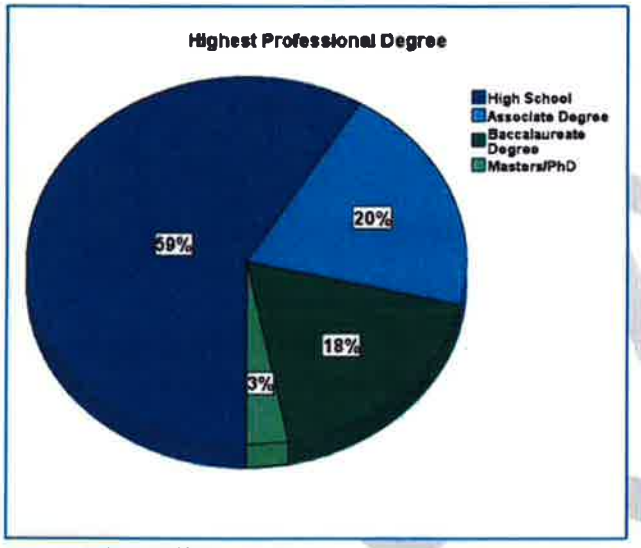
Total:	973
% of Licensees:	7%
Federal/Military:	5%
VA Border State/DC:	39%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Highest Professional Degree		
Degree	#	%
High School/GED	7,154	59%
Associate	**2,459**	**20%**
Baccalaureate	2,204	18%
Masters	**351**	**3%**
PhD	32	< 1%
Total	**12,200**	**100%**

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

40% of pharmacy technicians currently carry educational debt, including 51% of those under the age of 40. For those with educational debt, the median amount is between $16,000 and $18,000.

At a Glance:

Education

High School/GED: 59%
Associate Degree: 20%

Educational Debt

Carry debt: 40%
Under age 40 w/ debt: 51%
Median debt: $16k-$18k

59% of all 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	**5,920**	**60%**	**3,054**	**49%**
Less than $10,000	1,316	13%	1,042	17%
$10,000-$19,999	**842**	**9%**	**709**	**11%**
$20,000-$29,999	654	7%	538	9%
$30,000 or more	**1,115**	**11%**	**847**	**14%**
Total	**9,847**	**100%**	**6,190**	**100%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Top Certifications

PTCB:	65%
ExCPT:	9%
Total w/ Cert.:	74%

Nat'l Certifications

Required:	45%
Pay Raise w/ Cert.:	39%

Source: Va. Healthcare Workforce Data Center

Professional Certifications		
Certification	#	% of Workforce
Pharmacy Technician Certification (PTCB)	9,074	65%
Exam for Certification of Pharmacy Technicians (ExCPT)	1,255	9%
Total	**10,329**	**74%**

Source: Va. Healthcare Workforce Data Center

74% of Virginia's pharmacy workforce holds a professional certification, including 65% who have a Pharmacy Technician Certification (PTCB).

*45% of **pharmacy technicians** work for an **employer that requires** a national **certification as a condition of employment. In addition, 39% of employers offer a pay raise** for those pharmacy technicians that have earned a national certification.*

National Certifications		
Required for Employment?	#	%
Yes	5,353	45%
No	6,627	55%
Pay Raise with Certification?	#	%
Yes	3,969	39%
No	4,880	48%
No Certification Held	1,277	13%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Employment
Employed in Profession: 79%
Involuntarily Unemployed: 1%

Positions Held
1 Full-time: 64%
2 or More Positions: 9%

Weekly Hours:
40 to 49: 44%
60 or more: 3%
Less than 30: 18%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Current Work Status		
Status	#	%
Employed, capacity unknown	26	< 1%
Employed in a pharmacy technician-related capacity	**9,585**	**79%**
Employed, NOT in a pharmacy technician-related capacity	1,974	16%
Not working, reason unknown	**0**	**0%**
Involuntarily unemployed	160	1%
Voluntarily unemployed	**391**	**3%**
Retired	54	< 1%
Total	**12,189**	**100%**

Source: Va. Healthcare Workforce Data Center

79% of Virginia's pharmacy technicians are currently employed in the profession, while only 1% are involuntarily unemployed at the moment. 64% 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	605	5%
One Part-Time Position	**2,583**	**21%**
Two Part-Time Positions	232	2%
One Full-Time Position	**7,698**	**64%**
One Full-Time Position & One Part-Time Position	813	7%
Two Full-Time Positions	**37**	**< 1%**
More than Two Positions	57	< 1%
Total	**12,025**	**100%**

Source: Va. Healthcare Workforce Data Center

Current Weekly Hours		
Hours	#	%
0 hours	605	5%
1 to 9 hours	**419**	**4%**
10 to 19 hours	644	6%
20 to 29 hours	**1,007**	**9%**
30 to 39 hours	3,184	27%
40 to 49 hours	**5,106**	**44%**
50 to 59 hours	362	3%
60 to 69 hours	**158**	**1%**
70 to 79 hours	95	1%
80 or more hours	**115**	**1%**
Total	**11,695**	**100%**

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Income		
Annual Income	#	%
Volunteer Work Only	136	3%
Less than $10,000	705	13%
$10,000-$14,999	459	9%
$15,000-$19,999	472	9%
$20,000-$24,999	806	15%
$25,000-$29,999	768	14%
$30,000-$34,999	744	14%
$35,000-$39,999	499	9%
$40,000-$44,999	330	6%
$45,000-$49,999	166	3%
$50,000 or more	264	5%
Total	5,348	100%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Annual Income
Median Income: $25k-30k

Benefits
Employer Health Ins.: 61%
Employer Retirement: 54%

Satisfaction
Satisfied: 90%
Very Satisfied: 49%

Source: Va. Healthcare Workforce Data Center

Job Satisfaction		
Level	#	%
Very Satisfied	5,834	49%
Somewhat Satisfied	4,953	42%
Somewhat Dissatisfied	801	7%
Very Dissatisfied	346	3%
Total	11,935	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, 54% receive health insurance and 48% have access to a retirement plan.

Employer-Sponsored Benefits			
Benefit	#	%	% of Wage/Salary Employees
Paid Leave	5,865	61%	54%
Health Insurance	5,865	61%	54%
Dental Insurance	5,543	58%	51%
Retirement	5,199	54%	48%
Group Life Insurance	3,274	34%	30%
Signing/Retention Bonus	346	4%	3%
Received At Least One Benefit	7,576	79%	70%
*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?	173	1%
Experience Voluntary Unemployment?	450	3%
Work Part-time or temporary positions, but would have preferred a full-time/permanent position?	589	4%
Work two or more positions at the same time?	1,567	11%
Switch employers or practices?	642	5%
Experienced at least One	**2,818**	**20%**

Source: Va. Healthcare Workforce Data Center

Only 1% of Virginia's pharmacy technicians were involuntary unemployed at some point in 2017. For comparison, Virginia's average monthly unemployment rate was 3.8%.[1]

Location Tenure				
Tenure	Primary		Secondary	
	#	%	#	%
Not Currently Working at this Location	393	4%	251	11%
Less than 6 Months	1,029	9%	368	16%
6 Months to 1 Year	1,169	10%	250	11%
1 to 2 Years	2,890	26%	477	21%
3 to 5 Years	2,432	22%	410	18%
6 to 10 Years	1,404	13%	241	11%
More than 10 Years	1,891	17%	257	11%
Subtotal	**11,208**	**100%**	**2,254**	**100%**
Did not have location	**734**		**11,383**	
Item Missing	2,025		330	
Total	**13,967**		**13,967**	

Source: Va. Healthcare Workforce Data Center

92% of pharmacy technicians receive an hourly wage at their primary work location, while most remaining pharmacy technicians receive a salary or commission.

At a Glance:

Unemployment Experience 2017

Involuntarily Unemployed: 1%
Underemployed: 4%

Stability

Switched: 5%
New Location: 25%
Over 2 years: 51%
Over 2 yrs, 2nd location: 40%

Employment Type

Hourly Wage: 92%

Source: Va. Healthcare Workforce Data Center

51% of pharmacy technicians 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	#	%
Hourly Wage	9,760	92%
Salary/ Commission	**716**	**7%**
By Contract/Per Diem	47	< 1%
Unpaid	**44**	**< 1%**
Business/ Practice Income	24	< 1%
Subtotal	**10,591**	**100%**

Source: Va. Healthcare Workforce Data Center

[1] As reported by the US Bureau of Labor Statistics. The non-seasonally adjusted monthly unemployment rate ranged from 4.2% in January to 3.4% in December. At the time of publication, results from December were still preliminary.

At a Glance:

Concentration

Top Region:	25%
Top 3 Regions:	68%
Lowest Region:	2%

Locations

2 or more (Past Year):	22%
2 or more (Now*):	18%

Source: Va. Healthcare Workforce Data Center

Central Virginia, Hampton Roads, and Northern Virginia employ 68% of all pharmacy technicians in the state.

A Closer Look:

Regional Distribution of Work Locations				
COVF Region[2]	Primary Location		Secondary Location	
	#	%	#	%
Central	**2,754**	**25%**	**607**	**25%**
Eastern	218	2%	43	2%
Hampton Roads	**2,402**	**22%**	**564**	**23%**
Northern	2,396	22%	551	22%
Southside	**505**	**5%**	**100**	**4%**
Southwest	765	7%	123	5%
Valley	**733**	**7%**	**125**	**5%**
West Central	1,251	11%	249	10%
Virginia Border State/DC	**32**	**< 1%**	**45**	**2%**
Other US State	17	< 1%	43	2%
Outside of the US	**1**	**< 1%**	**6**	**< 1%**
Total	**11,074**	**100%**	**2,456**	**100%**
Item Missing	**2,159**		**128**	

Source: Va. Healthcare Workforce Data Center

Council On Virginia's Future Regions

Number of Work Locations				
Locations	Work Locations in Past Year		Work Locations Now*	
	#	%	#	%
0	**323**	**3%**	**599**	**5%**
1	**8,584**	**75%**	**8,820**	**77%**
2	**1,575**	**14%**	**1,287**	**11%**
3	**835**	**7%**	**696**	**6%**
4	**60**	**1%**	**33**	**< 1%**
5	24	< 1%	7	< 1%
6 or More	**64**	**1%**	**23**	**< 1%**
Total	**11,465**	**100%**	**11,465**	**100%**

*At the time of survey completion, December 2017.

Source: Va. Healthcare Workforce Data Center

18% of all pharmacy technicians currently have multiple work locations, while 22% had multiple work locations over the past year.

[2] These are now referred to as VA Perform's regions: http://vaperforms.virginia.gov/Regions/regionalScorecards.php

A Closer Look:

Location Sector				
Sector	Primary Location		Secondary Location	
	#	%	#	%
For-Profit	**7,794**	**74%**	**1,510**	**73%**
Non-Profit	1,572	15%	307	15%
State/Local Government	**761**	**7%**	**162**	**8%**
Veterans Administration	53	1%	5	< 1%
U.S. Military	**194**	**2%**	**43**	**2%**
Other Federal Gov't	139	1%	49	2%
Total	**10,513**	**100%**	**2,076**	**100%**
Item Missing	2,719		508	
Did not have location	734		11,383	

Source: Va. Healthcare Workforce Data Center

At a Glance:
(Primary Locations)

Sector

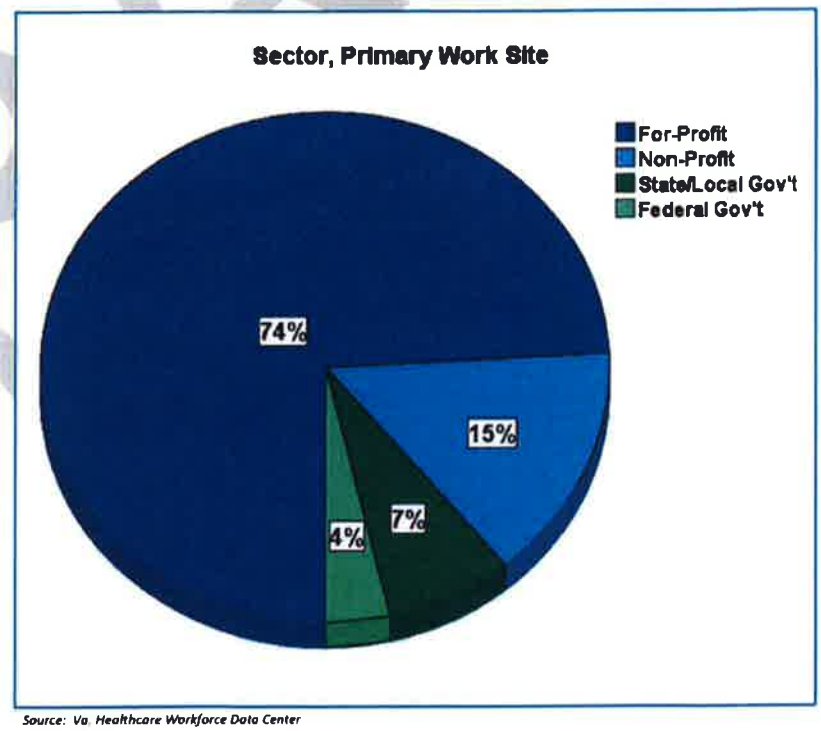
For Profit:	74%
Federal:	4%

Top Establishments

Large Chain Pharmacy: (11+ Stores)	34%
Hospital/Health System: (Inpatient)	14%
Independent Pharmacy: (1-4 Stores)	11%

Source: Va. Healthcare Workforce Data Center

89% 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.



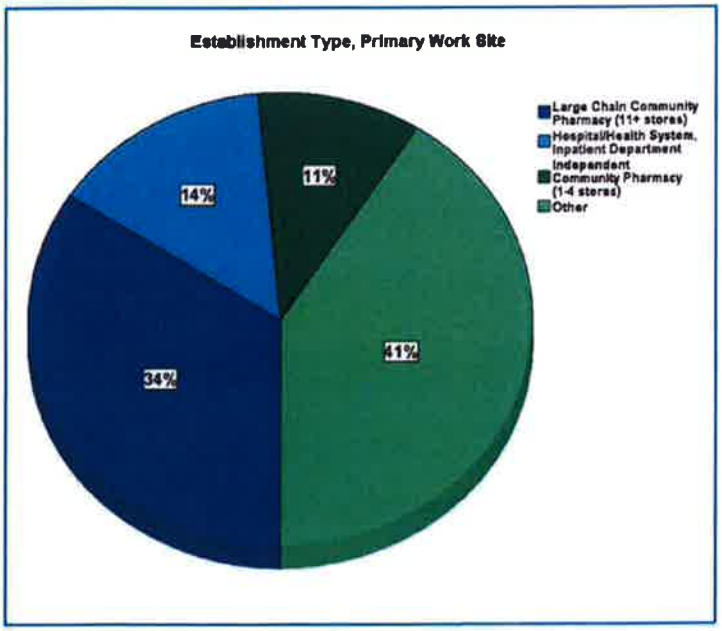
Source: Va. Healthcare Workforce Data Center

Top 10 Location Type				
Establishment Type	Primary Location		Secondary Location	
	#	%	#	%
Large Chain Community Pharmacy (11+ stores)	**3,555**	**34%**	**672**	**33%**
Hospital/Health System, Inpatient Department	1,482	14%	223	11%
Independent Community Pharmacy (1-4 stores)	**1,093**	**11%**	**181**	**9%**
Supermarket Pharmacy	839	8%	147	7%
Hospital/Health System, Outpatient Department	**567**	**5%**	**85**	**4%**
Nursing Home/Long-Term Care	503	5%	77	4%
Mass Merchandiser (i.e. Big Box Store)	**473**	**5%**	**89**	**4%**
Clinic-Based Pharmacy	292	3%	48	2%
Pharmacy Benefit Administration (e.g. PBM, Managed Care)	**209**	**2%**	**24**	**1%**
Home Health/Infusion	136	1%	34	2%
Small Chain Community Pharmacy (5-10 stores)	**108**	**1%**	**23**	**1%**
Mail Service Pharmacy	79	1%	11	1%
Academic Institution	**76**	**1%**	**44**	**2%**
Wholesale Distributor	56	1%	7	< 1%
Manufacturer	**39**	**< 1%**	**12**	**1%**
Other	879	8%	335	17%
Total	**10,386**	**100%**	**2,012**	**100%**
Did Not Have Location	734		11,383	

Source: Va. Healthcare Workforce Data Center

Large Chain Community Pharmacies (i.e. pharmacies with more than 10 stores) employ 34% of Virginia's pharmacy technician workforce, the most of any establishment type in the state.

For pharmacy technicians who also have a secondary work location, 33% 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

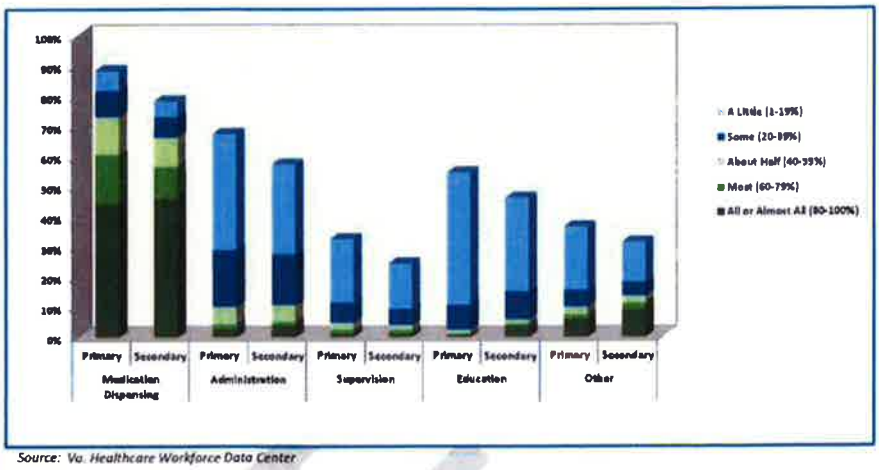
Medication Disp.:	60%
Administration:	4%
Supervision:	2%
Education:	1%

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

60% of 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%)	**44%**	**46%**	**3%**	**4%**	**1%**	**1%**	**1%**	**4%**	**6%**	**9%**
Most (60-79%)	**16%**	10%	2%	1%	1%	1%	0%	1%	1%	2%
About Half (40-59%)	**13%**	**10%**	**6%**	**6%**	**2%**	**2%**	**1%**	**1%**	**3%**	**2%**
Some (20-39%)	9%	7%	19%	17%	7%	5%	8%	9%	5%	5%
A Little (1-19%)	**7%**	**5%**	**39%**	**30%**	**21%**	**15%**	**44%**	**31%**	**21%**	**13%**
None (0%)	12%	22%	33%	43%	68%	76%	46%	54%	64%	69%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Retirement Expectations				
Expected Retirement Age	All		Over 50	
	#	%	#	%
Under age 50	**2,376**	**25%**	-	-
50 to 54	418	4%	37	2%
55 to 59	**615**	**7%**	**129**	**7%**
60 to 64	1,417	15%	427	22%
65 to 69	**2,304**	**24%**	**819**	**43%**
70 to 74	618	7%	224	12%
75 to 79	**154**	**2%**	**43**	**2%**
80 or over	115	1%	19	1%
I do not intend to retire	**1,443**	**15%**	**218**	**11%**
Total	**9,461**	**100%**	**1,916**	**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: 31%

Under 60: 9%

Time until Retirement

Within 2 years: 4%

Within 10 years: 14%

Half the workforce: By 2042

Source: Va. Healthcare Workforce Data Center

51% of all pharmacy technicians expect to retire by the age of 65, including 36% who expect to retire no later than the age of 60. Among pharmacy technicians who are age 50 and over, 31% expect to retire by the age of 65.

Within the next two years, 22% of all pharmacy technicians expect to pursue additional educational opportunities, and 7% want to increase their patient care hours.

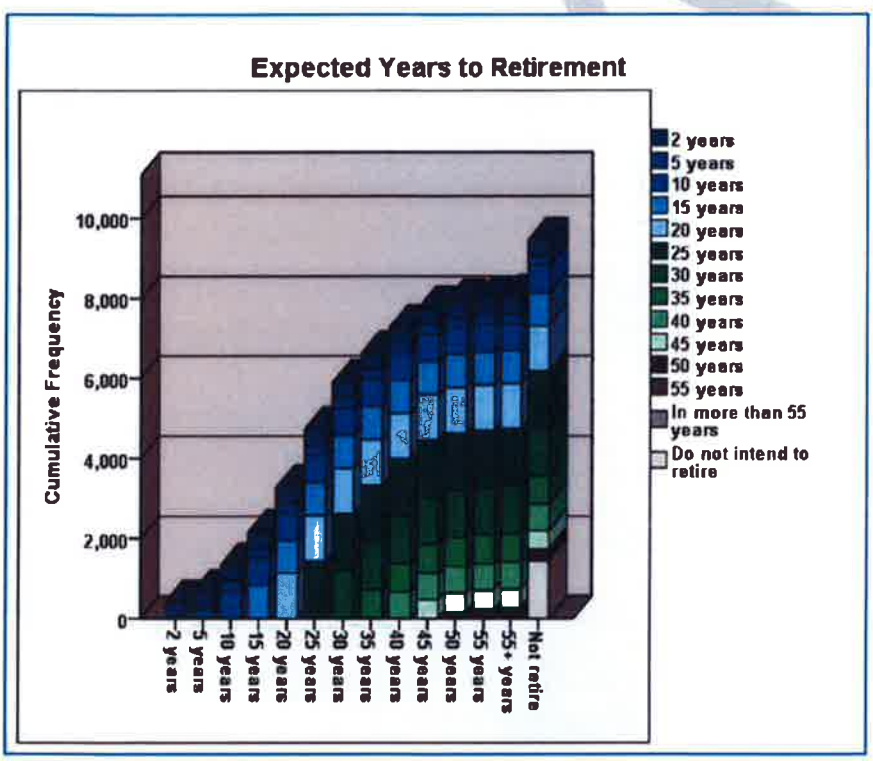
Future Plans		
2 Year Plans:	#	%
Decrease Participation		
Leave Profession	**1,187**	**8%**
Leave Virginia	537	4%
Decrease Patient Care Hours	**181**	**1%**
Decrease Teaching Hours	121	1%
Increase Participation		
Increase Patient Care Hours	**1,003**	**7%**
Increase Teaching Hours	670	5%
Pursue Additional Education	**3,136**	**22%**
Return to Virginia's Workforce	181	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 on retiring in the next two years, while 14% plan on retiring within the next ten years. Half of the current workforce expects to retire by 2042.

Time to Retirement			
Expect to retire within. . .	#	%	Cumulative %
2 years	400	4%	4%
5 years	251	3%	7%
10 years	675	7%	14%
15 years	825	9%	23%
20 years	1,129	12%	35%
25 years	1,439	15%	50%
30 years	1,180	12%	62%
35 years	719	8%	70%
40 years	654	7%	77%
45 years	468	5%	82%
50 years	173	2%	84%
55 years	67	1%	84%
In more than 55 years	38	< 1%	85%
Do not intend to retire	1,443	15%	100%
Total	9,461	100%	

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

Using these estimates, retirements will begin to reach 10% of the current workforce starting in 2037. Retirements will peak at 15% of the current workforce around 2042 before declining to below 10% of the current workforce again around 2052.

At a Glance:

FTEs

Total:	10,390
FTEs/1,000 Residents:	1.239
Average:	0.79

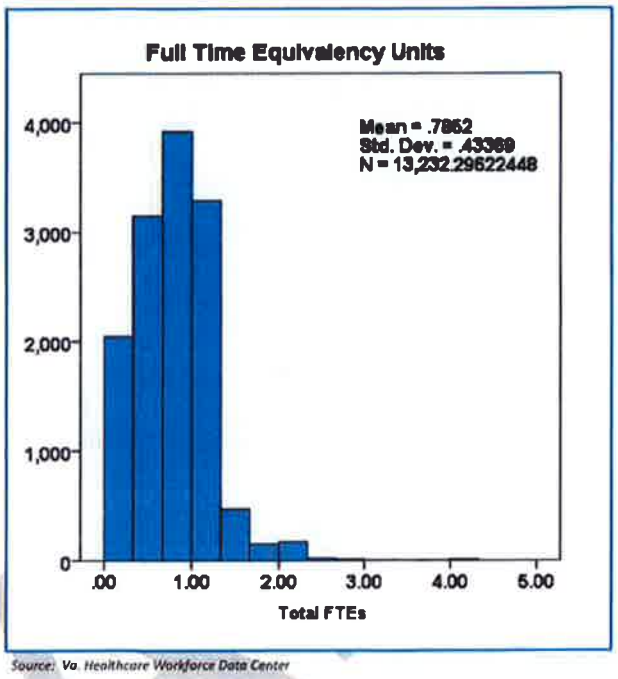
Age & Gender Effect

Age, Partial Eta^2:	Small
Gender, Partial Eta^2:	Negligible

Partial Eta^2 Explained:
Partial Eta^2 is a statistical measure of effect size.

Source: Va. Healthcare Workforce Data Center

A Closer Look:

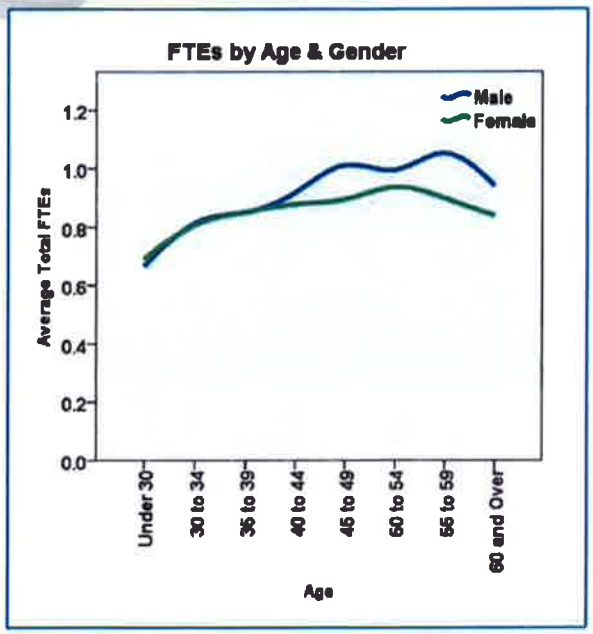


Source: Va. Healthcare Workforce Data Center

The typical pharmacy technician provided 0.83 FTEs in 2017, or approximately 33 hours per week for 50 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	**0.67**	**0.61**
30 to 34	0.79	0.82
35 to 39	**0.83**	**0.84**
40 to 44	0.83	0.90
45 to 49	**0.90**	**0.89**
50 to 54	0.93	0.95
55 to 59	**0.89**	**0.93**
60 and Over	0.81	0.83
Gender		
Male	0.81	0.88
Female	**0.81**	**0.89**

Source: Va. Healthcare Workforce Data Center

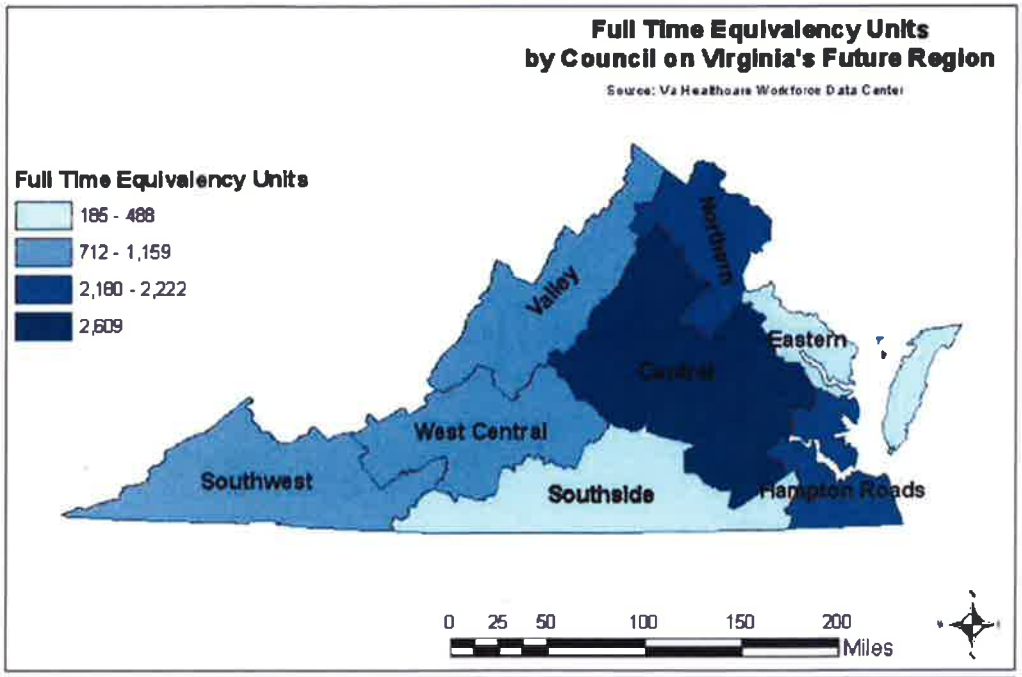


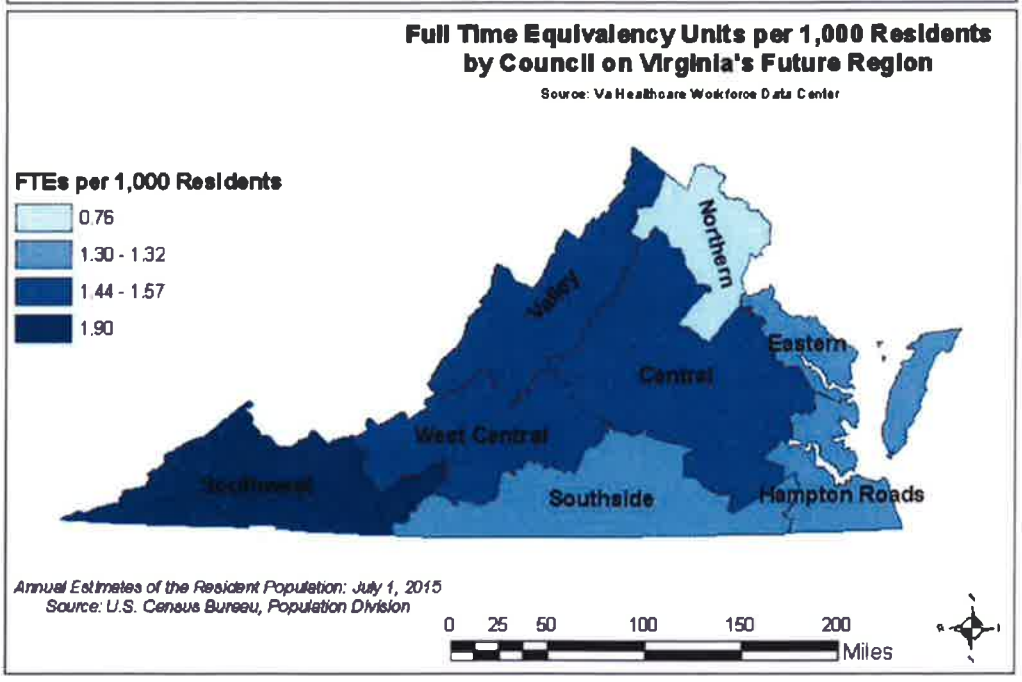
Source: Va. Healthcare Workforce Data Center

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

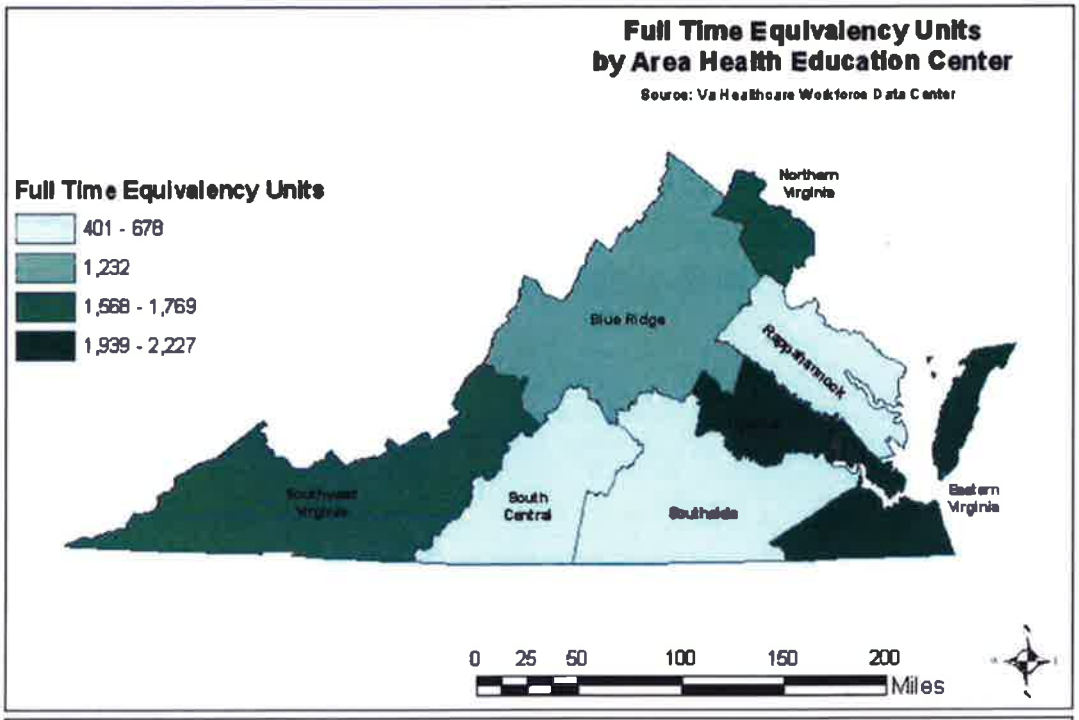
Maps

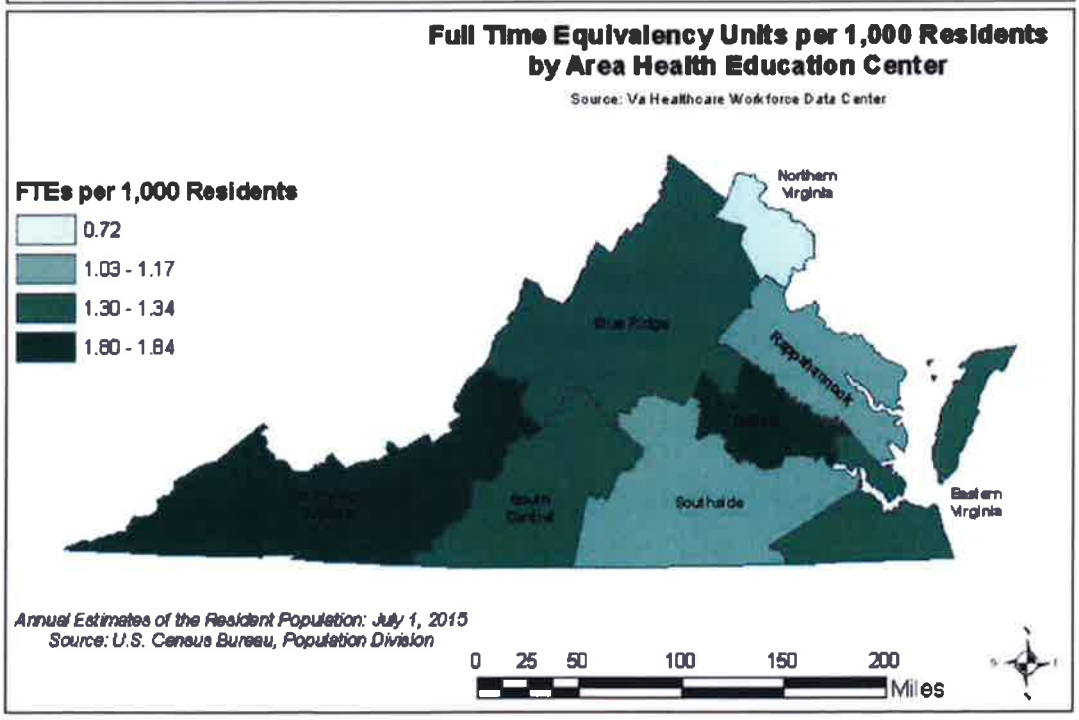
Council on Virginia's Future Regions



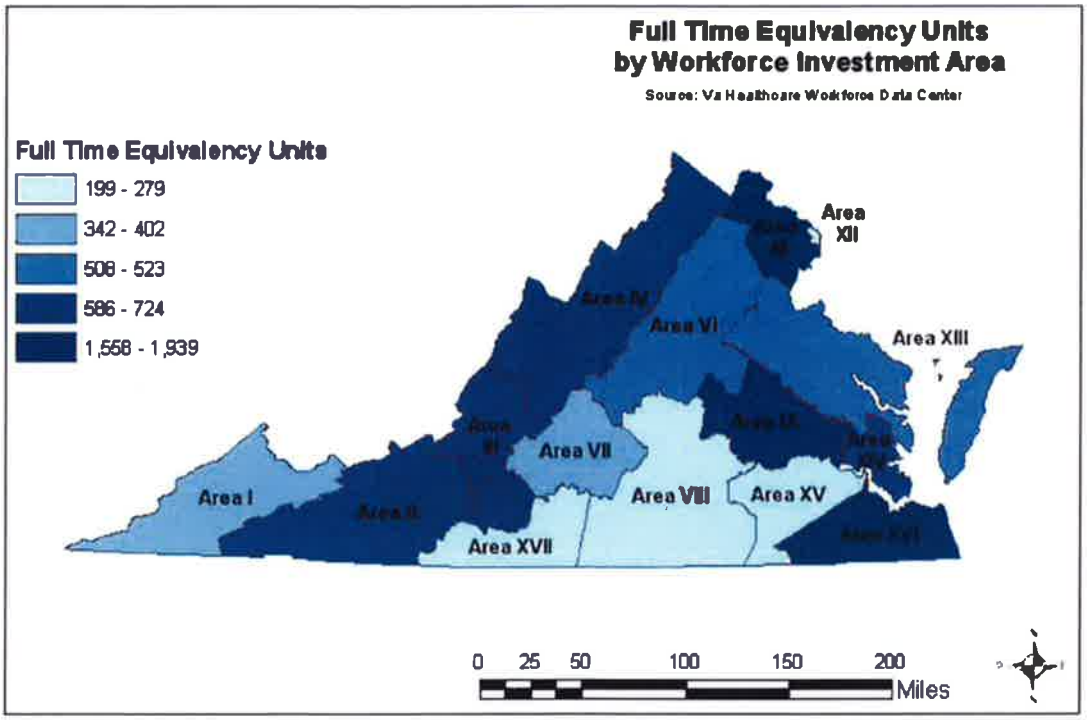


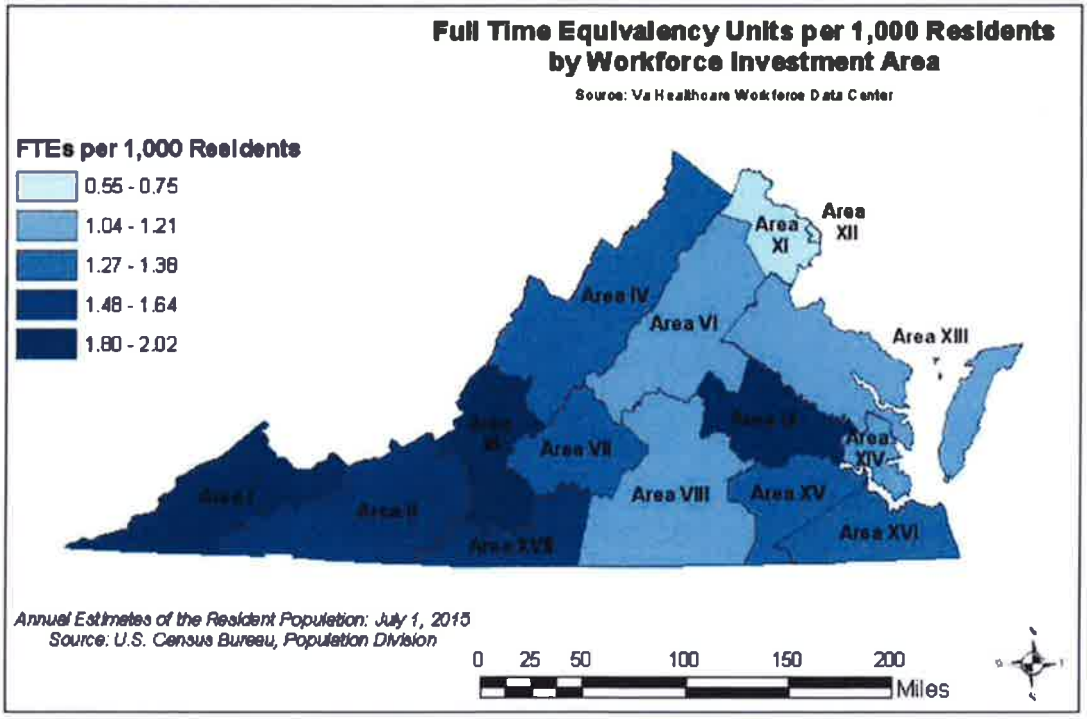
Area Health Education Center Regions



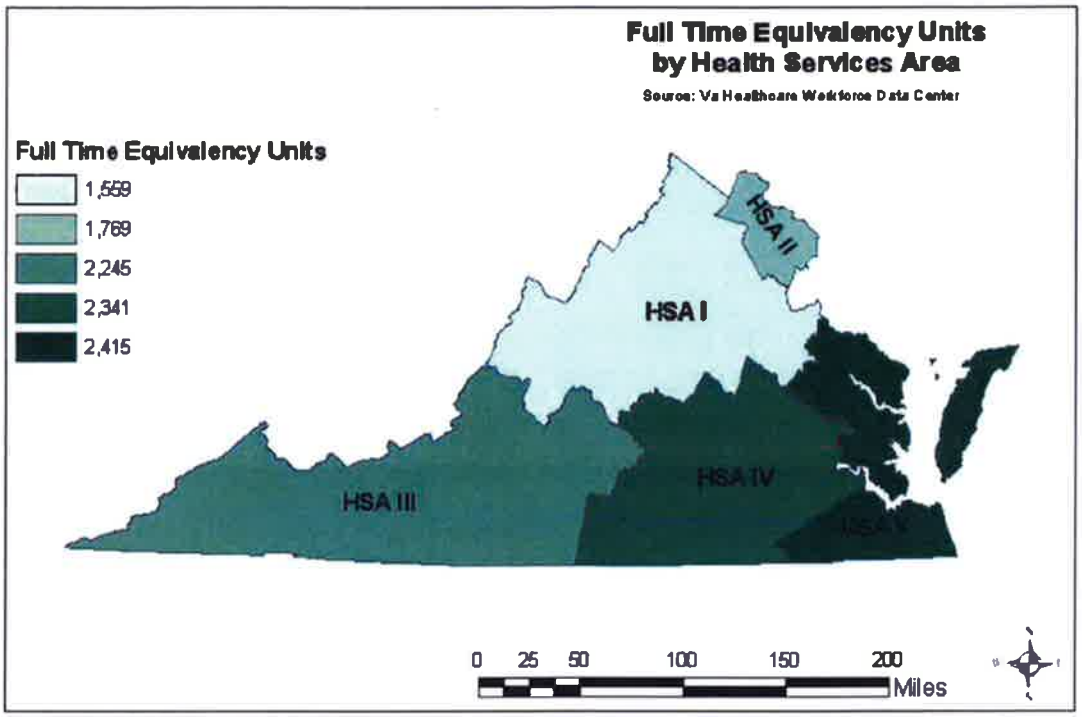


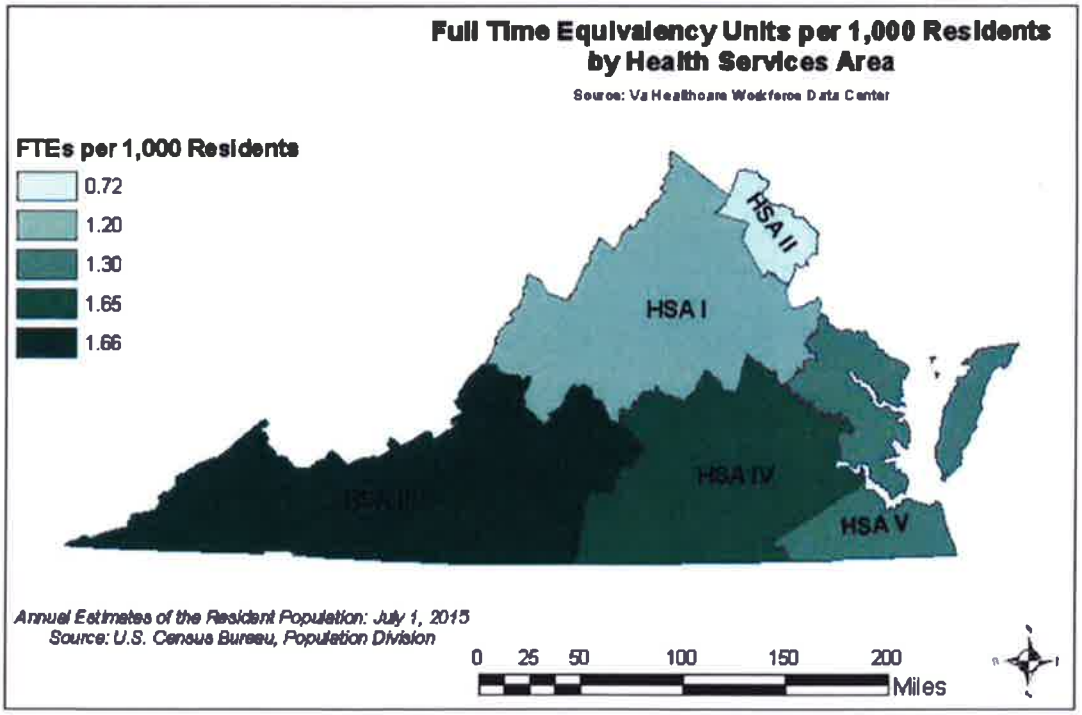
Workforce Investment Areas

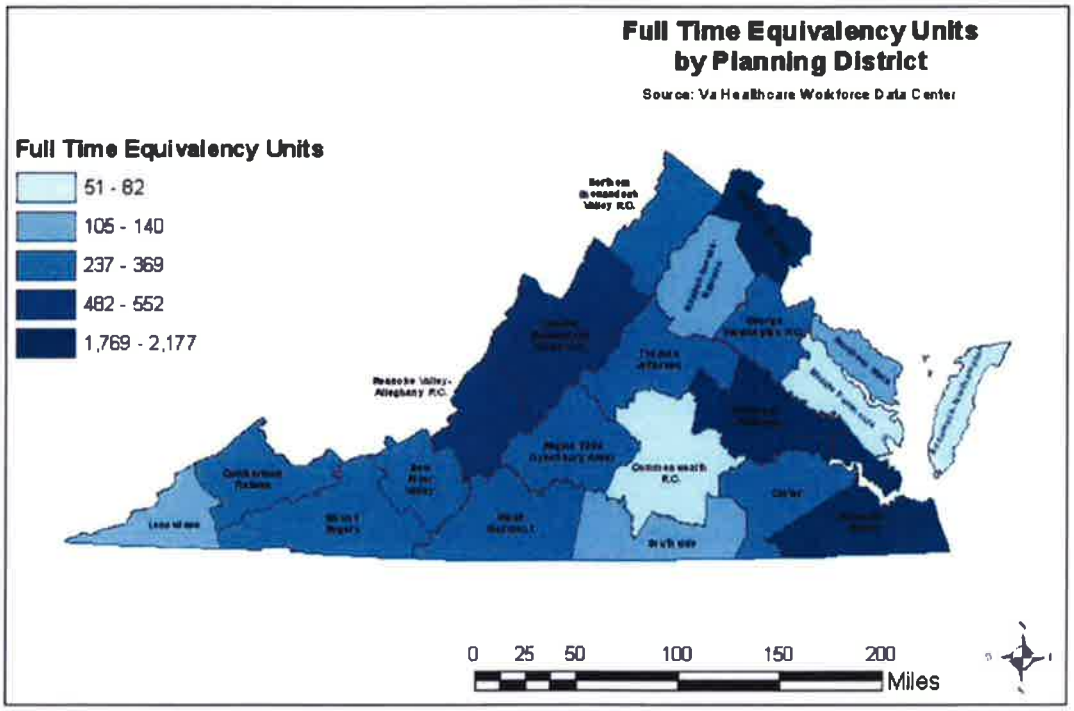


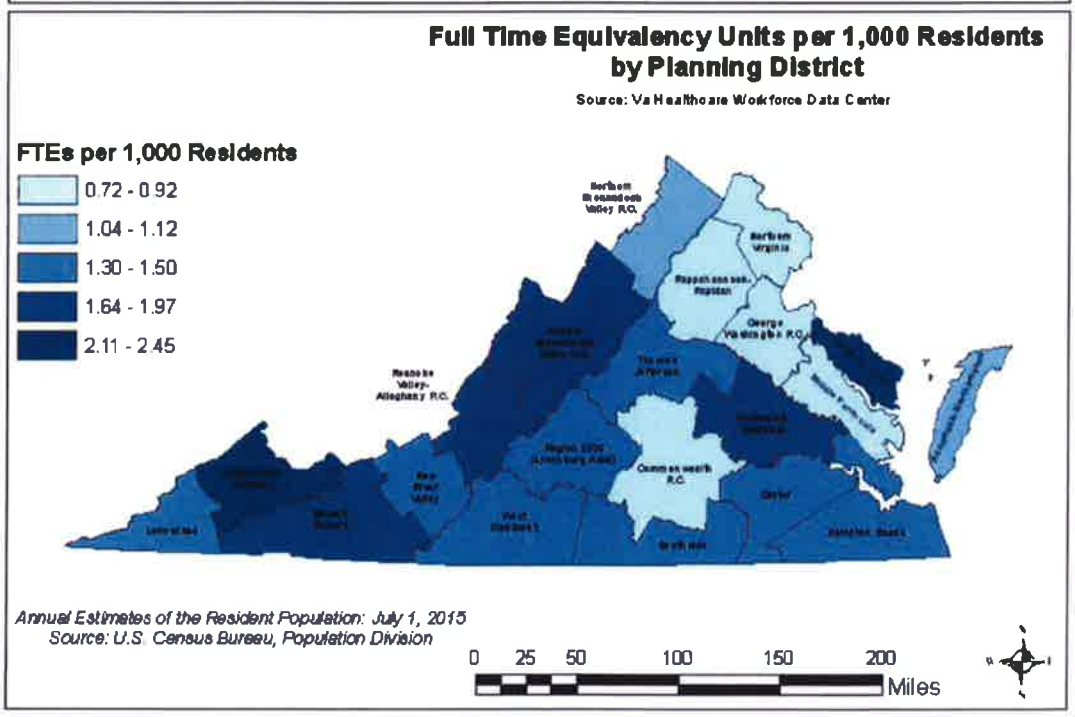


Health Services Areas






Full Time Equivalency Units
by Planning District
Source: Va Healthcare Workforce Data Center
Full Time Equivalency Units
51 - 82
105 - 140
237 - 369
482 - 552
1,769 - 2,177
0 25 50 100 150 200
Miles


Full Time Equivalency Units per 1,000 Residents
by Planning District
Source: Va Healthcare Workforce Data Center
FTEs per 1,000 Residents
0.72 - 0.92
1.04 - 1.12
1.30 - 1.50
1.64 - 1.97
2.11 - 2.45
Annual Estimates of the Resident Population: July 1, 2015
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+	9,157	76.50%	1.307209	1.177538	1.498259
Metro, 250,000 to 1 million	1,380	80.29%	1.245487	1.121939	1.427516
Metro, 250,000 or less	1,393	80.33%	1.244861	1.121375	1.426799
Urban pop 20,000+, Metro adj	313	83.39%	1.199234	1.080273	1.374502
Urban pop 20,000+, nonadj	0	NA	NA	NA	NA
Urban pop, 2,500-19,999, Metro adj	715	83.22%	1.201681	1.082477	1.377307
Urban pop, 2,500-19,999, nonadj	543	78.45%	1.274648	1.148207	1.460938
Rural, Metro adj	320	77.19%	1.295547	1.167032	1.484891
Rural, nonadj	229	79.91%	1.251366	1.127234	1.434254
Virginia border state/DC	642	66.36%	1.507042	1.357548	1.727297
Other US State	249	49.80%	2.008065	1.80887	2.301544

Source: Va. Healthcare Workforce Data Center

Age	Age Weight			Total Weight	
	#	Rate	Weight	Min	Max
Under 30	4,930	67.12%	1.489876	1.374502	2.301544
30 to 34	2,422	77.17%	1.29588	1.195529	2.001861
35 to 39	1,857	81.21%	1.231432	1.136072	1.902303
40 to 44	1,322	82.90%	1.206204	1.112798	1.863331
45 to 49	1,273	83.90%	1.191948	1.099645	1.841308
50 to 54	1,048	85.40%	1.17095	1.080273	1.80887
55 to 59	907	85.01%	1.176394	1.085296	1.817281
60 and Over	1,182	82.74%	1.208589	1.114998	1.867015

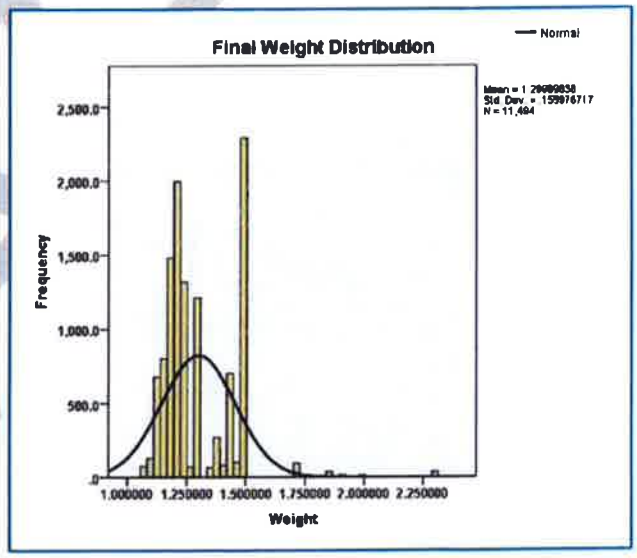
Source: Va. Healthcare Workforce Data Center

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: 0.769293



Source: Va. Healthcare Workforce Data Center